NHS Circular:
PCA (P) (2014) 15

Finance, eHealth & Pharmaceuticals Directorate
Pharmacy & Medicines Division

Dear Colleague

NHS (Pharmaceutical Services) (Scotland) (Miscellaneous Amendments) Regulations 2014 (SSI 2014/148)

Control of Entry to the Pharmaceutical List

1. The NHS (Pharmaceutical Services) (Scotland) Regulations 2009 determine the process to be followed when applications are made to NHS Boards to provide NHS pharmaceutical services (the Control of Entry arrangements). The Regulations were amended in 2011 introducing a number of changes to the application process.

2. Further amendments are being introduced as the 2014 Regulations come into force, on 28 June 2014.

3. This Addendum should be read alongside the Guidance issued to NHS Boards on 31 March 2011 in NHS Circular PCA (P) 7 (2011). The Guidance and this Addendum are not intended to replace the Regulations - the Control of Entry arrangements remain subject to the provisions and requirements set out in the Regulations.

Yours sincerely

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ANNEX A

This Addendum accompanies the coming into force on 28 June 2014 of the NHS (Pharmaceutical Services) (Scotland) (Miscellaneous Amendments) Regulations 2014 ("the 2014 Regulations"), and reflects the changes to the provisions and requirements of the NHS (Pharmaceutical Services) (Scotland) Regulations 2009, as amended in 2011.

This Addendum should be read alongside the Guidance issued to NHS Boards on 31 March 2011 in NHS Circular PCA (P) 7 (2011). The Guidance and this Addendum are not intended to replace the Regulations - the Control of Entry arrangements remain subject to the provisions and requirements set out in the Regulations. Its purpose is to support Health Boards in applying the 2014 Regulations.

Controlled Localities and the Prejudice Test

The 2014 Regulations introduce two new provisions, closely linked to each other. On receipt of an application, NHS Boards must consider whether the neighbourhood detailed in the application falls within a controlled locality. If an application is made to open a pharmacy in an area which is designated as a controlled locality, the Board's Pharmacy Practices Committee (PPC) must also consider the prejudice test at its hearing.

Taken together, these provisions will assist Boards in ensuring the stability of NHS primary medical services and pharmaceutical services for patients in particular geographical areas. Such areas would be remote or rural in character, or other non-urban areas where population, geography and disposition of services (and access to them) is finely balanced in terms of stability and sustainability.

Controlled Locality

The 2014 Regulations set out two requirements for a controlled locality area – that the area is remote or rural in character, and is served by a dispensing doctor. Although it will always be clear whether an area is served by a dispensing doctor, there is no one way to define whether that area is remote or rural in character. Assessing an area as being remote or rural will require consideration of specific individual circumstances and factors to take into account in each area, and each case must be judged on that basis. The decision-maker's judgement will depend on local knowledge and observation of each area under consideration. We would recommend a site visit as being particularly helpful.

Boards should consider the following factors as relevant in deciding whether an area has characteristics that are remote or rural:-

(1) The Scottish Government Urban/Rural Classifications (www.scotland.gov.uk/Topics/Statistics/About/Methodology/UrbanRuralClassification).

(2) The number and variety of amenities, facilities and services available to the local population.

(3) The purposes for which the land in the area is used, e.g. agricultural, forestry, industrial, commercial, residential, national park reserves, open countryside, tourism, recreational, etc.

(4) Employment in the area. For example, a remote or rural area need not necessarily have a high level of agricultural or other local employment. Many residents may commute to jobs in nearby towns or cities.

(5) Distance and ease of access between settlements and the quality of roads and streetlights**.** An area with a good road network which provides easy access to a larger settlement is more likely to be urban in character, whereas remote or rural communities are more cut-off.

(6) Population

- Population statistics should provide a valuable source of evidence that population is increasing or decreasing. A growing population can be an indication of expansion or that the area is more urban than rural. A remote or rural area would generally be expected to have small populations which increase little if at all.

- Density of population and patterns of housing – a rural setting, for example, is normally characterised by settlements which are more spread out, while urban areas tend to be more built up.

- Pending planning applications – proposed developments which would significantly increase the size and spread of population may indicate an expanding community or that an area is more urban in character. A remote or rural area is less likely to attract a significant level of development.

(7) The quality and availability of public transport links.

As soon as practical following the designation of a controlled locality within its area, a Board must give written notice of that designation to the dispensing GP practice as well as to the Area Pharmaceutical Committee, the Area Medical Committee, any contractor on the pharmaceutical list (or provisional list) who may be affected by the application, and any Board whose boundary is within 2 kilometres of the proposed premises, and any nominated community representative that covers the application neighbourhood.

In addition, Boards must map out the boundaries of the controlled locality, and record the designation in its Pharmaceutical Care Services Plan. Boards must also make available for public inspection details of any determination of a controlled locality within its area.

Prejudice Test

The prejudice test is an additional legal test set out at Regulation 5(10) (b) of the Pharmaceutical Services Regulations which must be considered by Boards' PPCs when making a determination on an application to open a pharmacy in a controlled locality. It is not the case that any application made in a controlled locality should be automatically refused, but rather that the PPC should give consideration to existing NHS healthcare services, specifically primary medical services and pharmaceutical services, and whether those services may be adversely affected were an application to be granted. PPCs should make use of all the evidence available to them, including but not restricted to, representations from the community representative and the analysis of the joint consultation.

PPCs should consider the prejudice test after applying the established test of "necessary or desirable", as set out in Regulation 5(10) (a) of the Pharmaceutical Services Regulations. If the PPC considers that the provision of existing services would be prejudiced by the granting of the application, to the extent where either primary medical services or pharmaceutical services may no longer be sustainable or secure, then they must refuse the application. Conversely, if the PPC determine that the application is necessary or desirable and it is satisfied that the stability of existing services will not be compromised by the opening of a pharmacy within the controlled locality, then it must grant the application.

Where an application is refused on the grounds of prejudice, the Board will not consider any further application for that neighbourhood until such times as the Board has reviewed the controlled locality designation, or the applicant can demonstrate that there has been significant change in the area.

Review of Controlled Locality designation

The designation of a controlled locality should be reviewed by Boards every 3 years. This is intended to ensure that Pharmaceutical Care Services Plans can be responsive. However, Boards may undertake that review at any time, if they consider that there have been significant changes in the area. Boards must make a judgement on what could be considered as a significant change. Again, there will be no single definition, but Boards should have particular regard to housing development and population changes, changes to local amenities, facilities and services, or changes to transport links.

Following a review, but prior to making a decision on whether to retain or change the controlled locality designation, Boards must give written notice of the proposal to the dispensing GP practice as well as to the Area Pharmaceutical Committee, the Area Medical Committee, any contractor on the pharmaceutical list (or provisional list) who may be affected by the application, any Board whose boundary is within 2 kilometres of the proposed premises, and any nominated community representative, and of their right to make representations within 30 days.

Any changes to the designation must be detailed on the map or removed from the map (see above) as appropriate.

Pre-application Stage

The pre-application stage is intended to facilitate early engagement between the Board and the applicant. The effective use and maintenance of the Board's Pharmaceutical Care Services Plan will help determine the scope of any proposed application. The pre-application stage should also be used to agree the approach to the joint public consultation, should the applicant intend to proceed with the application.

The pre-application stage should not be used to pre-judge the likelihood of an application being approved or rejected, and we would expect Boards to remain strictly neutral throughout the discussions.

Discussions should largely focus on existing services in the area, as well as on any unmet need in respect of NHS pharmaceutical services or the potential improvements to local services, such as increased access, the range of services that might be provided, the added value of these services to patients, and the benefits to other local NHS and social services. Boards might at this stage make it clear to any potential applicant of the legal test as set out in the Pharmaceutical Services Regulations.

Joint Consultation

The 2014 Regulations introduce a newly inserted Regulation 5A to the Pharmaceutical Services Regulation which changes the consultation process, previously undertaken separately by the applicant and the Board: a joint exercise undertaken in advance of any application being made. Although consultation must be undertaken jointly, we expect Boards to lead. Boards and applicants should share any associated costs and how this is split should be agreed before proceeding with the consultation.

The 2014 Regulations provide that the joint consultation must be undertaken for two purposes: to assess the current provision of pharmaceutical services in the neighbourhood and whether it is adequate, and to establish the level of support of residents in the neighbourhood for the application. Notwithstanding the overall consultation purposes, there is scope for deciding how a consultation will be most effectively conducted.

Agreement must be reached on the range of consultation activity to be undertaken, for example in the local press, free-sheets and social media, and the issues and proposed services to be consulted on which may be wider than the issues set out in Regulation 5A(3)(b), explained further below. The consultation will be conducted in such a way as to reach, as far as possible, the vast majority of residents in the neighbourhood affected by the proposed pharmacy.

The consultation should last for a period of 90 days and be conducted in line with Boards' duties of Patient Focus and Public Involvement, and should be completed immediately before any application is submitted. Boards should also have particular regard to NHS Circular CEL 4 (2010) and the National Standards for Community Engagement, endorsed by the Scottish Health Council.

The Scottish Health Council (www.scottishhealthcouncil.org), which has a local office in each NHS Board area, exists to promote improvements in the quality and extent of public involvement. The Scottish Health Council can provide guidance on consultation and engagement approaches as well as advice on how best to target local communities.

Regulation 5A (3) (b) sets out a list of minimum issues the consultation must seek views on. The full list of issues are not listed here, but include the NHS pharmaceutical services to be provided, any perceived gaps in the existing pharmaceutical services provision, the impact on other NHS services in the neighbourhood, and the level of support for the application by the local community.

Boards are now required to submit a factual consultation analysis report to the PPC, following agreement with the applicant, as part of the evidence for consideration as soon as is reasonably practical. A summary of the consultation analysis must be included in the PPC's published determination, and must illustrate how the consultation was taken into account in its determination.

Timescale for Submitting Application

Any application must be submitted to the Health Board no later than 90 days following the completion of the joint consultation.

Community Representative

The 2014 Regulations introduce provision for a community representative to participate directly in the consideration of an application and to have the same status and weight as other interested parties to an application. In effect, this means that the community representative is able to make written and oral representations to a PPC, and has the right to appeal against a decision.

The community representative must be a person nominated by the Community Council serving the neighbourhood in which the pharmaceutical services would be provided, from amongst their elected members. Where the area is covered by more than one Community Council, they must agree to nominate a single representative.

The primary purpose of a Community Council is to ascertain and express the views of the community to the local authority and other public bodies. There are currently around 1200 Community Councils in Scotland, all of which are composed of elected volunteers from the community.

Community Councils are governed by their Constitutions and Codes of Conduct which underline their duties to represent the interests of communities they represent objectively, with honesty, integrity and openness. Further information on Community Councils can be found on the Scottish Government website here:-
www.scotland.gov.uk/Topics/Government/local-government/CommunityCouncils/RelevantPublications

There may, however, be instances where it is not possible to nominate a community representative from the Community Council, for example where a Community Council does not exist. Boards should, therefore, seek alternatives who they believe will present a fair account of the views of the local community, such as other elected local representatives.

Assisting with Oral Representations

New provision is introduced which will enable those assisting "interested parties" in the making of oral representations during a PPC hearing to speak on behalf of those they are assisting. This should provide for views to be presented more knowledgeably and directly, lead to more constructive and better quality hearings, and lead to smoother and more streamlined hearings.

One person only from each interested party is entitled to speak, and each interested party should, therefore, agree beforehand who that will be.

Boards must be satisfied, however, that anyone participating in this capacity is not acting as a paid counsel, solicitor or advocate.

Timeframes for Reaching Decisions

NHS Boards must now reach a decision on a pharmacy application within 6 weeks of receipt of the joint consultation analysis report. It remains the case that the PPC notifies the Board of its decision within 10 working days of reaching that decision, and that Boards then have 5 working days to make that decision known to the applicant and interested parties.

In addition, a formal timescale has been introduced for a decision to be reached by the National Appeal Panel. A decision must now be made within a period of 3 months from the date of receipt of notice of an appeal.

We recognise, however, that in exceptional circumstances these timescales may not be met, for example due to challenging or unforeseen circumstances. This is reflected in the amendment Regulations, and in any case where an extension of these timescales is necessary, the Board or NAP must inform the applicant, interested parties and, if relevant, the appellant.

Independent Legal Assessor

This new provision has been included to allow, but not require, Boards to appoint a legally qualified person to facilitate better decision-making in a process which is increasingly complex. We expect the use of a legal assessor to guide a PPC through a hearing impartially, and to save Boards and the National Appeal Panel time and expense by reducing the number of appeals referred back to Boards by the NAP on the basis of a procedural defect.

The independent legal assessor will not participate in the decision making of the PPC, and is not entitled to vote.

Securing NHS Pharmaceutical Services

Applicants should be reassured that NHS Boards will not seek access to their business plans. This is commercially sensitive information and should be recognised as such. However, the stability and sustainability of local NHS pharmaceutical Services, in urban areas as well as remote and rural areas, should be among the key considerations for PPCs in looking at pharmacy applications under this new provision. Among the factors which PPCs should consider in making a determination on an application are:-

- the size of population which the proposed pharmacy will serve
- the likely demand for pharmaceutical services in the neighbourhood from both the resident and any transient population and the number and location of current providers of pharmaceutical services and primary medical services within the neighbourhood
- the ability of the neighbourhood population to access pharmaceutical services provided in adjacent or nearby neighbourhoods may also be relevant in certain cases
- the estimated number of NHS prescribed items that will require dispensing in a year based on the local population, as far as this can be ascertained, from usual sources
- the estimated uptake of additional pharmaceutical services – including the Minor Ailment Service, Public Health Service and Chronic Medication Service – based on the needs of the population
- the range of pharmaceutical services currently provided in the neighbourhood

The existing patterns of service provision are crucial. To a considerable extent this will be dependent on the number and location of GP practices, and the size of their lists.

Supplementing GP Dispensing Practices with Pharmaceutical Care

A new provision has been included whereby GP dispensing practices must receive the support of an appropriately qualified pharmacist for patients who would benefit.

This pharmacist support will be provided by the Board, and we would anticipate their role to be in the monitoring and the safe and effective prescribing and use of medicines to improve health outcomes for patients. This would include, for example, medicines reviews with patients and better management of patients on multiple medicines.

Separate Guidance to Health Boards is being issued in relation to this.