



Llywodraeth Cymru
Welsh Government

PUBLIC HEALTH (WALES) BILL

Explanatory Memorandum Incorporating the Regulatory Impact Assessment and Explanatory Notes

May 2017

PUBLIC HEALTH (WALES) BILL

Explanatory Memorandum to the Public Health (Wales) Bill

This Explanatory Memorandum has been prepared by the Health and Social Services Group of the Welsh Government and is laid before the National Assembly for Wales.

It was originally prepared and laid in accordance with Standing Order 26.6 in November 2016 and a revised Memorandum is now laid in accordance with Standing Order 26.28.

Member's Declaration

In my view, the provisions of the Public Health (Wales) Bill, introduced by me on 7 November 2016, would be within the legislative competence of the National Assembly for Wales.

Rebecca Evans AM

Minister for Social Services and Public Health
Assembly Member in charge of the Bill

2 May 2017

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List of Abbreviations

BCAP – Broadcast Committee of Advertising Practice

BMA – British Medical Association

BTA – British Toilet Association

CAP – Committee of Advertising Practice

CIEH – Chartered Institute of Environmental Health

DfT – Department for Transport

ECHR – European Convention on Human Rights

EHO – Environmental Health Officer

EIA – Environmental Impact Assessment

ENDS – Electronic Nicotine Delivery Systems

FE – Further Education

FGM – Female Genital Mutilation

FPN – Fixed Penalty Notice

FTE – Full Time Equivalent

GOWA – Government of Wales Act 2006

HIA – Health Impact Assessment

LHB – University or Teaching Health Board

MHRA – Medicines and Healthcare Products Regulators Agency

MUP – Minimum Unit Pricing for alcohol

NIDs – Nicotine Inhaling Devices

NPV - Net Present Value

NQA – National Quality Award

NRT – Nicotine Replacement Therapy

OFT – Office of Fair Trading

PNA – Pharmaceutical Needs Assessment

PSSRU – Personal Social Services Research Unit

QALY – Quality Adjusted Life Years

RAN – Remedial Action Notice

RIA – Regulatory Impact Assessment

RPO – Restricted Premises Order

RSO – Restricted Sales Order

RYO – 'Roll Your Own' (tobacco)

TAN – Technical Advice Note

UNCRC – United Nations Convention on the Rights of the Child

VOT – Value of time

WHIASU – Welsh Health Impact Assessment Support Unit

WHO – World Health Organisation

WLGA – Welsh Local Government Association

WNHSS – Welsh Network of Healthy School Schemes

Part 1 – Explanatory Memorandum

1. Description

1. The Public Health (Wales) Bill ('the Bill') utilises legislation as a mechanism for improving and protecting the health and well-being of the population of Wales. It comprises a set of provisions in discrete areas of public health policy.
2. While a number of the issues addressed in the Bill are already well established, the Bill also responds to new and emerging health challenges. Taken together the provisions are intended to have a cumulative positive benefit for the population of Wales and seek to put in place conditions which are conducive to good health, in which harms to health can be prevented.
3. In summary the Bill proposes to introduce changes that:
 - Re-state restrictions on smoking in enclosed and substantially enclosed public and work places, and give Welsh Ministers a regulation-making power to extend the restrictions on smoking to additional premises or vehicles;
 - Place restrictions on smoking in school grounds, hospital grounds and public playgrounds;
 - Provide for the creation of a national register of retailers of tobacco and nicotine products;
 - Provide Welsh Ministers with a regulation-making power to add to the offences which contribute to a Restricted Premises Order (RPO) in Wales;
 - Prohibit the handing over of tobacco and/or nicotine products to a person under the age of 18;
 - Provide for the creation of a mandatory licensing scheme for practitioners and businesses carrying out 'special procedures', namely acupuncture, body piercing, electrolysis and tattooing;
 - Introduce a prohibition on the intimate piercing of persons under the age of 18 years;
 - Require Welsh Ministers to make regulations to require public bodies to carry out health impact assessments in specified circumstances;
 - Change the arrangements for determining applications for entry onto the pharmaceutical list of health boards (LHBs), to a system based on the pharmaceutical needs of local communities;
 - Require local authorities to prepare a local strategy to plan how they will meet the needs of their communities for accessing toilet facilities for public use; and
 - Enable a 'food authority' under the Food Hygiene Rating (Wales) Act 2013 to retain fixed penalty receipts resulting from offences under that Act, for the purpose of enforcing the food hygiene rating scheme.

4. The issues covered in the Bill are relevant both to physical and mental health and well-being, and as such, references to public health throughout the Bill and Explanatory Memorandum should be considered as encompassing both of these aspects.

2. Legislative Competence

5. The National Assembly for Wales ('the Assembly') has the legislative competence to make the provisions in the Public Health (Wales) Bill ('the Bill') pursuant to Part 4 of the Government of Wales Act 2006 ('GOWA 2006'). The relevant provisions of GOWA 2006 are set out in section 108 and Schedule 7.
6. Paragraphs 9, 12 and 15 of Schedule 7 set out the following subjects on which the Assembly may legislate.

Paragraph 9 'Health and Health Services':

"Promotion of health. Prevention, treatment and alleviation of disease, illness, injury, disability and mental disorder. Control of disease. Family planning. Provision of health services, including medical, dental, ophthalmic, pharmaceutical and ancillary services and facilities. Clinical governance and standards of health care. Organisation and funding of national health service."

Paragraph 12 'Local Government':

"...Powers and duties of local authorities and their members and officers..."

Paragraph 15 'Social Welfare':

"...Protection and well-being of children (including adoption and fostering) and of young adults..."

7. The above subjects provide the National Assembly with the competence to make the provisions contained in the Bill.

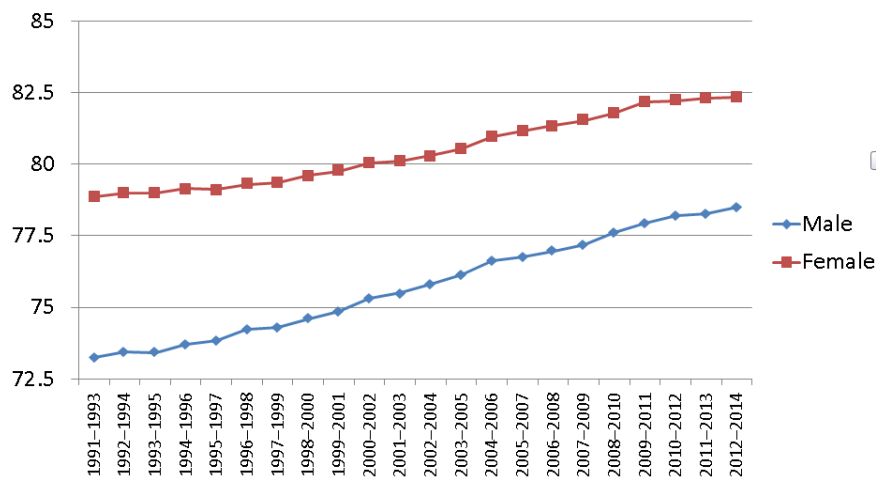
3. Purpose and intended effect of the legislation

Context

8. The health of the population of Wales is continuing to improve. In general, people are living longer and enjoy better health than ever before, and more can be done to deal with health problems. Life expectancy continues to improve and the gap between males and females is decreasing, although the gap between the most and least deprived areas remains a concern.

Figure 1¹

Life expectancy at birth by sex, Wales, 1991-1993 to 2012-2014



Source: Office for National Statistics

9. Whilst health is improving, it is also clear that Wales faces a number of specific and significant health challenges. These range from overarching demographic challenges such as an ageing population, high levels of chronic disease and persisting inequalities in health, to more discrete challenges posed by lifestyle choices and contemporary developments within society.
10. The Welsh Government's priorities for public health are clear and have been set out in key policy documents including *Our Healthy Future*², the national public health framework, and the *Fairer Health Outcomes For All*³ strategic action plan for reducing inequalities in health. The Welsh

¹ Source: Office for National Statistics

² Our Healthy Future – Technical Working Paper (2009) – Welsh Government

³ Fairer Health Outcomes For All (2011) – Welsh Government.

<http://gov.wales/topics/health/publications/health/reports/fairer/?lang=en>

Government has ambitions to accelerate the pace of improvement in the health and well-being of people in Wales, and for improvements to be shared more equally across the population. In realising these ambitions the Welsh Government has signalled its ongoing commitment to taking action in a range of ways, including through legislation, to help further improve and protect health for everyone.

11. The quickly developing nature of society means that it is ever more important for the Welsh Government to keep pace with emerging public health priorities. In particular it is increasingly crucial that preventative approaches drive actions, including legislative action, in order to place sustainability at the heart of the public health agenda.
12. Legislation has historically played an important role in tackling public health issues. It has proven to be one of the most powerful tools available to governments in responding to health challenges, both old and new. Legislation in areas as varied as the ban on smoking in enclosed public places and the use of seat-belts has made significant positive contributions to public health. The Bill seeks to build on this strong tradition.
13. In bringing forward this Bill, the focus of the Welsh Government is on shaping social conditions that are conducive to good health, and where possible, preventing avoidable health harms. As part of this approach, it is also recognised that individuals have a responsibility to look after their own health, and to act in ways which promote their own physical and mental well-being.
14. The Bill adopts a preventative approach across its provisions and is therefore consistent with the principles of prudent health care. It does this by seeking to intervene at points with significant potential for long-term benefits, both for the health of individuals and in avoiding the longer term burdens caused by avoidable ill health. In doing so the Bill also focuses on protecting the future health and well-being of children and young people in Wales.
15. Whilst a single piece of legislation cannot fully address all the issues affecting public health, the Bill seeks to make a positive contribution by bringing together a series of practical actions in specific areas. It is intended to have a positive cumulative impact on health and well-being, alongside a broader suite of actions for improving health, including other legislative action, public health services, programmes and campaigns.
16. The approach taken in the Bill also sits alongside and complements the overarching approach to legislation being implemented by the Welsh Government's Well-being of Future Generations (Wales) Act 2015. This means taking account of the importance of involving communities; reflecting the diversity of the population; public bodies acting in collaboration; prevention; and early intervention. Such principles are intrinsic to public health.

The Public Health (Wales) Bill

17. The Bill is structured into the following Parts:-

- Part 2: Tobacco and nicotine products, which is divided into four chapters:-
 - A re-statement of restrictions on smoking in enclosed and substantially enclosed public and work places, plus restrictions on smoking in school grounds, hospital grounds and public playgrounds;
 - A register of retailers of tobacco and nicotine products;
 - A regulation-making power to add offences to the Restricted Premises Order (RPO) regime; and
 - Handing over tobacco etc to persons under 18;
- Part 3: Special procedures;
- Part 4: Intimate piercing;
- Part 5: Health Impact Assessments;
- Part 6: Pharmaceutical services;
- Part 7: Provision of toilets; and
- Part 8: Miscellaneous and general.

18. The following pages describe the purpose and effect of each of the component parts. Each section includes the broad background to the proposals, the current position, the purpose of the legislation and its intended effect. No separate section is provided for Part 2, Chapter 3 of the Bill, which deals with the general operation of RPOs. This is covered in detail in relevant sections of the document which deal with the register of retailers of tobacco and nicotine products.

Tobacco and nicotine products

19. Tobacco smoking causes serious harm to the health of smokers and to non-smokers who are exposed to second-hand smoke. It continues to be the largest single preventable cause of ill health and death in Wales, causing around 5,450 deaths each year in those aged 35 and over⁴.

20. The significant burden of illness due to smoking has major economic costs for Wales. Research shows that treating smoking related diseases costs NHS Wales an estimated £302 million per year, with the estimated

⁴ Public Health Wales Observatory (2012) – ‘Tobacco and health in Wales, 2012’
<http://www.wales.nhs.uk/sitesplus/922/page/59800>

cost to the Welsh economy in sickness absence and smoking breaks amounting to just over £90 million per year. Smoking is also a main cause of health inequalities, having been identified as a leading cause for the gap in mortality rates between the most and least deprived areas⁵.

21. Smoking experimentation and uptake can begin as early as the primary school years, or can occur later in a young person's life. Two thirds of smokers started before the age of 18, and almost 40% started smoking regularly before the age of 16⁶.
22. It is clear that young people can quickly develop a dependence on nicotine and may be unable to reduce their risks of dependence due to addiction. It has been shown that smoking a single cigarette is a risk factor for children to become regular smokers up to three years later⁷. In addition, early uptake of smoking is associated with subsequent heavier smoking, higher levels of dependency, a lower chance of quitting, and higher mortality⁸. Interventions to reduce the uptake of smoking amongst young people are therefore crucial to meet the overall aim of reducing smoking prevalence rates.
23. Good progress has been made in Wales in reducing smoking among young people, with the number of 11-16 year olds who smoke at least once a week falling from 13% in 1998 to 4% in 2014⁹. Rates of smoking amongst adults have also dropped from 23% in 2010 to 19% in 2015. However, more still needs to be done to increase the number of adults successfully quitting smoking, whilst continuing to prevent young people from starting to smoke. Smoking addiction is something which many smokers are unhappy with. The 2015 Welsh Health Survey reported that 68% of smokers would like to give up, and 41% had tried to give up in the last year¹⁰.
24. In 2012, the Welsh Government published its Tobacco Control Action Plan for Wales¹¹ which sets out a comprehensive strategy on tobacco control, with the aim of protecting children and young people from the health harms of tobacco and reducing inequalities in health. The Tobacco Control Action Plan sets out a vision of a smoke-free society for Wales

⁵ ASH Wales and BHF Cymru (2013). The economic cost of smoking to Wales: a review of existing evidence.

⁶ Office for National Statistics. General Lifestyle Survey Overview: A report on the 2011 General Lifestyle Survey. 2013. <http://www.ons.gov.uk/ons/rel/ghs/general-lifestyle-survey/2011/rpt-chapter-1.html>

⁷ Fidler, JA et al. (2006) Vulnerability to smoking after trying a single can lie dormant for three years or more. Tobacco Control

⁸ Royal College of Physicians (2010) Passive smoking and children. London: Royal College of Physicians.

⁹ <http://gov.wales/docs/caecd/research/2015/151022-health-behaviour-school-children-2013-14-key-findings-en.pdf> .

¹⁰ <http://wales.gov.uk/statistics-and-research/welsh-health-survey/?lang=en>

¹¹ Welsh Government (2012) Tobacco Control Action Plan for Wales. Cardiff. Welsh Government.

with a challenging target of reducing adult smoking prevalence levels to 16% by 2020.





25. Evidence suggests that the most effective approach to tobacco control is a comprehensive strategy combining high taxation of tobacco products, regulation of tobacco advertising and sales, restrictions on smoking in public places, a tailored range of initiatives to help smokers to give up, and public awareness and education initiatives¹².
26. While many smokers quit without recourse to smoking cessation services and products, it is recognised that nicotine products can play an important role in helping smokers to quit altogether, or to reduce their consumption of tobacco products. Nicotine products include traditional forms of licensed nicotine replacement therapy (NRT), such as nicotine patches, gums and lozenges. There is strong evidence available for the long-term safety of NRT with concurrent smoking, suggesting that long-term use of NRT is not associated with an increased incidence of harm, including cardiovascular events or cancer, with the latest analysis of outcome at 12.5 years from study outset.¹³
27. Nicotine inhaling devices (NIDs) such as electronic cigarettes (hereafter e-cigarettes), are a new form of nicotine product. The function of these devices is to vaporise and deliver a chemical mixture to the user, typically composed of nicotine, propylene glycol and other chemicals. NIDs are normally battery operated devices that heat a liquid into an inhalable form for the user. NIDs are offered in a variety of nicotine levels and some 7,000 flavours, including tobacco, menthol, fruit, chocolate and bubble-gum.
28. There are various styles of NIDs in circulation. “Cig-a-like” products are the first generation devices which were designed to resemble tobacco cigarettes. They sometimes have a light at the end that glows when the user draws on the device to resemble a lit cigarette. These consist of either non-rechargeable disposable models or an electronic cigarette kit that is rechargeable and includes replaceable pre-filled cartridges. ‘Tank’ models (also known as vape pens) are rechargeable devices with a tank or reservoir which has to be filled with liquid nicotine. ‘Mods’ (or advanced personal vaporisers) are a more complex tank model which can be manually customised by, for example, adjusting the voltage on the device.¹⁴ Figure 2 below shows examples of different products currently available, though there are many more than these on the market and they are continually evolving.

¹² Gilbert A., Cornuz J. (2003) Which are the most effective and cost-effective interventions for tobacco control? Copenhagen, WHO Regional Office for Europe (Health Evidence Network report); <http://www.euro.who.int/document/e82993.pdf>

¹³ <https://www.nice.org.uk/guidance/PH45/chapter/9-The-evidence>

¹⁴ ASH Briefing on electronic cigarettes. February 2016.
http://www.ash.org.uk/files/documents/ASH_715.pdf

Figure 2¹⁵

Product	Description
Disposable e-cigarette 	Cigarette-shaped device consisting of a battery and a cartridge containing an atomizer to heat a solution (with or without nicotine). Not rechargeable or refillable and is intended to be discarded after product stops producing aerosol. Sometimes called an e-hookah.
Rechargeable e-cigarette 	Cigarette-shaped device consisting of a battery that connects to an atomiser used to heat a solution typically containing nicotine. Often contains an element that regulates puff duration and/or how many puffs may be taken consecutively.
Pen-style, medium sized rechargeable e-cigarette 	Larger than a cigarette, often with a higher capacity battery, may contain a prefilled cartridge or a refillable cartridge (often called a clearomizer). These devices often come with a manual switch allowing the user to regulate length and frequency of puffs.
Tank-style, large-sized rechargeable e-cigarette 	Much larger than a cigarette with a higher capacity battery and typically contains a large, refillable cartridge. Often contains manual switches and a battery casing for customising battery capacity. Can be easily modified.

29. The Medicines and Healthcare Products Regulatory Agency ('MHRA') has been accepting applications for licences for NIDs as medicines since June 2013.¹⁶ The Welsh Government understands that a number of applications have been made. A nicotine inhaler was granted a medicinal licence in September 2014.¹⁷ The first e-cigarette was licensed by the MHRA in November 2015.¹⁸ Manufacturers of NIDs that are granted

¹⁵ Background paper on E-cigarettes (Electronic Nicotine Delivery Systems), Rachel Grana, PhD MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD. Center for Tobacco Control Research and Education, University of California, San Francisco WHO Collaborating Center on Tobacco Control. Prepared for World Health Organization Tobacco Free Initiative December 2013.

¹⁶ <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Productspecificinformationandadvice%E2%80%9393M%E2%80%9393T/NicotineContainingProducts/index.htm>

¹⁷ <http://www.kindconsumer.com/products/voke-inhaler-technology>

¹⁸ <http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con616843.pdf>

medicinal licences will be able to make health claims about their product, whereas those being sold as consumer products are not able to make such claims.

30. NIDs have experienced a significant rise in public awareness in recent years. There have been a number of high profile advertising campaigns and sponsorships, as well as increased attention from the media that has helped increase the popularity of the devices. ASH England¹⁹ estimates the number of adult NID users in Great Britain increased fourfold since 2012, from 700,000 to 2.8 million.
31. Since October 2015, it has been an offence in England and Wales to sell certain NIDs to persons aged under 18 and for an adult to purchase NIDs on behalf of a person aged under 18.²⁰
32. The 2014 Health Behaviour in School-aged Children Study in Wales shows that 12% of 11-16 year olds have tried an e-cigarette, rising to 22% of Year 11 pupils. This proportion rose steadily with age for both boys and girls, but there was no difference by family affluence.²¹ ASH Wales' 2016 study into young people's, aged 18 and under, e-cigarette awareness and usage in Wales found that awareness of e-cigarettes was very high among the young people surveyed, with just over 90% of respondents reporting that they knew what an e-cigarette was prior to completing the survey. Use of e-cigarettes was far more prevalent among respondents who had previously smoked or currently smoke tobacco cigarettes. Of the 570 young people who had never smoked tobacco cigarettes 11% had ever used an e-cigarette, with the majority of these having tried an e-cigarette only once. Regular use of e-cigarettes (more than once a month) by never smokers was rare at 1.1%. Respondents from the most deprived parts of Wales were far less likely to have never used an e-cigarette (48.6%) relative to respondents located in the least deprived areas of the country (75.4%). A number of reasons were provided for using e-cigarettes by survey participants, including an inquisitorial attitude to their taste and because friends were using them. Of those respondents who reported using both e-cigarettes and tobacco at some point, 90% had first used tobacco.²²
33. The Bill contains a number of components which make a cumulative contribution to tobacco control. Detailed information about the intended purpose and effects of each component is provided in the following paragraphs. The Bill's provisions will also work alongside an extensive suite of measures at Wales, UK and European level, such as the Tobacco

¹⁹ Use of electronic cigarettes (vapourisers) among adults in Great Britain. May 2016. http://www.ash.org.uk/files/documents/ASH_891.pdf

²⁰ The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 <http://www.legislation.gov.uk/ukxi/2015/895/contents/made>

²¹ <http://gov.wales/docs/caecd/research/2015/151022-health-behaviour-school-children-2013-14-key-findings-en.pdf>

²² http://www.ashwales.org.uk/assets/factsheets-leaflets/ASHWales_EcigReport2016_Final.pdf

and Related Products Regulations 2016²³ and the Standardised Packaging of Tobacco Products Regulations 2015²⁴, which came into force on 20 May 2016.

34. Over time the proposed measures, along with non legislative programmes, are expected to impact on people's awareness of the health factors associated with tobacco products, which in turn will lead to a change in behaviour. Fewer young people will start smoking and some adults will successfully quit smoking. This is expected to lead to a reduction in smoking consumption/prevalence.

Restrictions on smoking in enclosed public and work places; and in school grounds, hospital grounds and public playgrounds

Background

35. Legislation to ban smoking in enclosed public places was introduced in Wales in 2007²⁵ to protect the public from the harms associated with second-hand smoke. The smoking ban has been a public health success. Research commissioned by the Welsh Government shows air quality in enclosed public places has improved significantly since the smoking ban was introduced²⁶. The number of non-smokers being exposed to second-hand smoke has also reduced from 66% in 2005-06 to 42% in 2007, and since 2008 has remained fairly constant²⁷.
36. A recent paper²⁸ concluded that smoke-free legislation may help reduce smoking uptake amongst teenagers, with stronger evidence for girls than for boys. It also suggested that the comprehensive nature of such legislation may serve to de-normalise smoking.
37. Normalisation is more than prevalence levels. It is about accepting a behaviour as a part of normal society and social interaction, being common among peers, and easy to access and to do. Reducing opportunities to smoke and making it more difficult to do so helps to

²³ <http://www.legislation.gov.uk/ukxi/2016/507/contents/made>

²⁴ <http://www.legislation.gov.uk/ukdsi/2015/9780111129876>

²⁵ The Health Act 2006 and The Smoke-free Premises etc. (Wales) Regulations 2007 (S.I. No.2007/787 (W.68)) came in to force on 2 April 2007.

²⁶ <http://gov.wales/topics/health/improvement/smoking/legislation/ban/?lang=en>

²⁷ Tobacco and Health in Wales 2012 – <http://www.wales.nhs.uk/sitesplus/922/page/50314>

²⁸ Has Childhood Smoking Reduced Following Smoke-Free Public Places Legislation? A Segmented Regression Analysis of Cross-Sectional UK School-Based Surveys. Srinivasa Vittal Katikireddi, Geoff Der, Chris Roberts, Sally Haw. Nicotine & Tobacco Research Advance Access published February 24, 2016.
<http://ntr.oxfordjournals.org/content/early/2016/02/22/ntr.ntw018.full.pdf+html>

challenge perceptions that smoking is normal behaviour²⁹ and reduces the social acceptability of smoking³⁰.

38. Smoking was once normal across much of society. It is now increasingly uncommon. This is the result of many measures – it has taken many years to get from post-war rates of over 80% of men and 40% of women to 21% and 18% respectively, in the latest Welsh Health Survey³¹.
39. Restricting smoking in non-enclosed spaces, namely hospital grounds, school grounds and public children's playgrounds, would contribute to the policy rationale of continuing the de-normalisation of smoking, as there would be less opportunities for the activity of smoking to be seen. The 2007 Regulations³² have demonstrated the effectiveness of smoke-free policies in de-normalising smoking behaviours even though those restrictions were limited to enclosed and substantially enclosed spaces.
40. The smoke emitted by cigarettes and exhaled by smokers contains more than 50 chemicals recognised as carcinogens, as well as many toxic irritant agents³³. Scientific evidence has been accumulated linking second hand smoke exposure to adverse health outcomes, including respiratory outcomes in children and adults, acute cardiovascular disease and lung cancer. Whilst most of this evidence is based on long term exposure, there are some studies that have reported effects following short term exposure to tobacco smoke, such as eye and respiratory irritation amongst non-smokers³⁴. Such studies show that even brief and short term exposure to second-hand smoke may generate significant adverse effects on the human respiratory system³⁵.
41. The consensus, therefore, is that there is no safe level of exposure to second-hand smoke and, while some progress has been made in non-enclosed smoke-free environments through voluntary action, there are suggestions that comprehensive legislation is the only way to make significant progress to protect public health.
42. A recent report from the Royal College of Physicians³⁶ states "Children may also be less likely to grow up thinking that smoking is a normal or aspirational adult behaviour if they were exposed less to smoking

²⁹ Alesci N, Forster J and Blaine T. Smoking visibility, perceived acceptability, and frequency in various locations among youths and adults. *Preventive Medicine* 2003;36(3):272-81.

Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12634018>

³⁰ Song A and Glantz S. Pushing secondhand smoke and the tobacco industry outside the social norm to reduce adolescent smoking. *Journal of Adolescent Health* 2008;43(4):315–17.

Available from: [http://www.jahonline.org/article/S1054-139X\(08\)00235-8/fulltext](http://www.jahonline.org/article/S1054-139X(08)00235-8/fulltext)

³¹ <http://gov.wales/statistics-and-research/welsh-health-survey/?lang=en>

³² The Smoke-free Premises etc. (Wales) Regulations 2007 (S.I. No.2007/787 (W.68))

³³ <http://www.surgeongeneral.gov/library/reports/secondhandsmoke/fullreport.pdf>

³⁴ <http://www.ncbi.nlm.nih.gov/pubmed/11675270>

³⁵ <http://www.ncbi.nlm.nih.gov/pubmed/21178628>

³⁶ Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London: RCP, 2016. <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

behaviour among adults in their everyday lives, which could be achieved by extending smoke-free policies to outdoor areas, e.g. at school gates, play areas, town centres and other areas where smokers congregate in view of children. Making hospital premises completely smoke-free generates an opportunity to initiate and support cessation among the many smokers, and their visitors, who use hospital services.”

43. Extensions to current smoking bans in selected outdoor areas are supported by the large majority of the population in Italy³⁷, with support for smoke-free school grounds and outdoor areas surrounding hospitals at 85.9% and 79.9% respectively. Further research³⁸ gathered in South Australia showed that pre-legislation support for banning smoking in children’s playgrounds was 94.8%, and this increased to 97.8% post legislation. A review³⁹ of public opinion surveys in the USA and Canada concluded that outdoor smoke-free regulations can achieve majority public support, including from smokers. Data from 89 cross-sectional surveys between 1993 and 2014 indicate that support for smoke-free regulations in outdoor places tended to be highest for smoke-free school grounds (range of 57–95%) playgrounds (89–91%), and building entrances (45–89%).
44. ASH Wales’ Smoke-free YouGov survey carried out in 2014 found that there was 71% support for a ban on hospital grounds and 74% support for a ban in children’s outdoor play areas. The 2016 survey only asked about playgrounds, with 82% supporting a ban⁴⁰. Based on these findings, a high level of compliance with legislation would be expected.

Current position

45. The latest Welsh Health Survey reports a further fall in smoking prevalence, with 19% of adults being regular smokers in 2015.⁴¹ Success has also been achieved in reducing the number of young people who smoke – from 13% of 11-15 year olds smoking at least once a week in 1998, to 4% in 2014⁴².
46. The percentage of non-smokers regularly exposed to second hand smoke dropped significantly from 66% in 2005-06 to 42% in 2007, and since 2008 has remained fairly constant⁴³.

Hospital grounds

³⁷ <http://tobaccocontrol.bmj.com/content/21/1/59.abstract>

³⁸ http://tobaccocontrol.bmj.com/content/early/2014/10/31/tobaccocontrol-2014-051825.short?g=w_tobaccocontrol_ahead_tab

³⁹ <http://tobaccocontrol.bmj.com/content/early/2015/09/13/tobaccocontrol-2015-052426.full?sid=813a5db4-124f-4a7d-8195-3c15ea9171eb&hwoasp=authn%3A1464436061%3A12615712%3A788449346%3A0%3A0%3A1aTOQJWgiBkHWQaOyL3Emw%3D%3D>

⁴⁰ <http://ashwales.org.uk/en/information-resources/factsheets-leaflets>

⁴¹ <http://gov.wales/statistics-and-research/welsh-health-survey/?lang=en>

⁴² <http://gov.wales/docs/caecd/research/2015/151022-health-behaviour-school-children-2013-14-key-findings-en.pdf>

⁴³ Tobacco and Health in Wales 2012 – <http://www.wales.nhs.uk/sitesplus/922/page/50314>

47. Action 4.3 in the Tobacco Control Action Plan 2012⁴⁴ states that “in recognition of the importance of the NHS taking an exemplar role in action to discourage smoking, Local Health Boards and NHS Trusts should introduce smoke-free policies throughout NHS grounds, in addition to the enclosed premises.”
48. In Wales, all seven health boards^{45,46,47,48,49,50,51} and Velindre NHS Trust⁵² currently have comprehensive smoke-free policies. Anecdotal evidence suggests that health boards are having some problems enforcing the voluntary bans on their grounds.
49. Information from one health board indicated that although there were only three or four public complaints to the Health and Safety Officer in the previous year, the staff forum intranet has seen 156 complaints or queries from staff. Also, security logs obtained from that health board show that their Security Officer made 741 challenges to smokers (either individuals or groups) in 2013, and more than 3,000 during 2014. A detailed log covering the period 29 January 2014 to 19 February 2014 lists 89 challenges, with only 11 noted as resulting in an apology, but 18 resulting in a refusal to stop smoking. Responses to the remainder of the challenges logged are either ambiguous or not recorded. A staff survey in the same health board, although with a low response rate, indicated that all staff were aware of the policy and 83% supported it. However, 88% felt that it was not successfully implemented, and 81% stated they would not feel confident to approach staff, patients or visitors regarding the policy.
50. Information from a second health board lists a total of 6,710 challenges in the 15 months for which data were recorded, between October 2014 and May 2016.
51. A newspaper reported in April 2016⁵³ that staff in Betsi Cadwaladr University Health Board were reluctant to challenge smokers defying the voluntary ban on their grounds as they were often met with a negative or aggressive reaction. The health board spokesperson commented on the lack of powers to enforce the ban due to the lack of legislation.
52. Hywel Dda University Health Board has implemented a PA system as a result of regularly receiving complaints about smoking in hospital

⁴⁴ <http://gov.wales/docs/phhs/publications/120202planen.pdf>

⁴⁵ <http://www.wales.nhs.uk/sitesplus/863/page/62820>

⁴⁶ <http://www.wales.nhs.uk/sitesplus/866/document/172145>

⁴⁷ <http://www.wales.nhs.uk/sitesplus/861/document/217609>

⁴⁸ <http://www.cardiffandvaleuhb.wales.nhs.uk/quit-smoking>

⁴⁹ <http://www.cwmtafuhb.wales.nhs.uk/welcome-to-the-smoke-free-environment-si>

⁵⁰ <http://www.wales.nhs.uk/sitesplus/862/document/194807>

⁵¹ <http://www.powysthb.wales.nhs.uk/opendoc/294526>

⁵² <http://www.velindrecc.wales.nhs.uk/smoking>

⁵³ <http://www.dailypost.co.uk/news/north-wales-news/betsi-cadwaladr-health-board-powerless-11170785>

grounds⁵⁴. It enables people to push a button if they see someone smoking outside the hospital building which triggers an announcement reminding people that the hospital is smoke-free.

53. Some health board personnel have suggested particular problems with voluntary bans in hospital grounds, for example tension with neighbours as smokers move off the premises, increased litter and non-compliance by staff.

School grounds

54. Action 4.4 of the Tobacco Control Action Plan 2012⁵⁵ stated that “local authorities should work with all schools to encourage them to adopt smoke-free policies across their school grounds and sports grounds.”
55. The smoke-free policies that are implemented in schools cover staff, pupils, parents and visitors. Some local authority personnel have suggested that the current voluntary bans are well embedded, and have been so for a number of years, with disciplinary and conduct processes in place to deal with non-compliance by staff and pupils. However, from a total of 67 Welsh secondary schools participating in the 2013/14 Health Behaviour in School-aged Children (HBSC) study and completing an additional questionnaire, only 54 (81%) stated that they had a smoke-free policy in place which covered school grounds during school hours⁵⁶.
56. The 2014 Children’s Exposure to Second Hand Smoke (CHETS)⁵⁷ survey found that of the 1,494 children surveyed, 6% reported seeing adults smoking in school grounds about every day, with 26% seeing it sometimes, 59% never seeing it and 9% saying they didn’t know (unpublished data).
57. The Welsh Network of Healthy Schools Schemes (WNHSS) National Quality Award (NQA) includes the requirement to have “policies in place which follow national and local guidance, show consideration of current legislation, include a commitment to smoke-free grounds, and preclude the use of e-cigarettes on school premises and grounds.” The NQA is independently assessed after a school has been involved in the WNHSS for more than nine years. 132 schools have currently been awarded the NQA.

Playgrounds

⁵⁴ <http://www.bbc.co.uk/news/uk-wales-36504482>

⁵⁵ <http://gov.wales/docs/phhs/publications/120202planen.pdf>

⁵⁶ Moore et al, BMC Public Health (2016) 16:138

<https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-016-2763-0>

⁵⁷ <http://gov.wales/statistics-and-research/exposure-secondhand-smoke-cars-ecigarette-use-among-children/?lang=en>

58. Action 4.5 of the Tobacco Control Action Plan 2012⁵⁸ states that “local authorities should be encouraged to introduce smoke-free policies for children’s playgrounds in Wales.” This has been undertaken by co-operative working between ASH Wales and the 22 local authorities in Wales to introduce voluntary bans on smoking in such areas.
59. Email responses from personnel responsible for playgrounds indicate that, in two authorities where monitoring has been undertaken, smoking related litter identified in playgrounds has reduced, but not stopped, since the introduction of voluntary bans. In one of these authorities parents have reported seeing fewer people smoking in the playground following the ban.

Purpose of the provisions

60. The purpose of the Bill provisions is to restate with minor amendments the smoke-free provisions of the Health Act 2006 in so far as it applies to Wales, and make schools grounds, hospital grounds and public playgrounds in Wales smoke-free.
61. These settings are included as voluntary bans have been in place for some time and they have been identified by local authorities, local health boards, third sector organisations and others as the most important settings in which to prevent children’s exposure to smoking behaviour (school grounds and playgrounds) and to support people trying to quit (hospital grounds). The legislation is intended to aid enforcement of the current voluntary bans and provide a coherent package to which to extend the existing smoke-free requirements at this time.
62. The Bill provides that hospital grounds include all grounds which adjoin NHS and private hospitals and are used by them. School grounds include the grounds of maintained and private schools which are used exclusively or mainly by the school for educational, sporting and recreational purposes.
63. Public playgrounds include non-enclosed premises open to the public which contain one or more items of playground equipment for use by children; and in which the local authority or community council has some element of control. These playgrounds will be smoke-free within clearly marked boundaries, or if there is no clearly marked boundary, only so far as within five metres of any item of playground equipment. A five-metre distance from play equipment is provided due to this being beyond the distance of potential second hand smoke harm from a single cigarette, plus an additional buffer to protect against weather elements (such as winds that may carry second hand smoke particulates further than the norm).

⁵⁸ <http://gov.wales/docs/phhs/publications/120202planen.pdf>

64. Managers of all these premises will be required to provide signage indicating that smoking in these grounds is against the law. Penalties for smoking in these premises will be the same as for smoking in enclosed or substantially enclosed public places and workplaces, as will penalties for failing to provide signage. In contrast to existing provisions for enclosed and substantially enclosed premises, no penalty is included for failing to prevent smoking in these places.
65. The Bill also provides that other non-enclosed/substantially enclosed premises could be made smoke-free in the future, through regulations subject to the affirmative procedure, if certain conditions are met. The test which will allow regulations to be made to extend the type of smoke-free premises will be that Welsh Ministers must be satisfied that in doing so they are likely to contribute to the promotion of the health of the people of Wales.
66. In addition, the Bill provides Welsh Ministers with powers to make provision for smoke-free vehicles, which may specify the types of vehicles that are to be smoke-free, the circumstances in which they are smoke-free, that vehicles are to be smoke-free when they are located in specific areas, and for exemptions to any of these requirements. Welsh Ministers may only do so where they are satisfied that this is likely to contribute to the promotion of the health of the people of Wales.

Intended effect of the provisions

67. The intended effect of the provisions is to further reduce children's exposure to adult smoking behaviours in their everyday lives, and therefore to make them less likely to grow up thinking that smoking is a normal or aspirational adult behaviour.
68. A Minnesota study⁵⁹ found an association between the frequency youth observe smoking in various locations and the perception that it is socially acceptable. Policies that restrict smoking in various locations will reduce both the visibility and perceived acceptability of smoking in those locations.
69. The provisions will work with other legislation to contribute to the continuing decline in the uptake of smoking by children and young people. They will work to ensure the further de-normalisation of smoking by restricting smoking in more public places, particularly where children are likely to be present on a regular basis.
70. In addition, the provisions relating to hospital grounds are intended to promote behaviour change and support smoking cessation among the many smokers who use hospital services.

⁵⁹ Alesci NL¹, Forster JL, Blaine T. Smoking visibility, perceived acceptability, and frequency in various locations among youth and adults. *Prev Med.* 2003 Mar;36(3):272-81.
<http://www.ncbi.nlm.nih.gov/pubmed/12634018>

Register of retailers of tobacco and nicotine products

Background

71. Protecting young people from purchasing tobacco and nicotine products (including e-cigarettes and other nicotine inhaling devices) is essential as they may have inadequate information about the health consequences and, in particular, their risk of developing an addiction. Even where they have information, adolescents may not accurately judge the risks of smoking relative to other environmental exposures.⁶⁰ In addition, the younger a person starts smoking, the greater the risk of smoking related disease⁶¹.
72. Nicotine is a potent and powerfully addictive drug, which is five to ten times more potent than cocaine or morphine in producing behavioural and psychological effects associated with addiction potential in humans⁶². Research shows the brain continues to develop during adolescence and it is different from the adult brain. One of the differences is that adolescents are more sensitive to the rewarding effects of nicotine, which may be a reason that many people start to smoke during their teens⁶³. Evidence also shows young people who develop a dependence to nicotine may be unable to reduce their risks due to addiction⁶⁴. With regard to nicotine from smoking tobacco, symptoms of dependence can develop soon after a young person's first puff on a cigarette. Novice users often do not recognise such symptoms as being related to nicotine dependence⁶⁵.
73. The Welsh Government's Tobacco Control Action Plan for Wales⁶⁶ acknowledges the possibility that further management of the tobacco retail environment may be required to combat underage sales, and states, 'The Welsh Government will explore the possibility of introducing a tobacco retail register in Wales.'

Current position

74. A range of legislation has been introduced in Wales to reduce the risk of young people accessing tobacco products. Measures have ranged from

⁶⁰ Tobacco control in developing countries. Oxford University Press. (2000).

⁶¹ British Medical Association (2007). Breaking the cycle of children's exposure to tobacco smoke. British Medical Association.

⁶² Harm Reduction in Nicotine Addiction: Helping People who can't quit. Royal College of Physicians. (2007)

⁶³ Development of the motivational system during adolescence, and its sensitivity to disruption by nicotine. Counotte, D. et al. (2011)

⁶⁴ Di Franza J et al (2007). Symptoms of tobacco dependence after brief intermittent use: the development and assessment of nicotine dependence in youth, Archives of Paediatrics and Adolescent Medicine 162 (7): 704-710

⁶⁵ Milestones in the natural course of onset of cigarette use among adolescents. Gervais, A., et al. (2006)

⁶⁶ <http://wales.gov.uk/topics/health/improvement/index/tobacco/?lang=en>

prohibiting the sale of tobacco products to under 18s to banning the sale of tobacco products from automated vending machines.

75. Currently there is no method of tracking retailers who sell tobacco or nicotine products in Wales, unlike alcohol where premises must have a licence prior to selling. Local authorities have to rely on local intelligence to enforce tobacco legislation.
76. Local authorities currently provide a wide range of advice and guidance to retailers on a number of issues. However, there are challenges in ensuring that tobacco and nicotine retailers are provided with the latest advice and support around relevant issues, due to the absence of a comprehensive list of businesses who sell these products. This means that local authorities may not be able to identify all of the businesses that may require advice or guidance, and could lead to some retailers not receiving crucial information such as changes in the law.
77. Data are available on underage sales of tobacco products in Wales. Trading standards departments conducted a total of 332 test purchase attempts at retail premises, using young volunteers, across Wales during 2012/13. Of these, 51 resulted in a sale, giving a failure rate of 15%. Data from previous years, shown in the table below, indicate that this is a continuing problem.

Table 3.1

Financial Year	Number of attempts to purchase cigarettes by young volunteers	Number of times young volunteers were served	Failure rate
2007-08	148	22	15%
2008-09	720	130	18%
2009-10	884	136	15%
2010-11	518	74	14%
2011-12	536	57	11%
2012-13	332	51	15%

78. Evidence from the North East of England in 2013⁶⁷ showed that young smokers (14-15 year olds) are significantly more comfortable than their adult counterparts in purchasing illegal tobacco. 30% of 14-15 year olds were buyers of illegal tobacco, making them twice as likely as adult smokers in having purchased illegal tobacco. In addition, research published by ASH Wales⁶⁸ indicates that approximately 19% of all illegal tobacco was purchased from a shop (based on the survey conducted for this research in 2014), and the average price of a pack of 20 illegal cigarettes was £4, compared to an average price just short of £8 for legally purchased cigarettes (post-2014 budget).

⁶⁷ NEMS Market Research (2013). North East Illicit Tobacco Survey. NEMS Market Research

⁶⁸ ASH Wales (2014). Illegal Tobacco: The Problem in Wales. ASH Wales

79. A tobacco retail register was introduced in Scotland in 2011 as part of the Tobacco and Primary Medical Services (Scotland) Act 2010⁶⁹. In October 2014 the Scottish Government published a consultation on electronic cigarettes and strengthening tobacco control in Scotland⁷⁰, which closed in January 2015. One of the options the Scottish Government was seeking views on was to establish a statutory requirement for e-cigarette retailers to register on the Scottish Tobacco Retailers Register. The majority of respondents (65%) were supportive of adding e-cigarette retailers to the register. Following this, in June 2015 the Scottish Government introduced the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill, which subsequently received Royal Assent on 6 April 2016. The Act includes provision which will require retailers of nicotine vapour products to register on the register of tobacco and nicotine vapour product retailers. In Northern Ireland, the Tobacco Retailers Act (Northern Ireland) 2014⁷¹ includes provisions on creating a tobacco retail register for Northern Ireland. The register went live on 6 April 2016.
80. In England and Wales, section 143 of the Criminal Justice and Immigration Act 2008 amended the Children and Young Persons Act 1933 to enable a magistrates' court to impose a Restricted Premises Order (RPO) or a Restricted Sale Order (RSO) on those who have persistently sold tobacco to under 18s (on at least three separate occasions within a two year period). A RPO prohibits all sales of tobacco products (including cigarette papers) from the premises for a period up to, but not exceeding one year. A RSO prohibits a person from selling any tobacco products (including cigarette papers), or having any management functions in respect of any premises in relation to the sale on the premises of tobacco products (including cigarette papers), to any person. A RSO can be for any period of time up to, but not exceeding, one year. The Children and Families Act 2014 extends the RPO and RSO regime to include nicotine offences, as well as prohibiting the sale of certain nicotine products as defined by the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015.
81. In Northern Ireland, a court can issue a RPO if the offender has committed three tobacco offences within the last five years. These offences must have resulted in either a Fixed Penalty Notice or a conviction; however this is not restricted to sales of tobacco to under 18s. In Scotland, the Sheriff can issue a Tobacco Banning Order if the person has been subject to three or more relevant enforcement actions within the last two years in respect of each premise specified in the Order. A person is the subject of a relevant enforcement action if they have been issued with a Fixed Penalty Notice or convicted of an offence within Chapter 1 (Display, Sale and Purchase of tobacco products) or Chapter 2 (Register of tobacco retailers) of the Tobacco and Primary Medical Devices (Scotland) Act 2010.

⁶⁹ <http://www.legislation.gov.uk/asp/2010/3/contents>

⁷⁰ Scottish Government (2015). A Consultation on Electronic Cigarettes and Strengthening Tobacco Control in Scotland. Scottish Government

⁷¹ <http://www.legislation.gov.uk/nia/2014/4/crossheading/register-of-tobacco-retailers/enacted>

82. In relation to nicotine products, sections 92 and 93 of the Children and Families Act 2014 provide the Secretary of State with the power to make regulations to prohibit the sale of nicotine products to persons under the age of 18. This is intended to protect children and young people from the risk of nicotine addiction and possible tobacco use. The UK Government ran a six week consultation on behalf of England and Wales on the draft regulations, which closed on 28 January 2015. The regulations were then made on 25 March 2015⁷² and came into force on 1 October 2015.
83. Results from a report⁷³, published in July 2014 by Public Health England and the Trading Standards Institute, of a test-purchasing study involving young people under the age of 18 attempting to purchase e-cigarettes from a variety of retailers, showed that 40% of young people were able to purchase nicotine inhaling products. However, at that time it was not the subject of a specific offence.
84. The Chartered Trading Standards Institute conducted a rapid review of the Nicotine Inhaling Products (Age of Sale & Proxy Purchasing) Regulations 2015 which came into force October 2015. A total of 634 test purchases of e-cigarettes were made by young volunteers under the age of 18 between January and March 2016. The results of the report showed that compliance with the new regulations prohibiting e-cigarettes being sold to persons under the age of 18 was still low, with 39% of young people able to purchase nicotine inhaling products⁷⁴.
85. In February 2016 HMRC launched a consultation on the control of tobacco manufacturing equipment and possible licensing of those involved in the supply chain for tobacco products.⁷⁵ HMRC is interested in gauging opinion on whether a licensing system for the tobacco products supply chain should be introduced to meet the UK's obligations under article 6 of the World Health Organisation Framework Convention on Tobacco Control (WHO FCTC) Protocol. The aim of the protocol is to eliminate illicit trade in tobacco products. The consultation closed on 20 May 2016.

Purpose of the provisions

86. In order to further strengthen the current tobacco control legal framework, the Bill includes provisions to establish a national register of retailers of tobacco and nicotine products. The primary purpose is to reinforce the importance of protecting under 18s from tobacco and nicotine

⁷² S.I. 2015/895 – The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015

⁷³ Trading Standards Institute (2014). Youth access to E cigarettes and associated products. Trading Standards Institute

⁷⁴ Rapid review of business compliance conducted by Trading Standards Services in England. 2016. Chartered Trading Standards Institute

⁷⁵ <https://www.gov.uk/government/consultations/tobacco-illicit-trade-protocol-licensing-of-equipment-and-the-supply-chain>

products, as well as reducing the risk of under 18s accessing these products.

87. All retailers who sell either tobacco products or nicotine products to the general public in Wales will have to register in order to be permitted to sell these products (as will be defined in regulations). The register will not capture any business which only sells to other retailers, traders or businesses. One application form per retailer will be submitted to cover all of their premises where these products are sold. Welsh Ministers may make regulations to require an application to be accompanied by a fee.
88. The creation of a national register of retailers of tobacco and nicotine products will provide local authorities with a definitive list of retailers within their authority who sell either tobacco or nicotine products. Local authorities will therefore be able to utilise the register to aid enforcement of tobacco and nicotine legislation, for example relating to the age of sale and display of tobacco products, and the age of sale of nicotine inhaling devices. This will lead to a significant change to the current position of fragmented intelligence.
89. The register will also be an invaluable tool in disseminating information and guidance to retailers around the sale of tobacco and nicotine products. This could include, for example, information on changes to legislation which retailers need to be aware of, or guidance which provides advice or support for retailers. Having a register of retailers of these products is intended to reduce the risk of retailers not being aware of important legislation on the way these products are sold, for example the ban on selling tobacco products in automated vending machines.
90. A Registration Authority will be named to manage the national register for the whole of Wales, which may be a local authority or other body (such as a voluntary sector or private organisation). This role will include processing applications for premises to be included on the register. The Registration Authority may not grant an application if it relates to premises which are currently under a RPO, or to an individual who is currently the subject of a RSO. If an application is received with multiple premises, only the premises currently subject to a RPO would not be added to the register.
91. The Bill provides that it will be an offence to sell tobacco or nicotine products from premises (including mobile units) in Wales if they are not on the national register. It also places a duty on retailers to notify the Registration Authority of certain changes (such as if a retailer is no longer selling tobacco or nicotine products, or a change of ownership). This is to ensure that the register contains the most up to date information possible on retailers of tobacco and nicotine products.
92. Local authorities will enforce offences relating to the register. In order to effectively enforce these offences, it may be necessary to gain entry to non-registered premises from which it is believed that tobacco products

and/or nicotine products are being sold. The Bill therefore provides a power of entry to local authority officers, along with an associated offence of obstructing an officer from exercising this power. If an enforcement officer enters unoccupied premises then the officer must leave the premises in a secure state.

93. In addition to creating a register, the Bill will also provide Welsh Ministers with powers to include other tobacco offences that may be counted towards the application for a RPO. In order to include new offences, the offence must be at least a Level 4 penalty and be an offence that relates to the supply, sale, transport, display, offer for sale, advertising or possession of tobacco or nicotine products. Such regulations will be subject to the affirmative procedure.
94. Adding other tobacco and/or nicotine offences to the current RPO regime will reinforce the importance of selling these products responsibly. Evidence indicates the most effective incentive for legislative compliance is the real threat of a loss of licence, rather than the possibility of a prosecution and a fine.⁷⁶
95. Having an enhanced RPO regime is intended to provide Wales with a more effective negative licensing model. A negative licensing system is one in which no licence or permit is required prior to trading, but a business committing serious breaches may be barred from selling products. For tobacco and nicotine products, this means that a retailer would not need to obtain a licence prior to selling these products, but if they commit three relevant tobacco or nicotine offences within a three year period they may be issued with a RPO, which will prohibit the selling of these products from the premises for a period up to one year. The length of time a retailer will be prohibited from selling tobacco products or nicotine products will be determined by a magistrates' court. If a premise is subject to a RPO, it may not be included on the retail register until such time as the Order expires.

Intended effect of the provisions

96. The intended effect of the legislation is to protect children and young people under the age of 18 from the harms associated with tobacco and nicotine use. This will be achieved by providing local authorities with a definitive list of retailers who sell tobacco and/or nicotine products within their authority area. This will assist trading standards officers within these areas in enforcing existing tobacco legislation, and provide retailers with guidance and information on their responsibilities linked to tobacco and nicotine products legislation.
97. In addition, it is anticipated that combining a strengthened RPO regime with a national register will add benefit by enhancing existing levers

⁷⁶ Licensing of Tobacco Retailers and Wholesales. The Allen Consulting Group. 2002

available to local authorities for enforcement of tobacco and nicotine offences. These provisions will also support the policy aim of reducing access to tobacco and nicotine products by under 18s.

Handing over tobacco etc. to persons under 18

Background

98. Most smokers start smoking during adolescence and, currently in Wales among school Year 11 pupils (i.e. aged 15-16), 7% of boys and 9% of girls are regular (weekly) smokers⁷⁷. Two thirds of adults who have ever smoked in the UK say that they started smoking before the age of 18 and two fifths had started smoking regularly before the age of 16⁷⁸. Those under the age of 18 are particularly vulnerable consumers, as previously outlined.
99. Controlling access is an established strategy for reducing consumption of substances harmful to health, in particular tobacco. Restricting young people's access to tobacco and nicotine products can therefore help protect them from developing an addiction to nicotine⁷⁹. Article 16 of the WHO Framework Convention on Tobacco Control states, "Each Party shall adopt and implement effective legislation, executive, administrative or other measures at the appropriate government level to prohibit the sales of tobacco products to persons under the age set by domestic law, national law or eighteen"⁸⁰.
100. Remote sales are purchases of tobacco products or nicotine products through the internet or phone sales, which are then delivered to a nominated address. Alternatively, they can involve paying for them at the point of order and arranging to collect the products at a later point.
101. Whilst there are no specific UK or Welsh studies on the number of under 18s currently attempting to purchase tobacco remotely, there is evidence of a problem with the delivery of online sales of other age restricted products, such as alcohol. A survey conducted by South Wales Police in March 2013 using 15 year old volunteers to attempt to purchase alcohol from major supermarket websites, found that in 44% of the cases alcohol was delivered to the volunteer with no proof of age requested⁸¹. Alcohol Concern Cymru conducted a survey of 1,000 14-17 year olds in 2013 and found that 15% of all the 14-17 year olds had successfully

⁷⁷ Welsh Government (2015). 2013/14 Health Behaviour in School-aged Children (HBSC) Wales: key findings. Social Research No. 58/2015. Cardiff: Welsh Government.

⁷⁸ Office for National Statistics. General Lifestyle Survey 2011. Office for National Statistics (2013)

⁷⁹ Stead L.F, Lancaster T. Interventions for preventing sales to minors (review). The Cochrane Collaboration 2008.

⁸⁰ World Health Organisation. WHO Framework Convention on Tobacco Control. World Health Organisation 2003.

⁸¹ Alcohol Concern Cymru. On Your Doorstep. Alcohol Concern Cymru 2013

purchased alcohol online, with 21% of those aged between 14 and 15⁸². It is considered reasonable to assume similar issues could become apparent for similar age-restricted goods, such as tobacco products and nicotine products.

102. There is already some evidence from the USA that there may be an issue with young people being able to access tobacco products via the internet. It has been found, for example, that in the majority of cases 11 to 15 year olds were able to purchase tobacco products via the internet. Out of 83 purchase attempts, 93.6% of purchases attempted by credit card and 88.9% of purchases attempted by money order were successful⁸³. Another recent study has also shown that minors were easily able to purchase e-cigarettes from the internet.⁸⁴

Current position

103. The current legal position on underage sales of tobacco (including cigarette papers) is set out in the Children and Young Persons Act 1933, the Children and Young Persons (Protection from Tobacco) Act 1991 and the Children and Young Persons (Sale of Tobacco) Order 2007. In summary, it is illegal to sell cigarettes or other forms of tobacco products, including cigarette papers, to a person under 18 years of age. Additional legislation has been introduced to prevent under 18s from gaining easy access to tobacco products, such as prohibiting the sale of tobacco from vending machines⁸⁵, and the Children and Families Act 2014 introduced an offence for someone over the age of 18 to purchase, or attempt to purchase, tobacco products for a person or persons under the age of 18⁸⁶.
104. In relation to nicotine products, sections 92 and 93 of the Children and Families Act 2014 provide the Secretary of State within the UK Government with the power to make regulations to prohibit the sale of nicotine products to persons under the age of 18 in England and Wales. Regulations were made on 25 March 2015 and came into force on 1 October 2015.⁸⁷
105. There is no current legislation which prevents tobacco products or nicotine products which have been purchased remotely from being handed over to a person or persons under the age of 18. As other opportunities to access tobacco products or nicotine products are reduced, remote sales could provide children and young people under the age of 18 with access to these products.

⁸² Same as previous reference

⁸³ Kurt M. Ribisl, PhD; Rebecca S. Williams MHS; Annice E. Kim, MPH. JAMA 2003

⁸⁴ Williams RS, Derrick J, Ribisl KM. Electronic Cigarette Sales to Minors via the Internet. *JAMA Pediatr.* 2015 Mar 2; 169(3): e1563. Doi:10.1001/jamapediatrics.2015.63

⁸⁵ The Protection from Tobacco (Sales from Vending Machines) (Wales) Regulations 2011

⁸⁶ Children and Families Act 2014

⁸⁷ S.I 2015/895 – The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015

106. Currently every major supermarket chain in Wales that makes home deliveries which include tobacco products has voluntary policies in place to govern their deliveries. These policies provide that their drivers are not permitted to hand over the tobacco products to any customer who appears to be under the age of 18, if they cannot provide proof of age to confirm they are 18 or over. It is likely that some retailers will extend their policies to cover nicotine products in response to regulations which introduced an age of sale for nicotine products in England and Wales in 2015.
107. While there are a number of retailers who currently have policies, this voluntary practice is not universal across all retailers who sell tobacco products remotely, and there is currently no legal requirement for retailers to ensure tobacco and/or nicotine products are only being handed over to persons aged 18 or over.
108. According to data published by the Office of National Statistics⁸⁸ internet sales have increased in recent years. In March 2012 internet sales contributed 8.9% of all retail sales, increasing to 31.3% in July 2016. For food stores this has increased from 2.9% in March 2012 to 4.6% in July 2016. This indicates that using the internet as a method for shopping is continuing to increase, and it is likely that this trend will continue. It has been assumed that this upward trend is likely to be reflected across the spectrum of goods available for remote purchasing, including tobacco and nicotine products.

Purpose of the provisions

109. In recognition of the potential for persons under the age of 18 to access tobacco and nicotine products via remote sales, and the voluntary nature of the policies currently in place, the Bill creates a new offence of handing over these products to a person under the legal age of sale in Wales. The primary purpose of the offence is to reduce the risk of young people under the age of 18 from accessing tobacco products and/or nicotine products which form part of the delivery.
110. The offence would only occur in situations where the delivery driver is aware that they are handing over either tobacco products and/or nicotine products to someone who is under the age of 18. As such, postal services such as Royal Mail, or courier services where the courier is delivering a fully enclosed and addressed package would not be covered by the offence.
111. It will be the responsibility of the person handing the tobacco or nicotine product over to the customer to ensure they have followed the appropriate age verification checks. It will not be an offence if the person handing over tobacco or nicotine products had taken reasonable steps to determine the age of the person, or that they could not have reasonably

⁸⁸ Retail Sales, June 2016. Office of the National Statistics

suspected from their appearance they were under the age of 18. A person who commits an offence of handing over a tobacco product or nicotine product to an unsupervised person under the age of 18 will be liable, on summary conviction, to a fine not exceeding level 4 on the standard scale. Local authorities will be responsible for enforcing the provisions.

112. It will not be an offence if the handing over of tobacco or nicotine products takes place in the presence of another person who is aged 18 or over.

Intended effect of the provisions

113. The intended effect of the provisions is to reduce the risk of young people under the age of 18 of accessing tobacco and /or nicotine products. This will be achieved by requiring delivery agents to visually assess if the person they are handing the tobacco products and/or nicotine products to is aged 18 or over, and verify their age where appropriate. This will be similar to the process of purchasing these products in a shop.
114. The provisions will also further enhance the overall legislative framework aimed at protecting children and young people from the harms associated with tobacco and nicotine, such as the age of sale legislation and the ban on selling tobacco products from vending machines.

Special procedures

Background

115. A number of cosmetic and therapeutic procedures have become increasingly popular over the last decade, both in Wales and further afield. These include acupuncture, body piercing, electrolysis and tattooing.
116. There are known and well reported health risks connected to these procedures defined within the Bill as 'special procedures'. Infections at the site of the procedure can occur, which can in rare events go on to have disfiguring and life threatening consequences. Improper and unhygienic practices may result in the spread of infectious diseases, such as blood-borne viruses,⁸⁹ that can affect the health of clients, as well as jeopardise the health of the practitioner themselves. Serious infection control deficiencies associated with a piercing and tattoo studio in Newport resulted in a number of customers suffering serious skin infections requiring in-patient care and reconstructive surgery, following piercings performed at the studio. A look-back exercise, affecting over 800 people, most of them young people, was also undertaken to identify any clients

⁸⁹ Hayes, MO. Harkness, GA. (2001) Body piercing as a risk factor for viral hepatitis: an integrated research review. American Journal of Infection Control. 29, 271-274.

potentially infected with blood borne viruses⁹⁰. To reduce the risk it is therefore important that practitioners employ safe working practices, and particularly that good infection control practices are followed at all times, so that both clients and practitioners are adequately protected.

117. Complications that can arise include swelling, infection, bleeding, allergic or toxic reactions to the substances used, as well as tears or other physical injury. Nerve damage and scarring may also occur if procedures are poorly performed. In relation to piercing, a survey carried out in England found that over a quarter of people who had a piercing procedure (other than of the earlobes) experienced complications, and around half of those who experienced complications considered them serious enough to seek further help.⁹¹ The prevalence was higher amongst those aged 16-24, with health problems occurring with around a third of piercings. Although most problems associated with a piercing are usually minor and self limiting, some complications are serious enough to require medical attention or admission to hospital, and there are individual cases of significant damage to health.^{92, 93} Poorly performed oral piercings can damage the tongue and teeth, cause airway obstruction through swelling, and affect speech.⁹⁴ Complications can be particularly serious for those with underlying health conditions, and cases of individuals who have died following a piercing have been recorded.^{95,96}

118. The risks associated with special procedures can be minimised by taking a number of steps. These include:

- Good cleanliness of the premises where the procedure is taking place, and of the fixtures and fittings;
- Hygienic practices by practitioners;
- Having correct processes in place for cleaning, sterilization or disposal of instruments, materials and equipment; and
- Pre and post-procedure consultations.

Current position

⁹⁰ Public Health Wales (2015) Newport tattooing and piercing concerns update. Available at: <http://www.wales.nhs.uk/sitesplus/888/news/37472/>

⁹¹ Bone, A. Ncube, F. Nichols, T and Noah, ND. (2008) Body piercing in England: a survey of piercing at sites other than earlobe. *BMJ*, 336, 1426.

⁹² M. L. Armstrong, S. DeBoer and F. Cetta, "Infective endocarditis after body art: A review of the literature and concerns," *Journal of Adolescent Health*, vol. 43, no. 3, pp. 217-225, 2008.

⁹³ BBC News online (2007) Belly stud 'almost killed teen' Available at: http://news.bbc.co.uk/1/hi/wales/south_east/7020936.stm

⁹⁴ L. R. Stead LR, Williams JV, Williams AC and Robinson CM (2006) An investigation into the practice of tongue piercing in the South West of England. *British Dental Journal* 200 103-107.

⁹⁵ BBC News online (2005) Lip piercing death 'misadventure'. Available at: http://news.bbc.co.uk/1/hi/england/south_yorkshire/4429298.stm

⁹⁶ BBC News online (2010) Caerphilly woman's infection death after tongue pierce. Available at: <http://www.bbc.co.uk/news/uk-wales-11543757>

119. Existing legislative controls in relation to special procedures aim to ensure that infection control arrangements are adequate and effectively carried out. The primary means of enforcing these arrangements is by use of the registration requirements in the Local Government (Miscellaneous Provisions) Act 1982 ('the 1982 Act'). In addition, there are other regulatory controls that contain provisions for the immediate prohibition of activities, or for the control of premises or things where a risk of significant harm to public health can be demonstrated.
120. The creation of a registration scheme under the 1982 Act is not mandatory. In addition, where local authorities have adopted the provisions, enforcement is often inconsistent across Wales. Many local authorities have not yet adopted the most recent Welsh Government model byelaws⁹⁷ relating to the cleanliness and hygiene of premises, practitioners and equipment.
121. Local authorities are only able to refuse an application for registration under the 1982 Act if the applicant has already had a previous registration cancelled by the courts as a result of being found guilty of an offence (such as breaching a byelaw on hygiene). The majority of applications have to be approved.
122. Enforcement of the registration requirement relies on a local authority being able to prove that a person is 'carrying on a business'. This can be difficult as, for example, some practitioners may work from home.
123. Registration under the 1982 Act is also not subject to a 'competency test' to require that those performing the procedures can demonstrate a level of hygiene and infection control knowledge that is appropriate. Neither is there any requirement for consent forms, pre- and post-procedure consultation, aftercare advice or record keeping. It is considered, therefore, that the current registration system does not address the public health concerns and protect the public effectively, and there have been examples of unregistered practitioners being prosecuted.⁹⁸

Purpose of the provisions

124. In response to the perceived inadequacies with the current system, the Bill seeks to repeal the 1982 Act provisions and replace it with a compulsory, national licensing system for practitioners of specified special procedures in Wales. The system will mean that in order to perform any of the special procedures defined within the Bill, an individual must be licensed and the premises or vehicle from which they operate approved. Individual licences and approvals will be valid for a period of three years.

⁹⁷ Welsh Government website:

<http://wales.gov.uk/topics/health/protection/communicabledisease/acupuncture/?lang=en>

⁹⁸ <http://www.walesonline.co.uk/news/local-news/illegal-tattooist-taken-court-fined-7691855>

Temporary licences and approvals will also be available for exhibitions and events.

125. This system aims to better meet customer expectations and respond to the different business models within the sector. The intention is to ensure that individual practitioners practice to appropriate standards (for example relating to hygiene, record keeping and age verification), as well as ensure that special procedures are only carried out in suitable environments. The overall purpose is to ensure that where these special procedures are provided in Wales, they are carried out in a manner which is not potentially harmful to health.

126. The procedures defined as 'special procedures' for the purposes of the licensing system are:-

- Acupuncture;
- Body piercing;
- Electrolysis; and
- Tattooing.

127. The Welsh Government is aware that the area of special procedures is a quickly evolving one, and is subject to a number of factors including changes in fashion trends. In order to ensure the legislation remains up to date and effective as new procedures are constantly being devised, the Bill provides Welsh Ministers with a power to amend the list of special procedures. This will be done following consultation, via secondary legislation, subject to the affirmative procedure.

128. Following the establishment of the licensing system, it will be an offence for a practitioner to conduct any special procedures without a licence or to perform them from premises or vehicles that are not approved. The Bill does provide exemptions to these requirements, for example members of specific professions (such as doctors, dentists and nurses) will not be required to have a licence to practice special procedures, unless regulations provide otherwise. A power is also available for Welsh Ministers to exempt members of other specified professions via regulations, subject to the affirmative procedure.

129. Welsh Ministers will, by way of regulations, set licensing criteria and mandatory licensing conditions, so that standards of practice and enforcement of special procedures are consistent throughout Wales. The licensing criteria will specify, amongst other things, an individual's eligibility for a licence based upon their ability to demonstrate knowledge of infection control, first aid and their legal obligations - for example not to tattoo an individual who is under the age of 18 years. The mandatory licensing conditions will set out the requirements a licence holder must meet in order to retain their licence. These will include conditions relating to verification of age, infection control practices, standards of hygiene, first aid, pre and post-procedure consultations and record keeping. The conditions will also prohibit a licence holder from performing a special

procedure on an individual who is, or appears to be, intoxicated from drinks, drugs, or any other means.

130. The Bill requires that licence holders and holders of premises/vehicles approvals will be under a duty to meet the requirements and to operate in accordance with the national conditions. This includes the display of licences and approval certificates which will assure consumers that the practitioner is licenced and the premises/vehicle has been approved by the local authority for the performance of special procedures.
131. In addition, the Bill provides that local authorities are to be responsible for enforcing the licensing requirements, and for keeping a register of special procedures licences issued by them that have not ceased to have effect and premises/vehicles that they have approved. A local authority must make the information on the register open to the public. Welsh Ministers can arrange for the duties imposed on local authorities (i.e. to keep a register) to be discharged by a single local authority. The single local authority would then keep a central register on behalf of the others. The register has the purpose of ensuring that anyone seeking to have one of the defined special procedures can search for information and know that the practitioner or business they choose has met the national standards.
132. The Bill also creates a number of requirements and offences. To prevent the provision of special procedures without holding a licence, or a non-approved premises/vehicle being used for the provision of special procedures, a local authority can issue a stop notice that will apply anywhere in Wales. The local authority may also take action by issuing a remedial action notice if a licence holder or premises/vehicle contravenes one or more of their applicable mandatory conditions. This remedial action notice will order specific action and steps to be taken to rectify the issue within 14 days. The Bill provides local authority officers with the power to enter premises for the purpose of determining applications for licences or approvals, to carry out inspections and to enforce the requirements.
133. If a local authority is satisfied that a licence holder has failed to comply with a mandatory licensing condition or has been convicted of a relevant offence, then the Bill provides that it may revoke a special procedure licence, either in full or in so far as it relates to the performance of a particular special procedure. Similarly, the local authority can revoke the premises/vehicles approval. Where the local authority has taken action such as issuing a stop notice, revoking a licence/approval or refusing an application, an individual has the right to make representations to the local authority and appeal to a magistrates' court against the decision.

Intended effect of the provisions

134. The legislation will introduce a system of mandatory licensing for those practitioners who provide special procedures in Wales, to which national standards will be attached and enforced by local authorities. The system

aims to drive up standards in relation to the performance of special procedures, and ensure an improved and consistent approach to the regulation of these procedures across Wales.

135. In addition to the benefits associated with improving standards of practice, individuals who wish to have one of the special procedures performed will also directly benefit by having improved access to information about the procedure before it is undertaken, as well as aftercare advice. People seeking to undergo these procedures will be able to assure themselves that the premises/vehicle they visit has been approved by the local authority for the performance of special procedures, and that the practitioner is competent to perform the procedure hygienically. They will also be able to access a register of licence holders and approved premises/vehicles for special procedures within their area. This will help improve transparency and ensure people in Wales are better informed about the practice of special procedures.
136. It is intended that the majority of licence holders who perform special procedures, and the premises/vehicles where they are performed, will gain reputational benefits from the system. By meeting the requirements, they will be able to demonstrate to the public that they practice to appropriate standards of hygiene and cleanliness, as well as protecting themselves from health risks by undertaking appropriate infection control procedures. Public confidence and client understanding will be further enhanced by the requirement for practitioners to provide pre- and post-procedure consultations to ensure that people are fully aware of the risks connected with the particular procedure, including aftercare advice. This should result in a lower incidence of infection, if the aftercare advice provided is appropriately adhered to.
137. As well as improving client and practitioner safety, the Bill will also provide local authorities with consistent and effective enforcement powers with which to inspect premises/vehicles and, where necessary, prevent unsafe practice.
138. Beyond this, the benefits of improved hygiene and cleanliness may extend to other procedures offered by practitioners, even though they are not covered by the requirements of the legislation.

Intimate piercing

Background

139. For the purposes of this Part of the Bill, “intimate piercing” includes piercings of the nipples, breast, genitalia, buttocks or tongue.
140. As previously indicated above within the section on special procedures, complications following body piercing can include swelling, infection, bleeding, allergy and tear or physical injury. Fracturing and chipping of

teeth have also been reported for tongue piercing, and nerve damage and scarring may occur if a body piercing is poorly performed⁹⁹. Complications can be particularly serious for those with underlying health conditions, and cases of individuals who have died following a piercing have been recorded^{100,101}. In addition, although uncommon, unsafe or unhygienic practices can lead to the transmission of infectious diseases such as blood borne viruses.¹⁰²

141. A study in England found that amongst individuals aged 16-24 complications were reported with around a third of all body piercings¹⁰³. The same study found a higher incidence of complications in connection with certain types of body piercings, including intimate piercings. Problems were most likely to be reported in the case of tongue piercing (50%), followed by piercings of the genitals (45%) and the nipples (38%).
142. Furthermore, as young people continue to grow during their teenage years, an intimate piercing performed at a young age could result in further complications arising as their bodies develop. Young people may also be less likely to have the experience or knowledge of how to clean or maintain an intimate piercing, leading to an increased risk of infection.
143. There are also issues around the sexualisation of young people: tongue piercings, for example, can be associated with sexual activity. Beyond this, the intimate piercing of children and young people may also be considered a child protection issue. By undergoing the procedure, young people may be placed in a vulnerable position in which their 'intimate' areas are exposed to, touched and pierced by an adult who may be previously unknown to them.
144. It is therefore considered that there is a need to strengthen the legislative framework relating to the intimate piercing of children and young people. This is considered necessary to both protect them from potential health harms and threats to their well-being.

Current position

145. In Wales there is currently no age restriction for any body piercing.

⁹⁹ Stead LR, Williams JV, Williams AC and Robinson CM (2006) An investigation into the practice of tongue piercing in the South West of England British Dental Journal 200 103-107.

¹⁰⁰ BBC News online (2005) Lip piercing death 'misadventure'.

http://news.bbc.co.uk/1/hi/england/south_yorkshire/4429298.stm

¹⁰¹ BBC News online (2010) Caerphilly woman's infection death after tongue pierce. Available at: <http://www.bbc.co.uk/news/uk-wales-11543757>

¹⁰² Hayes, MO. Harkness, GA. (2001) Body piercing as a risk factor for viral hepatitis: an integrated research review. American Journal of Infection Control. 29, 271-174

¹⁰³ Bone, A. Ncube, F. Nichols, T and Noah, ND. (2008) Body piercing in England: a survey of piercing at sites other than earlobe. BMJ, 336, 1426.

146. As a general principle, and where legislation does not provide to the contrary, a young person can give valid consent to a procedure if they are sufficiently capable of understanding the nature of the act to be done. In each case, the question of capacity must be determined in accordance with the *Gillick*¹⁰⁴ principles.
147. Due to the nature of the procedures and the intimate areas involved, criminal legislation such as the Sexual Offences Act 2003 ('the 2003 Act') may be relevant, particularly offences such as sexual assault. However, an intimate piercing is not automatically a sexual assault or criminal offence. Section 3 of the 2003 Act provides that a person commits an offence of sexual assault if:
- (A) intentionally touches another person (B);
 - the touching is sexual;
 - (B) does not consent to the touching; and,
 - (A) does not reasonably believe that (B) consents.
148. Section 7 of the 2003 Act provides for the offence of sexual assault of a child under the age of 13. Section 7 does not allow for a child to consent to the touching. This essentially means that a child under the age of 13 cannot consent to a sexual assault regardless of their mental capacity or comprehension. However, a person over the age of 13 can legally consent to a sexual assault.
149. In applying the section 7 test, there is no argument that a practitioner of intimate piercing would be intentionally touching another person if they were to perform a piercing on them. The question therefore is whether that touching is classed as 'sexual'.
150. The question of whether intimate piercing is 'sexual touching' as defined within section 78 of the 2003 Act depends on how a 'reasonable person' views the activity. If it is not considered to be sexual touching, a child under the age of 13 would be able to consent to the touching; if however it is considered to be sexual touching, then only a person over the age of 13 can consent to it.
151. It is understood from discussions with people within the sector that many practitioners already choose not to perform intimate piercing on young people. However, intimate piercing is not expressly prohibited by law.

Purpose of the provisions

152. The primary purpose of these provisions in the Bill is to protect children and young people from the potential health harms which can be caused by an intimate piercing, and to avoid circumstances where children and young people are placed in a potentially vulnerable situation. The Bill seeks to achieve this by prohibiting the intimate piercing of a person who is under

¹⁰⁴ *Gillick v West Norfolk and Wisbech Health Authority* [1986] AC 112, [1985] 3 All ER 402

the age of 18 in Wales, in any setting. It will also be an offence to make arrangements to perform such a procedure on a person under the age of 18 in Wales.

153. The provisions in the Bill only capture the perforation of the skin or mucous membrane of an intimate body part (including male and female genitals) if done for the specific purpose of attaching jewellery or an object (such as beads) to be attached to, implanted in or removed from an individual's body. These provisions are very different to those covered by the Female Genital Mutilation Act 2003. Female genital mutilation (FGM) involves procedures which include the partial or total removal of the external female genital organs for cultural or other non-therapeutic reasons. FGM has been a specific criminal offence in the UK since the passage of the Prohibition of Female Circumcision Act 1985. The Serious Crime Act 2015 has since placed a statutory duty on regulated health professionals, teachers and care workers to report FGM, including genital piercings in females under the age of 18, to the police¹⁰⁵. This reporting does not mean that the person who carried out the piercing has necessarily committed a crime – it is more a mechanism to ensure that cases of FGM are brought to light and investigated.

154. By setting the prohibition on intimate piercing at the age of 18, the Bill provisions are consistent with other public health age related interventions including the law relating to tattooing, the sale of alcohol and cigarettes.

155. The prohibition also aims to reinforce existing good practice within the piercing industry. Many practitioners choose not to perform intimate piercings on young people, but because the law does not expressly prohibit it, it is still possible for a person under the age of 18 to undergo these procedures.

156. The Bill provides that it will be an offence for a person in Wales to perform or make arrangements to perform an intimate piercing on a person who is under the age of 18. This means that a young person would not have to undergo an intimate piercing for an offence to be committed – making arrangements to carry out the piercing is sufficient for an offence to be committed.

157. The fact that a person under the age of 18 may have given their consent will not be a defence. Similarly, it will not be a defence to say that a parent or guardian of the person under the age of 18 consented to the intimate piercing on their behalf.

158. The Bill provides a defence that the practitioner believed the person was aged 18 or over and either they had taken reasonable steps to establish their age or that nobody could reasonably have suspected from the person's appearance that they were under 18. There is also a 'due diligence' defence for a person who is accused with an offence by virtue of

¹⁰⁵ <http://www.legislation.gov.uk/ukpga/2015/9/section/74>

the actions of another. It will be a defence for the person accused of the offence to demonstrate that they took reasonable precautions and exercised due diligence to avoid committing the offence, for example providing training to their staff or putting systems in place to avoid committing the offence.

159. The Bill places a duty on local authorities to undertake enforcement action in relation to the provisions, including bringing forward prosecutions, investigating complaints and taking other steps. These steps may involve communicating with body piercing practitioners to prevent an offence taking place or undertaking 'test purchasing' inspections to assess compliance. The local authority must also consider, at least once every 12 months, the extent to which it is appropriate for them to carry out a programme of enforcement action within their area to prevent the intimate piercing of persons under 18 years. The local authority must appoint 'authorised officers' for these purposes. In undertaking their programme of enforcement action, the local authority must consult with the Chief Officer of Police who may assist the local authority with the enforcement of the provisions.

160. In order to allow investigations as to whether a practitioner is making arrangements to, or performing intimate piercings on individuals aged under 18, it may be necessary to gain entry to premises from which intimate piercings are carried out. The Bill provides powers of entry to local authority authorised officers and the Police, although access to premises used as a dwelling will require a warrant by a Justice of the Peace. Once the officer or the constable has gained entry, they may undertake an inspection of the premises and obtain copies of, for example, CCTV records or consent documents. The power of entry is accompanied by an associated offence of obstructing an officer from exercising their powers. The Bill also provides safeguards in relation to the use of the powers of entry and inspection by providing a mechanism to appeal against the removal of property, and to apply for compensation in certain circumstances. These also apply to the equivalent powers of entry and inspection under different Parts of the Bill.

Intended effect of the provisions

161. Whilst many practitioners in Wales already choose not to perform intimate piercings on children and young people, the changes brought forward in the Bill will achieve greater clarity and consistency in the law. As such, practitioners should no longer be at risk of complaints from parents or allegations of improper conduct in relation to this issue. At the same time, young people under the age of 18 will be protected from being placed in potentially vulnerable situations.

162. Imposing an age restriction of 18 for intimate piercings in Wales will contribute to the promotion of good health by helping to avoid unnecessary harm. The Bill will do this by seeking to reduce the incidence of body

piercing-related complications (including infections and injuries) amongst young people whose bodies are still maturing, and who may be less adept at keeping up with aftercare requirements.

Health Impact Assessments

Background

163. Health Impact Assessments (HIAs) offer a systematic means of taking health into account as part of decision making and planning processes. They are a tool which can be used in any area of public, private or voluntary sector activity, and at both national and local levels.
164. A widely accepted definition for HIAs describes “a combination of procedures, methods and tools by which a policy, programme or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population.”¹⁰⁶ These effects can be on both mental and physical health, and be social, economic, environmental or cultural in origin. HIAs therefore take into account the broad range of determinants of overall health and well-being. While some effects explored by HIAs may be direct, obvious and/or intentional, others may be indirect, difficult to identify and/or unintentional. HIAs attempt to anticipate and mitigate such effects.
165. The World Health Organisation has noted a number of benefits of HIAs¹⁰⁷, including:
- Provision of the best available evidence to decision makers;
 - Improvement of health and reduction of inequalities;
 - Opportunities to strengthen features of a proposal which will positively impact on population health;
 - The promotion of cross-sectoral cooperation;
 - A participatory approach which values community views;
 - Flexibility; and
 - Links with sustainable development and resource management.
166. These benefits are a direct result of the guiding principles of HIAs as indicated by the Gothenburg Consensus¹⁰⁸, which stated that the process must be open, transparent, ethical, equitable, robust, participatory, sustainable and democratic.
167. HIAs already take place across Wales and are considered an important way of ensuring health and well-being is considered across a range of activity. For more than a decade the use of HIAs in Wales has been

¹⁰⁶ The European Centre for Health Policy (1999) Gothenburg Consensus

¹⁰⁷ WHO Health Impact Assessments: Why Use HIAs? At <http://www.who.int/hia/about/why/en/index1.htm1>

¹⁰⁸ <http://www.apho.org.uk/resource/item.aspx?RID=44163>

supported by a dedicated Welsh Health Impact Support Unit (WHIASU) within Public Health Wales.

Current position

168. HIAs are not currently specifically required by legislation in Wales generally, but are required to accompany applications for opencast coal operations. HIAs are also referred to in Welsh Government guidance including Technical Advice Note (TAN) 21 for Waste and Welsh Transport Appraisal Guidance (WeITAG).
169. Health impacts can be considered as part of a Strategic Environmental Assessment which is required in preparing local development plans and, if needed, master plans for larger sites. There is also a requirement that, if appropriate, Environmental Impact Assessments (EIAs) for large complex developments should include an assessment of effects, such as noise, dust and traffic on the population. The legislation governing this requirement will be amended by 2017 to make specific reference to the need to assess the impact and effects on human health.
170. Since 2001 WHIASU has worked to promote and encourage the use of HIAs in Wales. As part of its role WHIASU offers advice, guidance and support to organisations using HIAs, and has produced a range of guidance, toolkits, case studies and templates to assist them¹⁰⁹.
171. The Welsh Government, local authorities, third sector organisations, the NHS and community organisations have all undertaken HIAs. While the exact number of HIAs conducted in Wales is unknown, around 140 have been conducted with WHIASU support. While HIAs have been used by a broad range of organisations, it has been argued that their use is currently inconsistent and could be improved.
172. Depending on the scale and complexity of the proposal being considered, HIAs can take the form of either a rapid or comprehensive assessment. It is estimated that on average between 20-30 rapid assessments are undertaken each year in Wales, with one or two comprehensive assessments (which may span more than one year) also being progressed.¹¹⁰
173. In addition to HIAs, there are legislative mechanisms by which health more broadly can be considered within decision making processes. The Well-being of Future Generations (Wales) Act 2015 aims to ensure that sustainability and well-being, including achieving a healthier Wales, is at the heart of decisions taken by public bodies. In addition, the Planning (Wales) Act 2015 aims to ensure that planning policy contributes to the

¹⁰⁹ Welsh Health Impact Assessment Support Unit guidance note “HIA: A practical guide” [http://www.wales.nhs.uk/sites3/Documents/522/Whiasu%20Guidance%20Report%20\(English\)%20V2%20WEB.pdf](http://www.wales.nhs.uk/sites3/Documents/522/Whiasu%20Guidance%20Report%20(English)%20V2%20WEB.pdf)

¹¹⁰ Information provided by WHIASU

principle of sustainable development, including the health of the population of Wales.

174. While the use of HIAs is widespread beyond Wales, only a small number of jurisdictions have legislation in place to mandate their use. For example, in Australia, the Public Health and Wellbeing Act 2008 of the State of Victoria confers powers upon Ministers to require an HIA to be undertaken where they consider it appropriate to do so; and in Canada, Quebec's Public Health Act requires government ministries and agencies proposing laws or regulations to first undertake an HIA^{111 112}.

Purpose of the provisions

175. In order to further strengthen the position of HIAs in Wales, the Bill includes provisions which will require Welsh Ministers to make regulations about the circumstances in which public bodies in Wales must carry out HIAs.
176. The aim of the Bill is to take a proportionate approach which ensures that HIAs are used when it is appropriate to do so, but without requiring one to be undertaken on all decision making or planning processes. The provisions therefore provide that Welsh Ministers must make regulations setting out provisions about the carrying out of HIAs by public bodies. The aim is that the assessments should be limited to policies, plans and programmes which have outcomes of national or major significance, or which have a significant effect at the local level on public health. The detailed requirements for these assessments will be developed through a process of consultation and the final regulations setting out the circumstances and the way in which a public body must carry them out will need to be formally approved (pursuant to the affirmative procedure) by the National Assembly for Wales before taking effect.
177. To ensure alignment with the Well-being of Future Generations (Wales) Act 2015, it is proposed that all of the public bodies covered by that Act (including Welsh Ministers) will also be covered by the requirements to carry out HIAs. The aim is that HIAs are not stand-alone activities but that they clearly form part of the work of public bodies to achieve the health and other goals set out by the Well-being of Future Generations (Wales) Act 2015.
178. To ensure that excessive demands are not being placed on these public bodies and their clients, it is intended that decision making or planning processes would be exempt if there are impact assessments in place which meet the criteria outlined in the guidance on HIAs which would accompany the legislation. For example, it would be expected that when regulations for the Environmental Impact Assessment are updated, they

¹¹¹ Briefing note: implementation of s54 of Quebec's Public Health Act at <http://www.ncchpp.ca/docs/Section54English042008.pdf>

¹¹² Mendell, A. (2011). Four Types of Impact Assessment Used in Canada. Montreal: National Collaborating Centre for Healthy Public Policy.

would take into account the HIA criteria, so that anyone undertaking that assessment would not also have to undertake a separate HIA.

179. The Bill also provides that the regulations on HIA may require Public Health Wales to provide assistance to public bodies in carrying out HIAs. HIAs carried out under the regulations would have to be published and public bodies would be required to explain how they have taken account of the assessments or, if they have not taken account of them, explain why they have not done so. The overall purpose is to ensure that the HIA process will be proportionate, clear for all to understand, of high quality, and make a positive difference to the health of people in Wales.

Intended effect of the provisions

180. In order to address concerns that the use of HIAs can be patchy and inconsistent in Wales, the Bill seeks to strengthen the current position by making the use of HIA mandatory in specified circumstances. This is intended to be a significant step forward in providing a consistent mechanism to avoid or minimise any negative impacts on health and well-being from policy making and/or planning, as well as promoting positive health outcomes from such action.

181. The overall intention is to realise the benefits of HIA more widely in Wales, provide a significant contribution to improving the health and well-being of the nation and its communities, and position Wales as a world leader in the application of public health policy and legislation.

182. The provisions are also intended to complement and support the implementation of other Welsh Government legislation, most notably the Well-being of Future Generations (Wales) Act 2015. For example, they could assist public bodies in their work to achieve the health and other well-being goals they have set themselves, as well as contributing to the ways of working outlined by that legislation. In particular, HIA is concerned with both the short and long term effects of policies, plans and programmes, and provides an open and transparent process which promotes involvement through the active inclusion and participation of key stakeholders and communities in decisions and plans that affect them. HIA has already been shown to reassure communities and individuals that potential impacts on health and well-being have been adequately considered as part of decision-making processes.

Pharmaceutical services

Background

183. Community pharmacies have an integral role to play in shaping and contributing to improvements in public health. They are located on high streets, in supermarkets and GP practices in villages, towns and city

centres across Wales. Many are open six, and occasionally seven days a week. Community pharmacies are generally people's first and often their most frequent point of contact with a healthcare professional. As such, they are uniquely well positioned to make a wide range of services easily available to local people.

184. There are three main providers of NHS pharmaceutical services in Wales:-

- Community pharmacies;
- Dispensing doctors; and
- Dispensing appliance contractors.

185. There were 716 community pharmacies providing NHS services in Wales as at 31 March 2015.¹¹³ This compares with 703 at March 31 2004.¹¹⁴ Evidently, the current arrangements governing NHS pharmaceutical services result in a stable market with little net change in community pharmacy numbers over time. A positive relationship exists between deprivation and pharmacy numbers¹¹⁵, with pharmacies more prevalent in more economically deprived areas, meaning that access is generally better in areas with the greatest need. In addition, NHS dispensing doctors principally serve rural populations.

186. Around 70 million prescriptions (73.2 million in 2014/15¹¹⁶) are dispensed in community pharmacies in Wales every year. Furthermore, pharmacies are high street retailers, routinely visited by people who do not consider themselves to be ill. Each visit is an opportunity to engage with members of the public about their lifestyle and to make a contribution to improving their health.

187. Community pharmacies also provide a convenient and less formal environment for those who cannot or do not wish to visit other kinds of health services. For example, many provide emergency contraception, smoking cessation and sexual health advice, and in 2012, Wales was the first part of the UK to introduce free seasonal influenza vaccination for those aged 65 and over or in at risk groups from community pharmacies on a national basis.

188. As at 31 March 2015, 34.9% of community pharmacies were owned by independent contractors¹¹⁷ (i.e. those comprised of five NHS premises or

¹¹³ <http://gov.wales/statistics-and-research/community-pharmacy-services/?lang=en>

¹¹⁴ Statistics for Wales release (26 November 2009) <http://wales.gov.uk/statistics-and-research/community-pharmacy-services/?lang=en/statistics-and-research/community-pharmacy-services/?tab=previous&lang=en>

¹¹⁵ Hinchliffe A. 2012 Distribution of community pharmacies and deprivation in Wales. Public Health Wales.

¹¹⁶ Statistics for Wales release (14 October 2015) <http://gov.wales/docs/statistics/2015/151014-community-pharmacy-services-2014-15-en.pdf>

¹¹⁷ Statistics for Wales release (26 September 2015) <http://wales.gov.uk/statistics-and-research/community-pharmacy-services/?lang=en/statistics-and-research/community-pharmacy-services/?lang=en>

fewer), with the remainder owned by larger businesses with six or more NHS premises, including multinationals and supermarkets (referred to as multiples). There has been a trend towards greater market consolidation in the last decade.

189. As at 31 March 2014, there were four dispensing appliance contractors in Wales¹¹⁸ (who can only supply appliances such as incontinence aids and dressings). They are run by small to medium enterprises and often operate a distance-selling model, providing services to other parts of the UK.
190. There are a small number of pharmacies that do not provide NHS pharmaceutical services. These are not directly affected by the changes in the Bill and, as such, are not considered in this Explanatory Memorandum.

Current position

191. The Welsh Government establishes the overall structure in which community pharmacies operate by providing the legislative and policy framework. Within this the responsibility for planning and providing pharmaceutical services is vested in health boards (LHBs), which have responsibility for planning health services to meet the needs of their resident populations. This includes determining the number and location of pharmacies in their areas.
192. The general duty to provide NHS pharmaceutical services, as with other aspects of NHS primary care services, is conferred directly on LHBs under the NHS (Wales) Act 2006 (the 2006 Act). LHBs manage local lists of approved providers, referred to as pharmaceutical lists, and the inclusion of pharmacy premises on pharmaceutical lists entitles the pharmacy to provide NHS pharmaceutical services at those premises. These arrangements govern the provision of NHS pharmaceutical services and not the right to open and conduct a pharmacy business in Wales. This is dealt with under separate UK wide legislation, the Medicines Act 1968.
193. Welsh Ministers have extensive powers and duties to make regulations and to issue directions to LHBs, which govern the detail of the NHS pharmaceutical services system. This includes specifying the terms of service for NHS pharmacists and the application of the control of entry test, which is the test that must be satisfied before LHBs may grant an application for entry, or amendment to an entry, on their pharmaceutical list.
194. Section 80 of the 2006 Act places a duty on LHBs to make arrangements for the provision of the pharmaceutical services that are set out in subsections 80(3)(a) to (d). These core pharmaceutical services are essentially dispensing services. There is a duty on Welsh Ministers to

¹¹⁸ Same as previous reference

make regulations governing the way in which LHBs make these arrangements. All regulations are laid before the National Assembly for Wales using the negative resolution procedure.

195. Section 81 of the 2006 Act sets out arrangements that Welsh Ministers may make for the provision of additional pharmaceutical services. Additional pharmaceutical services are defined as services of a kind that do not fall within section 80. Section 81 gives Welsh Ministers the power to give directions to an LHB (i) requiring it to arrange for the provision of additional pharmaceutical services, or (ii) authorising it to arrange for the provision of services if it wishes.
196. Section 83 of the 2006 Act contains the core of the Welsh Ministers' regulation making powers in relation to the provision of pharmaceutical services and, amongst other things, sets out the requirement for regulations to require an LHB to prepare and publish a pharmaceutical list, and sets out the current control of entry test.
197. Section 84 sets out a requirement for Welsh Ministers to provide for rights of appeal against decisions that are made by LHBs in exercise of powers conferred upon them by regulations made under section 83.
198. The main instruments of subordinate legislation made under powers in the 2006 Act are:
- the Pharmaceutical Services (Wales) Regulations 2013 as amended¹¹⁹;
 - the NHS Pharmaceutical Services (Advanced and Enhanced Services) Directions 2005 as amended;
 - the NHS Pharmaceutical Services (Charges for applications) Directions 2013; and
 - the National Health Service Committees and Tribunals Regulations 1992 as amended¹²⁰.
199. This subordinate legislation describes in detail, amongst other things:
- the procedures by which persons wishing to provide NHS pharmaceutical services apply for inclusion in a pharmaceutical list;
 - the procedures which must be followed by an LHB in determining such applications;
 - the rights of appeal against the decisions of an LHB;
 - the terms of a person's inclusion in the pharmaceutical list; and
 - the procedures to be followed by an LHB when dealing with breaches of terms of service.
200. Since the late 1980s, applications for entry onto a pharmaceutical list (or applications to change an existing entry) have been determined by

¹¹⁹ S.I. 2013/898

¹²⁰ S.I. 1992/664

LHBs (or their predecessor health bodies) by applying what is commonly known as the control of entry test. This is set out in Section 83 of the 2006 Act. Broadly speaking, an application will only succeed if a LHB considers it necessary or expedient to grant it in order to secure (in the neighbourhood to which the application relates), the adequate provision of NHS pharmaceutical services. This test has been subject to considerable review by the courts, whose decisions have established various precedents and criteria as to how LHBs should apply the test when considering applications.

201. The NHS Pharmaceutical Services (Wales) Regulations 2013 set out the current control of entry arrangements. In addition to setting out the conditions under which pharmacists can apply to provide NHS pharmaceutical services, and the terms and conditions under which those services will be provided, the regulations make special provision for areas that are rural in character and they prescribe the circumstances in which, in those areas, doctors can apply for and be granted the right to provide pharmaceutical services to their patients. These are commonly known as dispensing doctors.
202. The current regulatory regime and approach has been in place for more than 25 years and does not adequately reflect the way in which the role of pharmacies has changed in that time. In the last 10 years community pharmacy numbers in Wales have been largely unchanged, however prescription volumes have grown by nearly 40% (from 53.1 million in 2005/6 to 73.2 million in 2014/15)¹²¹.
203. Under the current arrangements, when determining applications LHBs only consider the pharmaceutical services defined under section 80 of the 2006 Act. Broadly speaking this relates only to the dispensing of prescriptions. The onus on deciding when, and in relation to which areas applications to provide pharmaceutical services are made, rests with applicants.
204. However, community pharmacies also increasingly provide additional services. As set out above, these additional pharmaceutical services are covered under section 81 of the Act and are provided for by way of directions. They include the provision of emergency contraception, influenza vaccinations and support to stop smoking.
205. Decisions about whether pharmacies are allowed to provide NHS pharmaceutical services are made on the basis of whether there is adequate access to pharmacies for the dispensing of prescriptions, and not on whether these additional services are offered or needed. This has the effect that pharmacies wishing to offer additional services are unable to enter the market, because the market entry test fails to recognise the additional services they wish to offer and whether those services would support addressing local health needs.

¹²¹ Statistics for Wales release (14 October 2015)

206. Finally, there are existing provisions in the 2006 Act which allow an LHB to remove a person from a pharmaceutical list where there are fitness to practice concerns. These fitness matters are set out in section 107(2),(3) and (4) of the 2006 Act and relate to situations where it is determined that a person is no longer fit to be included in the pharmaceutical list for reasons of fraud, unsuitability or efficiency of service provision. There are no express powers to remove a person or an entry in respect of premises from a pharmaceutical list on other grounds¹²².

Purpose of the provisions

207. In order to maximise the public health role of community pharmacies, the Bill seeks to make a fundamental change to the way in which decisions about pharmaceutical services in Wales are made by LHBs, shifting from one driven by applications from pharmacy contractors and focused heavily on the dispensing of prescriptions, to one which is alert and responsive to the broader pharmaceutical needs of local communities.

208. The aim of the provisions is to improve the planning and delivery of pharmaceutical services in Wales. The Bill principally achieves this by amending the 2006 Act to require each LHB to prepare and publish an assessment of the need for pharmaceutical services in its area (a so called pharmaceutical needs assessment or PNA), to keep the PNA under review and revise it as appropriate. The Bill also amends the current control of entry test set out at section 83 of the 2006 Act. It moves away from the current test which is determining applications by reference to whether or not it is necessary or expedient to approve the application, to an assessment that is based on whether, having regard to its most recent PNA and to any matters that are specified in regulations, it is satisfied that to grant the application would meet a need in its area for services or some of the services specified in the application.

209. The above essentially provides for decisions about the location and extent of pharmaceutical services available in an LHB area to be determined on the basis of those assessments. The provisions also aim to improve the quality of pharmaceutical services by encouraging existing pharmacies to adapt and expand their services in response to local needs.

210. The Bill gives Welsh Ministers the power to set out in regulations the information that must be included in a PNA. It is intended that regulations will require a PNA to detail the current provision of pharmaceutical services, identify the pharmaceutical needs of its population and areas where pharmaceutical services do not meet needs, and where action is needed to ensure adequate provision. This could include describing the nature of pharmaceutical services required by particular areas.

¹²² Apart from those set out in section 83(6)(d) of the 2006 Act

211. The first PNAs will be produced in accordance with a timetable set out by Welsh Ministers in regulations. The regulations will ensure that the timing of subsequent PNAs will be arranged so as to coincide with the frequency of wider needs assessments, in particular the local well-being assessments provided for by the Well-Being of Future Generations (Wales) Act 2015.
212. Applications from persons wishing to provide pharmaceutical services in an LHB area will then be determined against the PNA. Therefore, pharmacies would be permitted to provide NHS pharmaceutical services if they are able to demonstrate that in doing so they will meet a particular unmet local need or service requirement identified in an LHB's PNA.
213. The Bill will also provide LHBs with a power to address gaps in pharmaceutical service provision, as identified in the LHB's PNA, by allowing Welsh Ministers to specify in regulations the circumstances in which an LHB may invite applications for the provision of pharmaceutical services. The regulations could, for example, specify that an LHB is able to invite applications to provide pharmaceutical services in areas where there are identifiable unmet pharmaceutical needs, but it is not in receipt of any applications to provide pharmaceutical services.
214. Alongside the changes to introduce a system of needs-based entry, an exit regime will also be introduced that enables graduated actions to be taken to deal with those providers who are failing to meet their terms of service obligations – and who may therefore be receiving NHS remuneration whilst inadequately fulfilling their contractual obligations. It is intended to commence the existing provisions in section 106A of the 2006 Act, which enables Welsh Ministers to set out in regulations a system of notices and penalties which apply where pharmacists breach their terms and conditions of service with an LHB. This will be coupled with a new power in the Bill which enables Welsh Ministers to set out in regulations the grounds or circumstances in which an LHB may remove a pharmacist or premises from a pharmaceutical list.
215. It is intended that regulations will set out that an LHB will be able to remove a pharmacy or premises from the pharmaceutical list, in cases where local resolution has failed and where a pharmacist has failed to comply with notices issued to it by the LHB setting out action it needs to take to comply with the terms and conditions of service. The Bill provides that Welsh Ministers must set out in regulations that an LHB is under a duty to notify a pharmacist about its intention to remove them from its list and the reasons for the intended removal, before a decision to remove is made. The pharmacist will be granted the right to make representations to the LHB before a decision is made. Regulations will also confer a right of appeal to Welsh Ministers against a decision of an LHB to remove a pharmacist or premises from a pharmaceutical list.

Intended effect of the provisions

216. The intended effect of the legislation is to improve the planning and delivery of pharmaceutical services by ensuring that LHBs robustly consider the pharmaceutical needs of their populations and align services more closely with them. This will require LHBs to take a more integrated approach to identifying the pharmaceutical needs of populations, including considering the contribution of all pharmaceutical services providers (e.g. pharmacies and dispensing doctors). LHBs will use these assessments to identify where additional pharmacies are required, where existing providers are adequately addressing pharmaceutical needs, and where additional services are required from existing pharmacies.
217. The changes will provide pharmacy contractors with increased certainty, reducing business risk and allowing them to invest in the delivery of wider services.
218. A further intended effect of the legislation is that pharmacies will be more responsive to the needs of the populations they serve, and provide services effectively to address identified pharmaceutical needs. Where there is a lack of quality or consistent delivery, LHBs will be able to implement improvement measures. These could include taking action against particular pharmacies for persistent breaches of terms and conditions of service, or inviting additional pharmacies to apply to provide particular services. This should result in pharmacies providing services more consistently and to a higher standard, and ensure that pharmacies provide services in locations where they are needed. These changes will also make decisions about the entry of new pharmacies more transparent.
219. Ultimately, the changes provided for in the Bill will allow for gradual improvement in the quality and consistency of NHS pharmaceutical services.

Provision of toilets

Background

220. Provision of, and access to, toilets is an issue that affects public health. Accessible, clean toilets that are well located in places such as town centres, parks, promenades, cycle trails and walking routes can help encourage the public to take exercise and stay more physically active. This has clear health and economic benefits. Conversely, toilets that are poorly designed, inadequately maintained and inappropriately located can create an atmosphere of neglect that discourages public use. A lack of adequate toilet facilities can also impact on an individual's physical and mental health, as well as affecting the wider environmental health of the population.

221. Toilets for public use matter to everybody and remain a high-profile issue. They are, however, even more important to certain groups within society, including older people, disabled people, people with particular needs (including certain medical problems), women, children and young people and their families. These groups can be disproportionately affected by poor provision. For example, poor provision is understood to have particular negative impacts on older people, as some may be less likely to leave their homes without having confidence that adequate facilities will be available to them. This can contribute to increased social isolation and inactivity, as well as affecting people's ability to maintain independence and dignity in later life.
222. In 2007, Help the Aged (now Age UK) published a report entitled *Nowhere to go – Public Toilet Provision in the UK*¹²³. This summarised a survey of older people's views on public toilet provision in their areas, and showed that more than half of older people found that a lack of public toilets prevented them from going out as often as they would like.
223. The House of Commons' Communities and Local Government Committee examined the evidence on the provision of public toilets in England and published its report, *The Provision of Public Toilets*, in 2008¹²⁴. The Committee recommended that "...the Government imposes a duty on each local authority to develop a strategy on the provision of public toilets in their areas, which should include consultation with the local community and which should be reviewed annually. The duty of compiling and reviewing a public toilet strategy is a simple requirement that will go a long way towards achieving the right of people who live in and visit this country to have accessible and clean public toilets, wherever they live, work or visit. The way in which local authorities plan and utilise their own strategic plan is a decision for them; the fact that they have a plan should be a duty placed on them by the Government." (Recommendation 26).
224. In the same report the Committee explained that: "our public toilet provision should not be allowed to decline at the current rate because of neglect arising from the lack of any clear strategy". The UK Government responded to the report in January 2009 and declined to implement the recommendation to impose a duty on local authorities to develop strategies on the provision of public toilets.
225. The National Assembly for Wales' Health and Social Care Committee conducted a short inquiry into the public health implications of inadequate public toilet facilities in Wales in 2012. The Committee concluded in its report¹²⁵ that there is a strong public health case for better public toilet provision, and that a set of potential practical solutions exist which could, if

¹²³ http://www.ageuk.org.uk/documents/en-gb/for-professionals/communities-and-inclusion/id6256_nowhere_to_go_public_toilet_provision_in_the_uk_2007_pro.pdf

¹²⁴ The House of Commons, Communities and Local Government Committee Twelfth Report of Session 2007–08 'The Provision of Public Toilets' printed 6 October 2008. Available at: <http://www.publications.parliament.uk/pa/cm200708/cmselect/cmcomloc/636/63602.htm>

¹²⁵ <http://www.senedd.assemblywales.org/mglIssueHistoryHome.aspx?lId=2572>

implemented, lead to improved local provision of public toilets. Suggested solutions included ensuring that local authorities make the most of existing resources, charging for use, making toilet facilities within public buildings available for public use, and the introduction of a strategy for Wales to ensure that public toilets are accessible to all.

226. In November 2013, a short debate took place in the National Assembly for Wales on the importance of public toilets¹²⁶. During the debate the Welsh Government acknowledged the importance of public toilets, and indicated that provision should remain a priority and that all possible efforts should be made to sustain provision.

227. The Welsh Government has previously sought to find creative solutions to help improve the provision of local toilets. The Public Facilities Grant Scheme was initially established in 2009/10 for three years to increase the provision of free public access to toilet facilities in Wales. This sought to improve the quality and accessibility of facilities by encouraging local authorities to work in partnership with local businesses to allow public access to their facilities. The scheme was extended annually from April 2012 before the funding (£200,000) was transferred into the Revenue Support Grant from 2014/15. It is now for each local authority to decide how this funding is utilised to deliver the range of services it is responsible for in order to meet the needs and priorities of its communities.

228. This issue is not unique to Wales. Major cities around the world, including Sydney, Australia¹²⁷, have identified public toilet access and provision as a key issue, and have developed strategies to address it.

Current position

229. It is known that public toilet provision currently varies between local authorities. Discussions also indicate that there are pressures around the provision of facilities, leading to reductions in the number of public toilets in Wales in recent years.

230. The current legal position in relation to toilet facilities is set out in various pieces of primary and subordinate legislation. The provision and maintenance of toilets in public places is at the discretion of local authorities, including community councils, who have the power, under section 87 of the Public Health Act 1936, to provide public conveniences, but no duty to do so. Section 87 also allows local authorities to charge for the use of the toilets that they provide.

231. A local authority has power under section 20 of the Local Government (Miscellaneous Provisions) Act 1976 to require toilets to be provided and

¹²⁶ National Assembly for Wales Short debate: A public inconvenience – why public toilets are important. 13 November 2013. Available at:

http://www.assemblywales.org/docs/rop_xml/131113_plenary_english.xml

¹²⁷ City of Sydney, Public Toilet Strategy 2014. Available at:

<http://www.cityofsydney.nsw.gov.au/explore/facilities/public-toilets#page-element-dload>

maintained in any place providing entertainment, exhibitions, sporting events, and places serving food and drink for consumption on the premises. A local authority may also use powers under section 106 of the Town and Country Planning Act 1990 to make an agreement with a developer for the provision of toilets as part of the approved development.

232. Where a local authority is a highway authority for a particular highway, section 114 of the Highways Act 1980 provides that it may provide public sanitary conveniences (including lavatories) in proper and convenient situations, and may manage such conveniences.

233. Whilst the current legislative framework enables local authorities to make provision for toilets, there are no legislative requirements on them to do so. It is for individual local authorities to decide whether or not to provide public toilets and, if so, how many. In doing this, each local authority must balance competing local demands for a broad range of public services against the need to avoid excessive burdens on local taxpayers.

234. The current system governing provision and access to public toilets poses a number of significant challenges. These can be summarised as follows:-

- The provision and maintenance of public toilets in Wales is at the discretion of local authorities, meaning provision in Wales varies according to local authority;
- There is poor planning around making the best use of toilets already accessible to the public within public buildings, for example those in public libraries, community and town halls, sports centres and museums;
- The provision and maintenance of public toilets in Wales is a considerable cost to local authorities and, as a consequence, provision is declining and toilets are under threat of closure across Wales;
- Public toilets that are poorly designed, inadequately maintained and poorly located can create an atmosphere which attracts vandalism, graffiti, criminal damage and anti-social behaviour (which increase costs even further for local authorities); and
- The previous Public Facilities Grant Scheme was limited in that it focused purely on improving public access to toilets within private establishments.

Purpose of the provisions

235. The aim of the provisions is to improve planning of provision of toilets available for use by the public by ensuring each local authority in Wales

assesses the needs of its community in relation to toilets, and then takes a strategic and transparent approach to best meet that need. This is intended to address the current challenges regarding the provision of these facilities within communities.

236. To achieve this, the Bill places a duty on each local authority in Wales to prepare and publish a local toilets strategy for its area. The Bill provides that this strategy must include an assessment of the community's need for toilets, including changing facilities for babies and changing places facilities for disabled persons. Changing places toilets are different to standard accessible toilets (or "disabled toilets") as they have extra features and more space to meet the needs of people who use them including a height adjustable changing bench and a hoist.
237. The strategy must also provide details of how the local authority proposes to meet identified need. There is no requirement for the strategies to be presented to the Welsh Government for approval, as instead there is an expectation that the strategies will be subject to local authorities' existing scrutiny structures.
238. The duty to prepare a local toilets strategy will not in itself require local authorities directly to provide and maintain public toilets, but will require them to take a strategic view across their area on how these facilities can be provided and accessed by their local population. In doing so it is envisaged that local authorities will consider a full range of options for making facilities available to the public. An illustration of this process is if a public toilet is not available at a park but a local authority identifies a need for one, then the local authority should consider different ways of ensuring that the need is met. This could be by the local authority directly providing the facility, but equally could be met in other ways, such as the local authority working with a private business within or near to the park to make their facilities available to the public.
239. The Bill's provisions on local toilets strategies are ultimately intended to benefit local communities across Wales. Accordingly, the provisions seek to ensure that appropriate engagement with communities takes place as part of the development of the strategies, and that the process takes place in a manner which is both transparent and supports local accountability.
240. Local authorities will therefore be required to consult with interested parties on their draft strategies and to publish their final strategies so that they are available to be viewed. Whilst the Bill does not prescribe the format of the consultation process, it is expected that local authorities will take an inclusive approach in order to ensure appropriate engagement across their communities.
241. In order to further support local accountability, the Bill provides a clear framework to govern the timescales for the production of local toilet strategies. The Bill requires the preparation and publication of interim progress statements which will be published around two years after the

local toilets strategy or the strategy's review, and will report on the steps the local authority has taken since the strategy's publication.

242. In order to provide local authorities with the flexibility to respond to changing circumstances, they will be able to review the strategies at any time. The Bill also provides for a mandatory review period, which is intended to align with the cycle for local government elections and local plans provided for in other legislation, in order to both reduce unnecessary bureaucracy and ensure a coherent approach to planning at community level. The importance of ongoing engagement with local communities is upheld within these provisions, through a requirement for any revised strategy to be published.
243. As it is recognised that there will be numerous considerations relevant to local authorities in preparing, reviewing, consulting and publishing their strategies, the Bill requires Welsh Ministers to issue guidance on this matter. Local authorities will then be required to have regard to the guidance produced. The topics which will be covered by the guidance include how local authorities will address toilet availability on highways (for example trunk roads like the A470), and how the facilities provided in settings which are already in receipt of public funding such as sports centres, libraries and other similar amenities can be made available to the public. The statutory guidance will also address how local authorities promote public awareness of the toilets that are available in their area for use by the public, including their location and availability to those residing, visiting and passing through the area.
244. In recognition of the importance of ensuring that the needs of different groups of people across communities are considered through local toilet strategies, the Bill explicitly provides that the term 'toilets' includes changing facilities for babies and changing places facilities for disabled persons.
245. For clarity, the Bill also repeals and restates existing local authority powers to provide public toilets.

Intended effect of the provisions

246. The legislation aims to result in improved planning of toilets that are available to the public, which better meets the needs of local communities. The process of preparing the local toilets strategies will enable a broader consideration of options available for providing toilets for use by the public, ranging from traditional stand-alone public toilets through to new and creative solutions. The Bill will also increase local engagement and transparency in relation to this issue.
247. The intended effect of the legislation is not to prevent local authorities from taking decisions which they need to take during the course of their activities, which may include decisions to close certain facilities when

appropriate to do so. Instead, the intended effect is to improve the planning of provision so that any such decisions are taken within the overall context of meeting the community needs which they have identified. This will also mitigate the impacts of changes to provision.

Food hygiene rating offences

Background

248. The Food Hygiene Rating (Wales) Act 2013 (“the 2013 Act”) requires food businesses in Wales to be rated on their food hygiene standards, and to display this rating where it can be easily seen by customers, such as at the entrance to their premises. The 2013 Act ensures customers have easy to understand information on the hygiene standards of a food business before they buy food, and has driven up the food hygiene standards of food businesses across Wales.

249. ‘Food authorities’ (primarily local authorities) are responsible for enforcing the food hygiene rating scheme in Wales. The 2013 Act allows food authorities to issue Fixed Penalty Notices (FPNs) to food businesses for non-compliance with the scheme. A FPN offers the opportunity for a person to pay a reduced penalty of £150 if payment is made within a period of 14 days, or £200 within a period of 28 days.

Current position

250. Section 22(1) of the 2013 Act currently requires the receipts from FPNs issued for offences under the Act to be returned to the Welsh Consolidated Fund from which the expenditure of the Welsh Government is allocated.

Purpose of the provisions

251. The Bill makes a minor change to the administration of FPN receipts under the Act, to alter the arrangements for the return of FPN receipts for food hygiene rating offences and their re-use. This is in response to views put forward by food authorities that their retention of FPN receipts will assist them to fund enforcement activity under the Scheme.

252. The Bill provides for section 22(1) of the 2013 Act to be repealed and replaced by a provision requiring the food authority to re-use FPN receipts received under Section 21 of the 2013 Act, for the purposes of enforcing the provisions of the Act and regulations made under it.

253. This approach will meet a recommendation of the Wales Audit Office report *Delivering with Less: the Impact on Environmental Health Services and Citizens*¹²⁸, which recommended the Welsh Government should

¹²⁸ <https://www.wao.gov.uk/publication/delivering-less-%E2%80%93-impact-environmental-health-services-and-citizens>

ensure that environmental health services, when given additional responsibilities through legislation, are suitably resourced to carry out those responsibilities. The retention of FPN receipts by local authorities will help to meet this recommendation and encourage enforcement of the food hygiene rating scheme.

Intended effect of the provisions

254. The change provided for by the Bill is intended to assist the local authorities which operate and enforce the food hygiene rating scheme, by simplifying the arrangements for dealing with FPN receipts, and ensuring the monies are used specifically to support the enforcement of the scheme. This brings the food hygiene arrangements into line with equivalent arrangements elsewhere in the Bill, by ensuring that FPN receipts created will be retained by the enforcement authority to support the new duties the Bill creates. The change therefore also contributes to consistency and clarity in how this issue is dealt with in public health legislation.

4. Consultation

255. The foundations for the preparation and development of this Bill were set in 2012. Following a commitment to consult on the need for public health legislation, a Green Paper was published by the then Minister for Health and Social Services,¹²⁹ which explored whether legislation could help efforts to further improve overall health and well-being in Wales. The Green Paper referenced a number of broad challenges facing public health in Wales, including the need to do more to prevent ill health occurring in the first place, and asked whether legislation would provide an effective way of making further progress in key areas.
256. A total of 371 responses were received to the Green Paper and a summary of the responses was published in May 2013.¹³⁰ A clear majority of respondents supported the idea that legislation could make a positive contribution to further improve and protect health. The responses indicated support for two distinct approaches to public health legislation: one for an overarching approach requiring organisations to consider health across their functions, and the other for a targeted approach aimed at addressing specific public health challenges.
257. The response to the Green Paper informed the development of an approach to public health legislation which responded to both of these messages. Firstly, it was recognised that the Well-being of Future Generations (Wales) Bill¹³¹ (now the Well-being of Future Generations (Wales) Act 2015) provided opportunities to ensure health considerations form a central part of the overall legislative framework for the public service in Wales. This Act provides seven well-being goals which public bodies in Wales will need to align themselves to. They include the specific goals of 'a healthier Wales' and 'a more equal Wales', with the other goals also playing an important role in furthering the public health agenda.
258. Secondly, developmental work took place to arrive at a series of legislative proposals for addressing specific public health concerns. These were developed and consulted upon in a Public Health White Paper.

Public Health White Paper

259. The Public Health White Paper entitled *Listening to you: Your health matters*¹³² was published in April 2014. This brought together a series of distinct yet related proposals for addressing priority public health issues through preventative approaches. The proposals were presented under three broad themes of improving health across the life course; building community assets for health; and regulation for health.

¹²⁹ <http://wales.gov.uk/consultations/healthsocialcare/publichealth/?lang=en>

¹³⁰ <http://wales.gov.uk/consultations/healthsocialcare/publichealth/?lang=en>

¹³¹ <http://wales.gov.uk/topics/sustainabledevelopment/future-generations-bill/?lang=en>

¹³² <http://wales.gov.uk/consultations/healthsocialcare/white-paper/?lang=en>

260. The proposals related to:
- establishing a national tobacco retailers' register requiring businesses to inform enforcement authorities if they sell tobacco;
 - prohibiting smoking in certain open spaces (such as hospital and school grounds);
 - considering the creation of an offence of delivering tobacco products to a person aged under 18;
 - strengthening the role of LHBs in planning and delivering the number, location and type of pharmaceutical services required to meet the needs of their communities;
 - requiring local authorities in Wales to develop a strategy to address the provision of and access to toilets for public use; and
 - introducing a National Special Procedures Register, to cover acupuncture, body piercing, electrolysis and tattooing.
261. The White Paper also consulted on other proposals, namely restrictions on the use of e-cigarettes in enclosed public places, the introduction of minimum unit pricing for alcohol sold and supplied in Wales (MUP), and the introduction of nutritional standards in specified settings.
262. Following the outcome of the previous National Assembly for Wales' consideration of the Public Health (Wales) Bill¹³³, the Bill no longer includes the previous provisions restricting the use of e-cigarettes in enclosed public places. Accordingly, the consultation responses to that element of the White Paper are not summarised in this Explanatory Memorandum. An overview of the previous Assembly's consideration of the original Bill is provided later in this chapter.
263. The Welsh Government has taken forward proposals on MUP separately to the Public Health (Wales) Bill, and so the consultation responses to that element of the White Paper are not summarised in this Explanatory Memorandum. A consultation on a draft Public Health (Minimum Price for Alcohol) (Wales) Bill was published in July 2015 and a summary of responses to this consultation was published on 11 March 2016.¹³⁴
264. The White Paper also made it clear that, if progressed, the nutritional standards proposals would be taken forward by way of secondary legislation and/or guidance. The proposals do not therefore form part of the Bill and, as such, they are not covered in this Explanatory Memorandum.
265. A total of 713 responses to the White Paper were received, and a consultation summary report was published in November 2014.¹³⁵ Responses were drawn upon in the course of the development and

¹³³ <http://www.senedd.assembly.wales/mglIssueHistoryHome.aspx?lId=12763>

¹³³ <http://gov.wales/consultations/healthsocialcare/alcohol/?status=closed&lang=en>

¹³⁵ <http://wales.gov.uk/consultations/healthsocialcare/white-paper/?lang=en>

refinement of the legislation. The responses were received from the following:-

Table 4.1: Responses to the Public Health White Paper, by type of respondent

Type of respondent	Number	Percentage of total response
Academic/Research bodies	8	1.2%
NHS organisations	15	2.2%
Health related organisations	22	3.3%
Local government	55	8.2%
Advisory groups	7	1.0%
Voluntary sector organisations	34	5.0%
Representative groups	48	7.1%
Private sector organisations	36	5.4%
Private individuals	434	64.6%
Specific responses to Youth Friendly version	39	5.5%
Specific responses to Easy Read version	2	0.1%
Others	13	1.9%
Total	713	100%

266. In general terms the consultation responses illustrated support for the role of legislation in improving and protecting health. They represented a full spectrum of views, ranging from arguments that the proposals should be extended and taken further, through to calls for more modest reform.

267. The nature of responses to the White Paper also varied significantly. Whilst some focused on single issues, others provided detailed comments on the full range of proposals.

268. Some of the most common overall themes and trends arising from the responses included:

- Levels of support for individual proposals often varied according to sector; for example health organisations and local authorities were generally supportive of most proposals, but in some cases there was opposition from bodies representing particular groups or interests;
- A number of respondents, whilst supportive of the policy intent, expressed reservations regarding implementation, including the potential implications for local government;
- A number of respondents (primarily health-related organisations) commented that the White Paper had in their view lost some of the

aspiration shown in the previous Green Paper, due to its focus on practical actions in discrete policy areas; and

- Some respondents expressed disappointment that the White Paper did not include specific proposals in additional policy areas relevant to public health, such as mental health and physical activity.

269. A series of public engagement events and stakeholder meetings were held to coincide with the White Paper consultation. These are summarised in the consultation summary report, and have been supplemented by further informal engagement with key stakeholders beyond the formal consultation period.

270. A brief overview of the written responses to the White Paper for each policy proposal in the Bill is provided in the following paragraphs. These are intended to provide a flavour of the response, but should be considered in the context of the additional detail available in the consultation summary report.

Tobacco retailers' register (relates to Part 2, Chapter 2 of the Bill - 'Register of retailers of tobacco and nicotine products')

271. 119 responses were received in respect of the tobacco retailers' register proposal. The majority indicated broad agreement that the introduction of a retailers' register would be helpful both in assisting in attempts to reduce under age sales of tobacco, and in assisting in the enforcement of the existing display ban. The minority of respondents who generally opposed the proposal were primarily from the private sector, including some retailers' representatives and a number of tobacco and e-cigarette companies. The principal concerns related to the registration of street traders and a view that a register could inadvertently increase the level of sales of illegal tobacco.

272. The registration fee structure proposed in the White Paper attracted a mixed response. Whilst a number of respondents agreed with the structure which was presented, others felt it would not result in a full cost recovery for the organisation tasked with managing and administering the register. Conversely, a small number of respondents commented that the proposed fee structure was too high, and that admission to the register should be either free of charge or lower than the level proposed.

273. The most commonly supported enforcement and penalty regime for the register was that of local authority trading standards officers, taking into account their ability to make applications for Restricted Sales Orders (RSOs) and Restricted Premises Orders (RPOs). A number of respondents emphasised the importance of having a method in place to ensure that retailers are required to keep the register updated with correct

information, and offered specific suggestions for how this could be achieved.

274. A number of respondents suggested that a national retailers' register should also cover retailers of Electronic Nicotine Delivery Systems (ENDS) such as e-cigarettes.

Smoke-free open spaces (covered in Part 2, Chapter 1 of the Bill – 'Smoking')

275. This section of the White Paper considered public places where voluntary smoking bans are currently in operation and sought views about whether legislation should be made in these areas. 121 responses were received, with two thirds suggesting the Welsh Government should consider making legislation on smoke-free open spaces. Responses focused on the three outdoor settings specifically referenced in the White paper, namely hospital grounds, children's playgrounds and school grounds, while some respondents also took the opportunity to make suggestions for further open spaces where smoke-free legislation could be considered.
276. Support for legislation was particularly strong from local health boards, health-related organisations and third sector organisations. Responses from individual members of the public also generally favoured legislation, particularly in relation to hospital grounds. Responses from the tobacco industry were almost entirely opposed to any such legislation being introduced.
277. The highest level of support amongst those responses favouring legislation related to hospital grounds (88%). These responses commonly noted that the absence of legislation makes effective enforcement of voluntary NHS smoke-free policies unachievable. A number also felt that legislation would help de-normalise smoking and support patients who want to give up, provided that sufficient cessation support is available in hospitals.
278. 72% of respondents who generally favoured legislation also suggested that this should cover children's playgrounds. These comments again emphasised how the de-normalisation of smoking could be reinforced, both for children and adults. Some respondents noted that current voluntary bans were starting to raise awareness and change attitudes, and suggested that these could be given more time to take effect before legislating.
279. School grounds received fewer direct comments, but the majority of respondents who directly referred to this setting generally favoured legislation. The most common reasons for favouring legislation corresponded with those for the other settings, primarily in relation to further de-normalising smoking and to strengthen enforcement of voluntary bans.

280. In addition to comments about the specific settings referenced in the White Paper, some suggestions were also made for further outdoor settings which could be considered for making smoke-free legislation. Suggestions included transport interchanges, sports grounds and leisure facilities, beaches, parks, railway stations and the outdoor areas of restaurants and cafes.

Internet sales of tobacco (this relates to Part 2, Chapter 4 of the Bill - 'Handing over tobacco etc. to persons under 18')

281. 104 responses were received in respect of this proposal. Respondents commonly felt there are likely to be problems connected with persons aged under 18 receiving a delivery of tobacco products purchased online by an adult, and that legislation would therefore be appropriate. Amongst these, some specific concerns were expressed that existing age verification checks are not sufficiently robust.

282. A number of respondents stated that they were either unaware or unable to find evidence of there being a problem in this area; although it was also suggested that current mechanisms would not allow such a problem to be easily identified.

283. Amongst responses which did not favour legislation, these most commonly referred to a lack of available evidence in this area, as well as a preference for other forms of action for ensuring tobacco products are not delivered to persons aged under 18.

National Special Procedures Register (this relates to Parts 3 and 4 of the Bill – 'Special Procedures' and 'Intimate Piercing')

284. 102 responses were received in respect of this proposal. The majority felt that current information, regulation and enforcement in relation to acupuncture, tattooing, semi-permanent skin colouring, cosmetic piercing and electrolysis do not protect the public effectively. This was a consistent message across responses from local authorities and LHBs.

285. A clear majority of respondents supported the establishment of a National Special Procedures Register, as this was commonly felt to have potential for achieving consistency of approach across Wales, helping individuals to make informed choices when deciding who to go to for a particular procedure, and ensuring practitioners and premises meet certain standards. There was also general agreement that local authorities would be best placed to administer and enforce the register.

286. A number of respondents suggested that additional procedures should be considered for inclusion on the register. A wide number of procedures were referenced, including dermal fillers, chemical peels, colonic irrigation, botox, scarification, branding, implants and tongue splitting. Conversely, some respondents argued that acupuncture should not be included on the register due to the other forms of regulation in operation in that area.

287. A number of specific points of detail were addressed by the consultation questions. In response to these the majority of respondents commented that it would be appropriate for the Welsh Government to be able periodically to amend the list of procedures covered by the register, in order to ensure it remains fit for purpose. A variety of views were offered in relation to registration fees, with a majority favouring a national approach and setting fees at a level which would not be prohibitive for small businesses and individual practitioners.
288. Amongst the other issues covered, a range of suggestions were provided for how frequently practitioners and businesses should be required to re-register, as well as suggestions for the composition of a 'fit and proper persons' test. Specific suggestions were also provided on information which could be covered by mandatory pre-and post-procedure consultation discussions.
289. The White Paper also continued previous discussions regarding the evidence of harm caused by cosmetic piercing, particularly the intimate cosmetic piercing of young people. Whilst the majority of respondents provided comments regarding health risks associated with cosmetic piercing in general, a number also strongly advocated a prohibition on the intimate cosmetic piercing of children and young people.

Health Impact Assessment (Part 5 of the Bill)

290. HIA was not included as a specific proposal for legislation in the Public Health White Paper consultation document. However, a number of respondents (primarily from health representative organisations) expressed disappointment that it was not included.
291. During the Public Health Green Paper consultation in late 2012, the mandatory use of HIA attracted general support. Respondents noted a number of benefits to HIA, including that it provides a tried and tested approach which encourages collaborative working and effective community engagement, and that its use is already considered good practice. It was also suggested that HIA provides a systematic yet flexible method for ensuring health issues are considered throughout the policy development process and that it helps avoid 'clashes' in the effects of some policies. Several respondents noted that HIA can contribute to transparent policy making, with some suggesting that completed HIAs should be published to strengthen public scrutiny of decisions.
292. Alternatively, a number of respondents expressed reservations regarding a legislative requirement to undertake HIA. These included concerns about the need to avoid any unnecessary or onerous bureaucracy, and any approach that might be disproportionate. Other comments included that HIA is too burdensome (either or both in terms of cost and time), and concerns were raised about the level of expertise needed to undertake the assessments. Some also pointed out that

although HIA may assist in identifying possible positive and negative impacts on public health, it does not guarantee that they will be addressed or rectified.

293. Although the responses indicated general support for HIA, a number of suggestions were made as to how HIAs could be approached. These included a more integrated approach to impact assessment, which comprises HIA along with other required assessments covering equality and sustainability issues. Others specifically argued the need for an outcome focus within the HIA process, rather than it being approached solely as a process-driven 'tick box' exercise.

294. When asked which bodies should be required to use HIA, a clear majority indicated that Welsh Ministers/ Welsh Government departments and local authorities should be required to use HIA, with many responses also indicating that this requirement should apply more broadly across the public sector and to organisations delivering services on their behalf. An additional suggestion was that decisions about which bodies should be required to use HIA could be based on those bodies which are required to complete other mandatory impact assessments. There was some support for taking a phased approach to introducing any new requirements across different sectors.

Better planning and delivery of public health services through community pharmacy (this relates to Part 6 of the Bill - 'Pharmaceutical Services')

295. 96 responses were received in respect of this proposal. The responses indicated broad support for the proposal, with common agreement that community pharmacies could play a stronger role in promoting and protecting health as part of a network of local health care services. A number emphasised that community pharmacies are locally based and convenient for the public to access, and also referred to the services community pharmacies currently provide which promote and protect public health.

296. A majority of respondents indicated that undertaking pharmaceutical needs assessments would result in better planning and delivery of pharmacy services. This view was apparent in responses from LHBs, Public Health Wales, pharmacy contractors, representative organisations and individual pharmacists. A number of suggestions were offered for how assessments could be carried out consistently and to best effect, as well as suggestions for what should be incorporated in a pharmaceutical needs assessment and the frequency of the assessments.

297. Specific consultation questions covered a range of points of detail in relation to the provision of pharmaceutical services within an area. For example, these covered issues such as the ability of LHBs to invite additional pharmacies to be established in order to meet locally identified pharmaceutical needs, and the availability of sanctions to LHBs to support

improved quality and consistency. Such elements of the proposal attracted broad general support, although there was an emphasis on the need for any sanctions to be reasonable and proportionate.

298. Amongst the general reservations expressed in relation to the proposal, these most commonly referred to the need to avoid unnecessary complexity or onerous bureaucracy.

Local authority strategies on the provision of and access to toilets for public use (relates to Part 7 of the Bill - 'Provision of toilets')

299. 120 responses were received in respect of this proposal. The majority favoured the introduction of a duty on local authorities in this area and commonly referred to the need to safeguard provision in times of austerity.
300. Responses from health organisations, community councils, representative organisations and members of the public indicated broad support for the proposals. A number referred to the potential health impacts associated with poor public toilet provision, and responses from representative organisations referred to the particular impacts which poor provision can have on the groups they represent.
301. Whilst responses from the local government sector recognised the importance of the issue, the majority did not favour the imposition of a duty to develop a strategy, due to concerns regarding the current financial climate facing local authorities. Conversely, a number of respondents felt that a local authority strategy on this issue would not in itself be sufficient, and suggested that the proposed duty should go further by requiring the provision of adequate facilities.
302. Amongst the other issues raised, respondents commented on the need to think of creative solutions in order to secure improved provision, the importance of involving local communities in local needs assessments, and the effectiveness of the previous Public Facilities Grant Scheme.

Other consultations

Consultation on how to make cosmetic piercing safer for young people

303. Following a commitment to consult on how to make cosmetic piercing safer for young people, a consultation document was published in 2011.¹³⁶ 228 responses were received and a summary of responses was then published.¹³⁷
304. As a result of further policy work and consideration, elements of the previous proposal (such as that relating to a standardised consultation for

¹³⁶ <http://wales.gov.uk/consultations/healthsocialcare/cosmetic/?lang=en>

¹³⁷ <http://wales.gov.uk/consultations/healthsocialcare/cosmetic/?lang=en>

all cosmetic piercing) were taken forward through the broader proposal for a National Special Procedures Register, which was consulted upon in the subsequent Public Health White paper. This was in recognition that the wider issues of improved regulation, information and enforcement apply more widely than just the cosmetic piercing industry.

305. In recognition of the ongoing support for restrictions in relation to the intimate piercing of children and young people which was illustrated in responses to the Public Health White Paper, this issue has also been addressed in the Public Health (Wales) Bill.

Consultation by the Health and Social Care Committee of the Fourth Assembly

306. The Public Health (Wales) Bill was firstly considered by the National Assembly for Wales during the Fourth Assembly, following its introduction on 8 June 2015. Upon introduction the Bill comprised the following main components:
- Restrictions on the use of tobacco and e-cigarettes in enclosed and substantially enclosed public and work places, with a regulation-making power to extend the restrictions to certain open spaces;
 - Creation of a national register of retailers of tobacco and nicotine products;
 - A regulation-making power to add to the offences which contribute to a Restricted Premises Order in Wales;
 - Prohibiting the handing over of tobacco and/or nicotine products to a person under the age of 18;
 - Creation of a mandatory licensing scheme for practitioners and businesses carry out 'special procedures', namely acupuncture, body piercing, electrolysis and tattooing;
 - Prohibiting the intimate piercing of persons under the age of 16 years;
 - Changing the arrangements for entry onto the pharmaceutical list of local health boards, to a system based on the pharmaceutical needs of local communities; and
 - Requiring local authorities to prepare a local strategy to plan how they will meet the needs of their communities for accessing toilet facilities for public use.
307. As part of the Assembly's scrutiny processes, the Bill was examined by a number of Committees of the National Assembly, with the then Health and Social Care Committee being the lead scrutinising Committee.
308. As part of its consideration of the Bill, the Health and Social Care Committee undertook a comprehensive stakeholder consultation exercise, during which it received written and oral evidence from a range of key stakeholders. A public survey was also undertaken as part of the Committee's work.

309. The Health and Social Care Committee published its report in November 2015.¹³⁸ It made 19 specific recommendations across different areas of the Bill as to how it could be strengthened. A number of these were addressed by later Government amendments to the Bill, for example the addition of new provisions relating to health impact assessments, and the addition of the tongue to the list of 'intimate body parts' to be covered by the prohibition of intimate piercing on persons aged under 16. Members of the Committee were unable to reach a consensus view about whether to support the Bill's restrictions on the use of e-cigarettes in public places, and so no specific recommendations were made about this topic in the report.
310. Due to the extensive consultation already undertaken in relation to the Public Health (Wales) Bill, including through the White Paper and Health and Social Care Committee consultations, no additional consultation on a draft Bill was undertaken in advance of introduction to the Fifth National Assembly for Wales.

¹³⁸ <http://www.senedd.assembly.wales/mglIssueHistoryHome.aspx?lId=12763>

5. Power to make subordinate legislation

311. The Bill contains provisions to make subordinate legislation and issue determinations. Table 5.1 (subordinate legislation) and Table 2 (guidance and byelaws) set out in relation to these:

- (i) The person upon whom, or the body upon which, the power is conferred;
- (ii) The form in which the power is to be exercised;
- (iii) The appropriateness of the delegated power; and
- (iv) The applied procedure - that is whether it is “affirmative”, “negative”, or “no procedure”, together with reasons why it is considered appropriate.

312. The Welsh Government will consult on the content of the subordinate legislation where it is considered appropriate to do so. The precise nature of consultation will be decided when the proposals have been formalised.

Table 5.1 (subordinate legislation)

Section	Power conferred on	Form	Appropriateness of delegated power	Procedure	Reason for procedure
Part 2 – Tobacco and Nicotine Products					
Chapter 1 – Smoking					
4(2)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to place a duty upon specified persons who control or	Affirmative	To provide additional security for the Assembly in that the range of persons subject to such a duty will not be widened – which

			are concerned in the management of premises or vehicles that are smoke-free under sections 7, 8 or 9, or by virtue of regulations made under sections 10 or 12, to take reasonable steps to cause a person to stop smoking in those places.		could potentially be regarded as placing an onerous duty on members of the public – without full consideration and the opportunity for debate.
7(6)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make provision about the process to be followed to designate an area on the grounds of schools that provide residential accommodation to pupils as not being smoke-free	Affirmative	To provide additional security for the Assembly that the detail of arrangements for designating areas of grounds of schools that provide residential accommodation to pupils as not smoke-free will not be determined without full consideration and the opportunity for debate.
8(5)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make provision about the process to be followed to designate an area on hospital grounds as not being smoke-free	Affirmative	To provide additional security for the Assembly that the detail of arrangements for designating areas of hospital grounds as not smoke-free will not be determined without full consideration and the opportunity for debate.

10(1)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to designate any places in Wales, or description of place in Wales, as being smoke-free through regulations. Such places or description of places need not be enclosed or substantially enclosed.</p> <p>The regulations may also provide for exemptions, including conditional exemptions. The conditional exemptions may include a condition requiring the person in charge of the premises to designate rooms or areas as being areas in which smoking is permitted.</p>	Affirmative	<p>To provide additional security for the Assembly in that additional smoke-free premises will not be added – which could potentially be regarded as placing an onerous duty on members of the public – without full consideration and the opportunity for debate.</p> <p>Section 10(3) also states that the regulations may provide for a place or description of a place to be treated as smoke-free premises only if the Welsh Ministers are satisfied that doing so is likely to contribute towards the promotion of the health of the people of Wales.</p> <p>Section 11 makes further provision about exercising the section 10 power to designate dwellings as additional smoke-free premises. Dwellings may only be designated as additional smoke-free premises to the extent they are not enclosed or substantially enclosed, and only if they are used as a place of work or open to the public and</p>
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					only when children are present.
12(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to designate the circumstances in which a vehicle (excluding ships and hovercraft) should be treated as a smoke-free vehicle.	Affirmative	<p>To provide additional security for the Assembly in that the circumstances in which a vehicle must be smoke-free will not be determined – which could potentially be regarded as placing an onerous duty on members of the public – without full consideration and the opportunity for debate.</p> <p>In addition, section 12(2) states that the regulations may provide for a vehicle to be treated as smoke-free only if the Welsh Ministers are satisfied that doing so is likely to contribute towards the promotion of the health of the people of Wales.</p> <p>The power is also comparable with that at section 5 of the Health Act 2006, to which the affirmative procedure applies.</p>
13(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to exempt premises, or specified areas within	Affirmative	To provide additional security for the Assembly in that premises or parts of premises exempted from the smoke-free requirements will

			<p>specified premises, from the smoke-free requirements.</p> <p>The regulations may also provide for conditional exemptions. The conditional exemptions may include a condition requiring the person in charge of the premises to designate rooms or areas as being areas in which smoking is permitted.</p>		<p>not be determined – which could significantly affect the operation of these provisions – without full consideration and the opportunity for debate.</p> <p>The power is also comparable with that at section 3 of the Health Act 2006, to which the affirmative procedure applies.</p>
14(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to prescribe for requirements for the display of smoke-free signs.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
14(3)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to impose a duty to display smoke-free signage on persons occupying or managing smoke-free vehicles and additional smoke-free places.	Affirmative	To provide additional security for the Assembly in that the range of persons subject to such a duty will not be widened – which could potentially be regarded as placing an onerous duty on members of the public – without full consideration and the opportunity for debate.

15(2)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the chief officer of police for a police area to be designated as an enforcement authority in relation to vehicles that are in that police area.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
25(7)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to specify what “enclosed”, “substantially enclosed” and “not enclosed or substantially enclosed” mean for the purposes of designating smoke-free premises and workplaces.	Affirmative	To provide additional security for the Assembly that these definitions will not be amended without full consideration and the opportunity for debate.
Chapter 2 – Retailers of Tobacco and Nicotine Products					
27(2)	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to specify a Registration Authority in respect of the register of retailers of tobacco and nicotine products	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
28(3)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to prescribe the detail as to the form and content of	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also,

			applications for registration, and on the accompanying fee.		<p>the content of these provisions may need to be updated from time to time.</p> <p>In addition, before making regulations under this section, the Welsh Ministers must consider where there are persons who appear to be representative of the interests of those likely to be affected by the regulations, and carry out consultation with any representative persons whom the Welsh Ministers consider it appropriate to consult.</p>
31(6)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the registration authority to impose a fee in connection with revising an entry on the register.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.
33	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to exempt certain businesses from the provisions of Chapter 2 of Part 2.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also the content of these provisions may need to be updated from

					time to time.
34	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to modify the way in which Chapter 2 of Part 2 applies to vehicles and other moveable structures.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
47(2)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to specify the definition of 'nicotine product' in respect of the register of retailers of tobacco and nicotine products.	Affirmative	To provide additional security for the Assembly in that the definition of 'nicotine product' will not be amended – which could potentially be regarded as placing an onerous duty on business – without full consideration and the opportunity for debate.
Chapter 3 – Prohibition on sale of Tobacco and Nicotine Products					
48	Welsh Ministers	Regulations	To enable the Welsh Ministers to specify the definition of a 'tobacco or nicotine offence' in respect to issuing Restricted Premises Orders in regulations.	Affirmative	<p>To provide additional security for the Assembly in that the definition of 'tobacco or nicotine offence' will not be widened – which could potentially be regarded as placing an onerous duty on business– without full consideration and the opportunity for debate.</p> <p>Section 48 also states that a 'tobacco or nicotine offence' may</p>

					<p>be specified in regulations only if the Welsh Ministers are satisfied that the offence is one that relates to the supply, sale, transport, display, offer for sale, advertising or possession of tobacco or nicotine products. And, in the case of an offence that is triable only summarily, it is punishable by a fine of an amount corresponding to, or greater than, level 4 on the standard scale.</p> <p>In addition, before making regulations, the Welsh Ministers must consider where there are persons who appear to be representative of the interests of those likely to be affected by the regulations, and carry out consultation with any representative persons whom the Welsh Ministers consider it appropriate to consult.</p>
Chapter 4 – Handing over tobacco etc. to persons under 18					
N/A					
Part 3 – Special Procedures					

57(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to specify that a special procedures licence is required in order for exempted individuals (members of a profession set out in paragraphs (a) to (ga) of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002) to undertake specified special procedures.	Affirmative	<p>To provide additional security for the Assembly that specified special procedures will not be able to be performed by exempted individuals without full consideration and the opportunity for debate of whether these individuals should require a licence.</p> <p>In addition, section 57(5) provides further detail in relation to these regulations.</p>
57(3)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to exempt individuals who are not members of a profession specified in paragraphs (a) to (ga) of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002, but who are members of a qualifying register, from the requirement to operate under the authority of a special procedures licence.	Affirmative	<p>To provide additional security for the Assembly that the list of exempted practitioners will be fully considered with the opportunity for debate.</p> <p>In addition, sections 57(4) and 57(5) provide further detail in relation to these regulations.</p>
57(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables Welsh Ministers	Affirmative	To provide additional security for the Assembly that the list of

			to add other registers to the list of qualifying registers for the purpose of granting an exemption under section 57(4).		qualifying registers will not be added to without full consideration and the opportunity for debate.
59(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the licensing criteria (which must include the requirements set out in section 59(2)) that must be met on an application for a special procedures licence in order for the application to be granted.	Affirmative	<p>To provide additional security for the Assembly that the licensing criteria – which could potentially be regarded as placing an onerous duty on those applying for a special procedures licence –will be fully considered with the opportunity for debate.</p> <p>Furthermore, section 61 states that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
59(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to set out the requirements, before a licence is issued or renewed, for a local authority to follow in relation to the inspection of those premises or vehicles identified in a licence application.	Affirmative	<p>To provide additional security for the Assembly that the licensing criteria – which could potentially be regarded as placing an onerous duty on local authorities –will be fully considered with the opportunity for debate.</p> <p>Furthermore, section 61 states</p>

					that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.
59(5)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make different provision for different purposes in respect of the licensing criteria. This includes providing different descriptions of premises and vehicles, different descriptions of special procedures and the different circumstances in which a special procedure is performed.	Affirmative	<p>To provide additional security for the Assembly that the licensing criteria – which could potentially be regarded as placing an onerous duty on those applying for a special procedures licence –will be fully considered with the opportunity for debate.</p> <p>Furthermore, section 61 states that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
60(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the mandatory licensing conditions that are to apply to those holding a special procedures licence. The mandatory	Affirmative	To provide additional security for the Assembly that the mandatory licensing conditions – which could potentially be regarded as placing an onerous duty on those holding a special procedures licence –will be fully considered

			licensing conditions must include the requirements set out in sections 60(2) and 60(3).		<p>with the opportunity for debate.</p> <p>Furthermore, section 61 states that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
60(5)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make different provision for different purposes in respect of the mandatory licensing conditions. This includes providing different descriptions of premises and vehicles, different descriptions of special procedures and the different circumstances in which a special procedure is performed.	Affirmative	<p>To provide additional security for the Assembly that the mandatory licensing conditions – which could potentially be regarded as placing an onerous duty on those holding a special procedures licence – will be fully considered with the opportunity for debate.</p> <p>Furthermore, section 61 states that before exercising this regulation making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
63(10)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to amend the list of relevant offences under section	Affirmative	To provide additional security for the Assembly that the list of relevant offences – which could potentially prevent an applicant

			63(8) by adding, varying or removing a description of offence.		from holding a special procedures licence – will be fully considered with the opportunity for debate before being extended.
66(8)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to exempt specified premises or vehicles from the requirement to obtain approval from the local authority and to exempt a person, premises or vehicle associated with an exhibition, entertainment or other event, from the requirement to obtain approval from the local authority.	Affirmative	To provide additional security for the Assembly that the list of excepted premises and vehicles will be fully considered with the opportunity for debate before being extended.
67(3)(a) or (c)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this requires the Welsh Ministers to make regulations in relation to the approval of premises and vehicles in respect of the performance of a special procedure.</p> <p>The regulations must specify the criteria that must be met and the mandatory approval conditions to which approval is to be</p>	Affirmative	To provide additional security for the Assembly that the criteria that must be met, and the mandatory approval conditions to which approval is to be subject, will be fully considered with the opportunity for debate.

			subject.		
67(3)(b) or (d)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this requires the Welsh Ministers to make regulations in relation to the approval of premises and vehicles in respect of the performance of a special procedure.</p> <p>The regulations must specify the circumstances in which an application for approval is to be granted, and make provision about appealing against refusal of an application.</p>	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/administrative in nature. Also, the content of these provisions may need to be updated from time to time.
67(7)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to make provision about the way in which applications for approval of premises or vehicles must be made and dealt with. This includes the payment of a fee, the circumstances in which an application must not be granted, or may be granted at the discretion of the local authority and the process for renewal of</p>	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/administrative in nature. Also, the content of these provisions may need to be updated from time to time.

			approval or variation of approval.		
67(8)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to make provision about how a local authority is to determine the amount of fee payable in respect of an application for approval and the consequences of failure to comply with a requirement to pay a fee.</p> <p>This provision provides further detail for how regulations under section 67(7) are to be made.</p>	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical/administrative in nature. Also, the content of these provisions may need to be updated from time to time.
67(9)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to make different provisions for different purposes to do with the approval of premises and vehicles in respect of the performance of a special procedure. This includes providing different descriptions of premises or vehicles, different descriptions of special procedures and the different circumstances in which a</p>	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.

			special procedure is performed. This provision provides further detail for how regulations under section 67 are to be made.		
68(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make further provisions about the form and content of approval certificates.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
69(5)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make further provisions about the notice of voluntary termination of approval, including the information to be included in the notice.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
73(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make provision about the way in which a local authority is to determine the special procedure licence or premises or vehicle approval fee to be paid by an applicant.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also the content of these provisions may need to be updated from time to time.
73(5)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh	Negative	The subject-matter is relatively minor in the overall legislative

			Ministers to make further provision in relation to the special procedure licence or premises/vehicle approval fee. This may include the way in which a fee is to be paid, repayment of a fee (or a proportion of it) in cases of overpayment, and recovery of a fee due to an authority and unpaid.		scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
90(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to amend the list of special procedures in section 54.	Affirmative	<p>To provide additional security for the Assembly that the list of special procedures will not be amended without full consideration and the opportunity for debate.</p> <p>In addition, section 90(3) states that this power is to be exercised only if the Welsh Ministers consider—</p> <p>(a) that the procedure is one that is capable of being performed for aesthetic purposes, or for purposes that the Welsh Ministers consider to be therapeutic, and</p> <p>(b) that its performance for those purposes is capable of causing</p>

					<p>harm to human health.</p> <p>Furthermore, section 90(4) states that before exercising this regulation-making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
91(1)	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to amend the definition of “body piercing” by describing objects that may be attached to, implanted in, or removed from an individual’s body. In addition, an object or description of object may be prescribed by reference to (among other things) the part of the body on which the perforation is performed.</p>	Affirmative	<p>To provide additional security for the Assembly that the definition of “body piercing” will not be amended without full consideration and the opportunity for debate.</p>
Part 4 – Intimate piercing					
N/A					
Part 5 – Health Impact assessments					
105	Welsh Ministers	Regulations	<p>Suitable for delegated powers as this enables the Welsh Ministers to make provision about the carrying out of health impact assessments by public</p>	Affirmative	<p>To provide additional security to the Assembly in that the specified circumstances and methodology for requirements to carry out health impact</p>

			bodies.		<p>assessments will not be determined without full consideration and the opportunity for debate.</p> <p>The regulations must cover the circumstances in which public bodies must carry out health impact assessments, and the way in which they are to be carried out.</p> <p>In addition, regulations may cover other matters such as assistance to be given to public bodies in carrying out health impact assessments.</p> <p>Furthermore, section 105(7) provides that before exercising this regulation-making power, the Welsh Ministers must consult with persons who appear to be representative of the interests of those likely to be affected.</p>
106(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh	Negative	The subject matter is relatively minor in the overall legislative

			Ministers to make provision about how health impact assessments are to be published, including the time at which they are to be published.		scheme and is technical.
107(2)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to amend the meaning of 'public body' for the purposes of carrying out health impact assessments, by adding, removing or amending the description of a public body.	Affirmative	To provide additional security to the Assembly in that the range of public bodies subject to a duty to undertake health impact assessments in certain circumstances will not be widened – which could potentially be regarded as placing an onerous duty on a public body – without full consideration and the opportunity for debate.
Part 6 – Pharmaceutical services					
108(1) Inserts section 82A(3) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to detail when and how a Local Health Board (LHB) should prepare and publish an assessment of pharmaceutical needs.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
108(1) Inserts section	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make further	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also,

82A(4) into the NHS (Wales) Act 2006			provisions about the preparation, publication, review and revision of assessments.		the content of these provisions may need to be updated from time to time.
108(2) Inserts section 203(6A) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	Suitable for delegated powers as this provides further detail about the operation of the Welsh Ministers' regulation-making powers under section 82A of the NHS (Wales) Act 2006.	Affirmative	<p>To provide additional security to the Assembly that the first regulations setting out the detail for preparing and publishing pharmaceutical needs assessments will be fully considered with the opportunity for debate.</p> <p>Any further regulations made will be subject to the negative procedure, as these subsequent regulations will be technical and may need to be updated from time to time.</p>
109(3) Inserts section 83 (2A) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to specify persons or descriptions of persons who are</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>

			not to be included within a pharmaceutical list.		
109(3) Inserts section 83 (2C) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to make provision as to the procedure that LHBs should follow, and matters they should take into account, when determining whether to grant an application to their pharmaceutical list.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
109(4) Inserts section 83 (3A) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to prescribe circumstances in which two or more applications to an LHB's pharmaceutical list may or must</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>

			be considered together.		
109(5) Amends section 83 (4) of the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to make provision for LHBs to take into account prescribed matters when considering two or more applications together.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
109(6) Inserts section 83 (4A) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to modify the application of section 83(5).</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
109(7)(a) Inserts section 83 (6) (za) into the NHS	Welsh Ministers	Regulations	The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from

(Wales) Act 2006			Suitable for delegated powers as this enables the Welsh Ministers to make provision as to the circumstances in which LHBs may invite applications for inclusion within their pharmaceutical list.		time to time. This procedure is located in section 203 of the NHS (Wales) Act 2006.
109(7)(b) Inserts section 83(6)(fa) into the NHS (Wales) Act	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to make provision as to the timescales for dealing with an application inclusion within a pharmaceutical list.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
109(7)(c)	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to make provision for</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales)</p>

			which sets out the grounds on which or circumstance in which a LHB can refuse to grant an application to be on a pharmaceutical list.		Act 2006.
109(7)(d) Inserts section 83 (6)(n) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh Ministers to make provision as to when a LHB may or must remove a person or an entry in respect of premises from their pharmaceutical list in relation to breaches of terms of service.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
109(9) Inserts section 83 (10A) into the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this enables the Welsh</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.</p>

			Ministers to require LHBs to give reasons for decisions made under section 83 NHS (Wales) Act 2006.		This procedure is located in section 203 of the NHS (Wales) Act 2006.
109(11) Inserts section 84 (4) of the NHS (Wales) Act 2006	Welsh Ministers	Regulations	<p>The regulation-making power is located in section 83 of the NHS (Wales) Act 2006. This provision amends that regulation-making power.</p> <p>Suitable for delegated powers as this requires the Welsh Ministers to make provision for LHBs to give notice of their intention to remove a person or premises from their pharmaceutical list, and to provide for the right to make representations.</p>	Negative	<p>The subject-matter is relatively minor in the overall legislative scheme and is technical/ administrative in nature. Also, the content of these provisions may need to be updated from time to time.</p> <p>This procedure is located in section 203 of the NHS (Wales) Act 2006.</p>
Part 7 – Provision of toilets					
N/A					
Part 8 – Miscellaneous and General					
122(1)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make consequential, incidental, transitional or saving provision as they consider appropriate in connection with the Bill.	Negative or Affirmative	This power is required to allow the Welsh Ministers to make supplementary, incidental, consequential, transitional or saving provisions if they consider it necessary or expedient for the purposes of, in consequence of

					<p>or for giving full effect to any provision of the Bill.</p> <p>If the regulations amend or repeal any provision of an Act of Parliament or Measure or Act of the National Assembly for Wales then they are subject to the affirmative procedure.</p> <p>If the regulations make any other consequential, incidental, supplementary or transitional provision the regulations will be subject to the negative procedure.</p>
123(2)	Welsh Ministers	Order	The Welsh Ministers may appoint by order that other provisions (not listed in section 123(1)) shall come into force on such date (or dates) as stated in the order.	No procedure applicable to commencement order	These orders will be confined to commencement and are technical in nature.
Schedule 1 – Fixed Penalties					
Paragraph 5	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to prescribe the form in which Fixed Penalty Notices (FPNs) for specified offences under the Bill must take. (Those	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.

			offences are of smoking in a smoke-free premises or vehicle; failure to prevent smoking in smoke-free premises; and failure to notify certain changes to or provide information in relation to the register of tobacco or nicotine products.)		
Paragraph 6	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the amount set for Fixed Penalty Notices under the Bill.	Affirmative	To provide additional security for the Assembly in that the amount set for FPNs – which could be regarded as an onerous duty on members of the public and/or will potentially place financial obligations on members of the public – will not be determined without full consideration and the opportunity for debate.
Paragraph 9	Welsh Ministers	Regulations	Suitable for delegated powers as this requires the Welsh Ministers to prescribe the discounted amount in relation to Fixed Penalty Notices under the Bill.	Affirmative	To provide additional security for the Assembly in that the discounted amount set for FPNs – which impose a financial burden on members of the public – will not be determined without full consideration and the opportunity for debate.
Schedule 2 – Smoking: consequential amendments					
Paragraph	Welsh Ministers	Regulations	Suitable for delegated powers	Negative	The subject-matter is relatively

17			as this retains the Welsh Ministers' current power to prescribe the form of the Fixed Penalty Notice that may be issued by a local weights and measures authority for the offence under section 91 of the Children and Families Act 2014 ('Purchase of Tobacco and Nicotine Products etc. on behalf of persons under 18')		minor in the overall legislative scheme and is technical.
Schedule 3 – Further provision in connection with special procedure licences					
Paragraph 4(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make provision about the way in which the local authority is to determine the amount of the fee that is to accompany an application for a special procedure licence and make further provision about applications, including the way in which an application will be dealt with by the local authority. These regulations will be in addition to the details provided in Schedule 3, paragraphs 1, 2, 3 and 4.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical /administrative in nature. Also, the content of these provisions may need to be updated from time to time.
Paragraph	Welsh Ministers	Regulations	Suitable for delegated powers	Negative	The subject-matter is relatively

5(3)			as this enables the Welsh Ministers to make provision about the form and contents of special procedures licences. These regulations will be in addition to the details provided in Schedule 3, paragraphs 5(1) and 5(2).		minor in the overall legislative scheme and is technical/administrative in nature. Also, the content of these provisions may need to be updated from time to time.
Paragraph 21(4)	Welsh Ministers	Regulations	Suitable for delegated powers as this enables the Welsh Ministers to make provision about the procedures applicable to a local authority licensing committee and their sub-committees.	Negative	The subject-matter is relatively minor in the overall legislative scheme and is technical. Also, the content of these provisions may need to be updated from time to time.
Schedule 4 – Provision of toilets: consequential amendments					
N/A					

Table 5.2 – Guidance and byelaws

Section or Schedule of Bill	Power conferred on	Form	Power
Part 3 – Special Procedures			
63(11)	Welsh Ministers	Guidance	The Welsh Ministers must issue guidance to local authorities about matters to be taken into account in deciding whether an applicant's fitness to perform a special procedure has been called into question.
Part 6 – Provision of toilets			
110(7)	Welsh Ministers	Guidance	The Welsh Ministers must issue guidance to local authorities about the

			matters which they should take into consideration when preparing, reviewing, consulting on or publishing their local toilets strategy.
111(5)	Welsh Ministers	Guidance	The Welsh Ministers must issue guidance to local authorities about the matters which they should take into consideration when preparing an interim progress statement in relation to their local toilets strategies.
114(1)	County, county borough and community councils	Byelaws	County, county borough and community councils may make byelaws as to the conduct of persons using public toilets that they provide.

6. Regulatory Impact Assessment

313. A Regulatory Impact Assessment has been completed for the Bill and it follows below.

314. There are no specific provisions in the Bill which charge expenditure on the Welsh Consolidated Fund.

Part 2 – Regulatory Impact Assessment

Summary – Regulatory Impact Assessment (RIA)

Summary table 1:

Public Health (Wales) Bill		
Preferred option: Introduce legislation to further improve and protect health and wellbeing, in a number of areas of public health policy.		
Stage: Following Stage 2	Appraisal period: 2017-18 – 2021-22	Price base year: 2016-17
Total cost Total: £7,509,700 Present value: £6,763,600	Total benefits Total: £7,740,000 Present value: £6,747,600	Net Present Value (NPV): £-16,000

Summary table 2:

Administrative cost

Costs: <p>Across the Bill's various provisions, there are a number of common administrative costs for the Welsh Government, primarily relating to the development and publication of guidance, communications work and the provision of training for those organisations implementing and/or enforcing the legislation. For local government, there are the related costs of engaging in this process, together with the additional costs of operating the register of retailers of tobacco and nicotine products and the licensing scheme for special procedures. Local government and health boards will have costs related to undertaking needs assessments for toilets for public use and pharmaceutical services respectively, and public bodies in general will incur administrative costs in carrying out health impact assessments in certain circumstances.</p> <p>Annex 4 provides a detailed breakdown of the costs of the Bill.</p>			
Transitional: £1,090,400	Recurrent: £1,521,600	Total: £2,612,000	PV: £2,379,500

Cost-savings:

A key area of cost-savings estimated in the RIA relates to savings from fewer appeals to health boards' decisions about applications for additional premises on pharmaceutical lists. A number of other cost-savings are identified but estimates are not given due to very limited data being available. For example, there could be cost savings relating to the enforcement of the existing voluntary bans on smoking in hospital grounds, but there is insufficient data to fully estimate cost-savings. In addition, there could be cost savings from preventing potential health harms resulting from poor practice relating to special procedures.

Transitional: £0	Recurrent: £93,600	Total: £93,600	PV: £81,600
Net administrative cost: £2,518,400			

Summary table 3:

Compliance costs

For both the register of retailers of tobacco and nicotine products and the licensing system for practitioners of special procedures, there will be compliance costs for private businesses. These include familiarisation with the relevant guidance, time spent and fees payable to register/apply and the costs of any fines from not adhering to the legislation. Some retailers of tobacco and nicotine products will also have costs in familiarising themselves with the guidance relating to the handing over of tobacco to persons aged under 18, for example, as will practitioners in relation to the intimate piercing of those aged under 18. The costs of fines will also be applicable to members of the public should they breach the smoke-free requirements in school grounds, hospital grounds and public playgrounds.

Transitional: £995,900	Recurrent: £3,995,400	Total: £4,991,300	PV: £4,465,700
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Summary table 4:

Other costs

The costs identified in the RIA fall into the category of either administrative or compliance costs.

Transitional: £0	Recurrent: £0	Total: £0	PV: £0
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Summary table 5:

Unquantified costs and dis-benefits

Potential unquantified costs could include loss of income from being unable to trade/practice. For example, if retailers of tobacco and nicotine products were prevented from selling either/both these products through a Restricted Premises Order, this could have an effect on their potential income, not only from the sales of these products but also from losing custom to competitors. A similar scenario could apply to special procedures practitioners who would not be able to practice if they do not meet the requirements of the new licensing/approvals system. The number of businesses whose trade will be restricted is unknown at this stage but is expected to be small.

It is expected that the Bill will attract high levels of compliance and a supportive enforcement environment, so while it has not been possible to fully assess some potential court costs, the overall impact is expected to be limited.

Summary table 6:

Benefits

The Bill is expected to lead to a range of benefits, although these cannot in every instance be quantified due to a high degree of variability or a lack of available data. For example, there will be health benefits from preventing access to tobacco and nicotine products by children and young people, and benefits to the NHS in preventing harm caused by poor practice relating to special procedures.

The area where benefits have been able to be quantified relates to the improved arrangements for the planning and delivery of pharmaceutical services. The conservative analysis carried out suggests the benefits of the change would be approximately £7,740,000 over the five-year period.

Total: £7,740,000	PV: £6,747,600
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Summary table 7:

Key evidence, assumptions and uncertainties

Throughout the RIA, a wide variety of academic, routine statistical and service data has been used in the assessment of costs. Where there is uncertainty, a cautious approach has been taken towards the calculation of estimated costs. This is likely to mean that in a number of areas the actual costs associated with implementing the legislation may be lower. There is also likely to be further potential for savings if certain aspects of implementation are co-ordinated across different areas of the Bill, for example if training sessions are combined for a number of related policies. In a number of places, where there is uncertainty, a range of potential costs has been applied.

7. Options, costs and benefits

315. This regulatory impact assessment (RIA) is structured around each policy element of the Public Health (Wales) Bill for ease of reference. It presents a series of options for each, followed by costs and benefits. Summary tables showing the additional cost associated with each preferred option are presented in annex four.
316. The costs and benefits associated with each option have been produced using the best information available at the current time. This information has been prepared through discussion with key stakeholders, including local authorities, health boards and other agencies. The costs and benefits associated with each option have been assessed over a five-year period from 2017-18, with a longer period used in some cases. Where costs are expected to extend beyond the initial five-year period (i.e. recurrent costs) these are identified in the text.
317. For clarity and consistency, costs in this RIA have been rounded to the nearest £100. Throughout the document figures are annual and pan-Wales unless specified. RIAs will be produced for the subordinate legislation arising from the Bill at the appropriate time; therefore whilst estimated costs for implementing the Bill are included where known, even when given effect through subordinate legislation, administrative costs for producing subordinate legislation have not been covered.
318. Throughout this RIA, where there is uncertainty, a cautious approach has been taken to the assessment of costs. This is likely to mean that in a number of areas the actual costs associated with implementing the legislation may be lower. There is also likely to be further potential for savings if certain aspects of implementation are co-ordinated across different areas of the Bill, for example if training sessions are combined for a number of related policies.
319. The following chapter is structured into the following areas:-
- Tobacco and nicotine products
 - Restrictions on smoking in school grounds, hospital grounds and public playgrounds;
 - Register of retailers of tobacco and nicotine products;
 - Handing over tobacco etc. to persons under 18.
 - Special procedures;
 - Intimate piercing;
 - Health impact assessments;
 - NHS pharmaceutical services;

- Provision of toilets.

320. No full assessment is included in relation to the miscellaneous provisions in Part 8 of the Bill, as these provisions only make a minor administrative change to the use of fixed penalty notice receipts for food hygiene rating offences. The provisions allow local authorities to keep fixed penalty notice receipts which were previously submitted to Welsh Ministers, and therefore do not give rise to any additional cost. As meeting this policy objective requires a change to the Food Hygiene Rating (Wales) Act 2013, no alternative ways of achieving it were considered.

Tobacco and nicotine products (Part 2)

321. In this section of the RIA an assessment of the options, costs and benefits is only provided for those elements of the Bill which involve changes to the current position. For example, an assessment is only provided for the new restrictions on smoking in school grounds, hospital grounds and public playgrounds. An assessment is not provided for any restatement of existing requirements, as this is not expected to have any additional costs or benefits.

322. Similarly, no separate assessment is included for Part 2, Chapter 3 of the Bill, which deals with the general operation of restricted premises orders. This is covered in detail in the relevant section of the RIA, which deals with the register of retailers of tobacco and nicotine products.

Restrictions on smoking in school grounds, hospital grounds and public playgrounds (Part 2, Chapter 1)

Options

323. Three options have been considered:

- Option one – Do nothing;
- Option two – Continue with the current voluntary smoking bans but with vigorous and sustained promotion;
- Option three – Introduce a mandatory smoking ban to be implemented in hospital grounds, school grounds and children's playgrounds. This is the preferred option.

324. Voluntary bans in other non-enclosed/substantially non-enclosed grounds could be added in the future under all three options.

Option one – Do nothing

Description

325. Under this option, the decision about whether or not to implement bans on smoking in these grounds would remain voluntary. Reported challenges in enforcing these voluntary bans would continue.
326. All seven health boards in Wales and Velindre Cancer Centre¹³⁹ have voluntary smoking bans in place. The status of the current bans would remain unchanged under this option.
327. There is anecdotal evidence¹⁴⁰ that most schools have voluntary bans in place which are well-embedded, some for many years. The bans generally include staff, pupils, parents, visitors and contractors. There are also schools without such bans; under this option these schools would receive no additional support to implement bans.
328. All 22 of Wales' local authorities have signed up to ASH Wales' smoke-free playgrounds campaign¹⁴¹ and have implemented smoke-free playgrounds. These would remain in place as long as the local authority continues to maintain the policy.

Costs

329. There would be no additional costs associated with this option but the costs associated with the current position may continue. For example, in a few cases those with voluntary bans are incurring costs in replacing signage due to theft and vandalism (two local authorities have indicated the need for 25% additional signs for playgrounds to cover this) and health boards are using security staff time, or specific officers, to enforce the voluntary bans.

Benefits

330. This option would maintain the status quo and it is therefore likely that there would be no additional benefits. It would allow schools, hospitals and local authorities to continue to implement their voluntary bans where they feel they are needed.

Option two – Vigorous and sustained promotion of the voluntary bans

Description

331. This option would seek to strengthen the existing voluntary bans in school grounds, hospital grounds and public playgrounds by increasing public awareness of them through a public communications campaign.

¹³⁹ For future references to Health Boards in this section, please read Velindre NHS Trust as included.

¹⁴⁰ Source: Information obtained by Welsh Government from School Governance Officers

¹⁴¹ <http://ashwales.org.uk/en/information-resources/topics/smokefree-playgrounds>

332. By increasing public awareness through a sustained promotion campaign, it can be reasonably expected that more people will be aware of, and comply with, the voluntary bans which are already in place. It is not known to what extent such a campaign would contribute to improved compliance but it would be reasonable to assume some effect, as shown in Omnibus surveys¹⁴² related to the Fresh Start Wales campaign about smoking in cars carrying children, which ran from February 2012 to March 2014, and that seen in the campaign in Llanfairpwll, Anglesey, to be Europe's first smoke-free village¹⁴³.
333. This option would allow health boards and local authorities to continue with their voluntary bans and the work done to date in these settings. The Welsh Government would also work with stakeholders in order to issue best practice guidance drawing on Welsh experiences of tackling smoking in hospital grounds, school grounds and children's playgrounds.
334. Any future work to implement voluntary smoking bans in other non-enclosed spaces could be incorporated into the campaigns.

Costs

Welsh Government

335. There would be a cost to the Welsh Government to implement a communication strategy to promote smoke-free open spaces. The campaign to raise awareness of the ban on smoking in cars carrying children can be taken as a comparator campaign in terms of style and size. It has been estimated that £60,000 would be required in the first year (2017-18), with a reduced spend in subsequent years – estimated at a maximum of £10,000 per annum. However, this cost could increase if it were decided to publicise additional smoke-free open spaces in the future.
336. There would also be costs to the Welsh Government associated with producing and issuing best practice guidance. Staffing costs to write the guidance (based on 6,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £8,000. This is based on approximately five weeks of a full-time equivalent (FTE) higher executive officer (£4,900) to develop the guidance, and five weeks of a FTE team support for administration support (approximately £3,100).¹⁴⁴
337. It is anticipated that design and typesetting would require one week of a 0.5 FTE executive officer, which would cost approximately £400. It is estimated that translation and proofreading would cost approximately

¹⁴² <http://gov.wales/docs/caecd/research/2014/140715-smoking-cars-carrying-children-monitoring-public-attitudes-november-2013-update-en.pdf>

¹⁴³ <http://www.wales.nhs.uk/sitesplus/888/news/32004>

¹⁴⁴ Based on Welsh Government staff planning costs

£600.¹⁴⁵ There would be no printing costs for the guidance as it would only be produced electronically. The total cost for the development, design and translation of guidance would therefore be £9,000. The costs associated with producing the guidance would be incurred in 2017-18.

338. The guidance would be updated every three years. It is anticipated that this would require approximately one week of a FTE higher executive officer, which would equate to approximately £1,000. Design and translation costs would amount to half the original costs, a total of £500. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,500, incurred every three years. The first review would take place in 2020-21.

339. Training sessions may need to be held for enforcement officers who would implement and/or support others to implement the guidance. It is envisaged that environmental health professionals would run these sessions, though costs would be met by the Welsh Government. Each session would be approximately a half day and it is envisaged that two sessions would be held, one in North Wales and one in South Wales. These sessions would cost approximately £2,400, which covers room hire and refreshments for 35 people for each session (approximately £1,200)¹⁴⁶, and possible costs for external staff to develop and run part of the sessions (£1,200). This cost would be incurred in 2017-18.

Local authorities, schools and hospitals

340. Local authorities, schools, relevant NHS Wales organisations – health boards and Velindre NHS Trust – as well as independent hospitals would need to allocate time to contribute to and read guidance and best practice studies. Organisations will vary in the amount of time they allocate to contributing to, and implementing, such guidance. It has been assumed that, on average, every local authority, school and relevant NHS organisation in Wales would spend an hour on this work. Assuming a person at an equivalent cost to a local government enforcement officer, plus on-costs, undertakes this work then the total cost would be £48,300¹⁴⁷ in the first year (2017-18), with half that cost for revised guidance three years later (£24,200 in 2020-21).

341. There would also be costs to local authorities for enforcement officers to attend training sessions on the guidance. It is estimated that this would cost £9,300 in 2017-18.¹⁴⁸

¹⁴⁵ Based on £75 per 1000 words for translation, £21 per 1000 words for proof reading

¹⁴⁶ Based on costs from similar training sessions organised by Welsh Government

¹⁴⁷ Based on local authority enforcement officer costs of £26.66 per hour; one hour's work in each of 22 LAs, 1662 schools, 7 LHBs, Velindre NHS Trust and 121 hospital sites

¹⁴⁸ Based on 5 hours at an hourly rate of £26.66 (to include a half-day training session plus travel time) for 70 enforcement officers to attend

342. In addition, costs associated with the current position may continue. For instance, in some cases voluntary bans are incurring costs for replacement signage due to theft and vandalism. Therefore costs outlined under option one would also be relevant to option two, but as these are not additional costs associated with this option, they are not included here.

343. A successful campaign may lead to an increase in public pressure for organisations to provide more smoke-free open spaces but this is not possible to predict. However, these would be on a voluntary basis and organisations would have the choice to implement them or not and would not be compelled to provide smoke-free open spaces.

Public

344. There would be no direct financial cost to the public associated with this option.

Table 7.1: Summary of additional costs associated with option two

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government					
Communications campaign	60,000	10,000	10,000	10,000	10,000
Staff costs for development of guidance	8,000	0	0	1,000	0
Design and translation	1,000	0	0	500	0
Training	2,400	0	0	0	0
Total cost for Welsh Government	71,400	10,000	10,000	11,500	10,000
Local authorities, schools and NHS Wales					
Contributing to, and reading, best practice guidance	48,300	0	0	24,200	0
Costs for local authority enforcement officers to attend training	9,300	0	0	0	0
Total cost for local authorities, schools and NHS Wales	57,600	0	0	24,200	0
Total costs for option two	129,000	10,000	10,000	35,700	10,000

Benefits

Welsh Government

345. Based on the experience of previous campaigns, such as Fresh Start Wales in relation to smoking in cars carrying children, and those used by health boards when implementing their voluntary bans in 2012, it is assumed that a well-planned campaign strategy would achieve some degree of success in achieving the desired change of attitude and behaviour. However, it is not possible to quantify the impact this may have.

Local authorities, schools and hospitals

346. This option may achieve the goal of increasing compliance with, and enforcement of, voluntary bans in school grounds, hospital grounds and children's playgrounds. There could therefore be some savings in enforcement costs which are unable to be quantified.

Public

347. A campaign would likely raise awareness and knowledge among the public, as well as contribute to attitudinal and behaviour change. It is not possible to accurately predict or quantify the impact a campaign may have but it may reduce the scope of exposure to smoking, thus resulting in health benefits.
348. Evidence^{149,150,151,152} suggests when a smoke-free policy is implemented in secondary schools, including the grounds, which prevents teachers and other school personnel from smoking, it may contribute to the de-normalisation of smoking.

Option three – Mandatory smoking bans in school grounds, hospital grounds and public playgrounds

Description

349. Under this option, the Welsh Government would introduce legislation to make school grounds, hospital grounds and public playgrounds smoke-free.
350. The existing voluntary bans would be backed by legislation that would allow for more effective enforcement through the use of fixed penalty notices. Two offences would apply – smoking in a smoke-free place and failing to display signage in accordance with regulations. Both of these offences apply to current legislation in relation to smoking in enclosed and substantially enclosed public places. Local authorities would be

¹⁴⁹ <http://www.ncbi.nlm.nih.gov/pubmed/17768283>

¹⁵⁰ <http://www.ncbi.nlm.nih.gov/pubmed/12198278>

¹⁵¹ <http://www.ncbi.nlm.nih.gov/pubmed/16267148>

¹⁵² <http://her.oxfordjournals.org/content/23/6/1029.short>

responsible for enforcing the legislation. Existing Welsh Local Government Association (WLGA) guidance¹⁵³ for officers about the enforcement of the current smoke-free requirements would need to be updated to reflect the new restrictions in these open spaces.

351. Some all-Wales communication – national and/or targeted – would be necessary to raise public awareness and to inform the relevant bodies of their obligations to implement and enforce the new legislation. Normal routes of contact would also be used between Welsh Government and the WLGA, local authorities, health boards, NHS trusts and bodies representing independent schools and hospitals, to explain the effects of the legislation. As voluntary bans are already in place, these organisations would be expected to use existing methods to inform their staff and the public using their services, that voluntary bans would now be backed by legislation.

Costs

Welsh Government

352. There would be a cost associated with this option in implementing the legislation and producing associated guidance.
353. A public information campaign would be required, in addition to the normal routes used by schools, hospitals and local authorities, to publicise legislation. Costs estimated by the Welsh Government for a two phase public information campaign would be between £48,500 and £68,500 in 2017-18.
354. The Welsh Government **guidance**¹⁵⁴ **to organisations and businesses** relating to the provisions in the Health Act 2006 and the Smoke-Free Regulations 2007 would need to be updated to include the new provisions. It has been estimated that the costs of updating the existing Welsh Government smoke-free guidance would be approximately the same as those associated with updating the voluntary Welsh Government guidance under option two. This cost of approximately £1,500 would be incurred in 2017-18. Further updates to the guidance could be required and it is estimated that these would cost approximately the same, and be incurred in 2020-21.
355. The WLGA **guidance**¹⁵⁵ **relating to enforcement** of the provisions in the Health Act 2006 and the Smoke-Free Regulations 2007 would similarly need to be updated to include a common support and enforcement approach to the new provisions, with best practice advice for those implementing the legislation. It has been estimated the costs of updating the existing WLGA smoke-free guidance would be

¹⁵³ <http://www.wlga.gov.uk/regulatory-services-publications/enforcement-guidance-and-protocols-smoke-free-public-places/>

¹⁵⁴ <http://gov.wales/docs/phhs/publications/150203smokingneedtoknowen.pdf>

¹⁵⁵ www.wlga.gov.uk/download.php?id=1235&l=1

approximately the same as those associated with updating the Welsh Government guidance referred to above. This cost of approximately £1,500 would be incurred in 2017-18. Further updates to the guidance could be required and it is estimated that this would cost approximately the same, with these costs being incurred in 2020-21.

356. Training sessions may need to be held for enforcement officers who would implement and/or support others to implement the guidance. It is envisaged that environmental health professionals would run these sessions, though costs would be met by the Welsh Government. Each session would be approximately a half day and it is envisaged that two sessions would be held, one in North Wales and one in South Wales. These sessions would cost approximately £2,400, which covers room hire and refreshments for 35 people for each session (approximately £1,200)¹⁵⁶, and possible costs for external staff to develop and run part of the sessions (£1,200). This cost would be incurred in 2017-18.
357. The need for a dedicated telephone compliance line has been considered but has been deemed unnecessary. However, consideration will be given as to whether an existing line could be used for reporting. This has not been costed as part of this assessment.

Local authorities, schools and hospitals

358. Local authorities, schools and NHS Wales organisations – health boards and Velindre NHS Trust – as well as independent hospitals would need to allocate time to consider the legislation against their existing policies and read any related guidance. Organisations will vary in the amount of time they allocate to this. As with option two, it has been assumed that, on average, every local authority, school, health board and hospital in Wales would spend an hour on this work. Assuming a person at an equivalent cost to a local government enforcement officer, plus on-costs, undertakes this work then the total cost would be £49,100¹⁵⁷ in the first year (2017-18).
359. Similarly, when the guidance is updated every three years, personnel in local authorities, schools, health boards and hospitals may incur some time familiarising themselves with the revised guidance in order to identify and implement any changes required. As it is anticipated only limited changes would be made to the guidance, these costs would be expected to be no more than half those experienced in 2017-18. These costs are therefore estimated at £24,600, and would be incurred in 2020-21.
360. As the legislation would create an offence for failure to display appropriate signage, organisations could be issued with Fixed Penalty Notices (FPNs) of £200, reduced to £150 if paid within a designated

¹⁵⁶ Based on costs from similar training sessions organised by Welsh Government

¹⁵⁷ Based on local authority enforcement officer costs of £26.66 per hour; one hour's work in each of 22 LAs, 1662 schools, 7 LHBs, Velindre NHS Trust and 148 hospital sites

period. Those affected would be local authorities, schools, health boards and hospitals – those in charge of school grounds, hospital grounds and public playgrounds. Using data from the monitoring of the Smoke-free Premises etc. (Wales) Regulations 2007, 41 sites in total were issued with fixed penalty notices for failure to display appropriate signage between 2007 and 2011, none of which were referred for further prosecution. Thirty three of these FPNs were issued as a result of unusual activity in one local authority in October and November 2010. As the additional legislation under this option would cover fewer places, it is assumed there will be few if any FPNs issued for failure to display appropriate signage. At this stage, the best estimate of this cost is therefore £0.

Local authorities

361. There would be a cost to local authorities in implementing, complying with, and enforcing the new legislation.

(i) Implementation and compliance

Local authorities would need to review existing voluntary policies against the legislation, and against any updated guidance. This has been accounted for above.

362. There would also be costs to local authorities for enforcement officers to attend training sessions on the legislation. It is estimated that this would cost £9,300 in 2017-18.¹⁵⁸

363. Local authorities would be responsible for putting signage in prominent areas in all of the sites where smoking would become illegal. Whilst the precise signage requirements would be set out in regulations, a current estimation of costs is provided in this assessment. As most of the sites already have signage linked to voluntary bans, estimates of cost have been prepared on the basis that a limited number of signs would be required in addition to those already in use, to make it clear that smoking is now against the law on these sites.

364. There may also be costs to remove current signs if managers believe they are superfluous or confusing but this has not been included as it is not the intention to require the removal of existing signage, particularly as many of the signs have been designed by local children.

365. Local authorities or schools would be responsible for ensuring there is appropriate signage at local authority-maintained schools. Responsibility depends on the category of school and the delegated responsibilities. For the purposes of this calculation, the costs for signage for all maintained schools for whom the local authority is the employer (not

¹⁵⁸ Based on 5 hours at an hourly rate of £26.66 (to include a half-day training session plus travel time) for 70 enforcement officers to attend

voluntary aided or foundation schools) are included under the local authority costs. There are 1,595 maintained schools in Wales; of which 167 are voluntary aided or foundation schools. Therefore a figure of 1,428 schools has been used for these calculations.¹⁵⁹

366. It has been assumed each school will need at least one weatherproof sign, A4 minimum, at the main entrance and further signs at a minimum of two exits from the building to the grounds. These signs could be in the form of A4 stickers.
367. Commercial A4 weatherproof signs have been identified, costing £11.50 for rigid plastic signs or £28 for aluminium signs. It could be argued that some larger school grounds may need signs equivalent to those proposed for hospitals at vehicular entrances. As we are unable to identify the number of schools to which this may apply, and in light of the fact that schools are used by a school community for whom other methods of information sharing are available, minimum costs have been applied here.
368. Door stickers, if ordered Wales-wide, have been estimated at £1.20 per sign (based on costs of stickers used for the Food Hygiene (Wales) Regulations 2013). Individual commercial stickers may cost as much as £8.50 per sign, as identified for an existing voluntary ban.
369. Minimum costs for each school could therefore vary from £13.90 to £45; with the cost for 1,428 schools ranging from £19,800 to £64,300 in total in 2017-18. Costs to local authorities would vary depending on the number of maintained schools in the appropriate categories. This ranges from 23 to 119 schools, with the costs for the smallest authority being £320 to £1,030 and for the largest being £1,650 to £5,350.
370. Local authorities are responsible for ensuring there is appropriate signage at all local authority owned playgrounds in Wales. The exact number of playgrounds in Wales is not known but figures provided by local authorities have indicated that there are between 2,000 and 2,250 public playgrounds in Wales.
371. As with schools, most of the playground sites already have signage linked to current voluntary bans. Costs have therefore been estimated on the basis that only one additional sign would be required for each playground to make it clear that smoking is now against the law on these sites.
372. Using the same costs as identified for school weatherproof signs, it is estimated that the total cost for signs in playgrounds could range from

¹⁵⁹ <https://stats.wales.gov.wales/Catalogue/Education-and-Skills/Schools-and-Teachers/Schools-Census/Pupil-Level-Annual-School-Census/Schools/schools-by-localauthorityregion-governance>

£23,000 for rigid plastic signs in 2,000 playgrounds to £63,000 for aluminium signs in 2,250 playgrounds in 2017-18.

373. Information supplied by some local authorities suggests that vandalism and theft of signs at these sites is prevalent. Information from two local authorities suggests that approximately 25% of additional signs were purchased as spares to account for this. Costs for an additional 25% spare signs have been attributed to the second year of implementation only (2018-19) assuming that this would provide a stock of spare signs which could be used in subsequent years; the estimated cost would be between £5,800 and £15,800. Equivalent costs have not been included for hospital and school sites as these areas are not considered to be as isolated and therefore the likelihood of vandalism and theft is thought to be lower.

(ii) Enforcement

374. Funds of £2,000,000 per annum were made available to local authorities when the 2007 Regulations¹⁶⁰ came into force. As the smoking legislation is virtually self-enforcing, enforcement of the extended smoke-free requirements would be expected to be accommodated within this existing budget.
375. The revenue from FPNs would be retained by the local authority responsible for enforcement of the requirements where the offence was committed and used for relevant enforcement purposes.

Schools (voluntary aided, foundation and independent)

376. Schools would need to review existing voluntary policies against the legislation and against any updated guidance. This is accounted for above in paragraphs 358 and 359.
377. Voluntary aided schools, foundation schools and independent schools would be responsible for their own signage. There are 155 voluntary aided schools, 12 foundation and 67 independent schools in Wales. Whilst the precise signage requirements would be set out in regulations, estimated costs are provided in this assessment. It is estimated that each school would need to provide a minimum of one standard sign at the main entrance and door stickers on the main entrance doors (assuming that two would be required). The minimum cost per school would therefore be between £13.90 and £45, as for local authority schools, providing a total cost of between £3,300 and £10,500 in 2017-18.
378. Schools which provide residential accommodation may designate an area of the grounds in which smoking is to be permitted. Signage would

¹⁶⁰ The Smoke-free Premises etc. (Wales) Regulations 2007 (S.I. No. 2007/787 (W.68) came into force on 2 April 2007.

be required for these areas but has not been costed as it is not a legal requirement to designate such an area.

Health boards

379. There would be a cost to health boards in implementing and complying with the legislation.
380. Health boards would need to review existing voluntary policies against the new legislation and against any updated guidance. This is accounted for above in paragraphs 358 and 359.
381. Health boards would be responsible for putting signage in prominent areas in all of the sites where smoking would be prohibited. There are currently 15 major hospitals, 20 minor injuries units, 19 clinics and 66 other hospitals (on 63 sites) run by Welsh health boards and Velindre NHS Trust. This is a total of 120 hospitals on 117 sites in Wales¹⁶¹.
382. As with schools and playgrounds, hospitals already have voluntary bans in place and have signage indicating that smoking is not allowed on the grounds.
383. Whilst the precise signage requirements would be set out in regulations, costs have been estimated on the basis that the following level of signage would be required for each hospital to make it clear that smoking is now against the law on these sites. These figures are based on the details of existing signage provided by one health board.
- All hospitals – large weatherproof sign at main entrance;
 - For major hospitals, second large weatherproof sign for alternative entrance, two smaller weatherproof signs for pedestrian exits from car parks and 25 stickers for entrance doors and bus shelters;
 - For other hospitals, two door stickers.
384. Large weatherproof signs are estimated to cost £104. Smaller weatherproof signs for pedestrian exits are estimated to cost £72, and door stickers could cost between £1.20 and £8.50, as per costs included for schools.
385. The total cost for large weatherproof signs is £104 x 2 x 15 for major hospital sites (£3,120), plus £104 x 102 for other hospital sites (£10,608) totalling approximately £13,700.
386. The total cost for smaller weatherproof signs is £72 x 2 x 15 sites, totalling £2,160.
387. The minimum total cost for stickers supplied nationally at £1.20 per sticker is:

¹⁶¹ <http://www.wales.nhs.uk/ourservices/directory/Hospitals>

- For major hospitals £1.20 x 25 x 15 sites, totalling £450;
 - For other hospitals £1.20 x 2 x 105 sites, totalling £252.
388. The maximum cost for customised stickers at £8.50 per sticker is:
- For major hospitals £8.50 x 25 x 15 sites, totalling £3,188;
 - For other hospitals £8.50 x 2 x 105 sites, totalling £1,785.
389. The estimated total cost to health boards in Wales for providing a minimum level of signage therefore ranges from approximately £16,600 to £20,900 in 2017-18. There may also be costs to remove the current signs if managers believe they are superfluous or confusing but these have not been included as it is not the intention to require the removal of existing signage.
390. Hospitals may designate an area of the grounds in which smoking is to be permitted. Signage will be required for these areas but has not been costed as it would not be a legal requirement to designate such an area.
391. Some health board staff have reported tensions with neighbours due to people leaving the site to smoke as a result of voluntary policies. There may be a cost to health boards in monitoring, and dealing with such situations. This cost cannot be quantified.

Independent hospitals

392. Independent hospitals would need to review existing voluntary policies against the new legislation, and against any updated guidance. This is accounted for above in paragraphs 358 and 359.
393. The Welsh Independent Healthcare Association is made up of six acute hospital organisations, six mental health organisations (comprising 23 units) and two organisations providing learning disability services¹⁶². Whilst precise signage requirements would be set out in regulations, estimated costs are calculated on the basis of 31 sites, requiring a minimum of one large sign at the entrance and two door stickers. Costs would therefore range from £3,300 to £3,800 in 2017-18, depending on whether Wales-wide or customised door stickers are used.
394. Hospitals may designate an area of the grounds in which smoking is to be permitted. Signage would be required for these areas but costs have not been included as it would not be a legal requirement to designate such an area.

Public

395. There would be costs to any members of the public who receive FPNs in relation to the extended smoke-free offences. These would be aligned to FPN amounts for existing smoke-free offences. FPNs in respect of the

¹⁶² www.wiha.org.uk

offence of smoking in a smoke-free place are issued at £50 per FPN, discounted to £30 if paid within 15 days of the date of the notice. Based on the experience of the Health Act 2006 and the Smoke-free Regulations 2007, the following table sets out the maximum estimated cost of FPNs for the first five years following implementation of the extended smoke-free requirements, and assumes that all fines issued are paid at the maximum.

Table 7.2:

Year	FPNs paid	FPN amount (£) (rounded to nearest £100)
2017-18	62	3,100
2018-19	83	4,200
2019-20	79	4,000
2020-21	40	2,000
2021-22	40	2,000

396. Based on the experience from the Health Act 2006 and the Smoke-free Regulations 2007, the estimated costs from fines associated with prosecutions relating to the offence of smoking in a smoke-free place are set out in the table below. This offence is subject to a fine not exceeding level one on the standard scale and it has been assumed all fines issued are at the maximum level of £200.

Table 7.3:

Year	Successful prosecution	Total Amount of Fine (£)
2017-18	10	2,000
2018-19	9	1,800
2019-20	11	2,200
2020-21	3	600
2021-22	3	600

397. These figures are likely to be an over-estimate as fewer places would be covered by the extended premises than by the original smoke-free requirements. People are now well-accustomed to smoking being restricted in public places and these open places already have voluntary bans in place.

398. The FPNs and fines imposed on individuals are transfer payments, which are paid by the individual to the relevant authority. The net economic impact of these FPNs and fines is therefore zero.

399. Smoking prevalence is markedly higher among disadvantaged communities and evidence suggests that smokers in these communities

are also less likely to comply with legislation¹⁶³. This may result in FPN costs being disproportionately incurred by disadvantaged communities.

Courts

400. As discussed above, it is assumed that the new legislation would have a high level of compliance and supportive enforcement so that a low number of cases would be taken to court. A detailed costing framework has not yet been discussed between the Welsh Government and the Ministry of Justice so these costs are unknown at present.

Table 7.4: Summary of additional costs associated with option three

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government					
Communications campaign	48,500 – 68,500	0	0	0	0
Producing and reviewing guidance	3,000	0	0	3,000	0
Training costs	2,400	0	0	0	0
Total costs for Welsh Government	53,900 – 73,900	0	0	3,000	0
Local authorities, schools, LHBs and hospitals					
Reviewing existing voluntary policies against the legislation	49,100	0	0	24,600	0
Total costs for reviewing legislation	49,100	0	0	24,600	0
Local authorities					
Costs to attend training	9,300	0	0	0	0
Signage for schools	19,800 – 64,300	0	0	0	0
Signage for playgrounds	23,000 – 63,000	5,800 – 15,800	0	0	0
Total costs for local authorities	52,100 – 136,600	5,800 – 15,800	0	0	0
Schools (independent, voluntary controlled and foundation)					
Signage	3,300 – 10,500	0	0	0	0
Total costs for schools (independent, voluntary controlled and foundation)	3,300 – 10,500	0	0	0	0

¹⁶³ <https://dspace.stir.ac.uk/handle/1893/779?mode=full>

Health boards					
Signage for hospitals	16,600 – 20,900	0	0	0	0
Total costs for local health boards	16,600 – 20,900	0	0	0	0
Independent hospitals					
Signage	3,300 – 3,800	0	0	0	0
Total costs for independent hospitals	3,300 – 3,800	0	0	0	0
Public					
Fixed penalty notices	3,100	4,200	4,000	2,000	2,000
Fines	2,000	1,800	2,200	600	600
Total costs for the public	5,100	6,000	6,200	2,600	2,600
Total costs *	178,300 – 294,800	5,800 - 15,800	0	27,600	0

*The total excludes the value of FPNs and fines

Benefits

Health

401. Legislation under this option would work alongside other tobacco control measures to further de-normalise smoking and reduce the risks from exposure to second-hand smoke.
402. Indoor workplace smoking policies lead to reduced cigarette consumption among smokers. Such policies are also associated with higher rates of quit attempts and lower rates of relapse in people who attempt to quit smoking because they reduce cues for smoking^{164,165}. It has been suggested that outdoor restrictions may have similar benefits¹⁶⁶.
403. A major difference between indoor and outdoor tobacco smoke is that levels of outdoor tobacco smoke drop almost immediately to background levels after the cigarette is extinguished, whereas indoor levels persist in the air for several hours¹⁶⁷. However, in outdoor settings where there are several people smoking, significant levels can persist as long as smoking continues. Atmospheric conditions, including wind direction, wind speed and atmospheric stability can also modify outdoor second-hand smoke levels. Research suggests that in outdoor settings, the harm from second-hand smoke begins to dissipate from a single cigarette after two metres,

¹⁶⁴ <http://tobaccocontrol.bmj.com/content/8/3/261>

¹⁶⁵ <http://www.annualreviews.org/doi/abs/10.1146/annurev.publhealth.23.100901.140551>

¹⁶⁶ <http://www.ncbi.nlm.nih.gov/pubmed/20576460>

¹⁶⁷ <http://www.ncbi.nlm.nih.gov/pubmed/17518219>

and continues to fall and approach zero at distances greater than this, particularly beyond five metres.

404. One review of research clearly indicates the potential for high second-hand smoke exposure in some outdoor settings and indoor locations adjacent to outdoor smoking areas. It shows high smoker density; highly-enclosed outdoor areas; low wind conditions and close proximity to smokers generate higher outdoor second-hand smoke concentrations¹⁶⁸.
405. One of the studies considered in the review concluded that smoke levels do not approach background levels for fine particles or carcinogens until about seven metres or 23 feet from the source, which is likely to be the smoke from no more than one or two smokers.¹⁶⁹ Greater numbers of smokers in the area could lead to higher concentrations.
406. Given these findings, the reduced scope of exposure to second-hand smoke may result in improved public health, by promoting smoking cessation and limiting exposure to tobacco smoke.
407. Another potential benefit is that the legislation may result in a small reduction of the perceived prevalence of adult smoking among children, and the idea that outdoor smoking bans in certain areas are normal.

Local authorities, schools, health boards and hospitals

408. The enforcement of smoking bans in school grounds, hospital grounds and public playgrounds should be easier as the bans would be backed by legislation.
409. There may also be less litter in the area due to the absence of smoking-related litter.

Health boards

410. The aim of the legislation would be for hospital grounds to become completely smoke-free, thus providing smoke-free environments for all staff, patients, visitors and contractors. If this is achieved, it will support health boards in becoming exemplars in being smoke-free sites.
411. As health boards have been incurring costs for enforcement, there would also be benefits as smoke-free grounds become easier to enforce and eventually become self-enforcing, thus reducing monitoring and enforcement costs. One health board has estimated a cost of £15,500 per annum¹⁷⁰ for security staff to enforce its voluntary ban at each major

¹⁶⁸ Sureda, X., Fernández, E., López, MJ. And Nebot, M. (2013) Second-hand Tobacco Smoke Exposure in Open and Semi-Open Settings: A Systematic Review, *Environmental Health Perspectives*. Vol. 121 Issue 7, p. 766-773. <http://ehp.niehs.nih.gov/1205806/>

¹⁶⁹ Repace J. Measurements of outdoor air pollution from second-hand smoke on the UMBC campus 2005. <http://www.repace.com/pdf/outdoorair.pdf>

¹⁷⁰ Based on 4.5 hours per day at £9.41 per hour

hospital site, with a second suggesting an average of £20,000 per annum for a dedicated officer¹⁷¹. With 14 major hospital sites in Wales, at an average cost for enforcement of £17,700, this gives an all-Wales cost of £247,800 per annum. Savings for enforcement at major hospital sites could therefore range from £0 - £247,800 per annum (ranging from no reduction in the need for enforcement officers, to no further need for enforcement). It has not been possible to calculate costs for smaller hospital sites.

412. Independent hospitals may have the benefit of their grounds becoming smoke-free if they are not already so. This may bring with it the positive image of being a health conscious and exemplar independent organisation in being smoke-free.

Summary and preferred option

413. Option one would maintain the existing situation and would not contribute to the ongoing de-normalisation of smoking in society or promote behaviour change to smoking cessation.
414. Option two would support the further de-normalisation of smoking and could be used to promote behaviour change. However it would not support the enforcement of the current voluntary bans. The publicity campaign outlined in option two could prove to be a costly option with no guarantee of the anticipated change in perception or behaviour.
415. Option three is the preferred option as it would be the most likely to support the further de-normalisation of smoking and contribute to behaviour change. It would also assist with the identified difficulties of enforcing existing voluntary bans.
416. It is estimated that, on average, preventing the uptake of smoking results in one year life gain per individual.¹⁷² This life gain is valued at £60,000 per person.¹⁷³ Applying these figures, option three would therefore need to prevent a minimum of 3.5 children in Wales from taking up tobacco smoking over the five-year period and a maximum of 5.6 for this measure to be cost neutral.

¹⁷¹ Based on 1.5fte Band 2, NHS Agenda for Change posts to cover 2 sites

¹⁷² Age of Sale for Nicotine Inhaling Products: Impact Assessment.

<https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

¹⁷³ A value of £60,000 is assigned to a Quality Adjusted Life Year. Where Quality Adjusted Life Year estimates are not readily available, and it is appropriate this value is used for Life Years. This is consistent with similar valuation of policies that mitigate mortality or morbidity risk by other Government departments, based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes.

Register of retailers of tobacco and nicotine products (Part 2, Chapter 2)

Options

417. Four options have been considered:

- Option one – Do nothing;
- Option two – Introduce a voluntary register of retailers who sell tobacco or nicotine products;
- Option three – Introduce a national register on which retailers have to register in order to sell tobacco and/or nicotine products, combined with an enhanced Restricted Premises Order (RPO) regime. This is the preferred option;
- Option four – Introduce a positive licensing scheme for retailers who sell tobacco and/or nicotine products.

Option one – Do nothing

Description

418. There would be no changes to current legislation under this option. Local trading standards officers would continue to monitor legislation designed to reduce children and young people's access to tobacco and nicotine products. In doing so they would use only local intelligence or data sources, without access to a national register containing details on retailers selling these products.

Costs

Welsh Government

419. There would be no new costs to the Welsh Government from this option. £2m was previously transferred into the local government revenue support grant (RSG) to support enforcement activities in relation to tobacco, as a result of the Smoke-free Premises etc. (Wales) Regulations 2007.¹⁷⁴ This funding would continue to be part of the RSG for future years.

Local authorities

420. There would be no additional costs to local authorities, including their trading standards departments, from this option. The existing funding would continue to be provided as part of the RSG to support enforcement activities.

Retailers

¹⁷⁴ The Smoke-free Premises etc. (Wales) Regulations 2007 (S.I. No. 2007/787 (W.68) came into force on 2 April 2007.

421. This option would not incur any new costs to retailers. There could still be some costs from fines relating to failing to adhere to existing legislation, but those costs would already exist. In 2013-14 a total of £1,500 worth of fines were paid by retailers in relation to underage sales of tobacco.

Benefits

422. This option maintains the current policy position and as such there would be no additional benefits associated with this option.

Option two – Introduce a voluntary register for retailers who sell tobacco or nicotine products

Description

423. This option would involve developing a national voluntary register of retailers who sell tobacco products and/or nicotine products. This could be hosted by a lead local authority or other body. Retailers who sell these products could choose to register their premises. Trading standards officers would have access to the data, which would provide some detail on retailers in their area who sell these products. As the register would be voluntary, there would be no registration fee for retailers.

Costs

Welsh Government

424. There would be an initial cost in developing the register. It would be developed and hosted online, with an online application form for retailers. The development of the register could be procured by the Welsh Government or be undertaken through a lead local authority. Based on information from Scotland (where a statutory register has been put in place), it is estimated that the costs of developing the register would be approximately £26,900. These costs would be split between 2017-18 (£21,500) and 2018-19 (£5,400). An alternative paper application form would also be developed for retailers who may not have access to the online version and this would be covered within these developmental costs.
425. In addition, some staff time would be required to procure and manage the contract throughout its development. It is estimated that this would take approximately three weeks FTE of a higher executive officer's time, costing approximately £2,900.¹⁷⁵ These costs would be split between 2017-18 (£2,200) and 2018-19 (£700).

¹⁷⁵ Based on Welsh Government staff planning costs

426. In addition to the developmental costs there would be ongoing ICT costs for the main database. These would cover, for example, back-ups to avoid data losses, server costs and costs to resolve technical issues. Based on information from Scotland it is anticipated that these annual costs would be approximately £10,000. This annual cost would be incurred from 2019-20 onwards.
427. To support the launch of a voluntary register there would also need to be some publicity during the initial period to raise awareness and encourage retailers to register. It is expected that the majority of this publicity would be generated by news stories in the press, as well as stakeholder networks (for example trading standards, the third sector and groups representing the retail sector). It is anticipated that this would require approximately six weeks FTE of a higher executive officer's time, equating to approximately £5,900¹⁷⁶. These costs would be split between 2017-18 (£3,000) and 2018-19 (£2,900).
428. There would also need to be some staff resource allocated to manage and monitor the register, as well as to log any registrations from retailers which are received in paper format. Due to the voluntary nature of the register it is difficult to judge how many of the estimated 8,225¹⁷⁷ retailers of tobacco and nicotine products would register and therefore how much staff time this would take. Given the low percentage of uptake of the Landlords Accreditation Scheme¹⁷⁸ (0.03%), a voluntary registration scheme, it is estimated that a 1.0 FTE higher executive officer post would be needed to cover the management of the register, as this officer would also have a role in encouraging retailers to register in order to maximise the level of uptake. It is expected that due to the voluntary nature of the register more time would be needed to encourage retailers to join, compared to a statutory register. The cost of the post would be approximately £43,200 in the first year (2018-19). In addition, there would be some staff support costs to cover the administration of the register. It is anticipated that this would take approximately 0.1 FTE team support officer per annum, equating to approximately £2,800. Based on these assumptions it is anticipated the total staff costs would equate to approximately £46,000 for the first 12 months (2018-19).
429. It is likely that the time needed to manage and administer the register would decrease over time. It is estimated a year after the launch, a 0.2 FTE higher executive officer would be needed to manage the register and continue to work with retailers to encourage further registrations. This would equate to approximately £8,600 annually. There would also be a

¹⁷⁶ Based on Welsh Government staff planning costs

¹⁷⁷ This figure is based on approximately 6,525 tobacco retailers (adjusted from Scottish data provided in the Enhanced Tobacco Sales Enforcement Programme Report 2010-14 produced by Trading Standards in Scotland) and an estimated 1,700 retailers of nicotine products (no reliable data available)

¹⁷⁸ Housing (Wales) Bill Explanatory Memorandum. Welsh Government November 2013
[http://www.assembly.wales/laid%20documents/pri-ld9784-em-r%20-%20explanatory%20memorandum%20housing%20\(wales\)%20bill/pri-ld9784-em-r-e.pdf](http://www.assembly.wales/laid%20documents/pri-ld9784-em-r%20-%20explanatory%20memorandum%20housing%20(wales)%20bill/pri-ld9784-em-r-e.pdf)

need for continued administrative support, although this would be likely to reduce to a 0.05 FTE team support, equating to an annual cost of £1,400. It is likely that most retailers would have joined the register during the initial period, with only a small percentage subsequently joining. This would reduce the annual staff costs to approximately £10,000 from 2019-20.

430. The staffing costs outlined above would be met by the Welsh Government. Alternatively the management and administration of the register could be outsourced (for example to a local authority or other body to run on behalf of the Welsh Government) with funding provided by the Welsh Government to cover the associated costs.

Local authorities

431. There would be no additional costs to local authorities or trading standards departments from this option. Existing funding for enforcement activities and providing guidance and information for retailers would continue to be provided through the local government RSG. As the register would be voluntary there would be no new offences linked to it and therefore there would be no additional enforcement costs. As indicated above, if a local authority runs the voluntary national register, the Welsh Government would provide funding on a full cost-recovery basis.

Retailers

432. This option would not involve any registration costs for retailers, apart from the staff time which it would take to consider registration and undertake the task of registering. The intention would be to keep the registration process as simple as possible, taking a similar approach to that adopted in Scotland¹⁷⁹.
433. Retailers may incur some costs from staff time in considering if they wish to join the voluntary register. Based on an hourly rate for retailers of tobacco/nicotine products of £12.57^{180,181}, an estimate of approximately 3,290 separate businesses covering the estimated 8,225 retailers of tobacco and nicotine products in Wales (it is assumed that a decision would be made centrally by a business, not individually within each outlet), and an assumption that the above actions would take approximately one hour, costs to retailers would amount to approximately £41,400 in 2018-19. The actual cost could vary depending on how long retailers spend on considering whether or not to join the register.

¹⁷⁹ Scottish Tobacco Retailers Register <http://www.tobaccoregisterscotland.org/> accessed Jan 2015.

¹⁸⁰ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Wales, Managers and Directors in Wholesale and retail). <http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

¹⁸¹ Hourly rates have been increased by a factor of 30% to incorporate on costs.

434. It is estimated the staff time involved in completing an application for the register would be approximately five to 10 minutes to register one premise and an additional one to two minutes for each additional premise. Staff costs have been estimated at the upper end of this range using the same assumptions as above.
435. There are an estimated 3,290 businesses selling tobacco and nicotine products in Wales. It is anticipated the completion of applications for these businesses, taking 10 minutes each, would cost approximately £6,900 in staff time. Applications taking two minutes each would then be required for the remaining 4,935 retailers, at a cost of approximately £2,100. The total cost to retailers of completing applications would therefore be £9,000.
436. As this option would involve a voluntary register, it is unlikely that all retailers would register. If a similar percentage of retailers registered as for the Landlords Accreditation Wales scheme, then only 3% of tobacco and nicotine retail businesses would register over a four-year period, equating to approximately 99 retail businesses. This would reduce the total cost of retailers registering to approximately £300¹⁸².
437. Every effort would be made by the Welsh Government, local authorities and stakeholders (such as retail representative groups) to encourage retailers to register. As such it is anticipated that the majority of the retailers would register in the first two years. The costs of registration for 2020-21 onwards are likely to be negligible (approximately £25 per annum) as it is anticipated very few retailers will be registering from this point.

Table 7.5 – Summary of additional costs associated with option two

	2017/18 £	2018/19 £	2019/20 £	2020/21 £	2021/22 £
Welsh Government					
Development of the register	23,700	6,100	0	0	0
Ongoing ICT costs	0	0	10,000	10,000	10,000
Communications and publicity	3,000	2,900	0	0	0
Ongoing staff costs	0	46,000	10,000	10,000	10,000
Total cost to Welsh Government	26,700	55,000	20,000	20,000	20,000
Retailers					

¹⁸² Housing (Wales) Bill, November 2013, Welsh Government. 3% of landlords registered under the Landlords Accreditation Wales Scheme registered over a five year period.

Staff costs to undertake registrations	0	100	100	*	*
Staff costs to consider joining the voluntary register	0	41,400	0	0	0
Total cost to retailers	0	41,500	100	*	*
Total cost	26,700	96,500	20,100	20,000	20,000

*Less than £100

Benefits

438. Implementing a voluntary register for retailers of tobacco and/or nicotine products would provide local authorities with additional intelligence on the number of retailers in their area who sell these products. This additional intelligence would support enforcement activities. However the benefits would vary according to how many retailers chose to register. If a similar percentage of retailers registered as with landlords who joined the Landlord Accreditation Wales Scheme (0.03%), then the benefit of the intelligence gathered would be very low. In addition, it is plausible to assume that a voluntary register may become out of date as there would be no incentive for retailers who do register to report any subsequent changes of details.
439. The main benefit that could be offered to retailers would be that by being included on a national voluntary register, trading standards officers would be able to circulate information and/or guidance to them which they may otherwise miss.

Option three – Introduce a national register on which retailers have to register in order to sell tobacco and/or nicotine products, combined with an enhanced Restricted Premises Order (RPO) regime.

Description

440. This option would involve the development of a national register of retailers who sell tobacco products and/or nicotine products. This could be hosted by a lead local authority or other body, who would perform the role of the registration authority. Retailers would have to register if they sell either of these products and it would be an offence to sell them if they were unregistered. There would be a fee for retailers to register, which would be set in regulations following a process of consultation and would

be fully compliant with the Hemming¹⁸³ judgment. For the purposes of this assessment this has been estimated at £30 for the first premise and £10 for each additional premise. There would not be a requirement for retailers to periodically re-register but retailers would instead be required to report any relevant changes to their details to the registration authority.

441. In addition to the creation of the register, additional tobacco offences would be added to the current list of offences which can trigger a local authority applying for a Restricted Premises Order (RPO). This would be intended to create a more effective negative licensing scheme for Wales, which would reinforce the importance of retailers complying with relevant legislation. Negative licensing means that all retailers have the ability to sell tobacco and nicotine products unless they are serving an RPO, at which point this is temporarily revoked. Once the RPO has expired a retailer could once again sell these products.

Costs

Welsh Government

442. There would be an initial cost for developing the register. These would be in line with those outlined under option two, which is £23,700 in 2017-18 and £6,100 in 2018-19.
443. To support the launch of the register there would also need to be some publicity to raise awareness and encourage retailers to register. It is expected that the majority of this publicity would be generated by news stories through the press as well as stakeholder networks (for example trading standards, the third sector and groups representing the retail sector). This approach has been used for other tobacco legislation such as the display ban. It is expected that the costs for publicity would be similar to those outlined under option two – £3,000 in 2017-18 and £2,900 in 2018-19.

Local authorities

444. There would be a need for some staff resource to manage and monitor the register on an ongoing basis. It is anticipated that a 0.5 FTE local authority enforcement officer could undertake this function for all local authorities across Wales for the first six months, decreasing to 0.05 FTE thereafter due to the likelihood of a high level of initial enquiries. This would equate to approximately £13,300 in the first year and then £2,400 annually.¹⁸⁴ In addition to managing the register there would be a need for administrative support to log any paper registrations and monitor the register. It is anticipated that this would require a 0.5 FTE administrator

¹⁸³ C-316/15 Judgment of the Court (Third Chamber) of 16 November 2016 – Timothy Martin Hemming and Others v Westminster City Council – Request for a preliminary ruling from the Supreme Court of the United Kingdom

¹⁸⁴ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

for the initial six months, which would subsequently decrease to 0.1 FTE. This is because it is likely that a greater amount of administrative support would be needed for the initial six months; this is when the bulk of the registration applications would be expected. It is therefore anticipated that this support would cost approximately £7,800 for the first 12 months following the national register going live, decreasing to approximately £2,600 annually. The total local authority staff costs for managing and monitoring the register are therefore £21,100 in 2018-19 and £5,000 per annum in subsequent years.

445. There would be some ICT costs associated with maintaining the register (for example creating back-ups, server costs), and these would be identical to those outlined under option two (£10,000 per annum from 2019-20). As a local authority would potentially be designated as the leading registration authority, these costs would fall to the local authority with this responsibility. However, costs would be covered by a combination of the registration fees raised from retailers, to cover the cost of processing the application, and funding provided by the Welsh Government.
446. Guidance for retailers would also need to be produced. It is anticipated that this would be developed by trading standards representatives, and would take approximately one month of a FTE local authority enforcement officer's time (based on 6,000 words). This would equate to £3,800. In addition to developing the guidance there would be associated translation and design costs. It is anticipated that design and typesetting would cost approximately £400. It is estimated that translation and proofreading would cost approximately £600.¹⁸⁵ The total cost for the development, design and translation of guidance would therefore be £4,800. This cost will be incurred in 2017-18.
447. The guidance would be updated every three years. It is anticipated that this would require approximately one week of a FTE local authority enforcement officer, which would equate to approximately £1,000. Design and translation costs would amount to half the original costs, a total of £500. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,500, incurred every three years. The first review would be held in 2020-21.
448. Training sessions would need to be held during 2018-19 for local authority enforcement officers and it is envisaged these would be run by trading standards officers. Each session would be approximately a half day and it is envisaged that two sessions would be held – one in North Wales and one in South Wales. These sessions are estimated to cost approximately £1,200, based on room hire and refreshments for 35 people for each session. There would also be some staff time involved in developing and running the training, which it is anticipated would equate

¹⁸⁵ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

to approximately two weeks of a FTE local authority enforcement officer's time, costing approximately £1,800 (the cost of developing the training is assumed to be incurred in 2017-18). In addition to the costs for running the sessions, there would be costs to local authorities for enforcement officers to attend. It is estimated that this would cost approximately £9,300¹⁸⁶. The training cost incurred in 2018-19 is therefore estimated to be £10,500.

449. While local authorities have funding through the RSG to cover enforcing existing legislation, such as legislation on the display of tobacco products at point of sale and age of sale legislation, they do not receive funding to cover any of the offences linked to the creation of the retailers' register. In Scotland, in 2010-11 it was estimated there were 19,678 tobacco retailers and, following the launch of the Scottish Tobacco Retail Register, this number decreased to 11,114 in 2012-13. While a number of factors could have contributed to this reduction, it is possible that some retailers have not registered. A similar situation could therefore happen in Wales. This would mean there would be a requirement for trading standards officers to investigate reports of unregistered retailers selling tobacco products and/or nicotine inhaling devices (NIDs). In Scotland, seven retailers were issued with FPNs for carrying on a tobacco business while unregistered¹⁸⁷.

450. The inclusion of additional offences which could trigger an RPO would also have an impact on staffing resources for taking retailers to court for an RPO. It is expected that there would be a minimal number of cases going to court.

Retailers

451. Retailers may incur some costs from time spent familiarising themselves with the guidance and legislation, in order to ensure they comply with the changes. Based on the hourly rate of retailers who sell tobacco (£12.57^{188,189}), the estimation of there being 3,290 separate businesses covering the estimated 8,225 retailers of tobacco products and nicotine products in Wales and that the above actions would take two hours, costs to retailers would amount to approximately £82,700 in 2018-19.

452. While the intention would be to keep the registration process as simple as possible, similar to the process adopted in Scotland, there would be

¹⁸⁶ Based on 5 hours at an hourly rate of £26.66 for a Local Government Enforcement Officer (to include the half day training session and travel time) for 70 enforcement officers to attend.

¹⁸⁷ Enhanced Tobacco Sales Enforcement Programme Report 2010-14. Trading Standards in Scotland

¹⁸⁸ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Wales, Managers and Directors in Wholesale and retail).
<http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupatiopn4digitoc2010ashtable15>

¹⁸⁹ Hourly rates have been increased by a factor of 30% to incorporate on costs.

some degree of staff time involved in completing an application. While the precise form and content of an application will be set out in regulations, for the purposes of this assessment it is expected that this would take approximately five to 10 minutes to register the first premise and an additional one to two minutes for each additional premise. These costs would be similar to those outlined under option two. However, as the register proposed under this option would be mandatory the costs have been calculated on all the estimated 8,225 retailers of tobacco and nicotine products registering. It is estimated that this would cost the retail sector approximately £9,000 in 2018-19 (this is based on the upper estimate of the time required to register in option two).

453. In addition to the staff time involved in following the registration process, there would be a registration fee for retailers. The registration fee will be set in regulations following a process of consultation, but for the purpose of this assessment it is estimated that this would be set at £30 for the first premise, and £10 per additional premise. It was estimated under option two that there are 8,225 retailers of tobacco and nicotine products in Wales, made up of 3,290 businesses. Applying these estimates would mean it would cost approximately £148,100 for all retailers who sell tobacco products and/or nicotine products to register. As retailers would have six months to register following the register going live it is expected that these costs would fall in 2018-19. While the registration fee represents a cost to retailers, it is a source of revenue for the lead authority which would be used to offset the costs of processing the application.
454. Following introduction of the register, existing retailers would have an initial six months in which to register. There would be no re-registration fee or fee for amending a retailer's details on the register. There would, however, be fees for a registered business to add additional premises, or for a new application to the register. Data are not available on how many new retailers would register each year, however it is expected that the number will be minimal. In Scotland the total number of retailers on the tobacco register has decreased year on year¹⁹⁰.
455. Retailers may also incur costs from the new offences which would be linked to the register, as well as existing offences linked to other relevant legislation. The majority of the costs linked to the register would be in the form of FPNs and therefore would not result in additional legal costs unless a retailer chooses not to or fails to pay the FPN. Based on Scottish data¹⁹¹, it is estimated that approximately seven FPNs (£1,100) for carrying on a tobacco business while unregistered and two fines (£10,000) (for non-payment of a FPN) would be issued per annum. It is estimated that this could amount to a total cost to retailers of approximately £11,100. However, it is likely that the actual costs would be

¹⁹⁰ Enhanced Tobacco Sales Enforcement Programme Report 2010-14. Trading Standards in Scotland

¹⁹¹ Enhanced Tobacco Sales Enforcement Programme Report 2010-14. Trading Standards in Scotland

less, as there would be a discount for early payment of FPNs and the fines actually issued may also be lower.

456. Due to linking other tobacco related offences to the RPO process, there could be an increase in the number of retailers who are issued with an RPO. This would prevent them from either selling tobacco or nicotine products, depending on which RPO is issued. This would have an effect on their potential income, not only from the sales of these products but also there would be a risk of losing custom of other products to competitors. Based on Scottish data¹⁹² it is estimated that approximately two applications for an RPO would be processed per annum.

457. While these are additional costs that retailers in England would not incur, there is unlikely to be an impact on competitiveness due to the scale of the cost imposed on each business and the activity involved.

Courts

458. Based on the number of cases referred for prosecution in Scotland from offences relating to the retail register it is estimated that approximately four cases would be referred to the courts in Wales. As such there would only be a limited impact on the courts in Wales. A detailed costing framework has not yet been discussed between the Welsh Government and the Ministry of Justice and so these costs are unknown at present.

Table 7.6: – Summary of additional costs associated with option three

	2017/18 £	2018/19 £	2019/20 £	2020/21 £	2021/22 £
Welsh Government costs					
Development of the register (including staff costs).	23,700	6,100	0	0	0
Communications and publicity	3,000	2,900	0	0	0
Total cost to Welsh Government	26,700	9,000	0	0	0
Local authorities					
Ongoing maintenance and administration	0	0	10,000	10,000	10,000
Staff costs	0	21,100	5,000	5,000	5,000
Costs to produce guidance	4,800	0	0	1,500	0
Training costs	1,800	10,500	0	0	0

¹⁹² Enhanced Tobacco Sales Enforcement Programme Report 2010-14. Trading Standards in Scotland

Total cost to local authorities	6,600	31,600	15,000	16,500	15,000
Retailers					
Staff costs for familiarisation the new legislation	0	82,700	0	0	0
Staff costs to make registrations	0	9,000	0	0	0
Registration fees	0	148,100	0	0	0
Costs from FPNs or fines ¹⁹³	0	11,100	11,100	11,100	11,100
Total cost to retailers	0	250,900	11,100	11,100	11,100
Total cost	33,300	291,500	26,100	27,600	26,100
Fee revenue to Local Authorities	0	148,100	0	0	0
Net cost	33,300	143,400	26,100	27,600	26,100

459. Registration fees incurred by retailers have not been included in the net cost as they are used to off-set local authority costs for processing applications. These costs are based on the upper estimates of £30 to register, including one premises, and £10 per additional premises. The registration fees will be consulted on prior to regulations being made and will only cover the cost for processing a retailer's application to the register.

Benefits

460. The main benefit of compelling retailers to register would be the production of a comprehensive list of retailers which sell tobacco or nicotine products. This would assist trading standards officers in their enforcement activities, for example in tackling underage sales of tobacco.

461. By having access to a comprehensive list of all retailers who sell tobacco and/or nicotine products, trading standards officers and local authorities would be able to target advice, guidance and campaigns relevant to these industries more effectively, ensuring that all registered retailers receive this information.

462. While it is unlikely that a retailers' register supported by an enhanced RPO regime would have the same level of impact as a positive licensing scheme, researchers have concluded the removal of licences for

¹⁹³ Only new offences linked to the register (or the chance of more RPOs based on the changes proposed by the Public Health (Wales) Bill) have been included. The numbers have been based on offences in Scotland.

infringements of the law as one of the strategies most likely to successfully reduce under-age sales.¹⁹⁴

463. Provided there is adequate enforcement of the legislation, the enhanced RPO should act as a powerful deterrent as retailers would be concerned about losing an important source of revenue. There would also be recognition that failure to adhere to tobacco and nicotine products legislation could result in loss of a retailer's ability to sell these products. This could bring with it the loss of revenue in other areas if customers choose to go elsewhere to make purchases.
464. It is estimated that, on average, preventing the uptake of smoking results in an average one-year life gain per individual.¹⁹⁵ This life gain is valued at £60,000 per person.¹⁹⁶ The net cost of option three over the initial five-year period is £256,300; therefore in order to be cost neutral approximately four young people would have to not start smoking.

Option four – Introduce a positive licensing scheme for retailers who sell tobacco and/or nicotine products

Description

465. This option would involve developing a tobacco and nicotine products licensing scheme, which would mean that, unlike option three, retailers would need to obtain a licence before being able to sell tobacco and/or nicotine products. It is anticipated a lead authority would manage the licensing scheme and maintain the database but officers based within each local authority area would review applications for a licence or a licence renewal. In addition, these local officers would be responsible for enforcing the licensing scheme. Retailers would have to evidence how they meet minimum criteria in order to be given a licence and this evidence would need to be reviewed prior to a licence being granted. It would be an offence to sell tobacco and/or nicotine products without a licence. The licence would only be valid for one year, which would mean retailers would have to apply for a licence renewal each year, similar to an alcohol licence which requires an annual renewal.

¹⁹⁴ Licensing of Tobacco Retailers and Wholesalers. Published by The Allen Consulting Group. December 2002

¹⁹⁵ Age of Sale for Nicotine Inhaling Products: Impact Assessment.

<https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

¹⁹⁶ A value of £60,000 is assigned to a Quality Adjusted Life Year. Where Quality Adjusted Life Year estimates are not readily available, and it is appropriate this value is used for Life Years. This is consistent with similar valuation of policies that mitigate mortality or morbidity risk by other Government departments, based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes.

466. Under this option existing retailers would need to apply for a licence in order to continue to sell tobacco and/or nicotine products, and new retailers wishing to sell these products would also need to apply for a licence. The intention would be to include a transitional period from the commencement of the provisions for existing retailers to apply for a licence. There would be likely to be a transitional period of six months but the appropriateness of this would be first discussed with the stakeholders affected.

Costs

Welsh Government

467. There would be an initial cost in developing the ICT element of the licence system. This would include a database of existing tobacco retailers who have been awarded a licence, as well as the provision for online applications and payments. It is anticipated that this database would be similar to that used for the register in options two and three and therefore the costs would be similar to those options. This would equate to costs of £23,700 in 2017-18 and £6,100 in 2018-19 to cover the development of the database and associated staff costs.

468. It would be necessary to alert retailers to the new statutory obligations and what would be required of them. This would be achieved through press and media articles, existing local authority communication channels (for example website, trading standards networks) and through stakeholders. This approach has been used for other tobacco legislation such as the display ban. These costs would be similar to the equivalent costs outlined under option three.

Local authorities

469. The costs to local authorities would be higher than in options two and three due to the increased requirements under a licensing system. Retailers could apply for a licence either by post or online and local authorities would be responsible for checking the eligibility of the retailer and issuing a licence. It is anticipated that these costs would be mitigated by the fees paid by retailers to obtain a licence.

470. It is estimated that 22 FTE local authority enforcement officers would be required to manage a licence scheme in 2018-19. This estimation is based on the time it would take to support retailers in completing an application for a licence, reviewing applications for a licence or licence renewal, enforcing offences relating to tobacco/nicotine products licences and reviewing appeals. Based on this estimation it is anticipated this would cost a total of £1,029,800 in the first year.¹⁹⁷ There would be an ongoing requirement for 22 0.75 FTE local authority enforcement officers

¹⁹⁷ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

to manage the scheme. This would amount to an annual cost of £772,300. In addition, the scheme would require a FTE administrator to support the scheme, including monitoring the database, processing paper applications on to the electronic database, issuing licences and providing a first point of contact for retailers. This post would be based with the local authority with lead responsibility for managing the scheme and would cover all of Wales. It is anticipated that this would cost approximately £26,000 annually.

471. ICT costs of £10,000 per annum, incurred under options two and three for the maintenance of the register, would be repeated under this option.
472. Guidance would also need to be produced to support a new licence scheme. Whilst a licensing scheme would be more complex for local authorities, it is anticipated that the guidance for retailers would be 6,000 words or less. As such it is envisaged that these costs would be the same as those outlined under option three.
473. Training sessions for local authority enforcement officers would also need to be held during 2018-19 to support the scheme and would be likely to be led by trading standards officers. It is anticipated that the training would take longer than option three due to the extra complexity that a licensing scheme creates. It is envisaged that each session would take approximately a day (lasting approximately six hours including breaks), with one being held in North Wales and one in South Wales. These sessions would cost approximately £1,900, based on room hire and refreshments for 35 people for each session. There would also be some staff time involved in developing and running the training and it is anticipated that this would equate to approximately three weeks of a FTE local authority enforcement officer's time, costing approximately £2,600¹⁹⁸, incurred in 2017-18. In addition to the costs for running the sessions, there would be costs to local authorities for enforcement officers to attend. It is estimated that this would cost approximately £14,900¹⁹⁹.

Retailers

474. Retailers may incur some costs from time spent to familiarise themselves with the new licence scheme to ensure they comply with it. As it is likely that this may be more complex than existing practices (where an application for a licence is not required in order to sell tobacco products and/or nicotine products), it is estimated that this could take retailers approximately three hours to fully familiarise themselves with the changes. Based on an hourly rate of £12.57²⁰⁰ and the estimate of 8,225

¹⁹⁸ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

¹⁹⁹ Based on 8 hours at an hourly rate of £26.66 (to include the training session and travel time) for 70 enforcement officers to attend.

²⁰⁰ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Wales, Managers and Directors in retail and wholesale).

retailers of tobacco products and nicotine products in Wales which would need to apply for a licence, costs to retailers would amount to approximately £310,200 in 2018-19.

475. It is estimated the cost of a new licence would be approximately £130. There would then be an annual charge of £90 per premise. This is based on the cost to local authorities to administer the scheme. It is anticipated that the cost to retailers in licence fees would be £1,069,200 in the initial year (2018-19) to obtain new licences and an annual cost of £781,400 for the annual renewal fees. This is based on an estimated 8,225 retailers across Wales who sell either tobacco or nicotine products. In addition to these costs, any new retailers from 2018-19 who wish to sell tobacco and/or nicotine products would need to obtain a licence before they could sell these products. There are no data on how many new retailers there are per year selling these products, however it is expected that the number of new retailers each year would be low. As with option three, these fees represent a source of revenue to local authorities and would be used to offset the administrative costs associated with the scheme.
476. In addition to the fee there would also be costs in relation to the staff time taken to complete an application and provide the required supporting evidence. It is anticipated that it would take approximately two hours to complete an application for a new licence and approximately one hour for an application for a licence renewal. Assuming a total of 8,225 retailers of tobacco and nicotine products and an hourly pay rate of £12.57 per hour^{201,202}, this would amount to £206,800 in initial staff costs for all retailers of tobacco and nicotine products and £103,400 per annum from 2019-20 for licence renewals.
477. Finally, there would be costs to retailers in relation to enforcement actions linked to the licensing scheme, such as fines or loss of sales from having a licence revoked. Where a retailer has its licence revoked, therefore preventing them from selling tobacco and/or nicotine products, regular customers who purchase these products would take their custom to a competitor who is able to sell these products and, as a result, could also lose trade of non-tobacco/nicotine goods.

Table 7.7: – Summary of additional costs associated with option four

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government costs					
Development of	23,700	6,100	0	0	0

<http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

²⁰¹ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Wales, Managers and Directors in retail and wholesale).

<http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

²⁰² Hourly rates have been increased by a factor of 30% to incorporate on costs.

the database					
Communications	3,000	2,900	0	0	0
Total cost to Welsh Government	26,700	9,000	0	0	0
Local authorities					
Ongoing maintenance of the database	0	0	10,000	10,000	10,000
Staff costs	0	1,055,800	798,300	798,300	798,300
Costs to produce guidance	4,800	0	0	1,500	0
Training costs	2,600	16,800	0	0	0
Total cost to local authorities	7,400	1,072,600	808,300	809,800	808,300
Retailers					
Staff costs for familiarisation with the new licensing scheme	0	310,200	0	0	0
Staff costs to apply for licence/renewal	0	206,800	103,400	103,400	103,400
Fees for licence/renewal*	0	1,069,200	740,000	740,000	740,000
Total cost to retailers	0	1,586,200	843,500	843,500	843,500
Total cost	34,100	2,667,800	1,651,800	1,653,300	1,651,800
Fee revenue to local authorities		1,069,200	740,000	740,000	740,000
Net cost	34,100	1,598,600	911,800	913,300	911,800

*Registration fees incurred by retailers have not been included in the net cost as they are used to off-set local authority costs.

Benefits

478. Introducing a positive licensing scheme would provide an opportunity for targeted education and information to be provided to retailers through the licence application process and through the provision of a comprehensive record of all retailers who sell tobacco and/or nicotine products.
479. This would also be consistent with the message that selling tobacco is similar to other activities which carry a potential health risk, in that it is a conditional privilege rather than an unconditional right to sell tobacco products. It may also increase retailers' awareness of their legal

responsibilities, and an offence of selling tobacco and/or nicotine products without a licence would act as a further deterrent.

480. Evidence suggests that out of the three different models of tobacco retailer licensing – registration, negative licensing or positive licensing – a positive licensing scheme has been identified as best practice in relation to tobacco control. In California, youth tobacco sales have dropped by more than 30% in 11 communities following the introduction of strong local licensing laws.²⁰³

Summary and preferred option

481. Option one retains the current position. It would involve existing legislation continuing to be monitored by trading standards officers and breaches of existing legislation being dealt with accordingly. Considering the trend of underage sales has not reduced since the change of age of sale from 16 to 18 in 2007, it is unlikely that this option would achieve any noticeable decrease in the prevalence of under-age sales of tobacco products. In addition, following the introduction of legislation of age of sale for nicotine products, there will be a risk that these products would also be sold to under-18s, in a similar way to other age-restricted products, such as tobacco and alcohol.
482. Option two proposes the introduction of a voluntary register. It is unlikely a voluntary register would provide trading standards officers with a comprehensive list of all retailers in their area who sell tobacco and/or nicotine products. This would be considered to greatly diminish the benefit of a register and could mean that any impact on the reduction of prevalence of underage sales of tobacco and access to tobacco and nicotine products by young people would be minimal. As such it is unlikely to have a significant effect on reducing the number of young people smoking. It is also envisaged that this would not have a major impact on preventing underage sales of nicotine products, nor help with enforcement.
483. Option four proposes introducing a positive licensing scheme. Evidence suggests that such a scheme can have a positive effect in reducing smoking prevalence levels, although the evidence is unclear about the benefit in reducing underage sales compared to negative licensing. However, the costs associated with delivering a positive licensing scheme are significantly higher than in any of the other options. In particular, this option would impose an additional ongoing cost on tobacco retailers in Wales due to the need to renew the licence on an annual basis.

²⁰³ Tobacco Supply Strategies in a Local Government Context. Published by Cancer Society Auckland Health Promotion Team in October 2013

484. Option three proposes the introduction of a national register combined with an enhanced RPO regime and is the preferred option. This option would ensure that local trading standards officers have a comprehensive list of tobacco and nicotine retailers in their area. This would help them to enforce existing legislation, such as age of sale and display regulations and enable them to target advice, guidance and support to relevant retailers.
485. It is also considered that the threat of licence withdrawal, by issuing an RPO, as well as increased monitoring and communication channels, would strengthen retailers' compliance with tobacco and nicotine products' legislation and therefore be more likely than current practice to impact on under-age sales. This would be reinforced by the ability to add further appropriate offences, such as the sale of illegal tobacco, to the list of offences which can trigger a local authority application for an RPO.

Handing over tobacco and nicotine products to under-18s

Options

486. Three options have been considered:
- Option one – Do nothing;
 - Option two – Issue guidance to retailers on remote sales and handing over of tobacco and nicotine products;
 - Option three – Introduce legislation to prohibit the handing over of tobacco and nicotine products to persons under the age of 18 and issue supporting guidance to retailers who offer remote sales, covering the handing over of these products. This is the preferred option.

Option one – Do nothing

Description

487. As this option proposes no change it would result in retailers continuing to decide their own policies about the remote sale and handing over of tobacco and nicotine products, without any guidance or steer from the Welsh Government. Currently it is against the law to sell tobacco and nicotine products to a person under the age of 18. However, this does not extend to the delivery of these products. All the major supermarkets currently have policies in place, which seek to prevent home shopping deliveries from being handed over to customers under the age of 18. However, there are other retailers who could offer a home delivery or click- and-collect service whose terms and conditions may not cover handing over of tobacco or nicotine products to someone under 18. Most of the major supermarkets' terms and conditions state that a sale is complete when money has been exchanged and not when the products are delivered.

Costs

488. There would be no additional costs from this option. A number of retailers have developed their own terms and conditions on remote sales and the handing over of their products, including tobacco and nicotine products and there would be no requirement for these to change. There would also be no obligation for any retailers who do not currently have such policies to implement any changes.

Benefits

489. This option would not address the potential risk of access to tobacco and nicotine products by children and young people under 18 from remote sales and the handing over of these products. As such, there are no additional benefits from this option.

Option two – issue guidance to retailers about delivery of tobacco and nicotine products

Description

490. This option would involve the production of guidance by the Welsh Government, working with stakeholders from the retail sector and other interested parties (for example, trading standards representatives). The guidance would identify best practice for retailers to follow and identify actions, which retailers could take to reduce the risk of tobacco and nicotine products being handed over to people under 18.

Costs

Welsh Government

491. There would be costs to the Welsh Government associated with producing and issuing the guidance. Staffing costs to produce the guidance (based on 6,000 words) including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £8,000. This is based on approximately five weeks of a FTE higher executive officer (£4,900) to develop the guidance, and five weeks of a FTE team support for administration support (approximately £3,100).²⁰⁴

492. It is anticipated that design and typesetting would require one week of a 0.5 FTE executive officer, which would cost approximately £400. It is estimated that translation and proofreading would cost approximately £600.²⁰⁵ The total cost for the development, design and translation of guidance would therefore be £9,000.

²⁰⁴ Based on Welsh Government staff planning costs

²⁰⁵ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

493. The intention would be to provide electronic versions of the guidance, with a small number of paper copies produced and distributed to local authorities. It is anticipated printing costs would be approximately £900. The costs associated with producing the guidance will be incurred in 2017-18.
494. The guidance would be updated every three years. It is anticipated this would require approximately one week of a FTE higher executive officer, which would equate to approximately £1,000. Design and translation costs would amount to half the original costs, a total of £500. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,500, incurred every three years. The first review would take place in 2020-21.
495. Training sessions would need to be held for trading standards staff who would be supporting retailers in implementing the guidance. It is envisaged that trading standards representatives would run these sessions, though costs would be met by the Welsh Government. Each session would be approximately a half day and it is envisaged that two sessions would be held, one in North Wales and one in South Wales. These sessions would cost approximately £2,400, which covers room hire and refreshments for 35 people for each session (approximately £1,200)²⁰⁶, and possible costs for external staff to develop and run part of the sessions (£800). This cost would be incurred in 2017-18.

Local authorities

496. Trading standards departments would also incur some staff costs, initially focused on helping to develop the guidance and attending the training sessions. Based on a total of 70 local authority enforcement officers attending the training this would cost approximately £9,300²⁰⁷ in 2017-18.
497. Once the guidance is published, trading standards officers would engage retailers to encourage them to implement actions from the guidance to reduce the risk of young people gaining access to tobacco and nicotine products. This would be essential due to the voluntary nature of the guidance. In addition, trading standards officers may need to deal with queries and support retailers in implementing the guidance. It is anticipated this support would be higher in the first year following the publication of the guidance but would then reduce as demand declines. It is estimated that for the initial 12 months the cost would be the equivalent of a 0.05 FTE enforcement officer post per local authority, then reducing to a 0.025 post per local authority. This would equate to approximately

²⁰⁶ Based on costs from similar training sessions organised by Welsh Government.

²⁰⁷ Based on 5 hours at an hourly rate of £26.66 (to include the half day training session and travel time) for 70 enforcement officers to attend.

£50,800 in total in 2017-18, reducing to £25,400 per annum from 2018-19.

498. It is recognised trading standards departments would need to identify retailers who offer remote sales and handing over of tobacco and nicotine products to ensure they are aware of the new guidance. It is anticipated one local authority would perform this function on behalf of all local authorities in Wales. This would take one month's time of a FTE local authority enforcement officer post, costing approximately £3,800.
499. In addition, a small number of retailers would be likely to require a paper copy of the guidance. It is expected postage and other costs relating to this would be approximately £400. These costs would be met by local authorities, though costs per local authority would be minimal.

Retailers

500. Retailers may incur some costs from time spent helping to develop the guidance, familiarising themselves with the final guidance and implementing any changes they make to reduce the risk of tobacco and nicotine products being delivered to young people under 18. Based on the hourly rate of retailers who sell tobacco (£12.57^{208, 209}), the estimate there are 3,290 separate businesses covering the estimated 8,225 retailers of tobacco and nicotine products in Wales and that the above actions would take one hour, costs to retailers would amount to approximately £41,400 in 2017/18. However, this is likely to overestimate the costs as it is likely that not all of these retailers will offer a remote sale service, including handing over tobacco and nicotine products.
501. Similarly, when the guidance is updated every three years, retailers may incur some time familiarising themselves with the revised guidance and on implementing any changes they need to make to reduce the risk of tobacco and nicotine products being delivered to young people under 18. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those experienced in 2017-18. These costs are therefore estimated at £20,700, and would be incurred in 2020-21.

Table 7.8: – summary of additional costs associated with option two

Costs	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government					
Staff costs for the development of guidance	8,000	0	0	0	0

²⁰⁸ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Wales, Managers and Directors in retail and wholesale).
<http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

²⁰⁹ Hourly rates have been increased by a factor of 30% to incorporate on costs.

Design and translation	1,000	0	0	0	0
Printing costs	900	0	0	0	0
Costs to review guidance	0	0	0	1,500	0
Costs to cover training	3,200	0	0	0	0
Total costs for Welsh Government	13,100	0	0	1,500	0
Local authorities					
Staff costs to encourage and support retailers implementing the guidance.	50,800	25,400	25,400	25,400	25,400
Staff time to attend training	9,300	0	0	0	0
Communications/postage	4,200	0	0	0	0
Total costs for local authorities (combined)	64,300	25,400	25,400	25,400	25,400
Retailers					
Cost to amend or develop Terms and Conditions and policies on the delivery of tobacco products	41,400	0	0	20,700	0
Total cost for retail sector	41,400	0	0	20,700	0
Total cost	118,800	25,400	25,400	47,600	25,400

Benefits

502. Producing the guidance and circulating it to retailers who offer remote sales of tobacco and nicotine products to customers may help to improve their policies and procedures around the handing over of these products, to help protect young people from accessing them. While there is no definitive evidence on the extent of access of tobacco and nicotine products purchased remotely by people under 18, producing guidance could help reduce access. However, as there would be no legislation to underpin the guidance, it would be reliant on retailers taking voluntary action. It has not therefore been possible to quantify these benefits.

Option three – Introduce legislation to prohibit the handing over of tobacco and nicotine products to persons under 18 and issue supporting guidance to retailers who offer remote sales, including the handing over of these products.

Description

503. This option is similar to option two but, in addition to the production of guidance for retailers, would also involve the creation of an offence of knowingly handing over tobacco and/or nicotine products to a person or

persons under the age of 18. It would be an offence if, when handed over, the tobacco or nicotine products are not contained in a package which is sealed and has the person's name and address on it.

Costs

Welsh Government

504. Costs for producing and reviewing the guidance and training costs are estimated to be identical to those outlined in option two.

505. It would be necessary to alert retailers to the new statutory obligations and what would be required of them. In order to achieve this, the Welsh Government would work with stakeholders and representative groups, in order to generate press and media articles about the new legislation in relevant trade publications and the Welsh press, similar to other tobacco legislation such as the display ban. It is anticipated this would take five weeks of a FTE higher executive officer in the build up to the legislation coming into force. This would cost approximately £4,900²¹⁰.

Local authorities

506. To support the communications work outlined above, trading standards officers would identify retailers who offer remote sales, including the handing over of tobacco and nicotine products, to ensure that they are aware of their statutory obligations. It is anticipated that one local authority would perform this function on behalf of all local authorities in Wales. This would take one month's time of a FTE local authority enforcement officer, costing approximately £3,800.

507. In addition, a small number of retailers would be likely to require a paper copy of the guidance. It is expected that postage and other costs relating to this would cost approximately £400. These costs would be met by local authorities, though the costs per local authority would be minimal.

508. Trading standards departments would incur some costs from helping to develop the guidance and supporting retailers in implementing any actions following the guidance being published. It is anticipated that this would be the equivalent of a 0.05 FTE local authority enforcement officer post for the first year, reducing to a 0.01 FTE post per annum for each local authority. Total costs would equate to £50,800 in 2017-18, reducing to an annual cost of £10,100 from 2018-19.

509. In addition to costs in supporting retailers, local authorities would incur costs in releasing enforcement officers for training covering enforcement issues. It is anticipated that this could be covered in a half day's training session, and as such these costs are identical to those outlined under option two.

²¹⁰ Based on Welsh Government staff planning costs

510. Trading standards officers would need to perform test purchases relating to the new offence. It is anticipated that each test purchase scenario would cost approximately £1,300 for staff time and £90 for purchasing the goods used in the test purchase.²¹¹ This covers the cost of locating a suitable vacant house that can be used for the test purchase scenario, recruiting a young volunteer to take part, supervising the test purchase, and the costs to cover the purchase of the tobacco and nicotine products being delivered. Each test purchase scenario would cover three test purchases. In order to conduct a reasonable sample size, but limited by the time taken to set up the testing, it is anticipated that between one and three test scenarios (covering three – nine test purchases) for each local authority would be run per year. This would give a total of between 66 and 198 across Wales, compared to 332 attempts to purchase cigarettes in shops by young people in 2012-13. These tests would therefore cost a total of between £31,000 and £93,000 annually.
511. There are currently no data about the levels of tobacco products being sold remotely in Wales, including how many young people purchase tobacco remotely. Scottish data about the number of FPNs issued to stores selling tobacco to under 18s have therefore been used to estimate how many FPNs would be issued regarding the handing over of tobacco products to under 18s. As there is not an option to issue a FPN for underage sales of tobacco in England and Wales, equivalent Welsh data about the number of FPNs issued does not exist.
512. In Scotland, a total of 169 FPNs were issued in 2013-14²¹². Trade statistics indicate that internet sales account for approximately 0.3% of all cigarettes sales. Taking into account the estimated number of retailers who sell tobacco and nicotine products in Wales of 8,225, it is estimated that approximately four offences per year may occur²¹³. It is unlikely, given the small number of FPNs in Scotland resulting in court action (approximately 15%), that any of these would result in a court case and could instead result in a warning, with trading standards officers working with the retailer to avoid repeat offences. It is anticipated these warnings would form part of the normal work routine of enforcement officers.

Cost to retailers (including delivery drivers)

513. Retailers may incur some costs from time spent familiarising themselves with the guidance and implementing any changes they make to reduce the risk of tobacco and nicotine products being handed over to young people under 18. Based on a two-hour familiarisation period, an

²¹¹ Based on information provided by local authorities

²¹² SCOTTS. Enhanced Tobacco Sales Enforcement Programme Report 2010-14. SCOTTS 2014

²¹³ This has been calculated by a pro rata number of FPNs for under age sales of tobacco (68.7% of Scotland's data as Wales has 31.3% less tobacco retailers) and estimating that 0.3% of these could be made by delivering tobacco.

hourly rate of £12.57^{214,215} and the estimate there are 3,290 separate businesses covering the estimated 8,225 retailers of tobacco products and nicotine products in Wales, costs to retailers would amount to approximately £82,700 in 2017-18. However, this is likely to overestimate the costs as it is likely that some of these retailers do not offer a remote sale service.

514. Similarly, when the guidance is updated every three years, retailers may incur some time familiarising themselves with the revised guidance and about implementing any changes they need to make to reduce the risk of tobacco and nicotine products being delivered to young people under the age of 18. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those experienced in 2017-18, at an estimated £41,400.
515. There could also be a cost to delivery drivers from fines being issued as a result of handing over tobacco products and/or nicotine products to a person or persons under 18 while unaccompanied by a person aged 18 or over. Based on a maximum of four cases²¹⁶ going to court per year (although it is likely that no cases would go to court and would instead be dealt with by warnings) and an assumption that each case results in a £250 fine and £250 costs (as per a case for an offence for selling tobacco to a person under the age of 18 in October 2014), it is estimated that the total cost per annum would range from £0 to £2,000. The proceeds from these fines would be retained by HM Courts and Tribunals Service.
516. As the offence would only cover situations where the delivery driver is aware that they are handing over either tobacco or nicotine products to someone who is under 18, services where a fully enclosed and addressed package is being delivered would not be covered by the offence. No data are available on the number of delivery drivers delivering open packets to Wales from across the border so these potential costs are currently unknown, but are likely to be minimal.

Table 7.9: – Summary of additional costs associated with option three

Costs	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government					

²¹⁴ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (Wales, Managers and Directors in retail and wholesale)
<http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

²¹⁵ Hourly rates have been increased by a factor of 30% to incorporate on costs.

²¹⁶ This has been calculated by a pro rata number of FPNs for under age sales of tobacco (68.7% of Scotland's data as Wales has 31.3% less tobacco retailers) and estimating that 0.3% of these could be made by delivering tobacco.

Staff costs for the development of guidance	8,000	0	0	0	0
Design and translation	1,000	0	0	0	0
Printing costs	900	0	0	0	0
Communications	4,900	0	0	0	0
Costs to review guidance	0	0	0	1,500	0
Costs to cover training	3,200	0	0	0	0
Total costs for Welsh Government	18,000	0	0	1,500	0
Local authorities					
Staff costs to support retailers implementing the guidance	50,800	10,100	10,100	10,100	10,100
Staff costs for staff to attend training	9,300	0	0	0	0
Communications/postage	4,200	0	0	0	0
Test purchases	31,000 – 93,000	31,000 – 93,000	31,000 – 93,000	31,000 – 93,000	31,000 – 93,000
Total costs for local authorities	95,300-157,300	41,100 – 103,100	41,100 – 103,100	41,100 – 103,100	41,100 – 103,100
Retail sector (including delivery drivers)					
Cost to retailers to amend or develop terms and conditions and policies on the delivery of tobacco products and nicotine products	82,700	0	0	41,400	0
Costs from fines ²¹⁷	0-2,000	0-2,000	0-2,000	0-2,000	0-2,000
Total cost for retail sector	82,700-84,700	0-2,000	0-2,000	41,400-43,400	0-2,000
Total cost	196,000-260,000	41,100-105,100	41,100-105,100	84,000-148,000	41,100-105,100

Benefits

517. The benefits outlined under option two would also be applicable to option three. These are therefore not repeated here.

518. Additionally, creating an offence to prohibit the handing over of tobacco and nicotine products to persons under 18 would further reinforce the

²¹⁷ Based on a maximum of 4 cases going to court (although it is likely that no case would go to court as they would be dealt with warnings), and each case receiving a £250 fine and £250 costs (as per a case for an offence in October 2014).

importance of preventing access to these products by children and young people. The offence would strengthen the legislative framework in this area and also help to reinforce a retailer's own policy, as well as improve clarity and consistency.

519. The offence would be supported by accompanying guidance for retailers, produced by the Welsh Government, which would outline actions they can take to reduce the risk of their employees or third party delivery agents handing over tobacco and nicotine products to under 18s. Retailers would be required to implement this guidance in order to avoid committing an offence and receiving a fine, increasing the impact of any guidance.
520. It is anticipated the introduction of this offence, along with the guidance for retailers, would reinforce other existing legislation, such as age of sale legislation²¹⁸ and the ban on selling tobacco from vending machines²¹⁹. When combined, these measures aim to reduce the risk to young people's health from the harms associated with nicotine use, although the specific contribution of this additional measure is not able to be quantified.
521. It is estimated that, on average, preventing the uptake of smoking results in an average of one year life gain per individual.²²⁰ This life gain is valued at £60,000 per person.²²¹ The total cost of the preferred option (option three) over the initial five-year period would be between £402,500 and £722,500. Therefore in order to be cost neutral approximately seven to 12 young people would have to not start smoking.

Summary and preferred option

522. Option one does not meet the policy objective as it would continue existing practice and the current risks of persons under the age of 18 accessing these products would remain. Option two may encourage retailers to take action to strengthen their existing policies regarding the handing over of tobacco and nicotine products, or encourage those retailers who do not currently have a policy to develop one. However, there is a significant risk that the coverage would be limited, resulting in a limited impact. This may mean that young people could still access tobacco and nicotine products remotely. In addition, evidence indicates

²¹⁸ Children and Young Persons Act 1933

²¹⁹ Protection from Tobacco (Sales from Vending Machines) (Wales) Regulations 2011

²²⁰ Age of Sale for Nicotine Inhaling Products: Impact Assessment.

<https://www.gov.uk/government/consultations/nicotine-inhaling-products-introducing-a-minimum-age-of-sale>

²²¹ A value of £60,000 is assigned to a Quality Adjusted Life Year. Where Quality Adjusted Life Year estimates are not readily available, and it is appropriate this value is used for Life Years. This is consistent with similar valuation of policies that mitigate mortality or morbidity risk by other Government departments, based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes.

that voluntary action on smoking in general has a negative impact on health inequalities, as groups with higher levels of inequalities are relatively disinclined to adopt them²²².

523. Option three is the preferred option as it combines two approaches – legislation and guidance – to restrict access to tobacco and nicotine products purchased remotely by persons under 18. These two approaches working collectively are considered to present the greatest likelihood of reducing the risk of young people under 18 from accessing tobacco and nicotine products via remote ordering and subsequent handing over of these products. This option would support other legislation to prevent children and young people from accessing tobacco and nicotine products, thereby making a cumulative positive impact on young people's use of such products.

Special Procedures

Options

524. Three substantive options have been considered, with the third split into two sub-options:
- Option one – Do nothing;
 - Option two – Develop and issue guidance in relation to best practice for acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis, and undertake an awareness-raising campaign;
 - Option 3A – Introduce a special procedures licensing system. This is the preferred option;
 - Option 3B – Introduce a special procedures licensing system with an added central register of all licensed practitioners and approved premises or vehicles providing special procedures in Wales.

Option one – Do Nothing

Description

525. There would be no change to the current legislation under this option. Local authorities' main powers for regulating businesses that carry out the procedures of acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis in their area are provided by the Local Government (Miscellaneous Provisions) Act 1982²²³. This Act includes the

²²² European Commission. Identifying best practices in actions on tobacco smoking to reduce health inequalities. European Commission 2014.

http://ec.europa.eu/health/social_determinants/docs/2014_best_practice_sum_en.pdf.

Accessed December 2014

²²³ Sections 14 and 15, Local Government (Miscellaneous Provisions) Act 1982

<http://www.legislation.gov.uk/ukpga/1982/30>

power to issue byelaws for the purpose of securing the cleanliness of registered premises and fittings, cleanliness of persons registered (and those assisting them) and the cleansing and sterilisation of equipment. Welsh Ministers have developed comprehensive model byelaws, which reflect current infection control guidance and industry best practice²²⁴. The powers provided by the Local Government (Miscellaneous Provisions) Act 1982 are adoptive and therefore local authorities are able to choose which procedures are subject to their control and whether or not to issue byelaws.

526. All local authorities in Wales have adopted the relevant provisions in the Act and, as of August 2016, the Welsh Government is aware that seven have chosen to adopt the Welsh Government model byelaws. Other local authorities have byelaws in place; however these vary in scope and content. For example, some local authorities have byelaws covering specific procedures, such as tattooing, whereas others have byelaws that apply to all procedures.
527. Local authorities have the ability to charge businesses that carry out any of the procedures a one off fee for registration under the Local Government (Miscellaneous Provisions) Act 1982. The fee structures vary according to local authority. All local authorities charge a registration fee in relation to premises where the procedures are performed, while some charge registration fees in respect of premises and individual practitioners.
528. The fee amount also varies between local authorities. For premises, the registration fee is between £49 and £300 (average £130); a personal registration fee is between £38 and £117 (average £73). Additional fees are also charged by local authorities for the variation of an existing registration²²⁵. These registration fees, in addition to the core funding provided to the local authority via the Revenue Support Grant (RSG) are currently used by local authorities to meet the costs of enforcement within this sector.
529. The Health and Safety at Work etc. Act 1974²²⁶ applies across Wales and makes general provision for workplace health, safety and welfare. This legislation applies to all persons engaged in special procedures, including peripatetic workers who carry out treatments in the client's home.

Costs

²²⁴ Welsh model byelaws for acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing, and electrolysis.

<http://wales.gov.uk/topics/health/protection/communicabledisease/acupuncture/?lang=en>

²²⁵ Information provided by local authorities

²²⁶ Health and Safety at Work Act 1974

<http://www.legislation.gov.uk/ukpga/1974/37/introduction>

530. As this is the baseline option, there are no additional costs. The following section provides an estimate of the costs currently incurred by the various parties.

Welsh Government

531. There are no costs to the Welsh Government associated with supporting local authorities in relation to their powers under the Local Government (Miscellaneous Provisions) Act 1982.

532. In addition to the Local Government (Miscellaneous Provisions) Act 1982, local authorities have powers under the Public Health (Control of Disease) Act 1984 to apply to a Justice of the Peace to make a Part 2A order for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination. The order may relate to persons, things or premises. Since the powers came into force in 2010, some local authorities in Wales have used them to apply for an order if they perceive there is risk of infection or contamination where procedures, such as tattooing and cosmetic piercing, are being carried out in unhygienic conditions. The Welsh Government undertakes an annual review of the use of these powers, using advice from local authority and medical professionals. This annual review is estimated to cost £2,500 in staff time each year (based on £1,700 Welsh Government costs, £400 local authority costs and £400 Public Health Wales costs). The outcome of the review is published bilingually on the Welsh Government website at minimal cost.

Local authorities

533. Local authorities are responsible for the control of businesses that undertake the procedures in commercial settings and undertake inspections and compliance work with these businesses to ensure they are working hygienically and within their statutory obligations (including their Health and Safety obligations).

534. As stated above, the Welsh Government is aware that seven local authorities have adopted the Welsh Government model byelaws as at August 2016. The cost per local authority of adopting these model byelaws is estimated to be approximately £5,000.²²⁷ The cost to local authorities to August 2016 is therefore estimated to be £35,000. As local authorities would continue to be encouraged to adopt these model byelaws there could be a further cost to the 15 remaining local authorities in Wales of up to £75,000 by the end of the five-year period. For the summary table of costs at the end of this section it has been assumed that all local authorities would adopt the model byelaws over the next five years, and that costs would be split across the five years (£15,000 per year).

²²⁷ Based on information provided by local authorities

535. The inspection regime varies according to the procedure undertaken and the level of risk. A local authority will undertake an initial inspection upon application for registration of premises. This inspection is estimated to cost around £170 and is recovered from the business applying for registration. It is estimated that there are 190 new premises registrations per year across Wales, which amounts to an annual cost of £32,300. These costs are met by the registration fees paid by businesses and practitioners.
536. Annual compliance visits are generally undertaken for those businesses providing tattooing and cosmetic piercing. It is estimated that there are around 462 businesses providing these procedures in Wales.²²⁸ One compliance visit is estimated to cost £170. Across all local authorities, compliance visits are therefore estimated to cost approximately £78,500 per year.
537. Intelligence provided by local authorities indicates that complaints are predominately received in relation to businesses providing tattooing and cosmetic piercing. It is estimated there are 70 complaints in relation to businesses and practitioners performing these procedures per year²²⁹. The costs to investigate and undertake follow up work in relation to a complaint can vary, as some complaints are resolved quickly, whereas others require detailed investigation and, in infrequent cases, the pursuit of a prosecution. An estimate of the cost to a local authority of investigating a complaint is £170²³⁰ per complaint, which equates to a total of approximately £11,900 annually across Wales. With regard to successful prosecutions, local authorities have the option of pursuing cost recovery. The following table sets out estimated inspection and compliance costs over five years.

Table 7.10:

Local authority inspection and compliance costs					
	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
New registration initial inspections	32,300	32,300	32,300	32,300	32,300
Compliance visit costs	78,500	78,500	78,500	78,500	78,500
Complaints investigation costs	11,900	11,900	11,900	11,900	11,900
Total	122,700	122,700	122,700	122,700	122,700

²²⁸ Based on data provided by local authorities

²²⁹ Based on local authority data which indicates complaints in relation to 15% of tattooing and cosmetic piercing businesses.

²³⁰ Based on data provided by local authorities

538. Local authorities currently have limited powers to stop individuals who perform procedures without being registered, particularly if there is a risk to public health. Some local authorities have used powers in the Public Health (Control of Disease) Act 1984²³¹ to apply for an order to prevent a person from practicing, for example tattooing, due to the risks they present to public health. In total, as of August 2015, 34 orders (called Part 2A Orders under the Public Health (Control of Disease) Act 1984) had been made in relation to tattooing since the legislation was introduced in 2010. The estimated cost to a local authority to seek and execute a Part 2A order is estimated to range between £800 and £3,000. This includes a £210 fee that some magistrates' courts have imposed on local authorities applying for an order. The table below shows the projected annual number of Part 2A orders over the next five years and the estimated costs associated with these.

Table 7.11:

Public Health (Control of Disease) Act 1984 – Part 2a orders for tattooing					
	2017-18	2018-19	2019-20	2020-21	2021-22
Projected number of cases	6	6	6	6	6
Associated costs	£4,800 – £18,000	£4,800 – £18,000	£4,800 – £18,000	£4,800 – £18,000	£4,800 – £18,000

539. The estimated total annual spend by local authorities is between £142,500 and £155,700 (which will reduce once all local authorities have adopted the model byelaws). The total annual spend amounts to a cost per local authority of between £6,500 and £7,100. However approximately £52,400 of the total is recoverable from new practitioner and business registrations in the year through their registration fees, as set out under costs to practitioners and businesses.

Costs to the NHS

540. There are costs to the Welsh NHS as a result of treating complications arising from the procedures, such as skin infections. The majority of costs arise from tattooing and cosmetic piercing procedures. The following paragraphs provide an assessment of some of the costs for these procedures for illustrative purposes but as an accurate assessment of all costs is not available these have not been included in the summary table at the end of this option. Although there are costs to the NHS associated with treating complications following acupuncture, semi-permanent skin-

²³¹ Public Health (Control of Disease) Act 1984 as amended by Part 3 of the Health and Social Care Act 2008 <http://www.legislation.gov.uk/ukpga/2008/14/part/3> The Health Protection (Part 2A Orders) (Wales) Regulations 2010. Available on the Welsh Government website: <http://wales.gov.uk/topics/health/protection/communicabledisease/legislation/?lang=en>

colouring and electrolysis²³², these are considered to be minimal and have not been assessed.

541. It is known that cosmetic piercing can result in complications, such as swelling, infection, bleeding, allergy and tear or other injury²³³. Nerve damage and scarring may also occur if procedures are poorly performed. Although rare, complications from a cosmetic piercing can result in a hospital admission and may be particularly serious for those with underlying health conditions.
542. Currently there are no data about the number of people having a cosmetic piercing in Wales nor is there any specific evidence about the rate of health complications from cosmetic piercings. As data from other countries are also limited, an estimate of the health costs has been based on the most relevant data available. This is from Bone et al's study²³⁴ in England, which showed that 10% of people aged 16 and over (range 9.4% - 10.6%) reported ever having a piercing other than in the ear lobe. There are 2,555,547²³⁵ people who are aged 16 or older in Wales and, assuming a prevalence of 10%, this would mean there are at least 255,554 people with piercings other than the earlobe. This figure is likely to be an underestimate as it does not include those under the age of 16.
543. As only 4.1% of those aged 45 and over have one or more body piercings other than the earlobe²³⁶, it is assumed the vast majority of body piercing procedures are performed on 16 to 44-year-olds. There is therefore a 29-year period within which most piercings are received. Using this assumption, a total of 8,812 body piercings other than the earlobe are likely to be performed in Wales each year. This is considered to be a conservative estimate given that it does not account for those individuals with multiple piercings or those under 16.
544. The Bone study found that complications were reported with 27.5% of body piercings – equivalent to approximately 2,423 people experiencing complications in Wales each year – with problems serious enough to seek further help in 12.9% of cases (this would equate to 1,137 people seeking further help in Wales each year).
545. The study undertook a more detailed analysis of complications associated with body piercings in 16 to 24-year-olds and estimated that 5.1% of these piercings resulted in help being sought from a pharmacist, 3% from a GP, 0.6% requiring attendance at an A&E department and

²³² BMJ 2001;323:486

²³³ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

²³⁴ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

²³⁵ Welsh Government 2014- based national population projections for Wales, 2014-2039. Updated 29 October 2015

²³⁶ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

0.9% requiring hospital admission. Those not seeking further help from NHS services are assumed to revisit the practitioner who performed the procedure. Assuming this pattern of access to NHS services is replicated across all age groups these data have been used as a basis to estimate the number of individuals accessing NHS services in Wales and the associated costs (table below). Where there is a range of possible treatment options, a range of costs has been provided.

Table 7.12:

Costs of access to NHS services following piercing procedure			
Description of help sought following piercing procedure	Number of those aged 16 and over seeking help each year	Unit cost	Yearly cost (£)
Consultation with a pharmacist	449	£5.44 (4.6 minute consultation) £13.85 (11.7 minute consultation)	£2,400-£6,200
GP consultation and antibiotic treatment	264	£33.98 (£31.70 for consultation and £2.28 for a seven-day course of oral antibiotics)	£9,000
Attendance at A&E	53	Cost unknown. Used weighted average of all outpatient procedures - £91 (lower quartile)	£4,800
Hospital admission	79	Non-elective inpatient short stay £399 (based on lower quartile). Non-elective inpatient long stay £1,902 (lower quartile)	£31,500-£150,300
Total	845	-	£47,700-£170,300

546. Tattooing is the other main source of costs to the NHS from these special procedures. There are no published data about the prevalence of tattooing in the UK – the most relevant data available is from outside the UK. According to the Harris Poll 2012, 21% of all adults in the US have at least one tattoo²³⁷. This finding is comparable with a further study carried out in the US in 2006, which found that 24% of respondents had tattoos²³⁸.

547. There are estimated to be 357 premises providing tattooing procedures in Wales and an average of two practitioners employed by each premise. It has been conservatively assumed that each practitioner works three

²³⁷ <http://www.harrisinteractive.com/NewsRoom/HarrisPolls/tabid/447/mid/1508/articleId/970/ctl/ReadCustom%20Default/Default.aspx>

²³⁸ <http://www.ncbi.nlm.nih.gov/pubmed/16908345>

days a week, 44 weeks a year, undertaking three procedures each day.²³⁹ Based on these assumptions it is estimated that the number of tattooing procedures undertaken in Wales each year is approximately 282,700. It is noted that some tattoos often require multiple sittings to complete.

548. The complication rate associated with tattoos in the US is 2% to 3%.²⁴⁰ Applying this rate to Wales and assuming a complication rate at the upper end of this scale, the number of people experiencing complications each year is estimated to be 8,500. However, it is unlikely all complications would result in an individual seeking help from NHS services. Many individuals experiencing a complication are likely to revisit the practitioner who performed the procedure or attempt self-medication. It is estimated approximately 10% of all complications result in NHS presentations (approximately 850 cases per year).

549. There are a range of complications and associated treatments associated with tattooing procedures. As with cosmetic piercing complications, individuals could seek help from a range of sources including pharmacists, GPs and A&E departments. There are no data available relating to NHS treatment of these complications so it has been assumed that treatment costs would be equal to the mean range of treating complications arising from piercings (£56 to £202). Using these assumptions, it can be estimated the total cost of treating complications arising from tattoos each year is £47,600 to £171,700.

Table 7.13: – Summary of NHS costs from body piercing and tattooing procedures

NHS costs from piercing and tattooing procedures					
Costs (£)	2017-18	2018-19	2019-20	2020-21	2021-/22
Complications from body piercings of those aged 16 to 24	£47,700-£170,300	£47,700-£170,300	£47,700-£170,300	£47,700-£170,300	£47,700-£170,300
Complications from Tattooing – all ages	£47,600-£171,700	£47,600-£171,700	£47,600-£171,700	£47,600-£171,700	£47,600-£171,700
Total costs	£95,300-£342,000	£95,300-£342,000	£95,300-£342,000	£95,300-£342,000	£95,300-£342,000

550. A number of other serious conditions can occur as a result of these procedures, as discussed below. Due to the relative rarity of such conditions occurring in Wales, the costs have not been included in calculations.

²³⁹ Based on information provided by local authorities

²⁴⁰ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3236178/>

551. Any procedures involving skin penetration can potentially lead to the transmission of blood-borne viruses such as hepatitis B, hepatitis C and HIV²⁴¹. The cost of treatment for these infections varies significantly but a course of treatment for hepatitis C ranges between £39,000 and £80,000²⁴².
552. There are also serious complications which can arise from infections acquired during a procedure, such as pseudomonas infection associated with cartilaginous piercings, serious cases of which can require reconstructive surgery.
553. In unusual cases, where there have been significant deficiencies identified in a business' infection control practices, it may be necessary to undertake a client notification ("look-back") exercise. Such a look-back exercise is undertaken to identify any clients who may have been potentially infected with a blood borne virus and involves identifying clients via customer records to contact them and offer relevant testing. The Exercise Seren look-back was announced on 6 May 2015 and involved over 800 people, most of them young people. It was conducted in response to serious infection control deficiencies associated with a piercing and tattoo studio in Newport. These resulted in a number of customers suffering serious skin infections requiring inpatient care and reconstructive surgery following piercings at the studio. The total cost of the look-back exercise was estimated to be £240,159.²⁴³ Costs of such exercises are likely to vary greatly from case to case and would predominantly fall to the NHS. However, due to the intermittent, unpredictable nature of look-back exercises, these costs have not been factored into annual costs for the NHS or local authorities. Although these costs would be incurred infrequently, each occurrence is likely to incur considerable expense.
554. Other complications – pain, discomfort and anxiety – have costs to individuals as well as the NHS. Although the level of such complications cannot be quantified, any reduction in them would be of benefit to the NHS. Complications can be particularly serious for those with underlying health conditions and cases of individuals who have died following a cosmetic piercing have been recorded^{244,245}.

²⁴¹ Hayes, MO. Harkness, GA. (2001) Body piercing as a risk factor for viral hepatitis: an integrated research review. American Journal of Infection Control. 29, 271-274.

²⁴² NICE consults on draft guidance recommending ledipasvir-sofosbuvir (Harvoni) for treating chronic hepatitis C (3 March 2015). <https://www.nice.org.uk/news/press-and-media/nice-consults-on-draft-guidance-recommending-ledipasvir-sofosbuvir-harvoni-for-treating-chronic-hepatitis-c>

²⁴³ The Technical Report of a Blood-Borne Virus Look Back Exercise related to a body piercing and tattooing studio in Newport, South Wales. Aneurin Bevan University Health Board, 26th July 2016.

²⁴⁴ BBC News online (2005) Lip piercing death 'misadventure'. Available at: http://news.bbc.co.uk/1/hi/england/south_yorkshire/4429298.stm

²⁴⁵ BBC News online (2010) Caerphilly woman's infection death after tongue pierce. Available at: <http://www.bbc.co.uk/news/uk-wales-11543757>

555. In addition to the treatment costs incurred by the NHS, any health complications from the procedures may also result in costs to employers in Wales if they result in sickness absence or reduced productivity. It has not been possible to quantify this economic cost.

Practitioners and businesses which carry out acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis

556. Businesses which provide these procedures are currently required to pay a one-off registration fee. As set out above, the registration fees vary between local authorities. It is estimated there are around 190 premises registrations each year and 380 individual registrations per year. Using the average fees of £130 for premises registration and £73 for individuals, this would amount to £24,700 for the registration of new businesses and £27,700 for the registration of new practitioners each year. The total annual cost to business is therefore estimated at approximately £52,400. Due to the variable charging mechanisms used by local authorities, such as the discretion about whether to charge for personal registrations, these numbers are indicative only.

557. There is also a cost to new practitioners and businesses for the time taken to complete an application. Although local authority application systems vary, it is estimated an application takes approximately 30 minutes to complete. Assuming a gross hourly rate for practitioners of £15.80^{246,247} and that there would be 380 individual applications and 190 premises applications, it is estimated costs incurred amount to approximately £4,500 annually. There is currently no requirement to renew applications.

558. There would be no other costs for businesses providing these procedures under this option.

Table 7.14 – summary of costs associated with option one*

Costs (£)	2017-18	2018-19	2019-20	2020-21	2021-22
Welsh Government costs					
Annual review of Part 2A Orders	£2,500	£2,500	£2,500	£2,500	£2,500
Total Welsh Government costs	£2,500	£2,500	£2,500	£2,500	£2,500
Local authority costs					

²⁴⁶ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (artist).
<http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

²⁴⁷ Hourly rates have been increased by a factor of 30% to incorporate on costs.

New registration initial inspections	£32,300	£32,300	£32,300	£32,300	£32,300
Compliance visit costs	£78,500	£78,500	£78,500	£78,500	£78,500
Complaints investigation costs	£11,900	£11,900	£11,900	£11,900	£11,900
Part 2A Orders	£4,800-£18,000	£4,800-£18,000	£4,800-£18,000	£4,800-£18,000	£4,800-£18,000
Adoption of model byelaws	£15,000	£15,000	£15,000	£15,000	£15,000
Total local authority costs	£142,500-£155,700	£142,500-£155,700	£142,500-£155,700	£142,500-£155,700	£142,500-£155,700
Local authority net costs**	£90,100-£103,300	£90,100-£103,300	£90,100-£103,300	£90,100-£103,300	£90,100-£103,300
Business costs					
One-off registration fees	£52,400	£52,400	£52,400	£52,400	£52,400
Application time	£4,500	£4,500	£4,500	£4,500	£4,500
Business costs	£56,900	£56,900	£56,900	£56,900	£56,900
Total Cost **	£149,500-£162,700	£149,500-£162,700	£149,500-£162,700	£149,500-£162,700	£149,500-£162,700

* The NHS costs have not been included in the table, as they could only be partially estimated.

** The one-off registration fees incurred by businesses and practitioners have not been included here as they are used to offset local authority costs.

Benefits

559. This option maintains the current policy position and as such there would be no additional benefits.

Option two – Develop and issue guidance in relation to best practice for acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis, and undertake an awareness-raising campaign.

Description

560. Non-statutory, best-practice guidance for practitioners would be developed and produced by the Welsh Government in relation to acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis. The development of the guidance would involve working with stakeholders from the sector, local authorities and other interested parties. The guidance would be evidence based and identify actions practitioners and businesses can take to employ safe working practices, with the aim of promoting safety and consistency across the sector. Copies of the guidance would be available online or in paper copy for distribution to those businesses and practitioners carrying out these procedures.
561. The Welsh Government would also undertake an awareness-raising campaign. It would have two major components – awareness raising among practitioners and businesses and disseminating information to the general public.
562. The guidance would be implemented in partnership with local authorities. Current local authority records would be used to identify relevant businesses in order to target the guidance. There would be no enforcement by local authority enforcement teams, although they would be expected to provide advice about the applicability of the guidance to individual practitioners and businesses. Awareness training about the guidance for local authority staff would be provided, along with an awareness campaign to inform the public of the possible health issues surrounding these procedures.
563. The guidance under this option would be in addition to the limited registration system under option one. All current costs incurred under option one are therefore carried forward under this option.

Costs

Welsh Government

564. There would be a cost to the Welsh Government for the development, design and translation of the guidance; staff costs would be included within these overall costs.
565. The guidance would be modelled on the *Tattooing and Body Piercing Guidance: Toolkit*²⁴⁸ and would focus on effective control of risks, standards of practice and practical requirements. It would therefore provide information for enforcing authorities, practitioners and businesses. This guidance would need to cover each of the procedures,

²⁴⁸ Chartered Institute of Environmental Health, Health and Safety Laboratory, Public Health England and the Tattoo and Piercing Industry Union (2013) Tattooing and body piercing guidance: Toolkit.

with each having distinctive issues. As such it is envisaged the guidance would need to be a comprehensive document and would require significant levels of staff input. To produce the guidance (approximately 20,000 words), it is anticipated it would take approximately six months of a 0.5 FTE senior executive officer (equating to approximately £13,800) and six months of a 0.2 FTE team support (equating to approximately £2,800).²⁴⁹

566. It is anticipated that design and typesetting would require two weeks of a FTE executive officer, which would cost approximately £1,500. It is estimated that translation and proofreading would cost approximately £1,900.²⁵⁰ The total cost for the development, design and translation of guidance is therefore £20,000.

567. To achieve maximum impact, copies of the guidance would be sent to all premises performing the procedures in Wales (approximately 890 registered premises in Wales). Five copies of the guidance would also be sent to each local authority, resulting in a total of approximately 1,000 paper versions being produced. Printing of this guidance would cost approximately £3,800 and distribution £1,500, amounting to a total of £5,300.²⁵¹ Electronic versions of the guidance would also be available.

568. The guidance would be updated every three years. It is anticipated this would require approximately one week of a FTE higher executive officer, which would equate to approximately £1,000. Design and translation costs would amount to half the original costs, a total of £1,700. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £2,700, incurred every three years. The first review would take place in 2020-21.

569. Training sessions may be necessary for environmental health officers (EHOs) or other relevant local government staff to support them in encouraging practitioners and businesses to take up the advice provided in the guidance. It is envisaged these costs would be met by the Welsh Government and be contracted out to a supplier credible to the environmental health profession. It is anticipated two sessions would be held, one in North Wales and one in South Wales. These training sessions would take place in 2017-18. The cost of the development of the course material and hand-outs would be approximately £800 and the cost of running the two sessions with 35 people attending each would be approximately £1,600, giving a total cost of £2,400. If the training was combined with that for a prohibition on the intimate piercing of persons under 18, the expectation is that savings could be made overall.

²⁴⁹ Based on Welsh Government staff planning costs

²⁵⁰ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

²⁵¹ Based on previous work undertaken by the Welsh Government

570. To maximise the potential impact of the guidance, there would need to be publicity to raise awareness among businesses and practitioners. This would be primarily through news stories in trade journals; stakeholder networks; use of online resources and social media. Wider communications work would also be required to alert the public, including young people and parents to the possible health issues surrounding these procedures and the importance of ensuring the practitioner and business visited for an acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing or electrolysis procedure is registered with the local authority. Such a campaign would include public relations, social media and working with schools/youth organisations and cost approximately £10,000. As this option would require voluntary action, it is expected the communications work would need to be repeated every three years. If the communication work was integrated with that for a prohibition on the intimate piercing of people under 18, the expectation is that savings overall could be made in 2017-18 and every subsequent three years.

Local authorities

571. Local authority staff would be encouraged to support the uptake of the guidance as part of their normal work routines but it is recognised there would be some associated staff costs. These would cover helping to develop the guidance, attending training sessions and engaging with practitioners and businesses to encourage them to follow the guidance. As businesses and practitioners would be able to choose whether or not to implement the guidance, encouragement from local authority staff to do so could play an important role.

572. It is also likely EHOs and other relevant staff may need to deal with ad hoc queries from practitioners and businesses on the guidance. Taking all the above into account, additional work would be likely to be greater in the run up to and during the first year following the introduction of the guidance and in total would amount to no more than the equivalent of half a month of a FTE EHO²⁵² per local authority in these two years, reducing to half this amount for subsequent years. This would equate to approximately £38,400 (£1,745 per local authority) in 2017-18 and 2018-19, with the cost subsequently reducing to approximately £19,200 (£872 per local authority) per year. However, if this work was integrated with that for a prohibition on the intimate piercing of persons under 18, the expectation is that savings could be made overall.

Practitioners and businesses that carry out acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis

573. Practitioners and businesses would be likely to incur costs from time spent familiarising themselves with the guidance and on implementing any changes to their practice. Although the guidance is estimated to be

²⁵² Based on local authority staff planning costs. On-costs have been incorporated into these costs.

approximately 20,000 words in length, the guidance would outline the recommended practices for each procedure in detail. It is therefore unlikely practitioners would be required to read the whole document in detail. It is assumed practitioners would only read in detail the guidance relevant to the procedure(s) they perform, estimated to be a quarter of the total guidance. Assuming a gross hourly rate for practitioners of £15.80²⁵³,²⁵⁴, there are approximately 2,086 practitioners undertaking the specified procedures in Wales²⁵⁵, and the above actions would take two hours per practitioner, costs to practitioners/businesses would amount to approximately £65,900 in 2017-18. There would also be an annual cost of approximately £12,000 for new practitioners to familiarise themselves with the guidance. However, this may overestimate the costs as it is likely that some of these practitioners and businesses already follow best practice methods, while others may decide not to follow the guidance as it would be voluntary.

574. Similarly, when the guidance is updated every three years, practitioners and businesses may incur some time familiarising themselves with the revised guidance and on implementing any changes. As it is anticipated that only limited changes would be made, the cost per practitioner would be expected to be no more than half those incurred in 2017-18, at an estimated total of £33,000.

Table 7.15 – summary of additional costs associated with option two

Costs (£)	2017-18	2018-19	2019-20	2020-21	2021-22
Welsh Government costs					
Staff costs for development of guidance	16,600	0	0	1,000	0
Translation and design	3,400	0	0	1,700	0
Printing and distribution of guidance	5,300	0	0	0	0
Training	2,400	0	0	0	0
Publicity	10,000	0	0	10,000	0
Total Welsh Government costs	37,700	0	0	12,700	0
Local authority costs					
Staff time dealing with	38,400	38,400	19,200	19,200	19,200

²⁵³ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime;(artist).

<http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable2015>

²⁵⁴ Hourly rates have been increased by a factor of 30% to incorporate on costs.

²⁵⁵ Based on information provided by local authorities

ad hoc queries from practitioners and businesses on the guidance					
Total local authority costs	38,400	38,400	19,200	19,200	19,200
Business costs					
Time spent familiarising themselves with the guidance and implementing any changes to their practice	65,900	12,000	12,000	33,000	12,000
Total business costs	65,900	12,000	12,000	33,000	12,000
Overall total cost	142,000	50,400	31,200	64,900	31,200

Benefits

575. It is estimated under option one there are complaints relating to 70 practitioners and businesses carrying out these procedures in Wales each year. It is possible that producing and circulating guidance about safe working practices for those performing these procedures, along with educational messaging and increased public awareness, could help to reduce this number. The production of guidance may also introduce a consistent approach with regard to enforcement. Any improvements would result in reductions to the NHS costs outlined under option one. However, as there would be no legal requirement underpinning the guidance, its impact is not likely to be high.

Option 3A – Introduce a special procedures licensing system

Description

576. This option would involve repealing the Local Government (Miscellaneous Provisions) Act 1982 in relation to Wales and introducing legislation to create a compulsory, national licensing system for the practice of special procedures in Wales. These special procedures would

be defined in the legislation as acupuncture, body piercing, electrolysis and tattooing (which includes semi-permanent skin colouring). In order to perform any of these special procedures, an individual would need to be licensed and the premises (including vehicles) which they practice from approved. Local authorities would be responsible for assessing practitioners and inspecting premises to ensure they meet specified criteria before a licence could be granted or premises approved. It is anticipated the earliest that the licensing system would become operational is in 2018-19 – until this point, the existing registration system is expected to continue.

577. Similarly to option two, the Welsh Government would develop guidance in relation to special procedures to assist practitioners and businesses in understanding the legislation and its requirements. Guidance aimed at local authorities would also be produced to assist local authorities with their enforcement of the legislation. The development of the guidance would involve working with practitioners and businesses from the sector, local authorities, Public Health Wales and other interested parties. Copies would be available online or in paper copy, and be distributed to local authorities and businesses and practitioners providing special procedures.

578. The Welsh Government would provide training and guidance to local authorities about the content and enforcement of the legislation.

579. In addition, the Welsh Government would undertake an awareness-raising campaign about the licensing system. The campaign would have two major components:

- a. Raising awareness about the licensing system among practitioners and businesses. This would involve direct correspondence with those who will be subject to the legislative requirements;
- b. Dissemination of information to the public to inform them of the licensing system and the risks of not visiting a licensed practitioner/ approved premises.

580. The licensing system proposed under this option would replace the system outlined under option one. The costs outlined below would be incurred in place of the costs under option one - the costs presented below are not additional to those under option one.

Costs

Welsh Government

581. There would be costs to the Welsh Government for the development, design and translation of two sets of guidance (one aimed at practitioners and businesses, the other at local authorities). To produce both sets of guidance (25,000 words for the practitioners' and businesses' guidance document and 25,000 words for the local authority guidance document), it

is anticipated it would take approximately six months of a 0.75 FTE senior executive officer (equating to £20,700) and six months of a 0.4 FTE team support (equating to £5,500). This would give a total cost of £26,200.²⁵⁶

582. It is anticipated that design and typesetting would require four weeks of a FTE executive officer, which would cost approximately £2,900. It is estimated that translation and proofreading would cost approximately £4,800.²⁵⁷ The total cost for the development, design and translation of guidance is therefore £33,900.

583. As set out in option two, distribution of the guidance would involve sending a copy to all premises undertaking special procedures in Wales (approximately 890 registered premises). Five copies of the local authority guidance would be sent to each local authority in Wales, resulting in a total of approximately 1,000 paper versions being produced. Printing would cost approximately £4,400 and the distribution £1,500, giving a total cost of £5,900 (based on previous work undertaken by the Welsh Government). Electronic versions of the guidance would also be available.

584. It would therefore cost a total of approximately £39,800 for the initial development, production and distribution of the guidance. These costs would be incurred in 2017-18.

585. The guidance would be updated every three years. It is anticipated that this would take approximately two weeks of a FTE higher executive officer's time, which would equate to approximately £2,000. Design and translation costs would amount to half the original costs, a total of £3,900. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £5,900, incurred every three years. The first review would take place in 2020-21.

586. Similar to option two, training sessions would be provided to EHOs or other relevant local authority staff to support them in their enforcement of the legislation. The training would be paid for by the Welsh Government and be contracted out to a supplier credible to the environmental health profession. It is anticipated that four sessions would be held across Wales. These training sessions would take place in 2017-18. The cost of the development of course material and hand-outs would be approximately £1,600, and the cost of running the four sessions with 35 people attending each would be approximately £3,200, giving a total cost of £4,800. If this training was combined with that for the implementation of the prohibition on the intimate piercing of persons under 18, the expectation is that savings could be made overall. The time required to attend training would be incorporated into annual training time.

²⁵⁶ Based on Welsh Government Staff Planning Costs

²⁵⁷ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

587. The awareness-raising campaign would focus on informing practitioners and businesses, as well as the public, of the licensing system. As the legislation would include new offences, it is envisaged a more extensive communications package would be required than that outlined in option two. To communicate with practitioners and businesses providing special procedures, the Welsh Government would communicate directly with those who would be subject to the legislation via direct mail, prior to the legislation coming into force. Local authorities currently register those providing these procedures and therefore those contact details would be used. News stories would be provided to trade journals and other stakeholder networks, as well as social media and targeting relevant websites would further raise awareness amongst the trade. This work is estimated to cost up to £10,000 and would be a one-off cost incurred in 2017-18. However, as part of the review process, consideration would be given to the need to repeat communications work at a later date, in order to maintain awareness of the new legislation. The precise costs associated with this work would depend upon the outcome of the review and are therefore currently unknown.
588. Wider communications work would focus on alerting the public, including young people and parents, of the possible health issues surrounding special procedures and the importance of ensuring the practitioners/business visited for an acupuncture, body piercing, electrolysis or tattooing procedure are licensed and the premises they operate from are approved. This would include public relations, social media and working with schools/youth organisations. The public awareness-raising campaign is estimated to cost £10,000. As with option two, if the communications work for special procedures were integrated with that for a prohibition on the intimate piercing of persons under 18, savings could be made. Although it is anticipated the communications costs would be incurred in 2017-18, consideration would be given to the need to repeat communications work at a later date, in order to maintain or enhance awareness of the new legislation. The precise costs associated with this work would depend upon the outcome of the review and are therefore currently unknown.

Local authorities

589. The legislation would require local authorities to enforce the requirements of the licensing system. Local authorities would be required to licence those individuals they consider meet the defined criteria and to monitor their adherence to the licensing conditions, as well as to approve premises/vehicles from which special procedures can be performed. In addition, local authorities would be required to enforce the legislation when necessary, including taking forward action to prevent special procedures being undertaken by unlicensed practitioners and in unapproved premises. As detailed in option one, local authorities already have limited powers to control businesses providing acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis, and already undertake enforcement activity in relation to

these businesses. However, the new licensing system would introduce more stringent requirements in order to protect public health and therefore it is expected that enforcement activity in relation to these procedures would need to increase.

590. With regard to the licensing of individual practitioners, local authorities would be required to consider and process an application and if agreed, produce a licence. It is anticipated the cost to local authorities would be around £60 per licence²⁵⁸. The legislation requires the licence to contain a photograph of the licence holder; the cost of producing a photographic licence is included in the £60. In some cases, the local authority may need to meet the applicant to discuss their application, but this would be decided on a case-by-case basis. Accordingly, no cost estimate has been included for such discussions.
591. It is estimated there are currently 2,086 individuals performing special procedures in Wales.²⁵⁹ Taking this figure as an estimate of the number of personal licences that would be issued, it is estimated the total cost to local authorities to process and issue personal licences would be £125,200. This would be incurred shortly following the licensing system becoming operational in 2018-19. It has been assumed that there are 380 new individual practitioners each year, resulting in licence costs for these new practitioners of £22,800 per annum from 2019-20. As the practitioner licences would be valid for three years, these costs would recur on a three-yearly basis. However, for the purposes of cost calculations it has been assumed that an equal number of practitioners will cease trading each year (380 individual practitioners will cease trading each year). Therefore the renewal costs in 2021-22 would be lower than the licence costs in 2018-19.
592. In order to approve premises from which special procedures are performed, it is expected that the local authority would process the application and undertake an inspection visit. If the premises were to meet the required conditions, it would be approved by the local authority and an approval certificate issued for display. It is anticipated the cost to the local authority would be around £170 per premises approval.²⁶⁰ It is estimated that there are currently 890 premises from which the defined special procedures are currently performed in Wales²⁶¹. Taking this figure as an estimate of the number of premises approvals that would be issued under the new licensing system, it is estimated the cost to local authorities to process and issue premises approvals would be £151,300 in 2018-19. It has been assumed that there are 190 new businesses opened per year, resulting in costs for these new businesses of £32,300 per annum from 2019-20.

²⁵⁸ Figure provided by local authorities

²⁵⁹ Based on information provided by local authorities

²⁶⁰ Figure provided by local authorities

²⁶¹ Based on information provided by local authorities

593. As the premises approval would be valid for three years, these costs would recur on a three-yearly basis. However, for the purposes of cost calculations it has been assumed that an equal number of businesses will cease trading each year (190 premises will cease trading each year). Therefore the renewal costs in 2021-22 would be lower than the costs in 2018-19, as shown in the table below. There would be ongoing renewal costs from 2022-23, but these would be lower than in 2021-22.

Table 7.16:

Registration administration costs					
	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Practitioner licences and Premises approval admin costs	32,300*	276,500	55,100	55,100	55,100
Renewal admin costs	0	0	0	0	166,300
Total costs	32,300	276,500	55,100	55,100	221,400

*registration costs incurred under the existing system (option one).

594. Should a local authority intend to refuse to grant, renew or vary a licence or application for approval of premises, it would have to issue a notice to the applicant, who could then make representations to the local authority's licensing committee. The applicant could appeal against the committee's decision to a magistrates' court. As it is anticipated local authorities would work closely with those seeking a licence/premises approval, it is not expected that there would be a high number of representations to be heard by a licensing committee or appeals heard by a magistrates' court. On that basis, it is estimated costs associated with representations or appeals would be minimal, but these are unknown at present.

595. Local authorities would also be responsible for monitoring compliance with the legislation during the duration of the licence or premises approval. This would involve working with licence holders and approved premises to ensure compliance. As is the case under the current registration scheme, it is expected that local authorities would undertake risk based compliance visits, with more frequent visits to those providing tattooing and body piercing than other special procedures. As described in option two, it is estimated there are around 462 businesses providing tattooing and body piercing procedures in Wales and one compliance visit is estimated to cost £170. Across all local authorities, compliance visits are estimated to cost a total of approximately £78,500 a year.

596. If a local authority had concerns (raised for example during a compliance visit or via a complaint) that a licence holder or an approved premises was contravening their mandatory licensing conditions, it could issue a remedial action notice (RAN) to the licence holder or the person holding the premises approval to require specified action. There would be a compliance period of at least 14 days within which the prescribed action must be taken to avoid committing an offence. It is estimated 5% to 10% of those holding a licence or premises approval would be issued with a RAN annually. The cost of a RAN is estimated to be £380²⁶², including officer time, visits, administration and notifying interested parties. Assuming there are between 150 and 300 RANs issued in the first year, the total cost is estimated to be between £57,000 and £114,000. It is assumed businesses and the public would become more familiar with the legislation over time and that this would drive up standards, leading to a 10% reduction in the number of RANs issued year-on-year until 2021-22, after which the number issued would level off.
597. Local authorities would also have the power to prevent special procedures being carried out by unlicensed persons or in unapproved premises. Local authorities would need to identify unlicensed individuals and then issue a stop notice, which would have the effect of prohibiting the performance of a special procedure. As outlined in option two, local authorities currently use powers under the Public Health (Control of Disease) Act 1984 to apply for a Part 2A Order to prevent a person from carrying out unregistered tattooing. It is estimated six Part 2A Orders are applied for and granted annually in relation to this practice.
598. This option would provide more comprehensive powers to deal with prohibited activity, via a more straightforward process. Given this more comprehensive approach, it is estimated there could be approximately 50 instances across Wales in the first year where a local authority would issue a stop notice. While the process set out under this option would be different to that provided for by the Public Health (Control of Disease) Act 1984, there would be parallels in relation to the cost of investigating and executing a Part 2A Order. It is therefore estimated the costs associated with preventing unlicensed/unapproved activity in the first year would be between £40,000 and £150,000 (the cost per case is estimated to be between £800 and £3,000, depending on the complexity of the case)²⁶³. It is assumed that businesses and the public would become more familiar with the legislation over time, and that this would drive up standards, leading to a 10% reduction in the number of stop notices issued year on year until 2021-22, after which the number issued would level off.
599. Some of these costs could be met if a magistrates' court awarded a contribution towards the prosecution costs to the local authority if the

²⁶² Data provided by local authorities

²⁶³ Based on the costs associated with current Part 2A Orders

case was successful. However, the court could also order the local authority to compensate an individual for loss of income. These costs have not been included as they are difficult to estimate due to their variability.

600. This option would also require local authorities to maintain a register of special procedures licences and approved premises to be available to the public. It is expected that local authorities would use their own websites to make this information available to the public at minimal additional cost. There would be a cost to maintain the information and ensure it is up to date. The annual administrative cost to local authorities to maintain the accuracy of their data is estimated to be approximately £9,300 (two hours of administrative time per month per local authority).

601. There would also be other local government staff costs associated with developing the guidance, attending training sessions, raising general awareness and dealing with ad hoc queries about the new legislation. It is estimated this work would be greater in the run up and during the first year following the introduction of the new legislation, and in total would amount to no more than the equivalent of a month of a FTE EHO per local authority each year in the first two years, reducing to half this for subsequent years. This would equate to approximately £76,800 (£3,490 per local authority) in 2017-18 and 2018-19, with the cost reducing to approximately £38,400 (£1,745 per local authority). However, if this work was integrated with that for a prohibition of the intimate piercing of persons under 18, the expectation is that some savings could be made overall. At this stage, it is not possible to accurately estimate these potential cost savings.

Table 7.17:

Compliance and other administrative costs					
	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Annual compliance checks	78,500*	78,500	78,500	78,500	78,500
Issuing RANS/compliance checks	11,900*	57,000 - 114,000	51,300 – 102,600	46,200 - 92,300	41,600 – 83,100
Preventing unlicensed activity	4,800 – 18,000*	40,000 – 150,000	36,000 – 135,000	32,400 - 121,500	29,200 – 109,400
Maintenance of data on register	-	9,300	9,300	9,300	9,300
Other general costs	76,800	76,800	38,400	38,400	38,400
Total costs	172,000-185,200	261,600-428,600	213,500-363,800	204,800-340,000	197,000-318,700

*cost under existing registration system (option one)

602. This option would enable local authorities to set reasonable fees to cover the costs of administering applications in line with the *Hemming* judgment, and to separately charge licence holders a fee for the cost associated with running and enforcing the licensing system. There would therefore be a significant degree of cost recovery available to local authorities in administering the system. Licensing/approval fees, in addition to the core funding provided to local authorities via the RSG, would meet the cost of running the licensing system.

Practitioners and businesses which carry out special procedures
(acupuncture, body piercing, electrolysis and tattooing)

603. Practitioners and businesses would be likely to incur costs from time spent familiarising themselves with the new requirements and associated guidance. Although the guidance is estimated to be approximately 25,000 words in length, it would outline the recommended practices for each special procedure in detail. It is therefore unlikely practitioners would be required to read the whole document in detail. It is assumed practitioners would only read the guidance relevant to the procedure(s) they perform – estimated to be a quarter of the total guidance. Failing to comply with the new legislation could lead to a prosecution, therefore it is envisaged that a longer period would be required for this familiarisation work (three hours) than with option two. However, the other assumptions relating to this work outlined for option two are considered to remain relevant. This would suggest a total cost for this familiarisation work to business of approximately £99,900 in 2018-19. This equates to a cost per practitioner of £47, given a total of 2,086 practitioners. There would be ongoing annual costs for new practitioners to familiarise themselves with the new legislation.

604. As with option two, the guidance would be updated every three years at which time practitioners and businesses may incur some costs from familiarising themselves with the revised guidance and in implementing any required changes. As this would be a revision of guidance it is anticipated that costs would be no more than half those experienced in 2018-19, at an estimated £50,000. The first update is expected to take place in 2021-22.

Table 7.18:

Practitioner familiarisation cost					
	2017-18 (£)	2018-19 (£)	2019- 20(£)	2020-21 (£)	2021-22 (£)
Familiarisation costs	0	99,900	18,600	18,600	18,600

Review familiarisation costs	0	0	0	0	50,000
Total cost	0	99,900	18,600	18,600	68,600

605. Practitioners and businesses would be required to apply to the local authority for a licence or premises approval. This application process is expected to be straightforward and in most cases would be carried out online. While the intention would be to keep the application process as simple as possible, there would be some degree of staff time involved in completing an application. It is expected a premises application would take approximately 30 minutes. The legislation would require a practitioner's special procedures licence to contain a photograph of the licence holder. In some cases this may require the applicant to visit the local authority office to have the photograph taken. The total time to apply for a practitioner special procedures licence would therefore be around 1.5 hours.

606. In addition, local authorities will have the power to request a practitioner to provide a Basic Disclosure Certificate as part of the application process. The cost to a practitioner of applying for such a certificate is £25²⁶⁴. This cost will be applicable for each new application or renewal of an application. Therefore, this cost will apply on the initial application and then every three years on renewal. Assuming all local authorities request a Basic Disclosure Certificate to be provided and there are 2,086 applications from current practitioners, this will cost £52,150 in the first year (2018-19) and then vary with the number of new applications or renewals in a particular year.

607. Assuming a gross hourly rate for practitioners of £15.80^{265,266} and there would be 2,086 applications for licences and 890 for premises approvals²⁶⁷, it is estimated costs incurred through making applications would amount in total to approximately £108,700. There would be annual costs for the completion of new applications of £10,500. Renewal of licences would take place every three years, although it is assumed the cost to business for the completion of applications would be halved as the process would be more straightforward.

Table 7.19:

Opportunity cost of application completion					
	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)

²⁶⁴ <https://www.mygov.scot/basic-disclosure/>

²⁶⁵ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (artist). <http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworking/hours/datasets/regionbyoccupation4digitsoc2010ashtable2015>

²⁶⁶ Hourly rates have been increased by a factor of 30% to incorporate on costs.

²⁶⁷ Based on information provided by local authorities

Premises applications	4,500*	7,000	1,500	1,500	1,500
Practitioner applications		49,500	9,000	9,000	9,000
Renewal of premises approval	0	0	0	0	2,000
Renewal of practitioner licence	0	0	0	0	15,700
Basic Disclosure Certificate	0	52,200	9,500	9,500	43,700
Total costs	4,500*	108,700	20,000	20,000	71,900

*cost under existing registration system (option one)

608. In addition to the staff time involved in following the application process, there would be a fee to obtain an individual licence or approval of premises. The fee structure would be set by each local authority but the Welsh Government would encourage local authorities to set proportionate universal fees in line with the *Hemming* judgment. It is anticipated an individual licence would cost £60 and premises' approval would cost £170. This would amount to an initial total cost of £276,500, which would be incurred in 2018-19. Assuming 190 new businesses starting each year and 380 new practitioners registering, there would be ongoing annual costs of £55,100 for new registrations. Renewal of licences would take place every three years as detailed in the table below:

Table 7.20:

Registration costs					
	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Individual and premises costs	52,400*	276,500	55,100	55,100	55,100
Renewal costs	0	0	0	0	166,300
Total costs	52,400*	276,500	55,100	55,100	221,400

*cost under existing registration system (option one)

609. It is expected there would be a high compliance rate with the legislation. Contraventions of the legislation, such as performing special

procedures without being licensed or performing special procedures from premises which have not been approved, would result in a stop notice. Breach of a stop notice would be subject to an unlimited fine to reflect the seriousness of the offence. It is not possible to provide a definitive figure as to the fines that would be given as magistrates' courts would have a wide discretion; however for the purposes of this exercise a £5,000 fine has been used to calculate costs. It was estimated earlier there could be approximately 50 cases of a person being issued with a stop notice in the first year. It is anticipated approximately 10 of these would result in a fine – giving a total annual cost of up to £50,000 to unregistered practitioners in the first year (2018-19). It was estimated earlier there would be a 10% reduction in the number of stop notices issued year on year and this would lead to approximately one fewer fine per year. The proceeds from these fines would be retained by HM Courts and Tribunals Service. It is envisaged there would be minimal appeals against stop notices.

610. It was estimated earlier that between 150 and 300 RANs, setting out required action in order to meet the mandatory licensing conditions, would be issued to registered practitioners and premises in the first year. It was also estimated there would be a 10% reduction in the number of RANs issued year on year. It is anticipated that in the vast majority of cases, practitioners and premises would work with the local authority to fulfil the recommended action. As the cost of remedial action could vary greatly, and is currently largely unknown, it has not been estimated here.
611. Contravention of a RAN would be subject to an unlimited fine. It is estimated 5% of RANs issued would result in a fine for non-compliance. Assuming individual fines would amount to £5,000, the total cost of fines to practitioners and businesses could therefore be between £40,000 and up to £75,000 in the first year (2018-19). It is anticipated this would reduce by approximately one RAN every year until 2021-22, after which the number issued would level off.
612. As the costs incurred would be proportional to the size of the business it is anticipated that any impact on competition would be minimal. Furthermore, better regulation may increase confidence in the special procedures sector in Wales and generate additional custom.

Courts

613. Appeals in relation to the legislation – such as an appeal against a refusal to grant a licence or premises approval application or against fines levied in relation to enforcement action such as contravention of a RAN – could be made to the magistrates' court. However, it is expected local authorities would assist practitioners and businesses and provide the opportunity for them to become compliant with the legislation before any further action was taken. As many representations would be heard in the first instance by a local authority's licensing committee, it is expected only a very small number of appeals would be made to a magistrates' court – this is estimated at 10 to 15 cases each year in Wales. A detailed costing

framework of the cost for these appeals has not yet been discussed between the Welsh Government and the Ministry of Justice so these costs are unknown at present.

Table 7.21: summary of costs associated with option 3A

Sector	Year				
	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government costs					
Development, design, translation, production and distribution of two sets of guidance	39,800	0	0	3,900	0
Staff costs for review of the guidance	0	0	0	2,000	0
Training sessions	4,800	0	0	0	0
Awareness raising campaigns for both practitioners, businesses and members of the public	20,000	0	0	0	0
Total cost to Welsh Government	64,600	0	0	5,900	0
Additional costs	62,100*	-2,500*	-2,500*	3,400*	-2,500*
Local authority costs					
Practitioner licences and Premises registration costs	32,300**	276,500	55,100	55,100	55,100
Renewal costs	0	0	0	0	166,300
Annual compliance checks	78,500**	78,500	78,500	78,500	78,500
Issuing of RANS /compliance checks	11,900**	57,000-114,000	51,300-102,600	46,200-92,300	41,600-83,100
Preventing unlicensed activity	4,800-18,000**	40,000 – 150,000	36,000 – 135,000	32,400-121,500	29,200-109,400
Maintenance of data on register	-	9,300	9,300	9,300	9,300

Other general costs	76,800	76,800	38,400	38,400	38,400
Total cost to local authorities	204,300-217,500	538,100-705,100	268,600-418,900	259,900 - 395,100	418,400 - 540,100
Additional costs	61,800	171,500-325,300	123,400-260,500	114,700 - 236,700	106,900 - 215,400
Business costs					
Guidance familiarisation costs	0	99,900	18,600	18,600	68,600
Application opportunity costs	4,500**	108,700	20,000	20,000	71,900
Registration costs	52,400**	276,500* **	55,100***	55,100* **	221,400 ***
RANs resulting in an unlimited fine	0	40,000-75,000	35,000-70,000	30,000-65,000	25,000-60,000
	56,900**	525,100-560,100	128,700 - 163,700	123,700 - 158,700	386,900 - 421,900
Additional costs	0	468,200 - 503,200	71,800 - 106,800	66,800 - 101,800	330,000 - 365,000
Unregistered practitioner costs					
Stop Notices issued – unlimited fine	0	50,000	45,000	40,000	35,000
Additional Costs	0	50,000	45,000	40,000	35,000
Total cost**	273,400-286,600	836,700-1,038,700	387,200-572,500	374,400 - 544,600	618,900 - 775,600
Costs additional to Option 1	123,900	687,200-876,000	237,700-409,800	224,900 - 381,900	469,400 - 612,900

* the Welsh Government currently incurs a cost of £2,500 per annum in option one for an annual review of Part 2A orders – but this cost would not be incurred under this option.

**costs under the existing registration system (option one)

***one-off registration fees incurred by practitioners and businesses have not been included in the total cost as they are paid to local authorities and used to off-set the costs incurred in administering the licensing scheme.

Benefits

NHS savings

614. The main benefit of the licensing system is savings to the NHS, in terms of treatment costs, and to individuals' health. As explained earlier, there are known and well-reported health risks, which are associated with skin piercing procedures. Under option one, it was estimated the complications associated with tattooing and cosmetic piercing result in a minimum annual cost to the NHS of £95,300 to £342,000. Any reduction in the complications arising from special procedures would result in a reduction in costs to the NHS.
615. Any avoided complications would also lead to QALY gains for individuals, although they cannot be quantified here. One QALY is valued at £60,000. The cumulative net cost of option 3A over and above maintaining the status quo outlined in option one is between £1,743,100 and £2,404,500 over a five-year period. The licensing scheme would need to lead to between 29 and 40 QALY gains in order to be cost neutral.

Other benefits

616. It is considered the current legislation is inadequate to sufficiently protect the public – this view is supported by stakeholder responses to the Public Health White Paper consultation.²⁶⁸ The licensing system under this option would impose requirements on practitioners and businesses, which would be expected to drive up standards and ensure all special procedures are undertaken in a safe and appropriate manner. As the legislation would also provide appropriate enforcement mechanisms, it is expected that local authorities would find they are able to deal with contraventions in a more straightforward way and therefore more effectively safeguard public health. In addition, it is unlikely local authorities would need to pursue Part 2A Orders as they would have more effective mechanisms to deal with unauthorised practices.
617. The majority of licence holders who perform special procedures and the premises where they are performed would also gain reputational benefits. By meeting the licensing requirements, they would be able to independently demonstrate to the public that they meet appropriate standards of hygiene and cleanliness as well as undertaking appropriate infection control procedures.
618. The communications package outlined earlier would be important in making practitioners, businesses and the public aware of the licensing system. Public knowledge about the dangers of using unlicensed practitioners and unapproved premises – and of undertaking the procedures themselves or from an untrained friend – would increase. As local authorities would be required to make information available to the public about the licences they have issued and the premises they have approved, anyone seeking to have a special procedure would be able to find out from their local authority's website which practitioners and

²⁶⁸ <http://wales.gov.uk/consultations/healthsocialcare/publichealth/?lang=en>

businesses have met the national standards. This would help to further improve transparency and ensure people are better informed.

619. In addition to the potential NHS savings identified above, the licensing system may have wider economic benefits if an improvement in standards within the sector results in fewer instances of workplace absence due to complications following a procedure.

Option 3B - Introduce a special procedures licensing system with a central register of all licensed practitioners and approved premises (or vehicles) providing special procedures

620. In addition to the compulsory, national licensing system detailed in option 3A, this option would include the development of a website to host a national register of all licensed practitioners and approved premises (including vehicles) providing special procedures in Wales. The central register would be hosted by a lead local authority and would be available to all local authorities for enforcement purposes, and be available to view by members of the public. The assessment of costs and benefits under option 3B therefore focuses solely on the element which is additional to option 3A.

Costs

Welsh Government

621. All costs discussed under option 3A are replicated in this option. In addition, there are the costs for the development of the central register and its ongoing management.
622. There would be an initial cost to develop the online register. It would include information about practitioners and premises gathered under the licensing system (fully outlined under option 3A). The development of the register could be procured by the Welsh Government or be undertaken by a lead local authority. Based on information from the Scottish tobacco retailers' register, it is estimated the initial cost of development could be approximately £26,900 in 2017-18.
623. Staff time would be required to procure and manage the web development contract. It is estimated that this would require approximately three weeks' of a FTE higher executive officer's time, costing approximately £2,900 in 2017-18.

Local authorities

624. Staff time would be required to populate the central register with data collected by each local authority. It is estimated that to transfer the data to a central register, approximately three weeks of a FTE administrative officer's time would be required, amounting to £2,100 incurred in 2018-19.

625. Once a central register was established, each local authority would be required to maintain the data relevant to its area, and update it as necessary. This would be similar to the requirement in option 3A whereby each local authority will be required to provide details to the public of all special procedures licences and approved premises. Under option 3A, it was estimated the annual administrative cost to local authorities would equate to approximately £9,300 from 2018-19 onwards (two hours of an administrative officer's time per month per local authority). It is anticipated these costs would be replicated under this option, as local authorities would be required to publish the data within a central register.

626. In addition to the development costs there would be ongoing ICT management costs to cover maintenance issues, such as back up to avoid data loss, server costs, and costs to resolve technical issues. Based on information from Scotland (in relation to its tobacco retailers' register), it is anticipated these annual costs could be approximately £10,000, to be shared between local authorities. These would be incurred annually from 2018-19.

Practitioners and businesses which carry out special procedures (acupuncture, body piercing, electrolysis and tattooing)

627. There would be no additional costs to practitioners and businesses beyond those outlined under option 3A. There would be no need to provide any information beyond the requirements set out in the licensing system under option 3A.

628. All costs outlined under option 3A would apply to this option. The costs outlined below are in addition to the costs set out in option 3A.

Table 7.22: summary of additional costs associated with option 3B

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government					
Management of web development contract	2,900	0	0	0	0
Development of central register	26,900	0	0	0	0
Total cost to Welsh Government	29,800	0	0	0	0
Local authorities					
Initial data transfer	0	2,100	0	0	0
Maintenance	0	9,300	9,300	9,300	9,300

and updating of data					
ICT Maintenance Costs	0	10,000	10,000	10,000	10,000
Total cost to local authorities	0	21,400	19,300	19,300	19,300
Total cost (additional to option 3A)	29,800	21,400	19,300	19,300	19,300

Benefits

NHS savings

629. The NHS savings outlined under option 3A would be the same under this option.

Local authorities

630. All information in relation to licence holders and premises would be located within one central database, with enforcement information available for viewing by all local authorities in Wales. It is anticipated that a central register would help local authorities in their monitoring and enforcement responsibilities. This would particularly be the case with respect to practitioners operating across local authority boundaries. This benefit is not able to be quantified.

Practitioners and businesses which carry out special procedures (acupuncture, body piercing, electrolysis and tattooing)

631. The central register would assist practitioners and businesses to raise awareness of their status as having met the licensing requirements and enable potential clients to contact them. If a practitioner, business or member of the public became aware of a person acting in contravention of the legislation, they would be able to check the central register and inform the local authority.

The public

632. The public would have access to a central accessible, searchable facility from which to find a practitioner in their area who is licensed, or premises which have been approved. This information would also be available under option 3A, but under this option, it would be available on a central online register rather than on separate local authority websites.

Summary and preferred option

633. Option one maintains the status quo and does not meet the policy objective. It continues the position whereby there is an inconsistent approach to enforcement adopted by local authorities. The powers which are available to control businesses providing acupuncture, tattooing, semi-permanent skin-colouring, cosmetic piercing and electrolysis are considered insufficient.
634. Option two takes a voluntary approach to the provision of guidance. This could encourage practitioners and businesses to take action to strengthen their existing practice and policies in relation to the performance of the procedures or encourage those who do not currently have a policy to develop one. There may also be increased awareness among the public of the possible health issues surrounding these procedures and the importance of ensuring the practitioner/ business they visit is registered. However, as this option is based on voluntary action alone, the impact is not likely to be significant.
635. Option 3A proposes mandatory licensing of those who provide special procedures in Wales, to which national standards would be attached. It aims to improve standards and ensure an improved and consistent approach to the regulation of these procedures across Wales. The supporting guidance and communications activity is considered to provide the best balance between cost and the likelihood of achieving the policy objective and the resulting tangible and intangible benefits for clients, the NHS, practitioners and businesses.
636. Option 3B extends the previous option further by creating a central register of practitioners and premises. It is recognised that such a central register would confer some benefits for local authorities, businesses and the public, increasing the ease with which information could be accessed. However, given the provisions which would already be made under option 3A, it is not anticipated that a central register would be pursued initially. Option 3A is therefore the preferred option at the current time. Option 3B could be given further consideration in due course.

Intimate piercing (Part 4)

Options

637. Three options have been considered:

- Option one – Do nothing;
- Option two – Issue guidance to practitioners/businesses discouraging the performing of an intimate piercing on a person who is under the age of 18;
- Option three – Introduce a prohibition on the performing of an intimate piercing on a person who is under the age of 18. This is the preferred option.

Option one – Do nothing

Description

638. There would be no change to the current situation under this option. While some practitioners/businesses in Wales already do not perform intimate piercing – a piercing of the nipples, breast, genitalia, buttocks or tongue – on young people, it would still be legally possible for a person under 18 to have an intimate piercing if they wished.

Costs

639. As this option proposes no change, there would be no additional costs. However, it is likely there will be some costs to the NHS in relation to the treatment of complications associated with a body piercing, such as swelling, infection, bleeding, allergy and tear or injury²⁶⁹. Nerve damage and scarring may also occur if procedures are poorly performed. In addition, for tongue piercing specifically, fracturing and chipping of teeth have been reported.²⁷⁰ While rare, complications from a body piercing can result in a hospital admission and may be particularly serious for those with underlying health conditions.

640. The health costs associated with one case of an infected intimate piercing treated within primary care can be estimated at around £34, as shown in the table below:

Table 7.23:

Description	Cost (£)
Consultation with a GP ²⁷¹	31.70
Treatment cost of a skin infection attributable to an intimate piercing ²⁷²	(Seven-day course of oral antibiotics) 2.28

641. It is not possible to accurately scale up these costs to the NHS in Wales. Although there are case study data on young people having an intimate piercing in Wales – for example, 75 under-18s were identified as having an intimate piercing in the look-back exercise related to a body

²⁶⁹ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

²⁷⁰ Stead LR, Williams JV, Williams AC and Robinson CM (2006) An investigation into the practice of tongue piercing in the South West of England British Dental Journal 200 103-107.

²⁷¹ Cost estimated by the Welsh Government, on the basis that the direct cost of providing GMS services through the contract is approximately £430 million (excluding out of hours), approximately 16,953,000 consultations for Wales' 3.082,400 population and that 25% of the consultations are excluded as they are with a nurse or other health professional at a weighting of 25% of GP cost.

²⁷² Drug Tariff August 2016:

http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PPD%20Drug%20Tariff/August_2016.pdf. Clarithromycin, 500mg 14-tab pack.

piercing and tattooing studio in Newport²⁷³ - the overall number of intimate piercings among under 18s in Wales is not known, nor is there any specific evidence on the rate of health complications from intimate piercing for this age group.

642. As data from other countries are also limited, an estimate of the health costs arising from this option has been based on the most relevant data available. These data are from Bone et al's study²⁷⁴ of 16 to 24-year-olds in England, which show that 6.5% (range 5.3% - 8.0%) reported having a tongue piercing, 3.5% (2.6 – 4.7%) having a nipple piercing and 0.8% (0.4%-1.5%) a genital piercing. Three per cent (1.8%- 4.8%) of those having body piercings reported seeking help for complications from a GP.

643. Using these data the following assumptions have been made:-

- There are 133,413 14 to 17-year-olds in Wales²⁷⁵;
- The prevalence of intimate piercing for under 18s varies from 0.8% for genital piercing (from Bone et al's study) to 6.5% for tongue piercing (from Bone et al's study);
- The rate of seeking NHS help for complications with an intimate piercing, from a pharmacist, GP, attendance at an A&E department or as an inpatient, is 7.7%, 4.8%, 2.3% and 3.2% respectively (the upper end of the range for each from Bone et al's study). It is considered the rate of seeking help with complications from intimate piercing will be at the upper end of the range in Bone et al's study, as people under 18 may have less experience or knowledge of how to clean or maintain a piercing to prevent infection.

644. Applying these assumptions suggests there are between 1,067 and 8,672 under 18s having an intimate piercing in Wales each year; between 82 and 668 seeking help from a pharmacist; between 51 and 416 seeking help from a GP; between 24 and 199 attending an A&E department and between 34 and 277 receiving inpatient care. On this basis, the estimated costs to the NHS for complications from an intimate piercing among under 18s could be between £17,929 and £146,402 per year.

645. It should be noted that caution is required in using these figures as they are based on assumptions derived from a single study. They might, in reality, be lower if the prevalence of intimate piercing is lower than estimated above. Equally, the figures could also be higher, as intimate

²⁷³ The Technical Report of a Blood-Borne Virus Look Back Exercise related to a body piercing and tattooing studio in Newport, South Wales. Aneurin Bevan University Health Board, 26th July 2016.

²⁷⁴ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

²⁷⁵ Welsh Government 2014- based national population projections for Wales, 2014-2039. Updated 29 October 2015

piercings have higher complication rates than piercings in most other sites of the body²⁷⁶.

646. In addition, there may be longer-term issues requiring NHS care. As young people continue to grow during their teenage years, an intimate piercing performed at a young age could result in complications as a result of a young person's changing physiology, or there might be psychological issues to address.

647. There may also be some costs to local authorities for the provision of advice to practitioners/businesses about intimate piercing for young people but these are considered to be very limited.

Benefits

648. There are likely to be no additional benefits from this option. Piercing practitioners/businesses would continue with their current activities as there would be no restrictions on their clientele.

Option two – Issue guidance to piercing businesses/practitioners discouraging the performing of an intimate piercing on a person under 18

Description

649. This option would involve the Welsh Government producing non-statutory guidance working with stakeholders from the body-piercing sector and other interested parties (for example, environmental health officers). The guidance would identify actions businesses/practitioners could take to reduce the likelihood of people under 18 having an intimate piercing, such as seeking age verification before performing a piercing. Copies of the guidance would be available online or in paper copy for distribution to those practitioners carrying out intimate piercings.

650. There would be no enforcement of the guidance by local authority enforcement teams, although they would be expected to provide advice on the applicability of the guidance to individual practitioners/businesses. Awareness training about the guidance for local authority staff would be provided, together with an awareness-raising campaign to inform young people about the risks and complications associated with intimate piercing.

Costs

Welsh Government

²⁷⁶ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piecing in England: a survey of piercing at sites other than earlobe BMJ 336 1426

651. There would be costs to the Welsh Government associated with the production of and issuing the guidance. Staffing costs to produce the guidance (based on 4,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £4,800. This is based on approximately three weeks of a FTE higher executive officer (£2,900) to develop the guidance, and three weeks of a FTE team support for administration support (approximately £1,900).²⁷⁷
652. It is anticipated that design and typesetting would require one week of a 0.3 FTE executive officer, which would cost approximately £200. It is estimated that translation and proofreading would cost approximately £400.²⁷⁸ The total cost for the development, design and translation of guidance would therefore be £5,400, incurred in 2017-18.
653. Currently, local authorities have powers under the Local Government (Miscellaneous Provisions) Act 1982 to register those businesses which provide cosmetic piercing but as it is not possible to consistently identify which piercing procedures each business provides, it is not known how many practitioners/businesses in Wales are undertaking intimate piercing. However, assuming priority would be given to providing electronic versions of the guidance, it is anticipated only a small number of paper versions of the guidance would be produced. This would cost no more than £400 and be incurred in 2017-18.
654. The guidance would be updated every three years. It is anticipated this would require approximately one week of a FTE higher executive officer, which would equate to approximately £1,000. Design and translation costs would amount to half the original costs, a total of £300. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,300, incurred every three years. The first review would take place in 2020-21.
655. Training sessions may be necessary for EHOs or other relevant local government staff to support them in encouraging practitioners/businesses to take up the advice in the guidance. It is envisaged this would be paid for by the Welsh Government and be contracted out to a supplier credible to the environmental health profession. It is anticipated two sessions would be held, one in North Wales and one in South Wales. These training sessions would take place in 2017-18. The cost of the development of the course material and hand-outs would be approximately £800 and the cost of running the two sessions with 35 people attending each would be approximately £1,600, a total of £2,400. If this training was combined with that for the implementation of the special procedures provisions, the expectation is that savings could be made overall.

²⁷⁷ Based on Welsh Government staff planning costs

²⁷⁸ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

656. To maximise the potential impact of the new guidance, there would need to be some publicity to raise awareness of the guidance among businesses/practitioners which provide intimate piercing, for example in trade journals and through stakeholder networks. Wider communications work would also be required to alert young people and parents to the possible health and child protection issues surrounding intimate piercing. Such a campaign would be likely to include public relations, social media and working with schools/youth organisations and cost £5,000. As this option requires voluntary action, it is expected the communications work would need to be repeated every three years. If the communication work was integrated with that for special procedures the expectation is that savings overall could be made in 2017-18 and every two years thereafter. The precise cost savings would depend on the activity undertaken and are therefore currently unknown.

Local authorities

657. Local government staff would be encouraged to support the uptake of the guidance as part of their normal work routines, however it is recognised that there would be some local government staff costs. These would cover helping to develop the guidance, attending the training sessions and engaging with practitioners/businesses to encourage them to follow the guidance. As businesses/practitioners would be able to choose whether or not to implement the guidance, encouragement from local government staff to do so could play an important role.

658. EHOs and other relevant local government staff may need to deal with ad hoc queries from practitioners/businesses about the guidance. Additional work would be likely to be greater in the run-up to and during the first year following the introduction of the guidance and, in total, would amount to no more than the equivalent of half a month of a FTE EHO²⁷⁹ per local authority in these two years, reducing to half this amount for subsequent years. This would equate to approximately £38,400 (£1,745 per local authority) in 2017-18 and 2018-19, with the cost subsequently reducing to approximately £19,200 per annum (£873 per local authority). However, if this work was integrated with that for special procedures, savings could be made. The precise cost savings would depend on the activity undertaken and are therefore currently unknown.

Practitioners/businesses

659. Practitioners/businesses may incur some costs from time spent helping to develop and familiarise themselves with the guidance and implementing any changes to prevent young people under 18 from having an intimate piercing. Assuming an average gross hourly rate for cosmetic piercers of £15.80^{280,281}, there are approximately 1,000

²⁷⁹ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

²⁸⁰ ASHE 2015 (provisional) Work Region Occupation Table 15.6a Hourly pay excluding overtime; (artist - non Wales data).

practitioners/businesses undertaking intimate piercing in Wales²⁸² and the above actions would take two hours, costs to practitioners/businesses would amount to approximately £31,600 in 2017-18. However, this may over-estimate the costs as it is likely that some of these practitioners already do not perform intimate piercing on under 18s, while others may decide not to follow the guidance as it would be voluntary rather than statutory. It is anticipated this option would lead to little loss of income for the piercing industry in Wales, although exact costs cannot be accurately assessed.

660. Similarly, when the guidance is updated every three years, practitioners/businesses may need to spend some time familiarising themselves with the revised guidance and implement any necessary changes to prevent young people under 18 from having an intimate piercing. As it is anticipated only limited changes would be made to the guidance, these costs would be expected to be no more than half those incurred in 2017-18, at an estimated £15,800.

Summary of additional costs associated with option two

Table 7.24:

Costs	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government					
Staff costs for the development of guidance	4,800	0	0	0	0
Design and translation	600	0	0	0	0
Printing costs	400	0	0	0	0
Review of guidance				1,300	
Training	2,400	0	0	0	0
Communication	5,000	0	0	5,000	
Total costs for Welsh Government	13,200	0	0	6,300	0
Local authorities					
Staff costs to attend training and encourage the	38,400	38,400	19,200	19,200	19,200

<http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable2015>

²⁸¹ Hourly rates have been increased by a factor of 30% to incorporate on costs.

²⁸² Based on information provided by local authorities

implementation of the guidance					
Practitioners/businesses					
Staff costs to familiarise themselves with the guidance	31,600	0	0	15,800	0
Total cost	83,200	38,400	19,200	41,300	19,200

Benefits

661. There is a lack of data about the number of under 18s having an intimate piercing but it is estimated – under option one – there are between 1,067 and 8,672 under 18s having an intimate piercing in Wales each year. It is possible that producing and circulating guidance discouraging the performing of an intimate piercing on a person under 18, together with educational messaging for young people and parents, could reduce this number. However, as there would be no legal requirement underpinning the guidance and, as some practitioners/businesses already do not perform intimate piercing on under 18s, the impact of this option is not likely to be high.

Option three – Introduce a prohibition on the performing of an intimate piercing on a person who is under the age of 18

Description

662. This option would introduce legislation that prohibits the performance of an intimate piercing on a person who is under the age of 18. This would make it an offence for a practitioner to perform such a piercing. It would also be an offence to make arrangements to perform an intimate piercing on a person who is under 18 and local authorities would be provided with the powers to investigate and bring forward a prosecution against any person found to be breaking the law.

663. In addition (and similar to that outlined in option two), the Welsh Government would produce guidance to assist local authorities in their enforcement of the legislation and an awareness-raising campaign to inform young people of the risks and complications associated with intimate piercing would take place.

Costs

Welsh Government

664. The costs to the Welsh Government for producing and reviewing the guidance would be similar to those outlined under option two. The costs

for training EHOs or other relevant local government staff would be slightly higher as offences are being created by this option, but if the training was integrated with that for the implementation of special procedures, the expectation would be that savings could be achieved.

665. It is also envisaged that a more extensive communications package would be required than under option two. This would target both practitioners and young people.

666. This package could include:

- An awareness campaign for all piercing practitioners/businesses about the new offence using, for example, trade publications and social media, with direct marketing for those known to offer intimate piercing;
- A campaign alerting young people and parents to the new legislation and the possible health and child protection issues surrounding intimate piercing. This may include public relations, social media and working with schools/youth organisations.

667. It is anticipated such a communications package would cost £10,000, although savings could be made if it was integrated with the communications work for special procedures. This one-off cost would be incurred in 2017-18 although, as part of the review process, consideration would be given to the need to repeat communications work at a later date in order to maintain or enhance awareness of the new legislation. The precise cost savings would depend on the outcome of the review and are therefore currently unknown.

Local authorities

668. While the legislation would not require a regular timetable of inspections of premises and EHOs already have duties in respect of businesses providing piercing procedures, it is recognised there would be some additional local government staff costs. These would include helping to develop the guidance; attending the training sessions; raising general awareness and dealing with ad hoc queries about the new legislation. In addition, the legislation would provide new powers to local authorities and require them to undertake enforcement action.

669. It is expected the legislation would have a high-level of compliance but there may be some practitioners/businesses which do not comply with the ban on performing an intimate piercing on under 18s. It is likely these cases would be identified to local authorities through complaints or by local authorities undertaking test purchasing exercises. It is expected complaints would be low in number and, depending on the intelligence available, each local authority would conduct an average of one test purchasing exercise per annum. On that basis, it is assumed there would be no more than six prosecutions by EHOs across Wales each year.

670. It is anticipated the workload for local authority staff would be greater in the run-up to and during the first year of the implementation of the new legislation. In total this would amount to no more than the equivalent of one month of an EHO's time per local authority in these two years, reducing to half this amount for subsequent years. This would equate to £76,800 (£3,490 per local authority) in 2017-18 and 2018-19, with the cost subsequently reducing to approximately £38,400 per annum (£1,745 per local authority). However, if this work was integrated with that for special procedures the expectation is that savings could be made. The precise cost savings would depend on the activity undertaken and are therefore currently unknown.

Courts

671. As noted above, the legislation is not expected to result in more than six prosecutions per annum. There would therefore only be limited impact on the courts in Wales. A detailed costing framework has not yet been discussed between the Welsh Government and the Ministry of Justice, and so these costs are unknown at present.

Practitioners/businesses

672. Practitioners/businesses may incur some costs from the time spent helping to develop and familiarise themselves with the new requirements, and on implementing any changes to their processes to ensure young people under 18 do not have an intimate piercing. As failing to comply with the new legislation could lead to a prosecution, it is envisaged that a longer period would be required for this familiarisation work (three hours) than under option two. However, the other assumptions relating to this work outlined for option two are considered to be relevant – the cost for this familiarisation work to practitioners/businesses would be approximately £47,400 in 2017-18.

673. As for option two, the guidance would be updated every three years, at which time practitioners/businesses may incur some costs in terms of familiarising themselves with the revised guidance and in implementing any necessary changes to ensure they are compliant with the legislation. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those experienced in 2017-18, at an estimated cost of £23,700.

674. In addition, there may be some loss of income for the piercing industry in Wales if the legislation is successful in preventing intimate piercing of young people below the age of 18. This has been calculated to be between £2,500 and £495,000 per annum, applying the assumptions that:

- There are between 1,067 and 8,672 young people in this age group having such a procedure each year;
- The cost of an intimate piercing is between £25 and £60²⁸³;

²⁸³ Based on an internet search of cosmetic piercing practitioners (August 2016)

- There is a compliance rate of 95% with the legislation, as it is in line with good professional practice²⁸⁴.

675. As discussions with practitioners have suggested that a ban on intimate piercing of under 18s would involve little or no financial cost for them, the lower end of the above cost range would seem more likely.

676. The expected high compliance rate with the legislation and the low number of breaches likely to be identified through complaints or test purchasing exercises indicates that few fines would be levied on piercing practitioners. It is estimated that there would be no more than six prosecutions by EHOs across Wales each year. It is proposed that the offences of making arrangements to perform or performing an intimate piercing on a person who is under the age of 18 would be subject to an unlimited fine to reflect the seriousness of the offences. It is not possible to provide a definitive figure about the fines that would be given as magistrates' courts have a wide discretion. For the purposes of this exercise, a £5,000 fine has been used for the calculations. The total cost of fines to practitioners is therefore estimated to be approximately £30,000 per year²⁸⁵. In addition, prosecuted practitioners/businesses may be subject to legal fees, recovery of costs by local authorities and victim compensation. These costs would be highly variable and as such cannot be accurately assessed.

Table 7.25: Summary of additional costs associated with option three

Costs (£)	2017-18	2018-19	2019-20	2020-21	2021-22
Welsh Government					
Staff costs for the development of the guidance	4,800	0	0	0	0
Design and translation	600	0	0	0	0
Printing costs	400	0	0	0	0
Training	2,900	0	0	0	0
Review of guidance	0	0	0	1,300	0
Communication	10,000	0	0	0	0
Total costs for Welsh Government	18,700	0	0	1,300	0
Local authorities					
Staff costs to support retailers in complying with the legislation	76,800	76,800	38,400	38,400	38,400
Practitioners/businesses					

²⁸⁴ Based on, for example, the Code of Practice and Ethics of the British Body Piercing Association

²⁸⁵ As fines are set periodically by the Ministry of Justice we have not taken into account any increase in fines over time.

Staff costs to familiarise themselves with the new requirements	47,400	0	0	23,700	0
Cost of lost business	2,500 - 495,000	2,500 - 495,000	2,500- 495,000	2,500 – 495,000	2,500 - 495,000
Cost of fines	0 – 30,000	0 – 30,000	0 - 30,000	0 – 30,000	0 – 30,000
Total costs for practitioner/businesses	49,900 – 572,400	2,500 - 525,000	2,500- 525,000	26,200- 548,700	2,500- 525,000
Total Cost	145,400- 667,900	79,300 – 601,800	40,900- 563,400	65,900- 588,400	40,900– 563,400

Benefits

NHS savings

677. The main quantifiable benefits from the proposed legislation are savings to the NHS in terms of avoidable treatment costs. An estimate of the costs to the NHS in Wales in treating health complications among under 18s as a result of intimate piercings was provided earlier in this section. Using these estimates, and assuming that the proposed legislation has a 95% compliance rate, the annual savings to the NHS are estimated at between £17,032 and £139,082.

678. However, it is possible that these potential savings for the NHS could not fully materialise. Young people under 18 who are intent on having an intimate piercing could seek out a disreputable practitioner or business which is willing to break the law and provide the piercing, or to perform the piercing themselves. Such practices may take place in unhygienic conditions, which in turn increases the risk of complications and the need for NHS treatment. The communications package, which is integral to option three, would be important in helping to make young people aware of the dangers of using practitioners and businesses which are not licensed to perform special procedures and of piercing themselves or their friends.

Other savings

679. Beyond the potential savings for the NHS identified above, there are a number of other benefits from the proposed legislation which are more difficult to quantify. Placing a prohibition on the intimate piercing of under 18s would bring clarity to the situation. Many practitioners who have contacted the Welsh Government have indicated that they do not perform intimate piercings on young people but because the law does not currently prohibit it, it is possible for under-18s to have an intimate piercing. This option would reinforce the good practice of practitioners and raise awareness of the potential seriousness of intimate piercing for young people.

680. There would be benefits to young people. It is estimated there are currently between 51 and 416 under-18s a year experiencing health complications following an intimate piercing, which require help from a GP. It is also estimated there may be between 82 and 668 under-18s undergoing an intimate piercing who seek help with health complications from pharmacists or from an A&E department (between 24 and 199) or from inpatient care (between 34 and 277), while others with health complications may seek help from piercing practitioners or no help at all. As health complications such as pain, discomfort and anxiety have costs to individuals as well as the NHS, reducing the risk of these complications by prohibiting the intimate piercing of under-18s is beneficial, even though they cannot be quantified.
681. There will also be benefits in terms of safeguarding children and young people who may be placed in a vulnerable position when having an intimate piercing performed. By undergoing the procedure, young people are placed in a situation in which their intimate areas are exposed to, touched and pierced by an adult who may previously be unknown to them.
682. If the intimate piercing of under 18s is prohibited and practitioners comply with the law they should no longer face complaints from parents in relation to this issue.

Summary and preferred option

683. Option one does not meet the policy objective. It continues the existing practice and would mean children and young people would continue to have little or no protection from the risks associated with intimate piercing. With the increasing popularity and acceptance of body piercings, including intimate body piercings, it is possible the health costs arising from treating complications from the intimate piercing of under 18s could rise over time.²⁸⁶
684. Option two may encourage practitioners/businesses to take action to strengthen their existing policies around the intimate piercing of under 18s or for those who do not currently have a policy to develop one. There may also be increased awareness of the risks associated with intimate piercing by young people and parents. However, as this option is based on voluntary action, the impact is not likely to be significant.
685. Option three is the preferred option. It uses two reinforcing approaches to prohibit the intimate piercing of under 18s. The combination of the two approaches – prohibiting the procedure through legislation and putting in place supporting communications activity with practitioners and young

²⁸⁶ Stead LR, Williams JV, Williams AC and Robinson CM (2006) An investigation into the practice of tongue piercing in the South West of England *British Dental Journal* 200 103-107.

people – provides the best balance between cost and the likelihood of achieving the policy objective and the resulting tangible and intangible benefits for young people, the NHS and practitioners. This is because practitioners would have a greater interest and incentive in implementing the guidance produced by the Welsh Government than in option two, mainly due to the potential risk of them committing an offence and facing punishment.

Health Impact Assessments (HIAs) (Part 5)

Options

686. Three options have been considered:

- Option one – Do nothing;
- Option two – Produce additional guidance aimed at encouraging and promoting further use of HIAs in Wales;
- Option three – Legislation to require HIAs to be undertaken by public bodies in Wales in certain circumstances. This is the preferred option.

Option one: Do nothing

Description

687. Under this option, the status quo would remain and the Welsh Government would not specifically require public bodies to undertake HIAs. The current limited requirements outlined in Part 1 of this Explanatory Memorandum would continue.

688. Public bodies in Wales are already required by the Well-being of Future Generations (Wales) Act 2015 to align themselves to a series of national wellbeing goals, including goals of a healthier Wales and a more equal Wales. HIAs would continue to be a method which could be used by public bodies to help them discharge their responsibilities under the Act.

689. HIAs are already used by a range of organisations in Wales as a method for assessing the potential impacts of policies or proposed actions on health and wellbeing. This practice would continue under this option but HIAs would not become a specific legal requirement.

690. The Welsh Health Impact Assessment Support Unit (WHIASU), located in Public Health Wales NHS Trust, would continue to promote the use of HIAs in Wales, including providing advice and support to those carrying out HIAs and developing resources and training. Information about HIAs

would also continue to be factored into relevant policy documents, as is the case currently.

691. Information provided by WHIASU indicates there are two main types of HIAs carried out in Wales. The first is referred to as a rapid health impact assessment, which is considered appropriate for assessing relatively small scale proposals and involves holding workshop sessions, which WHIASU may contribute to. It is estimated the average cost of producing a rapid HIA is approximately £2,000, including staff time (based on a small group of attendees), venue hire and refreshments.²⁸⁷ The vast majority of HIAs undertaken in Wales fall into this category.²⁸⁸
692. For some proposals, which have significantly larger scope and complexity, a more comprehensive HIA may be required. This type of assessment is more appropriate for large and major infrastructure projects, and may span a number of years. The method adopted is likely to include the consultation/workshop approach of a rapid HIA but is likely to be much more comprehensive and also require extensive desk-based evidence gathering and research. A comprehensive HIA can itself vary in its duration and complexity – for example, it can be adapted to suit different types of proposals, from an assessment of a new policy or strategy, through to a matter of national importance, such as a proposed nuclear power station. A comprehensive HIA is therefore estimated to have associated costs within a range of £30,000 to £150,000²⁸⁹ (which may include commissioning work from private consultants where appropriate). Due to the nature of proposals likely to be subject to a comprehensive HIA, it is estimated only one or two assessments are progressed in Wales in any given year.
693. As this option would only maintain the status quo, it is assumed the use of HIAs in Wales would continue at a relatively static level. The number of HIAs carried out would be unlikely to change significantly.

Costs

Welsh Government

694. There would be no additional costs to the Welsh Government from this option. WHIASU would continue to be supported from within the core budget allocation provided by the Welsh Government to Public Health Wales NHS Trust²⁹⁰.

Public Health Wales NHS Trust

²⁸⁷ Information provided by WHIASU

²⁸⁸ It is estimated that 20-30 rapid HIAs are carried out annually in Wales – information provided by WHIASU

²⁸⁹ Information provided by WHIASU

²⁹⁰ Public Health Wales NHS Trust has a core budget allocation of £86.7m in 2016-17

695. There would be no additional costs to Public Health Wales NHS Trust under this option. The organisation would continue to determine the level of support it provides to WHIASU from within its overall budget allocation, as part of its general budget-setting process. WHIASU currently has an annual budget of approximately £133,000 and is currently resourced by one full-time and two part-time members of staff, based in North and South Wales.
696. As part of its role, WHIASU offers a series of training opportunities about HIAs, ranging from formal training sessions, to informal mentoring, and the development of an *Introduction to HIA* e-learning course based on Cardiff Metropolitan University's platform, which cost approximately £15,000 to commission. Courses about *Rapid HIA Competency*, *Comprehensive HIA Competency* and *Quality Assuring a HIA Competency* are also run in conjunction with the Chartered Institute of Environmental Health Wales. In addition, WHIASU provides an *Introduction to HIA* session twice a year to public health practitioners and in-house training sessions to public bodies and third sector organisations on request. This spectrum of training activity would continue under this option.

Public bodies

697. As this option would maintain the status quo, any current costs incurred by public bodies in carrying out HIAs would continue. However, this would not be expected to lead to additional costs, as the number of HIAs carried out in Wales would be expected to continue broadly at current levels.

Benefits

698. There are likely to be limited or no additional benefits from this option. It is possible that the continued work of WHIASU would lead to a gradual increase in understanding of HIAs, potentially leading to an increase in use. Similarly, public bodies may look increasingly to HIAs as a way of discharging their responsibilities under the Well-being of Future Generations (Wales) Act, and the number could therefore increase. However, as there would not be any specific legal requirement in relation to HIAs, any increase is likely to be limited and gradual. There would also be no guarantee that the findings of HIAs would be appropriately considered.

Option two: Produce additional guidance aimed at encouraging and promoting further use of HIAs in Wales

Description

699. This option would involve updating current non-statutory WHIASU guidance on HIAs, working with relevant stakeholders and partners. The

guidance would reflect the current policy and legislative context, and aim to encourage further appropriate use of HIAs in Wales. Copies of the guidance would be available online and in paper copy for use by bodies carrying out HIAs.

700. The publication of the new guidance would be accompanied by some new publicity and awareness raising activity, and be supplemented by continuing the existing training programmes relating to HIAs.

Costs

Welsh Government

701. While it is envisaged that preparation of the new updated guidance would be led by WHIASU, there would be some limited costs to the Welsh Government arising from engaging with WHIASU to contribute to the guidance. Such a collaborative approach would be beneficial to ensure the guidance reflects all relevant aspects of the current policy and legislative context.
702. In order to work with WHIASU on the new guidance, it is anticipated that three weeks of a FTE senior executive officer's time would be required. This would cost approximately £3,800 and be incurred in 2017-18.
703. Welsh Government input would also be required as part of subsequent updates to the guidance. As updates would be expected to be less resource intensive than the initial task, it is envisaged that costs would be approximately half those incurred in 2017-18 – this would equate to costs of £1,900, with the first update to the guidance expected in 2020-21.

Public Health Wales NHS Trust

704. Public Health Wales NHS Trust (via WHIASU) would have primary responsibility for producing the updated guidance under this option.
705. WHIASU published comprehensive guidance, *Health Impact Assessment: A practical guide*, in 2012²⁹¹. It is estimated the total cost of preparing the guidance and supporting electronic resources (including staff time, peer review, stakeholder engagement, printing and translation costs) was £40,000.²⁹² However, as this option would involve updating the existing guidance, overall costs would be expected to be significantly lower.
706. It is estimated updating the guidance would take 12 weeks of a principal officer's time in Public Health Wales, including work to engage

²⁹¹ Welsh Health Impact Assessment Support Unit guidance note "HIA: A practical guide" [http://www.wales.nhs.uk/sites3/Documents/522/Whiasu%20Guidance%20Report%20\(English\)%20V2%20WEB.pdf](http://www.wales.nhs.uk/sites3/Documents/522/Whiasu%20Guidance%20Report%20(English)%20V2%20WEB.pdf)

²⁹² Information provided by WHIASU

with key stakeholders (approximately £8,200). In addition, design and typesetting would cost approximately £500. Based on guidance of 10,000 words, translation and proofreading would cost £1,000²⁹³. As some users may be unable to access electronic versions of the guidance, it is anticipated that a limited number of paper copies would need to be produced. Based on printing costs for the 2012 guidance, 250 paper copies of the new guidance pack would be produced, at a cost of approximately £1,000²⁹⁴. Total estimated costs of producing the revised guidance would therefore be approximately £10,700, and would be incurred in 2017-18.

707. To supplement the main guidance, a series of short guides and/or additional supporting resources would need to be produced. These would only be produced electronically. Total costs of producing and translating such supplementary resources are estimated at approximately £3,000 annually from 2017-18.²⁹⁵
708. The guidance would be updated periodically. For illustrative purposes it has been estimated this will take place every three years, although less frequent updates may be required. The guidance may not need to be revised too extensively and will be dependent on the evolution of health impact assessment practice in Wales, policy development and practitioner needs. It is anticipated each update would be less resource intensive than the initial comprehensive review of the guidance due to take place in 2017-18. Costs for each review are therefore estimated at half the costs of the original review, at £5,400. The first update would take place in 2020-21.
709. To maximise the potential impact of the new guidance, there would need to be some publicity to raise awareness of the guidance among relevant stakeholder networks. It is expected part of this publicity could be generated through relevant journals but could also include targeted social media activity and additional stakeholder engagement activity. Communications work would be expected to cost a maximum of £2,000 and would coincide with publication of the guidance in 2017-18. As the guidance would be voluntary, it is expected that the communications work would need to be repeated every three years to coincide with updates to the guidance (this cost would be first incurred in 2020-21). It is likely that cost savings could be made for future rounds of communications work, but the precise cost savings would depend on the activity undertaken and are therefore currently unknown.
710. It is possible the new guidance and associated promotional work would lead to a gradual increase in the number of HIAs being carried out each year in Wales. As the guidance would be non-statutory, it is assumed that any increase would be limited (estimated at a 10% increase year on year,

²⁹³ Based on £75 per 1000 words for translation and £21 per 1000 words for proofreading

²⁹⁴ Information provided by WHIASU

²⁹⁵ Information provided by WHIASU

equating to an additional two to three rapid HIAs being carried out year-on-year). However, any increase would have implications for WHIASU's capacity to fulfil its advisory and support role.

711. WHIASU commonly reviews and provides feedback about HIAs which have been carried out. On average, for a rapid HIA, this is estimated to cost approximately £100 but for a comprehensive HIA could cost approximately £500 in terms of WHIASU staff time.²⁹⁶ It is envisaged any sustained increase in the number of HIAs being submitted to WHIASU for review could lead to a need to review overall capacity. However, as this option would be likely to lead to a limited increase only, the expectation initially would be that this is met from existing resources.
712. The core training programme currently delivered by WHIASU and outlined under option one would continue under this option²⁹⁷, and so any costs associated with delivery would be replicated. However, as these costs are already incurred these are not additional to the status quo option and have therefore not been assessed here.
713. Specific additional training sessions may be necessary for relevant public sector staff about the new guidance. These would be additional to WHIASU's main training programme. It is envisaged these additional training sessions would be led by WHIASU or contracted out to another HIA/public health professional. It is anticipated two sessions would be held, one each in North and South Wales. The training sessions would take place in 2017-18. The cost of the development of the course material and hand-outs would be approximately £800, and the cost of running the two sessions with 20 delegates attending each would be approximately £1,600. This would give a total cost of £2,400 in 2017-18. These costs would be repeated when the guidance is updated next in 2020-21.

Public bodies

714. While public bodies would be encouraged to support the uptake of the guidance as part of their normal work routines, it is recognised there could be some additional staff costs, for example to cover considering how to implement the guidance, attending the training sessions and engaging with colleagues to encourage them to also follow the guidance.
715. Public bodies in Wales may incur some costs from time spent familiarising themselves with the new guidance. Assuming the organisations which would be most likely to undertake this task would correspond with the public bodies covered by the Well-being of Future Generations (Wales) Act 2015 – 42 bodies, given that Public Health Wales and Welsh Ministers would be closely involved in the preparation of the guidance – this task would take four hours per organisation and

²⁹⁶ Information provided by WHIASU

²⁹⁷ 163 officers received training between June 2014 and June 2015, and 217 officers received training between June 2015 and June 2016 – information provided by WHIASU

that this would cost an average of £33.93 per hour²⁹⁸, the costs to public bodies of familiarising themselves with the guidance would amount to £5,700 in 2017-18.

716. Similarly, when the guidance is updated every three years, public bodies may incur some time familiarising themselves with the revised guidance. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those incurred in 2017-18, at an estimated £2,900. The first review of guidance would be expected to take place in 2020-21.

717. It was noted earlier in this option that additional training sessions would need to be held specifically on the new guidance and these sessions would be delivered across Wales by WHIASU in 2017-18. It is not envisaged that these training sessions would attract a delegate fee. However, public bodies may incur some limited costs in releasing staff to attend the training sessions. While the staff that would be likely to attend (and their grade) are likely to vary significantly, an estimate of £6,800 has been made based on 40 attendees paid for five hours at Welsh Government management band one levels.

718. Public bodies may also incur some costs in attending current training courses run from within the core training offer delivered by WHIASU or the Chartered Institute of Environmental Health Wales. Delegates may be charged a fee for accredited courses as these would support professional development. Current delegate costs for attending courses are:-

- Two-day *Rapid HIA Competency* course (£240 per person or £115 for one day);
- Three-day *Comprehensive HIA Competency* course (£340 per person);
- One-day *Quality Assuring An HIA Competency* course (£180 per person).²⁹⁹

These costs are already incurred under the current arrangements. It is possible this option may lead to a small number of additional officers needing to attend these existing courses but any additional cost is expected to be minimal.

719. Public bodies already incur costs for the production of between 20 and 30 rapid HIAs each year and progressing between one and two comprehensive HIAs each year. It is possible the introduction and promotion of the new guidance would lead to an increase in the number of HIAs undertaken in Wales each year. As the guidance would be voluntary, it is envisaged that any increase in the number of HIAs carried out would be limited and is estimated at a 10% increase. This would lead to an increase of between two and three rapid HIAs each year at an additional cost of £4,000 to £6,000 a year from 2017-18. It is not

²⁹⁸ Pay rates will vary across different bodies and it is therefore not possible to provide a definite average hourly rate for this work. For illustrative purposes calculations have been based on Welsh Government staffing costs (management band one)

²⁹⁹ Information provided by WHIASU

envisaged that the number of comprehensive HIAs would increase from the current position.

Table 7.26: – Summary of additional costs associated with option two

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government					
Contribution to updated guidance	3,800	0	0	1,900	0
Total costs for Welsh Government	3,800	0	0	1,900	0
Public Health Wales					
Staff costs for development of guidance	8,200	0	0	0	0
Design and translation	1,500	0	0	0	0
Printing costs	1,000				
Additional supplementary resources	3,000	3,000	3,000	3,000	3,000
Review of guidance	0	0	0	5,400	0
Communications/promotion	2,000	0	0	2,000	0
Additional training	2,400	0	0	2,400	0
Total costs for Public Health Wales	18,100	3,000	3,000	12,800	3,000
Public Bodies*					
Staff costs to familiarise themselves with guidance and attend training	12,500	0	0	2,900	0
Costs to produce additional HIAs	4,000-6,000	8,000-12,000	12,000-18,000	16,000-24,000	20,000 - 30,000
Total cost to public bodies	16,500-18,500	8,000-12,000	12,000-18,000	18,900-26,900	20,000-30,000
Total cost	38,400-40,400	11,000-15,000	15,000-21,000	33,600-41,600	23,000-33,000

*Estimated costs have been calculated on the basis of total additional cost to public bodies in Wales. For summary tables elsewhere in this document, it is estimated that approximately one third of these costs will be incurred by local authorities.

Benefits

Welsh Government

720. The Welsh Government would gain an assurance that public bodies have up-to-date guidance produced by the main source of expertise on HIAs within Wales, which should lead to a more consistent approach to the carrying out of HIAs in Wales. The updating of the guidance would provide a timely opportunity to reflect the latest developments in the overall policy and legislative context relevant to the subject. The Welsh Government would also gain assurance that supportive mechanisms

were being put in place to support public bodies to implement the Well-being of Future Generations (Wales) Act 2015.

Public bodies

721. The main benefit to public bodies would be that they would have new and up-to-date guidance about how to carry out HIAs in a way which assists them to meet their obligations to consider the impact of their decisions on health and wellbeing. The updated guidance would also provide them with further opportunities to take advantage of the advice and support available to them through WHIASU and to benefit from additional training opportunities.
722. By having up-to-date guidance, public bodies will be able to ensure when they carry out HIAs (which they already do in a number of instances) they will be able to maximise the opportunities afforded by the health impact assessment process. It should enable more effective and active engagement with stakeholders with an interest in the specific issues raised as part of an HIA. This should, in turn, ultimately lead to decisions which are better informed and transparent in terms of how they may affect health and wellbeing, helping to maximise positive impacts and reduce or eliminate potential negative impacts.

Public

723. The public could see an increase in the number of HIAs being carried out across Wales, although any increase could be limited as the new guidance would not be statutory. Importantly, if organisations apply the guidance this could increase visibility of the health impact assessment process to relevant stakeholder groups and include additional opportunities for engagement.
724. Another potential benefit of this option would be that more consistent use of HIAs could make certain decisions more transparent to local populations. If the guidance is applied appropriately, this could help build the confidence of local populations or specific groups within them in certain decisions taken by public bodies, because they have taken into account a robust assessment of the likely impact on health and wellbeing.

Option three: Legislation to require HIAs to be undertaken by public bodies in Wales in certain circumstances

Description

725. This option would introduce legislation to make it a mandatory requirement for public bodies in Wales (including Welsh Ministers) to carry out, publish and take into account HIAs in specified circumstances. Welsh Ministers would be required to make regulations to specify the precise circumstances when HIAs would be required. This would be

subject to a process of consultation and be subject to the affirmative procedure. The regulations would be accompanied by a separate RIA. The public bodies to be captured by the new HIA requirements would correspond to those covered by the Well-being of Future Generations (Wales) Act 2015.

726. The estimated costs outlined under this option can only provide an indication of the anticipated additional costs, as the precise detail of the requirements would be determined through the development of the regulations. However, the legislation would aim to take a proportionate approach to requiring HIAs to be carried out in the most appropriate circumstances. The aim would not be to lead to vast increases in the number of HIAs carried out in Wales but would be to formalise and strengthen the current arrangements.

Costs

Welsh Government

727. It is envisaged the current WHIASU guidance³⁰⁰ about HIAs would need to be updated to coincide with the new regulations coming into force. Option two outlined that the Welsh Government would have a role in contributing to the updated guidance. It is envisaged that the same level of input would be required under this option, therefore the costs are estimated to be the same as outlined under option two. However, under this option these costs would not be incurred until 2018-19 as the guidance would need to reflect the regulations developed in 2017-18. Costs would therefore be an estimated £3,800 in 2018-19, with a further £1,900 in 2021-22.
728. There would be some additional limited costs associated with raising awareness of the new statutory obligations in advance of the legislation coming into force. In order to achieve this, the Welsh Government would work with stakeholder networks to generate press and media articles and seek to incorporate information in relevant circulars and communications with public bodies. It is anticipated that this would take four weeks' of a FTE higher executive officer's time in the run-up to the legislation coming into force, costing £3,900³⁰¹ in 2018-19. Costs would be repeated to coincide with the three-yearly updates to guidance; a further £3,900 would be incurred in 2021-22.
729. Welsh Ministers would be included in the list of public bodies required to carry out HIAs in specific circumstances. Assessments of impacts on health are already carried out in relation to a number of Welsh Government policies and programmes but the new legislation may require additional HIAs to be undertaken. There may be a need for additional

³⁰⁰ Welsh Health Impact Assessment Support Unit guidance note "HIA: A practical guide" [http://www.wales.nhs.uk/sites3/Documents/522/Whiasu%20Guidance%20Report%20\(English\)%20V2%20WEB.pdf](http://www.wales.nhs.uk/sites3/Documents/522/Whiasu%20Guidance%20Report%20(English)%20V2%20WEB.pdf)

³⁰¹ Based on Welsh Government staff planning costs

rapid HIA workshops to be held. Whilst the precise circumstances when a health impact assessment will be required would be set out in regulations, it is estimated for the purposes of this assessment that an additional five rapid HIAs would be carried out in 2018-19, increasing incrementally by a further two HIAs annually from 2019-20. Costs would be approximately an additional £10,000 in 2018-19, with a further additional £4,000 a year from 2019-20 onwards.³⁰² It is possible that a need for further comprehensive HIAs could be identified but these potential costs have not been included as it is not possible to accurately estimate if or when this may be needed.

Public Health Wales NHS Trust

730. WHIASU's current role to provide advice, guidance and support in relation to HIAs in Wales could be formalised by it being referenced in the regulations to be made by the Welsh Ministers. It is possible this could lead to an increase in approaches to WHIASU for advice about HIAs by public bodies. While it would not be the primary purpose of the legislation to significantly increase the number of HIAs carried out in Wales but rather to strengthen and standardise current arrangements, it is possible that a limited and gradual increase would take place. For illustrative purposes, it is estimated to be double the potential increase outlined under the voluntary guidance option (option two). There could therefore be a 20% increase in the number of assessments undertaken every year, equating to an additional four to six rapid HIAs being carried out every year³⁰³.
731. It is possible the regulations would result in the need for an additional number of comprehensive HIAs to be carried out in Wales. Due to the nature of proposals which would be likely to require a comprehensive HIA, it is not anticipated that more than three comprehensive HIAs on average would need to be progressed in any one year (up from one to two assessments currently).
732. While the estimated increases in the number of HIAs outlined above would be limited, any increase would have implications for WHIASU's capacity to fulfil its advisory and support role. It is envisaged that any sustained increase in the number of HIAs requiring WHIASU input could lead to a need to review its overall capacity. While the expectation initially would be that this is met from existing overall resources from within Public Health Wales' core budget allocation, it is possible that as the number of HIAs being carried out incrementally increases, there may eventually be a need to increase WHIASU's capacity. Due to the high level of uncertainty about any potential extra demand, these costs are currently unknown.

³⁰² Based on an average cost of £2,000 per rapid HIA workshop (information provided by WHIASU).

³⁰³ From a baseline of 20 to 30 rapid HIAs carried out each year – information provided by WHIASU

733. It is envisaged that WHIASU's current HIA guidance³⁰⁴ would need to be updated. The update would be similar in nature to that outlined under option two but framed in the context of the new legislative requirements. The costs of updating the guidance are estimated to be the same as outlined under option two, amounting to approximately £10,700. However, under this option these costs would not be incurred until 2018-19 as the guidance would need to reflect the final regulations developed in 2017-18. The guidance would instead be updated to coincide with the regulations coming into force in 2018-19.
734. Similarly to option two, a series of short guides and/or additional supporting resources would need to be produced. These would only be produced electronically. Total costs of producing and translating such supplementary resources are estimated to be the same as those outlined in option two, at approximately £3,000 annually. However, under this option the costs would be incurred from 2018-19 onwards.
735. The guidance would be updated periodically. For illustrative purposes it is assumed that this would take place every three years, although less frequent updates may be sufficient. The guidance may not need to be revised too extensively and would be dependent on the evolution of health impact assessment practice in Wales, policy development, practitioner needs and experience from the first years of implementing the new legislative requirements. It is anticipated each update would be less resource-intensive than the initial comprehensive review of the guidance due to take place in 2018-19. Costs for each review are estimated at half the costs of the initial review – at £5,400 (the same as in option two). However, under this option the first update would take place in 2021-22.
736. The core training programme currently delivered by WHIASU and outlined under option one would continue under this option³⁰⁵, and so any costs associated with delivery would be replicated. However, as these costs are already incurred they are not additional to the status quo option and have therefore not been included as additional costs for this option.
737. Similarly to option two, specific additional training sessions may be necessary for relevant public body staff on the new guidance. These would be additional to WHIASU's main recurrent training programme. These sessions would be similar to those envisaged under option two but would be framed in the context of the new legislative requirements. It is envisaged that the sessions would be led by WHIASU or contracted out to another HIA/public health professional. It is anticipated that two sessions would be held, one each in North and South Wales. The sessions would take place in 2018-19 so they reflect the detail of the final regulations developed in 2017-18 and coincide with the new legislative

³⁰⁴ Welsh Health Impact Assessment Support Unit guidance note "HIA: A practical guide" [http://www.wales.nhs.uk/sites3/Documents/522/Whiasu%20Guidance%20Report%20\(English\)%20V2%20WEB.pdf](http://www.wales.nhs.uk/sites3/Documents/522/Whiasu%20Guidance%20Report%20(English)%20V2%20WEB.pdf)

³⁰⁵ 163 officers received training between June 2014 and June 2015, and 217 officers received training between June 2015 and June 2016 – information provided by WHIASU

requirements coming into force. The costs of the sessions are estimated to be the same as under option two – £2,400. These costs would be incurred in 2018-19 and would be repeated after three years in 2021-22.

Public bodies

738. Public bodies in Wales would incur some costs from time familiarising themselves with the new legislation and updated WHIASU guidance. It was estimated under option two that this work would take on average four hours per organisation. As this option would involve familiarisation with both the new regulations and the supporting guidance, and will be likely to require greater dissemination within each public body, it is estimated that the time required would be double that of option two – the familiarisation work under option three would take on average eight hours per organisation. Based on 42 bodies undertaking this work (Public Health Wales and Welsh Ministers would already be closely involved in the preparation of the legislation and guidance), costs to public bodies of familiarising themselves with the legislation and updated guidance would amount to £11,400. These costs would be incurred in 2018-19 to coincide with the new legislation coming into force.

739. Similarly, when the guidance is updated every three years, public bodies may spend some extra time familiarising themselves with the revised guidance which will be updated to reflect the first years of implementing the new requirements. As it is anticipated that only limited changes would be made to the guidance, these costs would be expected to be no more than half those incurred in 2018-19, at an estimated £5,700. The first review of guidance would take place in 2021-22.

740. Additional training sessions would need to be held specifically on the updated WHIASU guidance about HIA, in the context of the new legislative requirements. Costs of running sessions across Wales in 2018-19 were assessed in the Public Health Wales section above. It is not envisaged that these additional training sessions would attract a delegate fee for attendees from public bodies. Public bodies may incur some limited costs in releasing staff to attend the training sessions. While the staff that would be likely to attend (and their grade) are likely to vary significantly, an estimate of £6,800 has been made based on 40 attendees paid for five hours at Welsh Government management band one levels.

741. Public bodies also may incur some costs in attending training courses run from within the core training offer delivered by WHIASU or the Chartered Institute of Environmental Health Wales. Delegates may be charged a fee for accredited courses as these would support professional development. Current delegate costs for attending courses are:

- Two-day *Rapid HIA Competency* course (£240 per person or £115 for one day);
- Three-day *Comprehensive HIA Competency* course (£340 per person);

- One-day *Quality Assuring An HIA Competency* course (£180 per person).³⁰⁶

These costs are already incurred under the current arrangements and so are not considered to be additional costs under this option. However, it is possible this option would lead to public bodies identifying additional members of staff who would need to attend these courses in order to comply with the new legislative requirements. For planning purposes it is estimated 10 additional members of staff would need to attend each of the above courses annually from 2020-21 onwards, as the numbers of HIAs being carried out cumulatively increases. This would lead to an additional cost of £7,600 annually from 2020-21.

742. Public bodies already incur costs from the production of between 20 and 30 rapid HIAs each year and progressing between one and two comprehensive HIAs each year. It would not be the primary purpose of the legislation to significantly increase the number of HIAs carried out in Wales however, it is possible that a limited and gradual increase would take place. Whilst the precise circumstances when HIAs will be required would be set out in regulations, for the purposes of this assessment it is assumed that the increases estimated under option two could be doubled under the legislative option. This would equate to a 20% year-on-year increase in the number of HIAs carried out by public bodies from 2018-19 onwards. This would equate to an additional four to six rapid HIAs being carried out every year, costing an additional £8,000 to £12,000 each year from 2018-19.³⁰⁷
743. In addition, it is possible that the regulations would result in the need for an additional number of comprehensive HIAs to be carried out in Wales. Due to the significant nature of proposals which would be likely to require a comprehensive HIA, it is not anticipated that more than three comprehensive HIAs on average would need to be progressed in any one year (an additional one assessment above the one to two assessments currently).
744. It was estimated under option one that a comprehensive HIA is estimated to have costs between £30,000 and £150,000³⁰⁸ (which may include commissioning work from private consultants where appropriate). Assuming that costs associated with a comprehensive HIA would be spread over an average period of two years, an additional comprehensive HIA would be expected to have an estimated cost of within a range of £15,000 to £75,000 per year. As the precise circumstances for when a HIA would be required would be specified in the regulations, it is not possible to envisage which public bodies may be required to undertake an additional comprehensive HIA.

³⁰⁶ Information provided by WHIASU

³⁰⁷ Based on an average £2,000 per rapid HIA – information provided by WHIASU

³⁰⁸ Information provided by WHIASU

745. As part of the new requirements, public bodies would be required to publish the HIAs which they have carried out. However, it is assumed that HIAs would only be published electronically and placed on the relevant public body's website – as is currently good practice. It is therefore not envisaged the requirement to publish HIAs would result in any additional cost.

Table 7.27: – Summary of additional costs associated with option three

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government					
Contribution to updated guidance		3,800			1,900
Awareness raising/communications		3,900			3,900
Additional HIAs		10,000	14,000	18,000	22,000
Total costs for Welsh Government		17,700	14,000	18,000	27,800
Public Health Wales					
Staff costs for development of guidance		8,200			
Design and translation		1,500			
Printing costs		1,000			
Additional supplementary resources		3,000	3,000	3,000	3,000
Review of guidance					5,400
Additional training		2,400			2,400
Total costs for Public Health Wales		16,100	3,000	3,000	10,800
Public Bodies*					
Staff costs to familiarise themselves with legislation and guidance and attend training		18,200			5,700
Additional training				7,600	7,600
Costs to produce additional rapid HIAs		8,000-12,000	16,000-24,000	24,000-36,000	32,000-48,000
Costs to produce additional comprehensive HIA		15,000-75,000	30,000-150,000	30,000-150,000	30,000-150,000
Total cost to public bodies		41,200-105,200	46,000-174,000	61,600-193,600	75,300-211,300
Total cost		75,000-139,000	63,000-191,000	82,600-214,600	113,900-249,900

*Estimated costs have been calculated on the basis of total additional cost to public bodies in Wales. For summary tables elsewhere in this document, it is estimated that approximately one third of these costs will be incurred by local authorities.

Benefits

746. While it is not possible to quantify the extent to which benefits would be achieved under this option, it can be assumed that they would be greater than under the other options as the expectation to carrying out an HIA in specific circumstances would be backed by legislation. For example, the requirement for public bodies to publish an HIA and take it into account when making a decision about a particular project or policy is likely to lead to increased uptake of recommendations from HIAs.

747. There are a number of examples which suggest that HIAs which are appropriately carried out have influenced decisions in Wales. The HIA in relation to the proposed extension to Margam open cast mine³⁰⁹ both informed the general evidence base and influenced the Welsh Government's decision in 2009 to introduce mandatory HIAs for all open cast mining proposals in Wales. An HIA for a pilot for a warm water modality scheme in North Wales led to two schemes being commissioned by Betsi Cadwaladr University Health Board, which implemented a number of the HIA recommendations.³¹⁰ An HIA in relation to proposed temporary changes to women's and maternity services in North Wales was a factor in decisions taken by Betsi Cadwaladr University Health Board³¹¹ and an HIA about the preferred strategy for the Wrexham Local Development Plan³¹² led to the local authority committing to implementing a number of recommendations. Internationally, evidence also indicates HIA recommendations have led to improved active travel opportunities³¹³.

748. Public bodies would benefit from the additional certainty and clarity legislation provides and WHIASU would also gain reputational benefits from a legislative basis for its role in supporting HIAs in Wales.

Summary and preferred option

749. Option one does not meet the policy objective of strengthening the current use of HIAs in Wales. It would continue the status quo in which the circumstances in which HIAs are used by public bodies in Wales varies. WHIASU would continue to provide support, advice and guidance to help promote the use of HIAs and disseminate good practice but the

³⁰⁹ <http://www.wales.nhs.uk/sites3/page.cfm?orgid=522&pid=50570>

³¹⁰

<http://www.wales.nhs.uk/sites3/Documents/522/Warm%20Water%20Modality%20HIA%20final.pdf>

³¹¹ <http://www.wales.nhs.uk/sites3/Documents/522/FinalHIAreport.pdf>

³¹² <http://www.wales.nhs.uk/sites3/news.cfm?orgid=522&contentid=42137>

³¹³ Suther, E and Sandel M Health Impact Assessments. Rhode Island Medical Journal July 2013

current perception of stakeholders that the status and use of HIAs should be strengthened would remain.

750. Option two may encourage some increased and more consistent use of HIAs in Wales through the publication and promotion of updated guidance. However, the impact of this option would be expected to be limited as the guidance would be voluntary. It would, however, play an important role by promoting HIAs in the context of the existing policy and legislative framework and providing information about the types of issues for which it would be appropriate to undertake an HIA.
751. Option three is the preferred option. This approach would seek to bring clarity and certainty to the use of HIAs in Wales. The focus of the approach would be to provide a specific legislative approach to HIAs which complements the existing legislative framework. Specifying the precise circumstances where HIAs must be carried out by public bodies would be more likely to realise the benefits which are outlined under option two. As the purpose of the legislation would be to clarify the requirements rather than require significant numbers of new HIAs, the additional costs of option three are considered reasonable as they would realise the anticipated benefits to a greater extent than option two. By developing the legislation in a way which reflects the broader policy and legislative context, it could also avoid duplication of effort, leading to some potential for cost savings.

Pharmaceutical services (Part 6)

752. Three options have been considered:
- Option one – Do nothing;
 - Option two – Replace the current system with needs-based entry using pharmaceutical needs assessments (PNAs) and introduce an exit regime that allows effective action to be taken against under-performing providers or those in breach of terms of service. This is the preferred option;
 - Option three – Abolish control of entry arrangements and allow a free market for the provision of NHS pharmaceutical services.

Option one – Do nothing

Description

753. Under this option, no policy changes would be made and it is anticipated that the incremental changes to pharmaceutical services provision seen in recent years would continue. The overall number of pharmacies in Wales would remain stable as the current arrangements would continue to act as a barrier to market entry. There would be a very gradual increase in the numbers of pharmacies which provide additional services.

754. There would continue to be variation in the planning of pharmaceutical services by health boards and service commissioning would continue to be disparate. Those pharmacies which currently choose not to provide additional services would continue to resist requests to enhance their service offer, to the detriment of local populations. The high proportion of applications to provide NHS pharmaceutical services resulting in appeals to Welsh Ministers would persist.

Costs

Welsh Government

755. As this option proposes no change, Welsh Ministers would continue to determine appeals made against the decisions of health boards, both in relation to applications to provide NHS pharmaceutical services and breaches of terms of service. Costs would therefore be the same as they are now and would be related to Welsh Ministers' duties to determine these appeals. The costs of an appeal to the NHS Litigation Authority under arrangements in England, which at the time were analogous to the arrangements in Wales, have previously been estimated at approximately £6,000 per appeal³¹⁴ (at 2007-08 prices). Albeit infrequently, on occasion the decisions of Welsh Ministers on appeal would be subject to challenge through judicial review.³¹⁵ From experience of previous reviews the costs of a judicial review are estimated at £30,000.

Health boards

756. Health boards would continue to determine applications made by people wishing to provide NHS pharmaceutical services against the existing statutory tests – whether it is necessary or expedient to grant an application in order to secure the adequate provision of (dispensing) services. There were 22 such applications in 2013-14³¹⁶. Health boards would also continue to determine alleged breaches of terms of service when asked to do so by other health boards. Costs would therefore be the same as they are now. In determining the fee to be paid by persons applying to be included in the pharmaceutical list, the NHS Wales Shared Services Partnership (NHSWSSP) estimated the associated cost to NHS Wales to be £600 per application.

Persons applying to be included in the pharmaceutical list

757. People who wish to be included in the pharmaceutical list would continue to apply to their health board. The decision about the location

³¹⁴ Department of Health (2008). *Impact assessment of proposals to reform 'market entry' based on pharmaceutical needs assessment*. DH. London.

³¹⁵ There has been only one such judicial review in the last four years.

³¹⁶ Welsh Government. (2014). *Community Pharmacy Services*. Welsh Government, Cardiff.

from which additional services will be provided would be made by the applicant.

758. As is the current situation, applicants would be required to pay a fee in relation to their application³¹⁷ in order to defray the costs incurred by NHS Wales in reaching a decision. This fee is currently set at £600 for full applications to provide pharmaceutical services with a lower fee for changes of ownership, which are associated with less administrative work for health boards. While these fees may change over time they would continue to be set at a level which is proportionate to the work health boards must undertake to determine each application.

Others

759. There would be no additional costs associated with this option for others such as existing pharmacy contractors, local pharmaceutical committees, local medical councils or community health councils, all of which may make representations in relation to applications to be included in the pharmaceutical list. Neither would there be additional costs for patients. Any costs associated with the current system would continue.

Benefits

760. No additional benefits would accrue as a result of this option relative to the current position.

Option two – Replace the current system with needs based entry using pharmaceutical needs assessments (PNAs), and introduce an exit regime that allows effective action to be taken against under-performing providers or those in breach of terms of service

761. The assessment of this option has been structured in two parts. The costs and benefits of the needs based entry component are assessed first, followed by an assessment of the costs and benefits of the proposed exit regime.

Description

762. Under this option, the current control of entry arrangements would be revoked and replaced by a new regime. Pharmacies wishing to be permitted to provide NHS services would be allowed to do so only if they are able to demonstrate that there is a particular unmet local need or service requirement that, in allowing them to provide pharmaceutical services, could be met.

³¹⁷ There were 22 applications made in 2013-14

763. In order to support this change health boards would be required to robustly assess the pharmaceutical needs of their populations, and to publish a statement of those needs in the form of a PNA. The content and timing of PNAs would be determined by legislation.
764. The PNA would be a transparent document that gives contractors and potential new entrants greater clarity and certainty in respect of the health needs of local communities, and the standards against which applications will be assessed. The PNA would therefore enable new entrants to align their services with local needs, and enable existing providers to align and potentially extend their services. There would be no costs to contractors in relation to the needs based entry component.

Costs

Welsh Government

765. The Welsh Government would develop guidance to support health boards in undertaking a PNA and overseeing market exit. This would include developing a standard template for a PNA. The guidance would be produced in 2018-19, following the development of and consultation on secondary legislation.
766. There would be costs to the Welsh Government associated with producing and issuing the guidance. Staffing costs to produce the guidance (based on 6,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £8,000. This is based on approximately five weeks of a FTE higher executive officer (£4,900) to develop the guidance, and five weeks of a FTE team support for administration support (approximately £3,100).³¹⁸
767. It is envisaged that a task and finish group would be established to oversee and develop the guidance. Due to the technical nature of the guidance it has been assumed that this would need to involve representatives of community health councils, community pharmacy contractors, GPs (including dispensing GPs) and representatives from Public Health Wales. It is estimated three people from each group would be involved in attending up to five half-day meetings.
768. Costs for attending task and finish group meetings are estimated at the opportunity cost of time – forgone earnings – and uplifted by 30% for on-costs. Patient time is evaluated at UK median earnings (£27,600 per annum), GP time is evaluated at average GP salary (£101,900 per annum) as estimated by the Personal Social Services Research Unit (PSSRU, 2015), pharmacist time is evaluated at average pharmacist earnings (£38,735 per annum, from PSSRU, 2014) and Public Health Wales personnel's time has been estimated at the mid point of the Agenda for Change band 8d (£75,573 per annum) (Agenda for Change

³¹⁸ Based on Welsh Government staff planning costs

2016-17). The task and finish group costs to develop guidance and the PNA template amount to £9,100 (based on £3,800 for GPs, £1,500 for pharmacists, £1,000 for patients and £2,800 for Public Health Wales representatives).

769. It is anticipated that design and typesetting would require one week of a 0.5 FTE executive officer, which would cost approximately £400. It is estimated that translation and proofreading would cost approximately £600.³¹⁹
770. The guidance would be published in an electronic format only. There would therefore be no publishing costs.
771. Therefore, the total cost of developing guidance (including costs of the steering group) would be £18,100. The guidance would cover all aspects of undertaking a PNA and overseeing market exit and would be produced in 2018/19.

Health boards

Cost of completing PNAs

772. Detail about the content and publication of PNAs would be set out in regulations. For the purposes of this assessment, it is assumed that completing a PNA would require input from one senior manager from a health board for three months and one administrative support officer for one month. Their annual salaries are valued at the mid-point of the Agenda for Change bands 8b and 4 at £53,285 and £21,052 (Agenda for Change 2016-17), uplifted by 30% to account for on-costs. It is assumed three public meetings would be required to publicise each PNA at a cost each of £600, adding £1,800 to costs. The direct cost to each health board to produce a PNA would therefore be £21,400. The first round of PNAs would be expected to be undertaken in 2018-19.
773. A PNA would need to be comprehensively reviewed every four years; it is estimated the costs outlined above would be repeated for this work. Additionally, it has been assumed that health boards will make small scale updates to their PNA in the intervening years between the comprehensive reviews, taking one week of senior management time and one week of administrative support. The cost per update would therefore be approximately £1,900 per health board.
774. There would be no formal requirement to do so, however due to the technical nature of the process it is envisaged that health boards may wish to establish a group to oversee the completion of their PNAs. It has been assumed that each health board would involve the community health council, community pharmacy contractors, GPs (including dispensing GPs) and representatives from the local public health team. It

³¹⁹ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

is estimated that three people from each group would be involved in attending up to five half-day meetings in the first year, and every fourth year thereafter. In intervening years it is estimated that they would only meet twice.

775. Costs for attending local steering group meetings are estimated at the opportunity cost of time, uplifted by 30% for on-costs. Patient time is evaluated at UK median earnings (£27,600 per annum), GP time is evaluated at average GP salary (£101,900 per annum) as estimated by the Personal Social Services Research Unit (PSSRU, 2016), pharmacist time is evaluated at average pharmacist earnings (£38,735 per annum, from PSSRU) and local public health team personnel's time has been estimated at the mid point of the Agenda for Change bands 8a (£44,703 per annum). The costs of individuals' time in supporting each health board in performing its PNA amount to £8,000 per health board in the first year and in each year in which the PNA is comprehensively updated, and £3,000 per health board in intervening years.

776. Each PNA would be published in an electronic format only. There would therefore be no publishing costs.

777. In addition to developing the PNA there would be associated translation costs. It is estimated that this would cost approximately £600 per health board for each comprehensive update (based on 6,000 words) and £100 for each intervening year (based on 1,000 words)³²⁰.

778. Therefore, the total cost of PNAs for all health boards (including costs of the steering group) is estimated at £210,100 every four years and £35,000 for each intervening year. This equates to estimated costs per health board of £30,000 every four years and £5,000 for each intervening year.

Cost arising from commissioning additional services to meet pharmaceutical needs

779. The costs arising from commissioning additional services would be dependent on what - if any – unmet needs are identified in each PNA. If a PNA identifies no unmet pharmaceutical need, there would be no additional cost. The costs presented in this section are therefore illustrative.

780. Costs and later benefits have been estimated by constructing a hypothetical scenario based on variation in the delivery of local enhanced services. To arrive at a conservative net benefit estimate, it has been assumed that the delivery of enhanced services, where necessary, will reflect the pharmaceutical needs of the local population. Assuming that a robust PNA would lead to further commissioning of services to meet the

³²⁰ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

needs of the local population, there would be costs to the health boards to provide these services.

781. Health boards would be able to influence the quality of service provision and patient access by commissioning services in locations of greatest need. Therefore, PNAs could result in health boards commissioning more services from existing providers as well as from new entrants. There would be a cost to health boards to provide these services.

782. Of the 716 pharmacies in Wales, in 2014-15 the following four local enhanced (public health) services were provided by:

- Emergency contraception – 515 pharmacies;
- Smoking cessation level three – 279 pharmacies;
- Syringe and needle exchange – 215 pharmacies;
- Seasonal influenza vaccination – 241 pharmacies.

This equates to 1.75 of these services provided per pharmacy on average.

783. Expenditure on these services was £1,770,191 in 2015-16. This is broken down as follows:

- Emergency contraception – £563,230
- Smoking cessation level three – £614,001
- Syringe and needle exchange – £283,350
- Seasonal influenza vaccination – £309,610

784. Published evidence³²¹ suggests there is considerable variation in the extent to which health boards commission additional pharmaceutical services. There are a number of reasons for this, not least that some services will be provided by providers other than pharmacies - however, it is considered that, at least in part, some of the variation can be put down to institutional factors, including health board commissioning decisions not being aligned to the pharmaceutical needs of their local populations. This view is supported by evidence provided to the National Assembly's health and social care committee in the Fourth Assembly during its inquiry into the contribution of community pharmacy to health services in Wales³²².

785. In the absence of PNAs there is no means by which to objectively quantify the extent to which needs are currently being met. Therefore, to ensure a conservative approach to estimating costs, it has been assumed that enhanced services commissioned by health boards already address the vast majority of the pharmaceutical needs of their populations. This is estimated to be between 70% and 90% of the total need.

786. Under the new arrangements, it is expected there would be a 10% to 30% increase in the provision of services, with costs increasing by the

³²¹ Welsh Government. (2015). *Community Pharmacy Services*. Welsh Government, Cardiff.

³²² National Assembly for Wales (2012). *Inquiry into the contribution of community pharmacy to health services in Wales*. NAW, Cardiff.

same proportion from 2019-20. A range of potential scenarios representing the best, worst and most likely cases following the change are provided in the table below. The most likely scenario figure has been used in the summary tables at the end of this option.

Table 7.28:

Average number of enhanced services provided by pharmacies	1.75
Total cost of enhanced services provided (£)	£1,770,191
Increase in enhanced service provision (best case)	30%
Increase in enhanced service provision (worst case)	10%
Increase in enhanced service provision (most likely case)	20%
Increase in enhanced service costs (£ per annum) (best case)	£531,057
Increase in enhanced service costs (£ per annum) (worst case)	£177,019
Increase in enhanced service costs (£ per annum) (most likely case)	£354,038

Benefits

787. In the following section overall net benefit has been calculated by taking the difference between the discounted benefits and the discounted opportunity costs.

788. The health benefits of only one pharmacy service have been modelled. This makes the estimate of benefits highly conservative.

Health benefits arising from increased service provision

789. While there are no data to prove conclusively that pharmaceutical needs are not being met presently in Wales, there is significant variation in service provision. There is scope to expand enhanced services in some health board areas, with the local population likely to benefit from those services.

790. In order to arrive at a conservative net estimate of benefit, it has been assumed that the delivery of enhanced services will contribute to meeting the needs of the local population. Pharmacy smoking cessation services have been used to model the benefits to patients from increasing enhanced service coverage.

791. In order to present an illustrative example of potential additional costs, it is conservatively estimated that the most likely scenario under this option is for a 20% increase in service provision (in absolute terms) resulting from the introduction of PNAs and the tailoring of enhanced services to reflect the needs of local populations. Therefore it has been assumed that 80% of the potential benefit is already being achieved.
792. In 2015-16, 279 pharmacies provided a stop smoking level three service. The benefits in terms of health outcomes are extrapolated from the Quality Adjusted Life Years (QALY) benefits of people quitting smoking as a result of the service.
793. In 2015-16, 5,600 people made an attempt to quit smoking through pharmacy stop smoking services and, of these, 1,945 were still not smoking at four weeks into their quit attempt.³²³ The life-time quit rate associated with stop smoking services is 7% (taking into account those who would have quit regardless of a stop smoking service) and it has been assumed that this is also the case for patients accessing pharmacy-led services.
794. The health benefits for people who stop smoking are significant. Individuals who quit smoking will gain both in terms of length and quality of life. The number of years of life gained by quitting smoking will vary depending on the age at which an individual quits. The University of Birmingham³²⁴ calculated the life years gained from quitting smoking by age groups as shown below:

Table 7.29:

Age at quitting (years)	Life years gained	QALY
<35	10	8.44
35-45	9	7.36
45-54	6	4.47
55-64	3	1.455

795. Data are not available on the age profile of pharmacy stop smoking service users. However, data were available for people quitting smoking

³²³ Based on management information held by the Welsh Government

³²⁴ Wang et al 2006. Cut Down to Quit with Nicotine Replacement Therapies (NRT) in Smoking Cessation: Systematic review of effectiveness and economic analysis. University of Birmingham.

in Wales through the national smoking cessation service provided by Stop Smoking Wales in 2012-13³²⁵. This is shown below:

Table 7.30:

Age group	Number of quits	% of all quits
<18	14	0.53
18-34	414	15.80
35-59	1518	57.96
60+	664	25.35

796. To calculate the average QALY gain associated with stopping smoking, it has been assumed the profile of people quitting in pharmacy would be the same as those using Stop Smoking Wales. Because the age groups reported by Stop Smoking Wales are not the same as those for which data for QALY gains are available, and to ensure a conservative estimate of benefits, QALY gains have been attributed to the age groups recorded by Stop Smoking Wales based on lower estimates, as below:

Table 7.31:

Age group	QALY gain	Discounted QALY gain ³²⁶
<18	8.44	2.22
18-34	8.44	2.22
35-59	4.47	2.14
60+	0	0

797. Applying these discounted QALY gains to the proportion of quits from each age group gives an average discounted QALY gain of 1.6 QALYs per quit.

³²⁵ Stop Smoking Wales. Stop Smoking Wales Annual Report 2012/13. Public Health Wales.

³²⁶ *QALYs have been discounted at 3.5% in the Wang et al (2006) paper. Health benefits are usually discounted at 1.5%, so this provides a conservative estimate of the QALY gain.

798. Using the data for pharmacy stop smoking services from 2013-14 and the estimated growth in such services resulting from PNA, the effect on annual numbers of long term quits is shown in the table below:

Table 7.32:

Number of treated smokers per annum under current arrangements	5,600
Number of smokers quit at four weeks	1,945
Estimated number of long-term quits (7% of four-week quits)	136
Increase in number of long-term quits (best case = 30% increase)	41
Increase in number of long-term quits (worst case = 10% increase)	14
Increase in number of long-term quits (most likely case = 20% increase)	27

799. At an average of 1.6 discounted QALYs gained per long-term quit, the range of QALYs gained per annum as a result of a PNA is estimated to be between 22 (worst case) and 66 (best case), with 43 QALYs the most likely estimate.
800. Valuing a QALY at £60,000, the benefit from additional long-term quits is therefore estimated to be between £1.32m and £3.96m, with the most likely estimate being £2.58m. This benefit is expected to accrue from 2019-20. This is likely to be a conservative estimate as it does not take into account other externalities that smoking causes (such as NHS or personal expenditure).
801. The potential benefits arising from the expected increase in other services that pharmacies provide have not directly been evaluated. Similar increases in provision and benefits would be expected; however these have not been quantified in order to ensure the net estimate of benefit is conservative.

Cost savings resulting from fewer applications

802. Currently a person wishing to provide NHS pharmaceutical services must make an application to the relevant health board to do so. Prospective applicants must make their own judgement about the pharmaceutical needs of the population that would be served by the pharmacy they propose to open and the adequacy of existing pharmaceutical services. Under this option, in the future applicants would

be able to refer to the health board's PNA when deciding whether or not to make an application. More than half of all applications (excluding those relating to minor relocations) made to health boards are currently refused (59% in 2013-14), therefore it is envisaged that a proportion of applications that would be made under the current system would not be made in future. This is because it would be immediately apparent from a health board's PNA that additional pharmaceutical services are not needed.

803. Applicants currently pay a fee on each occasion they make an application to be included in a health board's pharmaceutical list. The fee for a new inclusion is currently £600. It is expected that while the number of applications that are unlikely to succeed would reduce, this would be offset by an increase in applications which are not made currently but where a need identified in the PNA prompts one. It is estimated that there will be a zero net change in the number of applications. It is expected that some potential applicants would benefit relative to the current arrangements because applications would be more likely to be successful. The actual scale of the benefits will be dependent on the proportion of applications made which are successful, and so the precise savings are currently unknown.

Cost savings arising from fewer appeals over entry

804. The decisions taken by health boards in relation to the market entry of additional pharmaceutical service providers are frequently subject to appeal. Such appeals are made to Welsh Ministers.
805. Greater consultation during the preparation of PNAs and more clarity about decisions resulting from applications being judged against explicit statements of pharmaceutical needs should result in a reduction in appeals to Welsh Ministers. The numbers of appeals determined by Welsh Ministers between 2010-11 and 2014-15 are shown below:

Table 7.33:

Year	2010/11	2011/12	2012/13	2013/14	2014/15	Total
Appeals determined	29	28	39	11	10	117

806. The number of appeals to Welsh Ministers in any period is subject to significant variation. Appeals received in one year might be considered in the subsequent year and in some cases, such as those involving judicial review, appeal decisions may be delayed further. The average number of appeals determined by Welsh Ministers is estimated to be 23 per annum.
807. The costs of an appeal to the NHS Litigation Authority under arrangements in England, which at the time were analogous to the

arrangements in Wales, have previously been estimated at approximately £6,000 per appeal³²⁷. This would give a total annual cost of £156,000 to the Welsh Ministers in determining 23 appeals per annum (uprated from £138,000 at 2007-08 prices).

808. It is expected the number of appeals against health board decisions would reduce but there is uncertainty in estimating how many appeals would be made following the changes. This is because health board decisions would be more transparent and better understood but also because having a PNA in place is expected to lead to fewer speculative applications in the first place.
809. For the purpose of this RIA a range of potential scenarios are provided in the table below, representing the best, worst and most likely case scenarios following the change. It is assumed that regulations for a new needs-based entry regime would come into force in 2017, and that all appeals outstanding under the existing regime would be dealt with during 2017-18.

Table 7.34:

Year	2017-18	2018-19	2019-20	2020-21	2021-22
Appeals expected under current regime	23	23	23	23	23
Estimated cost of appeals (£ 000s)	156	156	156	156	156
Reduction in appeals under new regime (best case)	0%	0%	30%	30%	30%
Reduction in appeals under new regime (worst case)	0%	0%	10%	10%	5%
Reduction in appeals under new regime (most likely case)	0%	0%	20%	20%	20%
Estimated savings under new regime (£) (best case)	0	0	46,800	46,800	46,800
Estimated savings under new regime (£) (worst case)	0	0	15,600	15,600	15,600
Estimated savings under new	0	0	31,200	31,200	31,200

³²⁷ Department of Health (2008). *Impact assessment of proposals to reform 'market entry' based on pharmaceutical needs assessment*. DH. London.

regime (£) (most likely case)					
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810. Under the most likely case scenario, a 20% reduction in the number of appeals made to Welsh Ministers would be expected. This would result in savings of £31,200 per annum from 2019-20.

Wider benefits

811. It is anticipated this option also would bring about further indirect benefits. In particular it is envisaged that increasing these services would lead to reductions in travel time and inconvenience for individuals and may lead to a more efficient use of health services, including freeing up GP consultation time, allowing them to spend more time with people with more complex conditions. Economic benefits to local communities would also be expected where new pharmacies are established. Community pharmacies have been identified as one of the essential businesses which are key to economic prosperity in communities³²⁸. New entrants will therefore contribute to sustaining local communities, providing shopping access, local employment and building social capital. However, these social benefits cannot be quantified financially.

Disbenefits for pharmacy contractors resulting from market entry

812. It is not envisaged that there would be any net disbenefit for pharmacy contractors, since any disbenefits to existing contractors would be offset by equal benefits to the new entrants.

Exit regime

Description

813. Alongside the introduction of needs-based entry, an exit regime would also be introduced which would lead to effective graduated actions being taken to deal with those providers who fail to meet their terms of service obligations and who are receiving NHS remuneration without fulfilling their contractual obligations to the NHS. Ultimately, where a pharmacy persistently breaches its terms of service or where the breach is significant, a health board could remove the pharmacy from its pharmaceutical list.
814. It was noted in 2014's Public Health White Paper that the Welsh Government wished to ensure there were more effective sanctions to address poor performance. Introducing provisions directly related to quality would provide incentives for contractors to improve delivery and give health boards the power to de-commission services where there is

³²⁸ Department of Health. (1999) *Improving Shopping Access for People Living in Deprived Neighbourhoods – a paper for discussion*. DH. London.

already adequate service provision but the contractor does not meet minimum acceptable quality standards.

815. Alongside the existing powers in sections 82 and 83 of the NHS (Wales) Act 2006, additional powers are considered to be necessary to enable health boards to remove contractors from the pharmaceutical list where they seriously or persistently breach their NHS terms of service.
816. This option would enable health boards to take effective and proportionate action, including withdrawal of the right to provide pharmaceutical services, against those contractors operating below acceptable levels of quality. This is expected to have a direct benefit of reducing poor quality service provision by these providers, but would also provide incentives to all pharmacies to raise standards.

Costs

817. Health boards would be expected to incur costs in administering these measures – collecting and analysing information to identify poor quality contractors; pursuing the action against them; and managing appeals against their decisions.
818. Contractors would incur costs in gathering the information required by health boards in order to administer this system. Contractors against whom action is taken would also sustain costs in conducting their defence. The ultimate impacts of the proposal will depend on the detail of regulations brought forward under the primary legislation. Therefore, illustrative costs and benefits have been calculated for representative scenarios that may result following implementation. Regulations would be subject to usual consultation procedures and would be developed with due consideration of the consequent risks, costs and benefits.
819. Guidance regarding the exit regime would be provided by the Welsh Government and incorporated into the overall PNA guidance detailed earlier in the assessment of option two. There would be no additional costs beyond those outlined in paragraph 771.

Cost to health boards in undertaking performance management

820. Health boards already carry out performance management of pharmacy contractors as part of the current NHS pharmaceutical services contractual framework. It is assumed no additional costs would be incurred in identifying those against which action should be considered.
821. Based on discussions with health boards it is estimated action might be taken against up to five pharmacy contractors each year. Each action would incur staff costs of assembling additional information, managing the disciplinary process and defending any appeals – which are assumed, as a worst-case scenario, to be made against all actions. It is assumed this process would require a total of one senior manager and one

administrative support officer from a health board for up to 10 days – annual salaries are valued at the mid point of the Agenda for Change bands 8b and 4 at £53,285 and £21,052 (Agenda for Change 2016-17) uplifted at 30% for on-costs. Based on previous experience legal costs at an average of £3,900 per case are assumed. The total resulting annual cost to health boards is therefore estimated at £38,100, incurred from 2019-20.

Contractor compliance cost

822. Contractors would be expected to incur costs in providing the information required for assessment by health boards. It is expected that most contractors already undertake this work in order to fulfil their existing obligations for performance monitoring. However, a small number of contractors do not undertake this work and these would therefore incur additional costs. It is estimated that for 10% of contractors (approximately 70), this would represent additional workload and cost. The time taken to demonstrate compliance is estimated to be one week per year. If the work is carried out by a pharmacy technician, whose time costs £15 per hour (including on-costs)³²⁹, and there are 70 contractors to which this applies, the annual costs would be £39,000 per annum from 2019-20.

Contractor costs of defending actions

823. It is assumed that a contractor defending an action would incur the same costs as the health board bringing the action. This results in annual costs of £38,100 from 2019-20.

Costs to existing contractors through lost profits

824. It is assumed any profits lost by contractors no longer supplying the NHS would be directly offset by the profits gained by existing contractors or new entrants that replace them.

Table 7.35: - Summary of costs associated with option two

Costs (£)	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23
Welsh Government						
Costs for developing guidance	0	18,100	0	0	0	0

³²⁹ Based on top of scale agenda for change band 4 plus 30% on cost

Total cost to Welsh Government	0	18,100	0	0	0	0
All health boards						
Costs associated with undertaking PNAs	-	210,100	35,000	35,000	35,000	210,100
Cost arising from commissioning additional services to meet pharmaceutical needs (estimated)	-	-	354,000	354,000	354,000	354,000
Cost in undertaking performance management	-	-	38,100	38,100	38,100	38,100
Total cost to all health boards		210,100	427,100	427,100	427,100	602,200
Contractors						
Contractor compliance cost	-	-	39,000	39,000	39,000	39,000
Contractor costs of defending actions	-	-	38,100	38,100	38,100	38,100
Total cost to contractors		-	77,100	77,100	77,100	77,100
Total costs	-	228,200	504,200	504,200	504,200	679,300

Benefits

825. Giving health boards the power to take appropriate action against poor-performing contractors is expected to improve service quality, by improving the standards of poor and under-performing providers or

withdrawing their right to provide NHS services and by creating a universal incentive to raise standards.

826. It is not possible to forecast the value of the patient benefit likely to result from these measures. In order to evaluate whether the benefits outweigh the costs, it is therefore necessary to construct a credible, conservative scenario, which underestimates the likely net benefit of the measures. Accordingly the benefits associated with strengthened exit arrangements have not been quantified.

Table 7.36: - Summary of benefits associated with option two

Benefits	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £	2022-23 £
Health benefits	-	-	2.58m	2.58m	2.58m	2.58m
Reduced appeals to the Welsh Ministers under new regime	-	-	31,200	31,200	31,200	31,200
Total benefits		-	2.61m	2.61m	2.61m	2.61m

Table 7.37: - Overview of costs and benefits associated with option two

Overview of Costs and Monetised Benefits (£)	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £	2022-23 £
Total costs	-	228,200	504,200	504,200	504,200	679,300
Total benefits			2,611,200	2,611,200	2,611,200	2,611,200
Net benefits		- 228,200	2,107,000	2,107,000	2,107,000	1,931,900

Option three – Abolish control-of-entry arrangements and allow free market for the provision of NHS pharmaceutical services

Description

827. This option would enable market forces to determine the number, location and services offered by community pharmacies. It is likely there would be considerable growth in numbers of pharmacies, with associated increases in costs. It is not possible to estimate how significant the growth in pharmacy numbers would be, although experience from England is that the introduction of limited exemptions to the control of entry tests which came into force in 2005 resulted in an increase of 18% between 2005-06 and 2012-13³³⁰.

Costs and benefits

828. Abolition of control of entry arrangements would bring some benefits in terms of access, choice and competition. However, this is most likely in areas of highest economic demand, which are already well served. This would lead to diminishing economic returns since each incremental new entrant would bring lower associated benefits but the same fixed costs.

829. A change to the legislation would lead to a high level of market disruption. New entrants and many existing pharmacies would look to secure the most advantageous trading positions in order to maximise dispensing revenue.

830. It is extremely difficult to make plausible assumptions regarding the cost and benefits of this option. It is highly unlikely that market forces would deliver the policy objectives in terms of aligning services with local needs because most entrants would make the decision about where to locate on the basis of dispensing prescriptions rather than providing public health services. It is probable that some pharmacies would relocate from existing locations within communities to locations adjacent to large GP practices. In such situations access would diminish in some areas and improve in others. This would particularly impact on rural communities. This option is therefore considered unsatisfactory and has not been quantified.

Summary and preferred option

831. The evidence demonstrates the benefits of changing the current control-of-entry arrangements in Wales. The introduction of PNA and needs-based entry arrangements would address the current situation where pharmaceutical needs may not be routinely assessed and where pharmaceutical service planning is not necessarily aligned to identified health needs. The changes would also strengthen the role of health boards in determining where and by whom such services are provided, and provide performance management tools to improve the quality and consistency of service provision by pharmacy contractors.

³³⁰ HSCIC (2013) General Pharmaceutical Services in England - 2003-04 to 2012-13

832. Option one proposes no change to current arrangements but responses to a previous consultation³³¹ on control-of-entry in Wales suggests there is a consensus these arrangements are outdated and inadequate. In general, stakeholders recognise and support the need for change. Option three is not considered to deliver the key policy objective. There is evidence from England that deregulation leads to improved access through an increase in the number of pharmacies. However pharmacies tend to cluster close to one another generally in areas of low need³³². Option two is therefore the preferred option, as it addresses the need for better planning, improved decision making and performance management, with the benefits of the change outweighing the costs.

Provision of toilets (Part 7)

833. Four options have been considered:

- Option one – Do nothing;
- Option two – Re-hypothecate the Public Facilities Grant Scheme;
- Option three – Require each local authority to develop and publish a local toilets strategy. This is the preferred option;
- Option four – Require local authorities to ensure adequate provision of toilets for public use.

Option one – Do Nothing

Description

834. This option proposes no change to the current position. There would be no additional legislation involved and the provision of toilets for public use would continue to be at the discretion of each local authority.

835. The Public Facilities Grant Scheme was established in 2009-10 to increase the provision of free public access to toilet facilities in Wales. It sought to improve the quality and accessibility of these facilities, by encouraging local authorities to work in partnership with local businesses to allow public access to their facilities. All local authorities in Wales were invited to participate. The scheme reimbursed local authorities (to a maximum of £17,500 per local authority each year) for payments of up to £500 made to local businesses for allowing free public access to their toilet facilities.

³³¹ Welsh Government (2011). Proposals to reform and modernise NHS Pharmaceutical Services in Wales

³³² http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_06346

836. In 2014-15, £200,000 was transferred to the revenue support grant (RSG) in a move to increase flexibility of funding to local authorities. It is now for each local authority to decide how this funding is used to deliver its range of services, in order to meet the needs and priorities of its communities.

Costs

Welsh Government

837. There would be no additional costs to the Welsh Government associated with this option. As noted above, £200,000 per annum is included in the RSG to improve public access to toilet facilities in Wales.

Local authorities

838. There would be no additional costs for local authorities under this option. Local authorities could continue to administer funds from within the RSG to businesses for the purpose of allowing free public access to their toilet facilities. It is estimated local authority administration of the full £200,000 grant would equate to a total annual cost of £33,300. Information provided by local authorities indicates that current spending on grants is at approximately 75% of the amount made available under the Public Facilities Grant Scheme. Assuming continued use of the grant scheme at current levels, approximately 75% of those administration costs would be incurred, a total of £25,000 each year. Further information on the level of grant spending is provided under option two. There is a risk that provision of toilets for public use would decline under this option.

Table 7.37: Summary of costs associated with option one

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government Costs					
Contribution to Revenue Support Grant	200,000	200,000	200,000	200,000	200,000
Local authority costs					
Staff time	25,000	25,000	25,000	25,000	25,000
Total Costs	225,000	225,000	225,000	225,000	225,000

Benefits

839. As this option proposes no change, there would be no additional benefits to the Welsh Government or local authorities.

840. There would continue to be funds available within the RSG for local authorities to provide public access to toilet facilities. However, as these funds are not hypothecated there is a risk that due to financial pressures, local authorities could prioritise spending in areas other than toilet facilities. While improvements in toilet provision could result in benefits to health, tourism and the economy, it is unlikely there would be additional benefits to the general public under this option. Furthermore, there could be potential dis-benefits if the status quo is not maintained.
841. Businesses would continue to be able to apply to their local authority for funding to improve public access to toilet facilities. There would be no additional benefits to businesses. However, if the priority given by a local authority to this issue through its use of the RSG was reduced, there may be dis-benefits to the businesses currently receiving grants.

Option two – Re-hypothecate the Public Facilities Grant Scheme

Description

842. This option would involve the Welsh Government re-hypothecating the Public Facilities Grant Scheme by removing it from the RSG. The £200,000 annual funding would then be ring-fenced by the Welsh Government for improving provision of and access to toilets for public use across Wales.
843. During a short debate in the National Assembly for Wales³³³ in 2013, the then Minister for Local Government and Government Business confirmed that (along with other funding) the Public Facilities Grant Scheme fund would be mainstreamed into the RSG. The Minister stressed the importance of local authority provision of public toilets and said she had made it clear that this move could not and should not be seen as an excuse to downgrade provision.
844. Information gathered by the Welsh Government from local authorities during 2014 indicates that since the change in funding mechanism, seven local authorities either have or are suspending the Public Facilities Grant Scheme in their area or reviewed it during 2014-15. In addition, a further five local authorities have not taken part in the scheme. There are therefore 12 authorities where the scheme is inactive or was reviewed during 2014-15.
845. This option would involve the Welsh Government reviewing the implementation of the previous Public Facilities Grant Scheme, with a view to re-hypothecating it. All local authorities would be expected to take part and use their grant allocation.

Costs

³³³ <http://www.assembly.wales/en/bus-home/pages/rop-nolinks.aspx?meetingid=184#110676>

Welsh Government

846. The Welsh Government would review the previous Public Facilities Grant Scheme, considering any previous evaluations, and would then implement any necessary changes. Completion of this review, including engaging local authorities, businesses and any other relevant representative groups, is anticipated to cost £11,300 (approximately six weeks of a FTE senior executive officer, which would equate to £7,500, plus six weeks of a FTE team support, equating to £3,800).³³⁴ These costs would be incurred in 2017-18. This review would negate the need for local authorities to carry out their own reviews of the scheme.
847. There would be a further review of the scheme after three years, requiring the total Welsh Government costs of £11,300 to be repeated in 2020-21.
848. The £200,000 to fund a dedicated scheme would not be an additional annual cost, as it is currently provided to local authorities via the RSG. This amount would be re-hypothecated from that budget. The scheme would be managed in line with Welsh Government grant allocation guidance. It is anticipated that the management of the grant scheme would require 0.05 FTE executive officer at an annual cost of £1,600. This would equate to approximately two hours per week for the management of the scheme.

Local authorities

849. The allocation of funding to individual local authorities would be dependent on the outcome of the review of the scheme. The grant provided to a local authority could only be spent on issuing funding as part of the renewed grant scheme.
850. This option would reduce each local authority's ability to direct funding from the RSG to other priority areas. In cases where local authorities are not currently spending the equivalent of their grant allocation on access to toilet facilities, the hypothecation of this funding could necessitate cuts to other services.
851. In 2013-14, 327 businesses were issued with a grant by local authorities for making their toilet facilities available to the public, totalling £147,910³³⁵. Assuming similar figures for 2016-17, it can be estimated that £52,090 has been provided to local authorities but spent on areas other than public toilet provision. If the Welsh Government required the full allocation of £200,000 to be spent on public toilet provision, it is likely that this £52,090 would be deducted from other services. However, as a number of local authorities have suspended or are reviewing the scheme

³³⁴ Based on Welsh Government staff planning costs

³³⁵ Welsh Government figures

(as noted above), it is feasible that the shortfall to other services could be greater than £52,090.

852. Local authority staff costs would also need to be considered. This would include engagement with the Welsh Government during the review of the Public Facilities Grant Scheme, and then the ongoing annual cost of administering the grant to businesses. It is anticipated that this would require ongoing administration from an 0.05 FTE administrative officer, an annual cost of £1,500 to each local authority.³³⁶ This would equate to approximately two hours per week. As this cost would be duplicated across all 22 local authorities, there would be a total cost of £33,300. Taking into consideration the £25,000 cost incurred for administration of the grant scheme in option one, this would amount to an additional cost of £8,300.

853. A review of the Public Facilities Grant Scheme could result in changes to how the funds may be spent by local authorities in future. For example, costs for improving publicity and signage could potentially be financed from within the grant funds. The proportion of the overall funding which could be used for this purpose would vary dependent on local priorities and therefore cannot be assessed. However, the total funding available under a future revised grant scheme would remain at current levels.

Businesses

854. A reviewed version of the Public Facilities Grant Scheme could lead to an increase in publicity and signage, which would be intended to result in an increase in the use of toilets within those businesses receiving a grant. Although it is not possible to quantify, businesses could see an increase in the costs of maintenance, cleaning and disposables if their toilets are more frequently used. As these toilets are already in existence and are cleaned and maintained, any additional cost associated with additional usage would be minimal and would be covered by the grant of £500.

Table 7.38: Summary of costs associated with option two

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £
Welsh Government Costs					
Public Facilities Grant Scheme	200,000	200,000	200,000	200,000	200,000
Grant management staff time	1,600	1,600	1,600	1,600	1,600

³³⁶ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

Review staff time	11,300	0	0	11,300	0
Total Welsh Government costs	212,900	201,600	201,600	212,900	201,600
Local authority costs					
Staff time	33,300	33,300	33,300	33,300	33,300
Total local authority costs	33,300	33,300	33,300	33,300	33,300
Total costs	246,200	234,900	234,900	246,200	234,900
Additional Costs to option one	£21,200	£9,900	£9,900	£21,200	£9,900

Benefits

Welsh Government

855. The Welsh Government would have greater assurance the scheme was being administered in a largely consistent manner across each local authority in Wales and that a consistent sum would be dedicated to enhancing toilet provision. A review of the previous scheme, with engagement from key stakeholders, would seek to maximise the impact of the scheme overall. A review led by the Welsh Government would also allow for a consistent approach across Wales, rather than several different reviews being conducted using different methods.

Public

856. The general public would see an increase in the availability of toilets and the range of places where toilets are available to them under this option. If each local authority spends its maximum allocation on issuing grants alone, then there could be approximately 18 business premises with toilets available to the public within each local authority area.

857. However, there would be a risk that local authorities would seek to reduce the impact of cuts to other services by transferring funds currently used for direct public toilet provision to competing priorities. This would counteract any increase in access to toilets for public use which may be achieved.

Businesses

858. Businesses would have an opportunity to improve the previous scheme by engaging with the Welsh Government as part of a review. Businesses may also see an increase in footfall if their toilet facilities are made

available for use by the public. This could result in an increase in business turnover. It is not possible to quantify this and the other potential benefits.

Option three – Require local authorities to develop a local toilets strategy

Description

859. A duty would be placed on each local authority in Wales to prepare, consult on and publish a local toilets strategy. The current legal position whereby local authorities may provide toilets for use by the public would also apply. The Welsh Government funding for improving public access to toilet facilities would remain mainstreamed within the RSG.

Costs

Welsh Government

860. The Welsh Government would be required to produce guidance to accompany a new duty. There would be costs to the Welsh Government associated with producing and issuing the guidance. Staffing costs to produce the guidance (based on 6,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £8,000. This is based on approximately five weeks of a FTE higher executive officer (£4,900) to develop the guidance, and five weeks of a FTE team support for administration support (approximately £3,100).³³⁷

861. It is anticipated that design and typesetting would require one week of a 0.5 FTE executive officer, which would cost approximately £400. It is estimated that translation and proofreading would cost approximately £600.³³⁸ There would be no printing costs as it would only be produced electronically. The total cost for the development, design and translation of guidance would therefore be £9,000 and would be incurred in 2017-18.

862. The guidance would be updated every four to five years, to coincide with the cycle for preparation of the strategies by local authorities. It is anticipated that this would take approximately one week of a FTE higher executive officer's time, which would equate to approximately £1,000. Design and translation costs would amount to half the original costs, a total of £500. There would be no printing costs for the review as it would only be produced electronically. The total cost for each review would therefore be approximately £1,500, every four to five years. It is envisaged that the first review would take place in 2022-23.

863. The £200,000 allocation to the RSG each year would continue.

³³⁷ Based on Welsh Government staff planning costs

³³⁸ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

Local authorities

864. Local authorities would need to undertake an assessment of the need for toilets in their area to be available for use by the public and publish their first local toilets strategy within a year of the provisions coming into force. The needs assessment could involve analysing existing public toilet provision, engaging with local communities and stakeholders regarding their perception of need, and considering other factors such as appropriate methods for publicising facilities.
865. The strategies would include a statement setting out the steps the local authorities propose to take to meet the needs they have identified. The assessment of need and development of the strategy is anticipated to require two-thirds of an FTE officer's time for one month (equivalent to £2,300), with oversight from a FTE senior officer dedicating a third of their time for one month (equivalent to £2,000).³³⁹ These costs are based on the assumption the local authority currently has no local toilets strategy in place nor is one already in the process of development.
866. Assuming the preparation of the strategy follows a best practice model, it would progress through a local authority's specific scrutiny process. A task and finish scrutiny inquiry and a pre-scrutiny review would be likely to take place prior to the strategy being approved and published by the local authority. Progress in implementing the strategy would also be likely to be routinely monitored by a scrutiny committee within the local authority, subject to work programmes. It is estimated that the above process would require one third of a FTE grade nine scrutiny officer's time over a three-month period (equivalent to a cost of £3,900), and one month of a FTE grade eight scrutiny researcher (equivalent to a cost of £3,000).³⁴⁰
867. Prior to publication, local authorities would also be required to consult on their local toilets strategies. There would be a range of consultation options available to local authorities, with varying associated costs. This process would be likely to include questionnaires, drop-in sessions, local media coverage and online engagement, at a cost of approximately £6,000.³⁴¹
868. There would therefore be an approximate total cost to each local authority for the initial development of the strategies of £17,200. Repeating these costs for all 22 local authorities would amount to £378,400. These costs would be incurred in 2018-19.

³³⁹ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

³⁴⁰ Based on local authority staff planning costs. On-costs have been incorporated into these costs.

³⁴¹ According to figures provided by local authorities

869. Two years after the publication of its local toilets strategy, each local authority would be required to prepare and publish an interim progress statement. The statement would set out the steps that the local authority has taken in accordance with its strategy during the two years since it last published or reviewed it. The statement would be published no later than six months after the end of that two-year period. It is expected the preparation of the interim progress statement would involve local authorities undertaking a comprehensive review of their strategy and would take a FTE officer half of the time required for the initial development of the strategy (equivalent to approximately £1,200). Oversight from a FTE senior officer would be required with the officer dedicating one third of their time for a week (equivalent to £500).³⁴²
870. There would therefore be a total cost to each local authority for the production of an interim progress statement of approximately £1,700. Repeating these costs for all 22 local authorities would amount to £37,400. These costs would be incurred for the first time in 2021-22 and repeated in line with the cycle of the local toilet strategies.
871. Each local authority would also be required to undertake a review of its local toilet strategy every four to five years, within a year of local government elections. If changes are needed, the strategies would need to be revised and consulted on. As future reviews of the strategy are likely to be less resource intensive than the initial development, it is assumed that the staff time required to support this work would be reduced. However, it is anticipated that staff costs for scrutiny of the strategy would be replicated. If revised, consultation costs would also be repeated. A review of the strategy and associated scrutiny costs and a consultation exercise would therefore be estimated to cost a total of £331,100 (£15,050 for each local authority).
872. Local authorities would continue to administer funds from within the RSG to businesses for the purpose of allowing free public access to their toilet facilities. Administration of the full £200,000 grant would equate to a total cost of £33,300. It is assumed with the duty to prepare a local toilets strategy, local authorities would be more likely to use the full £200,000 for the purpose of grant allocations and administration costs would equate to £33,300 annually (approximately £1,500 per local authority) from 2019-20.

Table 7.39: Summary of costs associated with option three

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £	2022-23 £
Welsh Government						
Production of guidance	9,000	0	0	0	0	1,500

³⁴² Based on local authority staff planning costs. On-costs have been incorporated into these costs.

Addition to the RSG	200,000	200,000	200,000	200,000	200,000	200,000
Total Welsh Government costs	209,000	200,000	200,000	200,000	200,000	201,500
Welsh Government costs additional to Option 1	9,000	0	0	0	0	1,500
Local authorities						
Strategy development and consultation	0	378,400	0	0	0	331,100
Grant management staff time	25,000	25,000	33,300	33,300	33,300	33,300
Development of interim progress report	0	0	0	37,400	0	0
Total local authority costs	25,000	403,400	33,300	70,700	33,300	364,400
Total local authority costs additional to option one	0	378,400	8,300	45,700	8,300	339,400
Total Cost	234,000	603,400	233,300	270,700	233,300	565,900
<u>Additional costs to option one</u>	9,000	378,400	8,300*	45,700*	8,300*	340,900

* Additional costs in these years relate only to the increase in management costs to facilitate the full £200,000 spending on grants and the cost of developing interim progress reports. Further additional costs would be determined by the development and implementation of the strategies. As these strategies are at the discretion of each local authority following an assessment of need in its area it is not possible to estimate the additional costs to increase provision levels. However, greater spending on the implementation of strategies is likely to result in a greater degree of the benefits discussed below being realised.

873. Local authority and Welsh Government staff costs incurred in 2022-23 would be repeated every four to five years, aligning with the review period for the strategies.

Benefits

Welsh Government

874. The Welsh Government would gain an assurance that each local authority across Wales has a local toilets strategy in place to meet the needs of its community for these facilities. This strategy could include information such as the location of toilets and details of how need would be met over the long term. An emphasis on the provision of better information and better forward planning processes could encourage a more strategic use of funding in relation to public toilets.

Local authorities

875. In developing their strategies, local authorities would undertake an assessment of the needs for toilet facilities to be available for use by the public in their areas and would develop their strategies to meet those needs. Given the flexibility afforded to local authorities in implementing their strategies, it is difficult to accurately quantify the benefits to be derived from any improvements in local toilets provision. An indication of the range of benefits is provided below.

Health

876. An improvement in the quality and quantity of provision of toilets for public use can have positive impacts on health. A National Assembly Health and Social Care Committee inquiry³⁴³ into public toilet facilities took evidence from Age Cymru and the Welsh Senate of Older People, which described the lengths people take to avoid needing to use the toilet when away from home. This includes not taking essential medication that might exacerbate the need to urinate frequently or limiting fluid intake, which results in dehydration and associated health problems. These behaviours could lead to a requirement for further treatment.

877. Almost a quarter (23%) of people surveyed in a public facilities report from Guernsey³⁴⁴ said they plan or sometimes plan their journeys around toilet provision, with the main reasons given being medical conditions, such as bladder and bowel disorders, diuretic medication and dependant relatives or children.

878. The National Assembly's Health and Social Care Committee inquiry³⁴⁵ into public toilet facilities heard evidence that many people with bladder or bowel conditions do not go out in case they cannot access a toilet, and this can lead to people becoming more immobile, isolated, ill and/or depressed, leading to a possible need for further treatment. Research provided to the Committee estimated that within the 600,000 population of the Aneurin Bevan University Health Board area, approximately 22,000 people would suffer with bladder or bowel incontinence and could be affected by a lack of toilet provision.

³⁴³ <http://www.senedd.assembly.wales/mglIssueHistoryHome.aspx?lId=2572> Page 14.

³⁴⁴ McDermott, P & Kernohan, W. The adequacy and public perception of the public toilet provision on Guernsey. http://uir.ulster.ac.uk/21811/1/McDermott_2012.pdf

³⁴⁵ <http://www.senedd.assembly.wales/mglIssueHistoryHome.aspx?lId=2572> Page 13

879. Another potential benefit is a reduction in street fouling, which could decrease the cost of street cleaning for local authorities.

Tourism

880. An improvement in the quality and quantity of provision may have a positive impact on tourism in Wales.

Economy

881. Members of the public can be less inclined to spend time shopping in town centres if they know there is a lack of adequate toilet provision. This could significantly impact on local businesses.

Option four – Local authorities to ensure adequate provision of toilets for public use

Description

882. Each local authority in Wales would be under a statutory duty to ensure adequate provision of toilets for public use. There would be a requirement to complete a needs assessment to determine the quantity, location and type of facilities required for adequate provision. Local authorities would be under a duty to prepare a strategy and ensure this provision was secured.

883. In ensuring adequate provision of toilets for public use, a range of options would be available to local authorities. This would include those toilets provided to the public via schemes similar to the Public Facilities Grant Scheme, public toilets in places like shopping centres and public buildings (such as museums, sports centres), as well as providing local authority maintained facilities. This option is therefore similar to option three but accompanied by a further duty to ensure adequate provision of toilets for public use.

Costs

Welsh Government

884. The costs to Welsh Government would be the same as under option three.

Local authorities

885. The costs to local authorities associated with the development of a local toilets strategy would be the same as under option three.

886. Once a local authority has developed a local toilets strategy, there would be a further duty to implement the strategy to ensure adequate provision of toilets for public use. The range of approaches local authorities could take to secure access is too broad to accurately cost. However, in order to provide an estimate of the potential costs associated with this option, it has been assumed that local authorities would meet half the need for extra provision by building new facilities and the remaining half through the expansion of a scheme similar to the Public Facilities Grant Scheme. It is accepted that local authorities would vary greatly in their approach but the scenario outlined below is considered to provide a reasonable approximation.
887. A company specialising in the provision of public toilets has provided costs for blocks of four toilets (a unit of one accessible toilet plus three other cubicles). Only one company was contacted for prices for illustrative purposes. The cost for a block of four toilets was £107,500³⁴⁶. It is anticipated the local authority would spread the cost of building new toilet facilities over three years, from 2019-20 to 2021-22, ahead of a review on the implementation of its strategy.
888. An increase in such directly-provided toilets would also carry further cleaning, maintenance and cost implications for local authorities. While it is difficult to estimate these costs as each local authority would handle the matter differently, figures provided by a specialist public toilet provider indicated annual costs of £12,000 per unit for cleaning and maintenance and £6,000 to cover utilities and rates costs. Total spend of £18,000 would cover all costs, including revenue management, consumables, parts, utilities, rates, repairing vandalism, cleaning and maintenance. These costs could potentially be offset by placing a charge for the public to use the toilet facilities. Average revenue, based on a usage fee of 20p is estimated to be approximately £5,000 per unit annually. The net annual ongoing cost is therefore assumed to be £13,000 per unit annually.
889. It has been assumed any scheme similar to the Public Facilities Grant Scheme would continue to provide grants of £500 per year to businesses. It has also been assumed that each business receiving a grant provides four toilet cubicles for public use.
890. Current levels of toilet provision vary across local authorities. Current British Toilet Association recommendations provide suggested ratios for the number of toilets required for a given population. However these figures have not been applied in this estimate; an assessment of need would be determined at a local level, based on factors such as localised footfall, alternative provision and population demographic.
891. Based on figures provided by local authorities to the Welsh Government during 2014, there are approximately 950 public toilet facilities across Wales. This includes directly-provided local authority

³⁴⁶ Based on prices provided by a public toilet provider

facilities; community council facilities and those provided through the grant scheme. It is assumed that there is an average of four cubicles per toilet facility. As the level of unmet need that would be identified by local authority assessments of needs is unknown, an illustrative range of options have been calculated. These options consider the costs of increasing the levels of toilet provision across Wales by applying varying rates of increasing provision. It is anticipated that a conservative assessment of need could identify the need to increase provision by 50%. A higher estimate could identify the need to double toilet provision across Wales. The cost of a 75% increase has also been provided as a further illustrative example.

892. The following tables illustrate the estimated costs of increasing provision by 50%, 75% and 100%. These costs are based on the following assumptions:

- There are approximately 950 local authority public toilet facilities across Wales;
- Each local authority would meet identified additional need on the basis of half of the extra provision being met through directly provided toilet facilities, and the other half being met through allocation of grants;
- Creation of an additional directly-provided toilet facility (a block of four toilets) would have a capital cost of £107,500;
- The building of additional directly-provided toilet facilities would be spread evenly over three years, from 2019-20 to 2021-22;
- Any additional directly-provided toilet facility would have annual ongoing maintenance costs of £13,000;
- Any additional toilet facility secured through the allocation of grants would have ongoing annual costs of £500;
- There is an annual usage fee cost to the public of £5,000 per unit which will contribute towards the maintenance of additional directly provided facilities.

Table 7.40:

Option	Increase in provision	Additional units required	Total capital cost of direct provision £	Annual ongoing cost of direct provision £	Annual cost of grant allocation (in addition to current £200,000 funding) £	Total ongoing annual cost £
4a	50%	475	25,531,300	3,087,500	118,800	3,206,300
4b	75%	712.5	38,296,900	4,631,300	178,100	4,809,400
4c	100%	950	51,062,500	6,175,000	237,500	6,412,500

Table 7.41: Summary of costs associated with option 4a

Option 4a – 50% increase in provision

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £	2022-23 £
Welsh Government						
Production of guidance	9,000		0	0	0	1,500
Public Facilities Grant Scheme	200,000	200,000	200,000	200,000	200,000	200,000
Local authorities						
Strategy development and consultation		378,400	0	0	0	331,100
Grant management staff time	25,000	25,000	43,800	43,800	43,800	43,800
Capital investment		0	8,510,400	8,510,400	8,510,400	0
Annual maintenance		0	1,029,200	2,058,300	3,087,600	3,087,600
Additional Grant scheme annual cost		0	118,800	118,800	118,800	118,800
Public						
Usage fees	0	0	395,800	791,600	1,187,500	1,187,500
Total cost	234,000	603,400	10,298,000	11,722,900	13,148,100	4,970,300
Additional Costs to Option 1	9,000	378,400	10,073,000	11,497,900	12,923,100	4,745,300

Table 7.42: Summary of costs associated with option 4b

Option 4b – 75% increase in provision

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £	2022-23 £
Welsh Government						

Production of guidance	9,000		0	0	0	1,500
Public Facilities Grant Scheme	200,000	200,000	200,000	200,000	200,000	200,000
Local authorities						
Strategy development and consultation		378,400	0	0	0	331,100
Grant management staff time	25,000	25,000	50,100	50,100	50,100	50,100
Capital investment		0	12,765,600	12,765,600	12,765,600	0
Annual Maintenance		0	1,543,800	3,087,500	4,631,300	4,631,300
Grant scheme annual cost		0	178,100	178,100	178,100	178,100
Public						
Usage fees	0	0	593,800	1,187,500	1,781,300	1,781,300
Total Cost	234,000	603,400	15,331,400	17,468,800	19,606,400	7,173,400
Additional Costs to option one	9,000	378,400	15,106,400	17,243,800	19,381,400	6,948,400

Table 7.43: Summary of costs associated with option 4c

Option 4c – 100% increase in provision

	2017-18 £	2018-19 £	2019-20 £	2020-21 £	2021-22 £	2022-23 £
Welsh Government						
Production of guidance	9,000		0	0	0	1,500
Public Facilities Grant Scheme	200,000	200,000	200,000	200,000	200,000	200,000
Local authorities						
Strategy development and consultation		378,400	0	0	0	331,100
Grant	25,000	25,000	62,600	62,600	62,600	62,600

management staff time						0
Capital investment		0	17,020,800	17,020,800	17,020,800	0
Annual Maintenance		0	2,058,300	4,116,700	6,175,000	6,175,000
Grant scheme annual cost		0	237,500	237,500	237,500	237,500
Public						
Usage fees	0	0	791,700	1,583,300	2,375,000	2,375,000
Total cost	234,000	603,400	20,370,900	23,220,900	26,070,900	9,382,700
Additional Costs	9,000	378,400	20,145,900	22,995,900	25,845,900	10,344,700

893. The local authority and Welsh Government staff costs incurred in 2022-23 would be repeated every four to five years, in line with the review mechanism.

894. There would be significant costs associated with the building of new directly-provided toilet facilities. It is anticipated this cost would reduce with each iterative cycle of local authority strategies, as the gap between identified need and current provision should narrow as a result of the implementation of previous strategies.

Benefits

895. The benefits for this option are the same as those identified under option three. Again, it is not possible to quantify the extent to which these benefits would be achieved. However, it can be assumed this option would achieve the benefits to a greater extent, as the level of access to adequate toilet provision would be assessed and local authorities would be legally required to ensure any identified shortfall is addressed.

Summary and preferred option

896. Option one does not meet the policy objective. It continues existing practice and would not encourage the improvement of local toilet provision. There is an added risk that access to public toilet facilities would decline under this option.

897. Option two may encourage local authorities to increase spending on the provision of public toilets. However, re-hypothecation of the funding could necessitate cuts in other areas, and would not support the Welsh Government's general policy of affording flexibility to individual local authorities.

898. Option three is the preferred option. This approach places a duty on local authorities to produce a local toilets strategy, for which they are accountable. The strategy must take into account the needs of the local population. Local authorities would then be able to implement the strategy, in line with their means. Local authorities should develop a better understanding of their community's needs through this approach, and seek effective means of meeting that need.
899. Whilst option four would meet the policy objective, it would entail potentially prohibitive costs for local authorities at a time when budgets are already constrained. There is a lack of consensus on the levels of toilet provision required to be considered adequate. Dependent on the level of need identified during the development of the strategy, the duty within option four could become overly onerous on local authorities.

8. Competition Assessment and Specific Impacts

Competition Assessment

900. Due to the varied issues covered by the Public Health (Wales) Bill, the extent to which provisions impact on competition vary. Separate competition filter tests have therefore been completed and are presented below.

Tobacco and nicotine products

i) Restrictions on smoking in school grounds, hospital grounds and public playgrounds

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

ii) Register of retailers of tobacco and nicotine products

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes*
Q2: In the market(s) affected by the new regulation,	Yes*

The competition filter test	
Question	Answer yes or no
does any firm have more than 20% market share?	
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	Yes*
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

*As there are no data available about the market share of retailers for tobacco and/or nicotine products, the market share of grocery sales has been used

Handing over tobacco etc. to persons under 18

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes*
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	Yes*
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	Yes*
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	Yes

The competition filter test	
Question	Answer yes or no
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

*As there are no data available about the market share of retailers for tobacco and/or nicotine products, the market share of grocery sales has been used

Special procedures

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

Intimate piercing

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation,	No

The competition filter test	
Question	Answer yes or no
do the largest three firms together have at least 50% market share?	
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

Health impact assessments

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No*
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

*Health impact assessments can be undertaken in respect of a broad range of different of activities, some of which may be characterised by rapid technological change.

Pharmaceutical services

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	Yes
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	Yes (but no more than is currently the case)

Provision of toilets

The competition filter test	
Question	Answer yes or no
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market	No

The competition filter test	
Question	Answer yes or no
structure, changing the number or size of firms?	
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

Specific Impacts

901. A series of impact assessments relating to the policy areas contained within the Public Health (Wales) Bill – ‘the Bill’ – have been completed as part of the Regulatory Impact Assessment. The impacts varied in a number of policy areas but were largely positive. Examples of the main impacts are summarised in the following paragraphs.

Equality Impact Assessment

902. The Welsh Government is bound by the Equality Act 2010, and the Wales-Specific Equalities Duties Regulations, the Human Rights Act 1998 and the European Convention on Human Rights (ECHR). Assessments on the different components of the Bill found largely positive impacts for vulnerable and protected groups. The proposals are intended to benefit the health and wellbeing of the population of Wales as a whole; however, the process also identified specific impacts for protected groups. To avoid duplication the specific impacts on children and young people are summarised separately, at the United Nations Convention on the Rights of the Child (UNCRC) section.
903. The changes in relation to **pharmaceutical services** are relatively technical in nature but significant in terms of equality. Community pharmacies are easily-accessible and provide a convenient, less formal environment for those who cannot or do not wish to visit other kinds of health services. The changes to the way in which decisions about local pharmaceutical services are made, moving towards a system which is more alert and responsive to the pharmaceutical needs of local communities, will improve the planning and delivery of public health services and have a range of benefits. These will include better access to emergency hormonal contraception; increased access to seasonal flu vaccinations for those at increased risk; improved understanding of the

pharmaceutical needs of minority groups and timely access to the right services for pregnant or new mothers, older people and those with physical disabilities. Continuing to develop the public health role of community pharmacies could also widen access to services for people who are less likely to be registered with a local GP, for example, travellers and people seeking asylum.

904. Similarly, the changes to the planning of **provision of toilets** will have positive impacts for a number of specific groups. Some of these can be disproportionately affected by poor provision. Poor provision is known to have particular negative impacts on older people, including affecting their independence, community participation and contributing to social isolation. Improving provision will be beneficial for other groups, such as women, young families, those with certain medical conditions and homeless people. Each local authority's assessment of the needs of its community will also help ensure provision responds appropriately to the needs of their communities, including those of people with disabilities.
905. The creation of the **special procedures** licensing scheme will have a generally positive impact for all those who elect to have one of the defined special procedures, including people within protected or vulnerable groups. The requirements will help to drive up standards in a consistent way across Wales, ensuring individuals are better informed about the health risks associated with particular procedures and are able to identify providers who they know have achieved the requirements for licensing. It is intended that regulations will require pre-and post-procedure consultations with customers to be conducted, which should lead to better understanding about how to look after wounds and avoid infections. This will be beneficial to all but will have particular benefits for certain groups such as people with learning disabilities.

Human rights

906. The policy areas contained in the Bill raise a number of human rights considerations. For example, a number of the provisions involve placing restrictions on certain activities or behaviours, or on the use of certain products in defined circumstances. Detailed consideration has been given during the development of the Bill to strike an appropriate balance between protecting the rights of individuals in specific scenarios and protecting those of the population as a whole.
907. When legislating in areas of social policy, including public health, the National Assembly for Wales, as an elected legislature, is given a broad margin of appreciation in determining the appropriate balance to be struck between competing human rights. As set out below, it is considered that the balance struck by the Bill's provisions falls within this broad area of discretion and that the Bill is therefore within the National Assembly's competence.

908. In particular, it is noted that Part 2 of the Bill (Tobacco and Nicotine Products), may engage Articles 8 and 14 of the ECHR, and Article 1 of the First Protocol to the ECHR (“A1P1”).
909. Part 2 of the Bill restricts a person’s freedom to smoke in a private dwelling, which is also a workplace, but only in those parts of the dwelling that are used as a place of work and only at the times they are being used as a place of work. Article 8 ECHR sets out the right to respect for private life, for family life, for the home, and for correspondence. These rights are qualified rights – they are not absolute – and may be interfered with in pursuance of one or more legitimate aims, including the protection of health or morals.
910. It is considered from an Article 8 ECHR perspective that the provisions strike an appropriate balance – which is within the National Assembly’s margin of appreciation – between a homeowner’s freedom to smoke in the home and the right of workers and visitors to the property not to be exposed to the dangers of second hand smoke.
911. It is noted that the Bill’s restrictions on smoking in particular premises at particular times could be regarded as controlling to some extent the use that can be made of the property. This may therefore engage A1P1, which provides for the peaceful enjoyment of property. An interference with this right may be justified if it is in the public interest.
912. It is considered that the Bill’s provisions in this respect strike a fair balance between a person’s right to use their property without restriction and the potential health risks of not restricting smoking (due to the health dangers of second hand smoke). The balance struck falls within the margin of discretion afforded to Member States in this respect.
913. It is noted that the special procedure licensing system created in Part 3 of the Bill may constitute a control to some extent as to the use of premises. This may therefore engage A1P1. It is considered that the Bill’s provisions in this respect strike a fair balance between a person’s right to use their property without restriction and the potential health benefits to having a special procedure licensing system – infection control. The balance struck falls within the margin of discretion afforded to Member States in this respect.
914. In relation to Part 4 of the Bill, which creates a prohibition on the intimate piercing of children under the age of 18, consideration was given to whether such a restriction engages Articles 8 and 14. To the extent that the provisions interfere with the personal autonomy of children under 18 and this is protected by Article 8, the interference is necessary for, and proportionate to, the protection of the health and wellbeing of children. It is considered that, to the extent under 18s are not able to have an intimate piercing in Wales, the differential treatment (in comparison to those over 18) is justified as the provision protects children and young people from potential harm.

915. It is noted that the provisions in relation to pharmaceutical needs assessments in Part 6 of the Bill may constitute to some extent a control as to the use of property. This may therefore engage A1P1. It is considered that the Bill's provisions in this respect strike a fair balance between a person's right to use their property without restriction and the potential health benefits of assessing pharmaceutical needs in an area and therefore improving access to pharmaceutical services. The balance struck falls within the margin of discretion afforded to Member States in this respect.
916. A number of the proposals actively progress human rights principles. For example, the proposals relating to provision of toilets may reduce the possibility of a person being subject to degrading treatment (Article 3 ECHR).

United Nations Convention on the Rights of the Child (UNCRC)

917. The Rights of Children and Young Persons (Wales) Measure 2011 places a duty on all Welsh Ministers to have due regard to the substantive rights and obligations within UNCRC and its optional protocols when exercising any of their Ministerial functions. This means they need to consider all the issues which are relevant to the decisions they are making and do everything possible to ensure they further children's rights.
918. Through its combination of provisions the Bill supports several of the articles of the Convention, including:-
- Article 3 – All organisations concerned with children should work towards what is best for each child;
 - Article 6 – All children have the right of life. Governments should ensure that children survive and develop healthily;
 - Article 12 – Children have the right to say what they think should happen when adults are making decisions that affect them, and have their opinion taken into account;
 - Article 23 – Children who have any kind of disability should have special care and support so that they can lead full and independent lives;
 - Article 24 – Children should have the right to good quality healthcare;
 - Article 31 – All children have the right to relax and play, and join in a range of activities;
 - Article 36 – Children should be protected from any activities that could harm their development.
919. The importance of protecting the health of children, and preventing future health harms, is a common theme across many of the Bill's provisions. Articles 3 and 36 are particularly relevant to the provisions dealing with tobacco and nicotine products. Preventing access to tobacco

products by children and young people is a crucial part of protecting them from the health harms caused by smoking and is a key aim of both the **register of retailers of tobacco and nicotine products** and the provisions addressing **handing over tobacco to persons under 18**. Reducing the visibility and normalisation of smoking is another key aim of the Bill. The provisions placing **restrictions on smoking**, particularly in **school grounds, hospital grounds and public playgrounds** provide an example of this principle, with a particular focus on the impacts on young people.

920. The proposals relating to **intimate piercing** also have the need to protect children and young people from avoidable harm at their core. These provisions are consistent with Welsh Ministers' duty to act in children's best interests, and to protect them from harm and exploitation.
921. The provisions addressing **pharmaceutical services** will support Article 24 as these aim to ensure that the planning and delivery of these services appropriately meet the needs of local communities. This has the potential to have a range of positive benefits on the health and wellbeing of children and young people. Improving assessments of local pharmaceutical needs may lead to more pharmacies providing enhanced services, which may include medication for the treatment of minor ailments which are common in children, including constipation, earache, diarrhoea, hay fever, head lice, mild eczema, nappy rash and teething pain. At the other end of the age range, young people approaching or within the 16 to 18 age range may benefit from improved provision of emergency hormonal contraception and smoking cessation services.
922. Article 24 also promotes a right of access to information which will assist children and young people in safeguarding their health. This is supported by the provisions addressing **special procedures**. The intended requirements for pre and post-procedure consultations and public access to a register of licensed businesses will help young people to become better informed when considering a defined procedure.
923. Improving the planning of **provision of toilets** will support Articles 23 and 31. This may benefit children and young families who often rely on the availability of toilet and baby changing facilities when away from home, and provide greater opportunities for young people, particularly those who have a disability or certain medical conditions, to participate in a wide range of activities outside the home.
924. The **provision of toilets** also supports Article 12 as there will be an expectation for local authorities to assess the needs of their communities for toilet facilities, including those of children and young people, and to engage with them appropriately in assessing local needs. Similarly, in relation to **pharmaceutical services**, the pharmaceutical needs assessments prepared by health boards will be subject to public consultation. These provisions will therefore help support the rights of young people to express their views on matters which affect them.

Impact on the Welsh language

925. The Welsh Government's Welsh Language Scheme requires that an assessment of the impacts of proposed primary legislation on the Welsh language be carried out and a set of impact assessments for each individual policy area in the Bill has been carried out. The Welsh Government has also published its *laith Fyw; laith Byw* strategy for the Welsh language for 2012-17, which aims to see an increase in the number of people who speak and use the language. In relation to health specifically, the *More than just words* strategy aims to strengthen Welsh language services among frontline health and social care services.
926. The issues dealt with in the Bill primarily relate to discrete public health issues, rather than the provision and accessibility of general health services. As such there are limited direct impacts on the Welsh language, either positive or negative. However, there are a number of more indirect impacts, and the Bill's provisions indirectly support a number of the aims of *laith Fyw; laith Byw*. Of these, the most relevant is the aim of strengthening the position of the Welsh language within the community, particularly in the context of developing community health assets.
927. The Bill has the potential to positively impact the Welsh language in varying ways. For example, the proposals relating to **provision of toilets** and **pharmaceutical services** involve assessing the needs of local communities for services and facilities in a way which includes meaningful engagement with local citizens. In assessing local needs, the expectation will be that the engagement process will be inclusive of the spectrum of people in their communities, including Welsh-speaking members. This will therefore have potential to increase the visibility of the Welsh language in community settings and encourage community participation through the medium of Welsh in the process of planning and shaping local services and facilities.
928. In relation specifically to **pharmaceutical services**, in preparing their assessments of pharmaceutical need it will be necessary for health boards to consider any relevant factors, including the prevalence of Welsh speakers; the availability of pharmaceutical services in the Welsh language from existing pharmacies and the extent to which the availability of pharmaceutical services in the Welsh language contribute to the adequacy or inadequacy of access to pharmaceutical services. Where such assessments identify the pharmaceutical services available to a community are inadequate because they are not available in the Welsh language, a health board will need to consider this alongside other unmet pharmaceutical needs when planning pharmaceutical services.
929. A number of the Bill provisions will also require the provision of information to the public in a variety of forms. In a number of policy areas contained in the Bill this could involve opportunities for training through the medium of Welsh. The production of documentation will take place in

accordance with the Welsh language schemes; Welsh Language Standards or policies of the relevant organisation.

Sustainable development

930. As part of the policy impact screening for the Bill, consideration has been given to the five headline indicators in the Welsh Government's Sustainable Development Scheme. These are:

- Sustainable Resource Use
- Sustaining the Environment
- A Sustainable Economy
- A Sustainable Society
- The Wellbeing of Wales

931. The provisions contained within the Bill make an important contribution to a broader agenda focused on preventing avoidable harms to health and wellbeing. Such a focus on preventative principles is an intrinsic component of sustainable development, as it aims to achieve sustainable benefits for both individuals and society over the long term.

932. The Bill's **health impact assessments** provisions make an important contribution to sustainable development in Wales. They will require public bodies in Wales to undertake health impact assessments in certain circumstances to ensure the positive impacts on health of key decisions are maximised and potential negative impacts are avoided or mitigated. The provisions are aligned to the Well-being of Future Generations (Wales) Act 2015 and the Bill specifically provides that health impact assessments must be taken into account by public bodies in accordance with the sustainable development principle.

933. Due to the nature of the other issues included in the Bill, a number of the supporting indicators for the Sustainable Development Scheme are less directly affected, either positively or negatively, by the provisions. For example, there are no direct impacts in terms of the supporting indicators for sustainable resource use or sustaining the environment, including no impacts on biodiversity or Wales' ecological footprint, with the exception of any relevant decisions taken following the completion of a **health impact assessment** and potential reductions in travel time resulting from the changes to **pharmaceutical services**.

934. The indicators for a sustainable economy, a sustainable society and the well-being of Wales are directly relevant to different parts of the Bill.

A sustainable economy

935. The provisions relating to **pharmaceutical services** in particular support a sustainable economy by improving the planning and delivery of important community assets. Community pharmacies have been identified as one of the essential businesses which ensure economic prosperity within communities. Improving the planning and delivery of the

services they provide will therefore contribute to sustaining local communities, providing shopping access, local employment and helping to build social capital.

936. Improving the planning of the **provision of toilets** will help people (for example older people and those with specific medical conditions) to become more confident in playing a full and active role within their communities and therefore help promote local facilities and the wider local economy. It may also be the case that as local authorities will need to consider a full range of available opportunities for providing access to local toilets, this could lead to increased foot-fall for certain premises/businesses within the surrounding area. This could, for example, lead to more people accessing other services at the same premises, or encourage repeat visits.
937. Conversely, the impact assessments for the **register of retailers of tobacco products and nicotine products** recognised the potential negative effect that refusal of entry to a register, or suspension from it, may have on some local businesses. There may also be similar potential effects in relation to **special procedures** if a licence or approval application is refused or revoked. In both cases this will be mitigated by enforcement officers being able to provide advice and guidance about the steps which can be taken to ensure compliance with the relevant requirements. Furthermore, if the special procedures provisions in the Bill lead to fewer people contracting infections or suffering avoidable adverse effects (either through improved practices or better understanding of any after-care required), then other local businesses may benefit from fewer working hours lost due to illness.

A sustainable society

938. The provisions relating to **health impact assessments** will help ensure key decisions taken by public bodies in Wales take into account an assessment of the likely effect, both in the short and long term, of a proposed action on the physical and mental health of the people of Wales, or of particular groups. These provisions will therefore be important in ensuring the decisions taken by public bodies benefit the health and well-being of communities across Wales. The provisions relating to **pharmaceutical services** aim to improve the planning and delivery of these services by better aligning them with the needs of local communities. Similarly, improved **provision of toilets** will help encourage people who may need regular access and who are affected by poor provision to take more exercise and stay more physically active, thereby helping to address health inequalities. Furthermore, the provisions relating to **tobacco** have the potential to contribute to a further reduction in smoking rates, which generally tend to be higher in more deprived areas and amongst people in lower socioeconomic groups.

The wellbeing of Wales

939. The provisions in the Bill as a whole have the primary purpose of supporting and improving the overall wellbeing of Wales by seeking to address a series of specific public health concerns. The provisions about **health impact assessments** aim to complement the Well-being of Future Generations (Wales) Act 2015 by ensuring key decisions in Wales are taken following a specific assessment of the likely impact on physical and mental health and wellbeing. The provisions relating to **tobacco and nicotine products** collectively aim to reduce the visibility of smoking and prevent young people from accessing these products. They therefore seek to protect future health and wellbeing from the risks of smoking-related disease.
940. The contribution which improving the **provision of toilets** and access to **pharmaceutical services** will make to overall wellbeing in Wales is clearly set out in earlier paragraphs. In addition, the **special procedures** provisions and the prohibition of **intimate piercing** of persons under 18 will also protect future health and wellbeing by helping to avoid preventable health harms.

Rural proofing

941. The proposed changes within the Bill will impact on both urban and rural areas, and will apply equally to all parts of Wales. The rural proofing screening assessments found a number of the policy areas will also have considerations which are particularly relevant to rural areas.
942. The existing challenges regarding the **provision of toilets** have particularly acute impacts in rural areas and communities. The general issue of toilet provision and access has commonly been raised in the context of rural areas, where poor provision is understood to have a disproportionately large impact due to the greater distances between available facilities. Improving planning and access will therefore have particular benefits for those living in rural areas and will contribute to sustaining rural communities. The requirements to consult on the strategies will help ensure appropriate engagement takes place which reflects the make-up of local populations, including the particular needs of rural communities. There may also be indirect benefits for rural businesses if improved provision encourages greater community participation and repeated visits to an area.
943. Improving the planning and delivery of **pharmaceutical services** will have positive impacts for rural areas. People in rural areas may rely more heavily on the services provided by community pharmacies if these are more accessible to them than other services. If gaps in services are identified in rural communities through pharmaceutical needs assessments, this should lead to steps being taken to ensure adequate provision.
944. Some specific **health impact assessments** undertaken by public bodies may be informed by particular rural considerations, depending on

the proposal being subject to the assessment. There may therefore be specific positive impacts on health and wellbeing in rural areas as a result of findings of the assessments.

945. The **register of retailers of tobacco and nicotine products** will apply equally across Wales. However, the impact screening identified the potential for greater impact in rural areas of any retailers being prevented from selling these products if they fail to comply with the requirements. There may be fewer customers to help sustain small, independent shops if they lose income from selling these products. Customers may also have to travel further to purchase these products if there are fewer alternative options available locally. This potential impact will be mitigated by the role of local authority enforcement officers in providing advice and support to retailers to help them avoid breaches of the requirements. There could be similar impacts associated with the **special procedures** provisions, which will be mitigated in the same way.
946. There will be no difference in costs for registration solely by virtue of being situated in a rural area. However, there may be potential for some rural areas to be more affected by the need to pay fees, for example if an area has a higher proportion of small businesses or sole traders. This potential impact is mitigated by the setting of any fees at a level which is not considered prohibitive for sole practitioners or small retailers.
947. In general, the enforcement mechanisms for the changes provided for in the Bill will make use of existing local systems. This will ensure that local knowledge and expertise held by enforcement and inspection officers is harnessed, including experience of operating within a rural context.

Health and wellbeing

948. Improving and protecting the health and wellbeing of the Welsh population is the overall purpose of the Bill. It seeks to put in place a series of practical and preventative legal measures, each designed to help address a specific public health challenge. Taken together, the proposals aim to have a cumulative, positive impact on overall health and wellbeing. The provisions also make a positive contribution in relation to health inequality, as the issues addressed by the Bill can disproportionately affect the most disadvantaged individuals, families and communities.
949. The Bill combines a number of approaches for influencing the social and community influences on health. For example, the provisions for **health impact assessments** take forward a specific method for safeguarding the physical and mental health and wellbeing of people in Wales, in a way which complements and supports the contribution of the Well-being of Future Generations (Wales) Act 2015 to public health in Wales.

950. The provisions dealing with **tobacco and nicotine products** continue the strong tradition of legislating to address important lifestyle issues and seek to further strengthen the extensive legal framework in these areas.
951. In a similar way, the provisions relating to **special procedures** and **intimate piercing** seek to avoid and minimise the risk of potential harms to health. In relation to special procedures in particular, ensuring practitioners and their premises meet and maintain specified standards will have a positive effect on the conditions affecting the health of customers and employees.
952. The provisions dealing with **pharmaceutical services** and the **provision of toilets** focus on particular local services and facilities which have an important public health role. All community pharmacies are contracted to help promote healthy lifestyles, including the provision of healthy eating advice. Where pharmacies are accredited to provide enhanced services – such as smoking cessation services – this also supports healthier lifestyles. The local toilet strategies provided for by the Bill aim to reduce social isolation, particularly among vulnerable groups. Ensuring adequate provision therefore aims to improve community infrastructure and amenities in a way which supports good health and wellbeing.

Impact on privacy

953. The privacy impact screenings indicated a number of areas of the Bill will involve the handling and processing of personal information. Where this is the case the data controller will need to ensure its processing complies with the Data Protection Act 1998. The most directly relevant areas of the Bill are the proposed schemes for **retailers of tobacco and nicotine products** and **special procedures**. These will involve the handling of personal information about retailers, practitioners and their premises. Data about the register of retailers of tobacco and nicotine products will be maintained centrally, with access being available to local authorities for enforcement purposes. More limited information (for example a retailer's name and business address) will be available to the public. In the case of special procedures, data about licence holders will be held by local authorities and will be available to the public. Practitioners will also be expected to maintain appropriate customer records.
954. In submitting this type of personal information, individuals will be doing so due to their role within the business. The relevant data controllers and data processors for the registers will need to comply with appropriate data protection principles and legislation. Providing appropriate fair processing will be key to this, so individuals and/or the businesses they represent are aware of how the data will be used – especially where the provision of personal data is not optional. The same principles will apply to the personal information held by special procedures practitioners about their customers.

955. The changes to the planning of the **provision of toilets** include requirements to undertake local engagement and consultation. Some handling of personal information is likely to be involved in the administration of such exercises. The relevant data controllers will be responsible for ensuring that any personal data is processed in accordance with the Data Protection Act 1998. In the case of local authorities for example, they will have established procedures in place for conducting consultations, including relating to the handling of any personal information. Furthermore, it will be the choice of each individual about whether they wish to respond to a consultation exercise or to have their response anonymised.
956. In respect of **pharmaceutical services**, each health board already has its own pharmaceutical list and so will already have data protection protocols in place in order to comply with their statutory duties. Data collected through the new pharmaceutical needs assessments are unlikely to contain any sensitive personal information or will have any relevant details anonymised.
957. There is the potential for a small number of individuals to be subject to prosecutions resulting from the legal changes made by the Bill. In such circumstances, any personal information will be processed by the relevant authorities in accordance with established procedures and legislation. This will be of particular importance in some circumstances, for example where sensitive personal information may be held as part of any prosecution in relation to the intimate piercing of a person under 18. In such cases, the relevant authorities will be deemed the data controller and the onus will be on them to ensure compliance with the Data Protection Act 1998.

Impact on the voluntary sector

958. A range of voluntary sector organisations engage in the public health agenda, often with particular interests in certain issues. While the provisions in the Bill do not directly affect voluntary sector organisations, those representing particular sectors or groups within the population will have a keen interest in the implementation of the Bill.
959. Voluntary sector organisations are also likely to participate in engagement and consultation processes involved in implementing different areas of the Bill. The sector will also be likely to input into monitoring of the legislation and contributing to post-implementation reviews.

Impact on the judicial system

960. A number of new offences will be created under different parts of the Bill - for example, relating to the provisions on **tobacco and nicotine products, special procedures** and **intimate piercing**. There will also be

appeal mechanisms in place in relation to the various provisions included in the Bill. Applying previous experience from similar areas, it is envisaged that the legislation will attract generally high levels of compliance, with an anticipated minimal number of court cases. The overall impact on the courts and judicial system in Wales is therefore anticipated to be low. Where potential impacts have been identified, these have been referenced at the appropriate points within the Regulatory Impact Assessment.

9. Post-implementation review

961. The Public Health (Wales) Bill is multi-faceted and designed to provide a legislative basis for action in discrete subjects, in order to prevent avoidable health harms. The review, monitoring and evaluation arrangements must reflect this overall context.
962. A programme of monitoring and evaluation activity will be developed to correspond with key activities and dates. Various research and evaluation methods will be considered, depending on the nature of the data required. The monitoring and evaluation arrangements will comprise a coherent set of components, some of which will be common to two or more elements of the Bill while others, because of the specific nature of certain parts, will be bespoke. For some elements it will be necessary for a reasonable period of time to have elapsed before the outcome of the provisions can be assessed and the ability to demonstrate change may be constrained by the use of modelled or estimated baseline measures in some areas.
963. The proposed monitoring and evaluation arrangements can be grouped together into three broad categories. Taken together, these will encompass a blend of monitoring routine health data and statistics; administrative data and independent review. In addition, consideration will be given to commissioning specific research into the implementation of certain parts of the Bill as and when a need for such research is identified.

Health data and statistics

964. Activity to monitor the implementation of the Bill will, wherever possible, be aligned to other relevant work. Data provided in surveys routinely undertaken by the Welsh Government – and partners – will therefore provide an important source of data to aid in the monitoring of the legislation. At the same time, consideration may need to be given to new data collections as necessary.
965. While routine health data will provide an essential information source, it must be noted that a number of the issues addressed in the Bill are also being addressed by other forms of action. It will therefore be difficult to fully attribute certain population level trends (as may be identified through this type of data) to the effects of the Bill. For example, the Bill's provisions relating to tobacco and nicotine products seek to make a general contribution towards reducing smoking rates among children and young people, by further restricting the visibility of smoking and access to certain products. However, it would not be possible for such a trend to be attributed solely to the Bill, particularly given other relevant developments in legislation such as the introduction of age restrictions on the sale of nicotine products, standardised packaging for tobacco products, and the Tobacco and Related Products Regulations 2016, which transpose the EU Tobacco Products Directive, alongside other societal influences.

Administrative data

966. Similarly, best use will be made of the most relevant administrative information already collected. Importantly, this will include a range of data collected by local authorities in respect of the topics covered in the Bill.

This will include:

- Data about inspections undertaken;
- Enforcement information, including data on written warnings, fixed penalty notices and prosecutions;
- Data on complaints/enquiries received by trading standards and environmental health departments.

Independent review

967. The third component of the overall review arrangements will provide for a formal process of periodic independent review. It is envisaged this will involve the formal input of key stakeholders through established expert groups. Due to the varying issues addressed by the Bill, it is anticipated this role would most appropriately be fulfilled by different groups. Groups which could potentially undertake such a function across the Bill's different components could include the Tobacco Control Strategic Board and the Welsh Pharmaceutical Committee, although others could be considered or established as appropriate.

968. Each expert group allocated with this type of responsibility could formally be tasked with undertaking a review of the Bill (or part of the Bill), potentially following a three-year cycle. Each group would then report back to the Welsh Government in the first instance. This strand of review would not be mutually exclusive from the others, as routine data and administrative data would help inform the judgements of such expert groups.

969. A practical illustration of how the legislation will be monitored can be provided by reference to the provisions restricting smoking in public and work places and in school grounds, hospital grounds and public playgrounds. Compliance with the restrictions will be monitored by local authority enforcement teams. It is anticipated this will require completion of a quarterly return to the Welsh Government by each local authority, using a form no more than one side of A4 in size. Local authorities will be asked to provide details about the number of FPNs issued in relation to the smoke-free offences; the number of FPNs paid and the number of court hearings and prosecutions.

970. Monitoring of the impact of the restrictions will be through existing mechanisms to track rates of exposure to and use of tobacco among children and adults in Wales. Important sources for this work include the

Health Behaviours in School-aged Children (HBSC) survey and the National Survey³⁴⁷.

³⁴⁷ From 2016-17, the Welsh Health Survey was amalgamated with the National Survey, the Arts in Wales Survey and the Welsh Outdoor Recreation Survey into a single survey.

Annex 1 – Explanatory Notes

PUBLIC HEALTH (WALES) BILL

EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes relate to the Public Health (Wales) Bill as laid before the National Assembly for Wales on 7 November 2016.
2. They have been prepared by the Welsh Government's Health and Social Services Group in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by the National Assembly for Wales.
3. The Explanatory Notes should be read in conjunction with the Bill. They are not meant to be a comprehensive description of the Bill. Where an individual section of the Bill does not seem to require any explanation or comment, none is given.

POLICY BACKGROUND

4. The health and well-being of the population of Wales is continuing to improve. In general, people are living longer and enjoy better health than ever before. However, Wales still faces a number of specific and significant health challenges. These range from overarching demographic challenges such as an ageing population and continuing inequalities in health, to more discrete ones posed by lifestyle choices and contemporary developments within society.
5. Legislation has historically played an important role in improving and protecting health. Legislation in areas as varied as the ban on smoking in enclosed public places and wearing seat-belts has been seen to make significant contributions to health and well-being.
6. This Bill has been developed following consultation on a Public Health White Paper, which included a series of legislative proposals to address a number of public health issues in Wales. The focus of the Bill is on shaping social conditions that are conducive to good health, and where possible, avoiding health harms that can be averted.

GENERAL OVERVIEW OF THE BILL

7. The Bill includes provisions in a number of discrete policy areas, all of which aim to address contemporary challenges to health and well-being in Wales.
8. The Bill is comprised of 124 sections (within 8 Parts) and 4 Schedules.
 - Part 1 – Overview
 - Part 2 - Tobacco and Nicotine Products
 - Chapter 1: Restricts smoking in enclosed and substantially enclosed workplaces and public places, and in school grounds, hospital grounds and public playgrounds, and gives the Welsh Ministers power to extend the prohibition to other premises, and to vehicles;
 - Chapter 2: Establishes a national register of retailers of tobacco and nicotine products;
 - Chapter 3: Provides the Welsh Ministers with a regulation making power to add to the offences which contribute to a Restricted Premises Order (RPO) in Wales;
 - Chapter 4: Prohibits the handing over of tobacco or nicotine products (when delivered or collected in connection with their sale) to an unaccompanied person under the age of 18;
 - Part 3 provides for the creation of a mandatory licensing scheme for businesses/practitioners offering specified ‘special procedures’, namely acupuncture, body piercing, electrolysis and tattooing;
 - Part 4 introduces a prohibition on the intimate piercing of persons under the age of 18 years;
 - Part 5 contains provisions about the carrying out of health impact assessments by public bodies;
 - Part 6 changes the arrangements for determining applications for entry onto a Local Health Board’s pharmaceutical list, to a system based on the assessed needs of local communities;
 - Part 7 requires local authorities to prepare a local toilets strategy in order to plan how they will meet the needs of their communities for access to public toilets; and
 - Part 8 contains miscellaneous provisions about the use of fixed penalty receipts in respect of food hygiene rating offences, and a number of general provisions, including in relation to regulations, interpretation, powers to make consequential and transitional provisions, and coming into force arrangements.

COMMENTARY ON SECTIONS

PART 1 OVERVIEW

9. Section 1 provides an overview of the main provisions of the Bill. It summarises the subjects covered in each subsequent Part.

PART 2 TOBACCO AND NICOTINE PRODUCTS

CHAPTER 1: SMOKING

10. This Chapter contains provisions that make enclosed and substantially enclosed public premises and shared workplaces smoke-free, as well as some specific non-enclosed premises. These are referred to as 'smoke-free premises'. For the purpose of this Chapter, 'smoke-free' means that smoking is not permitted, unless the premises are exempted by regulations made under section 13 of the Bill.
11. This Chapter restates Chapter 1 of Part 1 of the Health Act 2006 ("Smoke-Free Premises, Places and Vehicles") in relation to Wales, with some minor modifications. It also brings additional settings into the smoke-free regime in Wales, namely school grounds, hospital grounds and public playgrounds.
12. Regulations can also provide for additional premises to be smoke-free in certain circumstances. These additional smoke-free premises need not be enclosed or substantially enclosed. Vehicles may also be smoke-free; such vehicles are referred to as 'smoke-free vehicles' in this Chapter.

Section 2: Smoking

13. This section provides the definition of "smoking" for Chapter 1 of Part 2 of the Bill. The definition covers the smoking of cigarettes, pipes, cigars, herbal cigarettes and waterpipes (often known as hookah or shisha pipes) etc.

Section 3: Offence of smoking in smoke-free premises or vehicle

14. This section makes it a criminal offence to smoke in smoke-free premises or in a smoke-free vehicle. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 1 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982. A fixed penalty notice may be issued by an authorised officer instead of prosecution (see section 24).

Section 4: Offence of failing to prevent smoking in smoke-free premises

15. This section requires managers of smoke-free workplaces and public premises to take reasonable steps to prevent smoking in those places. The Welsh Ministers may make regulations imposing corresponding duties in

respect of smoke-free school grounds, hospital grounds and public playgrounds, and any additional smoke-free premises and smoke-free vehicles designated by the Welsh Ministers under sections 10 or 12. Any person who fails to comply with these duties is committing an offence. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 4 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 5: Workplaces

16. This section details what is meant by “workplaces” in the context of the smoke-free premises in this Chapter. A “workplace” is a place that is used as a place of work by more than one person (irrespective of whether such people work there at the same time) or is a place of work for one person but is somewhere that the public may have access to for certain purposes. For instance, a shop where only one person works would be a workplace for the purposes of the Chapter. Where only parts of the premises are used as a place of work, only those parts are smoke-free. In all cases, only those areas that are enclosed or substantially enclosed are smoke-free. All workplaces are smoke-free all of the time, except that a dwelling used as a workplace is smoke-free only when being used as such. So for instance if a person uses their home as a workplace, and members of the public might come to it to obtain the goods or services offered, his/her home will be smoke free only in the parts of it used as a workplace, and only when those parts are being used by the person for work.

Section 6: Premises that are open to the public

17. This section details what is meant by “premises that are open to the public” in the context of smoke-free premises in this Chapter. It includes all premises that are open to the public or a section of the public (irrespective of whether this is by invitation or not, or whether there is a charge for entry or not). So, for example, places of worship, private members' clubs, prisons and all licensed premises would be open to the public for the purposes of this Chapter. Where only parts of the premises are open to the public, only those parts are smoke-free. All such premises are smoke-free only when open to the public and only in those areas that are enclosed or substantially enclosed.

Section 7: School grounds

18. This section provides that school grounds in Wales are smoke-free premises. It provides details about what is meant by “school grounds” in the context of smoke-free premises in this Chapter.
19. Grounds being used by a school but that do not adjoin the school are smoke-free only when, and in those parts, being used for the provision of education or childcare (subsection (3)). So for example, if a school has a sports field that is for its sole use, but which is across the road from the school, the sports field will be smoke-free only when being used for educational or childcare purposes. “Childcare” is defined in section 25.

20. But if the sports field adjoins the school, it will be smoke-free when it is being used for the purpose of education or childcare, or when the school itself is being used for education or childcare (subsection (2)). So, the sports field will be smoke-free both during school hours and if (for example) there is an after-school club in the school hall, while the club is being held.
21. Schools that provide residential accommodation to pupils may designate an area where smoking is allowed. The Welsh Ministers may specify in regulations conditions relating to any such designation, for example about the size or location of the designated area. Premises used to any extent as a dwelling are not smoke-free under this section.

Section 8: Hospital grounds

22. This section provides that hospital grounds in Wales are smoke-free premises. It provides details about what is meant by “hospital grounds” in the context of smoke-free premises in this Chapter. It includes all grounds that adjoin the hospital, are used by or occupied by it, and are not enclosed or substantially enclosed. An area may be designated within the hospital grounds where smoking is allowed. The Welsh Ministers may specify in regulations conditions relating to any designation, for example about the size or location of any designated area.
23. There is an exclusion for the grounds of adult care homes and of adult hospices, and for dwellings. So if, for instance, a member of staff has accommodation provided within the grounds of the hospital, the garden of his/her home will not be smoke-free. Nor will the garden of an adult hospice be smoke free.

Section 9: Public playgrounds

24. This section provides that outdoor public playgrounds in Wales are smoke-free premises. It provides details about what is meant by “public playgrounds” in the context of smoke-free premises in this Chapter. Outdoor premises will amount to a playground if they meet the requirements specified in subsection (4). These requirements focus on local authority involvement, the purpose for which the premises are used, and the presence of playground equipment. Premises that amount to a playground are smoke-free so far as within a boundary or (in the absence of boundary) so far as within 5 metres of playground equipment. “Playground equipment” is defined in section 25.

Section 10: Additional smoke-free premises

25. This section gives power to Welsh Ministers to make regulations to designate additional smoke-free premises. These need not be enclosed or substantially enclosed (i.e. they may be open spaces). The Welsh Ministers can only designate additional smoke-free premises where they are satisfied that designating those premises as smoke-free is likely to contribute towards the promotion of the health of the people of Wales.

26. The Welsh Ministers' regulations may also provide for exemptions to the smoke-free status of any additional smoke-free premises. The regulations may, for example, allow the person in charge of the additional smoke-free premises to designate areas in which smoking is to be permitted. The designation would have to be in accordance with any conditions set out in the regulations.

Section 11: Further provision about additional smoke-free premises: dwellings

27. This section limits the Welsh Ministers' power to designate dwellings as additional smoke-free premises. Dwellings may only be designated as smoke-free by the Welsh Ministers to the extent that they are not enclosed or substantially enclosed and are workplaces or open to the public, and may only be made smoke-free during the times that a person under the age 18 is present. For example, the garden of a dwelling being used for the provision of childcare could be designated as smoke-free but only in the parts, and when being used for, the provision of childcare, and only when a child is present.

Section 12: Smoke-free vehicles

28. This section gives power to the Welsh Ministers to make regulations providing for vehicles to be smoke-free.
29. An equivalent power to make regulations applying to vehicles for the purposes of smoke-free premises under the Health Act 2006, is included at section 5 of that Act. Regulation 4 of the Smoke-free Premises etc. (Wales) Regulations 2007, made in exercise of the power at section 5 of the Health Act 2006, sets out that enclosed vehicles shall be smoke-free if used for transport of members of the public, or as a workplace for more than one person.
30. The Welsh Ministers can only designate a vehicle as being smoke-free where they are satisfied that designating that vehicle is likely to contribute towards the promotion of the health of the people of Wales.

Section 13: Smoke-free premises: exemptions

31. This section gives power to the Welsh Ministers to make regulations to exempt premises or places in Wales from the requirement to be smoke-free. These regulations may exempt defined premises or specific areas within defined premises. For example, a designated bedroom within a hotel or a designated room in a research or testing facility could be exempted from the smoke-free requirements.
32. An equivalent power to exempt premises, for the purposes of smoke-free premises under the Health Act 2006, is included at section 3 of that Act. Regulation 3 of the Smoke-free Premises etc. (Wales) Regulations 2007, made in exercise of the power at section 3 of the Health Act 2006, sets out the premises within which managers may designate smoking rooms (i.e. may designate rooms as being exempt from the smoke-free requirements of the

Health Act 2006). Exemptions currently apply to specific rooms within care homes, adult hospices, mental health units, research or testing facilities, hotels, guesthouses, inns, hostels and members' clubs.

Section 14: Signs: smoke-free premises

33. This section requires a person who occupies or manages smoke-free premises to display smoke-free signs in accordance with regulations. Requirements for smoke-free signs may include how they are to be displayed, and specifications regarding the dimensions of the sign, the minimum text size and font, any graphic or symbol that must be included and any mandatory warning message. The Welsh Ministers may also make regulations that place a corresponding duty on those who occupy or manage additional smoke-free premises (section 10) and smoke-free vehicles (section 12). Regulations may also require signs to be displayed in areas designated as not smoke-free. Regulations made under this section cannot require smoke-free signs to be displayed in premises used as dwellings.
34. Failure to comply with these requirements is an offence. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982. A fixed penalty notice may be issued by an authorised officer instead of prosecution. Section 24 contains more details on fixed penalty notices.

Section 15: Enforcement authorities

35. This section names local authorities as the enforcement authorities for this Chapter. It also allows for the police to be named in regulations as an additional enforcement authority in relation to the smoking restrictions for vehicles.
36. This section also places a duty on enforcement authorities to enforce the smoke-free provisions in this Chapter. Enforcement authorities may arrange to transfer a particular case to another enforcement authority, for example, where those enforcement authorities are investigating the same person for offences relating to smoke-free premises and vehicles.
37. This section also sets out the meaning of the term "authorised officer." An authorised officer is any person authorised by the enforcement authority to carry out their enforcement functions. An authorised officer may or may not be an officer of the enforcement authority.

Section 16: Powers of entry

38. This section confers powers on an authorised officer to enter any premises in Wales, excluding premises used wholly or mainly as a dwelling, at any reasonable time if they consider it necessary to investigate an offence in this Chapter. The section applies to a vehicle as if it were premises.

39. Authorised officers must not use force to enter premises or vehicles when exercising their power under this section. Authorised officers must present evidence of their authority before entering any premises or vehicles if they are asked to do so. Section 67(9) of the Police and Criminal Evidence Act 1984 provides that, while acting in the course of their enforcement functions, authorised officers of the enforcement authority must have regard to the relevant code of practice made under that Act. Therefore, authorised officers must have regard to the PACE Code of Practice B in the exercise of their enforcement functions.

Section 17: Warrant to enter dwelling

40. This section provides that a justice of the peace may issue a warrant to enable an authorised officer to enter a premises used wholly or mainly as a dwelling in certain circumstances. A warrant may be issued only where the justice of the peace is satisfied that there are reasonable grounds to believe that an offence has been committed at the premises, and that it is necessary to enter the premises for the purpose of establishing whether such an offence has been committed. Entry may be obtained by force if need be. This section applies to a vehicle as if it were premises.

Section 18: Warrant to enter other premises

41. This section provides that a justice of the peace may issue a warrant to enable an authorised officer to enter any premises, including vehicles, in Wales, if they consider it necessary in relation to an offence in this Chapter. This excludes premises used wholly or mainly as dwellings which are dealt with in section 17. The section sets out the circumstances in which a warrant may be issued. Entry may be obtained by force if need be. A warrant can be issued in a format other than a hard copy document, such as an electronic version.

Section 19: Supplementary provision about powers of entry

42. This section enables an authorised officer entering premises under section 16, 17 or 18 to take with them any other persons or equipment as the officer considers appropriate. It also requires that if the occupier of premises that an authorised officers is authorised to enter under sections 17 or 18 is present at the time the authorised officer seeks to execute the warrant the occupier must be told the officer's name; the officer must produce documentary evidence that the officer is an authorised officer; the officer must produce the warrant and supply the occupier with a copy of it. It also requires that if the premises are unoccupied or the occupier is temporarily absent, the authorised officer must leave the premises as effectively secured against unauthorised entry as the officer found them. The provisions in this section also apply to a vehicle.

Section 20: Powers of inspection, etc.

43. This section confers power on authorised officers to carry out inspections of premises and vehicles. Officers may request items, inspect them, take samples from them and/or take the item(s) and/or samples from the premises. For example, officers may wish to review CCTV footage of the premises, retain smoking debris for evidence purposes or take documents or copies of documents. They may also request information and help from any person but that person is not required to answer any questions or produce any document which they would be entitled to refuse in the course of court proceedings in England and Wales. The authorised officer may analyse any samples taken. The authorised officer must leave a statement detailing any items that have been taken, and identifying the person to whom a request for the return of property may be made. The provisions in this section also apply to a vehicle.

Section 21: Obstruction etc. of officers

44. This section provides that any person who intentionally obstructs an authorised officer from carrying out their functions under this Chapter is committing an offence. Any person who fails without reasonable cause to provide the officer with facilities that are reasonably required by the officer to carry out their functions is committing an offence. However, a person is not required to answer any questions or produce any document which they would be entitled to refuse in the course of court proceedings in England and Wales. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out at section 37 of the Criminal Justice Act 1982.

Section 22: Retained property: appeals

45. This section provides an additional safeguard relating to the powers of entry and inspection provisions. It enables a person with an interest in anything taken away from the premises by an authorised officer under section 20(1)(c) to apply to a magistrates' court for an order requesting the release of the property. Depending on the court's consideration of an application, it may make an order requiring the release of the retained property.

Section 23: Appropriated property: compensation

46. This section provides a right for a person affected by the taking possession of property under section 20(1)(c) to apply to a magistrates' court for compensation. Where the circumstances set out in subsection (2) are satisfied (i.e. that the person has suffered loss or damage as a consequence of the property being taken and the loss or damage is not due to their neglect or default), the court may order the local authority to pay compensation to the applicant.

Section 24: Fixed penalty notices

47. This section allows authorised officers to issue fixed penalty notices (FPNs) to persons believed to have committed certain offences under this Chapter. A fixed penalty can be issued for the following offences:

- smoking in smoke-free premises or vehicles;
- failing to comply with signage requirements.

48. FPNs may be issued to a person, partnership or an unincorporated association other than a partnership. Payment of the FPN discharges the person believed to have committed an offence from being convicted for the offence in court. The section also introduces Schedule 1 on fixed penalties (for commentary on this, see Schedule 1 below).

Section 25: Interpretation of this Chapter

49. This section sets out the meaning of key terms used in this Chapter.

50. The section also provides that the Welsh Ministers may make regulations to define what is meant by “enclosed”, “substantially enclosed” and “not enclosed or substantially enclosed” for the purposes of this Chapter.

CHAPTER 2: RETAILERS OF TOBACCO AND NICOTINE PRODUCTS

51. This Chapter contains provisions which will create a national register of retailers of tobacco and nicotine products. All retailers who sell either tobacco products, nicotine products or both from premises to the general public in Wales will be required to register in order to sell tobacco and/or nicotine products. This will include those selling from moveable structures. The register will not capture businesses which only sell to other retailers, traders or businesses.

Section 27: Duty to maintain register of retailers of tobacco and nicotine products

52. This section establishes a register of retailers of tobacco and nicotine products in Wales which will contain details of businesses selling those products to the general public in Wales. The section places a duty on the registration authority to maintain the register. Regulations made by the Welsh Ministers will specify a body, for example a local authority, to act as the registration authority.

53. The register may include other appropriate information.

Sections 28 and 29: Application for entry in the register and Grant of application

54. Section 28 allows retailers to apply to be on the register of retailers of tobacco and nicotine products, and outlines the information required in any application. The registration authority can only refuse an application if the applicant is subject to a Restricted Sales Order under section 12B of the

Children and Young Person's Act 1933. Premises cannot be added to the register if they are currently subject to a Restricted Premises Order under section 12A of the Children and Young Persons Act 1933. If the application contains multiple premises then only the premises not subject to a Restricted Premises Order will be added to the register.

55. A Restricted Premises Order is an order made by a magistrates' court that prohibits retail premises from selling tobacco or nicotine products for a period of up to 12 months. A court can only issue a Restricted Premises Order if it is satisfied that a person convicted of a tobacco or nicotine offence on the premises in question has also committed other tobacco or nicotine offences on at least two previous occasions within a period of two years. A tobacco offence is defined in section 12D of the Children and Young Persons Act 1933 and includes selling tobacco to a person under the age of 18. From 1 October 2015 the definition of tobacco offences has been amended to include an offence under section 92 of the Children and Families Act 2014 (prohibition of sale of nicotine products to persons under 18).
56. A Restricted Sales Order prohibits a named person who has been convicted of a tobacco offence from selling tobacco or nicotine products for a period up to 12 months. As with a Restricted Premises Order, a magistrates' court can only make a Restricted Sales Order if it is satisfied that the named person has also committed other tobacco or nicotine offences on at least two previous occasions within a period of two years.
57. The Welsh Ministers may, through regulations, require additional information to be provided when submitting an application for inclusion in the register, and may make provisions for a fee to be paid when submitting an application.

Section 30: Duty to give notice of certain changes

58. This section places a duty on retailers to inform the registration authority within 28 days of changes to an entry contained in the register, for example if they no longer sell tobacco products from the premises included on the register. In addition, if a local authority becomes aware of any relevant changes to the retailers of these products, it must inform the registration authority.

Section 31: Duty to revise the register

59. This section sets out when the registration authority must make changes to the register and the process it must follow in doing this.
60. The Welsh Ministers may, by regulations, allow the registration authority to charge a fee for revising the register.

Section 32: Access to the register

61. Under this section the registration authority must publish a list of all those persons and premises on the register of retailers of tobacco and nicotine

products. Where the business is carried on from a vehicle, stall, tent or other moveable structure, the list must indicate the local authorities in which it operates.

Section 33: Excepted premises

62. This section gives the Welsh Ministers power to exempt premises from having to register on the register of retailers of tobacco and nicotine products in order to sell tobacco or nicotine products.

Section 34: Moveable structures etc.

63. This section gives the Welsh Ministers power to modify the application of this Chapter in relation to premises which consist of a vehicle, stall, tent or moveable structure, for example to require additional information to be provided when submitting an application for inclusion in the register in relation to such premises.

Section 35: Offences

64. This section creates offences in relation to the register. Subsections (6) and (7) set out the different levels of penalty for the offences. The fine for carrying on a tobacco or nicotine business without being registered is not limited by any levels on the standard scale, so its amount will be determined by the magistrates' court. The other offences are punishable by a fine not exceeding level 2 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982. A fixed penalty notice may be issued by an authorised officer in place of a fine. Section 46 contains more details on fixed penalty notices.

Section 36: Authorised officers

65. This section clarifies that any references to authorised officers in this Chapter are to an officer authorised by a local authority, whether or not they are an officer of the local authority.

Section 37: Powers of entry

66. This section outlines under what circumstances an authorised officer may enter premises in Wales for the purpose of enforcing provisions relating to the register of retailers of tobacco and nicotine products.
67. Authorised officers must not use force to enter premises when exercising their power under this section. If they are asked to do so, authorised officers must present evidence of their authority before entering any premises. Section 67(9) of the Police and Criminal Evidence Act 1984 provides that, while acting in the course of their enforcement functions, authorised officers of the enforcement authority must have regard to the relevant code of practice made under that Act. Therefore, authorised officers must have regard to the PACE Code of Practice B in the exercise of their enforcement functions.

Sections 38 and 39: Warrant to enter dwelling and Warrant to enter other premises

68. These sections set out the circumstances in which a justice of the peace may issue a warrant to enter domestic premises or business premises in Wales for the purpose of enforcing provisions relating to the register of retailers of tobacco and nicotine products. The warrant remains in force for 28 days commencing on the date the justice of the peace signed the warrant. Entry may be obtained by force if need be. A warrant can be issued in a format other than a hard copy document, such as an electronic version.

Section 40: Supplementary provision about powers of entry

69. This section enables an authorised officer entering premises under section 37, 38 or 39 to take with them any other persons or equipment as the officer considers appropriate. It also requires that if the occupier of premises that an authorised officer is authorised to enter under sections 38 or 39 is present at the time the authorised officer seeks to execute the warrant the occupier must be told the officer's name; the officer must produce documentary evidence that the officer is an authorised officer; the officer must produce the warrant and supply the occupier with a copy of it. It also requires that if the premises are unoccupied or the occupier is temporarily absent, the authorised officer must leave the premises as effectively secured against unauthorised entry as the officer found them. The provisions in this section also apply to a vehicle.

Section 41: Powers of inspection, etc.

70. This section allows for authorised officers to carry out inspections on premises. Officers may request and inspect items, take samples from them and/or take the item(s), documents or copies of documents from the premises. They may also request information and help from any person that may help them carry out their function, but that person is not required to answer any questions or produce any document which they would be entitled to refuse in the course of court proceedings in England and Wales. The authorised officer may analyse any samples taken. The authorised officer must leave a statement detailing any items that have been taken and identifying the person to whom a request for the return of the property may be made.

Section 42: Obstruction etc. of officers

71. This section provides that any person who intentionally obstructs an authorised officer from carrying out their function under this Chapter is committing an offence. Any person who fails without reasonable cause to provide the officer with facilities that are reasonably required by the officer to carry out their functions, fails to give information without reasonable cause, or gives a false or misleading statement is also committing an offence. However, a person is not required to answer any questions or produce any

document which they would be entitled to refuse in the course of court proceedings in England and Wales. The offence may only be tried in the magistrates' court and is punishable on conviction by a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 43: Power to make test purchases

72. An authorised officer may make purchases and secure the provision of services if the officer considers it necessary for the purpose of enforcement in relation to this Chapter.

Section 44: Retained property: appeals

73. This section provides an additional safeguard relating to the powers of entry and inspection provisions. It enables a person with an interest in anything taken away from the premises by an authorised officer under section 41(1)(c) to apply to a magistrates' court for an order requesting the release of the property. Depending on the court's consideration of an application, it may make an order requiring the release of the retained property.

Section 45: Appropriated property: compensation

74. This section provides a right for a person affected by the taking possession of property under section 41(1)(c) to apply to a magistrates' court for compensation. Where the circumstances set out in subsection (2) are satisfied (i.e. that the person has suffered loss or damage as a consequence of the property being taken and the loss or damage is not due to their neglect or default), the court may order the local authority to pay compensation to the applicant.

Section 46: Fixed penalty notices

75. This section provides details about when an authorised officer can issue a fixed penalty notice (FPN) in respect of an offence associated with the register. A fixed penalty can be issued for the following offences:-
- a. A registered person carrying on a tobacco or nicotine business in premises other than those noted in the person's entry on the register;
 - b. A registered person carrying on a tobacco or nicotine business at premises consisting of a moveable structure, such as a stall or vehicle, in a local authority area other than the ones noted in the person's entry on the register; and
 - c. A registered person failing to comply with section 30 (duty to give notice of certain changes).
76. FPNs may be issued to a person, partnership or an unincorporated association other than a partnership. Payment of the FPN discharges the person believed to have committed an offence from being convicted for the

offence in court. The section also refers to Schedule 1 on fixed penalties (for commentary on this, see Schedule 1 below).

Section 47: Interpretation of this Chapter

77. This section sets out the meaning of key terms used in this Chapter.

CHAPTER 3: PROHIBITION ON SALE OF TOBACCO AND NICOTINE PRODUCTS

Section 48: Restricted premises orders: tobacco or nicotine offence

78. This section amends section 12D of the Children and Young Persons Act 1933. That section sets out a number of offences that are a “tobacco or nicotine offence” for the purposes of section 12A. Restricted premises orders and restricted sale orders may be made in respect of persons who have been convicted of tobacco or nicotine offences. The amendment provides the Welsh Ministers with a regulation making power to add new offences, conviction of which may be used to support an application to make a restricted premises order.

CHAPTER 4: HANDING OVER OF TOBACCO ETC. TO PERSONS UNDER 18

Sections 49 and 50: Offence of handing over tobacco etc. to persons under 18 and Arrangements in connection with handing over tobacco etc.

79. Section 49 makes it an offence to hand over tobacco, cigarette papers or nicotine products during the course of a delivery of goods, to a person who is under the age of 18, unless they are accompanied by someone who is aged 18 or older, or the handing over takes place as part of their trade, profession, business or employment.
80. In order to avoid committing the offence, where tobacco, cigarette papers or nicotine products are included in a purchase of goods (whether on their own or as part of a larger purchase), the person delivering the goods might, for example, need to remove any tobacco, cigarette papers or nicotine products from the delivery if not satisfied the person receiving the goods is aged 18 or over.
81. The offence also covers any tobacco, cigarette papers or nicotine products which have been purchased remotely (for example by telephone or via the internet) for collection from premises in Wales (often referred to as “click and collect”).
82. The offence may only be tried in the magistrates’ court and is punishable on conviction by a fine not exceeding level 4 on the standard

scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

83. No offence is committed if the tobacco, cigarette papers or nicotine products are wrapped and sealed or the accused could not reasonably have suspected from the person's appearance that they were under the age of 18. For example they could be sealed in an envelope, or wrapped in brown paper and sealed with tape. The parcel must also have on it the name and address of the person to whom the parcel should be delivered.

Section 51: Enforcement

84. Section 5 of the Children and Young Persons (Protection from Tobacco) Act 1991 requires local authorities to consider, at least once a year, whether it is appropriate for them to carry out a programme of enforcement action relating to various tobacco related offences. A programme of enforcement involves bringing prosecutions, investigating complaints and taking measures to reduce offences.
85. Section 51 amends section 5 of the 1991 Act to make the offence of handing over tobacco, cigarette papers or nicotine products to a person under the age of 18, as detailed in section 49, one of the offences in respect of which a local authority in Wales must consider a programme of enforcement.

Section 52: Interpretation of this Chapter

86. This section sets out the meaning of key terms used in this Chapter.
87. "Nicotine product" is defined by reference to regulations under section 92 of the Children and Families Act 2014. That section allows the Secretary of State to make regulations prohibiting the sale of nicotine products to persons under 18 in England and Wales. The offence under section 49 applies to nicotine products that, in accordance with those regulations, are prohibited for sale to those under 18.
88. Regulations under section 92 of the 2014 Act may make different provision in respect of certain nicotine products. For example, some nicotine products may be prohibited for sale to those under 16 only. Defining "nicotine product" by reference to regulations under section 92 of the 2014 Act means that the offence under section 49 is committed only if the nicotine product in question is prohibited for sale to the person under 18 in question to whom it is handed over.

PART 3 SPECIAL PROCEDURES

Section 54: What is a special procedure?

89. This section lists those procedures that are considered to be a special procedure for the purposes of this Part. These are acupuncture, body piercing, electrolysis and tattooing. Each of the procedures is defined in section 91(1). The meaning of special procedure may be amended by regulations, as provided by section 90.

Section 55: Requirement for individual performing special procedure to be licensed

90. Section 55(2) provides that a person performing a special procedure in Wales on someone else in the course of a business must be licensed, unless they are an exempted practitioner under section 57. The requirement also applies to those persons designated in respect of a special procedure under section 58.

Section 56: General provision about special procedure licences

91. This section provides that a special procedures licence is issued by a local authority. The special procedure licence authorises the performance, by the licence holder, of the special procedure (or those special procedures) specified in the licence.
92. A special procedure licence does not, however, authorise a person to carry out a special procedure at premises or in a vehicle unless the premises or a vehicle from which the special procedure will be performed has been approved in respect of the procedure (as required by section 67). It also requires that the approved premises or vehicle from which a special procedure will be performed by the licence holder is identified on the special procedure licence. These requirements will ensure that the licence holder's terms of practice are clear to both clients and enforcement officers.
93. The requirement on the licence holder to only practice special procedures from an approved premises or vehicle does not apply if the premises or vehicle has been specified in regulations made under section 66(8). These regulations will therefore enable certain premises or vehicles to be exempt from the approval requirements and the requirement for identification on the licence.
94. A special procedures licence authorises that a special procedure may be carried out for the period specified on the licence. This period must either be no more than 7 days (to take account of temporary exhibitions, entertainment or other events), or three years. Once the licence has expired, an application to the local authority must be made for a replacement licence.
95. The procedure for applying for a special procedure licence, including the process for varying, reviewing or revoking a licence is provided for in Schedule 3.

96. Section 56(8) sets out the meaning of three key terms (“licence period”; “licence holder” and “temporary licence”) which are referred to in this Part of the Bill.

Section 57: Exempted individuals

97. This section provides the circumstances in which an individual is exempt from the requirement to obtain a special procedure licence in order to perform the special procedure. Subsection (2) provides that an individual who is a member of a profession mentioned in paragraphs (a) to (ga) of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 is exempt, unless regulations specify that a licence is required in relation to a specific special procedure. These professions include doctors, dentists and nurses.
98. Subsection (3) provides the Welsh Ministers with a regulation making power to enable individuals who are members of a profession (but not those specified in paragraphs (a) to (ga) of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002) or are workers of a description specified in regulations, to be exempt if they are registered with a qualifying register. A qualifying register is defined in subsection (4) as one maintained by the Health and Care Professions Council, or a voluntary register that is both accredited by the Professional Standards Authority for Health and Social Care and specified in or under regulations.
99. These regulation making powers provide the Welsh Ministers with the discretion to exempt qualifying professions from the requirement to obtain a special procedure licence.

Section 58: Designation of individual for the purposes of section 55(3)

100. If the local authority is satisfied that the condition in subsection (2) is met, this section enables the local authority to give notice to an individual thereby designating them as a person requiring a special procedure licence if they intend to perform a specified special procedure.
101. The condition at subsection (2) is that the person is likely to perform the specified procedure on someone else in Wales, that the procedure as likely to be performed by the person presents or could present significant risk of harm to human health, and in order to remove or reduce that risk, it is appropriate to designate the person. The local authority’s ability to designate the person does not rely on the special procedure being performed in the course of a business; therefore a person performing a special procedure in any circumstances and for any purpose (such as from home and not for remuneration) can be designated and therefore prohibited from performing the specified special procedure.
102. The notice provided to the individual must specify why the authority has decided to designate the individual, the date upon which the designation will take effect (which may be the date of the notice or a subsequent date),

and prohibit the individual from performing the specified special procedure, unless it is under the authority of a special procedure licence. The notice must also state that the person may appeal the designation and the timescale within which an appeal may be brought.

103. Once served the designation notice will be in place until the local authority withdraws it, thereby preventing the designated individual from performing the specified special procedure unless it is under the authority of a special procedure licence. If the designated individual wishes to perform a special procedure, they must apply to the local authority for a licence.

104. If the local authority withdraws the designation, the local authority must give notice to the individual. The notice must contain the reasons for the withdrawal and the date upon which the withdrawal is to take effect. Once the designation is withdrawn the prohibition on the performance of the special procedure will cease to have effect.

Section 59: Licensing criteria

105. This section requires the Welsh Ministers to make regulations that set out the licensing criteria. The licensing criteria will set out all the requirements that must be met in order for the application for a special procedure licence to be granted. The licensing criteria must relate to an individual's (an "applicant") knowledge of –

- a. infection control and first aid, in the context of the special procedure to which the application relates;
- b. duties imposed, under or by virtue of this Part, on a person authorised to perform the special procedure to which the application relates. An example of these duties is the requirements for age verification in relation to tattooing and intimate piercing.

106. The licensing criteria may also, amongst other things, relate to an individual's eligibility for a licence; the premises or vehicle from which a special procedure is to be performed and the equipment used in (or in connection with) the performance of a special procedure.

107. The licensing criteria may also cover such things as standards of competence to perform a special procedure. This may include the applicable training undertaken by the applicant or their knowledge of the special procedure.

108. Regulations made under this section may also require that the local authority undertakes an inspection of the premises or vehicle identified in the application before a licence is issued or renewed. This is to enable the local authority to determine the premises' or vehicle's compliance with the licensing criteria. The regulations may also make different provision for different descriptions of premises and vehicles; for different special procedures; and for the different circumstances in which a special procedure is performed. These circumstances may include the frequency, regularity or period during which a procedure is performed. The licensing criteria may

also address the basis upon which the special procedure will be performed, and specify the requirements in relation to each practice.

109. The basis upon which a special procedure is performed are: on a peripatetic basis (i.e. the applicant plans to practice a special procedure in various different premises, for example clients' homes); on a fixed site basis (for example from a specified clinic or studio); on a mobile basis (if the special procedure is performed in a vehicle) or on a temporary basis (if the special procedure will be performed in the course of an entertainment, exhibition or other event that does not exceed seven days). The regulations will therefore set out the criteria that must be met in relation to the practice of all special procedures, in all settings.

Section 60: Mandatory licensing conditions

110. This section requires the Welsh Ministers to make regulations that set out the mandatory licensing conditions. The mandatory licensing conditions will detail the requirements that the holder of a special procedure licence must adhere to in order to retain their licence. The mandatory licensing conditions may differ depending on the procedure being performed and the basis upon which it is being performed i.e. peripatetically or from a fixed location. Subsections (2) and (3) set out the elements that the mandatory licensing conditions must relate to and the requirements that must be included in the regulations. These include the requirements in relation to the verification of age of an individual on whom a special procedure is to be performed in relation to tattooing and intimate piercing; infection control practices; standards of hygiene; and how the licence holder must maintain their records. The regulations must also include a condition preventing a licence holder from performing a special procedure on an individual who is, or appears to be, intoxicated, whether by virtue of drinks, drugs, or any other means.
111. The mandatory licensing conditions may (among other things) also make further provision relating to the condition (including the cleaning and maintenance of the premises or vehicle from which a special procedure is performed or where the equipment or material is stored or prepared). The conditions may also relate to how a licence holder must display their licence, the information the licence holder must provide to the local authority in the case of conviction of a relevant offence, when an application for variation of a licence is to be made and when the licence must be returned.
112. The mandatory licensing conditions may also specify the way in which a special procedure is to be performed. This will include the equipment that should be used, how the procedure should be performed and the requirements in relation to the protective clothing worn by the licence holder. Provisions relating to information provided by the licence holder or to a licence holder before and after a special procedure is carried out may also be specified in the conditions, for example aftercare advice.

113. The regulations may provide that different mandatory licensing conditions apply in relation to different purposes. For example there may be different mandatory licensing conditions for different premises and vehicles, for different special procedures and to take account of the different circumstances in which a special procedure is practiced.

Section 61: Consultation about licensing criteria and mandatory licensing conditions

114. Before regulations under section 59 or 60 are made, this section requires the Welsh Ministers to consider whether there are persons who appear to represent the interests of those likely to be affected by them, and as appropriate consult with them. This will ensure that those who are affected by the regulations are consulted and have their views considered.

Section 62: Mandatory grant or refusal of application for special procedure licence

115. This section outlines the circumstances under which the local authority must grant or refuse an application for a special procedure licence. The detail of how a licence application must be made is set out in Schedule 3. The local authority must grant the special procedure licence application if they are satisfied that all the applicable licensing criteria are met in respect of the performance of the special procedure, thereby authorising the performance of the procedure on that basis and at or in the premises or vehicle, specified in the application. The local authority has the flexibility to grant a special procedure licence in circumstances where one or more premises or vehicles are listed on the application, but not all premises/vehicles meet the approval requirements. In such circumstances the person will only be licenced to practice from the approved premises/vehicle.

116. If the local authority is not satisfied that all the applicable licensing criteria are met, it must give notice to the applicant that the application has been refused. The process the local authority must follow in relation to providing notice and communicating with the applicant (including the process available to them for making representations) is provided in Schedule 3. The licensing committee of the authority (or one of its sub-committees) will consider the application and make a decision. The applicant may appeal against the local authority's decision to the magistrates' court.

Section 63: Discretion to grant application for special procedure licence

117. The requirement on the local authority to grant the application does not apply in the case of an applicant who has been convicted of a relevant offence. The relevant offences are provided under subsection (8). A regulation making power is available in subsection (10) to amend the list of relevant offences by adding, varying or removing a description of offence.
118. If the applicant has been convicted of a relevant offence, the local authority retains the discretion to grant a special procedures licence, if it

thinks fit, having regard to the nature of the offence and any special procedure to which the application relates. Alternatively, the local authority may decide not to issue a licence, in which case it must provide notice to the applicant that the application has been refused. A conviction for a relevant offence is to be disregarded by the local authority if it is spent for the purposes of the Rehabilitation of Offenders Act 1974 (c.53).

Section 64: Grant or refusal of application for renewal

119. Sections 62, 63 and 65 apply for the purposes of an application to renew a special procedure licence in the same way as if the application was for the issue of a licence.

Section 65: Revocation of special procedure licence

120. This section provides discretion for the local authority to revoke a special procedure licence (or revoke the licence in so far as it relates to the performance of a particular special procedure), if it is satisfied that the conditions in subsection (2), (3) or (4) are met. The first set of conditions (set out in subsection (2)) are (a) that the licence holder has failed to comply with an applicable mandatory licensing condition and (b) that the non-compliance presents or could present significant risk of harm to human health. The second set of conditions (set out in subsection (3)) relate to convictions for a relevant offence and also provide a basis upon which a local authority can revoke a special procedure licence, for example if the local authority was unaware of the conviction for a relevant offence at the time of granting the licence, or where the conviction did not precede the issue of the licence. The third set of conditions (set out in subsection (4)) relate to a statement made by the licence holder in connection with an application that was false or misleading, and had the authority known that the statement was false or misleading the licence would not have been issued at all or would not have been issued in so far as it relates to the performance of a particular procedure.
121. The revocation will have effect following the expiry of the period for bringing an appeal or further appeal, or the withdrawal of any appeal or further appeal, in respect of the revocation. Further detail on the procedure for revocations is provided in Schedule 3.

Section 66: Performance of special procedure in course of business: approval requirement

122. This section establishes that a person carrying on a business, in the course of which a special procedure is performed, must comply with two requirements. The first requirement is that the procedure is performed at premises or in a vehicle that has been approved by the local authority under section 67. The second requirement ensures that once approved, there is compliance with the mandatory approval conditions (provided at section 67(3)). The approval requirements will also apply in the case of an exhibition, entertainment or other event to which members of the public have access, and at which a special procedure is performed by a person in the course of

business. In these circumstances, the person who organises the exhibition, entertainment or event is responsible for ensuring the premises is approved and the applicable mandatory conditions of approval are complied with. Subsection (7) clarifies that it is the premises itself, rather than the individual businesses operating from that premises, which must be approved. An example may be where an exhibition taking place in a hotel is attended by individual businesses operating at tables. In this instance, the hotel premises would be required to be approved rather than the individual businesses operating from those stalls.

123. Subsection (8) provides the Welsh Ministers with a regulation making power to exempt certain premises or vehicles from the approval requirements. The premises or vehicle may be described in the regulations by way of reference to the persons by whom they are managed or controlled; the nature of activities carried on at or in them; the different circumstances in which a special procedure is performed at or in them; or the numbers of individuals performing special procedures. This may enable for example, the premises from which a special procedure is performed by an exempted individual to also be exempt.

Section 67: Approval of premises and vehicles in respect of performance of special procedure

124. This section enables a local authority to issue an approval certificate, thereby approving a premises or vehicle so that a special procedure (or special procedures) may be performed at the premises or vehicle. The approval of a premises or vehicle will last for either a maximum of seven days (if it relates to procedures carried out on a temporary basis (i.e. in the course of an entertainment, exhibition or other event)), or three years. The period for which the approval is valid must be specified on the approval certificate. The premises must be in the local authority's area and the vehicle must be considered to be driven, used or kept in the area of the local authority, in order for the local authority to approve it.

125. Subsection (3) requires the Welsh Ministers to make regulations in relation to the approval of premises and vehicles. These regulations must cover the criteria to be met in order for the application to be granted, the circumstances in which an application for approval is to be granted, and the process for an applicant to appeal against a refusal of an application. In addition, the regulations will specify the conditions (the "mandatory approval conditions") which must be complied with in order for the approval to be retained. These conditions may include the facilities available at the premises or vehicle, such as suitable hand cleansing facilities and provide details of the display of an approval certificate at an approved premises or vehicle. The purpose of the display of approval certificates is to improve transparency in relation to the practice of special procedures, and aims to enable consumers to identify that the premises or vehicle has been approved by the local authority for the purposes of a special procedure(s).

126. The regulations may also make provision about the way in which an application for approval is made and is dealt with (including the payment of a fee), the circumstances in which an application for approval must not be granted, or may be granted at the local authority's discretion, and the process that will apply to the renewal of an approval. In addition, the regulations may make provision about how a local authority determines the amount of fee payable by an applicant when applying for a premises or vehicle approval, as well as detail of the consequences of failure to comply with the requirement to pay a fee (such as a revocation of approval).
127. The regulations may also make different provision for different descriptions of premises and vehicles; for different special procedures; and for the different circumstances in which a special procedure is performed.

Section 68: Approval certificates

128. This section provides details on the form and content of approval certificates. The approval certificate must state the date the premises or vehicle was approved by the local authority (the "approval date"); the special procedure for which the premises or vehicle is approved; and the date upon which the approval will expire. If the approval certificate relates to a premises, the approval certificate must also state the address of the premises. In the case of a vehicle, the approval certificate must also state the registration number of the vehicle, if it has one, or otherwise identify the vehicle in whatever way the local authority considers appropriate. Subsection (4) enables the Welsh Ministers to make further provision by way of regulations about the form and content of approval certificates.

Section 69: Voluntary termination of approval

129. This section provides flexibility to a person who holds a special procedure premises or vehicle approval to voluntarily terminate the approval, for example if their circumstances change. The person may give notice to the local authority that issued the approval, specifying the date upon which the approval is to expire.
130. The local authority to which the notice is given must take reasonable steps to bring the notice of voluntary termination to persons it thinks likely to be affected by the notice, for example licence holders listed as operating from the premises or vehicle referred to in the notice. This is intended to avoid a situation where a practitioner continues to work at a premises or vehicle that they are not aware is no longer approved - as if they were to do so, they would be committing a criminal offence.
131. Subsection (5) provides that the Welsh Ministers may make further provisions about the notice in regulations, including (among other things) about the information to be included in the notice.

Section 70: Revocation of approval

132. This section provides the local authority with the ability to revoke a premises or vehicle approval if it is satisfied that both the conditions in subsection (2) are met. These conditions are that the mandatory approval conditions that apply to the premises or vehicle (as required by section 67(3)) have not been complied with, and that this non compliance presents or could present, significant risk of harm to human health. In order to revoke the approval, the local authority must serve a notice on the person who applied for the approval.

133. Schedule 3 outlines the process for the revocation of the approval. This process is the same as that for revocation of a special procedures licence (as provided by section 65) and provides that the person may appeal against the local authority's decision to the magistrates' court.

134. The date from which the revocation will have effect is provided for in subsection (4). This takes into account the appeal mechanisms and timescales set out in Schedule 3.

Section 71: Revocation of approval: notification requirements

135. This section requires a local authority to give notice to a person in respect of a revocation, or a proposed revocation, of a premises or vehicle approval. The local authority must take reasonable steps for bringing the notice to the attention of any persons it thinks likely to be affected by the revocation (for example, licence holders listed as operating from the affected premises or vehicle).

Section 72: Duty to maintain register of special procedure licences and approved premises and vehicles

136. As part of the local authority's requirements under this Part, section 72 requires a local authority to maintain a register containing details of all valid special procedures licences issued by it, as well as details of all those premises and vehicles currently approved by it. This register must be accessible to members of the public. This is to allow members of the public to view the details of licence holders and/or approved premises or vehicles in their area. The purpose of this provision is to improve transparency in relation to the practice of special procedures, and aims to provide consumer confidence.

137. Subsections (2) and (3) specify the information that must be provided in the register in relation to licences and approvals. In respect of licences, subsection (2) requires that the register must record information including the name of the licence holder, the date the licence was issued, the special procedure authorised by the licence and the period that the licence is valid for (i.e. 7 days or 3 years). If the licence relates to the performance of a special procedure in a specific premises or vehicle, the register must contain relevant information relating to the approval. For premises and vehicle approvals, subsection (3) requires that the register contains information such as the name of the person holding the approval, the date the approval was issued and its

period of validity, as well as the special procedure authorised to be performed on those premises or vehicle. Specific information such as the premises address or the vehicle's registration number will also be required.

138. Subsection (4) provides that the local authority maintaining the register may include such other information as it considers appropriate.

139. Although each local authority will be required by this section to maintain its own register, subsection (6) enables the Welsh Ministers to arrange for a central register to be kept by one appointed local authority. As the Welsh Ministers may require all local authorities in Wales to participate in and provide their information to the appointed local authority, this central register would contain information on all currently valid licences and approvals in Wales. The Welsh Ministers may also require all local authorities to contribute towards the costs of such a central register.

140. A central register would aim to assist local authorities with their enforcement functions in relation to special procedures, as well as provide a single source of information for the public to access.

Section 73: Fees

141. This section provides a local authority with the ability to charge a fee to the holder of a special procedure licence or a premises or vehicle approval. The fee may be applied either periodically or otherwise for as long as the licence/approval has effect. Regulations may make provision about the way in which a local authority is to determine the amount of the fee charged, having regard to the costs incurred or expected to be incurred by the authority in connection with this Part, as well as the way the fee is paid, repaid or recovered if unpaid.

Section 74: Stop notices

142. If the local authority is aware of an individual performing a special procedure in their area without a licence or carrying on a business from a premises or vehicle that has not been approved, the local authority may issue that individual or person with a stop notice. The aim of the stop notice is to prohibit the carrying out of the special procedure specified in the notice.

143. Breach of the stop notice is an offence (as provided by section 79(4)) and is punishable by an unlimited fine. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

144. The stop notice must be provided to the person concerned and contain the information required in subsections (4) and (5). This includes the reason for the stop notice, details of the prohibition and notifying the person subject to the notice of their right to appeal against its issue. The stop notice will apply anywhere in Wales and will be effective until the person obtains the relevant licence or approval.

Section 75: Special procedure licences: licence holder remedial action notices

145. If a local authority becomes aware that a licence holder is breaching an applicable mandatory licensing condition, it may issue the licence holder with a remedial action notice. The remedial action notice must specify the matters giving rise to the breach and the steps that the licence holder must take to secure compliance with the applicable mandatory licensing conditions. If the authority is satisfied that the breach of the mandatory licensing condition presents, or could present, significant risk of harm to human health, the notice may also prohibit the performance of a special procedure until the steps specified in the notice have been taken. The prohibition may relate to the performance of the special procedure in an area of Wales (for example the local authority's area) or may extend to all of Wales.
146. The notice must specify the compliance period (which must not be less than 14 days) within which the licence holder should take the steps specified in the remedial action notice. If the local authority is satisfied that the steps specified in the notice have been taken, it must issue the licence holder with a completion certificate to discharge the notice, as required by section 77.
147. The remedial action notice must also provide details of the licence holder's right to appeal to the magistrates' court against the local authority's decision.
148. Whilst contravention of the remedial notice is an offence (as provided by section 79(5)) and is punishable by an unlimited fine, the local authority must not begin proceedings against the licence holder until the compliance period has expired. If the licence holder takes the steps specified in the remedial action notice within the compliance period, no proceedings for an offence will be taken by the local authority. The local authority will, however, be able to undertake proceedings if the licence holder continues to practice a special procedure, despite the prohibition placed upon their practice. In addition to the remedial action notice, the local authority may also revoke a special procedures licence if the licence holder fails to comply with an applicable mandatory licensing condition.

Section 76: Approved premises and vehicles: premises remedial action notices

149. Similar to the provisions set out in section 75, this section provides the local authority with the ability to issue a remedial action notice to a person in respect of an approved premises or vehicle. The notice may be issued if the local authority is satisfied that the person is breaching an applicable mandatory condition of approval. The remedial action notice must specify the reason(s) for the breach and the steps that the licence holder must take to secure compliance. If the authority is satisfied that the breach of the mandatory condition of approval presents, or could present, significant risk of harm to human health, the notice may also prohibit the performance of the special procedure at the premises or in the vehicle, until the steps specified in

the notice have been taken. In this case, the local authority must take reasonable steps to bring the notice to the attention of any persons it thinks are likely to be affected (for example, licence holders listed as operating from the premises or vehicle). This ensures that people who perform special procedures from the premises/vehicle do not inadvertently commit an offence by breaching the prohibition.

150. The notice must specify the compliance period (which must not be less than 14 days) within which the licence holder should take the steps specified in the remedial action notice. If the local authority is satisfied that the steps specified in the notice have been taken, it must issue the licence holder with a completion certificate to discharge the notice, as required by section 77.

151. The notice must also provide details of the person's right to appeal to the magistrates' court against the local authority's decision to issue a remedial action notice. Contravention of the notice is an offence (as provided for by section 79(6)) and is punishable by an unlimited fine. However, the local authority must not begin proceedings until the compliance period has expired.

152. If the person takes the steps specified in the remedial notice within the compliance period, no proceedings for an offence will be taken by the local authority. The local authority will, however, be able to undertake proceedings if the person continues to practice the special procedure from the premises or vehicle specified in the notice, despite the prohibition. In addition to the remedial action notice, the local authority may also revoke a premises or vehicle approval if the person fails to comply with a mandatory approval condition.

Section 77: Completion certificate

153. In relation to a remedial action notice issued by the local authority under section 75 or 76, if the local authority is satisfied that the steps specified in the notice have been taken, it must provide the person with a certificate (a "completion certificate") discharging the notice. This to ensure that both the person who was subject to the notice and the local authority are aware that the remedial action notice has been complied with, and have a record of the steps which have been taken. The local authority must also take reasonable steps to bring the completion certificate or notice to the attention of any persons it thinks likely to be affected.

154. The person subject to the notice may apply to the local authority for a completion certificate at any time. The application process and the information required will be specified by the local authority. If the local authority refuses the application, it must give notice to the person that the application has been refused. In addition, the reasons for the refusal and information on the appeals process must be provided to the person.

Section 78: Appeals

155. This section provides a person with a right to appeal to the magistrates' court against a local authority's decision under section 74, 75 or 76. An appeal against the local authority's decision to refuse an application for a completion certificate (section 77(5)) may also be made. The magistrates' court may take any of the actions specified in subsection (5); these include confirming the notice or refusal, quashing or varying the notice, or referring the case to the local authority to dispose of in accordance with directions given by the court.

156. If the local authority's decision is varied or quashed, the magistrates' court may order the local authority to compensate the person for loss suffered as a result of the notice. For example, the person could be compensated for a loss of income due to the local authority's decision to prevent them from working.

157. An appeal to the Crown Court may also be made by either the person or the local authority against a decision of a magistrate's court.

Section 79: Offences

158. This section sets out the offences which apply in relation to the Part. Amongst others, offences will be committed if a person fails to comply with the licensing or approval conditions, or fails to comply with enforcement action ordered by a local authority such as a stop notice or a remedial action notice, without reasonable cause. There is also an offence for making a false or misleading statement (including if the person knows or is reckless as to whether it is false or misleading) when applying for a licence or approval of a premises or vehicle.

159. Upon conviction, a person found guilty of an offence under this section is liable for an unlimited fine.

Section 80: Authorised officers

160. This section clarifies that any reference to authorised officers in sections 81 to 89 are to any person authorised to exercise functions of a local authority, whether or not they are an officer of the local authority.

Section 81: Powers of entry, etc.

161. Section 81 enables an authorised officer to enter, at any reasonable time, premises (excluding premises used wholly or mainly as a dwelling) if the officer has reason to believe that a special procedure has been, is being, or is likely to be performed at the premises, or that material or equipment relating to a special procedure is stored or prepared at the premises. The power to enter premises does not enable the authorised officer to enter by force. If required, an authorised officer must, before entering the premises, show evidence of their authorisation. The power of entry also applies to a vehicle.

162. Section 67(9) of the Police and Criminal Evidence Act 1984 provides that, while acting in the course of their enforcement functions, authorised officers of the enforcement authority must have regard to the relevant code of practice made under that Act. Therefore, authorised officers must have regard to the PACE Code of Practice B in the exercise of their enforcement functions.

Section 82: Warrant to enter dwelling

163. If access to premises which are wholly or mainly used as a dwelling is necessary for the enforcement of this Part, a written application must be made by the local authority to a justice of the peace. Section 82 enables a justice of the peace to issue a warrant, thereby authorising an authorised officer to enter the dwelling, if needs be by force. A warrant can be issued in a format other than a hard copy document, such as an electronic version. The warrant will be in force for 28 days beginning on the date it was signed by the justice of the peace. This section also applies to a vehicle.

Section 83: Warrant to enter other premises

164. If access to premises that are not only used wholly or mainly as a dwelling is necessary, section 83 enables a justice of the peace to sign a warrant authorising any authorised officer to enter the premises, if needs be by force. The warrant can be obtained by making a written application to a justice of the peace. The premises to which entry is being sought must be used for business purposes, or for both business and as a dwelling. In the case of premises used wholly or mainly as a dwelling a warrant must be sought under section 82. This section also applies to a vehicle.

165. In order for a warrant to be signed, one or more of the requirements set out in subsections (2) to (5) must be met. The requirements include that a request to enter the premises has been, or is likely to be, refused and notice of intention to apply for a warrant has been given; an application for admission, or the giving of notice of an intention to apply for a warrant is likely to defeat the purpose of the entry; the premises are unoccupied; or the occupier is temporarily absent, and awaiting their return is likely to defeat the purpose of the entry. Once the warrant is issued, it will be in force for 28 days beginning on the date it was issued by the justice of the peace.

Section 84: Supplementary provision about powers of entry

166. This section enables an authorised officer entering premises under section 81, 82 or 83 to take with them any other persons or equipment as the officer considers appropriate, for example equipment used to examine electronic records. It also requires that if the occupier of premises that an authorised officers is authorised to enter under sections 82 or 83 is present at the time the authorised officer seeks to execute the warrant, the occupier must be told the officer's name; the officer must produce documentary evidence that the officer is an authorised officer; the officer must produce the warrant and supply the occupier with a copy of it. The section also requires that if the premises are unoccupied or the occupier is temporarily absent, the authorised

officer must leave the premises as effectively secured against unauthorised entry as the officer found them. The provisions in this section also apply to a vehicle.

Section 85: Powers of inspection, etc.

167. Once an authorised officer has gained entry to a premises, they may undertake inspections and examinations for the purposes of the local authority's functions in relation to special procedures. This may include inspecting and examining the premises, viewing and retaining closed-circuit television records and obtaining copies of documents, such as procedure records and consent documents. The authorised officer may also require the production of or take possession of anything and retain it for as long as the officer considers necessary for the purpose of exercising the authority's functions. In this instance, however, the officer must leave at the premises a statement containing the particulars of what has been taken and identify the person to whom a request for the return of the property may be made.

168. The authorised officer may also require any person to provide them with information, or afford facilities and assistance with respect to matters within the person's control. This may include providing an account of events, or supplying information that is stored on a computer or other device. However, a person is not required to answer any question or produce any document which they would be entitled to refuse to answer or produce during proceedings in a court in England and Wales. This section also applies to a vehicle.

Section 86: Obstruction etc. of officers

169. This section provides that a person commits an offence if they intentionally obstruct an authorised officer from exercising their functions under sections 81 to 85. They will also commit an offence if, without reasonable cause, they fail to provide an authorised officer with facilities that are reasonably required under section 85(1) or they fail to comply with a requirement under section 85(1)(b) or (d) such as producing CCTV footage, or provide information.

170. A person found guilty of an offence under this section is liable on summary conviction to a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 87: Power to make test purchases

171. An authorised officer may make purchases and arrangements, and secure the provision of services if the officer considers it necessary for the purpose of enforcement of the local authority's functions in relation to special procedures. This includes enlisting the assistance of a person to ascertain if a special procedure is being performed from a premises or vehicle in contravention of the requirements in this Part.

Section 88: Retained property: appeals

172. This section provides an additional safeguard relating to the powers of entry and inspection provisions. It enables a person with an interest in anything taken away from the premises by an authorised officer under section 85(1)(c) to apply to a magistrates' court for an order requesting the release of the property. Depending on the court's consideration of an application, it may make an order requiring the release of the retained property.

Section 89: Appropriated property: compensation

173. This section provides a right for a person affected by the taking possession of property under section 85(1)(c) to apply to a magistrates' court for compensation. Where the circumstances set out in subsection (2) are satisfied (i.e. that the person has suffered loss or damage as a consequence of the property being taken and the loss or damage is not due to their neglect or default), the court may order the local authority to pay compensation to the applicant.

Section 90: Power to add or remove special procedures

174. This section enables the Welsh Ministers to amend, via regulations, the list of special procedures contained in section 54. Before the regulations are made, subsection (4) requires the Welsh Ministers to consider whether there are persons who appear to represent the interests of those likely to be affected by them, and as appropriate consult with them. This will ensure that those who are affected by the regulations are consulted and have their views considered.

175. The amendment may add or remove a type or description of procedure to or from the list, or may vary the description of a procedure already contained in the list. The procedure may be described by reference to (amongst other things) the individual who carries out the procedure, or the individual on whom it is carried out. In order for the procedure to be added to the list, the Welsh Ministers must consider that the procedure is performed for aesthetic or therapeutic purposes and the performance of the procedure is capable of causing harm to human health. Harm to human health is defined in section 91(5) and includes harm to an individual's physical or mental health.

176. This provision enables the list of special procedures to remain up to date, thereby ensuring the requirements take account of changing practices and trends.

Section 91: Interpretation of this Part

177. This section sets out the meaning of the key terms used in this Part including the meaning of acupuncture, body piercing, electrolysis and

tattooing. The definition of tattooing includes micro pigmentation. The definition of body piercing means the perforation (including puncture or incision) of an individual's skin, or mucous membrane, with a view to enabling jewellery or another object to be attached to, implanted in or removed from the individual's body. Objects will be prescribed in regulations and may include for example, a bead.

178. Subsection (4) provides details on the meaning of the different basis (i.e. fixed site basis, mobile basis, peripatetic basis and temporary basis) referred to in the Part in relation to the practice of a special procedure. For example, different licensing criteria may be applied to these different bases by virtue of the regulations provided under section 59(5).

179. Subsection (5) provides the definition of the term "harm to human health". This includes (amongst other things) harm to an individual's physical health arising through physical injury or exposure to an infection, and harm to an individual's mental health. Any procedure considered for addition to the list of special procedures (and therefore captured by the provisions in this Part) must be capable of causing harm to human health. For example, a procedure may be considered for inclusion in the list if it is capable of causing physical injury.

PART 4

INTIMATE PIERCING

Section 92: Offence of performing or making arrangements to perform an intimate piercing on a child

180. This section makes it an offence for a person who is in Wales to perform an intimate piercing on a child in Wales. It also makes it an offence for a person in Wales to make arrangements to perform an intimate piercing on a child in Wales. A child in this Part is any person who is under the age of 18. A person convicted of either offence is liable on summary conviction to an unlimited fine. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

181. A person charged with the offence of piercing a child in Wales may put forward a defence that they believed the person was aged over 18. The accused would need to show that they either took reasonable steps to establish the person's age (for example by requesting proof of their age and that the evidence provided would have convinced a reasonable person) or that nobody could reasonably have suspected that the person was under the age of 18 from their appearance. If a person is charged with an offence under this section due to the actions of another person, it will be a defence that the accused took reasonable precautions and exercised due diligence to avoid committing the offence, for example by providing training to staff or putting systems in place to avoid committing the offence.

Section 93: What is an intimate piercing?

182. An intimate piercing is a body piercing performed on an intimate body part. The definition of “body piercing” is provided in section 91 and means the perforation (including puncture or incision) of an individuals’ skin, or mucous membrane, with a view to enabling jewellery or another object to be attached to, implanted in or removed from the individual’s body. Objects will be prescribed in regulations and may include, for example, a bead.
183. The intimate body parts are listed in subsection (2) and include the breast (including the nipple and areola), buttocks, genitals and tongue. The list captures parts of both the male and female anatomy. Mucous membranes are included in the definition as the surface of intimate body parts such as the vulva may comprise skin or mucous membranes.
184. The offences created by this section do not apply to intimate piercings of a person under the age of 18 if they occur in the course of a medical procedure carried out by a registered medical practitioner, a registered nurse or a registered midwife. A medical procedure is defined as any procedure carried out for the purposes of or in connection with the diagnosis, prevention, monitoring, treatment or alleviation of disease, ill-health, disability or other physical or mental abnormality, or birth control.

Section 94: Enforcement action by local authorities

185. This section enables a local authority to undertake enforcement action in relation to this Part. A local authority may:
- bring prosecutions in respect of offences under section 92;
 - investigate complaints in relation to alleged offences under section 92;
 - take other steps with a view to reducing the incidence of offences in its area. These may include actions such as communicating with and educating body piercing practitioners, or undertaking test purchasing inspections to assess compliance.
186. Subsection (2) requires a local authority to consider at least once every 12 months a programme of enforcement action aimed at preventing the intimate piercing offences set out in section 92. A local authority must also, to the extent that it considers it appropriate to do so, carry out such a programme of enforcement action. This enforcement action may involve any or all of the steps referred to in subsection (1).
187. In undertaking its enforcement action, a local authority must carry out such consultation as it considers appropriate with the police.

Section 95: Authorised officers

188. The section clarifies that any reference to authorised officers in this Part is to any person authorised by a local authority, whether or not they are an officer of the local authority.

Section 96: Powers of entry

189. This section enables a constable or an authorised officer to enter, at any reasonable time, premises (excluding premises used wholly or mainly as a dwelling) because there are reasonable grounds to believe that an offence under section 92 has been committed and entry is necessary to ascertain whether or not such an offence has taken place. This power to enter premises does not enable the constable or authorised officer to enter by force. If required, an authorised officer must, before entering the premises, show evidence of their authorisation by the local authority. The power to enter premises (as provided by sections 97 to 100) includes any place and any vehicle (other than an aircraft and hovercraft), stall or moveable structure.

190. Section 67(9) of the Police and Criminal Evidence Act 1984 provides that, while acting in the course of their enforcement functions, authorised officers of the enforcement authority must have regard to the relevant code of practice made under that Act. Therefore, authorised officers must have regard to the PACE Code of Practice B in the exercise of their enforcement functions.

Section 97: Warrant to enter dwelling

191. If access to a premises that is used wholly or mainly as a dwelling is necessary, because there are reasonable grounds to believe that an offence under section 92 has been committed and entry is required to ascertain whether or not such an offence has taken place, a written application must be made to a justice of the peace. This section enables a justice of the peace to issue a warrant authorising a constable or authorised officer to enter the dwelling, if needs be by force. A warrant can be issued in a format other than a hard copy document, such as an electronic version. The warrant will be in force for 28 days beginning on the date it was signed by the justice of the peace.

Section 98: Warrant to enter other premises

192. If access to premises that are not used wholly or mainly as a dwelling is required because there are reasonable grounds to believe that an offence under section 92 has been committed and entry is necessary to ascertain whether or not such an offence has taken place, section 98 enables a justice of the peace to issue a warrant authorising a constable or authorised officer to enter such premises, if needs be by force. The warrant can be obtained by making an application to a justice of the peace. The premises to which entry is being sought under this section must be used for business purposes, or for both business and as a dwelling. In the case of premises used wholly or mainly as a dwelling, a warrant must be sought under section 97.

193. In order for a warrant to be issued, one or more of the requirements set out in subsections (2) to (5) must be met. The requirements include that a request to enter the premises has been, or is likely to be, refused and notice of intention to apply for a warrant has been given; requesting to enter, or the giving of notice of intention to apply for a warrant, is likely to defeat the purpose of the entry; the premises are unoccupied; or the occupier is

temporarily absent, and awaiting the occupier's return is likely to defeat the object of the entry. Once the warrant is issued, it will be in force for 28 days beginning on the date it was issued by the justice of the peace.

Section 99: Supplementary provision about powers of entry

194. This section enables authorised officers or constables entering premises under sections 96, 97 and 98 to take with them any other persons or equipment as appropriate to ascertain whether an offence under section 92 has been committed, for example equipment used to examine electronic records. It also requires that if the occupier of premises that an authorised officer is authorised to enter under sections 97 or 98 is present at the time the authorised officer seeks to execute the warrant the occupier must be told the officer's name; if not a constable in uniform the officer must produce documentary evidence that the officer is a constable or authorised officer; the officer must produce the warrant and supply the occupier with a copy of it. The section also requires that if the premises are unoccupied or the occupier is temporarily absent, those authorised to enter the premises must leave it as effectively secured against unauthorised entry as the person found them.

Section 100: Powers of inspection, etc.

195. Once a constable or an authorised officer has gained entry to premises, they may undertake inspections and examinations to ascertain whether an offence under section 92 has been committed. This may include inspecting and examining the premises, viewing closed-circuit television records and obtaining copies of documents, such as procedure records and consent documents. The constable or authorised officer may also take possession of anything on the premises, and retain it for as long as necessary. The constable or authorised officer may also require any person to provide them with information, or afford facilities and assistance within their control. This may include providing an account of events, or supplying information that is stored on a computer or other device. If a constable or authorised officer takes anything away from the premises, they must leave at the premises a statement containing the particulars of what has been taken and identify the person to whom a request for the return of the property may be made. However, a person is not required to answer any question or produce any document which they would be entitled to refuse to answer or produce during proceedings in a court in England and Wales.

Section 101: Obstruction etc. of constable or officer

196. This section provides that a person commits an offence if they intentionally obstruct a constable or an authorised officer from entering premises when the constable or authorised officer is authorised to do so. They will also commit an offence if, without reasonable cause, they fail to provide facilities or comply with any requirements required of them under section 100 (i.e. to provide a constable or an authorised officer with anything on the premises or with facilities, assistance or information (for example access to

electronic records) that the constable or authorised officer reasonably requires).

197. A person found guilty of an offence under this section is liable on summary conviction to a fine not exceeding level 3 on the standard scale. The levels on the standard scale are set out in section 37 of the Criminal Justice Act 1982.

Section 102: Power to make test purchases

198. An authorised officer may make purchases and arrangements, and secure the provision of services if the officer considers it necessary for the purpose of enforcement of the offences. This includes enlisting the assistance of a young person to ascertain if a person is offering and making arrangements to intimately pierce those under the age of 18.

Section 103: Retained property: appeals

199. This section provides an additional safeguard relating to the powers of entry and inspection provisions. It enables a person with an interest in anything taken away from the premises by an authorised officer under section 100(1)(c) to apply to a magistrates' court for an order requesting the release of the property. Depending on the court's consideration of an application, it may make an order requiring the release of the retained property.

Section 104: Appropriated property: compensation

200. This section provides a right for a person affected by the taking possession of property under section 100(1)(c) to apply to a magistrates' court for compensation. Where the circumstances set out in subsection (2) are satisfied (i.e. that the person has suffered loss or damage as a consequence of the property being taken and the loss or damage is not due to their neglect or default), the court may order the local authority to pay compensation to the person.

PART 5

HEALTH IMPACT ASSESSMENTS

Section 105: Requirement to carry out health impact assessments

201. This section defines a health impact assessment (HIA) as an assessment of the likely effect, both in the short and long term, of a proposed action on the physical and mental health of all or some of the people of Wales. It requires the Welsh Ministers to make regulations about the carrying out of such assessments by public bodies. These regulations must specify the circumstances in which a HIA is to be carried out and how it is done.

202. This section also enables the regulations to require Public Health Wales NHS Trust who have expertise in this area to assist another public

body in carrying out a HIA, with the potential for those regulations to specify how and when such assistance might be given.

Section 106: Health impact assessments: publication and taking into account

203. Where a public body has carried out a HIA in accordance with regulations made under section 105, this section requires the public body to publish the assessment and to take into account its findings when exercising those of its functions in connection with which the assessment was carried out. The regulations may specify how and when the results of a HIA are to be published.

204. In taking the HIA into account, this section requires the public body to act in accordance with the sustainable development principle as defined in section 5 of the Well-being of Future Generations (Wales) Act 2015. This means that the body must take certain things into account in order to act in a manner which seeks to ensure that the needs of the present are met without compromising the ability of future generations to meet their own needs.

Section 107: Meaning of “public body”

205. This section sets out the public bodies to which the regulations on carrying out HIAs will apply.

206. The section also gives the Welsh Ministers the power by regulations to amend the list of public bodies by adding to the list, or amending or removing a public body (or description of body) which is already listed. Bodies may be added to the list only if they exercise functions of a public nature. If a body whose functions comprise a mixture of functions of a public nature and other functions were added to the list of public bodies, subsection (4) would operate to prevent the provisions of this Part from applying to those other functions.

PART 6

PHARMACEUTICAL SERVICES

207. This Part introduces changes to the way in which Local Health Boards (LHBs) determine applications to provide NHS pharmaceutical services. The principal changes require LHBs to prepare and publish a pharmaceutical needs assessment for their area, and to determine applications for entry onto the pharmaceutical list (or applications to amend entries on the pharmaceutical list) by reference to whether or not the application meets a need for a service or services identified in the assessment. Each LHB maintains a pharmaceutical list which includes details of the persons whose applications to provide NHS pharmaceutical services have been approved and the location from which they provide those services.

208. This new “control of entry test” replaces the existing test in section 83 of the National Health Service (Wales) Act 2006 (‘the 2006 Act’), which requires LHBs to determine whether it is “necessary or expedient” to grant

the application in question. Further changes authorise LHBs to remove a person from its pharmaceutical list for very serious or persistent breaches of terms and conditions of service.

Section 108: Pharmaceutical needs assessments

209. This section inserts section 82A into the 2006 Act which makes provision for a new duty for LHBs in Wales to prepare and publish an assessment of need for pharmaceutical services.

210. Section 82A(2) places a duty upon each LHB to keep its most recently published assessment under review and revise it as and when it is appropriate to do so.

211. Section 82A(3) requires regulations to make provision for:

- the date by which a LHB must publish its first assessment of pharmaceutical needs. This is to ensure that all LHBs have an assessment prepared and published by a set date so that there will be a smooth transition from the current arrangements to the new arrangements for determining applications;
- the circumstances in which a LHB is to revise its assessment. Regulations could, for example, require a LHB to review, and if appropriate revise, its assessment if there are significant changes to the demographics of an area which could have an impact upon the need for pharmaceutical services. Regulations could also stipulate that a LHB is required to revise its assessment every, for example, three years in order to ensure that the information in the assessment remains up to date; and
- the way in which an assessment is to be published. This could, for example, include a requirement to place a copy of the assessment on the LHB's website as well as making hard copies available in NHS pharmacies and GP surgeries so that the assessment is accessible to persons living in the LHB's area.

212. Regulations may also make provision about the preparation, publication, review and revision of an assessment under subsection (1) including, but not limited to:

- the information to be contained in an assessment. For example, regulations could specify that an assessment must contain information on the demography of the people in its area, any seasonal trends, age profiles and information about the provision of General Medical Services in the area covered by an assessment;
- the extent to which an assessment is to take account of likely future needs and of other matters. For example, regulations could specify that an assessment must consider the impact of planned housing or commercial developments;

- the consultation to be carried out in connection with an assessment. For example, regulations may require LHBs to consult specified persons about specified matters when preparing their assessment. LHBs may, for example, be required to consult with local authorities, patient and community groups and local professional representative committees; and
- procedural requirements.

213. Section 108(2) provides that for the first time the Welsh Ministers make regulations about pharmaceutical needs assessments under section 82A of the National Health Service (Wales) Act 2006, these will be subject to the affirmative procedure, meaning they must be laid before, and approved by, the National Assembly for Wales. Subsequent regulations will be subject to the negative procedure.

Section 109: Pharmaceutical lists

214. This section amends sections 83 and 84 of the 2006 Act. Section 83 of that Act sets out the principal regulation making powers governing the provision of NHS pharmaceutical services in Wales, whilst section 84 provides for rights of appeal resulting from decisions made under section 83.

215. Section 83(2)(c) of the 2006 Act sets out the legislative criteria which a LHB must apply when considering applications to be included on a LHB's pharmaceutical list and applications for changes to the list. These criteria are often referred to as the "control of entry test".

216. Subsections (2) and (3) modify the "control of entry test" that LHBs are required to apply when considering applications to join their pharmaceutical list. Subsection (2) removes the requirement for LHBs to consider whether it is "necessary or expedient" to grant the application in order to secure "adequate" provision of pharmaceutical services within the neighbourhood.

217. In its place, subsection (3) inserts the new subsection (2B) into the 2006 Act which provides that a LHB may grant an application where it is satisfied, having regard to its most recently published pharmaceutical needs assessment, and any matters that are specified in regulations, that to grant the application would meet the need/s identified within its assessment. This amendment means that the "control of entry test" will be clearly based on meeting assessed local pharmaceutical needs.

218. Section 109(3) also inserts a new subsection (2A) into section 83 of the 2006 Act which permits the Welsh Ministers to specify, in regulations, persons, or the description of persons, who are not to be included within a pharmaceutical list.

219. Section 109(3) also inserts a new subsection (2C) into the 2006 Act which makes additional provision in cases where a LHB is satisfied that an

application meets the criteria for grant of the application required under subsection (2B). First, new subsection (2C) provides that the regulations may set out the procedure which the LHB must follow when determining an application for inclusion in a pharmaceutical list. For example, the regulations may provide that a LHB must seek representations from local patient representative bodies and other key interested parties. Second, new subsection (2C) provides that the regulations may stipulate certain matters which a LHB must or must not take into consideration when deciding whether or not to grant an application under subsection (2B).

220. Subsections (4), (5) and (6) modify the existing provisions which enable regulations to specify the circumstances in which two or more applications are considered together by a LHB.

221. Subsection (4) inserts a new subsection (3A) into the NHS (Wales) Act 2006 to provide that the regulations may prescribe the circumstances in which two or more such applications may be considered together by a LHB. Subsection (5) amends section 83(4) of the NHS (Wales) Act 2006 to create a general power to make provision for the case where two or more applications, taken individually, meet the test under the new subsection (2B), but, taken together, do not.

222. Section 109(7) inserts a new subsection (6)(za) into section 83 of the 2006 Act, which permits the regulations to prescribe the circumstances in which LHBs may invite applications for inclusion in their pharmaceutical list. This will enable a LHB, if it is not receiving applications to provide the pharmaceutical services which are required to meet needs identified in their pharmaceutical needs assessment, to actively seek applications that will fulfil those needs.

223. Section 109(7)(b) inserts a new subsection (6)(fa) into section 83 of the 2006 Act, which permits the regulations to prescribe the timescale within which a LHB must determine applications for inclusion in or amendment to an inclusion in the pharmaceutical list.

224. Section 109(7)(d) makes amendments to section 83(6)(g) of the NHS (Wales) Act 2006 so that regulations under section 83 may provide grounds for removal of a person from the pharmaceutical list that are not connected with a person's fitness to practise. It is intended to use this power to enable LHBs to remove pharmacists from the pharmaceutical list for serious and/or persistent breaches to their terms and conditions of service. Before removing a person from the pharmaceutical list for persistent breaches of terms of service an LHB must first issue the person with a notice describing the alleged breach (a so called "breach notice") and any action required by the person to rectify it. A person may only be removed from the pharmaceutical list where, having been issued with a breach notice, fails to comply with the requirements stipulated therein. Appeals against removal will be to the Welsh Ministers.

225. Section 109(8) inserts subsection (10A) which requires LHBs to provide reasons for their decisions as to any matters covered within section 83.
226. The remaining subsections amend section 84 of the 2006 Act, which deals with appeals against decisions made by LHBs under the regulations provided for in section 83.
227. Section 109(9) amends section 84 of the 2006 Act so as to ensure that appeals against a LHB's determination of an application for inclusion in a pharmaceutical list are heard by the First Tier Tribunal only if they are on fitness to practise grounds. The amendment removes the requirement relating to redetermination so that the First Tier Tribunal is not limited in the way it determines the appeal, for example, it could remit the matter back to the LHB. Appeals on other grounds are to be made to the Welsh Ministers – including appeals against a removal from the list for breaches of terms and conditions of service.
228. Section 109(10) provides that if regulations made under section 83 of the 2006 Act include provision for removal of a person or an entry in respect of premises from a pharmaceutical list, the regulations must require LHBs to give a pharmacist notice of their intention to remove him/her from the list, together with their reasons for the intended removal. The regulations will also need to set out the rights that a pharmacist will have to make representations prior to a LHB taking a decision to remove. It is intended that regulations will require the LHB to give a pharmacist written notice of their right to make representations orally and/or in writing before a substantive decision is made.
229. Section 109(11) removes text relating to section 83(6)(d) of the National Health Service (Wales) Act 2006 from the table in Schedule 6 (repeals and revocations of the Health Act 2009).

PART 7

PROVISION OF TOILETS

Section 110: Local toilets strategies: preparation and review

230. This section places a duty on each local authority in Wales (i.e. each county and county borough council) to prepare and publish a local toilets strategy for its area.
231. An authority's strategy will include an assessment of the need for toilets, including changing facilities for babies and changing places facilities for disabled persons, in its area to be available for use by the public. The strategy will also set out how the authority plans to meet those needs. The strategy will also include any other information which the authority considers appropriate.

232. A local authority's first strategy must be published no later than 12 months following the commencement of this section. Following publication of the first strategy, an authority may review its strategy at any time, but it must review its strategy no later than 12 months after each ordinary election of councillors to the authority.

233. When a local authority undertakes a review, it must publish a statement of the steps it has taken in accordance with its strategy for the period from the date the strategy was last published to the date of the review. If during a review of its strategy, a local authority considers a change is needed, it must make the changes and publish its revised strategy.

234. The Welsh Ministers must issue guidance to local authorities about the matters which they should take into consideration when preparing, reviewing, consulting on, or publishing a local toilets strategy.

Section 111: Local toilets strategies: interim progress statement

235. This section places a duty on a local authority that has published a local toilets strategy, or carried out a mandatory review of a strategy, to prepare and publish an interim progress statement.

236. Each interim progress statement will review progress made by an authority in implementing its strategy during a two year-period, defined by subsection (3) as the "statement period".

237. The statement period in a case where an authority's most recently published strategy has not been reviewed under section 110 will begin on the date of publication. In the case of the first interim statement to be produced under this section, the first date of the statement period will be the date an authority's first strategy is published by virtue of the duty in section 110(1) to publish a strategy. The date of any subsequent publication of a revised strategy – whether following a mandatory review or a review an authority chooses to carry out – would mark the beginning of another statement period.

238. The statement period in the case of a mandatory review of a strategy begins on the date the review is carried out.

239. An interim progress statement must be published by an authority no later than six months after the last day of the relevant statement period.

240. The Welsh Ministers must issue guidance to local authorities about the matters which they should take into consideration when preparing an interim progress statement.

Section 112: Local toilets strategies: consultation

241. This section sets out what a local authority must do with regard to consultation before publishing its local toilets strategy or its revised strategy.

242. The section does not specify categories of persons with whom a local authority should consult. It will be for each local authority to decide who, in its opinion, is likely to be interested in the provision of local toilets. Similarly, neither the timescale for consultation nor the consultation methods to be used are specified in the section. It will be for a local authority to decide the timescale for an effective consultation and the appropriate consultation method to be used to engage with those interested in the provision of local toilets, having regard to any guidance issued under section 110 by the Welsh Ministers.

Section 113: Local authority power to provide public toilets

243. This section provides that local authorities in Wales may provide public toilets in any part of their areas, and restates the powers previously conferred on local authorities under section 87 of the Public Health Act 1936 in relation to the provision of public toilets and the power to charge for the use of the toilets that they provide.

244. In this section, and unlike the preceding sections of this Part, the expression “local authority” includes a community council. When deciding whether to provide toilets, where toilets are to be provided, or deciding the type of toilets to be provided, a local authority must have regard to the relevant local toilets strategy that is in place for its area. In the case of a community council, the relevant toilets strategy will be the strategy for the council of the county or county borough in which the community is located. A local authority may charge fees for the use of those toilets that it provides under this section.

245. If toilets are to be on or under land adjoining, or in the vicinity of, a highway or proposed highway, the relevant highway authority must consent to the provision of the toilets. In some cases, the local authority will be the highway authority, so no consent will be required. The definition of “highway” in this section takes the meaning given to the expression by section 328 of the Highways Act 1980; that definition captures bridges in cases where a highway passes over a bridge and tunnels in cases where a highway passes through a tunnel.

Section 114: Power to make byelaws in relation to toilets

246. Subsection (1) enables a local authority which provides toilets under the preceding section to make byelaws relating to the conduct of persons using or entering the toilets. As with section 113 above, this restates the power previously conferred on local authorities under section 87 of the Public Health Act 1936 to make such byelaws.

247. “Local authority” in this section includes a community council. If a community council makes such byelaws, any relevant byelaws made by a county or county borough council under section 2 of the Local Government Byelaws (Wales) Act 2012 in relation to the toilets will not apply for as long as the relevant community council’s byelaws remain in force.

Section 115: Consequential amendments

248. This section gives effect to Schedule 4, which makes consequential amendments in relation to the provision of toilets.

PART 8 MISCELLANEOUS AND GENERAL

Section 116: Fixed penalty receipts for food hygiene rating offences

249. This section amends section 22 of the Food Hygiene Rating (Wales) Act 2013. Section 22 regulates the use of monies received by county and county borough councils in Wales in payment of fixed penalties in connection with various offences relevant to the mandatory display of food hygiene rating stickers required by the 2013 Act.

250. Section 22 of the 2013 Act, as enacted, requires councils to pay monies received to the Welsh Ministers; the substitution of a new subsection (1) for the existing section of the Act will, instead, enable a council to use fixed penalty receipts for the purpose of its functions relating to the enforcement of the provisions of the 2013 Act and regulations made under it.

Sections 117 and 118: Offences by bodies corporate, partnerships and other unincorporated associations

251. These sections make provision in connection with offences committed, or alleged to have been committed, under the Bill by a body corporate; a partnership; or other unincorporated association (“relevant bodies”).

252. Section 117 makes it possible, in the circumstances described in subsection (2) of that section, for individuals holding positions of responsibility within a relevant body (the “senior officers” defined by the section) to be criminally liable for an offence committed by the body.

253. Section 118 makes provision about and in connection with bringing proceedings against partnerships or other unincorporated associations.

Section 119: Giving notices

254. This section provides detail about how a notice is to be given from a person to another person under the Bill or regulations made under it; the section imposes requirements in relation to the form of the notice (it must be in writing) and the method by which a notice may be delivered. This provides clarity for both the person giving the notice and the person receiving the notice.

Section 120: Regulations

255. This section explains that powers to make regulations under this Bill are to be exercised by statutory instrument (which means that certain procedural and other requirements contained in the Statutory Instruments Act 1946 apply to regulations made under the Bill), and sets out the procedure, in terms of the National Assembly for Wales' involvement, to be followed in making regulations under different sections of the Bill.

Section 121: Interpretation

256. This section defines general terms which apply throughout the Bill.

Section 122: Power to make consequential and transitional etc. provision

257. This section permits the Welsh Ministers to make supplementary, incidental, consequential, transitional, transitory or saving provision in regulations. Such provision must be for the purposes of the Bill, in consequence of such a provision, or necessary to give full effect to them. For example, transitional arrangements may be needed to allow appropriate time for a practitioner of a special procedure to comply with the new requirements introduced by the Bill.

Section 123: Coming into force

258. Subsection (1) of this section sets out the provisions of the Bill that will come into effect on the date of Royal Assent; any provision which is not mentioned in subsection (1) will come into force on a day specified by a commencement order made by the Welsh Ministers.

Section 124: Short title

259. This provides that the short title of the Act will be the Public Health (Wales) Act 2017.

[End of Bill]

Schedule 1: Fixed penalties

260. Schedule 1 contains provisions relating to fixed penalties and fixed penalty notices. These include the contents of the penalty notice form, powers for the Welsh Ministers to make regulations to set the penalty and discounted amounts, and the periods for payment of the penalty and discounted amounts. Paragraphs 15 and 16 enable a person to request to be tried for the offence in court instead of paying the fixed penalty. Paragraph 17 permits authorised officers of the issuing authority to withdraw a fixed penalty notice.

Schedule 2: Smoking: consequential amendments

261. Schedule 2 makes consequential amendments in relation to smoking. These amendments:

- Disapply Chapter 1 of Part 1 of the Health Act 2006 in relation to Wales because Chapter 1 of Part 2 of the Public Health (Wales) Bill restates the provisions of Chapter 1 of Part 1 of the Health Act 2006 in relation to Wales. Chapter 1 of the Health Act 2006 remains in force in relation to England; and
- Amend section 91 of the Children and Families Act 2014, which modifies section 9 of, and Schedule 1 to, the Health Act 2006. The amendment inserts a new paragraph at subsection (5)(c) of section 91 of the Children and Families Act 2014. The amendment maintains the Welsh Ministers' powers to make regulations to specify the form of fixed penalty notices in relation to an offence under that section (in relation to the offence of buying or attempting to buy tobacco for a person aged under 18).

Schedule 3: Further provision in connection with special procedure licences

262. Paragraphs 1-4 set out the process that an applicant for a special procedures licence must follow, including the information that they must provide to the local authority to obtain a licence. In the application, the applicant must specify the special procedure/s to which the application relates and provide details on the basis that the procedure is to be performed (i.e. peripatetic basis (i.e. the applicant plans to practice a special procedure in various different premises, for example clients' homes), fixed site basis, mobile basis, temporary basis, or otherwise). If the procedure is intended to be performed at a set premises or vehicle, details of that premises or vehicle must be provided in the application.

263. The application must also include the details of the applicant (including their full name, date of birth, address and contact details) together with other required information including, for example, information about any offence they have been convicted of. The application is to be accompanied by whatever fee required by the authority. In setting this fee, the local authority must have regard to the costs incurred or expected to be incurred by them in connection with dealing with applications. In considering the application, the local authority may require further information to be provided by the applicant including information necessary to verify their identity. Paragraph 4(4) provides the Welsh Ministers with a regulation making power to make further provision about the way in which a local authority is to determine the amount of fee that is to accompany an application made to it, and the procedure for dealing with applications. This may include the way an application is made, the information to be provided in the application and the way in which an application is to be dealt with by the authority.

264. Paragraph 5 specifies the content of a special procedures licence. The licence must, amongst other things, state the name of the licence holder, name

the authority by which the licence is issued and state the special procedure that is authorised by the licence. The period that the licence is valid for must also be included on the licence; in the case of a temporary licence that is valid for no more than seven days, this must be specified on the licence. If required by section 56, the licence must also include the details of the approved premises or vehicle from which the licence holder is authorised to perform special procedures. Paragraph 5(3) provides the Welsh Ministers with a regulation making power to make further provision about the form and contents of special procedure licences. These regulations may include, amongst other things, information about the applicable mandatory licensing conditions that the holder of the special procedure licence must adhere to. These mandatory licensing conditions may relate to the condition (i.e. cleanliness, maintenance and standards of hygiene) of the premises or vehicle from which the special procedure is performed or where the equipment or material is stored or prepared.

265. Paragraphs 6 and 7 enable the licence holder to apply to the local authority for a copy of their licence if their licence is mislaid, stolen or damaged. As the mandatory licensing conditions may require the licence to be displayed, the licence holder may require a copy of the licence in order to comply with the requirement. The application must be made in any way the local authority requires and must be accompanied by whatever fee has been set by the authority. If the local authority is satisfied that the licence has been mislaid, stolen or damaged, the local authority must grant the application and issue a copy of the licence to the applicant as soon as practicable. In the case of a mislaid or stolen licence, the local authority must also be satisfied that the loss or theft has been reported to the police. The copy of the licence must be certified by the local authority as a true copy and will be treated as being the original licence.
266. Paragraph 8(1) provides details of the circumstances under which a licence expires. These circumstances include the end of the licence period, the voluntary termination of a licence or the date that the revocation by the local authority (as provided by section 65) of the licence takes effect. A licence will also expire once withdrawal of an individual's designation under section 58 takes effect.
267. Paragraph 9 enables a licence holder to apply to a local authority for the renewal of their special procedures licence. The application must be submitted to the local authority that granted the original licence and must be made in whatever way and contain whatever information is required by the local authority. The application must also include the fee set by the local authority.
268. Paragraph 10 provides that a licence does not expire during the time that the local authority is considering the application for the renewal of a licence, during the appeal period available in respect of an application for renewal or whilst an appeal is pending in respect of an application for renewal.

269. Paragraphs 11, 12 and 13 enable a special procedures licence to be varied upon application from the licence holder. For example, the variation may be applied for because the licence holder wishes to add, amend or remove a description of special procedure from their licence. The variation may also be required to add reference to an approved premises or vehicle from which the licence holder intends to perform special procedures or to remove a premises or vehicle previously identified on the licence. If the licence holder is applying to add a special procedure to their licence, the licence holder must specify the special procedure they wish to be added to their licence and meet the licensing criteria in relation to that procedure. The variation cannot however transfer the licence from the licence holder to another individual or extend the licence period. The application must be made in whatever way is required by the local authority and be accompanied by whatever fee is set by the local authority.

270. If a licence holder intends to terminate their licence, paragraph 14 enables the licence holder to give notice to the local authority of voluntary termination of the licence. In giving notice, the licence holder must state the date with which the licence is to cease to have effect. Subject to any earlier expiry under paragraph 8(1)(a), (b) or (d), the licence will cease to have effect on the date specified in the notice.

271. Paragraph 15 provides that where a local authority proposes to give notice to an applicant, licence holder or individual (referred to as “A”), A has the right to make representations to the local authority licensing committee. The notice may relate to:

- the refusal of an application for a licence under section 62(2) or 63(2)(b) (including under any of those provisions as applying in respect of the application by virtue of section 64 or paragraph 13);
- the intention to revoke a licence (section 65); or
- the designation of an individual under section 58(1), requiring them to have a licence.

272. Before a decision is taken by the local authority, it must provide a warning notice to A that sets out what the local authority intends to do and why. The warning notice must state that within the period specified (which must not be less than 14 days) A may either make representations or inform the local authority that he/she wishes to make representations about the proposal. If A wishes to, the local authority must enable A to make representations (including oral representations if A or his/her representative wishes to do so) and it must consider those representations. If A does not wish to make representations, or does not inform the local authority that he wishes to make representations within the specified period, the local authority may take the steps specified in the warning notice.

273. Having complied with the requirements in paragraph 15, paragraph 16 enables the local authority to take the action set out in the warning notice and to issue a notice of decision. The notice of decision must set out the local authority’s reasons for giving it. Similarly, if the local authority decides not to take the action set out in the warning notice, it is also required to notify the

applicant or licence holder of their decision. This ensures that an applicant or licence holder is informed of the outcome in all scenarios. The notice of decision must also state that A may appeal the decision and provide details of the period within which an appeal may be brought. In the case of a revocation under section 65, the notice of decision must also state the date on which (in the absence of an appeal) the revocation will take effect.

274. Paragraph 18 provides that an applicant, licence holder or individual may appeal to a magistrates' court against the local authority's decision (as taken under paragraph 16). The appeal must be made within 21 days of the local authority's notice of decision. On hearing the appeal, the magistrates' court may confirm, quash or vary the decision made by the local authority; alternatively, the magistrates' court could remit the case to be considered by the local authority in accordance with directions given by the magistrates' court. The magistrates' court may also make an order for costs incurred to be paid. These may be the costs incurred by the applicant or the local authority in defending their decision.

275. Paragraph 19 provides that an appeal against the decision of the magistrates' court under paragraph 18 may be brought to the Crown Court. The Crown Court may confirm, vary or reverse the magistrates' court's decision or require that the case is considered by the magistrates' court or the local authority in accordance with the directions given by the Crown Court.

276. If on appeal under paragraphs 18 and 19, the local authority's decision is varied or reversed, the magistrates' court or the Crown Court may order the local authority to compensate the applicant, licence holder or person subject to designation under section 58, for loss suffered as a result of the decision. For example, the person could be compensated for a loss of income due to the local authority's decision to prevent them from working whilst the appeal was ongoing.

277. During the time that an appeal under paragraphs 18 and 19 is taking place, the decision made or the notice given by the local authority continues to have effect. Therefore, if it is the local authority's decision to revoke a licence under section 65, the decision will remain in force until the court makes their determination.

278. Paragraph 21 delegates the specified functions of a local authority to the licensing committee of the local authority. This allows the licensing committee to make the decisions in relation to those functions listed under paragraph 21(1). Whilst the functions remain functions of the local authority, requiring the licensing committee (or one of its sub-committees) to take the decision provides a level of oversight. Committees and their members have experience in taking licensing decisions which may affect people's livelihood. In taking a decision, the licensing committee will be required to hear any representations provided by 'A' following the issuing of a warning notice by the local authority under paragraph 15. The functions of the licensing committee are provided to it by section 6 of the Licensing Act 2003. In addition to enabling the licensing committee to take decisions in relation to

specific areas, these functions enable the licensing committee to refer specified decisions to the local authority and to sub-delegate decision making.

279. Paragraph 21(4) provides the Welsh Ministers with a regulation making power to make provision about the procedures applicable to licensing committees and their sub-committees for the purpose of the exercise of the delegated functions under this paragraph, including public access and the availability of records. Subject to any regulations made by the Welsh Ministers, paragraph 21(5) enables each licensing committee and its sub-committees to regulate its own procedure.

280. Paragraph 22 repeals provisions in Part 8 of the Local Government (Miscellaneous Provisions) Act 1982 in relation to Wales. This means that the current registration system available under that Act which covers acupuncture, tattooing, semi-permanent skin colouring, cosmetic piercing and electrolysis will no longer apply. References to sections 14 and 15 of the Local Government (Miscellaneous Provisions) Act 1982 will also be removed from the Schedule to the Local Government Byelaws (Wales) Act 2012. As these provisions will no longer apply, local authorities will be unable to run parallel systems which address the same concerns, thereby providing clarity for both local authorities and practitioners as to the scheme in operation.

Schedule 4: Provision of toilets: consequential amendments

281. Schedule 4 makes consequential amendments in relation to the provision made by Part 7 in relation to toilets. These amendments:

- i. Disapply section 87 of the Public Health Act 1936 in relation to local authorities in Wales because the Bill restates the powers previously conferred on those authorities by section 87 of the 1936 Act in relation to:
 - the provision of public toilets;
 - the power to make byelaws as to the conduct of persons using or entering the toilets; and
 - the power to charge for the use of the toilets that they provide.
- ii. Insert a reference to section 113 of the Bill in section 114 of the Highways Act 1980 to ensure that the powers in that section are not prejudiced by the provisions in section 113. Section 114 confers a power on local authorities to provide public sanitary conveniences for users of roads where they are the highway authority.
- iii. Insert a reference to section 114 of the Bill in the tables in Parts 1 and 2 of Schedule 1 to the Local Government Byelaws (Wales) Act 2012, so that the byelaws council councils, county borough councils and community councils may make in exercise of their power under section 114 are not subject to confirmation by the Welsh Ministers, and so that fixed penalties may be issued by

authorities in relation to breaches of these byelaws. As such, these changes preserve the current position under the 2012 Act in relation to local authority byelaws about toilets but replace references to section 87 of the Public Health Act 1936 with references to the relevant section of the Bill.

Annex 2

Index of Standing Order requirements

Standing order		Section	pages/ paragraphs
26.6(i)	Statement the provisions of the Bill would be within the legislative competence of the Assembly	Member's declaration	Page 2
26.6(ii)	Set out the policy objectives of the Bill	Chapter 3 - Purpose and intended effect of the legislation	Pages 9-59 Paragraphs 8-254
26.6(iii)	Set out whether alternative ways of achieving the policy objectives were considered and, if so, why the approach taken in the Bill was adopted	Part 2 – impact assessment	Pages 104-253 Paragraphs 315-899
26.6(iv)	Set out the consultation, if any, which was undertaken on: (a) the policy objectives of the Bill and the ways of meeting them; (b) the detail of the Bill, and (c) a draft Bill, either in full or in part (and if in part, which parts)	Chapter 4 – Consultation	Pages 60-70 Paragraphs 255-310
26.6(v)	Set out a summary of the outcome of that consultation, including how and why any draft Bill has been amended	Chapter 4 – Consultation	Pages 60-70 Paragraphs 255-

Standing order		Section	pages/ paragraphs
			310
26.6(vi)	If the Bill, or part of the Bill, was not previously published as a draft, state the reasons for that decision	Chapter 4 – Consultation	Page 70 Paragraph 310
26.6(vii)	Summarise objectively what each of the provisions of the Bill is intended to do (to the extent that it requires explanation or comment) and give other information necessary to explain the effect of the Bill	Annex 1 – Explanatory Notes	Pages 275-326
26.6(viii)	Set out the best estimates of: <ul style="list-style-type: none"> (a) the gross administrative, compliance and other costs to which the provisions of the Bill would give rise; (b) the administrative savings arising from the Bill; (c) net administrative costs of the Bill's provisions; (d) the timescales over which such costs and savings would be expected to arise; and (e) on whom the costs would fall 	Part 2 – impact assessment	Summary at pages 104-107 and at Annex 4. Full RIA at Pages 104-253, Paragraphs 315-899
26.6(ix)	Any environmental and social benefits and dis-benefits arising from the Bill that cannot be quantified financially	Part 2 – impact assessment	Summary at pages 104-107 Full RIA at

Standing order		Section	pages/ paragraphs
			Pages 104-253 Paragraphs 315-899
26.6(x)	<p>Where the Bill contains any provision conferring power to make subordinate legislation, set out, in relation to each such provision:</p> <ul style="list-style-type: none"> (a) the person upon whom, or the body upon which, the power is conferred and the form in which the power is to be exercised; (b) why it is considered appropriate to delegate the power; and (c) the Assembly procedure (if any) to which the subordinate legislation made or to be made in the exercise of the power is to be subject, and why it was considered appropriate to make it subject to that procedure (and not to make it subject to any other procedure); 	Chapter 5 - Power to make subordinate legislation	Pages 71-102
26.6(xi)	Where the Bill contains any provision charging expenditure on the Welsh Consolidated Fund, incorporate a report of the Auditor General setting out his or her views on whether the charge is appropriate	The requirement of Standing Order 26.6(xi) does not apply to this Bill	Paragraph 314
26.6B	Where provisions of the Bill are derived from existing	Annex 3 –Table of Derivations	Pages 331-332

Standing order		Section	pages/ paragraphs
	primary legislation, whether for the purposes of amendment or consolidation, the Explanatory Memorandum must be accompanied by a table of derivations that explain clearly how the Bill relates to the existing legal framework.		
26.6C	Where the Bill proposes to significantly amend existing primary legislation, the Explanatory Memorandum must be accompanied by a schedule setting out the wording of existing legislation amended by the Bill, and setting out clearly how that wording is amended by the Bill.	The requirement is Standing Order 26.6C for a Schedule of Amendments is not applicable to this Bill as the Bill does not propose to significantly amend existing primary legislation.	

Annex 3 – Table of derivations

The table below is intended to provide information about the derivation of the provisions of the Public Health (Wales) Bill. The table does not provide definitive or exhaustive guidance and should be read in conjunction with the Bill and with the Explanatory Notes to the Bill. While care has been taken to ensure the document is as accurate as reasonably practicable, it does not purport to be, and should not be relied upon as, authoritative.

Derivations are only relevant to Parts 2 and 7 of the Bill (Tobacco and Nicotine Products, and Provision of Toilets). Accordingly, the other Parts are not referenced in the following table.

ABBREVIATIONS:

HA: Health Act 2006
SF: The Smoke-Free Premises etc. (Wales) Regulations 2007
PHA: Public Health Act 1936

TABLE OF DERIVATIONS		
SECTION /PARAGRAPH	CORRESPONDING REFERENCE IN EXISTING LEGISLATION	SUBSTANTIVE CHANGE?
PART 2: TOBACCO AND NICOTINE PRODUCTS		
CHAPTER 1: SMOKING		
2	Section 1(2) HA	No
3(1)	Section 7(2) HA	No
3(4)-(6)	Section 7(4)-(6) HA	No
4(1)	Section 8(1) HA	No
4(2)-(6)	Section 8(3)-(4), 8(5)(b) and (c), 8(6)-(7) HA	No
5(1)-(6)	Section 2(1)-(4), 2(8) HA	Yes. A private dwelling that is a workplace is smoke-free only when used as a place of work.
6(1)-(5)	Section 2(1), 2(3)-(4), 2(7) HA	No
10(1)-(4)	Section 4(1)-(4) HA	No
10(5)-(6)	New	
12(1)	Section 5(1) HA	No
12(2)	New	
12(3)-(5)	Section 5(2)-(3)(a) HA	No
13(1)-(4)	Section 3(1), 3(6)-(7) HA	No
14(1)-(3)	Section 6(1)-6(4) HA	No
14(5)-(8)	Section 6(5)-6(8) HA	No
15(3)-(5)	Section 10(2b), 10(3), 10(5) HA	No

16(1)	Schedule 2: 2(a) HA	No
16(2)	Schedule 2: 2(a) HA	Yes
16(3)	New	
16(4)	Schedule 2: 2 HA	No
16(5)	Schedule 2: 1 HA	No
17	New	
18(1)-(6)	Schedule 2: 1, 6(1)-(4) HA	No
19(1)	Schedule 2: 7, HA	No
19(4)	Schedule 2: 1 HA	No
20(1)	Schedule 2: 2(b)-(e) HA	No
20(2)-(3)(a)	Schedule 2: 3, 9 HA	No
20(3)(b)	New	
20(4)-(5)	New	
20(6)-(7)	Schedule 2: 1, 5 HA	No
21	Section 11(1)-(2), 11(4) HA	Yes
24(1)-(3)	Section 9(1)-(2) HA	No
24(4)	Regulation 1(3) SF	No
24(5)-(7)	New	
24(8)	Section 9(3) HA	No
25(1)	Section 5(5) HA	No
25(7)	Section 2(5) HA	No
Schedule 1: 2-17	Schedule 1: 1-16 HA	
Schedule 1: 18	New	
PART 7: PROVISION OF TOILETS		
113(1)	Section 87(1) PHA	No
113(4)	Section 87(2) PHA	No
113(5)	Section 87(3)(c) PHA	No
114(1)	Section 87(3)(a) PHA	No

Annex 4 – Summary of Costs of Legislation

This section outlines a summary of the anticipated additional costs of the provisions within the Public Health (Wales) Bill. All costs are additional to maintaining the status quo, as set out in the “do nothing” option for each proposal. This section must be read in conjunction with the relevant sections within the main RIA to provide the context and associated detail for the figures.

The figures used are a mid point when calculated from a range within the RIA.

The figures in the tables derive from the costs of the preferred option for each subject as set out in the main RIA.

Where there are likely to be cost savings, the net cost of the preferred option has been included.

The tables set out the annual costs over five years across Wales for each subject.

Annual costs

Table A4.1: Restrictions on smoking in school grounds, hospital grounds and public playgrounds

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government	63,900	0	0	3,000	0
Local authorities, schools and hospitals (combined)*	49,100	0	0	24,600	0
Local authorities	94,400	10,800	0	0	0
Schools	6,900	0	0	0	0
Health boards	18,800	0	0	0	0
Independent hospitals	3,600	0	0	0	0
Total cost	236,700	10,800	0	27,600	0

*The total excludes the value of FPNs and fines

Table A4.2: Register of retailers of tobacco and nicotine products

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government	26,700	9,000	0	0	0
Local authorities	6,600	*- 116,500	15,000	16,500	15,000
Retailers		250,900	11,100	11,100	11,100
Total Net Cost	33,300	143,400	26,100	27,600	26,100

* Local authorities will retain registration fees amounting to £148,100 in this year, amounting to a net saving of £116,500.

Table A4.3: Handing over tobacco etc to persons under 18

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government	18,000	0	0	1,500	0
Local authorities	126,300	72,100	72,100	72,100	72,100
Retail sector	83,700	1,000	1,000	42,400	1,000
Total Cost	228,000	73,100	73,100	116,000	73,100

Table A4.4: Special procedures

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government	62,100	-2,500	-2,500	3,400	-2,500
Local authorities*	61,800	248,400	192,000	175,700	161,200
Practitioners /businesses	0	485,700	89,300	84,300	347,500
Unregistered Practitioners	0	50,000	45,000	40,000	35,000
Total cost	123,900	781,600	323,800	303,400	541,200

* Local authorities will retain registration fees from businesses and practitioners to off-set the costs incurred in administering the licence scheme. An amount equal to the anticipated registration fee total has therefore not been included in the total local authority costs.

Table A4.5: Intimate piercing

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government	18,700	0	0	1,300	0
Local authorities	76,800	76,800	38,400	38,400	38,400
Practitioners/ businesses	311,200	263,800	263,800	287,500	263,800
Total Cost	406,700	340,600	302,200	327,200	302,200

Table A4.6: Health impact assessments

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government	0	17,700	14,000	18,000	27,800
Public Health Wales	0	16,100	3,000	3,000	10,800
Public bodies (with an assumption that a third of these costs will fall to local authorities)	0	73,200 (including 24,400 to local authorities)	110,000 (including 36,700 to local authorities)	127,600 (including 42,500 to local authorities)	143,300 (including 47,800 to local authorities)
Total cost	0	107,000	127,000	148,600	181,900

Table A4.7: Pharmaceutical services

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government	0	18,100	0	0	0
Health boards	0	210,100	427,100	427,100	427,100
Contractors	0	0	77,100	77,100	77,100
Total cost	0	228,200	504,200	504,200	504,200
Monetised benefits			2,611,200	2,611,200	2,611,200
Net cost		228,200	- 2,107,000	- 2,107,000	- 2,107,000

Table A4.8: Provision of toilets

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)
Welsh Government	9,000	0	0	0	0
Local authorities	0	378,400	8,300	45,700	8,300
Total Cost	9,000	378,400	8,300*	45,700*	8,300

*Additional costs in these years relate only to the increase in management costs to facilitate the full £200,000 spending on grants and the cost of developing interim progress reports. Further additional costs would be determined by the development and implementation of the strategies. As these strategies are at the discretion of each local authority following an assessment of need in its area it is not possible to estimate the additional costs to increase provision levels. However, greater spending on the implementation of strategies is likely to result in a greater degree of the benefits discussed being realised.

Total Bill costs summary

Each part of the Bill is expected to impose additional costs on the Welsh Government. Each part of the Bill, with the exception of pharmaceutical services, is expected to impose additional costs on local authorities. The total impact of the Bill on these organisations over the five-year period is shown in the table below. The net cost has been used where there are likely to be savings to Welsh Government or local authorities. Other parties are impacted by individual parts of the Bill, as identified in the tables above.

Table A4.9:

	2017-18 (£)	2018-19 (£)	2019-20 (£)	2020-21 (£)	2021-22 (£)	Total (£)
Welsh Government	198,400	42,300	11,500	27,200	25,300	304,700
Local authorities	365,900	683,600	362,500	390,900	342,800	2,145,700