Regulations under the Health Act 2009: Performance sanctions including market exit for contractors providing pharmaceutical services

Information for Primary Care Trusts

August 2012

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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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Contents

Executive summary

- There are powers in sections 126 and 129 of the NHS Act 2006 which enable the terms of service under which NHS *pharmaceutical services* are provided to be specified in regulations. These provisions give Primary Care Trusts (PCTs) new powers to take action where there are concerns about the quality of performance of services provided by pharmacy and dispensing appliance contractors (DACs). They permit PCTs to impose sanctions such as remedial or breach notices, withholding payments and ultimately removing from the NHS pharmaceutical list.

- In Spring 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 primary purpose of this document is to help those working in PCTs with the task of managing performance-related concerns relating to the provision of *pharmaceutical services* in England from 1 September 2012 and removals from the pharmaceutical list ("market exit"). This guidance is also intended to be of assistance to those who provide or perform *pharmaceutical services*.

- These new provisions are not a means to close services. They are part of driving up the quality of the services provided. Contractors who provide services to good quality – and get rewarded for them – will want to demonstrate this to patients. The NHS needs to show that good value for money is being achieved. Above all, patients and consumers should be better informed about the quality and standards of services available so that they can make decisions about what best suits them.

- These sanctions apply to pharmacists and DACs but not dispensing doctors where performance issues are generally a matter to be dealt with under the relevant personal medical service contractual arrangements. However, Chapter 6 provides information about removal or withdrawal of dispensing doctors under the Regulations. Local pharmaceutical services (LPS) are outside the scope of these provisions – any contractual under- or over-performance should be dealt with under the terms of LPS contracts.

- It should be noted that when these Regulations come into force, *the National Health Service (Service Committees and Tribunal) Amendments Regulations 1996* will be repealed subject to any necessary transitional arrangements.

Content

- Chapter 1 of this guidance is an introduction to the guidance and includes information on the 2012 Regulations, the status of the guidance and the structure of the document.

- Chapter 2 of this guidance gives the background and overview of the new regulatory system for performance related sanctions including market exit.

- Chapter 3 of this guidance outlines the governance arrangements that PCTs will need to put into place in order to discharge their statutory duties set out in the 2012 Regulations.

- Chapter 4 of this guidance deals with matters relating to the performance related sanctions set out in Part 10 of the 2012 Regulations i.e. local dispute resolution, the ability to issue *breach* and *remedial notices*, and the ability to withhold payments.

- Chapter 5 of this guidance deals with the provisions within Part 10 of the 2012 Regulations for the removal of pharmacy contractors and dispensing appliance contractors (DACs) from the pharmaceutical list for reasons that do not relate to non-compliance with *breach* or *remedial notices*.

- Chapter 6 of this guidance deals with the provisions whereby a dispensing doctor may withdraw or be removed from the dispensing doctor list.

- Annex A is a list of the members of the regulatory Advisory Group and the sub-group who worked on the draft guidance.

- Annex B is a glossary of defined terms and phrases.

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 managing quality and performance-related concerns relating to the provision of *pharmaceutical services* in England from 1 September 2012 and removals from the pharmaceutical list ("market exit"). This document is also intended to be of assistance to those who provide or perform *pharmaceutical services*.

3. The law on the subject is contained in Acts of Parliament, Regulations and case law from the courts. Additionally over time, decisions made by the NHS Litigation Authority (NHSLA)'s Family Health Services Appeal Unit (FHSAU) will need to be taken into account by PCTs when using performance related sanctions and removing contractors or premises from the pharmaceutical list. 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.

5. This document's intended legal status is that it is a 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[1] and where they are in doubt, they should seek legal advice.

Regulations

6. The 2012 Regulations, Statutory Instrument (S.I.) 2012/1909 replace the NHS (Pharmaceutical Services) Regulations 2005 with effect from 1 September 2012. PCTs should ensure they have access to the 2012 Regulations to ensure they are acting within the law when taking performance related sanctions and managing removals from the pharmaceutical list. It should be noted that when these regulations come into force, *the National Health Service (Service Committees and Tribunal) Amendments Regulations 1996* will be repealed subject to any necessary transitional arrangements.

7. 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 2012 Regulations.

Other guidance documents

8. 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 main Annexes document), and market entry by means of pharmaceutical needs assessments.

[1] 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.

Structure of document

9. The document is structured so that chapters 4 to 6 contain all the information that PCTs will require without having to cross-reference to other chapters.

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

Chapter 2: Background and overview of the Regulatory system

Status of advice

1. This Chapter discusses the provisions within National Health Service Act 2006[2] (the 2006 Act) that allow regulations to be made for the issuing of *breach* and *remedial notices*, withholding payments and removal of contractors or premises from pharmaceutical lists. It also gives an overview of Part 10 of the 2012 Regulations that contains the regulatory requirements made under these powers.

2. For the purposes of Part 10 and this document, *pharmaceutical services* are defined as:

   - *essential*, *advanced* and *enhanced services* provided by pharmacy contractors; and
   - services set out in **Schedule 5** of the 2012 Regulations and *advanced* or *enhanced services* as provided by dispensing appliance contractors (DACs).

3. These new provisions are not a means to close services. They are part of driving up the quality of the services provided. Contractors who provide services to good quality – and get rewarded for them – will want to demonstrate this to patients. The NHS needs to show that good value for money is being achieved. Above all, patients and consumers should be better informed about the quality and standards of services available so that they can make decisions about what best suits them.

4. PCTs should note that these powers relate to the provision of *pharmaceutical services* by pharmacy contractors and DACs only. Where PCTs have concerns regarding the provision of services by dispensing doctors, they may wish to refer to the powers set out in the relevant primary medical services contract. However, Chapter 6 provides information about removal or withdrawal of dispensing doctors under the 2012 Regulations. Local pharmaceutical services (LPS) are outside the scope of these provisions – any contractual under- or over-performance should be dealt with under the terms of LPS contracts.

Local dispute resolution

5. An important first stage of any performance management policy is informal dispute resolution. Informal dispute resolution will help develop and sustain a partnership approach between contractors and the PCT, as well as avoiding bureaucracy and cost for both parties. It may be that informal dispute resolution will require a greater time

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

commitment when dealing with contractors that have not been open for very long or where the PCT has not undertaken annual monitoring visits previously.

6. The next stage is formal local dispute resolution. **Regulation 68** requires pharmacy contractors and DACs to make every reasonable effort to communicate and co-operate with the PCT with a view to resolving any dispute relating to compliance with the terms of service.

7. Similarly, **regulation 69** requires the PCT, before issuing a *breach* or *remedial notice* to make every reasonable effort to communicate and co-operate with the contractor with a view to resolving any dispute relating to compliance with the terms of service. See chapter 4 for more information on dispute resolution.

8. In some circumstances, local dispute resolution may not be appropriate and **regulation 69(3)** sets out the circumstances where the PCT may move straight to issuing a *breach* or *remedial notice*.

Arrangements for notices and penalties

9. Section 150A of the 2006 Act (inserted by the Health Act 2009[3]) allows for the making of Regulations that enable PCTs to issue notices to pharmacy contractors and DACs and to withhold payments in certain circumstances. These are new powers for PCTs and bring the performance management of *pharmaceutical services* more into line with the arrangements that exist for the other primary care contractors.

[3] http://www.legislation.gov.uk/ukpga/2009/21/section/28

Section 150A of the 2006 Act

(1) The Secretary of State may by regulations provide that where a practitioner who provides pharmaceutical services under arrangements with a Primary Care Trust breaches a term of those arrangements, the Primary Care Trust may-

(a) by a notice require the practitioner to do, or not do, specified things or things of a specified description within a specified period, or
(b) in prescribed circumstances or for a prescribed period, withhold all or part of a payment due to the practitioner under the arrangements.

(2) Regulations under this section must include provision conferring on such persons as may be prescribed rights of appeal from decisions of Primary Care Trusts made by virtue of this section.

(3) In this section-
"practitioner" means a person included in a pharmaceutical list, and
"specified" means specified in a notice under paragraph (a) of subsection (1).

10. The Regulations referred to within the 2006 Act are set out in Part 10 of the 2012 Regulations.

Types of notices

11. The 2012 Regulations provide for two types of notices – remedial and breach.

12. *Remedial notices* may be issued where a contractor has breached a term of service and that breach is capable of remedy, for example, a contractor does not have an effective clinical governance policy in place (**Regulation 70).**

13. *Breach notices* may be issued where a contractor has breached a term of service but that breach is not capable of remedy, for example, a contractor has persistently failed to open in line with its core and supplementary opening hours (**Regulation 71**).

14. Further information on notices can be found in chapter 4.

Withholding of payments

15. Where the breach relates to a failure to provide a service or a failure to provide a service to a reasonable standard, the PCT may withhold remuneration (**Regulations 70 to 72**). Remuneration refers to the payments made to the contractor for the provision of

pharmaceutical services (i.e. *essential* and *advanced services*) as set out in the Drug Tariff or a determination by a PCT of the remuneration for an *enhanced service* under **regulation 91(1)**.

16. Further information on withholding payments can be found in chapter 4.

Removal of contractors or premises from the pharmaceutical list

17. PCTs may remove contractors or premises from their pharmaceutical list where there has been a failure to address issues raised in *breach* and/or *remedial notices*, where such action is justifiable and proportionate (**Regulation 73**) – see chapter 4. They may also remove them due to death, incapacity or cessation of service provision (**Regulation 74**) – see chapter 5. **Regulation 75** makes provision for voluntary and automatic removal following change of ownership, relocation, temporary provision and voluntary closure.

18. **Regulation 76** places limitations on withdrawal or removal from a pharmaceutical list whilst fitness to practise investigations or proceedings are ongoing. This provision prevents contractors from trying to avoid negative outcomes of such investigations or proceedings by selling the premises or ceasing to provide services. See chapter 5 for further information on this.

Removal of a contractor or removal of specific premises?

Whether a PCT removes a contractor or specific premises will depend on the facts of the case and the number of premises that a contractor has in the PCT's pharmaceutical list.

Contractors are included in the pharmaceutical list for each of the premises from which they provide *pharmaceutical services*. *Breach* or *remedial notices* would generally only be issued for concerns relating to one set of premises. If a PCT has concerns about the ability of a contractor to provide *pharmaceutical services* in general, these should be addressed using its fitness to practise powers under Chapter 6 of Part 7 of the 2006 Act, read with Part 11 of the 2012 Regulations. An example of this may be where a contractor with several premises on the PCT's pharmaceutical list directs all its pharmacies to declare that 33 MURs are completed each month whether indeed they have or not, in order to maximise income for this type of service.

Therefore, if a PCT is considering removing a contractor for failure to address issues raised in *breach* and/or *remedial notices*, they are considering removing them in respect of the premises to which the concerns relate. If these are the only premises that the contractor has included in the PCT's pharmaceutical list, the PCT is also removing the contractor from its pharmaceutical list. If the contractor has other premises included in the PCT's pharmaceutical list, the PCT does not remove the contractor, merely the premises to which the concerns relate.

If a PCT issues *breach* and/or *remedial notices* to all the contractor's premises and the contractor fails to comply, the PCT could decide to remove all the premises and therefore, the contractor from its pharmaceutical list. In this instance, however, the removal of each set of premises would have to be considered on its own merits and not in relation to what has happened at other premises (although the Family Health Services Appeal Unit (FHSAU) could decide to hear any appeals together if it wanted to). In this type of situation, fitness to practise action may well be more appropriate, with consideration needing to be given to possibly applying for a *national disqualification* as well. See the Department's fitness to practise guidance for further information on this.

19. **Paragraph 10 of Schedule 6** sets out the requirements of the Regulations on dispensing doctors who wish to cease providing *pharmaceutical services*. Further information on this can be found in chapter 6.

Appeals against PCT decisions to issue notices, withhold payments or removal from pharmaceutical list

20. Contractors may appeal against PCT decisions to issue *breach* or *remedial notices*, withhold payments, not to restore certain payments or to remove from the pharmaceutical list (**Regulation 77**). For this reason, it is important that PCTs have robust policies and procedures and maintain full records of evidence and action taken.

21. Appeals are made 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 FHSAU. More information about their work is available on their website[4].

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

    - confirm the PCT's decision; or
    - substitute for that decision any decision the PCT could have taken when it took that decision.

23. 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.

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

[4] http://www.nhsla.com/FHSAU/Decisions/

Likely impact for PCTs and contractors

25. The Impact Assessment sets out the likely cost impacts of this new regime on PCTs and contractors.

Chapter 3: Governance arrangements

1. This chapter 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.

Decision-making process

2. The ability to impose performance related sanctions or to remove contractors or premises from the PCT's pharmaceutical list 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[5] (the 2002 Regulations), as amended, allows the Board to delegate this function to a committee, sub-committee or officer of the PCT.

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 to whether this has happened, it is recommended that the matter is discussed and agreed by the Board. Because some of the powers are new, it is recommended that the Board discusses the delegation by it of its functions once the 2012 Regulations have been laid and before they come into force.

4. Where PCTs have delegated some powers to their Family Health Services (FHS) agency they will need to ensure that this delegation is done in accordance with the 2002 Regulations. PCTs should note that if the PCT does not employ the FHS staff, then delegating decision-making responsibility may be in breach of the 2002 Regulations, which only allow delegation to individuals who are "officers" of the PCT.

5. Decision-making processes which 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 signed off by the Board rather than simply by 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.

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

6. Failure to ensure that the PCT has properly delegated its functions to a committee, sub-committee or officer means that decisions are not actually made. The consequences of this are:

- legal challenge through the courts, with the associated damage to reputation and liability for costs;
- appeals to the FHSAU being successful; or
- the matter being remitted back to the PCT by the FHSAU leading to increased costs in administration and damage to reputation.

7. It is imperative that PCTs and their agencies have robust decision-making processes for performance related sanctions including an assurance that there are no conflicts of interest. In addition to the recommendation in paragraph 3, 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 interested parties involved in the process. It is especially important for the committee or sub-committee involved in making the key decisions to be clear on its remit and responsibilities. The process for making the determination must also be in accordance with the fundamental principles of administrative law. These principles are:

- that the decision-taker(s) must not be “biased”, and
- that the procedure must be “fair”.

8. PCTs will already have in place policies and procedures for the performance management of other primary care contractors. These could be reviewed and adapted for use with pharmacy contractors and DACs.

9. Where policies and procedures already exist for performance management of pharmacy contractors and DACs under the previous Regulations, which already include powers for dealing with issues such as cessation of services, these should be reviewed to ensure they reflect the provisions within Part 10 of the 2012 Regulations.

10. All policies and procedures should be notified to, and where possible agreed with, the Local Pharmaceutical Committee (LPC) prior to being formally signed off by the Board. They should then be sent to the pharmacy contractors and DACs in the PCT’s area and placed on the PCT’s website.

Chapter 4: Performance related sanctions

1. This chapter deals with matters relating to the performance related sanctions set out in Part 10 of the 2012 Regulations, i.e. local dispute resolution the ability to issue *breach* or *remedial notices*, and the ability to withhold payments.

Introduction

2. PCTs should note that their powers to take action under Part 10 of the 2012 Regulations should only be used to address local issues of poor performance. Where a PCT has concerns about a contractor's fitness to practise, it should use its powers set out in Part 11 of the 2012 Regulations and Part 7, Chapter 6 of the National Health Service Act 2006, i.e. contingent removal, suspension and removal. For example, a contractor who runs pharmacies across the country may be a suitable person to run a pharmacy and may be able to run one efficiently, but there may be local failings such as repeated breaches of terms of service which means that one particular set of premises needs to be removed from the PCT's pharmaceutical list.

3. PCTs should note that the Regulations contained within Part 10 of the 2012 Regulations relate to pharmacy contractors and DACs only. They cannot be used where a PCT has a concern with the performance of *pharmaceutical services* by a dispensing doctor - it should use the performance related measures contained within the contracting arrangements with that doctor.

Local dispute resolution

4. **Regulations 68 and 69** require pharmacy contractors, DACs and PCTs generally to make every reasonable effort to communicate and co-operate with each other to resolve any dispute relating to a contractor's compliance with their terms of service. For contractors, this requirement is a condition of their inclusion in the PCT's pharmaceutical list.

5. **Schedule 4** of the 2012 Regulations set out the terms of service for pharmacy contractors, whilst **Schedule 5** sets out the terms of service for DACs.

6. If a pharmacy contractor decides to invite the LPC to participate in the attempts to resolve a dispute, the PCT must make every reasonable effort to communicate and co-operate with the LPC in its attempts to assist in resolving the dispute (**Regulation 69(2)**). DACs may choose to involve the LPC in dispute resolution if they so wish, but PCTs do not have the same statutory obligation to engage with the LPC if they do or for the LPC to participate. It would, however, be good practice for the PCT to respond positively to such an initiative.

7. There are four situations where the PCT may be satisfied that it does not wish to invoke local dispute resolution. The first of these is where the PCT is satisfied that the dispute relates to a matter that has already been through local dispute resolution and there are no new issues of substance that justify the delay in issuing a *breach* or *remedial notice* (**Regulation 69(3)(a)**).

Example

At a monitoring visit, it was noted that a DAC has failed to develop the standard operating procedures (SOPs) required by **paragraph 18(2)(c)(iv) of Schedule 5.** Following discussions at the visit, the DAC agreed to produce the SOPs within three months.

The PCT undertakes a follow-up visit four months later and the DAC has not developed the SOPs as agreed previously and has no good cause for this. Following further discussions between the PCT and the DAC, the PCT is not satisfied that the DAC intends to produce the SOPs and decides to issue a *remedial notice* under **regulation 70**.

If however, the DAC had good cause not to have developed the SOPs within the agreed timescale, for example, the premises had flooded and service provision had been temporarily suspended whilst repair work was undertaken, the PCT may then agree to a further period of time within which they are to be developed rather than issue a *remedial notice*.

8. The second situation is where the PCT is satisfied that it is appropriate to move straight to issuing a *breach* or *remedial notice* because the pharmacy or DAC premises are not, or have not been, open during core opening hours or supplementary opening hours without good cause, i.e. there has not been a temporary suspension of service provision under either **paragraph 23(1)** or **23(10) of Schedule 4** (pharmacy contractors) or under **paragraph 13(1)** or **13(9)** of **Schedule 5** (DACs)(**Regulation 69(3)(b)(i)**).

9. Thirdly, the PCT may move straight to issuing a *breach* or *remedial notice* where it is satisfied that to do so will protect the safety of any person to whom the contractor may provide *pharmaceutical services*.

Example

A pharmacy contractor has agreed to provide a needle exchange scheme as an enhanced service but it comes apparent on a visit to a pharmacy that some of the materials being received from drug misusers, for example, used needles, are being left in open bins. The PCT is satisfied that the safety of both staff and visitors to the premises is compromised by this and decides to issue a *breach notice*.

10. Finally, the PCT may move straight to issuing a *breach* or *remedial notice* where it is satisfied that this will protect the PCT from material financial loss.

Example

A DAC claims for more appliance use reviews (AURs) than it is entitled to do within a financial year. The PCT raises this issue with the contractor and it becomes apparent that there are no systems in place to identify:

- the number of AURs that the contractor may undertake in a year; or
- the number of AURs that have been claimed.

In this instance, the PCT is satisfied that it is necessary to issue a *breach* notice to protect itself from material financial loss.

11. Local dispute resolution may have two stages. The first is informal resolution which will help develop and sustain a partnership approach between contractors and the PCT, as well as avoiding bureaucracy and cost for both parties. It is the process that would generally occur at monitoring visits where the PCT identifies an area of concern and the contractor agrees to address this issue, i.e. the agreement that a contractor is not compliant with one or more of their terms of service requirements, and the drawing up of an agreed action plan with timescales to remedy this.

12. It may be appropriate for PCTs to adopt a greater time commitment to informal resolution when dealing with contractors that have not been open for very long or where the PCT has not undertaken annual monitoring visits previously.

13. Local dispute resolution leads on from informal resolution and may be detailed in the policies and procedures that the PCT already has in place for the monitoring of pharmacy contractors and DACs. It is recommended that PCTs review their performance monitoring procedures and ensure that they have an informal dispute resolution stage and a local dispute resolution stage that allows pharmacy contractors to invite the LPC to participate.

14. PCTs should also review their procedure for monitoring the opening hours of their contractors to ensure both stages are included, where appropriate. Just because it is not necessary to activate local dispute resolution in a case of unauthorised closure, it does not mean that local dispute resolution has no place in such cases. For example, a contractor may have an explanation for the failure to open that will satisfy the reasonable cause provision and this may only come to light during the local dispute resolution discussions.

15. The next stage in a performance management procedure is the issuing of *breach* or *remedial notices* and the possible withholding of remuneration.

Remedial notices

16. **Regulation 70** makes provision for PCTs to issue *remedial notices* to pharmacy contractors and DACs where they breach a term of service and the breach is capable of remedy. The effect of the notice is to require the contractor to make good the breach.

Breaches that are capable of remedy

In order for a *remedial notice* to be issued, the contractor must be able to remedy or "make good" the breach. These types of notice would, therefore, be suitable for the following examples of breaches:

- failures to make available a practice leaflet;
- lack of SOPs required by the terms of service;
- failure to undertake the pharmacy-based audit; and
- failure to appoint a clinical governance lead.

17. Before issuing a *remedial notice*, the PCT should seek to discover the grounds for the breach to ensure that issuing a *remedial notice* is the most appropriate action to take.

18. In order to be valid, the *remedial notice* must include the following information:

    - the nature of the breach – this should include what the contractor has or has not done and which term of service this breaches. The PCT should include the reference to the term of service in the relevant Schedule to the 2012 Regulations, for example failure by a pharmacy contractor to produce a practice leaflet is a breach of **paragraph 28(2)(a)(i) of Schedule 4**;
    - the steps the contractor must take, to the PCT's satisfaction, in order to remedy the breach, for example, to produce a practice leaflet that complies with the approved particulars;

- the period during which the required steps must be taken, for example within two months (but see the next paragraph); and
- how they may exercise their right of appeal under **regulation 77(1)(a)** to the FHSAU i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to the FHSAU within 30 days of the date on which the contractor received the *remedial notice* (**Regulation 70(2)**).

19. The notice period for remedy of the breach must not be less than 30 days, unless the PCT is satisfied that a shorter period is appropriate to protect:

- the safety of any persons to whom the contractor may provide *pharmaceutical services*; or
- the PCT from material financial loss (**Regulation 70(3)**).

Example

At a monitoring visit, it becomes apparent that pharmacy technicians are undertaking medicines use reviews. In this case, the safety of persons receiving that service is at risk and the PCT may require the contractor, via a *remedial notice*, to stop the provision of medicines use reviews by pharmacy technicians with immediate effect and for only accredited pharmacists to provide this service. Additionally, the contractor is required to identify and contact all persons who took part in a medicines use review with a pharmacy technician in order to invite them in for a second medicines use review with an accredited pharmacist within 30 days.

20. The *remedial notice* may also provide for the withholding of remuneration by the PCT where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that the contractor is required to provide (**Regulation 70(4)**). Remuneration refers to the payments made to the contractor for the provision of *pharmaceutical services*, as set out in the Drug Tariff or a determination by a PCT of the remuneration for an enhanced service under **regulation 91(1)**.

21. The *remedial notice* may provide that:

- during the period that the contractor failed to provide the service, or failed to provide it to a reasonable standard, the PCT will withhold all or part of the remuneration due to the contractor under the Drug Tariff or in respect of an enhanced service for that period (**Regulation 70(4)(a)**);
- pending the contractor taking the required steps to the PCT's satisfaction, the PCT will withhold all or part of the remuneration due. In these circumstances, any withholding relating to the period when the contractor was in breach will be permanent. Once the contractor has remedied the breach to the PCT's satisfaction,

if there has been withholding that related to a period when the contractor was in compliance, they may claim in accordance with the Drug Tariff, or the arrangements for providing the *enhanced service*, for the restoration of that withheld remuneration (**Regulation 70(4)(b)**).

22. Once the contractor has taken the required steps to remedy the breach, the PCT should promptly verify that the action is to the required standard. This may involve a visit to the premises.

23. If following receipt of a claim for the restoration of any withheld remuneration, the PCT refuses to restore all or part of the remuneration that has been withheld, it must notify the contractor of that decision. The notification must include:

- a statement of the reasons for the PCT's decision; and
- how they may exercise their right of appeal under **regulation 77(1)(b)** to the FHSAU i.e. be sending a notice containing a concise and reasoned statement of the grounds of the appeal to the FHSAU within 30 days of the date on which the contractor received the *remedial notice* (**Regulation 70(7)**).

24. **Regulation 70(6)** allows the withholding of payments to continue after the date by which the contractor is to have completed the required action. However, if the contractor completes the required action to the PCT's satisfaction within the PCT's timescale, they may submit a claim for the payments to recommence from the date on which they came into compliance; payments will not automatically be paid for that period, but must be paid if claimed.

25. Payments may only be withheld by the PCT if:

- the PCT is satisfied that the breach is or was without good cause;
- the amount to be withheld is justifiable and proportionate, having regard to the nature and seriousness of the breach and the reasons for it;
- it includes in the notice, its duly justified reasons for both the decision to withhold remuneration and the amounts that are, and are to be (where applicable), withheld (**Regulation 72(1)**).

26. The PCT needs to have regard to the reasons for the breach if it is to determine whether or not the withholding itself, as well as the amount of the withholding, is justified and proportionate. The PCT cannot simply apply the sanction without contacting the contractor for an explanation of the breach. The PCT must be satisfied that the withholding of remuneration is justified and so should make every reasonable effort to communicate with the contractor to establish the grounds for the breach (**Regulation**

72(2)). If the contractor fails to communicate with the PCT, the PCT is entitled to consider the information it has and whether this discloses justifiable grounds to withhold payment.

27. As indicated in the section below on withholding payments, factors likely to contribute to whether or not the amount of withholding, is justified and proportionate may include:

- the amount of money the contractor has saved by not being in compliance;
- the impact of the breach on patient safety;
- the duration of the breach; and
- the broader impact of the breach in the context of the statutory scheme.

Example

Following a monitoring visit in September, the PCT identifies that a contractor has not completed a clinical audit programme and has no intention of doing one for the remainder of the financial year (**paragraph 18(2)(b) of Schedule 5**). They are therefore not fully complying with their terms of service and cannot provide *advanced services*. The matter is escalated through the local dispute resolution procedure, but the contractor can provide no reasoning for this failure and the PCT is satisfied that the contractor has no good reasons for it. The PCT orders a *remedial notice* under **regulation 70** advising:

- the contractor has not completed the clinical audit programme required by **paragraph 18(2)(b) of Schedule 5**;
- the contractor is required to complete the required clinical audit programme and submit evidence of this to the PCT;
- the clinical audit programme is to be completed within two months of the date of the *remedial notice*;
- the PCT will withhold payment for the provision of *advanced services* until such time as the PCT is satisfied that the clinical audit programme has been completed. This takes account of the fact that a contractor is required to satisfactorily comply with their obligations. The PCT has decided not to withhold any of the other payments that the contractor is entitled to under the Drug Tariff, having concluded that the overall size of the withholding it is making is proportionate in the particular circumstances of the case; and
- the contractor may exercise their right of appeal under **regulation 77(1)(a)** by sending a notice including a concise and reasoned statement of the grounds of the appeal to the FHSAU within 30 days of the date of the *remedial notice*.

The *remedial notice* is sent on 4 January and the contractor therefore has until 4 March to complete the clinical audit programme. Payments for the provision of *advanced services* are withheld until such time as the PCT is satisfied that the clinical audit programme has been completed.

The PCT advises the NHS Business Services Authority (NHSBA) Prescription Service that payments for *advanced services* are to be terminated and that no claims for *advanced services* from 4 January onwards are to be paid.

The contractor completes the clinical audit programme by 1 February and sends evidence of this to the PCT. The PCT is satisfied and the PCT notifies the NHSBSA that payments for *advanced services* on or after 1 February may recommence.

If the contractor failed to complete the clinical audit programme by 4 March, then payments would continue to be withheld and the PCT would need to consider what, if any, further action to take.

28. The withholding of remuneration as a result of issuing a *remedial notice* under **regulation 70** is without prejudice to the arrangements that are in place for the recovering of overpayments under **regulation 94** and the Drug Tariff (**Regulation 72(3)**).

29. Using the third example in this chapter, the DAC complies with the terms of the *remedial notice* and payments for AURs were recommenced on 1 February. On reviewing the number of AURs that the DAC has claimed for that financial year, it is discovered that the DAC had claimed more than it was entitled to. The PCT draws this to the DAC's attention and seeks to recover the overpayment under **regulation 94**.

Breach notices

30. **Regulation 71** makes provision for PCTs to issue *breach notices* to pharmacy contractors and DACs where they breach a term of service but the breach is not capable of remedy. The effect of the notice is to require the contractor not to repeat the breach.

Breaches that are not capable of remedy

In order for a *breach notice* to be issued, the contractor must not be able to remedy or "make good" the breach. These types of notice would therefore be suitable for the following types of shortcomings – failure to:

- open on a specific day or days, or at specific times of a day or days, in line with agreed *core* and *supplementary opening hours*;
- ask patients to complete the declaration on the back of prescription forms;
- offer to deliver specified appliances to patients;
- offer a reasonable supply of disposable bags and wipes to patients using specified appliances;
- deal with past complaints; or
- provide updated fitness to practise information within the prescribed time.

31. Before issuing a *breach notice*, the PCT should seek to discover the grounds for the breach to ensure that issuing a *breach notice* is the most appropriate action to take.

32. In order to be valid, the *breach notice* must include:

    - the nature of the breach (including reference to the specific term of service that the contractor has breached); and
    - how they may exercise their right of appeal under **regulation 77(1)(c)** to the FHSAU i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to the FHSAU within 30 days of the date on which the contractor received the *breach notice* (**Regulation 71(2)**).

Example

A pharmacy with core opening hours on a Saturday and Sunday applies to its PCT to close on Saturday, 26th and Sunday, 27th December which are not public holidays. The PCT refuses the application and the contractor subsequently appeals to the FHSAU. The FHSAU upholds the PCT's decision and the contractor is required to open the pharmacy premises on those days for its *core opening hours*.

The pharmacy fails to open and after establishing that there was no good cause for this, the PCT decides that it is satisfied that it is appropriate to proceed with issuing a *breach notice* under **regulation 71**.

The PCT issues a *breach notice* under **regulation 71** advising:

- that the contractor is in breach of **regulation 65(2)** and **paragraph 23(1)(b) of Schedule 4** by failing to open for its core opening hours on Saturday, 26th and Sunday, 27th December; and
- the contractor may exercise their right of appeal under **regulation 77(1)(c)** by sending a notice including a concise and reasoned statement of the grounds of the appeal to be FHSAU within 30 days of the date of the *breach notice*.

33. The *breach notice* may also provide for the withholding of remuneration by the PCT where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that the contractor is required to provide (**Regulation 71(3)**). Remuneration refers to the payments made to the contractor for the provision of *pharmaceutical services*, as set out in the Drug Tariff.

34. Payments may only be withheld by the PCT if:

- the PCT is satisfied that the breach is or was without good cause;
- the amount to be withheld is justifiable and proportionate, having regard to the nature and seriousness of the breach and the reasons for it; and
- it includes in the notice its duly justified reasons for both the decision to withhold remuneration and the amounts that are, and are to be (where applicable), withheld (**Regulation 72(1)**).

35. Remuneration may be withheld for the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service. The PCT may withhold all or part of the remuneration due to the contractor under the Drug Tariff in respect of that period.

36. The PCT needs to have regard to the reasons for the breach if it is to determine whether or not a withholding, as well as the amount of the withholding, is justified and proportionate. The PCT cannot simply apply the sanction without contacting the contractor for an explanation for the breach. The PCT must be satisfied that the withholding of remuneration is justified and so should make every reasonable effort to communicate with the contractor to establish the grounds for the breach (**Regulation 72(2)**). If the contractor fails to communicate with the PCT, the PCT is entitled to consider the information it has and whether this discloses justifiable grounds to withhold payment.

37. As indicated in the section on withholding payments below, factors likely to contribute to whether or not the amount of a withholding, is justified and proportionate may include:

- the amount of money the contractor has saved by not being in compliance;
- the impact of the breach on patient safety;
- the duration of the breach;
- the impact of the breach in the context of the statutory scheme.

Example

Using the example in the box above, the PCT could simply decide to withhold part of the contractor's establishment and practice payment for that month, for example, by advising the NHS BSA to withhold 2/31 of that month's payment for those two allowances. In its notification, it makes clear that it believes that it has shown a significant degree of restraint in the amount imposed, given the timing of the closure and the benefits that accrued to the contractor because of it, and this decision should not be taken as having any precedent value if there is a similar breach in the future.

38. The withholding of remuneration as a result of issuing a *breach notice* under **regulation 71** is without prejudice to the arrangements that are in place for the recovering of overpayments under **regulation 94** and the Drug Tariff (**Regulation 72(3)**).

Withholding of payments

39. Provision is made for the withholding of remuneration where the breach relates to a failure to provide a service, or a failure to provide a service to a reasonable standard. PCTs should note that this is not a system of punishment by fines of specific amounts. Any decision to withhold remuneration must be justified and proportionate and PCTs should not simply escalate the amount withheld if a contractor repeatedly breaches a term of service.

40. PCTs should consider the fees and allowances paid to contractors, the nature of the breach and calculate a level of withholding that is justifiable and proportionate. In determining that amount, it is not necessary to demonstrate actual loss or damage. There is a fundamental difference between a civil liability for breach of a statutory duty (which is essentially about compensation for actual loss or damage), and a penalties scheme for such a breach (which applies whether or not actual loss or damage is proven). PCTs do not need to calculate a precise value of the service that has not been performed, or has not been performed to the requisite standard, in order to make a withholding.

41. In some (but not all) cases, the starting point for the amount of the withholding is likely to be the money that the contractor has saved itself by not providing the required service, or not providing the required service, or not providing it to the requisite standard. For example, deducting 10% of the payments for one month because a contractor has failed to produce a practice leaflet would not be proportionate to the breach. However, a monthly deduction, going forward, of a reasonable amount reflecting what it might cost to produce a reasonable stock of the leaflet should both have the desired effect of creating an incentive to comply, and be an amount that could straightforwardly be explained to the contractor as justified and proportionate. Conversely, a monthly penalty of the full annual cost of an acceptable system of clinical governance, pending the introduction of such a system in new pharmacy premises, would be disproportionate in this example.

42. Even if saved costs are the frequent starting point, it is likely that the amount of a withholding will generally relate to more factors than simply those costs. For example, a starting point for the proportionate level of penalty where a contractor has failed to open in *core* or *supplementary opening hours* without good cause might be a realistic estimate of the costs it is likely to have saved itself in doing so. However, it might also be appropriate to include in the withholding, an amount to dissuade contractors from such closures. If it was simply the case that the closure was cost neutral, the contractor might think it was worth, for example, closing early on the eve of a public holiday because ultimately there was no financial loss to itself in so doing and possibly a gain to itself, for example, in terms of its staff relations.

Amounts to deter future breaches/shortcomings

43. In determining the deterrent amount, it may be that the PCT will want to consider four additional factors. First and foremost is the issue of the impact on patient safety. In this case, the deterrent amount will need to reflect the potential seriousness of the consequences of the breach for those patients who as a result of the closure may have to go without prescribed medicines over the holiday period.

44. Indeed, that may offset, in this particular case, the second issue of general relevance, which is the duration of the breach. As will be clear from this holiday period example, a breach of short duration in some contexts will be more significant than a breach of longer duration in others, although generally the longer the breach, the more justifiable and proportionate the withholding.

45. Thirdly, the size of the contractor's NHS business may frequently be relevant. Just as the costs saved from not opening will depend on the extent of the contractor's NHS business (and consequently the loss of NHS income arising from the failure to open), so also will the value of the deterrent amount. For a deterrent amount to have an impact on behaviour, PCTs will need to have regard to the overall NHS income of the business. PCTs should note in this respect that the total turnover of the business (i.e. NHS plus

retail sales income - both pharmaceutical and non-pharmaceutical) is not a material consideration. The deterrent amount should be based only on the value of the NHS business to the contractor. Therefore, PCTs must exercise care, when taking into account the size of the NHS business, their calculation of any deterrent amount to ensure that the general principles of equal treatment, fairness and an absence of bias are rigorously observed.

46. Fourthly, regard will need to be made to the broader policy and objects of the legislation, and how that has been compromised. For example, in considering the appropriate withholding for an unauthorised closure, regard may need to be had to the overarching nature of the payment scheme and the size of the withholding may need to reflect the fact that the system of establishment payments is partly there to guarantee access to services at particular locations.

47. Another example of having proper regard to the policy and objects of the legislation is withholding payments for *advanced services* where a contractor is not providing all *essential services*, or not providing an acceptable system of clinical governance. This may be proportionate and justifiable because in the Directions establishing the current *advanced services*, a stated condition under which contractors provide *advanced services* is that they are satisfactorily complying with their obligations to provide *essential services* and an acceptable system of clinical governance.

48. PCTs should bear in mind when considering whether they are at risk of material financial loss, the risk to the public purse. For example, if a contractor failed to meet the requirements for the Electronic Prescription Service (EPS) allowance, it would be proportionate to withhold the EPS allowance for a period of time even though the PCT would only receive a small percentage of the withheld amount.

49. It is important to emphasise that the PCT need not always impose the maximum withholding that it could impose as a justified and proportionate amount. If it does decide to exercise restraint, it is advisable to make it clear in the notification that it is doing so.

50. PCTs should note that they may not seek to recover the costs of their investigations either directly from the contractor or indirectly by increasing the size of the withholding.

Removal of premises from the pharmaceutical list: cases relating to remedial or breach notices

51. **Regulation 73** deals with the removal of premises from the PCT's pharmaceutical list where failings have not been addressed by the issuing of *remedial* and/or *breach notices*. This is an extreme sanction, equivalent to the terminating of contracts with GPs, dentist and optometrists, and PCTs should ensure their policies and procedures include this step to ensure that such action is justifiable and proportionate. PCTs should remember that

this action is not requiring the premises to close (although this may well be the outcome depending on the ratio of NHS to private turnover). It is requiring the pharmacy to cease providing NHS *pharmaceutical services*.

52. **Regulation 73(2)** ensures that removal of any particular set of premises from the pharmaceutical list is by reference only to the *breach* or *remedial notices* issued in respect of those premises. The PCT cannot remove all of, or any other of, the contractor's premises if it has only issued notices regarding issues at one of them. Where a contractor has more than one set of premises listed on the PCT's pharmaceutical list and the PCT wants to remove the contractor completely, it would need to bring a fitness to practise case under Part 7, Chapter 6 of the 2006 Act. However, if the contractor has only one set of premises on the PCT's pharmaceutical list, the PCT may remove the contractor from its pharmaceutical list under this regulation.

53. The PCT has two discretionary grounds on which to remove a pharmacy contractor or DAC from its pharmaceutical list (if it only has one set of premises), or to remove particular premises for that contractor. The first is where the contractor has failed to comply with the steps set out in the *remedial notice* in order to remedy the breach, and the PCT is satisfied that it is necessary to remove the contractor or those particular premises from its pharmaceutical list in order to protect:

- the safety of any persons to whom the contractor may provide *pharmaceutical services*; or
- itself from material financial loss (**Regulation 73(1)(a)**).

54. The second is where the pharmacy contractor or DAC has breached their terms of service, and:

- the contractor has repeatedly been issued with *remedial* or *breach notices* or both in relation to the same term of service;
- has previously been issued with a *remedial* or *breach notice* in relation to the same term of service, and the PCT is satisfied that they are likely to persist in breaching that term of service without good cause; or
- the contractor has repeatedly been issued with *remedial* or *breach notices* or both in relation to different terms of service and the PCT is satisfied that the contractor is likely to persist in breaching their terms of service without good cause (**Regulation 73(1)(b)**).

55. **Regulation 73(1)(b)** therefore deals with the "persistent offender".

56. Where the PCT believes that the contractor is likely to persist in breaching their terms of service without good cause, it must have documented evidence to support this. For example, the PCT has evidence that a pharmacy whose core hours include Saturdays

from 09:00 -14:00 has failed to open on Saturdays for the last three months. A *breach notice* has failed to precipitate any change of attitude, and following discussions with the contractor, it has good cause to believe that this failure to open will continue.

57. Good record-keeping of failures is essential in order to provide robust evidence on which to base decisions to issue *breach notices*.

58. The PCT may only remove a contractor (if the contractor only has one set of premises on the PCT's pharmaceutical list) or one of the contractor's premises if:

- the removal is justifiable and proportionate, having regard to the nature and seriousness of the breaches (or likely breaches) and the reasons for them; and
- the PCT includes in the notice of its decision to the contractor, its duly justified reasons for its decisions (**Regulation 73(3)**).

Justifiable and proportionate

- A contractor fails to produce a practice leaflet and fails to comply with a *remedial notice* which requires them to produce one. In this instance, removal from the PCT's pharmaceutical list is unlikely to be justifiable. The PCT may decide that withholding payments of an amount that reflects the cost of producing such a leaflet is a justified and proportionate approach and may also wish to take into account the contractor's compliance record when considering whether or not to commission *enhanced services* from that contractor.

- A contractor fails to open one of its premises on a bank holiday when directed to do so. The PCT has records which show that the contractor regularly fails to open at these premises and has repeatedly issued *breach notices* requiring the contractor to open in line with its contracted opening hours, and has withheld payments. The PCT has received a number of complaints from patients who had gone to the pharmacy on the bank holiday in order to have prescriptions dispensed. The PCT decides that it is likely that the contractor will continue to persist in breaching this term of service to open in line with its contracted hours and decides that it would be justifiable and proportionate to remove the contractor from its pharmaceutical list under **regulation 73**.

59. The PCT must be satisfied that the removal from the pharmaceutical list is justifiable and proportionate and so should make every reasonable effort to communicate with the contractor to establish the grounds for the breach or breaches (**Regulation 73(4)**). If the contractor fails to communicate with the PCT, the PCT may conclude that it has proper grounds for removal, even though it has been unable to discover the contractor's reasons for the breaches.

60. Where a contractor has ceased to provide *pharmaceutical services* at particular premises, the PCT may not remove them from its pharmaceutical list under **regulation 73**. Provision for removal under these circumstances is made under **regulation 74** – see Chapter 5. It may, however, need to issue on ongoing *remedial notice* to prevent the need for payments during the cessation.

61. Similarly, PCTs should not use **regulation 73** to remove a contractor or premises from its pharmaceutical list for failure to provide *directed services*, or failure to provide them to a reasonable standard. The appropriate sanction in this instance is to terminate the arrangements for the provision of that *directed service*.

62. The only exception to this is where the contractor is under a condition to provide those *directed services* by virtue of **regulation 66(1)** or **(3)** to **(5)** which cover conditions relating to *directed services***.**

Pharmacies which opened under the 2005 Regulations

Under the 2005 Regulations, applications that were approved under **regulation 13(3)(b)** (premises within an approved retail area, premises open for at least 100 hours per week and premises in new one-stop primary care centres) were required to provide such *directed services* as the PCT may have specified. This condition could be varied in accordance with **regulation 14** of the 2005 Regulations.

Under the 2012 Regulations, **regulation 66(1)** carries forward this condition. Where the PCT has included such premises within its pharmaceutical list under the 2005 Regulations and has specified that particular *directed services* were potentially to be available from the contractor, if, before the 2012 Regulations came into force:

- the contractor has not been requested by the PCT to provide those *directed services*, the contractor is required to provide such services where requested to do so by the PCT (**Regulation 66(1)(a)**);
- the contractor was providing such services or has been asked to provide such services, they must provide those *directed services* at those premises (**Regulation 66(1)(b)**).

Contractors listed in respect of these premises may, under **regulation 66(2)** apply to vary the services specified in relation to them, or to remove the condition. However, they may not apply until at least three years have elapsed:

- since the condition was imposed by the 2005 Regulations; and
- during that time, the PCT has not requested that the services be provided.

If following such an application, the PCT does vary the services that are specified in relation to the contractor, it is a condition of the contractor's continued inclusion in the PCT's pharmaceutical list that they must:

- provide the varied services the PCT has specified as long as the PCT commissions them within three years of the date on which the condition is imposed;
- if the varied services are commissioned, provide them in accordance with an agreed service specification; and
- not withhold agreement to a service specification unreasonably.

Pharmacies which open under the 2012 Regulations

Where a *routine application* is made under the 2012 Regulations and as part of the application, the applicant undertakes:

- to provide the *directed services* mentioned in the application, if the PCT commissioned them within three years of the date the premises are included in the pharmaceutical list;
- if the *directed services* were commissioned by the PCT, to provide them in accordance with an agreed service specification; and
- not to unreasonably withhold agreement to the service specification.

However, the PCT is required to commission the services within three years of the date on which the premises are included in the pharmaceutical list.

63. In these **regulation 66** cases, if a contractor fails to provide *directed services*, the provision of which is a condition of their inclusion in the PCT's pharmaceutical list, the PCT may take action under **regulation 73** to remove them from the pharmaceutical list.

Example

A pharmacy contractor applies under the 2012 Regulations to open a new pharmacy and provide essential and *advanced services*, emergency hormonal contraception, smoking cessation and minor ailments in a housing development in response to a need identified in the PCT's PNA.

Their inclusion in the PCT's pharmaceutical list is subject to a condition that they provide the *directed services*.

The pharmacy duly opens and begins the provision of *essential* and *advanced services*. The contractor, however, refuses to provide the three *enhanced services*. Following local dispute resolution, the PCT issues a *remedial notice* requiring the contractor to commence service provision within three months. The contractor fails to comply and the PCT is satisfied that the contractor has no intention of providing these services, for example by failing to submit the evidence required to demonstrate that staff are accredited to provide such services. It therefore proceeds to remove the contractor under **regulation 73**.

64. Where the PCT is minded to remove a contractor from specific premises on its pharmaceutical list, it must:

- give the contractor at least 30 days' notice that it is minded to remove the contractor from its pharmaceutical list;
- as part of that notification, advise the contractor that they may make written representations to the PCT about the proposed action. If the contractor wishes to make written representations, they must be made within 30 days beginning with the date of the PCT's letter;
- as part of that notification, advise the contractor that they may make oral representations to the PCT about the proposed action. If the contractor wishes to make oral representations, they must be made within 30 days beginning with the date of the PCT's letter (the contractor may make both written and oral representations);
- consult the LPC for its area irrespective of whether the contractor wants to involve them or not (**Regulation 73(6)**).

65. If the contractor wishes to make oral representations, they or their representative must attend the hearing that the PCT arranges. The PCT must give reasonable notice of the hearing (**Regulation 73(6)(b)(ii)(bb)**).

66. What constitutes reasonable notice of the hearing will depend on the facts of the case. Only where patient safety is at significant risk should the PCT consider only giving one working day's notice, and such a short timescale would probably require wholly exceptional circumstances, given the powers to undertake fitness to practise suspensions that are available under Chapter 6 of Part 7 of the 2006 Act. A period of four weeks would be more reasonable particularly as removal from the pharmaceutical list is the ultimate sanction.

67. The ability to impose performance related sanctions or to remove contractors or premises from the PCT's pharmaceutical list lies with the PCT Board. If the Board delegates this function to a committee or sub-committee, that body should be properly constituted to hear the oral representations that the contractor may wish to make. Membership, terms of reference and delegated powers to make decisions should be covered in the policies and procedures covered in Chapter 3.

68. Following the hearing, if the committee decides to remove the contractor or specific premises from the pharmaceutical list, the contractor must be notified of the decision. The notification must include:

- a statement of the reasons for the decision; and
- how they may exercise their right of appeal under **regulation 77(1)(d)** to the FHSAU, i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to the FHSAU within 30 days of the date on which the contractor received the *breach notice* (**Regulation 73(7)**).

69. PCTs may need to have regard to any obligations arising from residual lease commitments if, as a result of action to remove the premises or business from the NHS pharmaceutical list, a contractor were subsequently to decide to close completely. PCTs will wish to bear in mind that action to remove a contractor from the NHS list does not, in itself, equal action to close the premises or business entirely. Nonetheless, depending on overall NHS income, subsequent closure could be an unavoidable result of de-listing. However, depending on the nature and severity of the breach, these are not, of themselves, sufficient grounds to override removal of a contractor's premises where the nature of the breach warrants it.

Rights of appeal

70. The 2012 Regulations make provision for certain persons to have a right of appeal against the PCT's decisions. Where an appeal right is provided in accordance with the Regulations, a person who is entitled to appeal must be provided with the following:

- notification of their right to make an appeal;
- confirmation of their entitlement to make an appeal within 30 days from the date of the PCT's letter;
- information on the FHSAU's contact details including address, e-mail and fax and telephone numbers. These can be found on the NHSLA's website[6]

71. **Regulation 77** sets out the rights of appeal that contractors have against decisions made by the PCT under Part 10.

[6] http://www.nhsla.com/ContactUs/

72. Where the PCT has issued a *remedial notice* under **regulation 70**, the contractor may appeal that decision including:

- the specified steps set out in the *remedial notice* that the contractor must take;
- the length of the notice period;
- any decision to withhold remuneration as set out in the *remedial notice*; and
- the amount of the withholding (**Regulation 77(1)(a)**).

73. Where the PCT has issued a *remedial notice* and decides not to restore remuneration to the contractor, or decides to restore a smaller amount than that which the contractor believes should be restored once the breach is remedied, the contractor may appeal that decision and the PCT must notify the contractor of this right of appeal (**Regulations 70(7) and 77(1)(b)**).

74. If the PCT has issued a *breach notice* under **regulation 72**, the contractor may appeal that decision including:

- any decision to withhold remuneration as set out in the *breach notice*; and
- the amount of the withholding (**Regulation 77(1)(c)**).

75. Finally, where the PCT decides to remove a contractor from its pharmaceutical list, or to remove one of the contractor's premises, under **regulation 73(1)**, the contractor may appeal that decision (**Regulation 77(1)(d)**).

76. In order to be valid, the notice of appeal must:

- be sent to the FHSAU within 30 days of the date on which the PCT notified the contractor of its decision; and
- contain a concise and reasoned statement of the grounds of the appeal (**Regulation 77(1) and (2)**).

77. The PCT cannot remove the contractor, or the contractor's specific premises, from its pharmaceutical list under **regulation 73(1)** until:

- the end of the 30 day appeal period, if the contractor does not appeal; or
- the appeal is determined by the FHSAU, if the contractor does appeal but is unsuccessful (**Regulation 77(3)**).

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

Chapter 5: Market exit – pharmacy contractors and dispensing appliance contractors

1. This chapter deals with the provisions within Part 10 of the 2012 Regulations for the removal of pharmacy contractors and DACs from the pharmaceutical list for reasons that do not relate to non-compliance with *breach* or *remedial notices*.

Introduction

2. **Regulation 74** sets out the circumstances in which the PCT must remove a contractor or premises from its pharmaceutical list due to death, incapacity or cessation of service.

3. **Regulation 75** provides for the voluntary and automatic removal of contractors or premises following changes of ownership, relocations, temporary provision and voluntary closure.

4. **Regulation 76** places limitations on withdrawals from pharmaceutical lists while fitness to practise investigations or proceedings are ongoing.

Removal of listings: cases relating to death, incapacity or ceasing to trade

5. **Regulation 74(1)** requires a PCT to remove a contractor where a:

   - sole trader dies;
   - pharmacy contractor (sole trader, partnership or body corporate) ceases to carry on a retail pharmacy business i.e. they have ceased to trade; or
   - a DAC ceases to carry on a business in the course of which it supplies appliances either by retail sale or in circumstances corresponding to retail sale i.e. they have ceased to trade (**Regulation 74(1)**).

6. However, if a contractor dies or a pharmacy contractor ceases to carry on a retail pharmacy business, the PCT may not remove them if:

   - a representative (as defined in section 72 of the Medicines Act 1968 (the 1968 Act)[7]) is carrying on the retail pharmacy business;
   - the conditions specified in section 72(2) of the 1968 Act are fulfilled in relation to the representative and the business;

[7] http://www.legislation.gov.uk/ukpga/1968/67/section/72

- the period applicable in accordance with section 72(3) of the 1968 Act has not expired; and
- the representative has agreed to be bound by, and continues to be bound by, the contractor's terms of service (**Regulation 74(2)**).

7. Section 72 of the 1968 Act makes provision for a representative to be appointed to carry on the retail pharmacy business where a pharmacy contractor dies, is adjudged bankrupt or enters in to a composition or scheme or deed of arrangement with his creditors, or becomes a person who lacks capacity, within the meaning of the Mental Capacity Act 2005, to carry on his business. Section 2 of that Act indicates that a person lacks capacity in relation to a matter, such as carrying on a business, if they are unable to make a decision for themselves in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain. In practice, this is not a decision that the PCT will need to make itself – the issue for it will be whether there is a donee[8] with power of attorney or the Court of Protection has stepped in to appoint a deputy.

8. As the regulatory authority for the 1968 Act is the General Pharmaceutical Council (GPhC), the PCT should liaise with them regarding the registration status of representatives.

9. Where a pharmacy contractor has ceased service provision, it is important to understand the reasons why. So long as under the 1968 Act, a representative is entitled to carry on the business and has agreed to be bound by the contractor's terms of service, the PCT should take no action that may affect the decisions the representative may make or undermine the value of any potential sale of the business. For example, a pharmacy may go into administration and the administrator appoints a pharmacist to run the pharmacy under their personal control whilst they try to find a buyer.

10. If, however, no *pharmaceutical services* are provided for six months, the PCT could take action to remove them from the pharmaceutical list under **regulation 74(3)**. If a contractor ceases to be a retail pharmacy, action can be taken more quickly under **regulation 74(1)** in circumstances where the exceptions relating to the appointment of representatives listed in paragraph 6 above do not apply.

11. If the PCT is in any doubt, it should seek legal advice.

[8] Donee is defined as "He to whom a gift is made, or a bequest given; one who is invested with a power to select an appointee, he is sometimes called an appointer." *http://legal-dictionary.thefreedictionary.com*

12. In order to meet the requirements of the 1968 Act and **regulation 74(2)(b),** a representative must ensure that:

- the name and address of the representative and the name of the pharmacist whose representative they are, are notified to the GPhC;
- a responsible pharmacist is in charge at the premises; and
- that pharmacist's name and registration number with the GPhC are conspicuously exhibited including the fact that they are for the time being in charge of the business at those premises.

13. The representative must also advise the PCT that they are carrying on the retail pharmacy business and the PCT should then ask them to confirm, in writing, that they agree to be bound by the contractor's terms of service. The PCT is not required to complete fitness to practise checks on the representative.

14. The representative may carry on the retail pharmacy business for:

- in the case of the death of a pharmacist, five years from the date of the death;
- in the case of the bankruptcy, three years from the date on which the pharmacist is adjudged bankrupt;
- in the case of a composition or scheme of deed of arrangement, three years from the date on which the trustee appointed becomes entitled to carry on the business; or
- where a donee or deputy is appointed under the Mental Incapacity Act 2005, three years from the date of the appointment.

15. The time period may be extended by the Fitness to Practise Committee of the GPhC.

16. The 1968 Act defines a representative as:

- in relation to a pharmacist who has died, their executor of administrator and, in respect of a period of three months from the date of their death, if the pharmacist died leaving no executor who is entitled and willing to carry on the business, includes any person beneficially interested in the pharmacist's estate;
- in the case of bankruptcy, the trustee in bankruptcy or any trustee appointed under the composition scheme, deed of arrangement, trust deed or composition contract; and
- in a case of registration of appointment of a donee or the appointment of a deputy by the Court of Protection, that donee or deputy.

17. When determining whether a contractor has ceased to carry on a business, no account is taken of any time spent by the contractor:

- suspended from the PCT's pharmaceutical list;

- in whole-time service in the *armed forces of the Crown* in a national emergency;
- in compulsory whole-time service in the *armed forces of the Crown* (including service resulting from reserve liability); or
- where the contractor is liable for compulsory whole-time service in the *armed forces of the Crown*, in any equivalent service (**Regulation 74(4)**).

18. Additionally, where the contractor has ceased to carry on a business, no account is to be taken of the first six months after the contractor completes that whole-time service in the *armed forces of the Crown* or any equivalent service (**Regulation 74(4)**).

19. Before taking a decision to remove the contractor or premises from its list, the PCT must:

- give the contractor (or person the PCT reasonably believes is representing the contractor or is an executor of the contractor), notice that the PCT is minded to remove them or specific premises from its pharmaceutical list;
- as part of that notification, advise that they may make written representations to the PCT about the proposed action. If they wish to make written representations, they must be made within 30 days beginning with the date of the PCT's letter;
- as part of that notification, advise that they may also make oral representations to the PCT about the proposed action. If they wish to make oral representations, they must be made within 30 days beginning with the date of the PCT's notice (the PCT must then give reasonable notice of the hearing, and the contractor or their representative or executor, or someone representing the representative or executor, would then be expected to attend the oral hearing that the PCT arranges).

20. The PCT must also consult the LPC before taking its decision (**Regulation 74(5)(c)**).

21. If the PCT then decides to remove the contractor or specific premises from its pharmaceutical list, it must notify the contractor of that decision and include in that notification:

- a statement of the reasons for its decision; and
- an explanation of how the contractor may exercise their rights of appeal under **regulation 77(1)(d)** to the FHSAU, i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to the FHSAU within 30 days of the date on which the contractor received the PCT's notification (**Regulation 74(6)**).

Removal of listings: cases relating to cessation of provision of pharmaceutical services

22. **Regulation 74(3)** provides for the removal of a contractor where the PCT determines that they have not provided *pharmaceutical services* in the preceding six months at particular premises. If the contractor has simply ceased to operate as a retail pharmacy, it is not

necessary to wait six months before removing them. This paragraph relates to cessation to provide *pharmaceutical services* only.

23. If the contractor has more than one set of premises included in the PCT's pharmaceutical list, the PCT may only remove those premises from which *pharmaceutical services* have not been provided. If the contractor has only one set of premises in the PCT's pharmaceutical list, the PCT must remove the contractor from its pharmaceutical list.

24. When determining whether a contractor has ceased to provide *pharmaceutical services*, no account is to be taken of any time spent by the contractor:

- suspended from the PCT's pharmaceutical list;
- in whole-time service in the *armed forces of the Crown* in a national emergency;
- in compulsory whole-time service in the *armed forces of the Crown* (including service resulting from reserve liability); or
- where the contractor is liable for compulsory whole-time service in the *armed forces of the Crown*, in any equivalent service (**Regulation 74(4)**).

25. Additionally, where the contractor has ceased to carry on a business, no account is to be taken of the first six months after the contractor completes that whole-time service in the *armed forces of the Crown* or any equivalent service (**Regulation 74(4)**).

26. Before taking a decision to remove the contractor or premises from its list, the PCT must:

- give the contractor (or person the PCT reasonably believes is representing the contractor or is an executor of the contractor), notice that the PCT is minded to remove them or specific premises from its pharmaceutical list;
- as part of that notification, advise that they may make written representations to the PCT about the proposed action. If they wish to make written representations, they must be made within 30 days beginning with the date of the PCT's letter;
- as part of that notification, advise that they may also make oral representations to the PCT about the proposed action. If they wish to make oral representations, they must be made within 30 days beginning with the date of the PCT's notice (the PCT must then give reasonable notice of the hearing, and the contractor or their representative or executor, or someone representing the representative or executor, would then be expected to attend the oral hearing that the PCT arranges).

27. The PCT must also consult the LPC before taking its decision (**Regulation 74(5)(c)**).

28. If the PCT then decides to remove the contractor or specific premises from its pharmaceutical list, it must notify the contractor of that decision and include in that notification:

    - a statement of the reasons for its decision; and
    - an explanation of how the contractor may exercise their rights of appeal under **regulation 77(1)(d)** to the FHSAU, i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to the FHSAU within 30 days of the date on which the contractor received the PCT's notification (**Regulation 74(6)**).

Voluntary and automatic removal of listings: change of ownership, relocation, temporary provision and voluntary closure

29. **Regulation 75** sets out the provisions for voluntary and automatic removal of contractors or specific premises from the PCT's pharmaceutical list.

30. Following a successful change of ownership application, if the previous owner has other premises included in the PCT's pharmaceutical list, the contractor remains included in the list for those premises, and the PCT only removes the premises that have changed hands with respect to that contractor (**Regulation 75(1)(a)**).

31. If, however, following a successful change of ownership application, the previous owner has no other premises included in the PCT's pharmaceutical list, then subject to **regulation 76**, the PCT must remove the contractor from its pharmaceutical list (**Regulation 75(1)(b)**).

32. If a contractor relocates from existing to new premises and also has other premises included in the PCT's pharmaceutical list, the PCT only removes those premises from which the contractor has relocated with effect from the date the contractor is required to notify to the PCT under **regulation 67(4)(b)** of their intention to start providing services at the new premises and cease service provision at the old premises (**Regulation 75(2)(a)**).

33. If a contractor relocates from one PCT to another PCT, and has no other premises on the pharmaceutical list of the PCT from which it is relocating, subject to **regulation 76**, the first PCT must remove the contractor from its pharmaceutical list with effect from the date that the contractor is required to notify it, under **regulation 67(4)(a)(ii)** i.e. it must tell the PCT it will cease service provision at the old premises at the same time as it tells the new PCT that it will commence service provision at the new premises (**Regulation 67(4) and 75(2)(b)**).

34. If a contractor has been providing *pharmaceutical services* on behalf of a suspended contractor, once the fixed period for which the contractor was included in the PCT's pharmaceutical list (referred to in **regulation 27(3)**) expires, then:

    - if the contractor has other premises included in the PCT's pharmaceutical list, the PCT only removes the contractor with respect to the premises at which they were providing services for the suspended contractor; or
    - if the contractor has no other premises included in the PCT's pharmaceutical list, the PCT must remove the contractor from its pharmaceutical list (**Regulation 75(3)**).

35. If a contractor wishes to cease to provide *pharmaceutical services*, for reasons other than those covered above, and so either to withdraw:

    - from the PCT's pharmaceutical list (where they have no other premises included in that list); or
    - to withdraw in respect to just one set of premises.

    they must provide a period of notice required by **regulation 67(2)**).

Periods of notice for voluntary cessation of pharmaceutical services provision

Regulation 67(2) sets out the notice periods to be given for voluntary closure of premises. Unless it is impractical to do so, the notice period must be three months' notice unless one of the following points apply:

- premises which are to be open for at least 100 hours per week – six months' notice; or
- 30 days, where a contractor who is conditionally included in the pharmaceutical list by virtue of **regulation 35**, appeals that decision to the First Tier Tribunal (FTT), the FTT confirms the imposition of that condition or imposes another condition, and within 30 days of being informed of the FTT's decision, the contractor advises the PCT that they wish to withdraw from the pharmaceutical list.

If these notice periods are impracticable, the contractor must notify the PCT as soon as it is practicable to do so.

36. Where the PCT receives such a notice, it must remove the contractor from its pharmaceutical list if the contractor has just one set of premises included in it, or if the contractor has more than one set of premises included, the PCT must only remove them for the premises which the contractor has included in its notice (**Regulation 74(5)***)*.

37. If the PCT decides not to remove the contractor under **regulation 74(5)**, it must notify the contractor of that decision, include a statement of the reasons for its decision, and where

appropriate, provide an explanation of how any rights of appeal that the contractor has under **regulation 77(1)(e)** may be exercised (**Regulation 75(6)**).

38. The contractor may appeal the PCT's refusal to remove them under **regulation 75(5)**, other than where the PCT decides to keep the contractor on its pharmaceutical list for limited purposes pursuant to **regulation 76**.

39. If the contractor wishes to appeal, they must notify the FHSAU, i.e. by sending a notice containing a concise and reasoned statement of the grounds of the appeal to the FHSAU within 30 days of the date on which the contractor was notified of the PCT's refusal to remove them from the pharmaceutical list (**Regulation 77(1)** and **(2)**.

40. 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.

Limitation on withdrawal from pharmaceutical lists

41. There are certain circumstances when the PCT may not remove a contractor from its pharmaceutical list under **regulation 75** without the FHSAU's consent. These are set out in **regulation 76** and relate to instances when fitness to practise investigations or proceedings are ongoing.

42. **Regulation 76(1)** sets out the specific instances when the PCT may not remove a contractor when it would otherwise do so. They are where the PCT:

- is investigating a contractor in order to see whether there are grounds to contingently remove or suspend them from the pharmaceutical list, or apply for a national disqualification;
- has decided to remove the contractor from its pharmaceutical list under section 151 or 152 of the 2006 Act or **regulation 80** (breach of a condition imposed on the contractor – conditional inclusion in the pharmaceutical list) but has not done so;
- has decided to contingently remove the contractor under section 152 of the 2006 Act but has not done so; or
- has suspended the contractor under section 154 of the 2006 Act.

43. In these circumstances, the contractor's name remains on the PCT's pharmaceutical list and may not be removed for one of the reasons listed in **regulation 75** until the investigation or proceedings have been concluded.

44. This provision will, therefore, prevent a contractor from trying to avoid investigation by voluntarily closing premises or selling them on, or relocating to the area of another PCT. If the PCT does receive a change of ownership application for premises which are currently owned by a contractor who is being investigated, or an application to relocate outside the

area, it may process the application but must keep the owner on the pharmaceutical list, without there being premises listed in relation to the contractor, until the conclusion of the investigations.

45. Whilst the contractor's name remains included in the PCT's pharmaceutical list, the PCT may exercise its functions under Part 11 of the 2012 Regulations and Chapter 6 of Part 7 of the 2006 Act (this sets out the PCT's fitness to practise powers). However, for all other purposes, the contractor is treated as having been removed from its pharmaceutical list under **regulation 75**.

Example

A contractor has one set of premises included in the PCT's pharmaceutical list and these premises are included in the PNA map (as required by **paragraph 8 of Schedule 1**).

The contractor is being investigated by the PCT following concerns about their fitness to practise and on 1 May, the contractor gives the PCT three months' notice that it will voluntarily close these premises under **regulation 75(4)** on 12 August. The PCT's investigations are still underway on 12 August and the contractor, therefore, remains on the PCT's pharmaceutical list by virtue of **regulation 76**. However, the PCT updates its PNA map to remove the premises.

46. This regulation does not apply where the PCT has issued a *breach* or *remedial notice*. In this case, the contractor may be removed from the pharmaceutical list under **regulation 75** and the notice lapses.

Chapter 6: Removal or withdrawal – dispensing doctors

1. This chapter deals with the provisions within **paragraph 10 of Schedule 6** whereby a *dispensing doctor* may withdraw from the dispensing doctor list.

Removal or withdrawal of dispensing doctors and dispensing premises

2. The PCT must prepare and publish a list of any *dispensing doctors* in its area (**Regulation 46(1)**). This could include doctors who are signatories to general medical services (GMS), personal medical services (PMS) or alternative provider medical services (APMS) contractors (in the case of an APMS contractor, with a registered patient list). It also includes any doctors who are not providers of primary medical services, but who do provide *pharmaceutical services* from premises in the area of the PCT.

3. The dispensing doctor list will also include the premises for which the doctor has premises approval.

4. Where a *dispensing doctor* wishes:

   - to withdraw from a dispensing doctor list (because they no longer wish to provide *pharmaceutical services*); or
   - for particular dispensing premises to no longer be included in relation to them,

   they must notify the PCT of that wish at least three months in advance of the date on which *pharmaceutical services* are no longer to be provided. A shorter period of notice may be given where it is impracticable for the doctor to give three months' notice. In this case, the doctor must notify the PCT as soon as it is practicable for them to do so (**paragraph 10(1) of Schedule 6**).

5. Particular dispensing premises may be removed from the list because of a relocation application under **regulation 55**. In this instance, before the date on which the doctor commences the provision of *pharmaceutical services* at the new premises, they must give notice to the PCT of when they will cease to provide *pharmaceutical services* at the existing premises (**paragraph 10(2) of Schedule 6**). The doctor must have ceased service provision at the old premises before commencing provision at the new premises.

Annex A – Membership of Advisory Group

Chairman	Paul Burns
NHS Employers	Taryn Harding Kelvin Rowland-Jones David Thorne
Patients Association	Kieran Mullan
National Voices	Mark Platt (to June 2010) Jules Acton (from June 2010)
Pharmaceutical Services Negotiating Committee	Sue Sharpe Steve Lutener Gary Warner
General Practitioners' Committee of the British Medical Association (BMA)	Dr Russell Walshaw Dr Richard West (Dispensing Doctors' Association) at the invitation of the BMA Matthew Isom (Observer)
British Healthcare Trades Association	Ray Hodgkinson Peter Bullen
Organisations receiving papers	Which? – Helen McCallum
Secretariat to the Advisory Group	Peter Dunlevy Catriona Patterson Gillian Farnfield Charlotte Goodson
Department of Health Lead Sponsor	Jeannette Howe
Departmental lawyer	Michael Adam

Members of the guidance sub-group

Chair	Taryn Harding
NHS Employers	Kelvin Rowland-Jones David Thorne
Pharmaceutical Services Negotiating Committee	Steve Lutener Mark Collins
General Practitioners' Committee of the British Medical Association (BMA)	Dr Russell Walshaw
Secretariat	Catriona Patterson Gillian Farnfield Charlotte Goodson

NHS representatives

Nick Ford, Hampshire & Isle of Wight Practitioner and Patient Services Agency
Lee Davies, NHS Western Cheshire
Paula Wilkinson, NHS Mid Essex
Tony Carson, East & South East England Specialist Pharmacy Services

Annex B – Glossary of defined terms and phrases

Term or phrase	**Definition as per regulation 2 of the 2012 Regulations**	**Explanation**
Armed forces of the Crown	Means the forces that are "regular forces" or "reserve forces" within the meanings given in section 374 of the Armed Forces Act 2006 (definitions applying for the purposes of whole Act).	
Breach notice	Is to be construed in accordance with regulation 71(1)	Where a pharmacy contractor or DAC is in breach of their terms of service, the PCT and the breach is not capable of remedy, the PCT may issue a notice requiring them not to repeat the breach.
Core opening hours	Is to be construed, as the context requires, in accordance with paragraph 23(2) of Schedule 4 or paragraph 13(2) of Schedule 5, or both.	Pharmacies are required to be open for 40 hours per week, unless they were approved under regulation 13(1)(b) of the 2005 Regulations, in which case, they are required to open for at least 100 hours per week. DACs are required to be open for not less than 30 hours per week.
Directed services	Means additional pharmaceutical services provided in accordance with directions under section 127 of the 2006 Act.	These are *advanced* and *enhanced services* as set out in Directions.

Dispensing doctor(s)	Is to be construed in accordance with regulation 46(1).	These are providers of primary medical services who provide pharmaceutical services from medical practice premises in the area of the PCT; and general practitioners who are not providers of primary medical services but who provide pharmaceutical services from medical practice premises in the area of the PCT.
Enhanced services	Means the additional pharmaceutical services that are referred to in direction 14 of the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Directions) 2011.	
Essential services	Except in the context of the definition of “distance-selling premises” is to be construed in accordance with paragraph 3 of Schedule 4.	
Notice	Except in the context of a period of notice, means a notice or notification in writing, which may (except in the context of a notice to be exhibited) be in an electronic form, and “notify” is to be construed accordingly.	
Notification	Except in the context of a period of notice, means a notice or notification in writing, which may (except in the context of a notice to be exhibited) be in an electronic form, and “notify” is to be construed accordingly.	

Notify	Except in the context of a period of notice, means a notice or notification in writing, which may (except in the context of a notice to be exhibited) be in an electronic form, and "notify" is to be construed accordingly.	
Pharmaceutical services	In the context of- (a) part 2 and Schedule 1, means the pharmaceutical services to which a pharmaceutical needs assessment must relate by virtue of regulation 3(2); and (b) arrangements made to or to be made for the provision of pharmaceutical services by a medical practitioner, means the dispensing of drugs and appliances but not pharmaceutical services as mentioned in section 132(7)(a) or (b) of the 2006 Act (persons authorised to provide pharmaceutical services).	There are two definitions of pharmaceutical services used within the 2012 Regulations. One definition is used for Part 2 and Schedule 2 (regulations relating to the PNA) and includes the services provided by pharmacy contractors, DACs and dispensing doctors that are described in Schedules 4, 5 and 6 respectively. It also includes those described in Directions. The second definition is used for all other Parts and Schedules and is narrower as it relates to only those services described in Schedules 4 to 6.
Remedial notice	Is to be construed in accordance with regulation 70(1).	Where a pharmacy contractor or DAC is in breach of their terms of service and the breach is capable of remedy, the PCT may issue a notice requiring them to put right the breach.
Supplementary opening hours	Is to be construed, as the context requires, in accordance with paragraph 23(3) of Schedule 4 or paragraph 13(4)(a) of Schedule 5, or both.	These are opening hours that are over and above the core opening hours.