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Welsh Government
Consultation – summary of responses

National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

Consultation on draft Regulations

January 2020

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The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020

Audience	Local health boards, persons who may wish to apply to provide NHS pharmaceutical services and representative bodies.
Overview	Summary of responses to the Welsh Government's consultation on the draft National Health Service (Pharmaceutical Services) (Wales) Regulations 2020
Action Required	None – for information only
Further Information	Further enquiries about this document should be directed to: PNA Consultation Pharmacy & Prescribing Branch Health & Social Services Group 4th Floor East G08 Welsh Government Cathays Park Cardiff CF10 3NQ pharmacy.appeals@gov.wales
Additional Copies	This document can be accessed from the Welsh Government's website at: https://gov.wales/national-health-service-pharmaceutical-services-wales-regulations-2020
Related Documents	The draft National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 https://gov.wales/sites/default/files/consultations/2019-09/consultation-document_2.pdf

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Summary

The Welsh Government consulted on proposals to change the way in which pharmaceutical services are provided in Wales through the introduction of pharmaceutical needs assessments. The consultation ran between 30 September and 25 November 2019.

The proposed draft NHS (Pharmaceutical Services) (Wales) Regulations 2020 (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. They will revoke and replace the NHS (Pharmaceutical Services) (Wales) Regulations 2013 (the 2013 Regulations).

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.

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.

Stakeholder Engagement Event

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 and facilitated by Primary Care Commissioning, who have been advising on the development of the policy of pharmaceutical needs assessments in Wales.

The main issues raised are summarised as follows:

- **Services** – it was questioned how a Pharmaceutical Needs Assessment would be used to manage the availability of services in an area; what changes would trigger a re-assessment; and whether there was the potential for a health board to refuse to commission a service. We have addressed this in our response to Question 1, below.
- **Re-assessment** – there was some uncertainty around when a new assessment would be required. It was felt that the terms “significant” and “disproportionate” were subjective. We have addressed this in our response to Question 5, below.
- **Private providers, online pharmacies etc** – there were questions around other providers of pharmaceutical services, including those provided by companies such as Kaleidoscope but funded by the Criminal Justice system; distance sellers and pharmacies in England, particularly for those localities sharing a border with England. It was understood that a Pharmaceutical Needs Assessment should acknowledge such services, but their presence would not necessarily change an assessment of need.
- **Consultation and timings** – It was noted that 6 months from the date the regulations come into force may be insufficient time to prepare an initial Pharmaceutical Needs Assessment. We have addressed this in our response to Question 4, below.

- **Market Entry** – It was questioned whether a health board should identify over-provision as part of its Pharmaceutical Needs Assessment. However, our responses to questions 12-17 address the points raised in more detail.
- **Market Exit** – A number of questions were raised, but were also raised during the consultation. We have therefore addressed these in more detail in our response to questions 18-23.

At the event attendees were encouraged to submit their questions or comments as part of their formal consultation response. Those issues discussed at the event and which have subsequently formed part of a consultee's response are dealt with in the relevant Welsh Government Response below.

Responses

In total, there were 19 completed responses to the consultation, from a mixture of health board representatives, independent pharmacists, major pharmacy chains and bodies representing the interests of pharmacists and GP services.

The Welsh Government is grateful to those who took the time to submit their views.

Questions and themes

Pharmaceutical Needs Assessments

Question 1: Do you agree that all services provided under sections 80 and 81 of the NHS Wales Act should be included in the definition of pharmaceutical services for the purposes of the Regulations?		
Agree: 19	Disagree: 0	Neither agree nor disagree: 0

Of the 19 responses received, all respondents agreed that all services provided under sections 80 and 81 of the NHS Wales Act should be included in the definition of pharmaceutical services.

However, some respondents questioned what would happen in a hypothetical situation where a health board identified a need for a particular service in its Pharmaceutical Needs Assessment, but then chose not to commission that service.

In our view, whilst this situation may be unlikely, it is ultimately for health boards to determine which services they wish to commission and when, based on its assessment of need for its area. This is in contrast to the existing arrangement where contractors positively assert in their application the services they believe should be provided.

Question 2: Do you agree that the health board should be placed under an obligation to consider all pharmaceutical services and are there any other persons providing those services that should be considered?		
Agree: 16	Disagree: 3	Neither agree nor disagree: 1

Of the 19 responses received, the majority of respondents agreed that the health board should be placed under an obligation to consider all pharmaceutical services. To the second part of the question, three respondents suggested Dispensing Appliance Contractors should be considered. Also proposed were dispensing hubs and out-of-hours medical services.

However, it was suggested by some respondents that the definition of pharmaceutical services within section 81 of the NHS (Wales) Act implies all pharmacy services and can therefore be provided by both pharmacies and dispensing doctors.

Welsh Government response

We are grateful for the responses received in relation to Dispensing Doctors and note the concerns raised. We will further consider the relevant provisions within the draft Regulations in order to ensure they meet the policy objectives and do not have any unintended consequences.

Question 3: Do you believe there is anything that could be added to the list of required information to improve the content of a pharmaceutical needs assessment?		
Yes: 11	No: 8	No response: 0

Of those who responded, eight respondents were content that there was nothing else they would add to the list of required information. Eleven of those who responded made a number of suggestions, including:

- Linking with primary care estates strategies;
- Reviewing rurality & dispensing doctor lists every five years with each new Pharmaceutical Needs Assessment;
- Levels of deprivation, in particular rural deprivation;
- Areas of over-provision;
- Consider the premises of existing pharmacies, as some may be unsuitable for providing some services;
- National programmes providing similar services –Stop Smoking Wales being one example given; and
- New pharmaceutical services that will become available during the life of the Pharmaceutical Needs Assessment, such as Sore Throat Test & Treat.

Welsh Government response

As there were a number of requests in responses to the consultation for the Welsh Government to provide guidance on a number of elements within the new Regulations, our view is that these suggestions for additional information are best contained within such guidance rather than the Regulations themselves. Our view is that the information a Local Health Board is required include within a PNA should encompass the suggestions made.

Question 4: Is five years an appropriate interval between pharmaceutical needs assessments?		
Agree: 19	Disagree: 0	Neither agree nor disagree: 0

All 19 respondents agreed that five years is an appropriate interval between assessments.

However, the health boards who responded were concerned that the proposed six months was insufficient time to complete their first Pharmaceutical Needs Assessment, especially when taking into consideration the need to translate and consult on a draft Assessment. It was also noted that Primary Care Trusts (now Clinical Commissioning Groups) in England were given twelve months to complete their first assessments.

As currently drafted, upon coming into force, the Regulations place a six month freeze on new applications for inclusion onto the Pharmaceutical List, as well as any permanent Relocations (temporary relocations will still be permitted in this period). The six month period for completing an initial Pharmaceutical Needs Assessment was proposed as a compromise between the business needs of contractors and the need to allow health boards a window of opportunity to assess their current pharmaceutical needs without having to account for what can often be frequent changes to the availability or the placement of pharmaceutical services.

Welsh Government response

Taking into account the consultation responses, we are currently considering a number of options, including extending the period for completing the initial assessment and postponing the freeze on applications to start at a later date.

Question 5: Do you agree the health board should be under a duty to revise its pharmaceutical needs assessment once it considers there are significant changes to the circumstances in its area; for example when a large housing development takes place?		
Agree: 19	Disagree: 0	Neither agree nor disagree: 0

Once again, all 19 respondents agreed that the health board should be under a duty to revise its assessment once it considers there are significant changes to the circumstances in its area. However, it was noted by a number of correspondents that "significant" was open to interpretation and there was, therefore, a need to define what should constitute a significant change.

Welsh Government response

The inclusion of "significant" will avoid placing an overly onerous duty on LHBs to have to reproduce a Pharmaceutical Needs Assessment whenever there is any change in circumstances in their area. Our view is that the Local Health Board are best placed to determine on a case by case basis whether any change to the provision of services in their area is significant and therefore requires them to produce a new Pharmaceutical Needs Assessment.

Question 6: Do you agree with the list of persons who must be consulted on the contents of an assessment?		
Agree: 19	Disagree: 0	Neither agree nor disagree: 0

Of the responses received, all 19 agreed with the list of persons to be consulted on the contents of the assessment. However, there were a number of additional suggestions provided, including:

- the armed forces (where appropriate);
- neighbouring Local Medical Committees (LMCs); and
- Clinical Commissioning Groups and LMCs in England, where a Welsh health board shares a border.

There is a second part to this question, in Question 7 we asked if there were any other persons who should be consulted:

Question 7: Are there any other persons who should be consulted?		
Yes: 11	No: 8	No response: 0

Of the 19 responses received, 11 provided suggestions for additional parties to include in a health board's consultation, including:

- Neighbouring contractors on the pharmaceutical list;
- Health Board Directors of Primary Care;
- Health Board Directors of Planning;
- Health Board Public Health teams;
- Providers of primary medical services (including out-of-hours services);
- Primary care clusters;
- Local Pharmaceutical Committees in England; and
- Regional Partnership Bodies.

Welsh Government response

We agree with the suggestion to include Regional Partnership Bodies on the list of mandatory consultees. However the list of persons to be consulted in the draft 2020 Regulations is not exhaustive and therefore represents the minimum parties that health boards must consult. They are of course able to consult more widely, if appropriate to their geographical location. Ultimately, Health Boards are best placed to decide how widely they should consult, beyond the minimum specified in the Regulations.

Question 8: Do you agree with the process for the health board's publishing of its assessment?		
Agree: 17	Disagree: 2	Neither agree nor disagree: 0

Of the 19 responses received, 17 agreed with the process for publishing the health board's assessment. There were, however, a number of common themes running through the comments submitted, including:

- Supplementary statements – consultees should be notified when a health board publishes a supplementary statement; and that supplementary statement should be published online in the same location as the latest Pharmaceutical Needs Assessment;
- PNAs should be published in a consistent location across all health boards, in both languages, along with any supplementary statements; and
- A 'live list' of services available at each pharmacy is needed.

Welsh Government response

We agree with the suggestion to notify consultees when a supplementary statement is issued and we will amend the draft Regulations accordingly.

Work is ongoing to deliver a live list of pharmaceutical services as part of the NHS Wales Directory of Services.

However, whilst we would hope that health boards take a consistent approaching to publishing their PNAs, we do not believe it is necessary to specify how it is presented on a Local Health Board's website in legislation.

Question 9: Are there any other factors a health board should have regard to when making an assessment?		
Yes: 8	No: 11	No response: 0

Of the 19 responses received, 11 were content with the factors a health board must have regard to in making its assessment. However, 8 respondents provided a number of suggestions for additional factors to consider, including:

- Primary Care Estates Strategies & capital investment pipeline;
- Demographic changes;
- Transport availability;
- Environmental impact (particularly in car-dependent communities);
- Future provision by existing contractors;
- Rural deprivation; and

- Existing pharmacy premises & whether they are able to meet growing needs.

In addition to the above, a number of respondents reiterated the need for comprehensive guidance and a standardised template for producing a Pharmaceutical Needs Assessment to ensure consistency across health boards.

Welsh Government response

Whilst health boards are best placed to identify the particular needs and challenges of its population, we will provide guidance to ensure health boards consider a broad range of factors that may not be immediately obvious, as well as ensure consistency. The responses to this question will be considered during the development of the necessary guidance.

Dispensing Doctors

Question 10: Do you consider it appropriate to maintain existing pharmaceutical and dispensing doctor lists when the 2020 Regulations come into force?		
Agree: 19	Disagree: 0	Neither agree nor disagree: 0

All 19 respondents considered it appropriate that existing pharmaceutical and dispensing doctor lists are maintained when the 2020 Regulations come into force**.** However, the overriding theme of the comments received pertained to the risk of speculative applications being received by health boards whilst they prepare their PNA.

Welsh Government response

We are aware of the risk of speculative applications and have attempted to mitigate them by incorporating a standstill period into the 2020 Regulations when they come into force. During the standstill period, no new application for inclusion will be considered. The assessment, once published, will outline the unmet pharmaceutical needs of the health board's population and the types of applications it would consider to meet those needs.

Crucially, it will no longer be for the contractor to assert that a new pharmacy is needed, but for the health board to determine the need for pharmaceutical services and decide whether to accept any applications made in respect of the identified needs.

Applications that do not demonstrate they meet a need in a relevant Pharmaceutical Needs Assessment will likely fail the new test.

Question 11: Do you agree to the maintaining of previously defined controlled areas?		
Agree: 14	Disagree: 5	Neither agree nor disagree: 0

Of the 19 responses received, 14 agreed with maintaining previously defined controlled areas. However, most comments appeared to agree that controlled areas should be reviewed periodically and all maps and documentation should be brought up to date and included in the PNA.

Welsh Government response

As is the case under the 2013 Regulations, a Local Health Board must, in response to an application submitted in writing by a Local Medical Committee or a Local Pharmaceutical Committee, or at any other time that it may decide, consider the question of whether or not any particular area within the area for which it is established is, because it is rural in character, a controlled locality or part of a controlled locality. Whilst we would expect health boards to periodically review their controlled localities, we will not be placing a requirement on them to do so as part of the PNA process at this stage.

Market Entry

Question 12: Do you consider the change of test as a consequence of the introduction of pharmaceutical needs assessment to be appropriate?		
Yes: 15	No: 3	Neither agree nor disagree: 1

Of the 19 responses received, 15 considered the change of test appropriate. However, a small number of common themes were present in the comments we received, including:

- There should be an opportunity for existing contractors to fulfil any identified need prior to new applications being allowed; and
- If an application is granted, the reasons for granting should be open to appeal.

Question 13: Are there any other criteria that should be applied to this test?		
Yes: 8	No: 11	Neither agree nor disagree: 0

Following on from question 12, question 13 provided an opportunity to outline additional criteria that should be applied to the new test. Of those that responded, 11 were content with the criteria as it stood, but 8 provided additional suggestions, including:

- Opportunity should be given to existing contractors to fulfil a need before additional applications are considered;
- Clarity around how control of entry will work is needed, particularly around competing applications;
- The lack of provision for “unforeseen benefits” applications risks criticism from the Competition & Markets Authority as being anti-competitive; and
- Guidance is needed on the change of terminology from “must grant” to “may grant” and in what situations it may be appropriate for a health board to refuse an application, such as those outlined in the equivalent NHS England Regulations, specifically, the undesirable increase in essentials services; that a future need identified is unlikely to arise etc.

Welsh Government response

Once a PNA has been published, applications may be made by anybody who believes they can meet a need identified. This of course includes existing contractors, but they will not be given preferential status by a health board when considering applications and all applications must be considered objectively on their merits. We will consider whether to revise the draft Regulations to include potential reasons for refusing an application, or whether to set out those reasons in guidance.

We have followed with interest the experience in England and noted the views of stakeholders in respect of unforeseen benefits applications. This has informed our

decision not to include such provisions in our regulations. We believe it stands to reason that as long as a health board provides a thorough assessment of its pharmaceutical needs, no benefit should be unforeseen.

Question 14: Do you agree with the removal of minor relocations for premises?		
Agree: 13	Disagree: 6	Neither agree nor disagree: 0

Whilst the responses to this question were broadly in favour, with 13 of 19 responses agreeing with the proposal, there were a number of counter-points submitted by those who responded. In particular, there were concerns that by limiting relocations to those that meet a need, it may prevent a pharmacy from relocating to a more suitable premises, or to respond to unforeseen circumstances**.** It was suggested by three respondents that a "very minor" relocation be allowed in the Regulations.

Welsh Government response

We are content that the relocation provisions within the draft 2020 Regulations adequately provide for those relocations which would have previously been determined under the Minor Relocation provisions of the 2013 Regulations.

Question 15: Do you consider a move between health board areas should only be allowed when a need has been identified in the health board's assessment and providing it does not disadvantage access by persons accustomed to accessing services in the current location?		
Agree: 13	Disagree: 6	Neither agree nor disagree: 0

Once again, the responses to this question were broadly in favour, with 13 of 19 responses agreeing to the proposal. However, many were unsure how the proposal would work in practice and requested example scenarios**.**

Welsh Government response

We have noted the comments received on example scenarios and will seek to include them in any guidance we produce.

Question 16: Do you have any comments to make on this consequential amendment?	
Yes: 8	No: 11

Eight of the respondents provided comments, all supportive of the removal of the 30 day consultation period for temporary relocations. However, one comment noted that there may be instances where the original premises that a pharmacy temporarily relocated from is damaged beyond economic repair and is therefore unable to return.

Welsh Government response

There is sufficient scope within the draft 2020 Regulations to enable a relocation in the scenario outlined. However, we will consider whether there needs to be any change to the relocation provisions to specifically account for such a situation in the new Regulations.

Question 17: Do you have any comments on the criteria relating to inclusion in the list under specific conditions?	
Yes: 8	No: 11

A number of comments were received in response to this question, with most centred around regulation 46, which consultees raised as having the effect of all core and supplementary hours becoming core hours when an application is granted**.** It was suggested that Regulation 46 should only apply to applications to meet a need identified in a Pharmaceutical Needs Assessment and not for applications to relocate for other reasons, or a change of ownership.

Also noted was that regulation 46(4), relating to three years before a variation is possible, is at odds with the five-year life of a Pharmaceutical Needs Assessment.

A typographical error was observed in the draft 2020 Regulations relating to regulation 47(4), referring to a paragraph 5 which did not exist in the draft.

Welsh Government response

We are grateful for this valuable feedback. Supplementary hours do not form part of core hours. However, to avoid any confusion we will revise the draft regulations to clarify the distinction between additional, supplementary and core hours.

However, we are not minded to agree that the period covered in regulation 46(4) needs to correlate with the period covered by the Pharmaceutical Needs Assessment.

We have noted and corrected the typographical error highlighted in the draft Regulations.

Market Exit

Question 18: Do you have any comments in relation to local dispute resolution prior to the issuing of remedial notices?	
Yes: 9	No: 10

A number of comments were submitted in response to this question, with the majority calling for the Welsh Government to provide guidance to ensure an agreed approach to dispute resolution is followed. It was also suggested that Regulation 49(3)(b)(i) be omitted, on the basis that such matters should be considered under local dispute resolution, adding that “the corresponding English regulations have been amended so that a notice cannot be issued until an explanation has been received from the contractor and that “good cause” for failure to open can be assessed”.

Welsh Government response

We agree that any guidance issued by the Welsh Government should set out an agreed approach on a number of issues, including with regard to dispute resolution.

Question 19: Is there any other information a remedial notice should contain?	
Yes: 5	No: 14

A number of responses were received for this question, with most requesting detailed guidance to ensure a consistent approach to remedial notices across Wales. There were also a number of questions relating to how the notices would be monitored in the case of repeat offenders.

One respondent suggested that Regulation 50 be revised to indicate that remedial notices can be issued where a breach can be substantially remedied, such as submitting required information after a deadline.

Welsh Government response

We agree that any guidance issued by the Welsh Government should set out an agreed approach, including with regard to breach and remedial notices.

Question 20: Are the terms under which the health board may withhold payment for a breach of services appropriate?		
Agree: 14	Disagree: 4	Neither agree nor disagree: 1

Of the 19 responses received, 14 believed the terms under which the health board may withhold payment were appropriate. However, there were concerns that withheld remuneration should only relate to the service which was not provided, noting that services such as dispensing are partly reimbursement for medications supplied.

Again, the majority of responses outlined the need for guidance from the Welsh Government to ensure a consistent approach across Wales.

Welsh Government response

We agree that any guidance issued by the Welsh Government should set out an agreed approach, including with regard to withholding payment related to breaches of terms of service.

Any decision to withhold remuneration should be proportionate to the level of breach.

Question 21: Do you have any comments about the process of remedial and breach notices?	
Yes: 4	No: 15

Of the 19 responses received, only 4 wished to comment on the process of remedial and breach notices. Once again, these comments repeated calls for guidance from the Welsh Government. However, it was also suggested that notices be copied to the business owner or superintendent pharmacist, not just to the premises in question.

Welsh Government response

We agree that any guidance issued by the Welsh Government should set out an agreed approach, including in relation to the process of remedial and breach notices.

Question 22: Do you have any comments on the criteria for removal from the pharmaceutical list in relation to performance matters?	
Yes: 8	No: 11

Whilst there were a number of comments submitted to this question, the overriding theme was the omission of any provision for suspension pending the completion of remedial actions.

Other comments received related to ensuring proportionality and clarification that a removal from the list was a last resort.

Welsh Government response

We agree that removal from a pharmaceutical list should only be an action of last resort. We do not believe that incorporating suspension into the remediation notice process would be proportionate in the circumstances.

Question 23: Do you have any comments with regard to appealing health board decisions in relation to performance matters?	
Yes: 7	No: 11

There were a number of comments received in response to this question. These are summarised as follows:

- Appeal process needs to be timely, tackling poor performance quickly;
- Notices should be copied to the business owner or superintendent pharmacist; and
- the potentially significant administrative burden, given the potential number of notices that could be triggered**.**

Welsh Government response

We note the comments submitted in response to this question.

Question 24: Do you agree with this 'stand still' concept and these timescales?		
Agree: 13	Disagree: 4	Neither agree nor disagree: 2

Whilst most respondents were supportive of the concept of a standstill period, the majority of comments also echoed concerns that six months was insufficient time to prepare, translate and consult on a draft Pharmaceutical Needs Assessment, noting that Primary Care Trusts in England were given twelve months to undertake the same task.

There was also some confusion around which types of applications would be subject to the standstill period.

Welsh Government response

As outlined in our response to question 4, taking into account the consultation responses, we are currently considering a number of options.

It should be noted that regulation 1(2) of the draft Regulations, which sets out which sections come into force and when, outlines that Regulations 15-18 come into force on 1st November 2020. This includes applications by NHS pharmacists and NHS appliance contractors for inclusion in or amendment to pharmaceutical lists, specifically, applications for inclusion; applications for preliminary consent; and application for

inclusion by dispensing doctors, as currently drafted. The regulations specifically related to relocations both permanent and temporary come into force on 1st April 2020.

Question 25: Are there any unintended consequences created by the draft regulations you can foresee?		
Yes: 7	No: 9	No response: 3

Whilst there were a number of responses to this question, many were raised as part of earlier responses, in particular:

- Regulation 46 and its effect on core opening hours;
- Pharmaceutical services applying to both section 80 and 81 services to both pharmacists and dispensing doctors; and
- The six month timeframe for producing an initial Pharmaceutical Needs Assessment.

Welsh Government response

We have responded to each of these points in more detail above.

Question 26: Are there any additional points you would like to make regarding the proposals set out in the draft regulations?		
Yes: 11	No: 6	No response: 2

There were a large number of comments submitted in response to this question. These are summarised as follows:

- Schedule 3 should provide LHBs with the power to defer consideration of applications to invite applications from existing providers if this is considered appropriate, to avoid the over-supply of essential services;
- The regulations should reduce spurious, often premature applications for pharmacies;
- The proposals represent an important step forward for the population in supporting the long term planning and investment into pharmaceutical services targeted appropriately at the population needs;
- Serious shortage protocols should be included in the final draft of these Regulations;
- There is no provision of conscientious objection within the regulations; and
- There should be equity between providers of pharmaceutical services, including dispensing doctors and appliance contractors, in dealing with breaches in relation to pharmaceutical services.

There were also a number of suggestions provided related to the terms of service, including:

- The requirement for Standard Operating Procedures is covered by General Pharmaceutical Committee requirements and is therefore an unnecessary duplication;
- The value of the Community Pharmacy Questionnaire is negligible. We would suggest working with CPW on a more useful and timely alternative as part of the quality scheme;

- Why does Fitness to Practice information have to be provided on the application form when a reference could be made to the home Local Health Board; and
- The role of the practice-based audit and Local Health Board audit is questionable, given the number of audits carried out under the quality scheme. It would be preferable to only conduct national audits.

Welsh Government response

Whilst comments on the terms of service element of the draft Regulations were not sought as part of this consultation, we are grateful for those who responded for taking the time to do so and will consider the suggestions made as part of ongoing contract discussions with Community Pharmacy Wales.

Question 27: We would like to know your views on the effects that the draft regulations would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favourably than English. **What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?**		
Some effect: 4	No effect: 10	No response: 5

Of those who responded, few could identify any effects the draft Regulations would have on the Welsh language. Many noted that pharmacies would normally employ staff from their local population and would inevitably employ Welsh speakers in an area with a significant proportion of Welsh speakers. However, it was felt the requirement to translate a Pharmaceutical Needs Assessment will make the 6-month deadline more difficult, but that doing so was vital to ensure Welsh speakers were treated equally, and with dignity and respect.

Welsh Government response

We agree with the comments submitted and will consider extending the transitional arrangements, which would incorporate more time and allow for translation.

Question 28: Please also explain how you believe the proposed regulatory provisions could be formulated or changed so as to have positive effects or increased positive effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language, and no adverse effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language.		
Some effect: 4	No effect: 10	No response: 5

Only two comments were submitted in response to this question, both broadly in agreement that the regulations already facilitate Pharmaceutical Needs Assessment in such a way as to have a positive effect on opportunities for people to use the Welsh language.

Welsh Government response

We are grateful for the comments submitted.

Question 29: We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:		
Comments: 8	No comment: 6	No response: 5

There were a number of comments submitted to this question, which are summarised below:

- In both the impact assessment and the consultation document (page 15) there are statements suggesting that under the revised regulations, LHBs will be able to require pharmacies to relocate to force a rational distribution of pharmacies. The Regulations do not permit this;
- If a suggestion is made in a Pharmaceutical Needs Assessment that a relocation would be welcomed, any relocating contractor should be exempt from the NHS relocation fee:
- What does a rational distribution mean?
- Pharmaceutical Needs Assessment's in England are plagued by inconsistency To avoid this in Wales it may be appropriate for an Local Health Board to review the Pharmaceutical Needs Assessment of a neighbouring health board;
- We are pleased to see the consultation document recognises the role of dispensing doctors in providing essential pharmaceutical services, primarily in rural areas of Wales; and
- Pleased the Welsh Government has, to date, taken a very inclusive approach to the introduction of these changes and provided the opportunity for stakeholders to attend a full briefing day.

Welsh Government response

First, to address the point regarding rational distribution of pharmacies, it is correct to state the regulations do not provide the means to force a contractor to relocate, nor should they. However, they will provide the health board with the means to state their observations with regard to availability and spread of existing pharmacies.

Health boards will be able to state they have sufficient pharmacies within their area and may not welcome an additional application for inclusion, but may welcome an application to relocate from an area with an over-supply to one that is under-served, to achieve a more rational distribution of existing pharmacies.

With regard to peer review of PNAs of neighbouring health boards, health boards are free to consult with whomever they wish under the regulations as they stand, including neighbouring health boards, but to mandate the practice in the regulations would be disproportionate.

Closing remarks and next steps

We are grateful for the responses to the consultation, which has proven to be a very valuable exercise. It is clear from the feedback we have received, in both the stakeholder engagement event and this formal consultation, that there is a great deal of support for the changes we are proposing to make to community pharmacy services in Wales.

What is clear from the responses is that the six month period proposed in the consultation document for health boards to prepare their initial Pharmaceutical Needs Assessment is considered insufficient. We have therefore decided to extend this period to twelve months.

Whilst the six month standstill period proposed will remain, this will now begin six months after the date on which the Regulations come into force, i.e. the standstill period will begin on 1 November 2020. Health Boards will then be expected to publish their first Pharmaceutical Needs Assessment by 1 April 2021.

However, what is also clear is the need for us to continue the collaborative approach we have taken to date when developing guidance to support health boards and contractors to assist them in their development and implementation of pharmaceutical needs assessments in Wales, as well as the process for market entry and market exit.

As we have outlined in our responses, where appropriate we will make changes to the draft regulations to incorporate the feedback received, before they are laid before the Assembly.