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Applications to Provide NHS Pharmaceutical Services: Consultation on the Control of Entry Arrangements and Dispensing GP Practices

Linda Nicholson, The Research Shop

The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 (amended by SSI 2011/32) provide the legal framework for applications to open new community pharmacies (known as "control of entry"), while the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 and the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 give Health Boards the power to require GP practices in some remote and rural areas (that is, where there is no local community pharmacy) to dispense medicines to their patients.

In 2013 the Scottish Government's Cabinet Secretary for Health and Wellbeing announced an immediate review of the existing regulations on the control of entry to ensure they are fit for current and future purpose. A consultation paper on the Control of Entry Arrangements and Dispensing GP Practices was published on 12 December 2013 and closed on 20 February 2014. The responses to the consultation will inform amendments to the associated regulations to be laid before the Scottish Parliament. 85 responses to the consultation were submitted.

Main Findings

- Two-thirds (66%) of the respondents who provided a view agreed with the proposals to introduce the designation of "controlled remote, rural and island localities" for the purposes of considering pharmacy applications, and introducing a "prejudice test" in addition to the test of "necessary or desirable". Many agreed that regular review of the designation is important to accommodate significant changes in localities.
- Just under three-quarters (72%) of those providing a view agreed that when dispensing by a GP practice is necessary, it should be supplemented with pharmaceutical care provided by a qualified, clinical pharmacist sourced by the NHS Board. In general, this was viewed as facilitating more equitable access to high standards of pharmaceutical care across Scotland.
- 61% of those who provided a view agreed with the proposal to include a community representative among those who should be notified, as an "interested party or persons", of any application to open a community pharmacy in the area. This was perceived by supporters as a way to enable the voice of communities to be heard, promoting democracy, transparency and autonomy.
- 61% of those who provided a view agreed that those applying to open a pharmacy, for the purposes of providing NHS pharmaceutical services, should first enter into a pre-application stage with the NHS Board to determine whether there is an identified unmet need in the provision of NHS pharmaceutical services. However, most NHS Board committees, NHS Boards, representative or professional bodies and pharmacy contractors opposed this proposal.
- Just under three-quarters (72%) of those who addressed the issue agreed that when assessing applications for new community pharmacies, NHS Boards should be able to take into account how NHS Pharmaceutical services would be delivered in practice in the long term.

The Scottish Government
Riaghaltas na h-Alba

Background

The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009[1] (amended by SSI 2011/32) provide the legal framework for applications to open new community pharmacies (known as "control of entry"), while the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 and the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 give Health Boards the power to require GP practices in some remote and rural areas (that is, where there is no local community pharmacy) to dispense medicines to their patients.

Over 100 GP practices across Scotland currently receive remuneration for the delivery of primary medical services and also funding for the dispensing of medicines to their patients. These are more commonly known as GP dispensing practices. Over recent years, some had expressed concern that future successful pharmacy applications in their areas could destabilise local services provided by the GP practices concerned, and, ultimately, the long term sustainability of the practices themselves.

The Scottish Government is committed to ensuring access to NHS pharmaceutical and primary medical services to all people of Scotland, whilst supporting the viability of remote and rural GP practices. In 2013 the Scottish Government's Cabinet Secretary for Health and Wellbeing announced an immediate review of the existing regulations on the control of entry to ensure they are fit for current and future purpose.

A consultation paper on the Control of Entry Arrangements and Dispensing GP Practices was published on 12 December 2013 and closed on 20 February 2014. The document sought views on issues relating to control of entry, on dispensing GP practice processes and on wider pharmacy application procedures. The responses to the consultation will inform amendments to the associated regulations to be laid before the Scottish Parliament.

Overview of respondents

85 responses to the consultation were submitted. Individuals formed the largest category of respondent, accounting for 40% of responses. Amongst the individuals were current and retired professionals associated with the NHS or pharmaceutical services.

The consultation was remarkable in that each question attracted a response from at least 90% of respondents suggesting a high degree of in-depth knowledge and understanding of the issues under consideration, and/or strong views stemming from personal experience.

Introducing the designation "controlled remote, rural and island localities" and introducing the prejudice test

Two-thirds (66%) of the respondents who provided a view agreed with the proposals to introduce the designation of "controlled remote, rural and island localities" for the purposes of considering pharmacy applications, and introducing a "prejudice test" in addition to the test of "necessary or desirable".

The designation was seen by some as beneficial in reflecting the distinction between rural and urban circumstances and contributing to national consistency in approach. Others, however, considered the designation too blunt to distinguish between the needs of different rural populations, with some calling for greater clarity of definition.

A common view was that implementation of the proposed prejudice test would ensure that the overall health needs of the population within an area would be taken into consideration in decision-making, reducing the risk of losing local health services altogether.

A common argument against the introduction of the prejudice test was that it may result in the refusal of genuine applications to open a community pharmacy which could be of benefit to local communities.

More information on the detail of the proposed prejudice test was called for with recommendations also made for providing accompanying guidance.

[1] http://www.legislation.gov.uk/ssi/2009/183/pdfs/ssi_20090183_en.pdf

Periodic review of the designation of an area as a "controlled remote, rural and island locality"

Just over half (56%) of those providing a view agreed that the designation of an area as a "controlled remote, rural and island locality" should be reviewed at a minimum of every three years. Many considered that regular review is important in order to identify and address any significant change in localities, and suggested that three years for review provides the right balance between keeping plans current, whilst avoiding unnecessary work.

Some respondents recommended more frequent review, largely in order to align with the timing of the local Pharmaceutical Care Services Plan (PCSP), thereby facilitating, in their view, a proactive rather than reactive approach. Others considered that reviews held more frequently than every three years would create uncertainty and present barriers to long-term planning by GP practices.

Supplementing GP dispensing with pharmaceutical care

Just under three-quarters (72%) of those providing a view agreed that when dispensing by a GP practice is necessary, it should be supplemented with pharmaceutical care provided by a qualified, clinical pharmacist sourced by the NHS Board. In general, this was predicted to result in more equitable access to high standards of pharmaceutical care across Scotland.

A few respondents felt that it would be more cost-effective for NHS Boards to contract with the existing network of community pharmacists rather than source a qualified NHS clinical pharmacist. Queries were raised over who would fund the provision, with clarity requested on lines of accountability and governance.

Public consultation and the community voice

The majority (61%) of those who provided a view agreed with the proposal to include a community representative among those who should be notified, as an "interested party or persons", of any application to open a community pharmacy in the area. This was perceived by supporters as a way to enable the voice of communities to be heard, promoting democracy, transparency and autonomy.

Opponents of the proposal argued that there are already mechanisms for community voices to be heard within the existing regulations, and that community representatives are unlikely to have the knowledge and expertise required of those involved in application representations.

Many respondents questioned how community views could be harnessed and then represented in a balanced fashion, considering the diversity of views within some communities. There were differing views on who would be best to represent community views, with community councils and local elected members of local authorities suggested most often.

Handling of NHS Board Pharmacy Practice Committee (PPC) hearings

Almost three-quarters (72%) of those who provided a view agreed that future PPC hearings should be handled in such a way that no one person or organisation is able to dominate the entire hearing.

Many respondents were cautious about limiting the time allocated to give oral representations, with some expressing concern that this could result in unfairness if a party is unable to present their full case, which in turn could lead to appeals. A common view was that an effective Chair could negate the need for the imposition of time limits.

Support from a range of categories was provided for the proposal that all PPC meetings in future follow a standard process in the management of PPC hearings.

Assisting those making representations at oral hearings

Around two-thirds (68%) of those who addressed the issue agreed that in the future, those assisting in oral representations by the applicant, the community and other interested parties in attendance, are able to speak on behalf of those they are assisting. The main reasons given in support of this proposal were that this would address current barriers to effective communication; it would lead to more constructive, higher quality debate which was in the interests of democracy; proceedings would be more streamlined; and the current flawed system needs to be replaced.

Common arguments in opposition to the proposal were that it would potentially slow down proceedings and risk "professionalising" the process.

Public consultation and pre-application stage

61% of those who provided a view agreed that those applying to open a pharmacy, for the purposes of providing NHS pharmaceutical services, should first enter into a pre-application stage with the NHS Board to determine whether there is an identified unmet need in the provision of NHS pharmaceutical services. However, most NHS Board committees, NHS Boards, representative or professional bodies and pharmacy contractors opposed this proposal.

Those in favour of the proposal considered that it would help to reduce frivolous applications. However, those opposed cautioned that involving NHS Board staff at the pre-application stage could be perceived as introducing bias into proceedings, with applications proceeding past this stage viewed as having been endorsed by NHS Boards. For the sake of fairness, some respondents argued that dispensing GPs should also be involved in the pre-application stage.

A recurring view was that the PCSP had potential to be used as a tool for assessing applications, but would need to be made more robust and open to scrutiny for this to happen.

A common recommendation was that rather than NHS Boards and applicants undertaking separate consultations with communities, only one should be conducted, by NHS Boards, with the outcome shared with the applicant, who would also pay for it.

The proposal that both applicant and NHS Boards advertise in newspapers and all circulating local news free-sheets and newsletters in a neighbourhood received a cautious welcome, although many respondents also identified practical challenges in ensuring comprehensive coverage. Calls were made for social media to be included as a vehicle for advertising applications.

Specifying the extent to which community views have been taken into account

Most (85%) of those who provided a view agreed that in future NHS Boards should have to specify the extent to which the views of the community have been taken into account in their published decisions on the outcome of a pharmacy application. Overall, this was seen as promoting transparency and openness, being more accountable to communities, and promoting public understanding and confidence in the decision-making process. A recurring view, however, was that the proposal should not result in additional weight being given to community views over the views of other parties.

Securing NHS pharmaceutical services

Just under three-quarters (72%) of those who addressed the issue agreed that NHS Boards should be able to take into account how NHS Pharmaceutical services would be delivered in practice in the long term after an application has been received.

Amongst the supporters of the proposal were many respondents who considered that such consideration would help to protect the rights of patients to receive sustainable NHS pharmaceutical services. Several suggested that a consideration of the potential viability of local businesses post contract should also be examined.

The most common reasons given in opposition to the proposal were that NHS Boards do not have the expertise to assess financial viability of applicants; and that NHS Boards will not have the full financial information needed on which to base their decisions on viability.

Timeframes for reaching decisions

Most (89%) of those who provided a view agreed with the proposal that the regulatory framework should require NHS Board PPCs to make a decision within six weeks of the end of the public consultation process and the National Appeals Panel (NAP) to make a decision within three months upon receipt of an appeal (or appeals) being lodged.

The proposal to introduce such timeframes was viewed as beneficial in helping to reduce uncertainty and providing an incentive to deal with applications promptly. Some NHS Boards perceived the proposed six week timeframe to be challenging. A dominant theme was that flexibility should be built in for unforeseen circumstances which could delay proceedings. Clear definitions of "good cause" for delay, and "complex cases" were requested.

Expert advice and support to PPCs during deliberations

The majority (79%) of those who gave their view agreed with giving NHS Board PPCs access to independent legal assessors to provide them with advice and guidance on technical and legal aspects of the application process during PPC deliberations. Overall, this was seen as leading to better decision-making in an area of increasing complexity. Some felt that an added benefit would be a reduction in appeals.

Many respondents expressed concern over how much the proposal would cost to operate and who would fund it. Another key concern was whether legal assessors would be readily available to meet demand, without causing delay.

Overview

The consultation attracted a modest number of responses, although a wide variety of respondent categories was represented. Many of the individual respondents had direct current or previous experience of working within the medical or pharmaceutical professions. Fewer community councils submitted responses than had been expected.

Prevalent themes throughout responses were the desire to maintain consistency of medical and pharmaceutical services provision across Scotland, with flexibility to adapt to changes in local demography and needs over time. There was a desire to ensure remote and rural communities benefit from genuine, sustainable services, with procedures in place to protect them from speculative, short-term ventures.

There was no consensus overall about how this could be achieved, with tensions emerging between those supporting more of a strategic, pro-active approach, underpinned by and building upon the PCSP, and those who saw the PCSP used as an assessment tool, against which to consider applications, driven largely by commercial interests.

Overall, respondents supported establishing a meaningful role for local communities in decision-making regarding applications for new community pharmacies. However, many acknowledged the difficulties in identifying appropriate community representatives, given the diversity of local communities and different needs within them. Respondents provided ideas for streamlining consultation processes, reducing duplication of effort and promoting higher quality of input and higher response rates.

One significant emerging theme which some respondents suggested may help to address a number of challenging practical and financial issues associated with local pharmaceutical service provision was to explore innovative approaches to delivering services using information technology and social media.

This document, along with full research report of the project, and further information about social and policy research commissioned and published on behalf of the Scottish Government, can be viewed on the Internet at: http://www.scotland.gov.uk/socialresearch. If you have any further queries about social research, please contact us at socialresearch@scotland.gsi.gov.uk or on 0131 244 2111.

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