POLICY NOTE

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) (SCOTLAND) (MISCELLANEOUS AMENDMENTS) REGULATIONS 2014

2014 No. 148

The above instrument was made in exercise of the powers conferred on Scottish Ministers by sections 2(5), 17E(1), 17N(1), 27, 28(2) and 105(7) of the National Health Service (Scotland) Act 1978 and all other powers enabling them to do so. The instrument is subject to negative resolution procedure.

Policy Objective

The National Health Service (Pharmaceutical Services) (Scotland) (Amendment) Regulations 2014 "the 2014 Regulations" principally amend provisions within the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 (as amended) "the principal Regulations" for applications to provide NHS Pharmaceutical Services by community pharmacy contractors. This is also known as the "Control of Entry" or the pharmacy application process.

The 2014 Regulations follow the consultation *"A consultation on the Control of Entry Arrangements and Dispensing GP Practices"*, which was undertaken between 12th December 2013 and 20th February 2014. The amendments build on the proposals tested during the consultation exercise and the responses to those proposals which were subsequently independently analysed and published on 30th May 2014 (http://www.scotland.gov.uk/Publications/2014/05/7116).

The revised procedures will apply to persons intending to make an application under the new procedure for entry to the pharmaceutical list, on or after 27th June 2014.

The 2014 Regulations are summarised as follows:

Interpretation and application

1. **Amendment Regulation 3 amends Regulation 2** of the Principal Regulations to add definitions for "controlled localities" in remote and rural areas and "NHS funded services" which health boards should have regard to when applying the 'prejudice test' when considering pharmacy applications in these geographical areas in accordance with **paragraph 1A of Schedule 3**.

2. The introduction of "controlled localities" and the "prejudice test" are described in more detail under **Amendment Regulation 8**.

Pharmaceutical List

3. **Amendment Regulation 4 amends Regulation 5** of the Principal Regulations, by removing the requirement for the applicant to undertake a separate consultation exercise and provides for the "Pre-application Stage" and "Joint Consultation" by the applicant and the health board. The "Pre-application Stage" and "Joint Consultation" by the applicant and the health board are described in more detail under **Amendment Regulation 5**.

4. In addition, **Amendment Regulation 4 amends Regulation 5(10) of the Principal Regulations** with reference to the provisions for "controlled localities" and the "prejudice test" in remote and rural areas. This is described in more detail under **Amendment Regulation 8.**

"Pre-application Stage" and "Joint Consultation"

5. **Amendment Regulation 5 introduces a new regulation, Regulation 5A,** which provides for the new requirements of the "Pre-application Stage" and "Joint Consultation" by the applicant and the health board.

6. The new **Regulation 5A** sets out the purpose and requirements of the "Pre-application Stage" and "Joint Consultation", which must be undertaken prior to the community pharmacy contractor submitting a pharmacy application to the Health Board.

"Pre-application Stage"

7. To date, the 'Control of Entry' arrangements have largely been an applicant driven process with health boards reacting to proposals presented by community pharmacy contractors to open new pharmacies. The introduction of the "pre-application stage" represents a shift away from this approach to one where health board Pharmaceutical Care Services Plans (PCSPs) will have a greater and more effective role.

8. The "pre-application stage" is **neither intended to be a gate-keeping process for pharmacy applications nor a mechanism for Boards to signal early rejection or endorsement of an application**. Rather, it is to facilitate early engagement between the health board and the applicant, and the effective use and maintenance of the Board's PCSP, which will in turn help to determine the scope of the proposals by the contractor to provide NHS pharmaceutical services from the intended premises.

9. The Scottish Government considers this to be an important first step towards the aims set out in *Prescription for Excellence* (http://www.scotland.gov.uk/Resource/0043/00434053.pdf) where health board PCSPs will be the main statutory vehicle through which NHS Scotland plans, provides and delivers pharmaceutical care and medicines to its communities

10. The "pre-application stage" will also provide the mechanism for the applicant and the health board to agree the approach to the joint consultation which replaces the existing requirements for the applicant and the health board to consult separately.

"Joint Consultation"

11. Consultation activity carried out by the applicant and health boards has been criticised by communities, and 'interested parties' central to the application process, as lacking transparency and rigour. In addition, the quality and thoroughness of consultation is regarded as highly variable from applicant to applicant and health board to health board.

12. The introduction of the "Joint Consultation" not only makes the consultation arrangements more focused, but they are to be conducted in line with the health board's duty of Patient Focus and Public Involvement and associated requirements. Although ostensibly a joint exercise, consultation will be health board led with the applicant contributing a proportion of the cost which will be agreed with the health board.

13. Consultation activity will be required to 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 and will be for the purposes of, for example, seeking views on the NHS pharmaceutical services to be provided, gaps in the existing pharmaceutical services provision, the impact on other NHS services in the neighbourhood and the level of support of residents in the neighbourhood.

14. The Board and the applicant will be required to produce a factual consultation analysis report for which the Board will be required to submit to the Chair of the health board Pharmacy Practices Committee (PPC) prior to the determination of the application.

Publication of Particulars

15. **Amendment Regulation 6 amends Regulation 15** of the Principal Regulations requiring the health board to publish details of any 'controlled localities' it has determined within the health board area and with reference to the health board's Pharmaceutical Care Services Plan (PCSP) and as detailed in **paragraph 1A of Schedule 3.**

Application Forms

16. **Amendment Regulation 7 amends Form A(1)** of the Principal Regulations to reflect new procedures in relation to joint consultation.

"**Controlled localities" and the "Prejudice Test"**

17. **Amendment Regulation 8 amends Schedule 3** of the Principal Regulations. In conjunction with **Amendment Regulation 4,** these miscellaneous amendments provide for: the requirements and process of determining 'controlled localities; the requirements and process of assessing pharmacy applications that fall within a 'controlled locality'; and the requirements and process for reviewing 'controlled localities'.

"Controlled localities"

18. To promote the **stability of NHS primary medical and pharmaceutical services** in remote and rural areas of Scotland, the amended regulations require health boards to designate certain areas as 'controlled localities' for the purpose of considering pharmacy applications. This is set out in **paragraph 1A of Schedule 3.**

19. "Controlled localities" are areas within a health board which are remote or rural in character and which are served by a GP dispensing practice. Remote or rural areas may

have a variety of characteristics, for example, a limited range of local services, the size of the community and overall population density, patterns of housing, the distance and ease of access between settlements and the availability or otherwise of public transport and its frequency. Importantly, **a GP dispensing practice area (including its branch surgeries/practices) will be a key determinant in setting the boundary for 'controlled localities'** in order to help safeguard the provision of local NHS primary care services.

"Reviewing Controlled localities"

20. **Paragraph 1B of Schedule 3** requires that "controlled localities" will be subject to review and that health boards will carry out such a **review every three years**.

21. Changes can occur that may affect the designation of an area as a "controlled locality". This could be, for example, where a housing development has been built, or is in the process of being built, and the population of a village has increased, or will increase as a consequence of increases in shopping, leisure and other facilities usually found in non-rural areas.

22. Local NHS services, therefore, **need to be able to respond to changing healthcare needs in these circumstances**. Three-yearly reviews were considered to **deliver the right balance between keeping plans current whilst avoiding unnecessary work of shorter review periods**.

23. The 2014 Regulations also make provision for earlier review to be undertaken in the light of new evidence which demonstrates a 'substantial change' in circumstances.

"Prejudice Test"

24. In conjunction with Amendment Regulation 8, **Amendment Regulation 4** makes provision for the requirement of the health board Pharmacy Practices Committee (PPC) to apply a 'prejudice test' when considering pharmacy applications in a 'controlled locality'. In essence, a PPC will refuse an application if, in its opinion, the granting of the application would adversely impact on the security and sustainable provision of existing NHS primary medical and pharmaceutical services in the locality concerned.

25. Where an application is refused on the grounds of prejudice, the health board PPC will not consider any further application from the applicant, or any other applicant, for that neighbourhood until the 'controlled locality' status is reviewed by the health board, or in the event that new evidence comes to light of 'substantial change'.

26. The 'prejudice test' is in addition to the 'necessary or desirable' test in order secure adequate provision of NHS pharmaceutical services in the neighbourhood of the proposed pharmacy.

Securing NHS pharmaceutical services

27. More generally, **Amendment Regulation 8** introduces a further requirement when the health board Pharmacy Practices Committee (PPC) is considering the 'necessary or desirable' test.

28. The likely long term sustainability of the pharmaceutical services which the pharmacy contractor proposes to provide is made more explicit among the considerations that the PPC shall have regard to. This goes to the heart of the health board's duty to secure adequate pharmaceutical service provision.

Community engagement and participation

29. **Amendment Regulation 8 amends Schedule 3** to also make provisions for the first time for a community representative to be involved at key stages in the pharmacy application process. This effectively gives the community the right to 'interested party status'.

"Community Representative"

30. As indicated above, the pharmacy application process has been subject to the criticism of lacking transparency to the communities affected with variability in the quality and effectiveness of community engagement and participation.

31. Through their local Community Council, the community will be able to make written representations to the health board Pharmacy Practices Committee (PPC) about plans for a proposed pharmacy as well make oral representations at PPC hearings. In addition, the community will also have the right of appeal where they believe the pharmacy application process has not been duly followed.

32. These rights not only apply to the Community Council (or Community Councils) covering the neighbourhood concerned, but also those Community Councils of a neighbouring health board within two kilometres of the proposed pharmacy.

"Determination of an Application"

33. In addition, **Amendment Regulation 8 amends Schedule 3** so that the health board PPC is required to include in its published determination a summary of the joint consultation analysis report submitted in accordance with the new **Regulation 5A.** The determination should also provide an explanation of how the consultation analysis report was taken into account in arriving at the decision with regard to the legal tests under Regulation 5(10).

34. Together with **community engagement and participation** requirements described above, this represents a significant step forward in improving the overall transparency of process to local communities which has been subject to criticism.

Those assisting in making representations at oral hearings

35. **Amendment Regulation 8 amends Schedule 3** to also make provisions for those assisting in making representations at oral hearings to speak on behalf of an interested party.

36. The applicant or any person making representations can nominate the person assisting them to speak on their behalf, but that the person assisting cannot appear in the capacity of paid counsel, solicitor or advocate. **This will also assist in strengthening the community voice**.

37. The current system was reported as creating a barrier to effective communication. This amendment is intended to enable views to be presented more knowledgeably and directly; lead to more constructive and better quality hearings, with hearing proceedings being smoother and more streamlined.

Timeframes for Determinations

38. To improve the overall experience of the pharmacy application process, **Amendment Regulation 8 amends Schedule 3** to introduce **statutory timeframes for reaching decisions** for both the health board PPC (6 weeks upon receipt of the consultation analysis report) and the National Appeal Panel (3 months upon receipt of appeal).

39. This amendment also makes allowance for exceptional circumstances that would give good cause for an extended timeframe and that all interested parties should be notified of any extended period and the reasons**.**

Independent Legal Assessor

40. **Amendment Regulation 9 amends Schedule 4** of the Principal Regulations to introduce the ability of health board PPCs to draw on the technical advice and support of an "independent legal assessor".

    "*Independent Legal Assessor*".

41. The constitution of the health board PPC largely consists of lay members or members who are generally not expert in the legal framework governing pharmacy applications and associated legal tests. This is compounded by the infrequent need to convene a PPC in most NHS Board areas, and the turnover and availability of those willing and prepared to serve as members

42. To assist in the quality of decision-making and delivery against statutory timeframes for reaching decisions, health board PPCs may appoint or have access to an independent legal assessor (an appropriately qualified person with relevant legal experience) to provide **technical advice and support to the PPC during its deliberations**.

43. Crucially, the "independent legal assessor" may not participate in the decision making of the PPC and is not entitled to vote.

Supporting GP Dispensing Practices with Clinical Pharmaceutical Care: provision of dispensing services

44. **Amendment Regulations 10 - 13 amends paragraph 44(3) of Schedule 5 to the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004, and paragraph 15(3) of Schedule 1 to the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004.**

45. The Scottish Government recognises the vital role that GP dispensing practices play in the dispensing and supply of medicines to patients in remote, rural and island communities. It is committed to ensuring that where patients have serious difficulty in obtaining (from a pharmacist) any drugs, medicines or appliances required for their treatment that the dispensing GP practice will continue to fulfil this vital role.

46. Over the next decade and beyond, advances in health care will continue to accelerate. In particular significant changes continue to occur in medicine and therapeutics which will require new and innovative models of care to enable patients to obtain the maximum benefit from their prescribed medicines. *Prescription for Excellence* (http://www.scotland.gov.uk/Resource/0043/00434053.pdf) makes a firm commitment to work with patients, dispensing doctors and appropriate stakeholders to explore how rural communities can be further supported in terms of pharmaceutical care

47. As an important step forward, **Amendment Regulations 10-13** provide that where **GP practices are authorised or required by the health board to provide a dispensing service** to patients on their lists, they **will be further required to receive the support of an appropriately qualified pharmacist independent prescriber.**

48. This support will be provided by the health board, where the health board considers that the health outcomes of patients is likely to be improved by the GP dispensing practice contractor receiving assistance in patients' clinical care with their prescribed medicines.

Transitional Provisions

49. **Amendment Regulation 14 makes provision for the transitional arrangements to support implementation of the new regulatory framework.** The transitional provisions will have a twofold purpose:

(a) To provide for circumstances in which applications made, or commenced, under the existing regulations will continue to be subject to the regulations as they were in force immediately before the coming into force date of the amendments, and

(b) To provide for a transitional period of 3 months to allow for the new arrangements to become fully operational. This would allow health boards to undertake the testing of national guidance, and for national and local training of the new arrangement.

Financial Effects

It is expected that the amendments to the Principal Regulations made by the 2014 Regulations will, in time, be overall cost neutral as they reinforce the duties of the health board in relation to Patient Focus and Public Involvement.

Health Boards already prepare Pharmaceutical Care Services Plans (PCSPs). These new arrangements place greater emphasis on the effective use and maintenance of PCSPs and will facilitate early engagement between the health board and the applicant regarding the likely long term sustainability of the pharmaceutical services which the pharmacy contractor proposes to provide.

In addition, the health board and applicant are already required to carry out separately public consultation activity incurring separate costs and resource. The amended regulation streamlines this consultation activity into a single joint exercise to be conducted over a 90 day period. As a result, the outcome will be more transparent and robust.

The new arrangements also provide safeguards around the existing provision of NHS primary medical and pharmaceutical services in remote and rural areas to help support stability of these local NHS services in these geographical areas. Recent examples of pharmacy

applications approved in these areas has resulted in the adverse impact on the security and sustainability of local primary medical services or increased costs to the health board concerned.

In respect of pharmacy contractors wishing to apply to open a community pharmacy in remote and rural areas, the public consultation which concluded in February 2014 highlighted concerns expressed by the pharmacy contractors' representative body and the pharmacists' professional body. The main focus of concern was that the additional requirements for considering pharmacy applications in these areas could preclude a legitimate business opportunity or prevent patients from accessing the full range of NHS pharmaceutical services. However, the Scottish Government considers that stability of NHS services and the needs of communities are paramount, rather than the potential business opportunities of pharmacy contractors. The priority is to have a "Control of Entry" framework that provides a more balanced solution to address these competing interests.

In respect of individual pharmacists – who in many cases are also pharmacy owners - these amendments hold out the prospect of potential increased need for clinical pharmaceutical care to support GP dispensing practices to provide clinical care to patients with their prescribed medicines. Funding has already been identified in 2014-15 to build pharmacist independent prescriber capacity across health boards and local plans are being developed by NHS Boards with support for GP dispensing practices as a key priority. This will include community pharmacists concerned to enter into arrangements with health boards.

SCOTTISH GOVERNMENT HEALTH DIRECTORATES
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