

WELSH GOVERNMENT INTEGRATED IMPACT ASSESSMENT

Title of proposal:	NHS (PHARMACEUTICAL SERVICES) (WALES) REGULATIONS 2020 – INTRODUCING PHARMACEUTICAL NEEDS ASSESSMENT IN WALES
Official(s) completing the Integrated Impact Assessment (name(s) and name of team):	Mark Welsby Pharmacy and Prescribing Branch Primary Care and Health Science
Department:	Health and Social Services Group
Head of Division/SRO (name):	Alex Slade, Deputy Director Primary Care
Cabinet Secretary/Minister responsible:	Vaughan Gething, Minister for Health and Social Services
Start Date:	

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SECTION 1. WHAT ACTION IS THE WELSH GOVERNMENT CONSIDERING AND WHY?

Provisions were made in the NHS Public Health Act (2017) to make regulations which introduce pharmaceutical needs assessment in Wales. These regulations will set out the requirements for pharmaceutical needs assessments and combine this with the parts of the existing NHS (Pharmaceutical Services Regulations)(Wales) 2013 that will still be required eg Terms of Service for Pharmacists and the system of entry onto the pharmaceutical list and amendments to that list.

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

The intended effect of introducing pharmaceutical needs assessments is to improve the planning and delivery of pharmaceutical services by ensuring that health boards robustly consider the pharmaceutical needs of their populations and align services more closely with them. The policy proposals make a fundamental change to the way in which decisions about pharmaceutical services are made by health boards, shifting from one driven by applications from pharmacy contractors and focused heavily on the dispensing of prescriptions, to one which is alert and responsive to the broader pharmaceutical needs of local communities.

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.

Long term

One of the four key themes in 'Prosperity for All' is 'Healthy and Active', with the Welsh Government's stated aim being to improve health and wellbeing for the citizens of Wales. Our health and social care services are critical to delivering this overarching objective, and *A Healthier Wales* sets out the ways in which we expect them to support it, both through the provision of effective and sustainable health and care services, and by requiring them to place greater emphasis on prevention and early intervention with the aim of promoting healthy lifestyles and reducing health inequalities.

The current regulatory regime and approach has been in place for more than 27 years and does not adequately reflect the way in which the role of pharmacies has changed in that time. In the last 10 years community pharmacy numbers in Wales have been largely

unchanged, however prescription volumes have grown by over 40% (from 53.1 million in 2005/6 to 74.7 million in 2017/18)¹.

Pharmacies will 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, or inviting additional pharmacies to apply to provide particular services. This should result in pharmacies providing services more consistently and to a higher standard, and ensure that pharmacies provide services in locations where they are needed. These changes will also make decisions about the entry of new pharmacies more transparent.

Prevention

Changes proposed will increase the effectiveness of planning for, and delivery of, community pharmacy services and will impact positively on tackling poor health for communities across Wales, including the most deprived areas.

Around 74.7 million prescriptions¹ are dispensed in community pharmacies in Wales every year. Community pharmacies also provide a convenient and less formal environment for those who cannot or do not wish to visit other kinds of health services, e.g. many provide emergency contraception, smoking cessation and sexual health advice. Preventative measures such as providing health and wellbeing advice in a readily accessible and professional environment will help address such issues.

Ensuring an appropriate spread of community pharmacies providing the range of services needed by local people, will also help reduce environmental impacts by providing services closer to home, by encouraging pharmacy locations to be accessible by public transport, and by reducing the need for additional car journeys,

Integration

PNAs 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.

The introduction of pharmaceutical needs assessment will enable pharmacies to provide services previously provided by GP and hospital services and therefore help relieve pressure on those services. This supports the move to a wider primary care offer.

The WFG Act provides for a set of integrated well-being goals for Wales. In addition to a specific well-being goal of a 'healthier Wales', which describes a society in which people's physical and mental well-being is maximised, there are strong links to the aspirations of other goals such as 'a more equal Wales' and 'a Wales of cohesive communities'.

¹ Statistics for Wales release (<https://gov.wales/community-pharmacy-services-april-2017-march-2018>)

The amended regulations allow health boards to focus on improved quality as well as securing better value for money. This contributes to the Future Generation Goals:

- a resilient Wales - by ensuring public bodies work in partnership to effectively plan the delivery of preventative services, making communities resilient to care and support needs;
- a healthier Wales - by ensuring public bodies work in partnership to effectively plan the delivery of care and support services to improve peoples' health and well-being;
- a more equal Wales - by ensuring public bodies work in partnership to effectively plan the delivery of services to meet the care and support needs of the local population and help people to meet their objectives and fulfil their potential.

Collaboration

The partners with a shared interest in this proposal include Health Boards, Community pharmacies; Dispensing doctors; Dispensing appliance contractors.

The overall policy of whether PNA should be introduced in Wales was set out and consulted on in 2012 during the policy consultation relating to the amendment of the NHS (Pharmaceutical Services) Regulations 1992, which were subsequently revoked and replaced by the NHS (Pharmaceutical Services) Wales Regulations 2013.

A wide range of stakeholders representing health boards, community pharmacy and dispensing doctors were engaged during 2017-18 through a formal working group to develop the detailed requirements for developing legislation to introduce PNA in Wales and make appropriate changes to the control of entry system. The draft Regulations will be published for formal public consultation.

Involvement

As noted above, partners affected by the proposal have been engaged in developing the proposal. The working group will continue to support the development of detailed policy and guidance throughout the lifetime of the project, including review of draft regulations and guidance.

Impact

The arguments for introducing amending regulations and guidance are set out in the Regulatory Impact Assessment for the for the Public Health Bill – Pharmaceutical Services Part 6, which received Royal Assent on 3 July 2017.²

Costs and Savings

The benefits, costs and risks associated with these new regulations and guidance have been set out in the Regulatory Impact Assessment for the Public Health Bill – Pharmaceutical Services Part 6, which received Royal Assent on 3 July 2017.

² <http://www.assembly.wales/laid%20documents/pri-ld10796-em/pri-ld10796-em-e.pdf>

There are no new costs for Welsh Government directly associated with this proposal. Whilst the Welsh Government establishes the overall structure in which community pharmacies operate by providing the legislative and policy framework, the responsibility for planning and providing pharmaceutical services to meet the needs of their resident populations is vested in health boards. Health Boards therefore already have this responsibility and whilst the development, consultation and publication of a PNA will be a new procedural requirement it will not confer any additional burden compared to their current responsibilities. This, therefore, would be met from existing Health Board budgets.

Mechanism

The proposals are for the introduction of new regulations relating to PNA as outlined in the Regulatory Impact Assessment for the Public Health Bill – Pharmaceutical Services Part 6, which received Royal Assent on 3 July 2017.

SECTION 2. WHAT WILL BE THE EFFECT ON SOCIAL WELL-BEING?

2.1 People and Communities

The intention of PNAs is to ensure pharmacies become more responsive to the needs of the populations they serve. Therefore, members of the public should be able to access an increased range of services and products closer to home, improving speed of, and access to, advice impacting positively on their health, and reducing the need to travel. This is likely to have a moderate positive impact on the general populace and specifically on older people, carers, those with disabilities and existing health conditions and families with young children who will have ready access to health and wellbeing advice and support.

The proposals are expected to have minimal effect on persons working within community pharmacies and dispensing doctor surgeries. However it is possible that some pharmacies, and therefore staff, may be required to relocate, though this is likely to be within a reasonable distance. As noted, there is potential for additional employment of local people as staff within pharmacies should new opportunities be identified in response to a PNA.

2.2 Children's Rights

The Rights of Children and Young Persons (Wales) Measure 2011 places a duty on all Welsh Ministers to have due regard to the substantive rights and obligations within UNCRC and its optional protocols when exercising any of their Ministerial functions. This means they need to consider all the issues which are relevant to the decisions they are making and do everything possible to ensure they further children's rights.

The UN Convention on the Rights of the Child (UNCRC) has been considered in developing pharmaceutical needs assessment policy.

Whilst there are no child or young person specific policies contained within PNA, access to NHS pharmaceutical services for children and young people are maximised through this proposal. The introduction of pharmaceutical needs assessment will help to maximise the outcomes within the articles of the UNCRC; particularly Article 24³. The provision of pharmaceutical services underpinned by a pharmaceutical needs assessment will support Article 24 as this type of service provision aims to ensure that the planning and delivery of these services appropriately meet the needs of local communities. This has the potential to have a range of positive benefits on the health and wellbeing of children and young people. Improving assessments of local pharmaceutical needs may lead to more pharmacies providing enhanced services, which may include medication for the treatment of minor ailments which are common in children, including constipation, earache, diarrhoea, hay fever, head lice, mild eczema, nappy rash and teething pain. At the other end of the age range, young people approaching or within the 16 to 18 age range may benefit from improved provision of emergency hormonal contraception and smoking cessation services.

³ Article 24: Children should have the right to good quality health care.

Specific engagement with children and young people has not been undertaken as the introduction of pharmaceutical needs assessment is, overall, a technical issue. The pharmaceutical needs assessments prepared by health boards will, however, be subject to public consultation. These provisions will therefore help support the rights of young people to express their views on matters which affect them. Article 12⁴ is therefore supported.

A Children's Rights Impact Assessment was completed in support of the Public Health (Wales) Act 2017, with a specific section (Part 6) on Pharmaceutical Services.
<https://gweddiill.gov.wales/topics/health/nhswales/act/?lang=en>

The impact on Children's Rights has been considered and remains unchanged.

2.3 Equality

An Equality Impact Assessment was completed in support of the Public Health (Wales) Act 2017, with a specific section (Part 6) on Pharmaceutical Services.
<https://gweddiill.gov.wales/topics/health/nhswales/act/?lang=en>

The impact on Equality has been considered and remains unchanged.

2.4 Rural Proofing

Improving the planning and delivery of **pharmaceutical services** will have positive impacts for rural areas. People in rural areas may rely more heavily on the services provided by community pharmacies if these are more accessible to them than other services. If gaps in services are identified in rural communities through pharmaceutical needs assessments, this should lead to steps being taken to ensure adequate provision.

Whilst the Welsh Government establishes the overall structure in which community pharmacies operate by providing the legislative and policy framework, the responsibility for planning and providing pharmaceutical services to meet the needs of their resident populations is vested in health boards.

In informing their PNA health boards will be required to assess the needs of local people to ensure there is sufficient provision of pharmacy services for people within rural communities.

2.5 Health

The introduction of pharmaceutical needs assessment will have a minimal positive impact on human health overall by virtue of the effects of wider determinants of health (Income,

⁴ Article 12: Children have the right to say what they think should happen when adults are making decisions that affect them, and have their opinion taken into account.

Crime, Environment, Transport, Housing, Education, Employment, Agriculture, Social cohesion).

Whilst the introduction of pharmaceutical needs assessment will allow health boards to identify a population's need for pharmaceutical services and commission services that relate to lifestyle related variables (physical activity, diet, smoking, drugs, or alcohol use and sexual behaviour), any increased demand is unlikely to have a negative impact on wider health and social care services.

The introduction of pharmaceutical needs assessment will allow health boards to identify situations where pharmacies are able to provide services previously provided by GP and hospital services and therefore help relieve pressure on those services. Access to a range of professional advice and services will therefore likely be increased, providing a positive impact on wider health services overall.

All community pharmacies are contracted to help promote healthy lifestyles, including the provision of healthy eating advice. Where pharmacies are accredited to provide enhanced services, such as smoking cessation services, this also supports healthier lifestyles.

The proposal is consistent with the developing Primary Care model, in which the social model of care requires a focus on wellbeing and prevention and an understanding the opportunities that exist across the health, social care and third sector workforce to support individuals in a more holistic way.

2.5b. Could there be a differential health impact on particular groups?

This is likely to have a moderate positive impact on the general populace and specifically on older people, carers, those with disabilities and existing health conditions and families with young children who will have ready access to health and wellbeing advice and support.

It is not, however, considered these proposals will have a significant differential impact on particular groups as pharmacy services are open and available to all within the community.

As noted previously, the overall policy of whether PNA should be introduced in Wales was set out and consulted on in 2012 during the policy consultation relating to the amendment of the NHS (Pharmaceutical Services) Regulations 1992, which were subsequently revoked and replaced by the NHS (Pharmaceutical Services) Wales Regulations 2013.

As the proposal seeks to amend existing regulations and will have a minimal impact on health it is not considered necessary to conduct a detailed health impact assessment.

2.6 Privacy

Each health board already has its own pharmaceutical list and so will already have data protection protocols in place in order to comply with their statutory duties. Data collected through the new pharmaceutical needs assessments are unlikely to contain any sensitive personal information or will have any relevant details anonymised.

SECTION 3. WHAT WILL BE THE EFFECT ON CULTURAL WELL-BEING AND THE WELSH LANGUAGE?

3.1 Cultural Well-being

The proposal has no impacts in respect of contributing to the goal to promote and protect culture and heritage and encourage people to participate in the arts sports and recreation.

3.2 Welsh Language

The regulations require health boards to consult on their PNA. In doing so, they will be subject to their own Welsh Language Scheme prepared in accordance with section 21 of the Welsh Language Act 1993.

A Welsh Language Impact Assessment was completed in support of the Public Health (Wales) Act 2017, with a specific section (Part 6) on Pharmaceutical Services.

<https://gweddill.gov.wales/topics/health/nhswales/act/?lang=en>

The impact on the Welsh Language has been considered and remains unchanged.

SECTION 4. WHAT WILL BE THE EFFECT ON ECONOMIC WELL-BEING?

Supporting growth in the Welsh economy, and through this tackling poverty, is at the heart of *Taking Wales Forward*, the Welsh Government's Programme for Government.

4.1 Business, the general public and individuals

It is considered the changes will have a moderate positive impact on pharmacy contractors, providing them with increased certainty, reducing business risk and allowing them to invest in the delivery of wider services than they do currently.

As previously noted in this Impact Assessment, the aim of the regulations is to ensure pharmacies become more responsive to the populations they serve through assessing their needs. In doing so, an increased range of services and products should be available and more accessible by being closer to home for members of the public.

There are no State Aid implications relating to this proposal.

4.2 Public Sector including local government and other public bodies

The regulations apply to all health boards in Wales. As the proposal seeks to amend existing regulations there will be a minimal impact on health boards. As noted under "Costs and Savings", whilst the development, consultation and publication of a PNA will be a new procedural requirement it will not confer any additional burden compared to their current responsibilities.

4.3 Third Sector

There are no direct implications for the third sector in respect of the regulations.

4.4 Justice Impact

The proposal will introduce new regulations requiring PNAs; it does not create, remove or amend an offence, nor bring forward new primary legislation nor will it have any other impacts on the justice system. Therefore no justice impact assessment has been completed.

SECTION 5. WHAT WILL BE THE EFFECT ON ENVIRONMENTAL WELL-BEING?

Under Section 9 of the Environment (Wales) Act 2016, the Welsh Ministers are required to prepare, publish and implement a natural resources policy and to take all reasonable steps to implement it and to encourage others to take such steps. The [Natural Resources Policy](#) was published in August 2017.

You will need to consider and, where required, complete the following assessments to ensure all reasonable steps have been taken:

Required for all proposals:	<ul style="list-style-type: none"> Natural Resources Policy national priorities, challenges and opportunities 	5.1a 5.1b
Required for all proposals	<ul style="list-style-type: none"> Biodiversity 	5.2 and Annex F
Required for all proposals	<ul style="list-style-type: none"> Climate Change 	5.3
Certain plans and programmes requiring SEA under the Environmental Assessment of Plans and Programmes (Wales) Regulations 2004	<ul style="list-style-type: none"> Strategic Environmental Assessment 	5.4 and IIA Guidance
Proposals which may affect a Special Area for Conservation or a Special Protected Area (SAC/SPA):	<ul style="list-style-type: none"> Habitats Regulations Assessment 	5.5 and IIA Guidance
Certain projects relating to town and country planning; transport; agriculture; forestry; marine, land drainage; and electricity which require EIA under the various EIA Regulations	<ul style="list-style-type: none"> Environmental Impact Assessment 	5.6 and IIA Guidance

5.1 Natural Resources

5.1a How will the proposal deliver one or more of the National Priorities in the Natural Resources Policy (NRP)?

The proposal will have no impact on the National Priorities in the Natural Resources Policy.

5.1b Does the proposal help tackle the following national challenges and opportunities for the sustainable management of natural resources?

N/A

5.2 Biodiversity

The Biodiversity Impact Assessment has been completed at annex A.

5.3 Climate Change

This proposal will have no direct impact on climate change or decarbonisation.

5.3a Decarbonisation

N/A

5.3 b Adaptation

N/A

5.4 Strategic Environmental Assessment (SEA)

There are no direct impacts to strategic environmental issues as a result of this proposal and therefore a SEA is not required.

5.5 Habitats Regulations Assessment (HRA)

There are no impacts to habitats regulations as a result of this proposal and therefore a HRA is not required.

5.6 Environmental Impact Assessment (EIA)

There are no environmental impacts as a result of this proposal and therefore an EIA is not required.

SECTION 6. RECORD OF FULL IMPACT ASSESSMENTS REQUIRED

You have now decided which areas need a more detailed impact assessment. Please list them below.

Impact Assessment	Yes/No	If yes, you should
Children's rights	Yes	A CRIA was completed in support of the Public Health (Wales) Act 2017, with a specific section (Part 6) on Pharmaceutical Services
Equality	Yes	An EIA was completed in support of the Public Health (Wales) Act 2017, with a specific section (Part 6) on Pharmaceutical Services
Rural Proofing	No	
Health	No	
Privacy	No	
Welsh Language	Yes	A WLIA was completed in support of the Public Health (Wales) Act 2017, with a specific section (Part 6) on Pharmaceutical Services
Economic / RIA	Yes	An EIA was completed in support of the Public Health (Wales) Act 2017, with a specific section (Part 6) on Pharmaceutical Services
Justice	No	
Biodiversity	Yes	See Annex A
Climate Change	No	
Strategic Environmental Assessment	No	
Habitat Regulations Assessment	No	

Environmental Impact Assessment	No	
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SECTION 7. CONCLUSION

(Please note that this section will be published)

7.1 How have people most likely to be affected by the proposal been involved in developing it?

The people most likely to be affected by the proposals are health boards and those persons who provide and those intend to provide pharmaceutical services in Wales. In 2010 the then Minister for Health and Social Services established a Task and Finish Group to:

- review the regulatory framework;
- consider Welsh Government policy on control of entry and the provision of pharmaceutical services by health professions other than pharmacists (e.g. doctors); and
- make recommendations for changes to legislation, if appropriate, to bring about a long term, cost effective and sustainable system which would afford patients appropriate access to pharmaceutical services.

In 2011 the Welsh Government consulted on the recommendations of the Task and Finish group. The consultation *Proposals to reform and modernise the National Health Service (Pharmaceutical Services) Regulations 1992* sought views on proposals to deliver a new approach for determining applications to provide NHS pharmaceutical services in Wales based more on an assessment of local needs by health boards.

The Welsh Government set up a working group to develop the detail of the draft 2020 Regulations which will introduce pharmaceutical needs assessment and, as a consequence, also change the criteria for making applications by those persons wishing to provide NHS pharmaceutical services in Wales. Membership of the working group was drawn from health board pharmacy leads and NHS Wales Shared Services Partnership.

Policy officials have also discussed the detailed proposals with Community Pharmacy Wales, the accepted representative body for retail pharmacists in Wales. Health board Directors of Primary Care and Directors of Public Health have been similarly engaged. The provision of pharmaceutical services is equal to all persons across all communities in Wales. The consultation in regard to the Public Health (Wales) Act 2017 was public and afforded an opportunity for response from:

- Children and their representatives;
- People with protected characteristics under the Equality Act 2010;
- Welsh speakers and Welsh language specialist groups; and,
- Other people who may be affected by the proposal.

7.2 What are the most significant impacts, positive and negative?

During the evidence provided on behalf of BMA Cymru Wales at the Health, Social Care and Sport Committee's evidence session on the Public Health (Wales) Bill on 15 December 2016 the then Minister for Social Services and Public Health was asked to provide assurance that the arrangements for the provision of pharmaceutical services by

dispensing doctors as set out in the NHS (Pharmaceutical Services)(Wales) Regulations 2013 would not change. This assurance was given and the arrangements for the provision of pharmaceutical services by dispensing doctors has not changed.

The introduction of pharmaceutical needs assessment will allow health boards to be better able to plan from where pharmaceutical services will be provided and to identify situations where pharmacies are able to provide services previously provided by GP and hospital services and therefore help relieve pressure on those services. Access to a range of professional advice and services will therefore likely be increased, providing a positive impact on wider health services overall.

Populations across Wales will benefit from an increase in the range of pharmaceutical services being provided.

The changes 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.

The introduction of pharmaceutical needs assessment will have a minimal positive impact on human health overall by virtue of the effects of wider determinants of health (Income, Crime, Environment, Transport, Housing, Education, Employment, Agriculture, Social cohesion).

Whilst the introduction of pharmaceutical needs assessment will allow health boards to identify a population's need for pharmaceutical services and commission services that relate to lifestyle related variables (physical activity, diet, smoking, drugs, or alcohol use and sexual behaviour), any increased demand is unlikely to have a negative impact on wider health and social care services.

7.3 In light of the impacts identified, how will the proposal:

- **maximise contribution to our well-being objectives and the seven well-being goals; and/or,**
- **avoid, reduce or mitigate any negative impacts?**

The introduction of pharmaceutical needs assessment across Wales will have a positive impacts on the Welsh Government well-being objectives promoting a healthier Wales. This will be achieved by improving access to a greater number of pharmaceutical services in a greater number of locations than are provided under the current system of determining what services are provided and from where. Improving access to pharmaceutical services will result in the better management of common ailments and chronic conditions closer to the patients' home.

A healthier population will contribute to a more prosperous and resilient Wales by increasing positive health outcomes of the working population, for example the common ailments service provided in community pharmacies can be expected to reduce the number of lost working days.

7.4 How will the impact of the proposal be monitored and evaluated as it progresses and when it concludes?

The Welsh Government will monitor levels of applications and appeals to assess whether the introduction of pharmaceutical needs assessment has a reducing effect. Officials will engage health boards for feedback on their experience of producing their first pharmaceutical needs assessment. Qualitative analysis will be undertaken to establish whether health boards have difficulty in conducting PNAs under the requirements of the 2020 regulations.

A similar process of engagement with providers of pharmaceutical services will be undertaken to establish their experiences of having to apply to provide pharmaceutical services under the pharmaceutical needs assessment system.

SECTION 8. DECLARATION

Declaration

I am satisfied that the impact of the proposed action has been adequately assessed and recorded.

Name of Senior Responsible Officer / Deputy Director: Alex Slade, Primary Care Division

Department: Health and Social Services

Date: 12 September 2019

A. BIODIVERSITY IMPACT ASSESSMENT

The factors of production involved in the provision of retail pharmacies and the pharmaceutical services they provide on a like for like basis will not change following the introduction of the pharmaceutical needs assessment.

Retail pharmacies are mostly located in built up urban areas and are unlikely to be located in sensitive habitats. A number of dispensing doctor premises may be more likely to be located in rural areas, however any general practitioner premises will be required to conform to relevant building and planning legislation.

There are no direct impacts in terms of the supporting indicators for sustainable resource use or sustaining the environment, including no impacts on biodiversity or Wales' ecological footprint, other than potential reductions in travel time resulting from the changes to pharmaceutical services.

It is therefore considered these proposals will have no impact on Biodiversity.