Department of Health

Regulations under the Health Act 2009: Market entry by means of Pharmaceutical Needs Assessments

Information for Primary Care Trusts
Executive Summary and Chapters 1-4

Introduction, background/overview of the regulatory system, governance arrangements and pharmaceutical lists/terms of service

August 2012

Regulations under the Health Act 2006 – Market entry by means of Pharmaceutical Needs Assessments

Information for Primary Care Trusts
Executive Summary and Chapters 1-4

Prepared by: Medicines, Pharmacy and Industry – Pharmacy Team with the assistance of the Advisory Group on the NHS (Pharmaceutical Services) Regulations

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Executive summary

- Following consultation in the autumn 2008, two clauses were proposed for the Health Bill (now Health Act 2009) to:
    - require PCTs to develop and publish pharmaceutical needs assessments (PNAs); and
    - then to use PNAs as the basis for determining market entry to NHS pharmaceutical services provision.
- In July 2009, a regulatory advisory group drawn from interested parties was set up and started its work to translate these proposals into reality (a list of members of the Advisory Group is at **Annex A**). The new regulations - The National Health Service (Pharmaceutical Services) Regulations 2012 and guidance are a result of their work on the first clause to require PCTs to develop and publish PNAs.
- The Advisory Group has considered the use of PNAs as the basis for determining market entry to NHS pharmaceutical services provision and has produced these regulations and guidance. This guidance has been produced to help PCTs in the assessment and determination of applications to provide NHS pharmaceutical services under the new market entry test.

Content

- Chapter 1 is a general introduction to the guidance.
- Chapter 2 discusses the provisions in the NHS Act 2006 relating to pharmaceutical services and gives an overview of the Regulations that provide further details of the requirements these provisions place on Primary Care Trusts (PCTs).
- Chapter 3 gives details of the governance arrangements that PCTs will need to put in place in order to discharge their statutory duties set out in the 2012 Regulations. It also provides an overview of the process of determining an application.
- Chapter 4 explains the requirement on PCTs to prepare, maintain and publish lists of contractors who undertake to provide pharmaceutical services within the PCT's area. It also covers the information that applicants must provide, the fee that must accompany the market entry application and the arrangements that PCTs are required to enter into when including a contractor onto one of their lists.
- Chapter 5 deals with routine applications submitted to meet current needs identified within a PCT's PNA.

- Chapter 6 deals with routine applications submitted to meet future needs identified within a PCT's PNA.

- Chapter 7 deals with routine applications submitted to secure improvements or better access identified within a PCT's PNA.

- Chapter 8 deals with routine applications submitted to secure improvements or better access where these were not included within a PCT's PNA, i.e. they provide "unforeseen benefits".

- Chapter 9 deals with routine applications submitted to secure future improvements or better access specified within a PCT's PNA.

- Chapter 10 deals with the procedures for applications which are "excepted" from the market entry test where contractors wish to relocate to different premises either within a PCT's area or to another PCT's area and the relocation would not result in significant change to pharmaceutical services or local pharmaceutical services.

- Chapter 11 deals with the procedures for applications which are "excepted" from the market entry test where pharmacy contractors wish to provide services where 'all persons receiving those services do so otherwise than at those premises' (distance-selling).

- Chapter 12 deals with the procedures for applications which are "excepted" from the market entry test where contractors wish to apply for a "change of ownership".

- Chapter 13 deals with the procedures for applications which are "excepted" from the market entry test where contractors wish to apply for a "change of ownership" and relocate to different premises either within a PCT's area or to another PCT's area and the relocation would not result in significant change to pharmaceutical services or local pharmaceutical services.

- Chapter 14 outlines the procedures for dealing with the provision of pharmaceutical services in controlled localities.

- Chapter 15 deals with the provision of pharmaceutical services by dispensing doctors.

Transitional provisions

- **Schedule 7** to the NHS (Pharmaceutical Services) Regulations 2012 (the "2012 Regulations") sets out the provisions for matters, which are not finally determined on the "appointed day". For the purposes the 2012 Regulations, the "appointed day" is 1 September 2012 when the 2012 Regulations come into force.

- In summary and in general, applications which do not have an equal provision in the 2012 Regulations are treated as void if the period for submitting comments ends on or after 1 September 2012. Any fees paid should be refunded. The only exception to this is where the PCT has decided to defer consideration of an application (but not because the application was incomplete). PCTs will therefore wish to review all current applications which:

  - have been sent out for notification but the period for submitting comments does not expire until on or after 1 September 2012; or
  - which have not yet been notified to interested parties,

  and inform applicants accordingly as soon as is practicable. It is good practice to copy the Local Pharmaceutical Committee (LPC) into the letter and to advise unsuccessful applicants that there is no right of appeal against the PCT's decision to treat such applications as void.

- Applications which have been notified and where the period for receiving comments ended on 1 September 2012 or earlier should continue to be determined under the 2005 Regulations.

- Applications which have an equivalent in the new 2012 Regulations are not affected and continue to be determined under the 2005 Regulations, including the procedures for notification, consideration of comments received, determination, communicating the decision and appeal rights.

- Separate guidance has been published on the transitional provisions.

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Chapter 1: Introduction

Status of advice

1. This guidance is a working document and may be subject to change as and when there are amendments to The National Health Service (Pharmaceutical Services) Regulations 2012(referred to in this guidance as the 2012 Regulations) or associated legislation. It has been written with the support and input of a sub-group of the Advisory Group on the NHS (Pharmaceutical Services) Regulations. A list of members of the Advisory Group can be found at **Annex A**.

2. The primary purpose of this document is to help all those working in PCTs with the task of determining[1] applications relating to the provision of *pharmaceutical services* in England from 1 September 2012. This document is also intended to be of assistance to all others who are affected by such decisions.

3. The law on the subject is complex and contained in Acts of Parliament, Regulations and case law from the courts. Additionally over time, decisions made by the NHS Litigation Authority's Family Health Services Appeal Unit (FHSAU) will need to be taken into account by PCTs when determining applications. This document is designed to provide staff at all levels with information on the relevant legal provisions and interpretations of those provisions. It is also intended to provide practical advice in relation to the operation of the legal provisions.

4. Although this document contains a lot of detailed reference in the footnotes to the legal provisions, the rules themselves are not, in the main, set out word for word in this guidance. In order to make the document easier to read, the detailed rules have, in most cases, been paraphrased. However, all those responsible for administering or applying the law must bear in mind that it is the **law** that must be applied, not the interpretation that is set out below.

[1] Reference is made in the Regulations to the determination of applications. Effectively, this means making a decision on an application, i.e. approval, conditional approval, deferral or refusal.

5. This document's intended legal status is that it is non-statutory guidance, designed to assist PCTs in reaching decisions within the framework of the law. It is not an authoritative statement of the law. In practice, there is no substitute for referring to the law itself, or seeking professional advice as to what the law says and how it applies in particular circumstances. It is essential to understand that decisions must be taken in accordance with the law, and not simply based on the analysis and advice contained in this guidance (or indeed any other commentary on the law). Furthermore, although it is hoped that PCTs will find this guidance helpful, the Department's view is that PCTs are not obliged to take this guidance into consideration when formulating their decisions. PCTs' own understanding of the law is fundamentally a matter for them[2] and where they are in doubt, they should seek legal advice.

Previous guidance and transitional arrangements

6. This document relates to applications received under the 2012 Regulations from 1 September 2012 onwards and replaces the original control of entry guidance produced by the Department on 17 September 2009[3] to accompany the NHS (Pharmaceutical Services) Regulations 2005 (referred to in this guidance as the 2005 Regulations). PCTs should retain that previous guidance, however, as there will be applications that by virtue of the transitional provisions within the 2012 Regulations fall to be dealt with under the 2005 Regulations even after the 2012 Regulations have come into force. This includes any appeals that may arise from decisions on such applications. Separate guidance has been issued regarding the transitional provisions.

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[2] It should be noted that in a 2008 Court of Appeal decision, Lord Justice Lawrence Collins stated that "*if the Secretary of State issues non-statutory guidance for decision-makers, and there is a radical departure from the guidance, then, although not relevant to the construction of the relevant provisions, the guidance may be relevant to a challenge because the decision-maker may be under an obligation to take it into account and to explain why he has taken that radically different approach*." (Assura Pharmacy Ltd and NHS Litigation Authority (Family Health Services Appeal Unit) and E Moss Ltd (trading as Alliance Pharmacy) December 2008 – available on http://www.bailii.org/ew/cases/EWCA/Civ/2008/1356.html).
In the light of this, the Department has sought to make its own view clear that decision-makers are not bound to take this particular example of non-statutory guidance into account. However, as Lord Justice Sedley notes in his judgment in Assura, it is currently unresolved at appellate level how an independent tribunal should treat departmental guidance given otherwise than under statutory authority, and reserves his view on the matter to a case where the issue is pivotal. It seems likely therefore that this issue will come up for further judicial consideration in the future.

[3] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_105361 Gateway reference 12573

The Regulations

7. The 2012 Regulations, Statutory Instrument (SI) 2012/1909 replace the 2005 Regulations with effect from 1 September 2012. PCTs should ensure they have access to these Regulations to ensure they are acting within the law when determining applications.

8. As with the 2005 Regulations, it is possible that the 2012 Regulations will be amended over time and PCTs should ensure they have access to an up-to-date version of the Regulations.

Transitional provisions

9. **Schedule 7** to the NHS (Pharmaceutical Services) Regulations 2012 (the "2012 Regulations") sets out the provisions for matters, which are not finally determined on the "appointed day". For the purposes the 2012 Regulations, the "appointed day" is 1 September 2012 when the 2012 Regulations come into force.

10. The transitional arrangements are:

- In summary and in general, applications which do not have an equal provision in the 2012 Regulations are treated as void if the period for submitting comments ends on or after 1 September 2012. Any fees paid should be refunded. The only exception to this is where the PCT has decided to defer consideration of an application (but not because the application was incomplete). PCTs will therefore wish to review all current applications which:

  ✓ have been sent out for notification but the period for submitting comments does not expire until on or after 1 September 2012; or
  ✓ which have not yet been notified to interested parties,

  and inform applicants accordingly as soon as is practicable. It is good practice to copy the Local Pharmaceutical Committee (LPC) into the letter and to advise unsuccessful applicants that there is no right of appeal against the PCT's decision to treat such applications as void.

- Applications which have been notified and where the period for receiving comments ended on 1 September 2012 or earlier should continue to be determined under the 2005 Regulations.

- Applications which have an equivalent in the new 2012 Regulations are not affected and continue to be determined under the 2005 Regulations, including the procedures for notification, consideration of comments received, determination, communicating the decision and appeal rights.

Pharmaceutical Needs Assessments

11. This document does not cover those regulations (regulations 3-9) and Schedule 1 that relate to PCT pharmaceutical needs assessments (PNAs). Separate guidance has been produced to assist PCTs in understanding the requirements of these.

Other guidance documents

12. Other guidance has been produced to assist PCTs in understanding the requirements of the 2012 Regulations. These include the charging of fees for applications (see Annex F), and performance related sanctions including market exit.

Structure of the document

13. The document is structured so that each type of application that a PCT may receive has its own chapter. PCTs will then be able to work through the correct process for each type of application without having to cross-reference to other chapters. This does mean that the document as a whole is repetitive in parts but it is hoped that the repetition of certain elements within each chapter provides a clearer process which is easy to follow for PCTs.

14. Throughout the document, where reference is made to another document, the web address will be given. Where documents are Department of Health publications, the Gateway reference will also be given.

15. Within **Regulation 2** of the 2012 Regulations, there is a list of definitions. Where one of these terms is used in this document, it will appear in italics so that readers are able to understand each term in the correct context. **Annex B** contains a glossary of such terms.

Chapter 2: Background and overview of the Regulatory system

1. This chapter discusses the provisions within the National Health Service Act 2006[4] (the 2006 Act) relating to *pharmaceutical* services and gives an overview of the Regulations that provide further details of the requirements these provisions place on Primary Care Trusts (PCTs).

2. This document provides guidance on the following Parts of the Regulations:

- Part 3 – general matters relating to pharmaceutical lists and applications in respect of them;
- Part 4 – excepted applications;
- Part 5 – specific grounds for refusal or deferral of applications that are not linked to fitness to practise grounds;
- Part 6 – refusal, deferral and conditional inclusion in the pharmaceutical list on fitness to practise grounds;
- Part 7 – *controlled localities*, *reserved locations* and pharmacies in these areas;
- Part 8 – *dispensing doctors*; and
- Schedules 2 (procedures) and 3 (appeals).

Arrangements for pharmaceutical services

3. Sections 126 to 133 inclusive of the 2006 Act cover the provision of *pharmaceutical services*.

4. Section 126 of the 2006 Act places an obligation on PCTs to put arrangements in place so that drugs, medicines and listed appliances ordered via NHS prescriptions can be supplied to persons. This section makes provision for the types of healthcare professional whom the Regulations may allow to order drugs, medicines and listed appliances on an NHS prescription.

[4] http://www.opsi.gov.uk/acts/acts2006/ukpga_20060041_en_1

5. Appliances must be listed in the Drug Tariff in order to be prescribed on NHS prescriptions and are therefore referred to as listed appliances[5].

6. This duty on PCTs to make arrangements set out in Section 126 of the 2006 Act is alongside a duty on the Secretary of State to make Regulations to facilitate PCTs to discharge this duty.

7. Section 126 requires PCTs to ensure that they have arrangements in place for:

- the provision of proper and sufficient drugs, medicines and listed appliances which are ordered on NHS prescriptions by doctors;
- the provision of proper and sufficient drugs, medicines which are ordered on NHS prescriptions by dentists;
- the provision of proper and sufficient drugs, medicines and listed appliances which are ordered on NHS prescriptions by other specified descriptions of healthcare professionals; and
- such other services that may be prescribed.

8. It is this duty that underpins the provision of those services set out in Schedules to the Regulations by pharmacy contractors and dispensing appliance contractors. Section 132 makes provision for regulations that allow for arrangements to provide dispensing services by GPs. Their terms of service are set out in Schedule 6 to the Regulations.

9. Section 127 of the 2006 Act allows the Secretary of State to make provision for other services in Directions. It is from this Section that advanced and enhanced services are derived. The requirements for these services are set out in Directions and are referred to as *directed services* in the 2012 Regulations.

10. The 2006 Act allows for arrangements to be made for the provision of three types of *pharmaceutical services*, depending on the type of contractor providing the services:

- essential[6] services, other mandatory arrangements, advanced services and enhanced services provided by pharmacy contractors;

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[5] The exhaustive list of appliances that may be supplied under the Regulations is set out in Part IX of the Drug Tariff. Any drug/medicine may be supplied unless it is included in the selected list set out in Schedule 1 to the NHS (General Medical Services Contracts)(Prescription of Drugs etc) Regulations 2004, which is reproduced in Part XVIIIA of the Drug Tariff. There is also a “grey list” of drugs that GPs should only prescribe on the NHS under restrictive conditions.

[6] Essential services are defined as those set out in paragraph 3 in Schedule 4 and does not include other mandatory arrangements that apply to all pharmacy contractors, such as clinical governance arrangements. The term “essential services” is not used to describe those services provided by dispensing appliance contractors as set out in Schedule 5.

- services set out in **Schedule 5** and advanced services as provided by dispensing appliance contractors; and
- dispensing services provided by dispensing GPs as set out in **Schedule 6**.

11. Within the 2012 Regulations, the definition of *pharmaceutical services* differs between the Parts and Schedules:

- Part 2 and **Schedule 1** – provisions regarding pharmaceutical needs assessments (PNAs) – as per the definition in paragraph 10 above, plus local pharmaceutical services (LPS);
- Parts 7 and 8 and **Schedule 6** – provisions regarding controlled localities, reserved locations and dispensing doctors, and the terms of service for dispensing doctors – in the context of service provision by services provided by *dispensing doctors*, *pharmaceutical services* means the dispensing services provided by dispensing GPs as set out in **Schedule 6**. In the context of service provision by pharmacy contractors or appliance contractors, it means the services mentioned in relation to those types of contractor in paragraph 10 above, but not LPS; and
- Parts 3 to 6 and 9 to 13 – as per the definition in paragraph 10 above, although in practice, services provided by dispensing GPs will generally not be relevant where *pharmaceutical services* is used in these Parts, as these Parts relate almost exclusively to market entry and performance sanctions for pharmacy and dispensing appliance contractors.

12. Originally, the underlying policy objective of the legislation was that there should be a distinction between those who prescribe drugs and those who dispense drugs. This principle has, however, always been subject to exceptions, most notably in rural areas – which are known in the Regulations as *controlled localities*. It is increasingly less distinct as more health professionals, including pharmacists, are able to qualify as prescribers in order to improve access to, and choice of, services for patients.

Regulations for the provision of pharmaceutical services

13. Detailed regulations relating to the arrangements for securing the provision of these services are made under the authority principally of Section 129 of the 2006 Act. Section 129 was amended by the Health Act 2009[7] to reflect the move towards using PNAs as the basis for determining applications for inclusion in a pharmaceutical list and is reproduced in **Annex C** for ease of reference. In summary, Section 129 makes provisions for Regulations that will govern the provision of *pharmaceutical services* to assist PCTs in discharging their duty set out in Section 126.

14. Section 129 also includes provision for Regulations to deal with the process of creating a pharmaceutical list, removing persons from such a list and setting the entry requirements of those entitled to be entered on the list.

15. The drugs, appliances and chemical reagents to be supplied within the NHS and payments for such are listed in the Drug Tariff. The Drug Tariff, which is a statutory requirement under Section 164 is available from The Stationery Office and is available on the NHS Business Service Authority website[8].

16. There are two modes of provision of *pharmaceutical services* in the Regulations:

    (a) by chemists (and in the context of the 2012 Regulations this covers individual pharmacists, bodies corporate, partnerships and suppliers of appliances); and
    (b) by doctors (see Chapter 15 of this guidance).

Market entry test

17. The market entry test describes the system whereby the PCT assesses an application that offers to:

    - meet an identified current or future need or needs;
    - meet identified current or future improvements or better access to *pharmaceutical services*; or
    - provide unforeseen benefits, i.e. applications that offer to meet a need that is not identified in a PNA but which the PCT is satisfied would lead to significant benefits to people living in the PCT area.

18. Section 129 (2A) and (2B) sets out the market entry test as follows:

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[7] http://www.opsi.gov.uk/acts/acts2009/ukpga_20090021_en_1
[8] http://www.ppa.org.uk/ppa/edt_intro.htm

Provision within the Act	Explanation
(2A) *The PCT is satisfied as mentioned in this subsection if, having regard to the needs statement and to any matters prescribed by the Secretary of State in the regulations, it is satisfied that it is necessary to grant the application in order to meet a need in its area for the services or some of the services specified in the application*.	Section 129(2A) requires Regulations to make provision for PCTs to be required to approve applications where they are satisfied that it is necessary to grant the application in order to meet the need identified within its PNA. However, the Regulations may provide overriding reasons for the PCT not to approve such an application, for example, where there are concerns relating to the applicant's fitness to practise.
(2B) *The PCT is satisfied as mentioned in this subsection if, having regard to its needs statement and to any matters prescribed by the Secretary of State in the regulations, it is satisfied that to grant the application would secure improvements, or better access, to pharmaceutical services in its area.*	Section 129(2B) requires Regulations to make provision for PCTs to be able (but not required) to approve applications if they are satisfied that to do so will secure improvements or better access to *pharmaceutical services* in their area, again based on needs identified within their PNA and subject to any prescribed overriding reasons for not doing so.

Types of applications

19. There are two types of application that can be made by pharmacy or dispensing appliance contractors within the 2012 Regulations:

- *routine applications*; and
- *excepted applications*.

20. **Regulation 12** defines the types of applications that are termed *routine application*. These are applications that are submitted under Part 3 of the Regulations, namely applications:

- to be included in a pharmaceutical list by persons not already included in it; and

applications by persons already included on the PCT's pharmaceutical list to:

- open, within the area of the PCT on whose pharmaceutical list they are included, additional premises from which to provide the same or different pharmaceutical services;
- relocate to different premises and to provide the same or different *pharmaceutical services* from those new premises; and

- provide services in addition to those that are already provided at the *listed chemist premises*.

21. In practice, contractors and PCTs may rarely use the 2012 Regulations to submit and consider applications to provide additional services to those that they already provide (**Regulation 12(b)(iii)**). It is more likely that PCTs will use normal tendering processes when commissioning enhanced services, but they should be aware of this route and ensure they have processes to determine such applications. If an application to provide directed services is received, the PCT has a duty to determine it unless it is withdrawn by the applicant.

22. Sections 129(2A) and (2B) do not apply to some types of application and these are known as *excepted applications*.

23. Provision for these types of application are included in Part 4 of the Regulations and include:

- applications to provide *directed services* (**Regulation 23**);
- relocations that do not result in significant change to *pharmaceutical services provision* (**Regulation 24**);
- *change of ownership* applications (**Regulation 26**);
- applications for temporary listings arising out of suspensions (**Regulation 27**);
- applications from persons exercising a right of return to a pharmaceutical list (**Regulation 28**); and
- applications relating to *emergencies requiring the flexible provision of pharmaceutical services* (**Regulation 29**).

Applications to relocate to new premises

24. PCTs should note that there are two different types of relocation applications.

25. The first type is a *routine application* that falls under **Regulation 12(b)(ii)**. This is an application to relocate to new premises in order to meet a need identified within the PNA, and which would result in a significant change to *pharmaceutical services provision* in the PCT's area.

Example

The lease on the premises of a contractor is due to expire and the new rent would make the pharmacy financially unviable. The premises are on the High Street of a town. Within the PCT's PNA, there is an identified current need for a pharmacy within a new housing development on the other side of the town. The contractor could therefore submit an application under **Regulation 12(b)(ii)** to relocate from their current premises to new premises within the housing development and offer to provide the services that the PNA identifies are needed at that new location.

26. Where a PCT receives an application to relocate under **Regulation 12(b)(ii)**, then apart from not needing further fitness to practise information from the applicant, they should treat it as though it was an application to join the pharmaceutical list to meet a need identified within the PNA. PCTs should refer to Chapters 5 to 9 to see how to process and determine such an application.

27. The second type is an *excepted application* that falls under **Regulation 24**. In order to meet the requirements of **Regulation 24**, the relocation must not result in a significant change to *pharmaceutical services* provision.

Example

The lease on the premises of a contractor is due to expire and the building is due to be demolished. The contractor identifies suitable premises 200 metres down the road and therefore submits an application under **Regulation 24** to relocate to these new premises. Further information on this type of application can be found in Chapter 10.

Rural dispensing

28. Where a PCT has determined that an area is "controlled" (i.e. rural in character - see Chapter 14), provided certain conditions are met, doctors as well as pharmacists can dispense NHS medicines. GPs, may, in general, dispense NHS prescriptions only with PCT approval and only to their own patients who live in such *controlled localities* and live more than 1.6 km (as the crow flies) from a pharmacy. The main purpose of this is to ensure patients in rural areas who might have difficulty getting to their nearest pharmacy can access the dispensed medicines they need.

29. A GP who wishes to apply to dispense to patients need only show that to do so would not prejudice the proper provision of *relevant NHS services locally* (known as the "prejudice test"). Relevant NHS services for these purposes are medical, pharmaceutical or local pharmaceutical services provided by other contractors.

30. The "prejudice test" will also apply to applications from pharmacy contractors in rural areas and further information can be found in Chapter 14.

31. PCTs may determine *reserved locations* in *controlled localities* (see Chapter 14 for further information). If an application is made for new pharmacy premises in a *reserved location*, only the market entry test is applied to the application, not the prejudice test.

32. Further information on rural dispensing can be found in Chapter 14 and 15 of this document.

Appeals against PCT decisions on pharmaceutical applications

33. Under the Regulations, most PCT decisions on market entry applications are appealable to the Secretary of State for Health who has delegated this responsibility to the NHS Litigation Authority (NHSLA). The appellate function is undertaken by the NHSLA's Family Health Services Appeal Unit (FHSAU). More information about their work is available on their website[9].

34. **Schedule 3** of the 2012Regulations sets out the actions that the FHSAU may take. In summary, the FHSAU may generally:

- confirm the decision or determination of the PCT;
- quash the decision or determination of the PCT and re-determine the application;
- substitute its decision or determination for any decision or determination the PCT could have made; or
- quash the PCT's decision and remit the matter to the PCT for it to re-determine the application.

35. Where the FHSAU remits the matter back to the PCT, this is generally where there have been procedural concerns of an administrative nature (i.e. the PCT has not followed a procedure set down in the 2012 Regulations).

36. For the purposes of the 2012 Regulations, the FHSAU's decision becomes the PCT's decision on the matter. The FHSAU's decision may only be overruled by a court.

37. PCTs may find it useful periodically to view the FHSAU's decisions for learning and training purposes.

[9] http://www.nhsla.com/FHSAU/Decisions/Pharmacy+2005+Regulations/

Chapter 3: Governance arrangements

1. This chapter gives details of the governance arrangements that Primary Care Trusts (PCTs) will need to put in place in order to discharge their statutory duties set out in the 2012 Regulations. It also provides an overview of the process of determining an application. Further detailed information on this process can be found in the subsequent chapters.

Decision-making process

2. The duty to make decisions on applications submitted under the 2012 Regulations lies with the PCT Board. Regulation 10(1)(d) of the NHS (Functions of Strategic Health Authorities and Primary Care Trusts and Administrative Arrangements (England) Regulations 2002[10]) (the 2002 Regulations), as amended, allows the Board to delegate this function to a committee, sub-committee or officer of the PCT. As the 2012Regulations are new, it is recommended that the Board discusses the delegation by it of its functions once the 2012 Regulations are laid and before they take effect.

3. It is important that due process is followed in the delegation of this function and that the decision to delegate is formally recorded in the minutes of the Board meeting. If a PCT is unsure as whether this has happened, it is recommended that the matter is discussed and agreed by the Board.

4. Where PCTs have delegated some decisions to their Family Health Services (FHS) agency, they will need to ensure that this delegation was done in accordance with these Regulations. If the PCT does not employ FHS staff, then delegating decision-making responsibility may be in breach of these Regulations, which only allow delegation to individuals who are “officers” of the PCT.

[10] The reference for the 2002 Regulations is Statutory Instrument (SI) 2002/2375. It has been amended by Sis 2003/1497, 2004/865, 2008/3166 and 2009/462. A consolidated version is not available on a government website but copies of the original and amending regulations can be found on http://www.legislation.gov.uk/uksi.

5. Decision-making processes that allow some decisions to be made by individual officers but which ensure that the key decisions are made by the committee or sub-committee to which they report will need to be signed off by the Board, rather than simply the committee or sub-committee to which the key decisions have been delegated. Even if the committee or sub-committee takes the lead in designing the decision-making processes, the Board will need to approve them formally.

6. It is imperative that PCTs and their agencies have robust decision-making processes for market entry decisions including an assurance that there are no conflicts of interest. In addition to the recommendation of paragraph 3 above, it is good practice that terms of reference are developed for the committee or sub-committee that makes the key decisions and that these are made open and transparent with all stakeholders involved in the process. It is especially important for the committee or sub-committee involved in making the key decisions to be clear on their remit and responsibilities. Examples of terms of reference can be found on the NHS Primary Care Commissioning (PCC) website[11].

Decision-making group

7. Those persons who are involved in the determination or deferral of an application must have access to the 2012 Regulations and any amending Regulations. PCTs should also consider the training that such persons have received and should ensure that members of committees are advised of subsequent amendments and receive training where this is appropriate.

8. **Paragraph 26, Schedule 2** sets out a list of persons who must take no part in determining or deferring any *routine or excepted application*. They are:

- a contractor included in the PCT's pharmaceutical list or any employee of such a contractor;
- a person who assists in the provision of *pharmaceutical services* under Part 1 of Chapter 7 of the 2006 Act;
- Local Pharmaceutical Services (LPS) contractors, or someone who provides or assists in the provision of LPS;
- providers of primary medical services;
- members of a provider of primary medical services that is a partnership, or shareholders in a provider of primary medical services if that provider is a company limited by share;
- persons employed or engaged by a primary medical services provider or a (Primary Care Trust Medical Services) PCTMS practice; or

[11] http://www.pcc.nhs.uk/market-entry

- persons employed or engaged by an (Alternative Provider Medical Services) APMS contractor in any capacity relating to the provision of primary medical services.

9. These persons must take no part in decisions, whether their involvement would give rise to a reasonable suspicion of bias or not.

10. Additionally, no person with an interest or association in the application may take part in determining or deferring a particular application where their involvement would give rise to a reasonable suspicion of bias. For example, a lay member who sits on the panel should be excluded from taking part in the determination of an application which has been submitted for the village they live in.

11. Furthermore, any person who may be subject to pressure about a particular application must not take part in the determining or deferral of it (**paragraph 26(2) of Schedule 2**). PCTs should therefore check the membership of the committee that considers applications to ensure it complies with this paragraph. Additionally, PCTs may wish to seek declarations of conflict of interest from members at the beginning of the meeting and to record any such declarations formally.

12. Committees may wish to take professional advice from persons who are excluded by virtue of **paragraph 26 of Schedule 2** to aid the determination or deferral of an application. Such persons are able to give advice to the committee, but must not be seen to be part of the determination or deferral of an application. Hence, if any persons are present to give professional advice to the committee, they should withdraw before any vote on a decision is made. It is important to take account of the provisions of Article 6 of the Human Rights Act 1998 (right to a fair trial), as well as general public law considerations of fairness, when deciding whether to include such people.

13. Where professional advice is sought, it is good practice to declare at the start of any committee meeting that these individuals are excluded from any determination or deferral of an application. It is also good practice to make a note in the minutes that any professional advisers have retired from the room before decisions are finalised and voting takes place.

14. The importance of these points is that if this is not followed, an appeal or judicial review could be based on an argument that due process has not been followed and that inappropriate persons have been party to the determination of deferral of an application. Equally, however, the panel has a duty to make a sufficient enquiry into the matter before it, so that it has a sufficiently full picture for a fair decision to be made. Therefore, sometimes, obtaining the advice of professional advisers will be unavoidable.

15. Appeals against PCT decisions to the NHS Litigation Authority (NHSLA) are difficult to avoid, but with appropriate and robust decision-making processes, their likelihood of success can be minimised. Appeals procedures can be difficult and require a lot of time and effort.

16. PCTs need to be sure that data protection and confidentiality is monitored throughout the whole process and sound administrative and audit processes for applications are important.

17. Some decisions may be delegated to an officer of the PCT and need not go to a full committee meeting for approval, for example, where a change of ownership application has been received. If it meets the requirements of the Regulations and no issues have been identified in any fitness to practise checks, the PCT may decide it is appropriate for an officer to determine the application instead of the committee. Again, good governance should be followed and any such delegation formally ratified by the Board.

Oral hearings

18. Oral hearings are not required to be held for all decisions and PCTs should make a judgement on when and for what type of decisions an oral hearing is necessary. This is likely to be based on the complexity of the application, previous applications in the locality, the number and type of representations made in respect of the application from those notified of it, and decisions of the NHSLA.

19. Where a PCT decides to hold an oral hearing, the procedure to be followed is set out in **paragraph 25 of Schedule 2**.

Notification of decision

20. The PCT must make a decision on the application as soon as is practicable and no later than:

    - four months after receiving the application and all supporting information or documentation, if it is one that is *notifiable* (see later chapters); or
    - within 30 days if the application is not a *notifiable* one (see later chapters). (**Paragraph 27 of Schedule 2**)

21. Once the decision is made, the PCT must *notify* certain persons of that decision (**paragraph 28 of Schedule 2**). The decision letter must include the reasons for the decision (**paragraph 28(6) of Schedule 2**), and should not simply say that the application has been granted or refused.

22. Where an application is approved, the PCT is also required to send a template *notice of commencement* with the decision letter (**paragraph 29 of Schedule 2**). The PCT may choose to pre-fill the template with the relevant data, but in any case, the applicant is required to complete and return the template to the PCT fourteen days prior to their intention to commence the provision of *pharmaceutical services* (**paragraph 34(2) of Schedule 2**). Commencement must begin within the period for which an application is approved.

Appeals against PCT decisions on pharmaceutical applications

23. The main procedures regarding appeals are set out in Schedule 3.

24. An appeal must be made in writing to the NHSLA within 30 days from the date on which the PCT decision letter is sent. Appeals are heard by the Family Health Services Appeal Unit (FHSAU) on behalf of the Secretary of State for Health.

25. In order to be valid, the appeal must contain a concise and reasoned statement of the grounds for appeal. Appeals may be sent by e-mail attachment initially, but should always be followed up by hard copies by letter or by fax.

26. An appeal under Schedule 3 can generally only be made by the applicant or by a contractor who has been notified of the decision by the PCT. There are some exceptions to this relating to *controlled localities* and *reserved locations* (see Chapters 14 and 15 for further information).

27. Apart from some *controlled locality* and *reserved location* appeals, an appeal cannot be made, for example, by a Local Pharmaceutical Committee (LPC) or Local Medical Committee (LMC). Where more than one appeal is received in relation to a decision, the FHSAU can determine them at the same time.

28. Market entry appeals are determined by the Pharmacy Appeals Committee of the FHSAU. Some other types of appeal are determined by a senior officer of the FHSAU.

29. The FHSAU's deliberations are not limited to simply reviewing the PCT's decision. It may determine the appeal by reconsidering the application *de novo* (i.e. from the beginning).

30. The majority of cases are decided based on correspondence with the FHSAU and other documentation related to the original decision. Occasionally, for example, if there are material differences in the facts presented by the parties, the FHSAU will convene a panel to hold an oral hearing.

31. The FHSAU must give at least 14 days' notice of the hearing to the appellant and a list of other persons who are entitled to make oral representations at the hearing. This list includes:

- the applicant (if different from the appellant);
- the PCT;
- the relevant local representative committees; and
- any "additional presenters" – that is, any person to whom a copy of the *notice* of appeal is sent who made written representations on the appeal in the course of which they indicated they would wish to make oral representations if there were a hearing, provided that the FHSAU is satisfied that it would be desirable to hear further evidence from them at the hearing.

32. The appellant and any person who whom a *notice* of the hearing is sent can attend with any representatives they wish to accompany them.

33. The FHSAU's target is to ensure all appeals are processed within 26 weeks. For those appeals determined without an oral hearing, the target is to process appeals within 15 weeks.

34. Whilst there are standard complaints procedures that apply to any NHS body, there are no further powers for review of an appeal decision once it has been issued. The FHSAU's decision can only be set aside by the High Court.

Database of applications

35. In chapter 4 of the PNA guidance[12] it was suggested that PCTs may find it useful to maintain a list of applications along with the dates of key steps in the process, for example, receipt, date of notification to interested parties, scheduled date of determination, actual date of determination, decision and date of final grant.

36. By making this document publicly available, it will assist potential applicants in deciding whether or not to submit an application. This would need to be a live document, and in the case of *notifiable applications*, these should be added at the point the PCT *notifies* interested parties of it.

37. PCTs may also like to consider publishing the outcome of each application in the same way the FHSAU does[13].

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[12] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_114953 Gateway reference 14083
[13] http://www.nhsla.com/FHSAU/Decisions/Pharmacy+2005+Regulations/

Chapter 4: Pharmaceutical lists and terms of service

1. This chapter explains the requirement on Primary Care Trusts (PCTs) to prepare, maintain and publish lists of contractors who undertake to provide *pharmaceutical services* within the PCT's area. It also covers the information that applicants must provide, the fee that must accompany the market entry application and the arrangements that PCTs are required to enter into when including a contractor onto one of their lists.

Pharmaceutical lists

2. PCTs are required to prepare, maintain, publish and make available for public inspection, lists of persons (other than GPs and dentists) who undertake to provide *pharmaceutical services* from premises in the PCT's area (**Regulation 10(1)**). PCTs should note that although the regulation makes reference to persons being included on the list, the word "persons" refers to the contractor. In that respect, the pharmaceutical list differs from the "performer lists" that PCTs hold for individual GPs, dentists and optometrists. Currently, there is no pharmaceutical equivalent of the performer list.

3. **Regulation 10(1)** requires PCTs to prepare:

   - a list of persons who undertake to provide *pharmaceutical services*, in particular by way of the provision of drugs and the appliances that they supply in their normal course of business, i.e. community pharmacies run by sole traders, partnerships or bodies corporate (**Regulation 10(2)(a)**); and
   - a list of persons who undertake to provide *pharmaceutical services* only by way of the provision of appliances, i.e. dispensing appliance contractors (**Regulation 10(2)(b)**).

4. Not all PCTs will have two lists. PCTs should note that community pharmacies that also provide a range of appliances should only be included on the first list; they do not also need to be included in the list of persons providing appliances.

5. Each list must contain as a minimum, the following information:

   - the contractor's name (this should not be the trading name, rather the name of the organisation that is running the pharmacy);
   - the address of the premises from where the contractor has undertaken to provide pharmaceutical services – the *listed chemist premises* (**Regulation 10(3)(a)**); and

- the days and times at which services are provided, during both *core opening hours* (**Regulation 10(3)(b)(i)**) and *supplementary opening hours* at those premises (**Regulation 10(3)(b)**).

6. The lists must be available for public inspection (**Regulation 10(3)**) and PCTs should consider how they will meet this requirement and how they will keep the lists up-to-date, for example via the PCT website. In order to ensure the lists are accurate, it is recommended that all changes go through a single point of contact within the PCT. PCTs should also consider how they will incorporate these changes into the PNA map or maps.

7. **Regulation 10** sets out the minimum information requirements of the lists and PCTs are free to add additional information to their list(s) and may wish to include the following:

   - the trading name of the pharmacy; and
   - any advanced and enhanced services that are provided.

8. **Regulation 10(4)** also requires PCTs to prepare, maintain, publish and make available for public inspection, a list of all *NHS chemists* in their area who participate in the electronic prescription service (EPS) service. Included in this list is the address of any premises at which the EPS service is provided. PCTs may wish to incorporate this list into their lists prepared under **Regulation 10(2)** (**Regulation 10(5)**).

9. In addition to these two lists, PCTs are also required to prepare and publish a list of any dispensing doctors in their area (**Regulation 46(1)**). Further information on this list can be found in Chapter 15.

Inclusion in or amendment to a pharmaceutical list – information to be provided

10. **Regulation 10(6)** refers to Schedule 2 of the Regulations. **Part 1 of Schedule 2** contains the information to be supplied by a person who is:

    - seeking inclusion in a pharmaceutical list that they are not already included in; or
    - included in that pharmaceutical list and is seeking to:
      i. open additional premises from which to provide the same or different *pharmaceutical services*;
      ii. to relocate to different premises to provide the same or different *pharmaceutical services*; or
      iii. to provide additional services to those they are already listed to provide at their *listed chemist premises*.

11. Where the applicant is not already included in the PCT's pharmaceutical list, they are required to submit information on their fitness to practise to the PCT or in some instances, to their *Home PCT* (for further details, please see guidance on fitness to practise[14]). PCTs must ensure that where they need to come to a decision as to whether the applicant is suitable to be included on their pharmaceutical list or not, this decision must be made before considering the market entry application.

12. Schedule 2 also sets out the procedure to be followed by applicants when they make an application and other related matters such as *notification* and determination of applications by PCTs.

13. The Regulations do not set out a template form to use for the purposes of providing this information. However, applications should include such information as the PCT considers necessary for it to be able to determine the application. **Paragraph 11 of Schedule 2** sets out the procedure to be followed where not all the relevant information and documentation is provided to the PCT.

14. PCTs may, therefore, wish to develop template application forms which they then make available to applicants via the PCT website. It should be noted, however, that applicants would not be obliged to use those forms and PCTs cannot refuse to determine an application simply because the information has been provided in a different format.

Terms of service: general

15. When including a contractor on one or other of their pharmaceutical lists, **Regulation 11** requires PCTs to ensure that the terms of their inclusion include the following:

- their terms of service as set out in Schedules 4 (community pharmacy contractors) or Schedule 5 (dispensing appliance contractors);
- any obligation in the 2012 Regulations that is only applicable if the contractor is a person to whom the obligation is applicable, for example, the 100 hours per week condition that is applicable to some pharmacies that relied on that exemption under the 2005 Regulations;
- the conditions set out in the Drug Tariff, where applicable;
- the terms of the arrangement for the provision of any directed services; and
- Regulation 3 of the Local Involvement Networks (Duty of Services Providers to Allow Entry) Regulations 2008[15] as it applies to pharmacy and dispensing appliance contractors.

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[14] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108206 Gateway reference 4728
[15] http://www.legislation.gov.uk/ukdsi/2008/9780110809311/regulation/3

16. Additionally, where the PCT has placed fitness to practise conditions on the inclusion of that contractor under **Regulation 35** or Chapter 6 of Part 7 of the 2006 Act, the arrangements must make reference to those conditions.

17. PCTs should, therefore, ensure that when writing to *notify* applicants that their application has been approved, reference is made to these requirements.

18. This requirement applies equally to both pharmacy and appliance contractors. **Regulation 47** makes similar provision for dispensing doctors (see chapter 14).

Charges for applications

19. Since April 2008, PCTs have been required to charge for certain types of application. Details on this are set out in Directions and guidance produced to assist PCTs.

20. Applicants should, therefore, ensure they submit the information set out in Part 1 of Schedule 2 where applicable and also the appropriate fee. PCTs are reminded that until all these elements are received, the application is deficient and they should not begin to process the application.

21. The fees are non-refundable as they are a contribution towards the PCT's costs of processing and determining the application.

22. During the passage of the Health Act 2006 a general review, after 18 months of implementation, of charging for NHS pharmaceutical services applications was promised (September 2009). The review looked at progress in implementing charging as well as the impact of charging on the NHS, pharmacy and appliance contractors and applicants. It also sought to find out whether the current fee levels were fair and reasonable.

23. The Government published the outcome of the review in October 2011[16]. The Government notes that the experience of the effect of charging by the NHS is variable. However, chemist contractors have not felt significantly affected by charging for applications. Thus, the fees for applications will be retained. The Government also notes that most respondents felt that the current fee levels are fair and reasonable. Therefore, it does not feel there is sufficient evidence to change current fee levels.

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[16] http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_130489 Gateway reference: 16516

24. Fees will continue to be paid for applications under the 2012 Regulations. Further details of this are set out in The Pharmaceutical Services (Fees for Applications) Directions 2012 and guidance to these Directions is included in **Annex F**.