



Llywodraeth Cymru
Welsh Government

Explanatory Memorandum to the NHS (Pharmaceutical Services) (Wales) Regulations 2020

This Explanatory Memorandum has been prepared by the Pharmacy and Prescribing Branch of the Directorate of Primary Care & Health Science, Health and Social Services Group, Welsh Government and is laid before the Senedd in conjunction with the above related subordinate legislation in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the NHS (Pharmaceutical Services) (Wales) Regulations 2020. I am satisfied that the benefits outweigh any costs.

Vaughan Gething
Minister for Health and Social Services
6 August 2020

PART 1 – EXPLANATORY MEMORANDUM

1. Description

1.1. The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (“the 2020 Regulations”) change the control of entry and market exit regimes in relation to the provision of pharmaceutical services in Wales. The 2020 Regulations introduce Pharmaceutical Needs Assessments which Local Health Boards must prepare and publish in relation to their localities. The Regulations will revoke and replace the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013, subject to the transitional provisions within the 2020 Regulations.

2. Matters of Special Interest to the Legislation, Constitution and Justice Affairs Committee

2.1 The 2020 Regulations are the first set of regulations made pursuant to section 82A of the NHS (Wales) Act 2006 (“the 2006 Act”). In accordance with section 203(6A) of the 2006 Act, a statutory instrument containing the first regulations pursuant to section 82A (pharmaceutical needs assessments) may not be made unless a draft of the instrument has been laid before, and approved by resolution of, the Senedd. The 2020 Regulations will therefore follow the Senedd’s affirmative legislative procedure.

2.2 The draft Statutory Instrument (SI) was originally laid before Senedd Cymru on 17 March 2020 in advance of a plenary debate scheduled for 28 April 2020. It was subsequently withdrawn on 21 April 2020 as a consequence of the Covid-19 pandemic. The draft SI was then laid before the Senedd on 8 July 2020 with a plenary debate set for 23 September 2020.

2.3 On 28 July 2020 the Legislation, Justice and Constitution Committee produced a draft report highlighting one technical scrutiny point under Standing Order 21.2(vi). Whilst the point raised was technical in nature, it related to four substantive provisions within the draft SI, such that the SI would be defective were it made in the form it had been laid and meant it was not possible to rectify via the publishing process.

2.4 The Welsh Government, accepting the points raised by the Legislation, Justice and Constitution Committee draft report, wish to ensure that legislation is clear and certain in its effect and so took the opportunity to correct the necessary provisions, there being sufficient scope within the legislative timetable to do so without a consequential impact on the scheduled plenary date of 23 September 2020 and subsequent coming into force dates.

2.5 Certain provisions of the 2013 Regulations are not revoked immediately that the 2020 Regulations come into force, and certain provisions of the 2020 Regulations also do not take immediate effect.

2.6 Regulation 8(1)(a) of the 2013 Regulations is revoked on 31 March 2021 but replacement regulation 15(1)(a) of the 2020 Regulations does not come into force until 1 October 2021. A 6 month ‘standstill’ period has been created by the gap in between the 2013 regulations’ application provision being revoked and the 2020 regulations’ application provision coming into force. During this time, no applications to be included on a pharmaceutical list will be able to be made. This is intentional. It would not be practicable for Local Health Boards to continue to receive applications under the 2013 Regulations’ provisions right up until their first

Pharmaceutical Needs Assessment (PNA) is published, whilst it is impossible for an application to be made under the new regulations until a PNA has been published, as applicants would not know what need they are applying to meet. The 6 month gap will enable Local Health Boards to deal with those applications made under the 2013 Regulations (up to the point it is possible to do so) whilst at the same time allowing them to finalise and publish their first PNA in readiness for the date by which they must publish their PNA and applications will then be able to be made (this will be 1 year from the date on which the initial provisions come into force).

2.7 Similarly, regulation 20 of the 2013 Regulations is revoked on 31 March 2021 but its replacement, regulation 26 of the 2020 Regulations, does not come into force until 1 October 2021. Again, the gap created is intentional in order that there is a 6 month 'standstill' period during which no applications may be made by doctors wishing to provide pharmaceutical services. As set out above, this will also enable the health boards to focus on finalising and publishing their PNAs, which will need to take into consideration the existing provision of dispensing doctors.

2.8 After the draft Regulations were withdrawn on the first occasion in April 2020, the original dates on which the relevant parts of the 2020 Regulations were due to come into force were changed to those set out in paragraphs 2.5 to 2.7. This was a necessary consequence of the subsequent decision to re-lay the draft Regulations in July 2020 and also having to reschedule plenary to the September date. It is also worth noting that there is a significant retention of provisions from the 2013 Regulations within the 2020 Regulations.

3. Legislative Background

3.1 The Public Health (Wales) Act 2017 ("the 2017 Act") seeks to improve and protect the health and well-being of the population of Wales, through provision, in discrete areas of public health policy. Part 7 of the 2017 Act amends the 2006 Act in relation to pharmaceutical services in Wales and was brought into force by the Public Health (Wales) Act 2017 (Commencement No.4) Order 2019 on 1 April 2019.

3.2 Part 7 of the 2017 Act inserts a new section 82A into the 2006 Act which places a new duty on Health Boards in Wales to prepare and publish an assessment of need for pharmaceutical services (a pharmaceutical needs assessment) as well as conferring a power on the Welsh Ministers to make regulations in relation to pharmaceutical needs assessment in Wales. The 2017 Act also amends section 83 of the 2006 Act so that regulations made in accordance with section 82A may provide grounds for removal of a person from the pharmaceutical list that are not connected with a person's fitness to practise (i.e. a market exit regime).

3.3 Section 80 of the 2006 Act places a duty on health boards to make arrangements for the provision of the pharmaceutical services that are set out in subsections 80(3)(a) to (d). These core pharmaceutical services are essentially dispensing services. There is a duty on Welsh Ministers to make regulations governing the way in which health boards make these arrangements.

3.4 Section 83 of the 2006 Act contains the core of the Welsh Ministers' regulation making powers in relation to the provision of the pharmaceutical services and, amongst other things, sets out the requirement for regulations to require a health board to prepare and publish a pharmaceutical list, and sets out the tests which those persons wishing to provide pharmaceutical services must pass in order to do so (known as the 'control of entry test').

3.5 Section 84 sets out a requirement for Welsh Ministers to provide for rights of appeal against decisions that are made by health boards in exercise of powers conferred upon them by regulations made under section 83.

3.6 The 2020 Regulations are made pursuant to the Welsh Ministers' powers in sections 15, 80, 82A, 83, 84, 86, 88, 104, 107, 110, 115, 116, 118, 203(6A), (9) and (10) and 205 of the 2006 Act.

3.7 These Regulations are subject to approval of the Senedd via the affirmative procedure.

4. Purpose & Intended Effect of the Legislation

Background

4.1 The Welsh Government sets the overall structure in which community pharmacies operate by providing the legislative and policy framework. Within the framework, the responsibility for planning and providing pharmaceutical services is vested in health boards who must plan health services to meet the needs of their resident populations. This includes determining the number and location of pharmacies in their areas.

4.2 The general duty to provide NHS pharmaceutical services, as with other aspects of NHS primary care services, is conferred directly on health boards under the NHS (Wales) Act 2006 ("the 2006 Act"). Health boards manage local lists of approved providers, referred to as pharmaceutical lists, and the inclusion of pharmacy premises on pharmaceutical lists entitles the pharmacy to provide NHS pharmaceutical services at those premises.

4.3 These arrangements govern the provision of NHS pharmaceutical services and not the right to open and conduct a pharmacy business in Wales. That is dealt with under separate UK-wide legislation, the Medicines Act 1968.

4.4 The Welsh Ministers have extensive powers and duties to make regulations and to issue directions to health boards, which govern the detail of the NHS pharmaceutical services system in Wales. This includes specifying the terms of service for NHS pharmacists and the application of the control of entry test, which is the test that must be satisfied before a health board may grant an application for entry, or amend an entry, on the pharmaceutical list.

4.5 Currently those persons wishing to provide NHS pharmaceutical services submit an application to the health board in accordance with the NHS (Pharmaceutical Services) (Wales) 2013 ("the 2013 Regulations"). The health board then decides whether or not the application satisfies the relevant test. The 2013 Regulations allow for the health board's decision to be challenged by submitting an appeal to the Welsh Ministers.

4.6 The current system of NHS pharmaceutical services delivery is therefore driven by those who wish to provide NHS pharmaceutical services. It is they who decide which services they wish to provide and from what location. This means that the current system is reactive to applications and health boards are not able to plan where pharmacies are located or direct which services must be provided from those locations.

Purpose of the Regulations

4.7 The primary purpose of these Regulations is to change the way in which pharmaceutical services are provided in Wales through the introduction of pharmaceutical needs assessments.

4.8 A pharmaceutical needs assessment is a statement of the assessment a health board must make, at least every 5 years, of the needs in its area for pharmaceutical services provided as part of the NHS in Wales.

4.9 The 2020 Regulations will introduce the requirement for health boards to conduct pharmaceutical needs assessments and, as a consequence, also change the criteria for making applications by those persons wishing to provide NHS pharmaceutical services in Wales. The Regulations will revoke and replace the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (“the 2013 Regulations”) which, in Wales, govern the provision of pharmaceutical services as part of the National Health Service.

Intended effect of the provisions

4.10 The intended effect of introducing pharmaceutical needs assessments is to improve the planning and delivery of pharmaceutical services by ensuring the health boards robustly consider the pharmaceutical needs of their populations and align services more closely with them. This will require health boards to take a more integrated approach to identifying the pharmaceutical needs of populations, including considering the contribution of all pharmaceutical services providers (e.g. pharmacies and dispensing doctors). Health boards will use these assessments to identify where additional pharmacies are required; where existing providers are adequately addressing pharmaceutical needs; and where additional services are required from existing pharmacies.

4.11 The change will provide pharmacy contractors with increased certainty, reducing business risk and allowing them to invest in the delivery of wider services than they do currently.

4.12 Importantly, pharmacies will also become more responsive to the needs of the populations they serve, and provide services effectively to address identified pharmaceutical needs. Where there is a lack of quality or consistent delivery, health boards will be able to implement improvement measures. These could include taking action against particular pharmacies for persistent breaches of terms and conditions of service. This should result in pharmacies providing services more consistently and to a higher standard, and ensure that pharmacies provide services in locations where they are needed. These changes will also make decisions about the inclusion of new pharmacies onto the pharmaceutical lists more transparent. Ultimately, the changes will allow for improvement in the quality and consistency of NHS pharmaceutical services across Wales.

4.13 The Regulations set out the requirement for health boards to prepare and maintain pharmaceutical lists of NHS pharmacists and NHS appliance contractors who undertake to provide pharmaceutical services from premises in the area; and dispensing doctor lists of doctors who undertake to provide pharmaceutical services from premises in the area. The Regulations also provide the terms of service on which persons are included in a pharmaceutical or dispensing doctor list and on which they undertake to provide pharmaceutical services as part of the National Health Service.

4.14 Provision is made that in certain circumstances doctors can provide pharmaceutical services to their patients who satisfy specific criteria. The types of applications in respect of pharmaceutical lists are also set out and the criteria which they must satisfy in order to be granted.

4.15 The Regulations also introduce arrangements for dealing with breaches of terms of service by NHS pharmacists and NHS appliance contractors.

4.16 As previously noted, there is also a significant retention of provisions from the 2013 Regulations within the 2020 Regulations.

5. Consultation

5.1 A public consultation on the draft 2020 Regulations was conducted over an 8 week period from 30 September to 25 November 2019.

5.2 The consultation set out in detail those changes to the current regulatory framework, but did not cover every provision of the draft 2020 Regulations as not all provisions require updating from the 2013 Regulations.

5.3 The consultation sought the views of health boards, persons who may apply to provide NHS pharmaceutical services or dispensing doctor services, professional bodies with an interest in NHS pharmaceutical services, as well as other stakeholders and the wider public on the draft 2020 Regulations proposed by the Welsh Ministers.

5.4 On 11th October 2019 a stakeholder engagement event was held at the Welsh Government offices in Cardiff. It was attended by a variety of community pharmacy, primary care and health board representatives.

5.5 Nineteen responses to the formal consultation exercise were received from retail pharmacy companies; representative organisations and individuals. The responses were largely in support of the proposals presented in the consultation document and proposed draft Regulations.

5.6 A number of respondents were concerned about the time period in which health boards had to conduct and publish their first pharmaceutical needs assessment and requested this be extended. Officials considered these concerns and subsequently amended the draft regulations to allow a health board 12 months to complete and publish their pharmaceutical needs assessment from the coming into force of the 2020 Regulations. This means health boards will have to complete and publish their PNA by 1 October 2021 and from then all applications for inclusion on or amendment to the pharmaceutical lists must be determined against the relevant PNA.

5.7 An analysis of the responses received, and the Welsh Government's response, is included in the Consultation Response document, which can be seen on the Welsh Government website: <https://gov.wales/sites/default/files/consultations/2020-01/national-health-service-pharmaceutical-services-wales-regulations-2020-summary-of-responses.pdf>

PART 2 – REGULATORY IMPACT ASSESSMENT

Regulatory Impact Assessment which relates to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

Introduction

This Regulatory Impact Assessment (RIA) has been developed to consider the implications of introducing the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (“the Regulations”). The principal effect on the provision of pharmaceutical services in Wales brought about by the Regulations is to prescribe the requirement for health boards to produce pharmaceutical needs assessments.

Cost and Benefit Considerations

Detailed consideration of the costs and benefits of the introduction of pharmaceutical needs assessments were considered during the development of Part 7 of the Public Health (Wales) Act 2017 and as such feature in the RIA for the Public Health (Wales) Bill – Pharmaceutical Services Part 6 (as it was then known and which became an Act upon receiving Royal Assent on 3 July 2017) is available on the Senedd website¹. The analysis conducted during the passage of the Bill remains valid and therefore, for the purposes of the Regulations the costs and benefits are summarised in this RIA and updated where more recent data is available.

Options

The Public Health (Wales) Bill set out three policy options in respect of the provision of pharmaceutical services:

- **Option one** - Do nothing – make no change to the current system of provision of pharmaceutical services.
- **Option two (Recommended Option)** – Amend the 2006 Act to enable the Welsh Ministers to make regulations which would replace the current system with needs based entry using pharmaceutical needs assessments (PNAs), and introduce performance related sanctions and a market exit regime that allows effective action to be taken against under-performing providers or those in breach of terms of service.
- **Option three** – Abolish control-of-entry arrangements and allow free market for the provision of NHS pharmaceutical services.

Option two (the Recommended Option) was enacted in the Public Health (Wales) Act 2017.

For the purposes of the Regulations, this EM/RIA therefore considers two options:

- **Option One** – Do nothing.
- **Option Two (the recommended option)** – Use the newly conferred powers within sections 82A and 83 of the 2006 Act (in conjunction with other pre-existing powers) to

¹ <http://www.assembly.wales/laid%20documents/pri-ld10796-em/pri-ld10796-em-e.pdf>

make regulations to introduce pharmaceutical needs assessments and a market exit regime in Wales.

Option One – Do Nothing

Description

There would be no change to the current legislation under this option. This would mean that those persons wishing to provide NHS pharmaceutical services would still be required to submit an application to the health board in accordance with the 2013 Regulations. The health board would continue to decide whether or not the application satisfies the relevant test and being reactive to applications and not able to plan where pharmacies are located or direct which services must be provided from those locations. Health boards would continue to not be able to respond appropriately to the pharmaceutical needs of their populations.

Under this option, no policy changes would be made and the overall number of pharmacies in Wales would remain stable as the current arrangements would continue to act as a barrier to market entry. There would be a very gradual increase in the numbers of pharmacies which provide additional services.

There would continue to be variation in the planning of pharmaceutical services by health boards and service commissioning would continue to be disparate. Those pharmacies which currently choose not to provide additional services would continue to resist requests to enhance their service offer, to the detriment of local populations. The high proportion of applications to provide NHS pharmaceutical services resulting in appeals to Welsh Ministers would persist.

Costs

Note: Each quantum in this analysis has been rounded to the nearest £100.

Welsh Government

As this option proposes no change, there would be no additional costs to the Welsh Government. Welsh Ministers would continue to determine appeals made against the decisions of health boards, both in relation to applications to provide NHS pharmaceutical services and breaches of terms of service. Costs would therefore be the same as they are now and would be related to Welsh Ministers' duties to determine these appeals. The costs of an appeal to the NHS Litigation Authority under arrangements in England, which at the time were analogous to the arrangements in Wales, have previously been estimated at approximately £6,000 per appeal² (at 2007-08 prices – uplifted for inflation £7,300 at 2018-19 prices³), this being the latest information available. Albeit infrequently, on occasion the decisions of Welsh Ministers on appeal would be subject to challenge through judicial review⁴. From experience of previous reviews the costs of a judicial review are estimated at £30,000.

² Department of Health (2008). Impact assessment of proposals to reform 'market entry' based on pharmaceutical needs assessment. DH. London.

³ GDP Deflator Series 2018-19 (<https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-december-2019-quarterly-national-accounts>)

⁴There has been only one such judicial review in the last six years.

Health boards

Health boards would continue to determine applications made by people wishing to provide NHS pharmaceutical services against the existing statutory tests. There were 10 such applications in 2018-19⁵. Health boards would also continue to determine alleged breaches of terms of service when asked to do so by other health boards. The current situation requires applicants to pay a fee in relation to their application in order to defray the costs incurred by NHS Wales in reaching a decision. This fee is currently set at £600⁶ for full applications to provide pharmaceutical services with a lower fee for changes of ownership, which are associated with less administrative work for health boards. While these fees may change over time they would continue to be set at a level which is proportionate to the work health boards must undertake to determine each application. Costs would therefore be the same as they are now.

Others

There would be no additional costs associated with this option for others such as existing pharmacy contractors, local pharmaceutical committees, local medical councils or community health councils, all of which may make representations in relation to applications to be included in the pharmaceutical list. Neither would there be additional costs for patients. Any costs associated with the current system would continue.

Benefits

There are no additional benefits from this option.

No additional benefits would accrue as a result of this option relative to the current position.

Conclusion

The option to do nothing is not considered sufficient or appropriate as health boards would continue to have no effective means of planning the provision of pharmaceutical services in relation to their population needs. Knowledge of the population's need for pharmaceutical services across Wales will remain limited.

Option 2 - Replace the current system with needs based entry using pharmaceutical needs assessments (PNAs), and introduce an exit regime that allows effective action to be taken against under-performing providers or those in breach of terms of service

Description

This option introduces pharmaceutical needs assessments and a market exit regime in Wales. The Regulations would require health boards to produce and publish an assessment of the pharmaceutical needs for their areas and to subsequently use that assessment to determine applications from persons wishing to provide NHS pharmaceutical services. They would also

⁵ <https://gov.wales/sites/default/files/statistics-and-research/2019-10/community-pharmacy-services-april-2018-march-2019.pdf>

⁶In determining the fee to be paid by persons applying to be included in the pharmaceutical list, the NHS Wales Shared Services Partnership (NHSWSSP) estimated the associated cost to NHS Wales to be £600 per application at the time of introduction in 2013.

introduce a system of market exit which would allow health boards to address poorly performing providers of pharmaceutical services.

Pharmacies wishing to be permitted to provide NHS services would be allowed to do so only if they are able to demonstrate that there is a particular unmet local need or service requirement that, in allowing them to provide pharmaceutical services, could be met.

Costs

Welsh Government

The costs to the Welsh Government to announce the coming into force of these Regulations in October 2020, along with the production and distribution of non-statutory guidance to support health boards in producing a pharmaceutical needs assessment and determining applications for market entry, were identified in the RIA for the 2017 Act.

A small scale communication exercise with key stakeholders will need to be undertaken to introduce these Regulations. This exercise will notify those key stakeholders of the new Regulations and make them aware of the requirements of pharmaceutical needs assessments and the market exit regime. Communication will take place via a number of existing and different bilingual modes, such as emails and letters to respective stakeholders as appropriate.

Staffing costs to produce the guidance (based on 18,000 words), including engaging stakeholders to ensure the guidance is fit for purpose, are estimated at approximately £6,000. This is based on approximately 25 days of a FTE executive officer (£28,200⁷ to develop the guidance) and contracted provision from Primary Care Commissioning (PCC) to review and contribute to drafting guidance at a cost of £2,800. It is estimated that translation and proofreading would cost approximately £1,700⁸. The guidance would be published in an electronic format only. There would therefore be no publishing costs.

The number of appeals to Welsh Ministers in any period is subject to significant variation. Appeals received in one year might be considered in the subsequent year and in some cases, such as those involving judicial review, appeal decisions may be delayed further. The average number of appeals determined by Welsh Ministers is estimated to be an average of 4 per annum based on the number of appeals determined as below.

Year	2015-16	2016-17	2017-18	2018-19
Number of appeals determined	7	3	2	4

The costs of an appeal to the NHS Litigation Authority under arrangements in England, which at the time were analogous to the arrangements in Wales, have previously been estimated at approximately £6,000 per appeal⁹ (£7,300 uprated for inflation¹⁰). The number of appeals

⁷ Based on Welsh Government staff planning costs @ April 2019 and rounded to nearest £100

⁸ Based on £75 per 1000 words for translation £21 per 1000 words for proofreading.

⁹ Department of Health (2008). *Impact assessment of proposals to reform 'market entry' based on pharmaceutical needs assessment*. DH. London.

¹⁰ <https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-december-2019-quarterly-national-accounts>

being determined in 2019-20 is expected to remain at 4. This would give a total annual cost of £29,200 to the Welsh Ministers in determining 4 appeals in 2019-20. Following the introduction of pharmaceutical needs assessment it is expected that there will be a most likely case scenario reduction of 25%

Cost Savings to Welsh Government

The Welsh Ministers are responsible for determining appeals made against the health boards' decisions in regard of applications for inclusion or amendment to the pharmaceutical and dispensing doctor lists. Under the current arrangements the Welsh Government expects to determine circa 4 appeals per annum.

It is expected the number of appeals against health board decisions would reduce but there is uncertainty in estimating how many appeals would be made following the changes. This is because health board decisions would be more transparent and better understood but also because having a PNA in place is expected to lead to fewer speculative applications in the first place. This is because it would be immediately apparent from a health board's PNA that additional pharmaceutical services are not needed.

For the purpose of this RIA a range of potential scenarios are provided in the table below, representing the best, worst and most likely case scenarios following the change. Health boards will be required to consider applications for inclusion in the pharmaceutical list against the criteria of the 2020 Regulations from October 2021. It is assumed that all appeals outstanding under the existing regime would be dealt with during 2020 - 21.

Year	2019-20	2020-21	2021-2022	2022-23
Appeals expected under current regime	4	4	4	4
Estimated cost of appeals (£ 000s)	29,200	29,200	29,200	29,200
Reduction in appeals under new regime (best case)	0%	50%	50%	50%
Reduction in appeals under new regime (worst case)	0%	0%	0%	0%
Reduction in appeals under new regime (most likely case)	0%	25%	25%	25%
Estimated savings under	0	14,600	14,600	14,600

new regime (£) (best case)				
Estimated savings under new regime (£) (worst case)	0	0	0	0
Estimated savings under new regime (£) (most likely case)	0	7,300	7,300	7,300

Under the most likely case scenario a 25% reduction in the number of appeals determined by the Welsh Ministers is expected. This would result in estimated savings of £7,300 per annum from 2020 – 21.

Health Boards

Cost of completing PNAs

It is assumed that completing a PNA would require input from one senior manager from a health board for 60 days and one administrative support officer for 20 days. Their annual salaries are valued at the mid-point of the Agenda for Change bands 8b and 4 at £80,600 and £31,400 (Agenda for Change 2020-21 and uplifted by 30% to account for on-costs). It is assumed three public meetings would be required to publicise and consult upon a PNA at a cost of £600 per meeting, adding £1,800 to costs. The direct cost to each health board to produce a PNA would therefore be £26,700. The first round of PNAs would be expected to be undertaken in 2020-21.

A PNA would need to be comprehensively reviewed every 5 years; it is estimated the costs outlined above would be repeated for this work. Additionally, it has been assumed that health boards will make small scale updates to their PNA in the intervening years between the comprehensive reviews, taking 5 days of senior management time and 5 days of administrative support. The cost per update would therefore be approximately £2,500 per health board.

Summary of estimated costs of completing PNAs for each health board

Cost Element	Initial Year (£s)	Intervening Years per annum (£s)
Band 8b Salary	22,000	1,800
Band 4 Salary	2,900	700
Public meetings	1,800	0
Total	26,700	2,500
Total across Wales	186,900	17,500

There would be no formal requirement to do so, however due to the technical nature of the process it is envisaged that health boards may wish to establish a steering group to oversee

the completion of their PNAs. It has been assumed that each health board would involve the community health council, community pharmacy contractors, GPs (including dispensing GPs) and representatives from the local public health team. It is estimated that three people from each group would be involved in attending up to five half-day meetings in the first year, and every fifth year thereafter. In intervening years it is estimated that they would only meet twice.

Costs for attending local steering group meetings are estimated at the opportunity cost of time, uplifted by 30% for on-costs. Patient time is evaluated at UK weekly median earnings at April 2019 (£760 per week)¹¹, GP time is evaluated at average GP gross earnings and expenses (£271,300 per annum (2017-18)) as reported by NHS Digital (29 August 2019)¹². Pharmacist time is evaluated at mean pharmacist salary (£37,100 per annum, uprated to £48,300 for on – costs (Office National Statistics Annual Survey of Hours and Earnings 2019)¹³. Local public health team personnel’s time has been estimated at the mid-point of the Agenda for Change bands 8a (£51,700 per annum (2020 - 21)¹⁴. The costs of individuals’ time in supporting each health board in performing its PNA amount to £13,800 per health board in the first year and in each year in which the PNA is comprehensively updated, and £5,500 per health board in intervening years.

Summary of estimated Steering Group Costs for each health board

Cost element	Initial Year (£s)	Intervening Years per annum (£s)
Patient (x 3 persons)	1,200	500
GP (x 3 persons)	9,200	3,700
Public Health (x 3 persons)	1,800	700
Pharmacist (x 3 persons)	1,600	700
Total	13,800	5,600
Total across Wales	96,600	39,200

Each PNA would be published in an electronic format only. There would therefore be no publishing costs.

In addition to developing the PNA there would be associated translation costs. It is estimated that this would cost approximately £600 per health board for each comprehensive update (based on 6,000 words) and £100 for each intervening year (based on 1,000 words)⁸.

¹¹<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/annualsurveyofhoursandearnings/2019>

¹²<https://digital.nhs.uk/data-and-information/publications/statistical/gp-earnings-and-expenses-estimates/2017-18/chapter-2>

¹³<https://www.ons.gov.uk/redir/eyJhbGciOiJIUzI1NiJ9.eyJpbmRleCI6MTAsInBhZ2VtaXpljoxMCwicGFnZSI6MiwidXJlpljoilL2VtCgXveW1lbnRhbmsRyYwJvdXJtYXJrZXQvcGVvcGxlaW53b3JrL2Vhcm5pbmdzYW5kd29ya2luZ2hvdXJzL2RhdGFzZXRL3JlZ2l2bWJ5b2NjdXBhdGlvbjRkaWdpdHNvYzlwMTBhc2hldGFibGUxNSIsImxpc3RUeXBlljoicmVsYXRIZGRhdGEifQ.fFThv6FEXU0inte3Mc4jZDI3FtoTscDyddGdm2-8Pns>

¹⁴<https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nhsconfed.org%2F-%2Fmedia%2FConfederation%2FFiles%2FWales-Confed%2FWales-Employers%2FFINAL-Framework-agreement-21-March-2018-amended-for-NHS-Wales-28-9-18.pdf%3Fla%3Den%26hash%3D60EF8EA28C962C12BF101C3C5E4D2AE3EBAC156B&data=02%7C01%7CMark.Welsby%40gov.wales%7Ce1b170eec8124f41a96408d79e92a726%7Ca2cc36c592804ae78887d06dab89216b%7C0%7C0%7C637152225016129043&sdata=yNHK0gm5SmaKulr5FACY23Oq%2FkBVNv%2F0NG0uv05YGA%3D&reserved=0>

Therefore, the total cost of PNAs for all health boards (including costs of the steering group) is estimated at £ 284,100 every five years and £56,800 for each intervening year. This equates to estimated costs per health board of £ 40,600 every five years and £ 8,100 for each intervening year.

Cost to health boards in undertaking performance management

Health boards already carry out performance management of pharmacy contractors as part of the current NHS pharmaceutical services contractual framework. It is assumed no additional costs would be incurred in identifying those against which action should be considered.

Based on discussions with health boards it is estimated action might be taken against up to five pharmacy contractors each year. Each action would incur staff costs of assembling additional information to identify poor quality contractors, managing the disciplinary process and defending any appeals – which are assumed, as a worst-case scenario, to be made against all actions. It is assumed this process would require a total of one senior manager and one administrative support officer from a health board for up to 10 days – annual salaries are valued at the mid-point of the Agenda for Change bands 8b and 4 at £80,600 and £31,400 (Agenda for Change 2020-21 and uplifted by 30% to account for on-costs). Based on previous experience if similar performance management systems legal costs at an average of £3,900 per case are assumed. The total resulting annual cost to health boards is therefore estimated at £24,600.

Summary of estimated costs to each health board of performance management

Cost Element	Year (£s)
Band 8b Salary	3,700
Band 4 Salary	1,400
Legal costs	19,500
Total	24,600

Cost arising from commissioning additional services to meet pharmaceutical needs

The costs arising from commissioning additional services would be dependent on what - if any – unmet needs are identified in each PNA. If a PNA identifies no unmet pharmaceutical need, there would be no additional cost.

It is assumed that the delivery of enhanced services, where necessary, will reflect the pharmaceutical needs of the local population. Health boards would be able to influence the quality of service provision and patient access by commissioning services in locations of greatest need. Therefore, PNAs could result in health boards commissioning more services from existing providers as well as from new entrants. Assuming that a robust PNA would lead to further commissioning of services to meet the needs of the local population, there would be costs to the health boards to provide these services.

There is considerable variation in the extent to which health boards commission additional pharmaceutical services. There are a number of reasons for this, not least that some services will be provided by providers other than pharmacies - however, it is considered that, at least in part, some of the variation can be put down to institutional factors, including health board commissioning decisions not being aligned to the pharmaceutical needs of their local

populations. This view is supported by evidence provided to the Senedd’s health and social care committee in the Fourth Assembly during its inquiry into the contribution of community pharmacy to health services in Wales¹⁵.

In the absence of PNAs there is no means by which to objectively quantify the extent to which needs are currently being met. The cost to provide the additional pharmaceutical services is therefore unknown at this stage.

Summary of estimated costs to each health board

Year	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
<u>Cost of completing PNAs</u>	<u>£40,600</u>	<u>£8,100</u>	<u>£8,100</u>	<u>£8,100</u>	<u>£8,100</u>	<u>£40,600</u>
<u>Cost of undertaking performance management</u>	<u>£24,600</u>	<u>£24,600</u>	<u>£24,600</u>	<u>£24,600</u>	<u>£24,600</u>	<u>£24,600</u>
<u>Total for each health board</u>	<u>£65,200</u>	<u>£32,700</u>	<u>£32,700</u>	<u>£32,700</u>	<u>£32,700</u>	<u>£65,200</u>
<u>Total across Wales</u>	<u>£456,400</u>	<u>£228,900</u>	<u>£228,900</u>	<u>£228,900</u>	<u>£228,900</u>	<u>£456,400</u>

Others

Cost savings resulting from fewer applications

Currently a person wishing to provide NHS pharmaceutical services must make an application to the relevant health board to do so. Prospective applicants must make their own judgement about the pharmaceutical needs of the population that would be served by the pharmacy they propose to open and the adequacy of existing pharmaceutical services. Under this option, in the future applicants would be able to refer to the health board’s PNA when deciding whether or not to make an application. More than half of all applications (excluding those relating to minor relocations) made to health boards are currently refused (59% in 2013-14), therefore it is envisaged that a proportion of applications that would be made under the current system would not be made in future. This is because it would be immediately apparent from a health board’s PNA that additional pharmaceutical services are not needed.

Applicants currently pay a fee on each occasion they make an application to be included in a health board’s pharmaceutical list. The fee for a new inclusion is currently £600. It is expected that while the number of applications that are unlikely to succeed would reduce, this would be offset by an increase in applications which are not made currently but where a need identified in the PNA prompts one. It is estimated that there will be a zero net change in the number of applications. It is expected that some potential applicants would benefit relative to the current arrangements because applications would be more likely to be successful. The actual scale of the benefits will be dependent on the proportion of applications made which are successful, and so the precise savings are currently unknown.

¹⁵ National Assembly for Wales (2012). Inquiry into the contribution of community pharmacy to health services in Wales. NAW, Cardiff. <http://www.senedd.assembly.wales/mgIssueHistoryHome.aspx?IId=1532>

Contractor compliance cost

Contractors are expected to incur costs in providing the information required for assessment by health boards. It is expected that most contractors already undertake this work in order to fulfil their existing obligations for performance monitoring. However, a small number of contractors do not undertake this work and these would therefore incur additional costs. It is estimated that for 10% of contractors (approximately 70), this would represent additional workload and cost. The time taken to demonstrate compliance is estimated to be 5 days per year. If the work is carried out by a pharmacy technician, whose time costs £700 per 5 days (including on-costs)¹⁶, and there are 70 contractors to which this applies, the annual costs would be £ 49,000 per annum from 2020-21.

Contractor costs of defending actions in respect of performance management

It is assumed that a contractor defending an action would incur approximately the same costs as a health board bringing the action. This results in annual costs of £24,600 from 2020-21.

Costs to existing contractors through lost profits

It is assumed any profits lost by contractors no longer supplying the NHS would be directly offset by the profits gained by existing contractors or new entrants that replace them.

Summary of estimated costs to Contractors

Year	2020-21	2021-22	2022-23	2023-24	2024-25	2025-2026
Compliance costs	£49,000	£ 49,000	£ 49,000	£ 49,000	£ 49,000	£ 49,000
Cost of defending actions	£ 24,600	£ 24,600	£ 24,600	£ 24,600	£ 24,600	£ 24,600
Total	£ 73,600	£ 73,600	£ 73,600	£ 73,600	£ 73,600	£ 73,600

Summary of costs associated with Option 2

Year	2019-20	2020-21	2021-22	2022-23
Welsh Government	£71,900	£21,900	£21,900	£21,900
All Health Boards	£0	£456,400	£228,900	£228,900
Contractors	£0	£ 73,600	£ 73,600	£ 73,600
Total	£ 71,900	£ 551,900	£ 324,400	£ 324,400

¹⁶ Based on top of scale agenda for change band 4 plus 30% on cost

Benefits

Health Board

Giving health boards the power to take appropriate action against poor-performing contractors is expected to improve service quality, by improving the standards of poor and under-performing providers or withdrawing their right to provide NHS services and by creating a universal incentive to raise standards.

It is not possible to forecast the value of the patient benefit likely to result from these measures. In order to evaluate whether the benefits outweigh the costs, it is therefore necessary to construct a credible, conservative scenario, which underestimates the likely net benefit of the measures. Accordingly the benefits associated with strengthened exit arrangements have not been quantified.

Others Savings

Under the new arrangements retail pharmacy businesses will be able to clearly identify where applications to open new premises and move existing premises are likely to be granted by the health board. Applicants will therefore no longer make speculative applications without knowing the likelihood of whether they will be granted. This will mean savings to the applicant from the application fee and in the uncertainty of entering into lease arrangements on premises prior to knowing whether an application has been granted.

It is not envisaged that there would be any net dis-benefit for pharmacy contractors, since any dis-benefits to existing contractors would be offset by equal benefits to the new entrants.

Social benefits

It is anticipated this option also would bring about further indirect benefits. In particular it is envisaged that increasing these services would lead to reductions in travel time and inconvenience for individuals and may lead to a more efficient use of health services, including freeing up GP consultation time, allowing them to spend more time with people with more complex conditions. Economic benefits to local communities would also be expected where new pharmacies are established. Community pharmacies have been identified as one of the essential businesses which are key to economic prosperity in communities¹⁷. New entrants will therefore contribute to sustaining local communities, providing shopping access, local employment and building social capital. However, these social benefits cannot be quantified financially.

SUMMARY AND PREFERRED OPTION

Option One would maintain the overall number of pharmacies in Wales at a stable level as the current arrangements would continue to act as a barrier to market entry.

Option one proposes no change to current arrangements but responses to a previous consultation¹⁸ on control-of-entry in Wales suggests there is a consensus these arrangements are outdated and inadequate. In general, stakeholders recognise and support the need for change.

¹⁷ Department of Health. (1999) Improving Shopping Access for People Living in Deprived Neighbourhoods – a paper for discussion. DH. London.

¹⁸ Welsh Government (2011). Proposals to reform and modernise NHS Pharmaceutical Services in Wales

Option Two The evidence demonstrates the benefits of changing the current control-of-entry arrangements in Wales. The introduction of PNA and needs-based entry arrangements would address the current situation where pharmaceutical needs may not be routinely assessed and where pharmaceutical service planning is not necessarily aligned to identified health needs. The changes would also strengthen the role of health boards in determining where and by whom such services are provided, and provide performance management tools to improve the quality and consistency of service provision by pharmacy contractors.

The introduction of PNA and needs-based entry arrangements addresses the current situation where pharmaceutical needs may not be routinely assessed and where pharmaceutical service planning is not necessarily aligned to identified health needs. The changes also strengthen the role of health boards in determining where and by whom such services are provided, and provide performance management tools to improve the quality and consistency of service provision by pharmacy contractors. Also improved is the potential for health boards to effectively plan pharmaceutical services to meet the needs of the local population.

Option two is therefore the preferred option, as it addresses the need for better planning, addressing local population pharmaceutical needs, improved decision making and performance management, with the benefits of the change outweighing the costs.

Competition Assessment

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

The above competition filter test does not indicate the need for a full competition assessment. There are no detrimental effects on competition expected.