Explanatory Memorandum to:

The Special Procedure Licences (Wales) Regulations 2024
The Special Procedures Approved Premises and Vehicles (Wales)
Regulations 2024

The Special Procedures Exempted Individuals (Wales) Regulations 2024 The Prescribed Objects for Body Piercing (Special Procedures) (Wales) Regulations 2024

The Special Procedures Licensing Committees (Wales) Regulations 2024

This Explanatory Memorandum has been prepared by Health Protection Policy and Priority Programmes branch of the Welsh Government and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Cabinet Secretary's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Special Procedure Licences (Wales) Regulations 2024; The Special Procedures Approved Premises and Vehicles (Wales) Regulations 2024; The Special Procedures Exempted Individuals (Wales) Regulations 2024; The Prescribed Objects for Body Piercing (Special Procedures) (Wales) Regulations 2024; The Special Procedures Licensing Committees (Wales) Regulations 2024 and I am satisfied that the benefits justify the likely costs.

Jeremy Miles MS
Cabinet Secretary for Health and Social Care

14 November 2024

PART 1

1. Description

- 1.1 These regulations and statutory guidance fully enact Part 4 and Schedule 3 of the Public Health (Wales) Act 2017 ('the Act'). They deal with the creation of a mandatory licensing scheme for practitioners, premises and vehicles associated with the performance of special procedures. There are four special procedures named in section 57 of the Act: acupuncture (including dry needling); body piercing; electrolysis and tattooing (including semi-permanent make up).
- 1.2 The mandatory scheme, when commenced, will be operated by all local authorities in Wales and enforcement requirements of the scheme will be consistent across all 22 local authorities. There are no inherited rights from the existing local authority registration scheme, so the licensing scheme will apply equally to all new and current practitioners of the four special procedures, and all premises or vehicles within which these procedures are performed.
- 1.3 The requirements of the scheme are that all practitioners of any of the four procedures will require a licence and all premises or vehicles in which any of the procedures are performed will require an approval certificate. In addition, there are mandatory licensing conditions and premises/vehicle approval conditions which will apply in all cases. This will ensure a consistency of approach across Wales in terms of standards of practice relating to infection protection and control procedures to assure the health and safety of all clients and practitioners. The requirements of the scheme apply to anyone who performs these procedures in Wales, so will also apply to practitioners who reside outside Wales but visit occasionally or cross the border to work, and to those purpose-equipped vehicles brought into Wales from which special procedures are performed.
- 1.4 The overarching purpose of the legislation is to improve standards of hygiene and safety for the general public who wish to obtain any of the four special procedures. This legislation provides the detail of the requirements of the scheme to allow it to operate and to be administered and enforced by local authorities. The legislation does not attempt to address or improve any specific societal disadvantages or issues, but to ensure that these special procedures are performed to consistent standards in every area of Wales.
- 1.5 Under section 66(11) of the Act, 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. This 'fitness' is related solely to whether the individual has unspent convictions for 'relevant offences' as defined in section 66(8) of the Act. These are largely offences of violence,

sexual misconduct or offences under health and safety legislation or other parts of the Act. This guidance will be published on the Welsh Government website and issued to local authorities in due course.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

2.1 The Special Procedure Licences (Wales) Regulations 2024 have been revised and re-laid to address errors identified in those Regulations which were laid on 17 September 2024 and subsequently withdrawn, ref SL(6)524¹.

3. Legislative background

- 3.1 The Public Health (Wales) Act 2017 ("the Act") was passed by the National Assembly for Wales on 16 May 2017, and Royal Assent was received on 3 July 2017. This is the parent Act for these regulations and was 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 Act is on shaping social conditions that are conducive to good health, and where possible, avoiding health harms that can be averted.
- 3.2 The Act is wide ranging in its subject matter and includes provisions in a number of discrete policy areas, all of which aim to address contemporary challenges to health and well-being in Wales. It is comprised of 127 sections within 9 Parts and 4 Schedules.
- 3.3 This Explanatory Memorandum and Regulatory Impact Assessment (RIA) are concerned solely with regulations to be made to fully enact Part 4 and Schedule 3 of the Act, that deal with special procedures and the related statutory guidance.
- 3.4 Part 5 of the Act in respect of intimate piercing of minors under the age of 18 is closely related to Part 4 and has already been commenced. This Part has the effect of defining the body parts considered 'intimate' and prohibiting body piercers from performing or arranging to perform piercings of those body parts on children under the age of 18 years. The Prescribed Objects for Intimate Piercing (Wales) Regulations 2019 (S.I. 2019/1120 W. 194) are in force and have the effect of defining an object for the purposes of the prohibition within Part 5 of the Act. As this Part has been commenced and the Regulations are in force, these

¹ https://senedd.wales/media/xkqp4fo5/cr-ld16698-e.pdf

do not form part of this Explanatory Memorandum and RIA.

The Special Procedure Licences (Wales) Regulations 2024

- 3.5 Sections 62(1), (4) and (5), 63(1) and (5), 76(4) and (5) of, and paragraphs 4(4) and 5(3) of Schedule 3 to the Act gives the Welsh Ministers the power to make regulations about special procedure licences. These Regulations relate to a number of various aspects including the criteria that must be met for a special procedure licence to be granted, the form and content of the special procedure licence and the mandatory licensing conditions that must be attached to the licence and adhered to by the licence holder.
- 3.6 Section 123(2)(b) of the Act provides that the draft affirmative resolution procedure will apply to Regulations made under sections 62 and 63 of the Act.
- 3.7 Section 123(3) of the Act provides that the negative resolution procedure will apply to any other Regulations made under the Act.
- 3.8 Under section 40 of the Legislation (Wales) Act 2019, provision subject to the negative procedure may be combined in the same instrument as provision subject to the draft affirmative procedure. As a result, the draft affirmative procedure applies to these Regulations.

The Special Procedures Approved Premises and Vehicles (Wales) Regulations 2024

- 3.9 Sections 69(8) and (9), 70(3), (7), (8) and (9), 71(4), 72(5) and 76(4) and (5) of the Act give the Welsh Ministers the power to make regulations about approved premises and vehicles. For context the new licensing scheme will require special procedures to be performed at a premises or in a vehicle that has been approved by a local authority for that purpose unless that premises or vehicle is exempt. If a local authority is satisfied the premises or vehicle is to be approved, they will issue an approval certificate authorising that approval.
- 3.10 These Regulations relate to a number of various aspects around approvals including the criteria that must be met for an approval certificate to be granted, the form and content of the approval certificate, the mandatory approval conditions that must be attached to the approval certificate and adhered to and appealing against the refusal of an approval.
- 3.11 Section 123(2)(b) of the Act provides that the draft affirmative resolution procedure will apply to Regulations made under sections 69(8) and 70(3)(a) or (c) to the Act. Section 123(3) of the Act provides that the negative resolution procedure will apply to any other Regulations made

under the Act.

3.12 Under section 40 of the Legislation (Wales) Act 2019, provision subject to the negative procedure may be combined in the same instrument as provision subject to the draft affirmative procedure. As a result, the draft affirmative procedure applies to these Regulations.

The Special Procedures Exempted Individuals (Wales) Regulations 2024

- 3.13 Section 58(2) of the Act 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 exempt. Section 60 of the Act gives the Welsh Ministers the power to make regulations to exempt qualifying professions from the requirement to obtain a special procedure licence.
- 3.14 These Regulations are being made under the draft affirmative resolution procedure as required by section 123(2)(b) of the Act.

The Special Procedures Licensing Committees (Wales) Regulations 2024

- 3.15 Under Part 4 of the Act, a local authority may be required to hold a hearing in specified circumstances. Examples include but are not limited to where the local authority intends to refuse an application for a special procedure licence, where the local authority intends to revoke a special procedure licence, or where the local authority wishes to designate an individual as a person requiring a special procedure licence if they intend to perform a special procedure (section 61(1) of the Act). A local authority is under a duty to issue a warning notice (under paragraph 15 of Schedule 3 to the Act) and is required to consider representations made after it has issued a warning notice (paragraph 15(8) of Schedule 3 to the Act).
- 3.16 For information purposes, paragraph 18 of Schedule 3 to the Act provides that an applicant, licence holder or individual may appeal to a magistrates' court against the local authority's decision, and paragraph 19 of Schedule 3 to the Act provides that an appeal against the decision of the magistrates' court may be brought to the Crown Court.
- 3.17 Paragraph 21(1) of Schedule 3 to the Act delegates specified functions of a local authority to the licensing committee of the authority established under section 6 of the Licensing Act 2003 which includes considering such representations and issuing a notice of decision.
- 3.18 Paragraph 21(4) of Schedule 3 to the Act gives the Welsh Ministers the power to make regulations about the procedures applicable to licensing committees or their sub-committees for the purpose of the exercise of functions under or by virtue of Part 4, including (among other things):

provision as to:

- (a) validity and quorum
- (b) public access
- (c) publicity
- (d) records.
- 3.19 These Regulations are being made under the negative resolution procedure.

The Prescribed Objects for Body Piercing (Special Procedures) (Wales) Regulations 2024

- 3.20 Under Part 4 of the Act, the special procedure of "body piercing" is currently defined in section 94(1) of the Act as 'the perforation of an individual's skin or mucous membrane, with a view to enabling jewellery, or an object of a description prescribed in or under regulations, to be attached to, implanted in, or removed from the individual's body'. Perforation means 'breaching the integrity of the skin or mucous membrane in any way including (among other things) by way of puncture or incision' (section 94(2) of the Act).
- 3.21 Section 94(1) of the Act gives the Welsh Ministers the power to make regulations to prescribe an 'object' to further define what 'body piercing' means.
- 3.22 These Regulations are being made under the draft affirmative resolution procedure as required by section 123(2)(b) of the Act.

4. Purpose and intended effect of the legislation

- 4.1 A number of cosmetic and therapeutic procedures have become increasingly popular over the last two decades, both in Wales and further afield. These include acupuncture (including dry needling), body piercing, electrolysis and tattooing (including semi-permanent make up).
- 4.2 There are known and well reported health risks connected to these procedures defined within the Act 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 bloodborne viruses², 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

² 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

studio in Newport in 2015³ 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 potentially infected with blood borne viruses⁴.

- 4.3 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. 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 help⁵. The prevalence was higher among those aged 16 to 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 health⁶. Complications can be particularly serious for those with underlying health conditions, and cases of individuals who have died following a piercing have been recorded⁷.
- 4.4 A rapid review⁸ commissioned by the Welsh Government and conducted by Health and Care Research Wales in 2023 demonstrates that infection affecting the skin and other physical symptoms (such as allergic reaction) can be associated with all four special procedures.
- 4.5 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, sterilisation or disposal of instruments, materials and equipment, and

³ www.bbc.co.uk/news/uk-wales-south-east-wales-32607788

⁴ Public Health Wales (2015) Newport tattooing and piercing concerns update. No longer available online.

⁴ 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

⁵ 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.

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

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]

⁸ A rapid review of physical health risks associated with special procedures (tattooing, body piercing, acupuncture, electrolysis) | medRxiv

Pre- and post-procedure consultations.

Current regulatory position

- 4.6 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 Part 8 of the Local Government (Miscellaneous Provisions) Act 1982 ('the 1982 Act'), which includes acupuncture, ear piercing, electrolysis and tattooing, later amended to include cosmetic piercing and semi-permanent skin-colouring. 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. However, these are now proving inadequate to respond to the challenges of the modern special procedures industry as this has grown from a minority interest to mainstream.
- 4.7 Local authorities are required to register practitioners and premises under Part 8 of the 1982 Act but the process varies between local authorities in Wales. Some local authorities register premises, some register practitioners, some both. In addition, where local authorities have adopted the provisions, enforcement is often inconsistent across Wales. To address these inconsistencies, the Welsh Government published model byelaws⁹ in 2011 for the adoption of a registration scheme under the 1982 Act relating to the cleanliness and hygiene of premises, practitioners and equipment, but a number of local authorities did not adopt them. Local authorities are now not likely to do so, as since the Act was passed in 2017, they have been waiting for the creation of the mandatory licensing scheme for special procedures which is the subject of this Explanatory Memorandum.
- 4.8 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 therefore have to be taken at face value and approved.
- 4.9 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 if practitioners are not operating from commercial premises, as, for example, some practitioners may work from home. This situation has been exacerbated by the Covid-19 pandemic, with more practitioners choosing to work from their residential premises.
- 4.10 Registration under the 1982 Act is also not subject to a requirement for those performing the procedures to demonstrate they have a level of hygiene and infection control knowledge that is appropriate to the

rw.gov.waio

⁹ https://www.gov.wales/byelaws-acupuncture-tattooing-skin-colouring-piercing-and-electrolysis

special procedure(s) they perform, although some are very knowledgeable in this regard. 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 scheme no longer adequately addresses the public health concerns and protects the public effectively. There have been examples of unregistered practitioners being prosecuted and having their equipment seized. Anecdotal evidence suggests that, due to the rise of social media, there are likely to be a number of individuals who advertise their services online and operate outside the current registration scheme. As these individuals are unregulated, whether they apply appropriate standards of hygiene and safety or operate in suitable environments is unknown. Local authorities are largely dependent upon receiving local intelligence or a complaint being made to become aware of these practitioners and when Part 2A orders have been served (under the Health Protection (Part 2A Orders) (Wales) Regulations 2010 (S.I. 2010/1544 W.142))¹⁰ the standards of hygiene and safety have been found to be poor.

- 4.11 In response to the perceived inadequacies with the current scheme, the Act seeks to repeal the 1982 Act provisions as applied to Wales and replace them with a compulsory, national licensing scheme for practitioners of the specified special procedures and related premises and vehicles in Wales. These provisions have been made in Part 4 and Schedule 3 of the Act but have not yet been commenced and require these regulations to be made to fully enact them. The scheme set out in Part 4 of the Act will mean that to perform any of the special procedures defined within the Act, an individual must be licensed and the premises or vehicle from which they operate approved by the relevant local authority. Individual licences and approval certificates will be valid for a period of three years. Temporary licences and approval certificates with a time limitation of no longer than seven days will also be available for exhibitions and events. This enables unlicenced individuals within Wales to apply for a temporary licence to practise at such events, as well as visiting practitioners outside of Wales and/or the UK. Similarly, people in control of venues in Wales and/or purposely equipped vehicles to be used for such temporary events will be able to apply for a temporary approval certificate.
- 4.12 This scheme aims to better meet customer expectations and respond to the different business models within the sector. The intention is to ensure that individual licensed practitioners practise to appropriate standards such as hygiene, client and practitioner safety, record keeping and age verification, as well as to ensure that special procedures are only carried out in suitable environments which are approved for that purpose. 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. It is not the

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¹⁰ list-of-part-2a-orders-issued-in-wales-as-advised-to-the-chief-medical-officer-for-wales.pdf (gov.wales)

intention of the scheme to assess, guarantee or provide assurance of a practitioner's skill in technique, qualifications or any other aspect of their work.

4.13 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. To ensure the legislation remains up to date and effective as new procedures are constantly being devised, section 93 of the Act provides Welsh Ministers with a power to amend the list of special procedures. This power will be commenced along with the other provisions in Part 4, but no additional special procedures will be added at this point. The intention has always been that the scheme should be established for the four named special procedures before consideration is given to bringing additional procedures into the scheme. There would need to be a scoping exercise to identify which procedures (if any) should be added in the future and a public consultation putting forward proposals. The requirement is that any additional procedures to be included are ones that are capable of being performed for aesthetic purposes, or for the purposes that the Welsh Ministers consider to be therapeutic, and that their performance for those purposes is capable of causing harm to human health (section 93(3) of the Act). Previous Health Ministers have made statements committing the Welsh Government to running a further consultation on this matter at some time in the future and, following that consultation, should it be required, to utilise the commenced power to pursue this via further subordinate legislation, which would be subject to the draft affirmative procedure.

Practitioners

- 4.14 Following the establishment of the licensing scheme, it will be an offence for a practitioner to conduct any of the special procedures without a licence or to perform them from premises or vehicles that are not approved. As the licence is issued to the specific practitioner, this means they can operate from any approved premises or vehicle within Wales, or more than one as long as all premises/vehicles are named on their licence. The Act does provide for exemptions to be made for these requirements, for example, to exempt members of specific professions (such as registered and licensed doctors, registered dentists and registered nurses) from needing a licence to practise 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 draft affirmative procedure.
- 4.15 Welsh Ministers are able, by way of regulations, to set licensing criteria and mandatory licensing conditions, so that standards of practice and enforcement of special procedures are consistent throughout Wales. The licensing criteria specify, among 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, the prohibition on tattooing an individual who is under the age of 18 years. The mandatory licensing conditions set out the requirements a licence holder must meet to retain their licence. These include conditions relating to verification of each client's age, application of required infection control practices and standards of hygiene, undertaking pre and post procedure client consultations and appropriate record keeping. The conditions also prohibit a licence holder from performing a special procedure on an individual who is, or appears to be, intoxicated from alcohol, drugs, or any other means.

4.16 The Act at s62(3)(a) enables the licensing criteria for the licensing scheme to relate to (among other things) an individual's eligibility for a licence. This provision enables the licensing criteria to be specified to include requiring all applicants for a special procedure licence to declare any unspent convictions for 'relevant offences' as part of the application process and to submit a recent DBS certificate. What constitutes a 'relevant offence' is set out in section 66 of the Act. The purpose of this is to ensure that individuals that may present a risk to the public because of their offending history are scrutinised carefully by the local authority before any decision to grant or refuse a licence is made. The Statutory Guidance to be issued by the Welsh Ministers under section 66(11) of the Act includes guidance to local authority about what matters are to be taken into account in deciding whether, and if so, to what extent, an applicant's fitness to perform a special procedure has been called into question. The Statutory Guidance considers a number of elements to this including the local authority considering the nature of the offence, and the circumstances, such as whether there has been repeat offending, the sentences passed and any mitigating evidence the applicant may wish to provide. The Act provides for an applicant to make representations to the licensing committee of the local authority against a refusal issued by the local authority, and to bring appeals before the magistrates' court and the Crown Court if necessary.

Premises and Vehicles

4.17 All persons who are in charge of a premises at which any of the special procedures are performed must make an application to the relevant local authority for the approval of those premises before any practitioners can perform the procedures in that premises. The applicant does not have to be a practitioner themselves in order to be included within this obligation. Section 82 of the Act provides that it will be an offence to perform any of the special procedures or permit someone else to perform the procedures within the premises unless an approval certificate has been granted and remains valid. As each premises is inspected before approval, the approval certificate can only apply to that premises and is not transferrable. If the applicant owns or

- manages more than one premises, an application for approval must be submitted for each.
- 4.18 Provision has been made for vehicles in which special procedures are performed to be approved as if they were static premises. Vehicles that will meet the approval criteria will be larger vehicles and trailers that have been custom fitted as mobile treatment rooms, and there are very few of these in operation. Any vehicle to be used in this way has to meet the same set-up and operating conditions as a fixed premises and will be inspected and subject to the same approval process as a fixed premises.
- 4.19 The provision in the Act is such that the licensing committees cannot be used to arbitrate in the same way for refusals of premises/vehicle applications. However, consultees indicated that applicants for premises/vehicle approval should be able to make representations to local authorities if refused. Local authorities are therefore required in the relevant regulations to ensure applicants for premises/vehicle approvals that are to be refused have a similar right of representation.

All scheme licence/approval certificate holders

4.20 The Act requires that licence holders (i.e. practitioners) and approval certificate holders (for premises/vehicles) will be under a duty to meet all the requirements placed upon them and to operate in accordance with the mandatory licensing conditions relevant to the special procedure(s) they perform and/or the mandatory approval conditions applicable to the premises/vehicle that has been approved as set out in the regulations. This includes the display of licences and approval certificates within the premises/vehicle which will assure clients that the practitioner is licensed, and the premises/vehicle has been approved by the local authority for the performance of special procedures.

Licensing authorities

4.21 The Act provides that local authorities are to be responsible for enforcing the licensing requirements, and for keeping a register of special procedure licences and premises/vehicle approvals issued by them that have not ceased to have effect (section 75 of the Act). A local authority must make the information relevant to each licence/approval certificate on the register accessible to the public. The Welsh Ministers can arrange for the duty to keep a register imposed on local authorities to be discharged through the establishment of a single all-Wales register hosted by one local authority. All 22 local authorities have confirmed that this is their preferred approach. A central national register has been created as an online resource in advance of the regulations being made to allow for its immediate use when the Regulations come into force. The public-facing part of the register has

the purpose of ensuring that anyone seeking to have any of the defined special procedures can search for information and check that the practitioner or business they choose has met the safety and hygiene national standards required for the provision of special procedures in Wales. The public part of the register will be driven by a secure, limited-access database shared by all 22 local authorities to allow for the effective monitoring of licence and approval data and enforcement activity across Wales from within any local authority.

- 4.22 As set out in paragraph 4.16, each local authority's licensing committee will be the first stage arbiter of any representations against a refusal of a licence and as explained in paragraph 4.19 local authorities are to hear representations in respect of refusals of premises/vehicle approval certificates. Refusals for either type of application may be made for a range of practical reasons that become apparent through the application and inspection processes which require further discussion and deliberation. The Regulations are required to set out the details of how the licensing committees/local authorities are to arbitrate in such cases. Should these representations fail, the applicant is able to appeal to the magistrates' court and ultimately the Crown Court.
- 4 23 The Act creates a number of enforcement tools and offences. A local authority will be able to take action to prevent an unlicensed practitioner from performing special procedures or to stop a premises/vehicle that has not been approved from being used for the provision of special procedures. This will be done through issuing a stop notice that will apply anywhere in Wales in the case of a practitioner or for example a vehicle to prevent evasion through relocation. The local authority may also take action in the case of licence holders or premises/vehicle approval certificate holders, by issuing a remedial action notice if the practitioner or premises/vehicle contravenes any of their applicable mandatory licensing/approval conditions. This remedial action notice will order specific action and steps to be taken to rectify the issue within 14 days. The Act provide local authority officers with the power to enter premises/vehicles for the purpose of carrying out 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.
- 4.24 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 since their licence was granted, then the Act 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 a premises/vehicle approval certificate (under section 73 of the Act) where the approval certificate holder has failed to comply with any mandatory approval conditions. Where the local authority has taken action, such as issuing a stop

notice or revoking a licence/approval certificate, an individual has the right to make representations to the local authority in the first instance, and appeal to a magistrates' court should their representations fail. As a last resort, an appeal may be made to the Crown Court if all previous appeals have failed.

Intended effect of the provisions

- 4.25 The mandatory licensing scheme aims to drive up hygiene and safety standards in relation to the performance of special procedures by practitioners and within premises/vehicles where they are performed and ensure local authorities have an improved and consistent approach to the regulation and enforcement of the scheme across Wales.
- 4.26 In addition to the benefits associated with improving standards of practice, individuals who wish to have one of the special procedures will also directly benefit, as they will be given an in-depth pre-treatment consultation with the practitioner. This is to ensure that any health or safety issues related to their personal health, or the procedure have been considered, by providing information about the procedure before it is undertaken, as well as advice on the necessary aftercare required. People seeking to undergo these procedures will be assured that the premises/vehicle they visit has been approved by the local authority for the performance of special procedures in terms of hygiene and safety standards, and that the licensed practitioner they select to undertake the procedure is competent in infection prevention and control and can perform the procedure hygienically and safely. They will also be able to access the public register of licence holders and approved premises/vehicles for special procedures provided within their area, and those available across Wales. This will help improve transparency and ensure people in Wales are better informed about the practice of special procedures and can therefore make informed choices should they wish to undergo any of the procedures.
- 4.27 It is anticipated that most licence holders who perform special procedures, and the approved premises/vehicles where they are performed, will gain reputational benefits from the scheme. By meeting the requirements, they will be able to demonstrate to the public that they practise to appropriate standards of safety, hygiene and cleanliness, as well as protecting themselves and their clients from health risks by undertaking appropriate infection control procedures. This will be further confirmed by being included in the National Special Procedures Register. Public confidence and client understanding will be further enhanced by the pre and post procedure consultations to ensure that people are fully aware of the risks connected with the particular procedure they are seeking, including the applicable aftercare advice. This should result in a lower incidence of postprocedure complications and infection if the aftercare advice provided is appropriately adhered to by those clients.

- 4.28 As well as improving client and practitioner safety, the Act also provides local authorities with consistent and straightforward enforcement powers. These will allow them to take action against anyone operating outside the scheme as well as against licence/approval certificate holders who are non-compliant with scheme requirements.
- 4.29 Beyond this, the benefits of improved safety, hygiene and cleanliness may extend to other procedures offered by practitioners, even though they are not covered by the requirements of the legislation.

The Regulations to be made

4.30 The provision in Part 4 and Schedule 3 to the Act to be implemented via the content of the Regulations which are the subject of this Explanatory Memorandum are set out below.

The Special Procedure Licences (Wales) Regulations 2024

4.31 The new licensing scheme will require that the performance of a special procedure by an individual in the course of a business, must be performed under the authority of a special procedure licence (unless that individual is exempt). If a local authority is satisfied that an application is to be granted, they must issue the applicant with a special procedure licence and the applicable mandatory licensing conditions to which the licence holder must adhere. The licence holder will be authorised to perform the special procedure/s identified in their licence at the approved premises/vehicle(s) specified in their licence. This will include all approved premises/vehicles they have named in their application, anywhere in Wales.

4.32 These Regulations include:

- the criteria that must be met in order for an application for a special procedure licence to be granted ("the licensing criteria"), including a minimum age of the applicant, and the documents to be provided in support of an application,
- the form and content of an application form for a special procedure licence, the form and content of a special procedures licence, the mandatory licensing conditions for all special procedure licences (regardless of whether a special procedure licence is granted for a period of three years or no more than 7 days),
- the mandatory licensing conditions relevant to the special procedure(s) being performed, provision for fees in relation to special procedure licences.

The Special Procedures Approved Premises and Vehicles (Wales) Regulations 2024

- 4.33 The new licensing scheme will require special procedures to be performed at a premises or in a vehicle that has been approved by a local authority (unless that premises or vehicle is exempt). If a local authority is satisfied the premises or vehicle meets the requirements for approval, they will issue an approval certificate authorising that approval.
- 4.34 The regulations include the wider detail around approvals such as:
 - the criteria that must be met for a new approval certificate to be granted, including a minimum age requirement for the applicant and the documents to be provided in support of an application
 - the application form that is to be used when applying for a new approval certificate
 - what an approval certificate will look like once an approval has been granted
 - the mandatory conditions that an approval certificate will be subject to
 - the premises and vehicles that will be exempt from the requirement to be approved by the local authority
 - provision in relation to variations of an approval certificate
 - the renewal of an approval certificate (for example what criteria must be met for an approval certificate to be renewed)
 - provision around replacement copies of an approval certificate
 - provision for fees in relation to approval certificates
 - voluntarily termination of an approval certificate
 - what a local authority is required to do if they intend to refuse an application and the applicant's right to make representations to the local authority, and
 - the appeals process in respect of applications that are refused.
- 4.35 This part of the Act also allows the Welsh Ministers to set out the circumstances when a premises or vehicle is exempt from needing to

be approved by a local authority. Exemptions have been made within the Regulations for premises/settings regulated by Healthcare Inspectorate Wales (HIW) to be exempt from the requirement to be approved for the performance of any of the four special procedures. Additionally, an exemption from the requirement for premises approval has been provided for a client's dwelling for the delivery of acupuncture only. Reasons for this may be because the client is unable to access acupuncture in any other premises. 'Dwelling' includes (but is not limited to) an adult care home or hospice.

The Special Procedures Exempted Individuals (Wales) Regulations 2024

- 4.36 An individual who performs a special procedure on someone else, in the course of a business, must be licensed, unless they are exempt. These Regulations detail the circumstances in which an individual is exempt from the requirement to obtain a special procedure licence. The circumstances in these Regulations are on the basis of specific professional registration and regulation and additional criteria. The licensing scheme is in relation to special procedures being performed in the course of a business. Special procedures being performed as part of NHS treatment in an NHS setting (for example an NHS hospital) are not intended to fall within the scope of this licensing scheme. Policy officials have also taken the decision that special procedures performed by relevant medical/health professionals within equivalent independent healthcare settings regulated by HIW should not fall within the scope of this licensing scheme and are therefore included for exemption under the Regulations.
- 4.37 Section 60(2) of the Act 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 namely:
 - (a) the General Medical Council
 - (b) the General Dental Council
 - (c) the General Optical Council
 - (d) the General Osteopathic Council
 - (e) the General Chiropractic Council
 - (f) the General Pharmaceutical Council
 - (g) subject to Section 26(6), the Pharmaceutical Society of Northern Ireland
 - (ga) the Nursing and Midwifery Council.

is exempt from the requirement to obtain a licence unless Regulations specify otherwise in relation to specific special procedure(s). The Regulations require that:

- unlicensed medical practitioners, optometrists, dispensing opticians, pharmacists and pharmacy technicians will not be exempt from requiring a special procedure licence. This means that these individuals will have to be licensed to perform acupuncture, body piercing, electrolysis, and/or tattooing.
- registered and licensed medical practitioners, registered dentists or dental care professionals, registered midwives, registered nurses and registered nursing associates will not be exempt from requiring a special procedures licence to perform any of the four special procedures unless all of the following conditions apply:
 - (1) they are current members of the registers kept by their respective professional bodies,
 - (2) the individual is performing the special procedure in a regulated independent healthcare establishment, and
 - (3) they are not subject to any conditions, restrictions or sanctions on their professional registration. If one or more of these conditions are not met, then that individual is required to be licensed to perform acupuncture, body piercing, electrolysis and/or tattooing.
- registered chiropodists, podiatrists, physiotherapists, chiropractors and osteopaths will be exempt from the requirement to obtain a special procedure licence for acupuncture only if all of the following conditions apply:
 - they are current members of the registers kept by the Health and Care Professions Council
 - (2) acupuncture is performed in a regulated independent healthcare establishment, and
 - (3) the individual does not have any conditions, restrictions or sanctions on their professional registration, in relation to their fitness to practise.
- 4.38 Professionals listed in the second bullet point of paragraph 4.37 are listed in the Regulations as exempt from licensing for all four procedures if they meet all the conditions. However, realistically it is only acupuncture and possibly medical tattooing that are likely to be relevant to these professionals.

The Special Procedures Licensing Committees (Wales) Regulations 2024

- 4.39 These Regulations deal with the procedures that apply to local authority licensing committees (and their sub-committees) in order to exercise the functions they have been given under Part 4 of the Act. A local authority must issue a warning notice to an individual in instances such as when it intends to refuse an application for a special procedure licence, designate an individual as a person requiring a special procedure licence or revoke a special procedure licence or approval certificate amongst other reasons.
- 4.40 The local authority licensing committee is required to consider any representations made to it after a warning notice has been issued to an individual and a hearing may be held before a final decision is made by the committee (or sub-committee) to whom the application, designation or revocation applies. These functions have been delegated to the licensing committee (or sub-committee) of the local authority.
- 4.41 The Regulations include matters relating to the procedures a licensing committee (or sub-committee) must follow, such as what process must be followed before a hearing is held, the procedure to follow at a hearing, and when a decision is to be made.

The Prescribed Objects for Body Piercing (Special Procedures) (Wales) Regulations 2024

- 4.42 Under Part 4 of the Act, "body piercing" currently means 'the perforation of an individual's skin or mucous membrane, with a view to enabling jewellery, or an object of a description prescribed in or under regulations, to be attached to, implanted in, or removed from the individual's body'. Perforation means 'breaching the integrity of the skin or mucous membrane in any way including (among other things) by way of puncture or incision'.
- 4.43 The purpose of these Regulations is to prescribe an 'object' to further define what 'body piercing' means. Extensive consultation and engagement with stakeholders including local authorities and the body piercing sector confirmed that there is no standardisation to the names applied to objects that are attached to, implanted in, or removed from an individual's body. Common descriptions of objects include 'hooks', 'macro-dermals', 'micro-dermals', 'near-field communication chips' and 'silicone beads'. Also, the range of objects used continues to change as body piercing evolves. Any prescription of an 'object' therefore needs to be flexible enough to accommodate the diverse and creative and ever-evolving nature of this procedure and the definition should be broad and all-encompassing.

- 4.44 The experience of developing and consulting upon the Prescribed Objects for Intimate Piercing (Wales) Regulations 2019 identified the difficulty of defining 'object' in terms of shape, material or size. It would not be possible to list in regulations every object that could be used that would not require regular amendment to take account of continual developments, and to prescribe size, shape or material would effectively provide the parameters for legal circumvention.
- 4.45 The effect of these Regulations is to provide a definition of "object" so that the definition of "body piercing" under Part 4 of the Act will read as follows:

'body piercing' means 'the perforation of an individual's skin or mucous membrane, with a view to enabling jewellery, or **any object that is not jewellery**, to be attached to, implanted in, or removed from the individual's body'.

4.46 It was not considered necessary to define 'jewellery' in the Act or Regulations, as what constitutes jewellery is generally understood through common experience. This definition also aligns with the definition of an 'object' prescribed under the Prescribed Objects for Intimate Piercing (Wales) Regulations 2019, although in that case, the definition is used to effect a prohibition.

5. Consultations

5.1 The full text of previous consultations that were undertaken in respect of the Act can be seen in the final Explanatory Memorandum and Regulatory Impact Assessment document for the Act¹¹. The following section outlines the formal consultations, both public and with statutory/required consultees, that have been undertaken in relation to the current Regulations.

Formal public consultation on policy principles

5.2 The Welsh Government consulted on the principles of the special procedures licensing scheme (from here referred to as the 'first consultation') with a view to informing draft Regulations that would enable the commencement of the provisions of Part 4 and Schedule 3 of the Act. That 12-week consultation ran between 25 January and 19 April 2023 and the draft version of the RIA formed part of the consultation materials along with an Integrated Impact Assessment (IIA). This document contains the statutory impact assessments that the Welsh Government is required to make when introducing new legislation. The Data Protection Impact Assessment (DPIA) included in

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¹¹ pri-ld10796-em-r-e.pdf (senedd.wales)

the IIA indicated that the Information Commissioner's Office (ICO) should be formally consulted as a statutory consultee, and this is discussed below. No further comments were received about the contents of the IIA through the first consultation.

Formal consultation with the Information Commissioner's Office

- In advance of the publication of the first consultation documents, the ICO was consulted about the DPIA section of the IIA prepared for that consultation. Article 36(4) of the General Data Protection Regulation applied making consultation with the ICO compulsory as the mandatory licensing scheme met three separate criteria:
 - <u>Sensitive data or data of a highly personal nature:</u> Met by the requirement for all applicants for individual licences to declare on the application form any unspent convictions for relevant criminal offences and to provide a basic DBS certificate in support of this declaration.
 - Sensitive data or data of a highly personal nature: Met by the
 potential processing of special category data (health data) due to the
 requirement in the Act for licensed practitioners to record and retain
 client consultation records.
 - <u>Data processed on a large scale.</u> Met due to the potential number of individuals across the whole of Wales providing personal data through applications and client consultations, the range of personal data items being processed, the duration of the scheme and the geographical extent of the processing.
- The ICO gave their feedback on the content of the DPIA form and made a number of helpful observations and suggestions to improve information for local authorities, practitioners, and individuals in control of premises/vehicles on data processing and retention requirements. A follow-up meeting was held with the ICO to provide them with further context of the requirements of the scheme, and revisions were made to the DPIA based on their comments and questions. The DPIA was incorporated into the IIA that was published as part of the first consultation. The ICO was included in the formal distribution of both the first consultation and the one that followed (Paragraph 5.9 below refers). The ICO have confirmed that they have no further comments to make.

Formal consultation with the Ministry of Justice

5.5 As offences and the use of the courts service to hear appeals against refusals of licences/approval certificates will form part of the proposed licensing scheme, permission was obtained from the then Minister for Health and Social Services to formally consult with the Ministry of

Justice (MoJ). Welsh Government officials are obliged to liaise with MoJ officials, on a confidential inter-governmental basis, to ensure that impacts on the justice system arising from both primary and subordinate legislation are identified at the earliest stage possible. That consultation took the form of a justice system impact identification form to identify estimated numbers of cases to be brought before the courts. The MoJ was asked to consider the information provided and identify any impacts and the potential costs to the Courts Service to implement the new requirements and hear those cases. That consultation was made during the first consultation period and the applicable costings were received from the MoJ along with their assessment of the impact on the work of the different justice services under their control. This assessment is included in the relevant section of the current RIA.

- The MoJ was consulted further by officials after the close of the first consultation, as policy changes made as a result of responses received would mean fewer cases being brought before the courts. As a result, the MoJ revised their costs, and the final Justice Impact Assessment is included in the relevant section of the RIA.
- 5.7 The first consultation document, draft RIA and IIA and the Welsh Government's analysis of the responses received can be seen on the following link:

 Mandatory licensing of special procedures in Wales | GOV.WALES
- The IIA has since been updated to include the JSII form and an assessment of the Duty of Quality, which came into force after the draft IIA was published. It has also been reviewed generally to ensure that it has remained relevant. The final IIA has been republished on the Welsh Government website Mandatory licensing of special procedures in Wales | GOV.WALES

Formal consultation on draft regulations and statutory guidance

- 5.9 A further consultation (from here referred to as the 'second consultation') ran for eight weeks between 12 February and 8 April 2024 and followed on from the first consultation referred to above. This second consultation presented the final drafts of the Regulations to be made under Part 4 and Schedule 3 of the Act. This second consultation also included the draft Statutory Guidance for local authorities on how they are to determine a 'person's fitness to perform a special procedure' (where their fitness has been called into question) for the purpose of being granted a new licence, renewal of a licence, variation of a licence or for the purpose of revoking a licence.
- 5.10 As the policy proposals for the mandatory licensing scheme had already been consulted upon, this second consultation was considered a technical consultation specifically on the wording of the draft

Regulations and draft Statutory Guidance, although the draft Regulations provided further detail around the new scheme, including those subjects where the statutory duty to consult under section 64 of the Act applied. For this reason, the Cabinet Secretary for Health and Social Services gave her consent for the consultation to run for eight weeks instead of the standard 12-week period.

- 93 separate responses were received from a range of stakeholders, although some of these were duplicates. The majority of responses were from local authorities, professional regulatory bodies and individual practitioners or business operators. As a broad summary, comments on the wording of the draft Regulations and Statutory Guidance were received, but the majority of responses to all questions raised practical issues that would not be included in Regulations but should be addressed in non-statutory guidance for licensing authorities and special procedure practitioners and businesses.
- 5.12 The Welsh Government's full analysis and response to this second consultation has been published on the relevant <u>closed consultation</u> page of the Welsh Government's website.

Duty to consult

- 5.13 Before making Regulations under section 62 or 63 of the Act (in relation to licensing criteria and the mandatory licensing conditions which form part of one of the sets of Regulations) under section 64 of the Act the Welsh Ministers must:
 - (a) consider whether there are persons who appear to be representative of the interests of those likely to be affected by the Regulations ("representative persons"), and
 - (b) carry out consultation with any representative persons whom the Welsh Ministers consider it appropriate to consult.
- 5.14 The Welsh Ministers have complied with this statutory duty by engaging and undertaking both the first and second consultation exercises.

PART 2 - REGULATORY IMPACT ASSESSMENT

6. Options

- There are no specific provisions in the Act which charge expenditure on the Welsh Consolidated Fund.
- 6.2 An RIA¹² (referred to in this document as the '2017 RIA') accompanied the Act at its introduction to the Senedd and was updated following the completion of Stage 2 scrutiny in 2017. The preferred options that became law are set out below and have been updated where relevant to represent current procedures and costings.
- 6.3 This RIA has been prepared for the regulation-making process, and was published in draft form as part of a public consultation on policy principles that ran between 25 January and 19 April 2023. A separate consultation was held with the Ministry of Justice in respect of the impact upon the justice system of introducing the mandatory scheme.
- This RIA has been updated following that consultation process to include additional costs identified by local authorities; reflect changes in process that have been made as a result of the consultation, and the inclusion of the Explanatory Memorandum.
- Three substantive options were originally considered, with the third split into two sub-options:
 - Option 1 Do nothing
 - Option 2 Develop and issue guidance in relation to best practice for acupuncture, tattooing, semi-permanent skin-colouring, body piercing and electrolysis, and undertake an awareness-raising campaign
 - Option 3A Introduce a special procedures licensing scheme. This
 was the preferred option
 - Option 3B Introduce a special procedures licensing scheme with an added central register of all licensed practitioners and approved premises or vehicles providing special procedures in Wales.

Costs and benefits calculated for the original Public Health (Wales) Bill

6.6 The costs and benefits associated with each option were produced using the best information available at the time. The information was prepared through discussion with key stakeholders, including local authorities, health boards and other agencies. The costs and benefits associated with each option were originally assessed over a five-year period from 2017-18 to 2021-22, with a longer period used in some

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¹² http://www.assembly.wales/laid%20documents/pri-ld10796-em-r/pri-ld10796-em-r-e.pdf

- cases. Where costs were expected to extend beyond the initial fiveyear period (i.e. recurrent costs) these were identified in the text.
- Option 3A is the option that was preferred and pursued and was embodied in the Act, with provision made at section 75 of the Act for the central register element of option 3B to be pursued later if local authorities were in agreement to create a single all-Wales register.
- 6.8 Since the Act was passed, local authorities approached Welsh Government officials to request that section 75 be commenced as they wished to pursue a central register in order to discharge their individual duties to keep a register. It was not possible to commence section 75 in advance of the commencement of Part 4 and Schedule 3, but the request was noted and therefore is taken account of in this RIA in relation to development work and funding of a central register.

Options now under consideration in this RIA

- 6.9 As the Act received Royal Assent on 3 July 2017 and provision was made under Part 4 for a licensing system, the framework for which is set out on the face of the Act, the options for consideration in this RIA are limited. The options reviewed at this current time are:
 - **Option 1** do nothing: i.e. do not commence any of the provisions of Part 4 of the Act and do not make the necessary subordinate legislation required under Part 4 and Schedule 3 of the Act;
 - **Option 2** commence all sections of Part 4 and Schedule 3 of the Act and make the necessary subordinate legislation required, to include the creation of a central register (the former Option 3B).
- 6.10 Consideration has also been given as to whether there is an intermediate option to commence some sections of Part 4 and not others. As Part 4 of the Act sets out a unified licensing scheme, it would be difficult to commence some of the provisions and not others. It is therefore considered that there is no middle option, i.e. to only commence certain parts of Part 4 and make limited subordinate legislation as Part 4 is designed to work as a whole.
- The costings given for the previous Options 1, 3A and 3B (now Option 2) are reviewed here as they were originally presented but updated with additional costs identified by local authorities, the fees for the scheme set by local authorities and current costs wherever possible. A substantial amount of the preparatory work required to introduce the mandatory licensing scheme has now been completed, so those activities and costs no longer form part of the costings but are summarised for information in the relevant section as sunk costs. Some adjustment has also been made to take account of updated procedures, for example, less reliance on hard copy documents for

communications. This RIA has also been updated to reflect changes of processes made as a result of the first consultation in respect of hearing appeals in the courts and to correct minor errors.

6.12 The numbers of practitioners and premises given in this document are based on figures submitted by local authorities in 2019, 2022 and 2024. As local authorities have not been obliged to keep up to date information on individuals or premises they have previously registered, in 2018 they were asked to contact people to commence the refinement of the information they were holding. Local authorities were further asked to provide updated figures in 2022 and 2024. We have not used the 2019 figures, as this was the start of the data refining process, so the 2022 and 2024 figures have been used as more reliable, although still identified as estimates. The numbers of new registrations have been based on the difference between the numbers given for 2022 and 2024, divided by 2. Based on two years' figures, it is not possible to say with any reliability whether the figures for new registrations are typical for any year, and no figures have previously been sought or submitted on how many cease trading every year. We have had to assume for the purposes of this document that these are equal numbers.

The baseline figures of people and premises currently registered with local authorities for the whole of Wales are estimated as follows:

	2022	2024	difference	÷2
personal/practitioner registrations	3,516	4,419	+903	452
premises registrations	1868	2,036	+168	84

7. Costs and benefits

Option 1 - Do Nothing

Description

7.1 The particulars of the current registration scheme are set out in the Explanatory Memorandum at paragraphs 4.6-4.10. 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, body piercing and electrolysis in their area are provided by the Local Government (Miscellaneous Provisions) Act 1982 ('1982 Act'). 13 This Act includes

¹³ Sections 14 and 15, Local Government (Miscellaneous Provisions) Act 1982 http://www.legislation.gov.uk/ukpga/1982/30

the 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 produced comprehensive model byelaws, which reflected applicable infection control guidance and industry best practice¹⁴. The powers provided by the 1982 Act are adoptive and therefore local authorities have been able to choose which procedures are subject to their control and whether or not to issue byelaws.

- 7.2 All local authorities in Wales have adopted the relevant provisions in the 1982 Act and 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 set out in paragraph 12.
- Act. 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 to include one or more individual practitioners, and some charge separate 'premises' and 'personal' registration fees. As there is so much variation between local authorities between who/what is registered, we have separated out the calculations to 'premises' and 'personal', on the understanding that each contains certain elements of the other when looked at across all 22 local authorities.
- 7.4 The fee amount also varies considerably between local authorities and not all publish them. For premises, the registration fee range is between £55 and £293 and, where this is charged separately, a personal registration fee ranges between £49 and £293¹⁵. For the purposes of these costings, the ranges of fees were averaged from all the different published amounts available, and the amounts used here therefore are £154 for premises and £110 for personal registrations. Additional fees are also charged by local authorities for the variation of an existing registration¹⁶. 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. Local authorities have identified that in 2024 there are currently about 4,419 personal practitioner registrations and 2,036 premises registrations across Wales.

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¹⁴ Welsh model byelaws for acupuncture, tattooing, semi-permanent skin-colouring, body piercing, and electrolysis. Byelaws on acupuncture, tattooing, skin-colouring, piercing and electrolysis | GOV.WALES

¹⁵ Based on information from local authority websites, where fees listed, July 2024, some authorities charge a flat fee that covers both premises and 1 practitioner

¹⁶ Information provided by local authorities.

- 7.5 The Health and Safety at Work Act 1974¹⁷ 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.
- 7.6 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

- 7.7 There are no costs to the Welsh Government associated with supporting local authorities in relation to their powers under the 1982 Act.
- 7.8 In addition to the 1982 Act, local authorities have powers under the Public Health (Control of Disease) Act 1984 '(the 1984 Act') 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 body piercing, are being carried out in unhygienic conditions. In the 2017 RIA, it was indicated that the Welsh Government undertook an annual review of the use of these powers, using advice from local authorities and medical professionals. It was estimated that this annual review 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). Since the 2017 RIA was last published, the Welsh Government rationalised how it scrutinises these Part 2A orders and has moved to monitoring orders received from local authorities over a calendar year and publishing a list of orders received annually, which has a minimal cost using existing resources. The full list of all Part 2A orders reported to the Chief Medical Officer is published bilingually on the Welsh Government website¹⁸.

Local authorities

7.9 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

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¹⁷ Health and Safety at Work Act 1974 http://www.legislation.gov.uk/ukpga/1974/37/introduction

¹⁸ Health protection Part 2A orders 2010 to 2021 | GOV.WALES

are working hygienically and within their statutory obligations (including their health and safety obligations).

- 7.10 As stated above, the Welsh Government is aware that seven local authorities have adopted the Welsh Government model byelaws as of August 2016. The cost per local authority of adopting these model byelaws was estimated to be approximately £5,000¹⁹. However, it has transpired that since that date no additional local authorities have adopted the model byelaws in relation to acupuncture, body piercing, electrolysis and tattooing since 2017. This is because they anticipated at the time that Part 4 and Schedule 3 of the Act and the regulations that are the subject of this RIA would have been in put in place fairly soon after the passing of the Act. The remaining local authorities are not likely to adopt the byelaws in 2024, therefore the cost to them for this is zero.
- 7.11 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, and this is included in the registration fee paid by the business making the application. Between 2022 and 2024, there were 168 new premises registrations which amounts to an average of 84 per year. In addition, in 2024, local authorities have estimated that there are around 4,419 personal registrations across the whole of Wales, an increase of 903 since 2022, so this averages at 452 a year. As stated above, most local authorities register persons separately to premises, but some charge a flat fee covering the premises plus one practitioner.
- 7.12 As for premises, the fee for a personal registration varies considerably between local authorities, ranging between £49 and £293, with those at the higher end representing the flat fee referenced above. We have averaged all the fees for the purpose of these calculations, to give a representative amount of £110 per personal registration application.
- 7.13 We have been advised that in general terms, local authorities set their scheme fees based on covering their essential costs of processing the application, to include making an inspection for premises, hence the higher fee for premises. Using the averaged fees, indicative total receipts for premises would be £12,936 and for personal registrations £49,720, making a total of £62,656 annually, and this amount can be taken as a rough indicator of the costs to local authorities of processing applications. However, as this is not a cost-recovery scheme, the receipts from application fees do not entirely cover the costs to the local authorities of running the scheme and any enforcement activities.
- 7.14 The granting of registration is likely to be the end of formal contact with local authorities for the majority of businesses, unless there are problems. Local authorities do make annual compliance visits, which

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¹⁹ Based on information provided by local authorities

are spot-checks on whether the business is complying with the terms of their registration, but these are usually based on local priorities and intelligence received, therefore not every premises is visited every year, and these visits are separate to those undertaken as part of the application process. It is difficult to put a figure on how many premises would be visited across Wales, and it is inevitable that a number of businesses would cease trading every year. Local authorities estimate that in 2024 there are approximately 2,036 registered premises. It is not possible to quantify how many, as there is currently no requirement for follow up by either local authority or premises once the registration has been granted. For the purposes of these calculations, we have assumed that the number ceasing trading equals the number starting up each year (42), thereby giving a stable number of 2,036. For this RIA, we have assumed that about half of all premises registered at any time (other than new registrations) will be visited each year, which would be 1,018 premises. Local authorities have advised for the unit costs of this RIA that one compliance visit is estimated at the upper end of inspection and assessment to cost £115. Across all local authorities. premises compliance visits are therefore estimated to cost approximately £117,070 per year.

7.15 Intelligence provided by local authorities indicates that complaints are predominately received in relation to businesses providing tattooing and body piercing. It is estimated there are around 200 complaints in relation to businesses and practitioners performing these procedures per year for the whole of Wales²⁰. The costs of investigation and followup work in relation to a complaint varies, depending on the complexity of each case. An estimate of the cost to a local authority of investigating a complaint is £1,000²¹ per complaint, which equates to a total of approximately £200,000 annually across Wales. Regarding successful prosecutions, local authorities have the option of pursuing cost recovery. The following table sets out estimated local authority scheme and compliance costs over five years.

Table 1 - Local authority inspection and compliance costs (all-Wales) **Existing Registration Scheme**

	2024-25	2025-26	2026-27	2027-28
Cost of processing new registrations - premises, n=84 @ £154 each	£12,936	£12,936	£12,936	£12,936
Cost of processing new registrations - personal, n=452 @ £110 each	£49,720	£49,720	£49,720	£49,720
Subtotal new registrations	£62,656	£62,656	£62,656	£62,656
Compliance visit costs – 50% of total premises 2,036 @ £115 each	£117,070	£117,070	£117,070	£117,070
Complaints investigation costs – 200 @ £1,000 each	£200,000	£200,000	£200,000	£200,000

 $^{^{20}}$ Based on local authority data which indicates complaints in relation to 10% of all registered businesses, based on 2036 premises ²¹ Based on data provided by local authorities

Subtotal compliance	£317,070	£317,070	£317,070	£317,070
Total	£379,726	£379,726	£379,726	£379,726

- 7.16 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 1984 Act²² to apply for a Part 2A orders to prevent a person from practising, for example tattooing, due to the risks they present to public health. In total, as of July 2024, 37 Part 2A orders have been made in relation to tattooing or piercing since the legislation was introduced in 2010 (including two renewals of the initial orders granted). This gives an average of three per year, but to use an average would give a misleading figure of how many part 2A orders are currently pursued for special procedures. Local authorities have been of the opinion that it is more likely that there would be two applications in every three years, but no orders have been made since 2019 for issues in relation to tattooing or piercing. The reasons for this are varied, many local authorities preferring to deal with illegal activity informally without recourse to the courts except in the most extreme cases, because the process to be followed to obtain an order is cumbersome and expensive in terms of staff time and court costs, and also because budgetary cuts within local authority public health departments has meant that officers have been forced to concentrate their resources on fulfilling their statutory functions for the wider population (such as food business inspections) rather than proactively seeking out individuals providing special procedures illegally. Pursuing a Part 2A order is therefore seen as a procedure of last resort, applied where there is a present risk of harm to health and other ways of securing a remedy have been unsuccessful.
- 7.17 If the legislation that is the subject of this RIA is never commenced, local authorities would have to continue to rely on part 2A orders to deal with the issue of special procedures practitioners operating illegally, and it is likely, therefore, that more than two orders in three years would be pursued. However, as it is difficult to predict a different figure, for the purpose of these costings, two cases in three years for the whole of Wales has been used. The estimated cost to a local authority to seek and execute a Part 2A order is estimated to range between £800 and £3,000, although it could in some circumstances be much more depending on the complexity of the case. 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.

²² 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: Health protection Part 2A orders 2010 to 2022 | GOV.WALES

Table 2 - Public Health (Control of Disease) Act 1984 - Part 2a orders for tattooing and piercing (all Wales)

	2024-25	2025-26	2026-27	2027-28
Projected number of	2	0	0	2
cases				
Associated costs	£1,600-	0	0	£1,600-
	£6,000			£6,000

7.18 The estimated total annual spend by local authorities is between £379,726 and £385,726 depending on whether any Part 2A orders are required in any year and the cost is at the upper end of the range. The average annual spend amounts to a cost per local authority of between £17,260 and £17,533. However, approximately £62,656 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' resulting in the total adjusted net annual spend by local authorities of between £317,070 and £323,070.

Costs to the NHS

- 7.19 There are costs to the Welsh NHS as a result of treating complications arising from the procedures²³²⁴, such as bacterial skin infections, allergic reactions and the more common systemic illnesses that result from these adverse health effects, namely sepsis and anaphylactic shock. Most costs arise from tattooing and body 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 (Table 5) at the end of this option. Although there are costs to the NHS associated with treating complications following acupuncture, semi-permanent skin colouring and electrolysis²⁵, these are considered to be minimal and have not been assessed.
- 7.20 It is known that body piercing can result in complications, such as swelling, infection, bleeding, allergy and tear or other injury²⁶. Nerve damage and scarring may also occur if procedures are poorly performed. Although rare, complications from a body piercing can result in a hospital admission and may be particularly serious for those with underlying health conditions.
- 7.21 The study referred to in footnote 25 undertook a more detailed analysis of complications associated with body piercings in 16 to 24-year-olds and estimated that 5.1% of all piercings resulted in help being sought

²³ Sindoni, A et al, Health risks for body pierced community: a systematic review https://doi.org/10.1016/j.puhe.2022.01.035

²⁴ Sindoni A, et al. Adverse effects related to tattoos in the community setting: a systematic review - PubMed (nih.gov)

²⁵ BMJ 2001;323:486 earlobe BMJ 336 1426

²⁶ Bone A, Ncube F, Nichols T and Noah ND (2008) Body piercing in England: a survey of piercing at sites other than

from a pharmacist, 3% from a GP, 0.6% requiring attendance at an A&E department and 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 3) below).

- 7.22 Currently, there are no data about the number of people having a body piercing in Wales nor is there any specific evidence about the rate of health complications from body piercings, or from tattooing. As data from other countries are also limited, an estimate of the health costs has been based on the most relevant data available. The 2017 RIA made use of a study from the USA from 2006 to calculate how many of the population have tattoos, then used the figures from the Bone study²⁷ to calculate how many people with complications presented at each type of health outlet for treatment.
- 7.23 Tattooing is the other main source of costs to the NHS from these special procedures. Published data from 2015 about the prevalence of tattooing in the UK suggests 18.7% of people have tattoos, (312 of 1,669) although this survey had a small sample number²⁸.
- 7.24 The Royal Society of Public Health (RSPH) carried out a survey²⁹ of individuals who had experienced at least one special procedure (tattooing, micro blading/micro pigmentation, body piercing, acupuncture and electrolysis) in the previous five years.
- 7.25 While most respondents in this survey did not have any negative effects as a result of their procedure (82%), a significant minority (18%) did. Of those who had a negative side effect, 10% required medical treatment. This survey had a very small sample size of 886, and many of the details are not recorded, but some useful inferences can be drawn to inform these costings. It is implied that the age range was over 18 (the legal age for tattooing) and drew on both male and female respondents.
- 7.26 The latest available population statistics from the 2021 Census indicates that the population of Wales was 3,107,500 in 2021³⁰. Census data³¹ suggests there is a total of 2,559,400 people over 16 in Wales. We acknowledge that children below the age of 18 can obtain any of the special procedures except intimate piercing or tattooing, but there are no statistics available to identify how many may have had one or more piercing, acupuncture or electrolysis.

²⁷ As footnote 25

²⁸ YouGov Survey Report (d25d2506sfb94s.cloudfront.net)]

²⁹ RSPH I Skins and Needles

³⁰ Population and household estimates, Wales - Office for National Statistics (ons.gov.uk)

³¹ TS007 - Age by single year - Nomis - Official Census and Labour Market Statistics (nomisweb.co.uk)

- 7.27 Projecting the percentage from the YouGov survey referenced above of 18.7%, if this was applied to the population over 16, it could be inferred that 478,608 have had at least one of the special procedures listed. Applying the percentages from the RSPH survey, it can be inferred that 86,149 (18%) of that number had complications and 8,615 of those (10%) required medical treatment. Then, applying the percentages from the Bone study as to who presented at any particular health outlet to this number of 8,615, a rough indication of costs can be calculated as presented in Table 3 below, although it should be borne in mind these are illustrative only.
- 7.28 However, it is not possible to attribute accurate costs for treatment due to the variations in pay for health professionals depending on point in pay scales, terms of NHS contract etc. The NHS Payment Scheme for England³² identifies unit costs for a wide range of medical interventions. The unit used is for "intermediate skin procedure, person over 19 years". This unit covers attendance costs only as outpatient, or inpatient per day to a maximum of five days. The unit cost does not include other interventions such as tests, prescriptions, or disposables such as dressings.

Assumptions made: Pharmacist pay range³³ £35,392-£114,949, gross, 37.5 hr week; Wales GP pay based on combined (contracted/salaried) average³⁴ of £104,100, gross, 37.5 hr week³⁵. The quality standard of 10 mins per GP consultation³⁶ has been applied and has been used for the pharmacist consultation also.

Table 3 - Costs of access to NHS services following special procedures

Description of help sought following procedure	Number of those aged 16 and over seeking help each year n = 8,615	Unit cost	Yearly cost (£)
Consultation with a pharmacist 5.1%	439	£ 605.82 – £1979.01 (4.6 minute consultation) £1,317.00 - £4,302.20 (10 minute consultation)	£605.82 – £4,302.20
GP consultation and antibiotic treatment 3%	258	£8.90 per consultation and £2.29 for a seven-day course of oral antibiotics)	£2,887.02
Attendance at A&E 0.6%	52	Cost unknown. Used nearest relevant intervention on NHS Payment Scheme for (intermediate skin procedure,	£14,716

³² NHS England » 2023-25 NHS Payment Scheme, 2024-25 tables https://www.england.nhs.uk/wp-content/uploads/2023/03/23-25NHSPS Annex-A 2024-25.xlsx

³⁵ General practice workforce: as at 31 December 2021 | GOV.WALES

³³ Pharmacist | Health Careers; Agenda for change - pay rates | Health Careers

³⁴ GP Earnings and Expenses Estimates, 2021/22 - NHS Digital

³⁶ International variations in primary care physician consultation time: a systematic review of 67 countries | BMJ Open

Total		-	Minimum £103,294 – maximum £447,330
Hospital admission 0.9%	77	person over 19, outpatient) of £283 per consultation. Non-elective inpatient short stay 1-5 days at £1,105 per day (based on NHS Payment Scheme for intermediate skin procedure, person over 19, per day to maximum of 5 days).	£85,085 - £425,425

- 7.29 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.
- 7.30 Any procedures involving skin penetration can potentially lead to the transmission of blood-borne viruses such as hepatitis B, hepatitis C and HIV³⁷. The cost of treatment for these infections varies significantly but a course of treatment for hepatitis C³⁸ ranges between £25,987 and £38,980.
- 7.31 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.
- 7.32 In unusual cases, where there have been significant deficiencies identified in a business's 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 £240,159³⁹. 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

³⁹ 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

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³⁷ 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

³⁸ Based on NICE and BNF listed prices. ledipasvir-sofosbuvir (Harvoni) for treating chronic hepatitis C (July 2024)

- authorities. Although these costs would be incurred infrequently, each occurrence is likely to incur considerable expense.
- 7.33 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 body piercing have been recorded⁴⁰.
- 7.34 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, body piercing and electrolysis

- 7.35 Businesses which provide these procedures are currently required to pay a one-off registration fee. As set out in the 'local authorities' section above, the registration fees vary between local authorities. It is estimated there are an average of 84 premises registrations each year and 452 individual practitioner registrations per year. Using the average fees of £154 for premises registration and £110 for individuals, this would amount to estimates of £12,936 for the registration of new premises and £49,720 for the registration of new practitioners each year. The total annual cost to business of application fees is therefore estimated at approximately £62,656. Due to the variable charging mechanisms used by local authorities, such as charging a flat fee to include premises and one practitioner or the discretion about whether to charge for personal registrations, these numbers are illustrative only.
- 7.36 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 £21.20 (£16.31 per hour FTE for Wales with 30% added for on-costs)⁴¹, and using the same average numbers of registrations of 452 individual applications and 84 premises applications, it is estimated costs incurred amount to approximately £5,682 annually. However, some may be making an application for both practitioner and premises registration at the same time, and it is not possible to quantify this. There is no

⁴¹ ASHE 2023 provisional edition Work Region Occupation Table 15.6a Hourly pay excluding overtime, Wales; (mean hourly rate for artistic, literary and media code 341 Wales) <u>Earnings and hours worked, region by occupation by four-digit SOC: ASHE Table 15- Office for National Statistics (ons.gov.uk)</u>. 247 Hourly rates have been increased by a factor of 30% to £21.20 to incorporate on costs.

⁴⁰ BBC News online (2005) Lip piercing death 'misadventure'. Available at: http://news.bbc.co.uk/1/hi/england/south_yorkshire/4429298.stm; BBC News online (2010) Caerphilly woman's infection death after tongue pierce. Available at: http://www.bbc.co.uk/news/uk-wales-11543757

- requirement to renew applications under the 1982 Act, so this is a one-off payment.
- 7.37 The total estimated annual cost to businesses of new registrations is therefore £68,338. There would be no other costs for businesses providing these procedures under this option.

Table 4 - Practitioner and Business Costs

Costs (£)	2024-25	2025-26	2026-27	2027-28
Registration	£62,656	£62,656	£62,656	£62,656
fees				
Application	£5,682	£5,682	£5,682	£5,682
time cost				
Total	£68,338	£68,338	£68,338	£68,338

Summary of costs associated with Option 1 – Do nothing

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

Table 5 - Summary of costs associated with Option 1 - Do nothing

Costs (£)	2024-25	2025-26	2026-27	2027-28
Welsh Government				
Annual review of Part 2A Orders	0	0	0	0
A - Total Welsh Government costs	0	0	0	0
Local authorities – Table 1				
Cost of processing new registrations - premises	£12,936	£12,936	£12,936	£12,936
Cost of processing new registrations - personal	£49,720	£49,720	£49,720	£49,720
Compliance visit costs	£117,070	£117,070	£117,070	£117,070
Complaints investigation costs	£200,000	£200,000	£200,000	£200,000
Part 2A Orders (Table 2)	£1,600 -	0	0	£1,600 –
, ,	£6,000			£6,000
Adoption of model byelaws	0	0	0	0
Total local authority costs	£381,326 - £385,726	£379,726	£379,726	£379,726 - £385,726
Less value of registration fees	-£62,656	-£62,656	-£62,656	-£62,656
B - Local authority net costs	£318,670 - £323,070	£317,070	£317,070	£318,670 - £323,070
Practitioner and business costs – Table 4				
One-off registration fees	£62,656	£62,656	£62,656	£62,656
Application time	£5,682	£5,682	£5,682	£5,682
C - Total Business costs	£68,338	£68,338	£68,338	£68,338
Total net Cost A+B+C	£387,008 – £391,408	£385,408	£385,408	£387,008 – £391,408

Benefits

7.38 This option maintains the current policy position and as such there would be no additional benefits. The fee structure would remain the same.

Disbenefits

7 39 The main disbenefit of this option is that it would allow a scheme that is no longer fit for purpose to continue. Once a practitioner or premises is registered, there is no requirement for any follow up contact between the registered practitioner/premises and local authority to ensure that the standards of hygiene are maintained following registration. This is an unsatisfactory situation that may allow unsafe and unhygienic practises to develop and continue undetected, as there is no incentive for a practitioner/premises to ensure appropriate standards are maintained. Where legal action is required to address any such situation, the remedy is cumbersome and costly for a local authority to pursue in court. If a practitioner wishes to work in more than one local authority area, they are required to pay a fee and take out a registration in each area and may be subject to different requirements in each for the same work. As each local authority has developed its own version of the scheme, with separate fees, there is therefore no consistency of approach between different local authorities across Wales.

Option 2 – Introduce a special procedures licensing scheme, with a central register

Description

- 7.40 This option involves Part 4 of the Act when commenced repealing the 1982 Act as applied to Wales to create a compulsory, national licensing scheme for the practise of special procedures in Wales. These special procedures are be defined in the Act as acupuncture, body piercing, electrolysis and tattooing (which includes semi-permanent skin colouring). To perform any of these special procedures, an individual would need to be licensed and the premises (including vehicles) from which they practice 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/vehicle approved. It is anticipated the earliest that the licensing scheme would become operational is towards the end of 2024 until this point, the existing registration scheme under the 1982 Act continues.
- 7.41 The licensing scheme proposed under this option will replace the registration scheme outlined under option one (i.e. under the 1982 Act).

The costs outlined below will be incurred in place of the costs under Option 1.

Sunk costs of completed actions

- 7.42 The Welsh Government and local authorities have undertaken a substantial amount of preparatory work to get to the point of being able to set a coming into force date for the mandatory licensing scheme. This has included running two public consultations; providing free training for local authorities; free awareness sessions for practitioners; the development of five sets of regulations and a statutory guidance document; the development of non-statutory guidance documents for each of the special procedures and other materials aimed at practitioners and IT works. These activities were costed and included within the draft RIA when it was initially published in January 2023.
- 7.43 Much of this work has been completed, and as such is now treated as sunk costs. The costings in this section are therefore no longer included in the summary tables of overall costs. They are therefore presented for information purposes and should not be considered as exhaustive, as it is not possible to itemise and cost every activity that has been pursued. For the 2024-25 financial year, these sunk costs are apportioned from the start of the financial year to the end of August inclusive, which is the point prior to the RIA being laid before the Senedd. The costs of the formal legislative process before the Senedd from 1 September 2024 are treated as future costs in the relevant section.

Welsh Government

- 7.44 The policy division taking forward Part 4 (special procedures) and Part 5 (intimate piercing) commenced work on the development work for the necessary regulations to enact those parts almost immediately following the passing of the Act in 2017. Part 5 was addressed first and is outside the scope of this RIA, the work being completed in 2019. The same staff were also developing the policy work for the current legislative programme for Part 4 and Schedule 3 during the latter part of 2019, but this was halted due to the necessity of redeploying all staff to manage the response to the pandemic early in 2020. It is difficult to place a value on staff resource deployed on Part 4 and Schedule 3 until the financial year 2022-23, when the work was resumed, so this financial year has been used as the starting point for costings.
- 7.45 The Welsh Government has retained a full-time specialist environmental health officer on a secondment basis to advise on technical aspects of special procedures policy in developing this statutory scheme and to take forward various aspects of the special procedures work. The cost of this secondment in 2022-23 was

- £80,000, in 2023-24 and 2024-25 Q1 it was £84,000 and £21,000 respectively.
- 7.46 A FTE HEO and SEO within the Health Protection Division of the Welsh Government have been deployed to the special procedures work in 2022-23, this is estimated at 0.75 for the HEO and 0.25 for the SEO, and full-time since the financial year 2023-24 onwards.. The Welsh Government average staff costs (which includes salary plus on-costs such as employers' pension and National Insurance contributions) in 2022-23 were pro-rata £39,581 for the HEO and £16,591 for the SEO; in 2023-24 were £5,948 for an SEO and £4,755 for an HEO. This work continues into 2024-25 on a full-time basis.
- 7.47 These average band costs cover all activities to develop and run the two consultations, including writing, formatting and publishing all documents produced for the purpose, following internal legislative processes, advising Ministers, analysing information and developing policy, both internally and with stakeholders. For 2024-25, these sunk costs have been calculated for five months to the end of August inclusive, prior to this RIA being laid before the Senedd. The work to pursue the legislative process from the publication of this RIA to the proposed coming into force date at the end of November is costed separately as future costs in the relevant section.
- 7.48 In addition, the legislative work has required the deployment of one of the Welsh Government lawyers on a 0.8 FTE basis, which would equate to a Grade 7 policy officer at £6,190 monthly. It is estimated that approximately 60% of that lawyer's time in 2022-23 increasing to 80% in subsequent years has been dedicated to the special procedures work, which has included providing legal advice on policy objectives; drafting legislation; considering and providing legal clearance for all published documents and other internal processes related to the development of new legislation. It is estimated that the lawyer costs for 2024-25 April-August inclusive would be £24,760.

Table 6 - Welsh Government staff costs - sunk costs

	2022-23	2023-24	2024-25	
SEO	£16,591	£71,380	£29,740 Apr-Aug incl	
HEO	£39,581	£57,059	£23,775 Apr-Aug incl	
Grade 7 lawyer	£41,631	£74,280	£24,760 Apr-Aug incl	
Specialist secondee	£80,000	0,000 £84,000 £21,000*		
total	£177,803 £286,719 £99,275			
	*This covers Apr-June inclusive, which was the end of the secondment.			

7.49 Many other people within the Welsh Government have also contributed to the delivery of the materials for this licensing scheme. These have included Translation Services; Design Team; the Health and Social Care Web Team and others who have worked on the consultation

documents, guidance documents and other materials that have been required to disseminate information about the scheme. This would have been done as a part of their routine work, so it would be very difficult to apportion time/cost to processing each document. In addition, in 2022-23 the amount of just over £3,400 was paid to secure an external translator to translate the draft version of this RIA and other documents in relation to the first consultation.

Central register of all licensed practitioners and approved premises/vehicles providing special procedures

- 7.50 In addition to the introduction of the national licensing scheme, Option 2 now includes the previous Option 3B from the 2017 RIA, which proposed the development of an online national register of all licensed practitioners and approved premises/vehicles providing the four named special procedures in Wales. Since the 2017 RIA was published, the Welsh local authorities agreed that it would be preferable to create one central register, and all contribute to its data and maintenance. The central register will be hosted by a lead local authority and will be available to all local authorities for enforcement purposes and be available to view by members of the public.
- 7.51 The lead local authority acting on behalf of all 22 local authorities tendered for the necessary IT services to build and test the register according to the requirements of the Act. The Welsh Government was asked to fund the necessary IT work to build the required database and online portal. This was agreed as a grant in the sum of £89,950 to fund the initial cost of development. This funding was split equally between 2022-23 and 2023-24. This overall sum included a discretionary amount of £2,000 to cover additional testing if required, but ultimately this discretionary amount was not needed.

Table 7 - Cost of grant for IT works - Welsh Government

2022-23	£43,975
2023-24	£43,974
total	£87,949
Discretionary amount for additional testing (not claimed)	Not exceeding £2,000

7.52 Considerable staff time was taken in determining the funding request, obtaining the necessary clearances for the grant from internal governance teams and obtaining the agreement to the funding from the Welsh Ministers. This took place throughout 2022 and is difficult to quantify. Staff time was required to manage the funding for development of the register during 2023-24, and this will have been absorbed within the staff costs previously given. This element of the work has been completed.

Guidances

- 7.53 The 2017 RIA gave detailed costings for the development and publication of three sets of guidance:
 - Statutory guidance that assists local authorities on the definition of a 'fit and proper person' under section 66(11);
 - Non-statutory guidance aimed at local authorities to assist local authorities with their enforcement of the legislation;
 - Non-statutory guidance aimed at practitioners and businesses to assist them in compliance with the new regulations and the operation of the scheme.
- 7.54 The statutory guidance was developed for and included in the second consultation that was held on the draft statutory instruments.
- 7.55 The guidance aimed at practitioners is still in development as of August 2024 but is likely to be completed by the time this RIA is published. It will be issued in a number of versions specific to the four different procedures, plus one additional for semi-permanent skin colouring practitioners, as this is a distinct and separate form of tattooing. The information about the scheme will be consistent through all versions, but scenarios, examples and illustrations will be specific to the procedure addressed.
- 7.56 The development of these guidance documents has involved working with practitioners and businesses from the sector, local authorities, Public Health Wales and other interested parties. This work is in the process of completion (as of August 2024), and the documents will be made available online. In addition, the links will be distributed to local authorities and businesses and practitioners providing special procedures.
- 7.57 The specialist secondee and the substantive SEO already referred to have provided significant input into drafting these three documents, so this work is included within those staff costs given in Table 6.

Training

7.58 The Welsh Government has been providing training and guidance to local authorities about the content and enforcement of the legislation throughout the calendar year 2024, so the identified costs have been split between 2023-24 and 2024-25. The training sessions have largely been provided to local authority environmental health officers or other relevant local authority staff to support them in their enforcement of the legislation, but awareness events have also been held for practitioners and others with an interest in all four special procedures. These sessions have been free of charge to the recipients.

7.59 Costs identified in the 2017 RIA in relation to this training were based upon delivery of the courses being contracted out to a training supplier, and delivered in person at different venues, with paper copies of course materials being produced. The original cost of the development of course material and hand-outs were calculated as approximately £1,600, and the cost of running the four sessions with 35 people attending each as approximately £3,200, giving a total cost of £4,800. However, the courses have been largely delivered online by the specialist secondee with downloadable materials, but there have also been in person events managed by other bodies such as the Chartered Institute of Environmental Health. The cost to the Welsh Government has therefore been absorbed in the cost of the secondee.

Sunk costs - Public Health Wales

- 7.60 Relevant staff of Public Health Wales (PHW) have been engaged in the development and delivery of training materials and workshops, as well as input into the design of the non-statutory guidance and other relevant guidance documents including an infection prevention and control guidance. The Welsh Government direct-funds PHW as a body, and infection prevention and control are part of PHW's remit. The Welsh Government has not, therefore been charged specifically for this work. However, it would be appropriate to put a notional time cost on this work as an internal cost to PHW in the utilisation of its staff.
- 7.61 PHW has provided professional input on the infection prevention and control elements of the webinars, guidance and other materials related to the scheme. Since the end of March 2023, approximately 22.5 hours a week for 20 weeks of a lead nurse specialist's time has been committed to this work. The hourly rate has been given at £30.60, so this would give a total of £13,770 for this time. This has been apportioned as one week in 2023-2024 and 19 weeks in 2024-2025.
- 7.62 In addition, PHW has provided administrative support in arranging and managing the webinars and providing other administrative support which took around 37.5 hours of a Band 4 administrator's time at £13.05 per hour between March 2023 and the end of August 2024. This has been apportioned as one quarter in 2023-24, three quarters in 2024-25. Additional input was provided by two training officers to develop and deliver the webinars and three e-learning modules between October 2023 and 22 July 2024 as follows, totalling £30,197:

Administration (roughly 640 hours): £20,941

• Meetings (roughly 12 hours): £393

Study Days: £1,942Video Editing: £1,036

• eLearning Modules: £5,885

7.63 As PHW has not identified how these amounts were apportioned between the two financial years, we have split them as one quarter in 2023-23 and three quarters in 2024-25.

Table 8 – PHW sunk staff costs for input into scheme deliverables

	2023-24	2024-25 (to end August)
Lead specialist nurse	£689	£13,081
Band 4 administrator	£122	£367
Training development and delivery	£7,549	£22,648
total	£8,360	£36,096

Sunk costs - Local Authorities

7.64 Local authorities have undertaken a significant amount of work to inform the policy making of the Welsh Government in relation to this scheme. For the draft version of this RIA, local authorities had given the following hourly rates as typical of their staff employed in this area of work, and so the costs in this section have been based on those figures:

• Licensing manager £61.23

- Environmental health officer (EHO) £56.67
- Licensing officer £39.96

Policy development input

- 7.65 The specialist secondee established a task and finish group with a limited number of local authority representatives (10 in all), with which to discuss policy development issues in relation to the mandatory licensing scheme, and to obtain their professional input. This task and finish group was established in May 2022, and it met five times until July 2022 and each meeting took approximately two hours. There would have been a staff/time cost to those local authorities to attend the meetings and undertake any follow-up work. The attendees were largely drawn from the senior officer band, so can be costed roughly at £6,123.
- 7.66 The Special Procedures Implementation Group was established by local authorities as a sub-group of Environmental Health Wales (a local authority expert community of practice), and the membership was open to all 22 local authorities. The first meeting took place in February 2024 and has continued monthly to the end of June and on an ad hoc basis to the end of August. Membership has been drawn from a range of officer bands, as some local authorities have more than one attendee. As for Welsh Government staff, the costings for sunk costs have been calculated for the six formal meetings that took place to the end of August 2024, most have been of approximately two hours duration, so this time has been used. As each meeting may have had different

attendees, for the purpose of these calculations it has been assumed that all 22 local authorities have fielded one senior officer, and the costings are based on 30 attendees from local authorities, the remaining eight being costed at EHO level.

Training

- 7.67 Local authority staff were to attend online training on the new legislation and enforcement and one in-person event. These were sessions on the new legislation and enforcement hosted by third parties (Public Health Wales, local authorities and the Chartered Institute of Environmental Health) but delivered in the most part by the specialist secondee. Four of these sessions were offered in all between January and May 2024. There would have been a time cost to local authority staff to attend the sessions provided, but detailed attendee lists are not available to indicate which staff attended. The in-person event had 97 attendees and ran for approximately six hours and 45 minutes, and as it was delivered by a third party, attendees were asked to pay £99 each to attend. If at least one person of each of the given three officer bands attended for each local authority, then by way of example, it could have cost £1,065.55 per local authority in time/staff costs and £297 attendee costs; and for all 22 local authorities £23,442 in time/staff costs and £6,534 in attendee fees. This does not include any other incidental expenses of attending, such as travel costs. However, this was an inperson day conference, so the most expensive to attend, whereas the other sessions were delivered entirely online and ran for about two hours (18 January), three hours (22 May) and five hours (28 February) respectively, depending on subject matter. In staff/time costs, therefore. it would have cost the same three local authority staff to have attended all of the online events £1,579 in time/staff costs for one local authority, £34,729 for all 22, falling in different financial years.
- 7.68 In addition, 17 short workshops were provided for the elected members of local authorities who make up the members of the licensing committees. Attendance at these workshops comprised part of their committee duties, so were not costed.

Table 9 - local authority sunk costs, meetings and training

	2022-23	2023-24	2024-25 (to end August)
Task and finish group 5 meetings x 10 officers @ £61.23 ph x 2 hrs each	£6,123		
Special Procedures Implementation Group 6 meetings @ 2 hrs each 22 licencing managers @ £61.23 ph 8 environmental health officers @ £56.67 ph		£5,388 £1,813	£10,776 £3,627
CIEH conference x 3 officers x 22 Online training 3 sessions, 10 hrs total x 3 officers x 22		£24,310	£29,976 £10,419
total	£6,123	£31,511	£54,798

Internal costs of management systems

7.69 Following the publication of the draft RIA as part of the first consultation, local authorities indicated to the Welsh Government that they were likely to incur internal costs to establish their respective IT systems before the scheme comes into force, and that these had not previously been included. The Welsh Government requested further information from local authorities for inclusion in this final version of the RIA, and they are now considered sunk costs. The internal costs for one local authority additional to those identified above were given as follows, using the hourly rates for local authority staff given in the published draft RIA:

Table 10 - additional pre-introduction internal costs identified by local authorities

Training of licensing manager on scheme processes: 6 hrs @£61.23 per hour	£367.38
Training of licensing staff additional to that delivered by Welsh Government	
public health manager 1 hr @£61.23 per hour	£61.23
Licensing manager 2hrs @£61.23 per hour	£122.46
Two licensing officers attending 2 hrs each @£39.96 per hour	£159.84
Briefing of licensing committee additional to that provided by Welsh Government	
Public health manager 3 hrs @£61.23 per hour	£183.69
Licensing manager 3 hrs @£61.23 per hour	£183.69
Revising and developing internal administrative systems:	
Licensing manager 8 hrs @ £61.23 per hour	£489.84
Public health manager 4 hrs @ £61.23 per hour	£244.92
Training environmental health staff on attending licensing committee:	
Public health manager 2 hrs @ £61.23 per hour	£122.46
Licensing manager 2 hrs @ £61.23 per hour	£122.46
Environmental Health Officers – 4 x 2hrs @£56.67 per hour	£453.36
Building new IT systems and training relevant staff and updating templates:	

Licensing manager 3 hrs @ £61.23 per hour	£183.69
Public health manager 3 hrs @ £61.23 per hour	£183.69
Environmental Health Officer 3 hrs @ £56.67 per hour	£170.01
IT support (costed at licensing officer level) 12 hrs @£39.96 per hour	£479.52
Subtotal for 1 local authority	£3,528.24
x 22 local authorities	£77,621.28

7.70 It has been assumed that these preparations and training within local authorities took place from the end of the calendar year 2023 through 2024 so the costs identified above would have been split between two financial years.

Local authority sunk costs in relation to the National Register

- 7.71 Considerable staff time was taken by the lead local authority in running the tendering process for the contract to secure an IT company to build the register according to the specifications the local authorities provided, selecting the successful company and liaising with them, submitting the funding request and obtaining the funding from the Welsh Government. This took place over a number of years as the process was interrupted by the pandemic and resumed throughout 2022.
- 7.72 In addition, staff time was required by the lead authority to manage the contract for the IT work with the company which was selected by tender and to provide project management to ensure the register was delivered according to the requirements of the Act and according to deadlines. The lead authority was asked to quantify the time and staff cost to them for this work, and they provided the following for completed actions.

Table 11 – lead local authority costs for procurement and management of IT contract for national register

Activity	Time (Hrs)	Cost
Procurement 2019 (Sell2Wales):		
Setting up project area (1hr)	13hrs	£377
Preparing specification (3hrs)		
Evaluation (3hrs)		
Meeting time (4hrs)		
Email queries and general administration (2hrs)		

Draguramont 2022		
Procurement 2022:	24hrs	£626
Setting up new project area (1hr)	241113	1020
Revising specification (1hr)		
Pulling together queries raised by Project Team into a log for		
evidence/clarifications (2hrs)		
Supplier framework direct award documentation (4hrs x 2)		
Meeting time for assisting with coordination of other		
associated actions inc proj area and templates set up (4hrs x		
2).		
Email queries and general administration (2hrs x 2)		
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Consultee Support for implementation stage based on current	13 (2 x 6.5)	£286
support provided to date – this may increase. 5/9/23 6.5 hrs x 2		
TOTAL – Digital Programme (DPO) team	50	£1289
Procurement with DPO (meetings and follow up work) Set up,		
specification, review, GDPR, DPIA, queries from LAs.	40	£1600
Development with (software provider) Developing the	20	£800
appearance and scope of the database along with search fields		
and search options.		
Constitution where Control Constitution Builting	20	5000
Consultation with Welsh Govt. Compliance. Draft conditions for	20	£800
licences. Training requirements.		
Consultation with Task and Finish Group. Implementation of the	20	£800
registration scheme. Fielding queries from LA officers	20	1800
registration scheme. Helding queries from LA officers		
TOTAL – 2 x Environmental Health Officers	100	£4000
Procurement 2019 –	_	
Attending meetings, internal & external	25	£1375
Specification, etc.		
Liaison with supplier, WG, various internal colleagues		
Procurement 2022		
Attending meetings, internal & external	15	£825
Specification, etc.		
Liaison with supplier, WG, various internal colleagues		
TOTAL – Head of Public Protection		£2,200
GRAND TOTAL		,
		£7,489

Table 12 - Summary of representative sunk costs to end August 2024

	2019	2022-23	2023-24	2024-25
Welsh Government				
Staff costs (to end August 2024) – table 6	Not	£191,680	£286,719	£99,275
	costed			
External translation		£3,400		
Grant for IT works – Table 7			£43,975	£43,974
Public Health Wales - Table 8			£8,360	£36,096
Local Authorities – Table 9				
Task and Finish Group - attendance		£6,123		
Special Procedures Implementation			£7,201	£14,403
Group - attendance				
CIEH conference x 3 officers x 22				£29,976
Online training 3 sessions, 10 hrs total x 3			£24,310	£10,419
officers x 22				
Internal preparation work – Table 10			£38,811	£38,811
Cost to lead authority in respect of	£1,752	£5,451	£286	
register – Table 11				
total	£1,752	£206,654	£409,662	£272,954

Future costs of delivery of Option 2

7.73 Future costs of delivery of the mandatory licensing scheme can be measured from the coming into force date, planned for 29 November 2024, which will be the point at which local authorities will be able to accept applications, and all current registered practitioners and premises/vehicle operators will be required to make an application. The scheme will also be open from the same date to new entrants. However, some costs are provided for the three months of the formal legislative process starting in September 2024.

Welsh Government

- 7.74 The formal legislative process to make the final regulations has been initiated by the laying of these regulations before the Senedd. The proposed coming into force date for the regulations is 29 November 2024. There is therefore a period of three full months in which the Welsh Government staff referred to in the sunk costs section will be working on implementation and the legislative process.
- 7.75 It is intended to re-engage the specialist secondee from the end of September on a contract basis, that will not exceed 31 days in total, for the purpose of supporting local authorities with the introduction of the licensing scheme. An extension of the secondment was originally costed at approximately £7,000 for one month, originally proposed for July 2024.

7.76 The Welsh Government staff costs for the three months of implementation and the formal legislative process are as follows:

Table 13 – Welsh Government staff costs for implementation and formal legislative process

	Sept-Nov (incl) 2024- 25
SEO – Sept-Nov incl	£17,844
HEO – Sept-Nov incl	£14,265
Grade 7 lawyer	£14,855
Specialist Adviser	£7,000
total	£53,964

7.77 Once the coming into force date has been reached, it is intended that the management of the mandatory licensing scheme will become the sole responsibility of local authorities as regulators and enforcers of the scheme. Any work that is required to support local authorities, dealing with enquiries from the public or practitioners, or Ministerial correspondence in respect of the scheme will be absorbed into the standard business of the Health Protection Policy and Priority Programmes branch. Staff will monitor the uptake of the scheme and overall compliance by examination of statistics provided by local authorities from the first year of operation. As this will have become part of Divisional business, it is difficult to quantify the amount of time that will be needed for any ongoing work in relation to this scheme.

Publicity for the Licensing Scheme

- 7.78 The 2017 RIA set out plans and costings for an extensive awareness-raising campaign, to focus on informing practitioners and businesses, as well as the public, of the licensing scheme when it is commenced. As the legislation includes new offences in relation to non-compliance with the scheme, it was envisaged an extensive communications package would be required, to be largely managed in electronic formats, though some print materials such as posters were considered.
- 7.79 Since that time, the Welsh Government has to a certain extent changed how it communicates using mass media, not least because of budget constraints. To communicate with practitioners and businesses providing special procedures, the Welsh Government would now do this largely through local authorities. This is because UK GDPR restrictions have been introduced since the 2017 RIA was developed, so the Welsh Government cannot request the lists of practitioners from

- local authorities to communicate directly with the target audience as may have happened in the past.
- 7.80 The Welsh Government does have access to stakeholder groups for both local authorities and the special procedures industry, and has been utilising these groups to disseminate information, and will continue to do so. As this will be done by some of the staff costed in Table 13 as part of their ongoing work, this has not been costed separately.
- 7.81 The Welsh Government's Communications Division has been asked to prepare a communications plan for the dissemination of messages initially to practitioners and people in charge of premises/vehicles, but also to members of the public. They have been asked to develop this plan on the basis of utilising existing public channels that would come at zero cost to the policy division. A package of online materials for use with social media is being prepared by the Welsh Government for its own use and for local authorities to use to communicate directly with those who would be subject to the legislation when it comes into force. Development of these materials will be done largely by the SEO and specialist secondee that have been costed above.
- 7.82 News stories would be provided to trade journals and other stakeholder networks, as well as the utilisation of social media and selected stakeholder websites to further raise awareness among the trade. There may be a need for wider communications work after the coming into force date which would focus on alerting the public of the possible health issues surrounding special procedures and the importance of ensuring the practitioners visited for an acupuncture, body piercing, electrolysis or tattooing procedure are licensed and the premises/vehicles they operate from are approved.
- 7.83 The online public register element of the mandatory scheme will also need to be publicised after the first licences and approvals are issued, to alert the public to the availability of this resource that they can consult. This may include public relations, and we will utilise existing Welsh Government social media channels and work with industry-specific representative organisations. We had previously identified an estimate of up to £10,000 for this work, as a one-off cost incurred towards the end of 2023, but this amount of budget is no longer available. Consideration is being given within the communications plan as to the most appropriate time to publicise the online register, as it will take a few months for the details of the first licences/approval certificates to appear on the register. It is likely that this will be done at about nine months after the coming into force date.
- 7.84 A total of £1,000 is being held in reserve in the 2024-25 financial year for any incidental expenditure in relation to publicity in the run up to the mandatory licensing scheme coming into force.

- 7.85 When the RIA for the Act was published in 2017, distribution was still largely dependent upon printing and postage of hard copies of documents. Distribution of the guidance documents would now involve sending an electronic copy via email wherever possible to anyone with an interest in these special procedures in Wales, via local authorities, or through circulating the weblink on the Welsh Government's social media channels. The Welsh Government no longer collects mailing lists from local authorities for reuse, as it would have done in the past, because of UK GDPR restrictions on reuse of contact details. The Welsh Government will therefore largely be reliant upon local authorities to disseminate the information to the practitioners and persons in charge of premises/vehicles that they have registered with them.
- 7.86 All of the public documents will be published on the Welsh Government website. It is therefore unlikely that printed copies of the guidance documents will need to be produced or posted in bulk as may have been the case in the past. Hard copies would only be made available on request and printed and posted to order via standard Welsh Government printing and postage processes. It is anticipated that very few hard copies will be requested if any, and the cost would be absorbed in standard running costs.
- 7.87 In the 2017 RIA, it was considered that there would be three sets of guidance, and they would be updated every three years. This was costed at approximately two weeks of a FTE higher executive officer's time, which would equate to approximately £2,146, with design and translation costs amounting to half the original costs, making a total of £4,999. The total cost for each review was therefore costed at approximately £7,145, incurred every three years, and this was included in the costs tables.
- 7.88 On reviewing this RIA, we now consider that the guidances will most likely only be reviewed if it became apparent that there was a need to do so, for example, if the Act or the regulations were amended, or if we were advised by the guidance users that information was incorrect or out of date. There would be a staff/time cost involved with updating the guidances. It will not be possible to predict at this stage if and when the guidances might need revision, therefore this activity is not costed and has been removed from the tables.
- 7.89 Amending the statutory guidance would require significant input from Legal Services and a public consultation on any amendments that were made, so this would need to be factored into any future activity in this regard.
- 7.90 Although it is anticipated that the communications activity would be pursued towards the end of 2024, consideration will be given to the need to repeat communications work at a later date, possibly after nine months, by which time practitioners and premises formerly registered

will have transitioned to the licensing scheme. Repeating communications at that point will further enhance awareness of the new legislation. The precise costs associated with this work would depend upon the outcome of any review of the scheme and are therefore currently unknown.

Public Health Wales

7.91 PHW have indicated that the lead nurse previously identified in the 'sunk costs' section will provide further support in relation to the infection prevention and control element of the scheme between September – end November 2024. This equates to 13 weeks, which when applying the same rate of 22.5 hours a week @ £30.60 per hour, gives a total cost of £8,951.

Local authorities

- 7.92 The legislation will require local authorities to administer the requirements of the licensing scheme. 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 will be required to enforce the legislation when necessary, including taking forward any action to prevent special procedures being undertaken by unlicensed practitioners and in unapproved premises/vehicles. As detailed in Option 1, local authorities already have limited powers to control businesses providing acupuncture, tattooing, semi-permanent skincolouring, body piercing and electrolysis, and already undertake enforcement activity in relation to these businesses. However, the new licensing scheme will introduce more stringent requirements to protect public health and more robust enforcement powers for local authorities provided by the legislation. Local authorities will therefore be enabled to take effective enforcement action quickly, so these activities in relation to these procedures may increase.
- 7.93 It is the intention of the mandatory licensing scheme that the costs of processing applications and updating the public register accordingly are covered by the application fees that are charged for the scheme. In addition, because of the Hemmings v Westminster Supreme Court judgment, a separate fee to fund the overall running of the scheme (referred to as the 'compliance fee') will be charged to practitioners who have been licensed and people in charge of premises/vehicles that have been approved. These fees will cover visits and advice to licensed practitioners and approved premises/vehicles, compliance activities in relation to issuing notices and any follow-up work and taking action against unlicensed practitioners and premises which have not been approved.

- 7.94 Since the draft of this current RIA was published for consultation in January 2023, local authorities have undertaken substantial work on costing the activities they will need to pursue to process an application and manage the running of the scheme. The fee tariffs for 2024-28 have been agreed by the Directors of Public Protection Wales for all 22 local authorities as the reasonable amounts to charge to cover their costs, subject to ratification by each local authority. These fees have been agreed provisionally for the first three years of the scheme to include the first renewal, although these amounts are being kept under review and may change before three years have elapsed. Table 14 below shows the fee tariff which has been agreed provisionally.
- 7.95 Local authorities are not permitted to make a profit from such a scheme. As this is a cost-recovery scheme, the total cost to the applicant/licensed person/premises/vehicle can be used as a proxy for the costs to the local authority. The costings for local authorities and applicants in this section are based on these figures, so the total costs of running the scheme shown should be covered by the combined total receipts from application and compliance fees shown. Other fees will be payable by licence/approval certificate holders for making variations to their licence/approval and incidental requests such as providing replacement certificates. It is not possible to predict future demand for these kinds of administrative requests, so they cannot be costed. However, the fees payable are intended to balance the administrative cost.

Table 14 - Figures used in local authority costings

4,419
2,036
452
84
£159
£44
£244
£141
£147
£41
£204
£141

7.96 The estimated numbers of current practitioners and premises/vehicles given above have been provided by local authorities based on the number of registered practitioners and premises they have on record under the current registration scheme for 2024. They previously

provided figures for 2022, so the average number of new registrations each year has been based on the difference between the 2022 figures (3516 practitioners, 1868 premises) and the 2024 figures given in the table above divided by 2 to give 452 practitioners and 84 premises/vehicles. Local authorities currently consider that roughly 5% of these numbers will not apply for the mandatory scheme for a variety of reasons. Some practitioners would not need to apply for licensing under the new scheme as they would meet the criteria for exemptions as members of regulated professions, so will be completely outside the scheme. There will be others who will not apply for licensing or premises/vehicle approval as they have since gone out of business, intend to retire, or will stop doing special procedures if they consider it is not cost effective to continue.

Licensing practitioners

- 7.97 With regard to the licensing of individual practitioners, local authorities would be required to consider and process an application, make an assessment visit to each practitioner to conduct an interview including a practical demonstration of procedure related practices and if a licence is agreed, produce and issue a licence. The legislation requires the licence to contain a photograph of the licence holder; the cost of producing a photographic licence is included in the application fee, as is the cost of visiting the practitioner as part of the application process. In some cases, the local authority may also need to discuss an application with the applicant prior to the assessment visit, but this would be decided on a case-by-case basis. Accordingly, no cost estimate has been included for such discussions.
- 7.98 All practitioners who are currently registered with their local authorities will have to apply for a licence under the new scheme as there are no transferrable rights between the old scheme and the new scheme. It is estimated there are currently 4,419 (formerly 3,516) individuals performing special procedures in Wales⁴². If approximately 5% of existing registered practitioners did not pursue practitioner licensing further, this would mean 4,198 existing practitioners would potentially apply, starting towards the last quarter of the 2024-25 financial year.
- 7.99 It is not possible to estimate exactly how many of this number will be licensed at the end of the process and how many will be refused. Local authorities have given percentages of how many applicants they think will make representations or appeals at each stage of the process built into the scheme, and these figures are given in the relevant section below. However, this rough estimate cannot predict how many individuals will be successful in their appeals and will go on to obtain licences. The costs to local authorities in this section are therefore based on all 4,198 practitioners passing the licensing process and being charged the compliance fee, which is therefore likely to be an

⁴² Based on information provided by local authorities

overestimate. This cost would be incurred following the licensing scheme becoming operational towards the end of the calendar year 2024. This will continue into 2025-26 as practitioners who have previously registered under existing legislation will be subject to a transitional period of nine months during which they have to make their application and the local authority has to process those applications.

- 7.100 In addition, it has been assumed that there will be an average of 452 applications from new practitioners each year for the whole of Wales, starting from the end of the calendar year 2024 onwards. It is also assumed that for the 452 new registrations every year, a similar number of the original cohort of existing practitioners would cease trading. Therefore, of the original cohort of practitioners who gained licences in 2024-25, there would be 2,842 still in business applying to renew their licences in 2027-28.
- 7.101 As all practitioner licences would be valid for three years, each practitioner will be required to renew their licences on a three-yearly basis, counting from the date of issue of their licence. Local authorities will therefore incur costs in processing renewal applications as well as the ongoing cost of operating the scheme as a whole. As the first renewal fees have been indicated, these have been used to demonstrate these costs to local authorities for the third year of operation. However, local authorities have indicated that they will review the fees after a year, so the renewal figures are indicative only, and are likely to change after that time.

Approving premises and vehicles

- 7.102 The application and approval of premises and vehicles will follow the same process as practitioner licences, but the fees are different because the work involved in inspecting a premises/vehicle to determine an application is more complex. In order to approve premises/vehicles from which special procedures are performed, it is expected that the local authority would process the application and undertake an inspection of the premises/vehicle. These costs are covered by the application fee, as for practitioners. If the premises/vehicle meets the required conditions, it would be approved by the local authority and an approval certificate issued for display. As for practitioners, any premises/vehicle that is approved will be expected to pay a compliance fee to cover the cost of running the scheme as a whole.
- 7.103 The cost to the local authority can be calculated using the application fees and compliance fees per premises/vehicle approval, with the fees covering the costs of processing the application, making an inspection and providing ongoing scheme support⁴³. It is estimated that there are

⁴³ Figure provided by local authorities.

currently 2,036 premises/vehicles from which the defined special procedures are currently performed in Wales⁴⁴. As with the existing practitioners, local authorities consider that approximately 5% of existing registered premises/vehicles will not apply for premises/vehicle approval under the new scheme for a range of reasons. This means that approximately 1,934 will apply in 2024-25. We have assumed that all of this cohort are approved for costing purposes, but this is likely to be an overestimate, as it is unlikely that all premises/vehicles will ultimately be approved.

- 7.104 As set out in paragraph 7.96, we estimate that there will be 84 new premises/vehicles entering the scheme each year, based on the difference between the estimated numbers of premises/vehicles for 2022 and 2024, divided by 2.
- 7.105 As the premises/vehicle approval would also be valid for three years, the costs to local authorities would recur on a three-yearly basis as all persons in charge of approved premises/vehicles will be required to renew their approvals. However, for the purposes of cost calculations, the overall number of existing premises/vehicles requiring renewal in the third year is expected to decrease by 84 each year as it has been assumed that an equal number of businesses will cease trading as will start up each year. Therefore, in these costings, of the original 1,934 premises/vehicles that applied in 2024-25, it is assumed that 1,682 would still be in business in 2027-28 to apply for renewal.

Table 15 - Licensing scheme application and compliance administration costs – local authorities

Reference figures	5% will not apply	2024-25	2025-26	2026-27	2027-28
Number of existing practitioners 2024 - 4,419	minus 221	4,198	3,746	3,294	2,842
Number of existing premises/vehicles 2024 – 2,036	minus 102	1,934	1,850	1,766	1,682
Number of new practitioners a year - 452		452	452	452	452
Number of new premises/vehicles a year - 84		84	84	84	84
Existing practitioners – application 4,198 @ £159 each		£667,482			
		£667,482			£417,774
4,198 @ £159 each Existing practitioners – renewal –		£667,482 £71,868	 £71,868	 £71,868	£417,774 £71,868
4,198 @ £159 each Existing practitioners – renewal – 2,842 @ £147 each New practitioners applications–				 £71,868	,

⁴⁴ Based on information provided by local authorities

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New premises/vehicles applications – 84 a year @ £244 each	£20,496	£20,496	£20,496	£20,496
Subtotal costs based on application fees (a)	£1,231,742	£92,364	£92,364	£853,266
Compliance fee existing practitioners - 4,198 @ £44 each	£184,712			
Compliance fee – existing practitioners renewal 2842 @ £41 each				£116,522
New practitioners compliance fee - 452 a year @ £44	£19,888	£19,888	£19,888	£19,888
Compliance fee – existing premises/vehicles 1,934 @ £141	£272,694			
compliance fee – renewal existing premises/vehicles 1,682 @ £141 each				£237,162
New premises/vehicles Compliance fee 84 @ £141	£11,844	£11,844	£11,844	£11,844
(b) Subtotal costs based on compliance fees	£489,138	£31,732	£31,732	£385,416
(c) total costs	£1,720,880	£124,096	£124,096	£1,238,682
(d) Total fee receipts (= c)	-£1,720,880	-£124,096	-£124,096	-£1,238,682
Local authority net costs (c minus d)	0	0	0	0

Compliance of practitioners, premises and vehicles

7.106 Local authorities would also be responsible for monitoring compliance with the legislation during the three-year duration of the licence or premises/vehicle approval. This would involve working with licence holders and people in control of approved premises/vehicles to ensure compliance. As is the case under the current registration scheme, it is expected that local authorities will undertake risk-based compliance visits. Not all practitioners, premises or vehicles will therefore be visited a second time in the three-year period of their licence/approval, and local authorities consider that about 17% of all practitioners, premises and vehicles, (both existing and new entrants) are likely to require a second visit at some time in any given financial year. It is assumed that the numbers of the original cohort of practitioners, premises and vehicles will diminish year on year, although new entrants will replace them. As the local authority costs for undertaking these compliance activities are included within the overall 'compliance fee' costings set out in Table 15, the figures in Table 16 showing the notional costs of making compliance visits is given for illustrative purposes only to avoid double counting. The cost of £115 per visit is based on the figure previously identified by local authorities in Option 1.

Table 16 – local authority costs of undertaking compliance visits

Compliance visits	2024-25	2025-26	2026-27	2027-28
Existing practitioners – compliance visit –	n=714	n=637	n=560	n=483
17%@ £115 each	£82,110	£73,255	£64,400	£55,545
New practitioners compliance visit – 17%	£8,855	£8,855	£8,855	£8,855
n=77 @ £115 each				
Existing premises/vehicles – compliance	n=329	n=315	n=300	n=286
visit – 17% @ £115 each	£37,835	£36,225	£34,500	£32,890
New premises/vehicles compliance visit -	£1,610	£1,610	£1,610	£1,610
17%, n=14 @ £115 each				
total compliance visits	£130,410	£119,945	£109,365	£98,900

7.107 The overall costs to local authorities for processing premises/vehicle applications are likely to be overestimates, because of the assumption that all applications will be approved, and this carries through into the calculations of numbers who will require compliance visits. It is unlikely that every premises/vehicle application will be approved, and equally, it is not possible to say with any certainty how many new premises/vehicles will start up or existing ones go out of business.

Appeals process for all practitioners, premises and vehicles

- 7.108 Should a local authority consider that an application to grant, renew or vary a practitioner licence or premises/vehicle approval certificate should be refused, it would first have to issue a notice to the applicant to inform them of the fact. In the case of a practitioner licence, the applicant could then make representations to the local authority's licensing committee as to why their application should be granted, and if the committee considered that the application should be refused, the applicant could appeal against the local authority's decision to a magistrates' court and ultimately a Crown Court.
- 7.109 The Act does not provide for representations to be made to the licensing committee in the case of a refusal of an application relating to a premises/vehicle approval certificate The applicant would have the right of appeal directly to the magistrates' court and if refused, to the Crown Court. However, as a result of the first consultation on policy principles, respondents indicated that they would prefer that regulations should be made to require a similar process to be put in place as for the practitioner licences. The licensing committees cannot be used in the same way because of the terms of the Act, but each local authority will be required to review and determine representations relating to refusals of premises/vehicle approval applications. It will be for each local authority to decide how they do this, but for these costings we have assumed there will be a similar 'licensing committee' stage for premises/vehicle applications before the formal appeal stages to the

- magistrates' court and ultimately to the Crown Court and have referred to them as 'similar hearing' for convenience.
- 7.110 Local authorities consider that approximately 5% of all practitioner and 5% of all premises/vehicle applications will need to be determined through the licensing committees or similar hearing, though it is not possible to say with any certainty as to how many will be successful. However, the percentages they have estimated suggest that they anticipate the numbers at each stage will be very small. Using the reference numbers of practitioners, premises and vehicles set out in the grey boxes in Table 15, the numbers of each that might make representations to the licensing committees or similar hearings in this way can be calculated.
- 7.111 Local authorities have also estimated how much it would cost them in time and staff costs to handle one case at each appeal stage. They have provided the estimates of £212 for a practitioner application and £298 for a premises/vehicle application going to the licensing committee or similar hearing. We have therefore used a midway amount of £250 per licensing committee or similar hearing for the purposes of this RIA. They then consider that if an applicant was refused by the licensing committee/similar hearing and chose to make an appeal to the magistrates' court, it would cost the local authority an estimated time/staff cost of £670 for each case to prepare the necessary documents and attend court. Should any case fail at that stage, and the applicant chose to make an appeal to the Crown Court, then it would cost the local authority a similar amount again for this stage of proceedings.
- 7.112 It is not known how many practitioners or people in control of premises/vehicles would take appeals to the magistrates' courts if they were unsuccessful at the licensing committees/similar hearings. Enquiries made of London boroughs in respect of the London licensing scheme for special procedures suggest that less than 2% require action by the boroughs and go before the courts.
- 7.113 A summary table (Table 17) of numbers of applicants estimated to make representations to the licensing committees/similar hearings and to go to appeal in the courts, along with estimated staff/time costs is given below. Please note that the final Crown Court stage percentage returns figures of less than one. As the figures represent applicants, these have to be counted as one person for costing purposes but may not actually transpire. Therefore, the cost values for these are given in brackets, but are included within the total.
- 7.114 As with the costs to local authorities pursuing compliance activities, it is intended that the costs of any enforcement activity will be covered by the overall scheme receipts.

Table 17 – estimated numbers of applications at three stages of appeal against refusal of licence/approval certificate and related local authority costs

Reference figures	5% will not apply	2024-25	2025-26	2026-27	2027-28
Number of existing practitioners 2024 - 4,419	minus 221	4,198	3,746	3,294	2,842
Number of existing premises/vehicles 2024 – 2,036	minus 102	1,934	1,850	1,766	1,682
Number of new practitioners a year - 452		452	452	452	452
Number of new premises/vehicles a year - 84		84	84	84	84
5% practitioners 1st stage representation to licensing committees	existing	210			142
	new	23	23	23	23
5% premises/vehicles 1st stage representation to local authority	existing	97			84
	new	4	4	4	4
total		334	27	27	253
Cost to local authorities per case @£250 each		£83,500	£6,750	£6,750	£63,250
2% of the 5% will make an appeal to the magistrates' courts		7	1	1	5
Cost to local authorities per case @ £670 each		£4,690	£670	£670	£3,350
2% of that 2% will make an appeal to the Crown Courts		Less than	Less than 1	Less than	Less than 1
Cost to local authorities per case @ £670 each		(£670)	(£670)	(£670)	(£670)
Total costs to local authorities		£88,860	£8,090	£8,090	£67,270

7.115 The cost to the magistrates' and Crown Courts for dealing with appeals and hearing prosecutions are discussed in the Courts section starting at paragraph 7.111 onwards of this RIA.

Enforcement costs - enforcement notices

7.116 If a local authority had concerns (raised for example during a compliance visit or via a complaint) that a licence holder or a person in control of an approved premises/vehicle was contravening their mandatory licensing/approval conditions, it could issue a stop notice or a remedial action notice (RAN) to the licence holder or the person holding the premises/vehicle approval certificate to require specified action, depending on the severity of the risk to public health.

Local authorities would also have the power to prevent special procedures being carried out by unlicensed persons or in unapproved premises/vehicles. 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. Using the experience of the London boroughs, we consider that approximately 2% of all practitioners and premises/vehicles (existing and new) will require either a RAN or a stop notice served upon them each year, 133 in total for 2024-25, decreasing to 101 in 2027-28. Welsh local authorities have costed issuing all enforcement notices at £142 each, and if court action is required after that (if the person appeals the enforcement notice or does not comply so a court hearing is required to impose a penalty), the cost to the local authority is £670 per court appearance as previously given. Using the diminishing numbers of existing practitioners and premises/vehicles year on year given in previous tables added to the number of new entrants each year, provides the annual costs presented in Table 18. As before, it is intended that the overall costs to the local authorities of pursuing formal enforcement action will be covered by the scheme fees.

Table 18 – number and cost to local authorities of issuing enforcement notices

	current	5% will not apply	2024-25 Start	2025- 26	2026-27	2027-28 Renew
Estimated number of practitioners in Wales 2024	4,419	minus 221	4,198	3,746	3,294	2,842
Estimated number of premises/vehicles in Wales 2024	2,036	minus 102	1,934	1,850	1,766	1,682
Estimated number of new practitioners a year			452	452	452	452
Estimated number of new premises/vehicles per year			84	84	84	84
Total practitioners, premises, vehicles			6,668	6,132	5,596	5,060
2% of total number will have enforcement notices served (all types, annually)			133	123	112	101
Cost to LAs of issue @ £142 each			£18,886	£17,466	£15,904	£14,342
2% of that 2% will appeal notices			3	2	2	2
Cost to LAs of appeals @ £670 each			£2,010	£1,340	£1,340	£1,340
A further 2% will require court action			3	2	2	2

Cost to LAs of the court action@ £670 each		£2,010	£1,340	£1,340	£1,340
2% of those will appeal the		Less than	Less	Less	Less than 1
court action		1	than 1	than 1	
Cost to LAs of those appeals@ £670 each		(£670)	(£670)	(£670)	(£670)
Total cost to LAs		£23,576	£20,816	£19,254	£17,692

- 7.118 Practitioners and persons in control of premises/vehicles will have the ability to appeal any enforcement notice that is served upon them, and any such appeal would be heard by the magistrates' court. Local authorities' experience through nearest comparable licensing schemes is that very few individuals appeal against such notices. We have therefore applied a percentage of 2% to calculate the number of all practitioners and premises/vehicles requiring enforcement notices who might appeal those notices at the cost of £670 each to the local authority as given before.
- 7.119 In addition, local authorities have been of the opinion that about 2% of the total number of practitioners and persons in control of premises/vehicles will require court action to be taken following the service of an enforcement notice, to seek a penalty to be imposed by the magistrates' court such as a fine. If a penalty is imposed, there is the possibility of appeal. As can be seen from the table, the percentages of people who may make appeals diminishes at each stage. As the number of people who might appeal any penalty imposed by the court is less than one in any year, the cost to the local authority is given in the overall total but is shown in brackets. In all cases, the costs identified to local authorities will be covered by the scheme fees.

Preventing unlicensed activity

- 7.120 Local authorities currently use powers under the 1984 Act to apply for a Part 2A order to prevent a person from carrying out unregistered tattooing or piercing activities. It was estimated in Option 1 that two Part 2A orders are applied for and granted in a three-year period in relation to these practices in the cost range of £1,600–£6,000.
- 7.121 Introducing a mandatory special procedure licensing scheme in Wales will provide more comprehensive powers to deal with prohibited activity, via a more straightforward process. Table 18 includes the numbers of practitioners and premises/vehicles local authorities consider may require enforcement notices to be served upon them, and the costs of processing. It is not possible to predict how many practitioners might be identified as operating without a licence or premises or vehicles that have not been approved. Local authorities will, however, be able to serve stop notices and/or designation notices which compel those

people to obtain a licence and will be able to pursue the same legal remedies as for licenced practitioners/approved premises/vehicles. As it is not possible to predict how many individuals might be identified, and the numbers given in Table 18 may be an overestimate, it is reasonable to consider that any enforcement action against unlicensed individuals and unapproved premises/vehicles is represented within that table.

- 7.122 It is assumed that as businesses and the public would become more familiar with the legislation over time, this would drive up standards, leading to a reduction in the number of stop notices and RANs issued year-on-year until 2027-28, after which the number issued would level off.
- 7.123 Some of these costs could be met if a magistrates' court awarded a contribution towards the prosecution costs to the local authority if the 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.

Public Register – local authority costs

- 7.124 The I2017 RIA gave an option for the duty on local authorities to keep a public register to be discharged by the creation of one central register to which all local authorities contribute, and this was included in the Act. Local authorities indicated that they wished to exercise this option, and the register has been built and is in a state of readiness to receive licensing data. The bulk of the data upload will occur in 2024-25 and part of 2025-26 as all practitioners and people in control of premises/vehicles make their applications and are given decisions. After this time new licences/approvals and variations to existing licences/approvals will be added as they are processed.
- 7.125 Renewal applications would be received every three years, which would require amendment of existing records. There would be a cost to enter the initial information and ensure it is up to date. The administrative cost to local authorities to maintain the accuracy of their data has previously been costed by them at £30 per registration. As each local authority will be responsible for maintaining their own data, these costs have been factored into local authority running costs.
- 7.126 There will 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. There will therefore be a recurrent annual fee of £33,000 for IT licence, ongoing technical support and the ongoing cost of the host data server, which has been costed on an all-Wales basis, which amounts to £1,500 per local authority. It is the intention that these ongoing costs would be offset by receipts from the scheme

licence fees, and that each local authority will make payment of their contribution to the lead local authority. These would be incurred annually from the end of 2024-25, as the local authorities start licensing practitioners and approving premises/vehicles.

- 7.127 There would also be other local government staff costs associated with the guidance, 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. Based on the hourly rate of £56.67 per hour and a 37.5 hour working week, this would equate to approximately £202,595 (£9,209 per local authority) in 2024-25 and 2025-26, with the cost reducing to approximately £101,298 (£4,604 per local authority) thereafter.
- 7.128 Local authorities have established a community of practice for special procedures, named the Special Procedures Implementation Group (SPIG). This was established as a formal group in 2024 and has met monthly, the meetings being roughly two hours in length. The sunk costs in relation of meetings of this group up to the end of August was given in Table 9 in the relevant section.
- 7.129 It was intended that this group would continue to meet from September onwards at least monthly after the coming into force date. However, it appears likely that this pattern will not continue after the coming into force date in November and will likely be absorbed into the work of the other local authority communities of practice. Costings therefore are only given for three months at the rates given for Table 9.

Table 19 - Local authority ongoing costs

	2024-25	2025-26	2026-27	2027-28
IT licencing and technical support	£33,000	£33,000	£33,000	£33,000
Other general costs	£202,595	£202,595	£101,298	£101,298
Special Procedures Implementation Group meetings @ 2 hrs each				
3 meetings Sept- Nov 2024- March 2025				
22 licencing managers @ £61.23 ph	£8,082			

8 environmental health officers @ £56.67 ph	£2,720			
Total costs	£246,397	£235,595	£134,298	£134,298

7.130 This option enables local authorities to set reasonable fees to cover the costs of administering applications in line with the Hemmings v Westminster Supreme Court judgment⁴⁵, and to separately charge licence/certificate holders a fee for the cost associated with running and enforcing the mandatory licensing scheme. There would therefore be a significant degree of cost recovery available to local authorities in administering the scheme. Licensing/approval fees, in addition to the core funding provided to local authorities via the RSG, would meet the cost of running the licensing scheme.

Justice Impact Assessment and Costs to the Courts Service

- 7.131 Appeals in relation to the legislation such as an appeal against a refusal to grant a practitioner licence that has already been before the licensing committee or against the refusal of a premises/vehicle approval application that has been reviewed by the local authority or against enforcement notices 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.
- 7.132 That consultation was made at the same time as the first consultation and costings were received from the MoJ.

Justice Impact Assessment

7.133 As the mandatory scheme described in the RIA section of this document utilises the magistrates' and Crown Courts for hearing appeals under the scheme as well as processing court orders for enforcement activities, permission was obtained from the then Minister for Health and Social Services to consult with the Ministry of Justice (MoJ) which is responsible for the administration of the Courts Service, to ascertain what impact the introduction of the licensing scheme might have on court business.

7.134 The Act sets out that if the local authority intends to refuse a special procedure licence to an individual, that person can make representations to the local authority's licensing committee. Should that fail, then the individual may bring an appeal before the magistrates' court, and ultimately the Crown Court. The Act made no similar

⁴⁵ R (on the application of Hemming (t/a Simply Pleasure Ltd) and others) (Respondents) v Westminster City Council (Appellant) - The Supreme Court

provision in relation to a refusal of a premises/vehicle approval certificate. The relevant regulations bring the process for appeals against the refusal of a premises/vehicle application in line with that of licences, as far as possible, although the licensing committees cannot be used in exactly the same way.

- 7.135 No provision was made in the original 2017 RIA for court costs and the MoJ was not formally consulted at that time. The administration of the justice system is a reserved matter; therefore, the Welsh Government's position is that it is expected that the MoJ will meet the costs associated with the enforcement of Welsh legislation. However, where decisions taken by any of the devolved administrations or bodies under their jurisdiction have financial implications for departments or agencies of the UK government, where other arrangements do not exist automatically to adjust for such extra costs (e.g. if the Barnett formula does not apply), the body whose decision leads to the additional cost will meet that cost, as detailed in the Statement of Funding Policy.
- 7.136 There is no alternative other than to use the courts service to hear appeals where the local authority licensing committees have upheld a refusal decision, because of the terms of the Act requiring appeals to be heard by the courts.
- 7.137 A Justice System Impact Identification (JSII) form was completed for the mandatory licensing scheme as a whole to identify the potential impact upon the Courts Service of hearing appeals and the justice system as a whole. The completed JSII form was sent to the MoJ and they were asked to give their opinion of the impact of the proposals based on our best estimates of numbers of potential appeals to be brought before the courts. This consultation was done at the same time as the first public consultation and they responded in June 2023 with their assessment and costings.
- 7.138 The first consultation identified that the majority of stakeholders thought the appeals process for premises/vehicle approval certificates should replicate that of licences for practitioners, and that there should be a right of representation to the licensing committee. Local authorities considered that the creation of a licensing committee stage for premises/vehicle approval refusals would deal with the majority of such cases, and so a reduced number would reach the courts. However, the Act does not provide for the sub-delegation of this power to licensing committees and therefore provision has been made for each local authority to independently review a refusal for an approval certificate. How this is done will be for each local authority to decide, but in practice, this is likely to mean that a panel similar to a licensing committee will be convened.
- 7.139 This adjustment to the proposals necessitated revising the JSII form and resubmitting it to the MoJ. They were asked to review the changes

to the estimated numbers and revise their costs based on our re-cast figures. The MoJ responded as follows:

Following the review of the Welsh Government's JSII- 1001- Special Procedures under Part 4 Public Health (Wales) Act 2017, please see below the individual responses from each of our Business Groups confirming this:

Business Area	Responsibility	Response
NOMS (HMPPS)	Prison and Probation	Nil / Minimal Impact
	Courts - Crime Operations	Nil / Minimal Impact
HMCTS	Courts - Criminal enforcement	Nil / Minimal Impact
HIVICIS	Courts - Civil and family	Nil / Minimal Impact
	Tribunals	Nil / Minimal Impact
	Criminal Legal Aid (covering policy)	Nil / Minimal Impact
Logal Aid	LAA - Criminal	Nil / Minimal Impact
Legal Aid	LAA - Civil	Nil / Minimal Impact
	Civil Legal Aid (covering policy)	Nil / Minimal Impact
	Criminal Courts	* Financial Impact
Criminal law	Criminal income	Nil / Minimal Impact
Criminal law	Offender/Prison Policy	Nil / Minimal Impact
	Sentencing - policy	Nil / Minimal Impact
	Analytical services	Nil / Minimal Impact
Civil law	Administrative justice	Nil / Minimal Impact
	Civil justice policy	Nil / Minimal Impact

Criminal Court Cost are set out below from 2024-25 to 2027-28 and thereafter:

FY	2024-25	2025-26	2026-27	2027-28
Additional cost to the Criminal Courts	£5,827	£3,626	£3,370	£3,614

7.140 Since this second exchange with the MoJ, local authorities have revised their estimates of how many practitioners, premises and vehicles they consider are currently in operation, and the percentages they considered would make appeals at each stage, to include the changed proposals discussed above. These figures and percentages are those used in this RIA. Although their revised figures have identified more applications entering the process overall, the inclusion of a local authority review stage for all first stage representations and the resultant reduced numbers making appeals to the two tiers of the courts, the tables have been revised further, and it was anticipated that the costs to the MoJ would be reduced significantly.

- 7.141 These adjustments to the proposals necessitated consulting again with the MoJ to ask them to review and revise their figures based on our recast figures in Table 17 of this RIA. The MoJ have indicated that the numbers that might possibly bring appeals to the courts or will require court action following the service of enforcement notices to be such that they can absorb any additional work in their routine running costs.
- 7.142 Welsh Government officials will monitor numbers of people making appeals or requiring court action carefully once the scheme is in place. Should the volume of cases rise to a level whereby the MoJ considers a charge should be made to the Welsh Government for the additional work the scheme has created for the Courts Service, the Welsh Government will liaise with them accordingly. Provision has been made within the Welsh Government budgets in the sums given above in the case that there are more cases brought than anticipated and the MoJ requires payment. As there is an element of uncertainty in relation to whether these costs will transpire, the reserved amounts are not included as costs to the Courts Service or Welsh Government in the summary table for Option 2 (Table 24).

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

- 7.143 Practitioners and people who are in control of premises/vehicles would be likely to incur costs from time spent familiarising themselves with the new requirements and associated guidance for applicants. The guidance will be specific to each procedure with elements in common across all procedures and is estimated to be approximately 25,000 words in length, outlining the recommended practices for each special procedure in detail. It is assumed practitioners and people who are in control of premises/vehicles would only read the guidance relevant to the procedure(s) they perform. Failing to comply completely 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).
- 7.144 We have previously estimated that there are an approximate total of 4,419 practitioners currently registered (formerly 2,086) and 2,036 existing premises/vehicles in 2024-25. In addition, as given previously, it is estimated there would be 452 new practitioners and 84 new premises/vehicles each year. Local authorities have estimated that approximately 5% of all those currently registered may not apply for the new scheme, but we have made the assumption that all of the numbers above will read the guidance before making that decision. Using the hourly rate plus on-costs of £21.20 given previously under Option 1, the cost to each practitioner and each person in control per premises/vehicle can be calculated as £63.60. Scaling this up by the total numbers we have used for people who potentially could apply in

2024-25 totals £410,538 for existing applicants, £34,090 for new applicants. There would be ongoing annual costs for new practitioners and people in control of premises/vehicles.to familiarise themselves with the requirements of the new scheme of £34,090.

- 7.145 The 2017 RIA assumed that the guidance would be updated every three years at which time practitioners and people in control of premises/vehicles who have remained in business may incur some costs from familiarising themselves with the revised guidance and in implementing any required changes. However, we now consider that the guidance will only be updated when there is a change in the Act or regulations, or if stakeholders identify anything that is incorrect or out of date. It is difficult to predict when any such revision might be required, so for this reason future revisions have not been costed but would be the time cost of reading the updated guidance at whatever the hourly rate from the ASHE tables would be at the time.
- 7.146 It should be noted that there will be an element of double counting in all of these figures, as a proportion of practitioners will also be the person in control of a premises/vehicles and will therefore be applying for both a practitioner licence and a premises/vehicle approval. There is also the business model where the person in control of a premises/vehicle does not actually perform special procedures themselves but employs others or rents space to others. It is not possible at this stage to be able to identify what proportion of applicants will have this dual status.

Table 20 – practitioner familiarisation cost

	2024-25	2025-26	2026-27	2027-28
Familiarisation costs– all existing	£410,538	0	0	0
practitioners and premises /vehicles				
Familiarisation costs – new	£34,090	£34,090	£34,090	£34,090
practitioners and premises/vehicles				
Total cost	£444,628	£34,090	£34,090	£34,090

- 7.147 Practitioners and people in control of premises/vehicles would be required to apply to the local authority for a practitioner licence or premises/vehicle 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 time involved in completing an application.
- 7.148 The previous RIA assumed that the practitioner licence application form would take approximately 30 minutes to complete and the premises/vehicles approval application 1.5 hours. However, work that has been done subsequently suggests that completion of each form and the collection of necessary supporting documentary evidence is likely to take 1.5 hours per application form to complete at a cost of £31.80 per applicant. Although there is common information that would

be included in both types of form, the information and documentary evidence is different for practitioners to premises/vehicles, so a person applying for both types of licensing may take the same amount of time on each.

- 7.149 As stated previously, it is not possible to quantify how many people will be applying for both. The legislation requires a practitioner's special procedures licence to contain a photograph of the licence holder, and all applicants will be asked to provide documentary evidence in support. There may be a small outlay of expense to obtain photos or copy documents, but it is anticipated that most will be able to supply electronic copies at no expense to themselves. Using the numbers of practitioners, premises/vehicles and hourly rates from the previous table, the cost of completion of the forms can be calculated. As stated previously in this RIA, local authorities have estimated that approximately 5% of all currently registered practitioners and people in charge of premises will decide not to apply for the scheme. The total number of potential existing applicants therefore reduces to 4,198 practitioners and 1,934 people in charge of premises/vehicles completing the forms.
- 7.150 Applicants for practitioner licences will need to obtain and provide a Basic Disclosure and Barring Service (DBS) Certificate as part of the application process. The cost of applying for such a certificate is £18, which has reduced from the £25 quoted in the previous RIA⁴⁶. 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. Applicants for premises/vehicle approvals only are not required to provide a DBS certificate, as it is the suitability of the premises/vehicle that is the subject of the application.
- 7.151 In addition, all applicants for the scheme, whether as a practitioner, or as a person in control of a premises/vehicle have to demonstrate that they have first completed and passed a regulated Level 2 course in infection prevention and control relevant to special procedures. A pass certificate is a required document for all applications. These courses are accredited by the Royal Society of Public Health and delivered by a number of different providers around Wales as well as online, therefore the fees vary between provider, between £139 and £179, depending on whether they charge the exam fee separately, although most charge around £150 all-inclusive. Applicants for renewal are not required to retake the course, but they will be expected to demonstrate that they have kept their knowledge up to date. As with the other applicant costs in this section, the figures given will be an overestimate, as it is not possible to quantify how many applicants will be applying for themselves and their premises/vehicle, the cost of the course has had to be based on the total number of practitioners and people in control of premises/vehicles who could potentially apply.

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 $^{^{\}rm 46}$ Request a basic DBS check - GOV.UK www.gov.uk

7.152 It is estimated costs incurred through making applications in 2024-25 for existing practitioners and people in control of premises/vehicles would amount in total to an estimated £1,190,362. There would be estimated annual costs for the completion of new applications of £105,581. 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, being based on updating information. In addition to this, we have made the assumption that the number of this initial cohort still in business will reduce over time as identified in Table 15. However, it is anticipated that practitioners will need to provide a new DBS certificate with each renewal application, so this cost has been included. Taking all this into consideration, the cost to the remaining cohort to make renewal applications is estimated at £123,088.

Table 21 - Opportunity cost and wider fees of application process

	2024-25	2025-26	2026-27	2027-28
Completing forms: Existing practitioners and premises/vehicle applications @£31.80 each (n=6,132)	£194,998			
Renewal of practitioner licence/premises/vehicles approval @ £31.80 each (n= 4,524)				£71,932
Basic DBS certificate – existing practitioners @ £18 each (n=4,198, 2,842)	£75,564			£51,156
Cost of IPC course 6,132 x £150	£919,800			
Subtotal	£1,190,362			£123,088
New practitioner and premises/vehicles applications @ £31.80 each (n=536)	£17,045	£17,045	£17,045	£17,045
Basic DBS Certificate- new practitioners @ £18 each (n=452)	£8,136	£8,136	£8,136	£8,136
Cost of IPC course – 536 x £150	£80,400	£80,400	£80,400	£80,400
Subtotal	£105,581	£105,581	£105,581	£105,581
Total costs	£1,295,943	£105,581	£105,581	£228,669

7.153 In addition to the staff time involved in following the application process, there would be an application fee to obtain a practitioner licence or approval of premises/vehicles. The fee structure has previously been discussed in the 'local authorities' section for this option and has been agreed and set by local authorities for the whole of Wales in line with the Hemming judgment. The application cost for a practitioner licence

- will be £159 and the application cost for a premises/vehicle approval will be £244.
- 7.154 Because of the Hemming v Westminster judgment, the running costs of the scheme as a whole have to be charged separately to those practitioners and premises/vehicles who are licensed/approved, in the form of a 'compliance fee'. These fees have also been set at £44 for a practitioner and £141 for a premises/vehicle. All existing practitioners and persons in control of premises/vehicles will need to apply under the new scheme, but only those who are granted licences or approval certificates will be charged the compliance fee. Using the practitioner/premises/vehicle figures from Table 15, there would be the initial application fee cost of £667,482 for 4,198 existing practitioners and £471,896 for 1,934 persons in control of premises in 2024-25. In addition, assuming 452 new practitioners starting each year and 84 new premises/vehicles, there would be ongoing annual fee costs of £71,868 for new licence applications and £20,496 for new approval applications.
- 7.155 It is not possible to predict the percentages of the numbers of practitioners and persons in charge of premises who will be granted licences and/or premises/vehicle approval certificates. Estimates made by local authorities of the numbers who might make appeals against refusal to the licensing committees and the courts would suggest that it will be less than 1% of the total making any application. Therefore, the assumption is made that all applicants numbered in Table 15 will be granted a licence/approval certificate and will therefore be charged the compliance fees. This is therefore considered to be an overestimate but can be calculated at £489,138 for 2024-25.
- 7.156 Renewal of practitioner licences and premises/vehicles approval certificates would take place every three years as detailed in Table 21 above. Indicative renewal application fees have been published as £147 for a practitioner application and £41 compliance fee, and £204 for a premises/vehicle application and £141 compliance fee. The fees overall are subject to review and agreement by local authorities so might change in future. Using the figures in Table 15 as before, the cost of renewal for those original practitioners and people in control of premises/vehicles still in business in 2027-28 are likely to be in the region of £1,114,586.

Table 22 – application and compliance fee costs

	2024-25	2025-26	2026-27	2027-28
Application fee				
Existing practitioners (n= 4,198 x £159)	£667,482			
Existing premises/vehicles (n= 1,934 x	£471,896			
£244)				
New practitioners (n= 452 x £159)	£71,868	£71,868	£71,868	£71,868
New premises/vehicles (n= 84 x £244)	£20,496	£20,496	£20,496	£20,496

Renewal – existing practitioners (n= 2,842 x £147)				£417,774
Renewal – existing premises/vehicles (n= 1,682 x £204)				£343,128
subtotal	£1,231,742	£92,364	£92,364	£853,266
Compliance fee				
Existing practitioners (n= 4,198 x £44)	£184,712			
Existing premises/vehicles (n=1,934 x	£272,694			
£141)				
New practitioners (n= 452 x £44)	£19,888	£19,888	£19,888	£19,888
New premises/vehicles (n= 84 x £141)	£11,844	£11,844	£11,844	£11,844
Renewal – existing practitioners (n=				£116,522
2,842 x £41)				
Renewal – existing premises/vehicles				£237,162
(n= 1,682 x £141)				
subtotal	£489,138	£31,732	£31,732	£385,416
Total application and compliance fees	£1,720,880	£124,096	£124,096	£1,238,682

- 7.157 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 breaching the conditions of a licence would result in a Stop Notice or a RAN depending on circumstances. Breaches of both types of notice are 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.
- 7.158 It was estimated earlier (in Table 18) there could be approximately 133 cases of a person being issued with a Stop Notice or a RAN in the first year. Local authorities estimated that approximately 2% of these would result in court action leading to a fine - three in total in the first year of operation, falling to two a year thereafter, giving a notional total annual cost in fines of up to £15,000. It was also estimated in the same table that there would be a reduction in the number of Stop Notices and RANs issued year on year due to the assumed diminution of the number of the existing cohort of practitioners and premises/vehicles year on year. This would give a total of two receiving fines in 2027-28 at a notional cost of £10,000. 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 or RANs. There is a right of appeal against enforcement notices, but local authorities consider, based on their experience of other licensing schemes, that very few will make an appeal. Notional annual figures of the total number of practitioners and persons in charge of premises who may appeal such notices of all types have been given in Table 18, but for practitioners and persons in control of premises/vehicles, a court fee is likely to be payable to lodge an appeal in court.

- 7.159 In addition, any practitioner or person in charge of a premises/vehicles who wishes to appeal to the magistrates' court against a refusal of application or against a notice (as set out in Table 17) may be charged a fee by the Courts Service. This fee would be to register the appeal, and a further hearing fee may also be applied, and the appellant will have to pay these costs. This is separate to any fees that may be required to instruct solicitors etc. By way of indication, the current Civil and Family Court fee⁴⁷ to lodge an appeal in the County Court is £166 and in the High Court is £285. (excluding any applicable hearing fees), and this amount has been applied to the numbers bringing appeals previously identified in Tables 17 and 18.
- 7.160 As the issue of court fees has not been settled, the totals in the following Table 23 are illustrative only and have not been included in the overall summary totals at the end of this document.
- 7.161 There are other types of application included within the Act that are available to practitioners and people in control of premises/vehicles, such as application to vary a licence and/or premises/vehicle approval, replacement certificates and other administrative applications. All such additional applications will attract a fee for processing, and there will be a related administrative cost to the processing local authority. It is not possible to quantify how many of these applications will be made in any year. For this reason, these applications cannot be costed.

Table 23 – illustrative cost to practitioners and businesses – court fees and fines

	2024-25	2025-26	2026-27	2027-28
Fines* (all practitioners and premises/vehicles, @ £5,000 each)	n=3	n=2	n=2	n=2
	£15,000	£10,000	£10,000	£10,000
Court fees* – appeals to magistrates @ £166 each	n= 7	n=1	n =1	n =5
	£1,162	£166	£166	£830
Court fees* – appeals to Crown	n =less than 1	n =less	n =less	N =less
Court @ £285 each		than 1	than 1	than 1
All appeals against enforcement notices @ £166 each	n=3	n=2	n=2	n=2
	£498	£332	£332	£332
*illustrative amounts only– value of fines and fees may vary substantially				

7.162 It is anticipated that in the majority of cases, practitioners and people in control of premises/vehicles would work with the local authority to fulfil the recommended action and comply with any notices served. As the

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⁴⁷ EX50 - Civil court fees (EX50) - GOV.UK (www.gov.uk)

- cost to individual businesses of remedial action could vary greatly, and is currently largely unknown, it has not been estimated here.
- 7.163 There are no additional costs to practitioners and businesses in relation to the register. There would be no need to provide any information beyond the requirements set out in the licensing scheme, as the register and its database will only contain the details of each licence/approval certificate, not the persons holding them, other than their name and business premises/vehicle's address (where relevant).

Table 24 – summary of costs associated with Option 2

Sector	2024-25	2025-26	2026-27	2027-28		
Welsh Government						
Staff costs Sept-Nov 2024	£53,964	0	0	0		
(Table 13)						
Publicity	£1,000	0	0	0		
Total cost to Welsh	£54,964	0	0	0		
Government* (A)						
Dublic Health Wales (D)	C0 0E4		0	0		
Public Health Wales (B)	£8,951	0	0	0		
Local Authorities						
Applications administration	£1,231,742	£92,364	£92,364	£853,266		
(Table 15)	1,231,742	192,304	192,304	£033,200		
Annual compliance visits	£130,410	£119,945	£109,365	£98,900		
(Table 16)	2100,110	2110,010	2.00,000	200,000		
Cost of appeals (Table 17)	£88,860	£8,090	£8,090	£67,270		
Cost of enforcement	£23,576	£20,816	£19,254	£17,692		
notices/appeals (Table 18)						
Other general costs (Table	£246,397	£235,595	£134,298	£134,298		
19)						
subtotal cost to local	£1,720,985	£476,810	£363,371	£1,171,426		
authorities	04 700 000	0404.000	0404.000	04 000 000		
Less adjustment for total receipts (Table 15)	-£1,720,880	-£124,096	-£124,096	-£1,238,682		
Local authority net costs	£105	£352,714	£239,275	-£67,256		
(c)	2100	2002,714	2203,210	-201,200		
Practitioners and people in	Practitioners and people in control of premises/vehicles					
Guidance familiarisation		£34,090	£34,090	£34,090		
costs (Table 20)						
Application opportunity	£1,295,943	£105,581	£105,581	£228,669		
costs (Table 21)						
Application fees and	£1,720,880	£124,096	£124,096	£1,238,682		
scheme charges- (Table						
22)	00 101 1-1	2222 - 22	0000	04 -0		
Total cost to	£3,461,451	£263,767	£263,767	£1,501,441		
practitioners/						
premises/vehicles* (D)	£3,525,471	C646 404	CE02.040	C4 424 40F		
Total cost Option 2* (A+B+C + D)	23,323,471	£616,481	£503,042	£1,434,185		
*Other costs have been identified under this ontion for all parties which cannot be accurately						

*Other costs have been identified under this option for all parties which cannot be accurately quantified, so are not included in the total. These include the costs to the Welsh

Government/Courts Service; the NHS of treating individuals; fines imposed on practitioners/people in control of premises/vehicles

Benefits

Health benefits

- 7.164 The main benefit of the licensing scheme is expected to be avoided costs for 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 1, it was estimated the complications associated with tattooing and body piercing result in a minimum annual cost to the NHS of £103,294 to £447,330. Any reduction in the complications arising from special procedures would result in the NHS avoiding at least part of these costs.
- 7.165 Any avoided complications would also lead to QALY gains for individuals, although they cannot be quantified here. One QALY is valued at £70,000. The cumulative net cost of Option 2 over and above maintaining the status quo outlined in Option 1 is £4,525,547 based on the higher values of the difference range over a four-year period. The licensing scheme would need to lead to approximately 65 QALY gains to be cost neutral.

Other benefits

- 7.166 It is considered the current legislation is inadequate to sufficiently protect the public this view was supported by stakeholder responses to the Public Health White Paper consultation⁴⁸. The licensing scheme under this option would impose requirements on practitioners and people in control of premises/vehicles, 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.
- 7.167 Most licence holders who perform special procedures and the premises/vehicles 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

⁴⁸ No longer available online Written Statement - Public Health White Paper: Consultation Summary Report (6 November 2014) | GOV.WALES

undertaking appropriate infection control procedures. The mandatory scheme is designed to allow practitioners to work anywhere in Wales in approved premises/vehicles, so provides greater flexibility than the registration scheme outlined in Option 1.

- 7.168 The central register for special procedures would assist practitioners and people in control of premises/vehicles to demonstrate their status as having met the licensing scheme requirements and enable potential clients to contact them. If a practitioner, person in control of a premises/vehicle 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.
- 7.169 The public would have access to a central accessible, searchable facility in both Welsh and English covering the whole of Wales from which to find a practitioner working in their area who is licensed, or premises/vehicles which have been approved.
- 7.170 The communications package outlined earlier would be important in making practitioners, businesses and the public aware of the licensing scheme. 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/vehicles they have approved on the public register, anyone seeking to have a special procedure would be able to find out from the register which practitioners and premises/vehicles have met the national standards. This would help to further improve transparency and ensure people are better informed.
- 7.171 In addition to the potential avoided costs for the NHS identified above, the licensing scheme 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.

Disbenefits

7.172 There may be a disbenefit in economic terms for the client if practitioners and persons in control of premises/vehicles choose to offset the higher cost of application and renewal and other scheme fees on to their clients by raising the charges for their services. The requirement to undertake the infection prevention and control course at cost to the applicant and to renew a licence/approval certificate every three years are costs that practitioners/people in control of premises/vehicles currently do not have to pay under Option 1. Passing on these additional costs to the client in turn might lead to a reduction in custom, however, these possible disbenefits are unquantifiable. It is also the case that all practitioners and people in

control of premises/vehicles will be required to pay the same costs for applications wherever they are in Wales, therefore this is a more equitable scheme in relation to those costs and standards of approval by local authorities. It is anticipated, however, that the benefits of the scheme to the client in increased standards of hygiene and safety and to the practitioner/person in control of a premises/vehicle in consistency of approach by local authorities outweigh any disbenefits of cost.

- 7.173 Some practitioners in the public consultations have given the opinion that the costs of the application and renewal fees along with any work that may be required to bring standards of practice or premises up to the required standard to enter the scheme may drive some of these practitioners or premises out of business or create an 'underground' market of unlicensed practitioners who are prepared to operate illegally. These are possible risks, but Option 2 provides local authorities with simpler and more adaptable enforcement tools to be able to tackle such practitioners. It is also anticipated that as the scheme becomes better known to clients and they gain a knowledge of the potential health risks involved, they will be more inclined to use a licensed practitioner.
- 7.174 There may also be a perceived disbenefit to local authorities in that the requirements of the licensing scheme will require initially a high volume of work to migrate existing practitioners and premises/vehicles into the new scheme as well as dealing with new applicants. Local authorities have indicated that the demands of this additional work have to be met from existing resources, which may not be sufficient. As the scheme as a whole is designed to be a full cost-recovery scheme and local authorities are not permitted to make a profit, they should at least break even. In addition, they have confirmed to us that they will keep their fees under review to ensure that they continue to recover the costs of administration of the scheme. The staffing that they will require is a matter for their own management to consider.

Cost comparison

Table 25 – comparison of costs of options

	2024-25	2025-26	2026-27	2027-28	
Option 1 costs (from Table 5)					
A - Total Welsh Government costs	0	0	0	0	
B - Local authority net costs	£318,670 – £323,070	£317,070	£317,070	£318,670 – £323,070	
C - Total Business costs	£68,338	£68,338	£68,338	£68,338	
Option 1 - Total net costs (A+B+C)(Table 5)	£387,008 - £391,408	£385,408	£385,408	£387,008 – £391,408	
Option 2 Costs (from Table 24)					

a - Total Welsh Government costs	£54,964	0	0	0
b - Public Health Wales	£8,951	0	0	0
c – Local authorities net costs	£105	£352,714	£239,275	-£67,256
d – total costs practitioners/premises/ vehicles	£3,461,451	£263,767	£263,767	£1,501,441
Option 2 - total net costs (a+b+c+d)	£3,525,471	£616,481	£503,042	£1,434,185
Cost of Option 2 additional to Option 1	£3,138,463 – £3,134,063	£231,073	£117,634	£1,047,177 – £1,042,777

- 7.175 It will be seen from Table 25 that the costs of Option 2 in the startup year 2024-25 and renewal year 2027-28 are substantially higher overall than those for Option 1. This is because of the necessity of migrating all currently registered practitioners and people in control of registered premises/vehicles into the new scheme, the more rigorous requirements and the requirement for renewal of licences/approval certificates every three years increases the overall costs to local authorities and applicants. In addition, the costs to other parties such as the Welsh Government and Public Health Wales are front loaded, in that the work to deliver the scheme so local authorities and applicants can take it forward from the proposed coming into force date are included in 2024-25.
- 7.176 It will also be noted that local authorities effectively demonstrate a deficit in most years in both options, as the net figures have taken account of the application fee receipts, and in the case of Option 2, the compliance fee receipts also. Table 15 identified that all the receipts from the application fees and compliance fees chargeable under Option 2 are intended to balance out to zero as the fees are intended to cover the cost of running the scheme, and the local authorities calculated the initial application and compliance fees accordingly.
- 7.177 The calculations we have presented in this RIA have taken account of all the <u>potential</u> costs in addition to processing the initial applications to the point of making a decision, and as a result, the potential total receipts do not entirely cover these costs. There are a number of reasons for this:
 - Local authorities cannot state with any certainty how many practitioners or premises they have in business who will apply but have had to provide us with estimates.
 - In addition, each local authority has different staffing and fee structures and different ways of working, which has made identifying common work processes and assigning unit costs complex.

- It is impossible to predict how many people will apply for the scheme, how many of those applicants will be licenced or how many premises/vehicles will be approved, so the assumption has had to be made that all applicants will be approved.
- Many people will be applying for both a practitioner licence and a premises approval, and it is impossible to identify where there is duplication.
- Many of the unit costs cannot be specified, as they are dependent upon a range of other factors that will be different in each case, for example, the numbers of applicants who might make an appeal of any kind, how much the court costs would be, what level of enforcement action might need to be applied in any situation, or how much any fines imposed might be.
- 7.178 As discussed in the 'local authorities' section for Option 2, the calculations in this RIA are based on the local authorities' latest estimates of numbers of practitioners and premises who are currently registered with them, and the experience they have of enforcement activity of comparable licensing schemes.
- 7.179 It is very likely that the costs presented here for both options are an overestimate, as the assumption has had to be made that all applicants will be licensed/approved.
- 7.180 In addition, the costings for Option 2 include costs for an increased level of enforcement activity, because the option presents more legal remedies for local authorities to take than available for Option 1, under which formal court action is a rare occurrence because of its complexity and expense. With so many variables in numbers entering the scheme and requiring enforcement activity for both options, the figures are not necessarily representative of what currently happens in local authorities or will happen if Option 2 is introduced. The actual numbers of applicants and activity under any heading are therefore highly speculative and could therefore be less, or conversely, substantially more, and in relation to practitioners and persons in control of premises/vehicles, contain a currently unquantifiable number that have been double counted as they will be applying for both a practitioner licence and a premises/vehicle approval.
- 7.181 That said, when the net costs to local authorities only for Option 2 are compared to the net costs to local authorities of Option 1 (Table 25), it will be seen from the annual net cost to local authorities that it would cost them only slightly more or less to pursue Option 2. This is because Option 2 is designed to cover ongoing costs of running the proposed licensing scheme as well as the initial cost of processing and determining each application. Local authorities set the indicative fees for the scheme but have since considered that they will not fully cover their costs, and so intend to keep the fees under review. That said, in

2027-28 the local authority net costs appear to make a small profit. It is unclear why that should be, other than it is anticipated that there will be fewer of the original cohort in business to apply for renewal, and this may be an anomaly.

7.182 The biggest difference between the two options is the fees that will be chargeable to all applicants, although in some local authorities, some of the fees currently charged for registration are within the same price range as some of those proposed under Option 2. We acknowledge, however, that some of the fees are more than double those currently charged by some local authorities. In addition, the opportunity costs for applicants are higher for Option 2 because the application requirements are more rigorous and require the applicant in every case to have undertaken and passed a level 2 award course in infection prevention and control course. This course has to be taken before any application can be made and the applicant has to finance it themselves. The benefit of this requirement, however, is to ensure that everyone making application has the same knowledge of infection prevention and control and should be able to apply the information to their work practises and their workplace. There is no such requirement under Option 1, and effectively anyone can set up in business with little knowledge of how to practise safely, and this would continue if Option 1 continued.

Summary and preferred option

- 7.183 **Option 1** 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, body piercing and electrolysis are considered insufficient to protect public health.
- 7.184 **Option 2** proposes mandatory licensing of practitioners who provide the four named special procedures in Wales, and the premises/vehicles from which they are performed. National standards would be applied through mandatory licensing conditions, infection prevention and control training, a consistent application and approval process and fee structure and enforcement framework. It aims to improve standards create a level playing field for reputable businesses and ensure an improved and consistent approach to the regulation of these procedures across Wales. The supporting guidance documents and communications activity are 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.
- 7.185 The previous RIA gave the opinion that pursuing a central register immediately had limited benefits for local authorities, businesses and the public, in that it increased the ease with which information could be

accessed. However, it has since been decided by local authorities acting together that, it would be preferable for them to collaborate on establishing and maintaining one central register. As the mandatory information to be included in the register is set out in the Act, the local authorities considered it preferable to build the register in advance of commencing the legislation and introducing the mandatory scheme, and this work has been completed. This has had a number of advantages in that the register has been tested and made ready, and local authorities have been familiarising themselves with its use ahead of live applications for licensing/approval registration being made.

Consultation on this RIA

7.186 The draft version of this RIA formed part of the documents that were presented for public consultation in January 2023. Information provided in responses that were received on the RIA from local authorities have been included in this final version.

Other Impacts

Integrated Impact Assessment

- 7.187 A full Integrated Impact Assessment (IIA) has been completed for these regulations and can be seen here: https://www.gov.wales/mandatory-licensing-special-procedures-wales
- 7.188 No adverse impacts were identified in any of the parts of the integrated impact assessment. The main positive impact common to all parts was that clients would benefit overall from the four special procedures being delivered to a consistent standard of infection prevention and control, and this would apply equally across all socio-economic and societal groupings.
- 7.189 The greatest overall impact identified in the IIA was in relation to data protection through the mass collection and retention of data by both local authorities through the application and licensing/approval process, and for practitioners through the collection and retention of client data.

Revenues and Benefits

7.190 There are no identified impacts upon the Welsh tax, UK tax or UK benefits systems in relation to this option.

8. Competition Assessment

8.1 All existing practitioners and people in control of premises/vehicles will be required to apply for licensing and/or approvals of premises/vehicle

as well as new entrants. It is expected that the application and compliance fees will be the same across all local authorities in Wales, therefore all applicants will be subject to the same charges. Any costs incurred by businesses in respect of training or in equipping a premises to meet a standard required for approval would be proportional to the size of the business, so 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.

Preferred Option 2: commence all provisions of Part 4 and Schedule 3

The competition filter test				
Question	Answer			
	yes or no			
Q1: In the market(s) affected by the new regulation,	No			
does any firm have more than 10% market share?				
Q2: In the market(s) affected by the new regulation,	No			
does any firm have more than 20% market share?				
Q3: In the market(s) affected by the new regulation,	No			
do the largest three firms together have at least				
50% market share?				
Q4: Would the costs of the regulation affect some	Initially re			
firms substantially more than others?	workplace			
	equipment etc?			
Q5: Is the regulation likely to affect the market	Possibly some			
structure, changing the number or size of firms?	go out of			
	business?			
Q6: Would the regulation lead to higher set-up costs	No			
for new or potential suppliers that existing suppliers				
do not have to meet?				
Q7: Would the regulation lead to higher ongoing	No			
costs for new or potential suppliers that existing				
suppliers do not have to meet?				
Q8: Is the sector characterised by rapid	No			
technological change?				
Q9: Would the regulation restrict the ability of	No			
suppliers to choose the price, quality, range or				
location of their products?				

Notes

Q4: The proposed legislation does not allow for grandfather rights (i.e. transferrable acquired rights) for existing practitioners and businesses. All practitioners who are currently operating and all operators of premises or vehicles used for the specified special procedures will need to apply for licences and premises/vehicle approval certificates under the proposed new scheme. As the standard of competence to be demonstrated and the licensing

conditions are significantly more rigorous than the existing registration scheme allows, it is possible that some practitioners and businesses will find the new licensing scheme financially challenging, and some may not ultimately get through the licensing process. Significant work has been done with existing practitioners to ensure that they are aware of future standards that will be required, and many are already meeting those standards.

Q5: for the reasons outlined in Q4 above, it is possible that the number of licensed practitioners and premises will change because of the proposed licensing scheme in the short term following the introduction of the scheme.

9. Post implementation review

- 9.1 Post implementation review forms an integral part of this proposal. The purpose of the regulations to be made is to set the details of the mandatory licensing scheme for special procedures in Wales with the intention of:
 - 1. providing a consistent and more effective legal framework for local authorities to regulate this industry.
 - 2. raising consistent standards of infection prevention and control in this sector.
 - providing better safeguards to members of the public who wish to use these services and thereby reducing adverse health impacts associated with special procedures.
- 9.2 We anticipate that points 1 and 2 will be a relatively straightforward part of the review because of the systems that we have already set up to facilitate this. Our well-established local authority and practitioner networks have indicated that they will support this work.
- 9.3 The local authority public protection network comprises of specialist expert panels that report into a national group of heads of environmental health which is overseen by the Directors of Public Protection Wales. This framework facilitates partnership working and supports local authorities in committing to national decisions on a range of public protection disciplines. All 22 local authorities have committed to this for the implementation and review of the special procedures licensing scheme.
- 9.4 Section 75 of the Act requires all Welsh local authorities to maintain and publish a register of all licensed special procedure practitioners and approved premises/vehicles. The Act also allows for Welsh Ministers to make arrangements for a central register to be set up and maintained on an all-Wales basis by one local authority on behalf of all 22 Welsh local authorities. This has the benefit of ensuring that a consistent set of data is collected by all 22 local authorities and the data published by each local authority is available in one place. The register will therefore cover the whole of Wales and will be available

- online for the public to consult. It is this data that will form the foundation of the post implementation review.
- 9.5 Data associated with the enforcement and compliance of the licensing scheme will be monitored for the first year of operation on a quarterly basis to ascertain the progress of the transition phase and provide the baseline number of licensed practitioners and approved premises/vehicles. It is anticipated that the majority of applications will be received in the first nine months of the scheme's operation as this is the length of time that current practitioners and people in control of premises will have to make their applications to transition from the old registration scheme to the new scheme. The database that will drive the online central register will be utilised to generate these statistics, and the staff/time cost of generating the data reports and reporting to the Welsh Government will be absorbed in standard running costs of each local authority. Likewise, the Welsh Government will incur a staff/time cost to review the data received which will also be absorbed within standard divisional running costs.
- 9.6 Appraisal of the data from the first 12 months of this review will determine the frequency of data collection in the second year of its operation. We anticipate that data will be reviewed both on a national and local basis and by type of special procedure. This approach will help inform the need for any targeted education, promotional or enforcement interventions. Local authorities have committed to review their own data and to record the costs of implementing the scheme and the first year of operation. The intention of this is so that they may more accurately determine the reasonable fees to be charged for new applications to the scheme. The costs of this work within local authorities are currently unknown.
- 9.7 The Act requires special procedure practitioners to undertake a consultation with their client before and after a special procedure is performed. This includes keeping a record of the aftercare advice given, including steps the client should take to prevent infection. These practices along with others will be monitored by local authorities and therefore could be collected as part of the enforcement review.
- 9.8 Point 3 will present more challenges but may be achievable through utilisation of established links with Public Health Wales and local authority communicable disease teams who investigate cases and outbreaks of infection associated with special procedures.
- 9.9 Consideration will be given as to whether the practitioner network, expert panels and colleagues in relevant university disciplines would be able to assist in assessing the benefits of the licensing scheme to businesses and the health of their clients. Any commission to a third party to make any assessment of the scheme is likely to be subject to a fee. This is not costed, as the terms of any commission will dictate what work is required and therefore what fee would be appropriate.

- 9.10 It has been the intention to run a further public consultation with a view to identifying other special procedures that should be included in the mandatory scheme. The intention has been to do this once the proposed licensing scheme is established to allow local authorities sufficient time to operate the scheme with the four named procedures. It is likely that any unintended consequences or operational issues will be identified by local authorities within this period, which may require adjustment of the guidance or regulations. This is usual with any new scheme, and Welsh Government officials will be receptive to feedback from local authorities in this regard.
- 9.11 It would be logical to review the scheme as a whole at the same point to ascertain whether it is achieving the policy objectives of improving infection prevention and control standards within the industry and effectively curb the activities of those practitioners who operate illegally.