Local Pharmaceutical Services

Guidance Notes

First published March 2008

Published to DH website, in electronic PDF format only.
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Document Purpose	Best Practice Guidance		
ROCR Ref:		**Gateway Ref:**	8808
Title	Local Pharmaceutical Services, National Health Service (Local Pharmaceutical Services) Regulations 2006		
Author	Medicines, Pharmacy & Industry Group, Pharmacy Team		
Publication Date	March 2008		
Target Audience	PCT Primary Care Service Commissioners		
Circulation List	PCT Local Pharmaceutical C'ttees (LPC) & Community Pharmacists		
Description	This document provides best practice information on Local Pharmaceutical Services (LPS) for PCTs which, if they are considering commissioning LPS services, they may wish to use. It covers the main aspects of LPS and explains details of specific parts of the process.		
Cross Ref	Regulations: NHS (LPS) Regulations SI 2006/552		
Superseded Docs	LPS Guidance for LPS pilot schemes		
Action Required	N/A		
Timing	N/A		
Contact Details	Medicines, Pharmacy & Industry Group, Pharmacy Team Zone D 4th Floor Skipton House 80 London Road, Elephant & Castle SE1 6LH 0207 972 2715 http://www.dh.gov.uk/en/Policyandguidance/Medicinespharmacyandindustry/Lc		
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Executive summary

This guidance states the law as at March 2008

This document provides information on Local Pharmaceutical Services (LPS) and details of the issues to be addressed by those developing and commissioning LPS contracts.

This document also provides information for PCTs which, if they are considering commissioning LPS services, they may wish to use. It covers the main aspects of LPS and explains details of specific parts of the process.

Local Pharmaceutical Service (LPS) contracts allow Primary Care Trusts to commission community pharmaceutical services tailored to specific local requirements. LPS complements the national contractual framework for community pharmacy but is an important **local commissioning tool** in its own right. LPS provides flexibility to include within a single local contract a broader or narrower range of services (including services not traditionally associated with pharmacy) than is possible under national pharmacy arrangements.

PCTs are not constrained from using other commissioning processes but may find this guidance a useful support. This document includes guidance on the following LPS commissioning processes:

- Development of LPS schemes
- Designation of priority neighbourhoods or premises
- LPS providers (who can be an LPS provider)
- LPS services (which services can be included in LPS schemes)
- Commissioning
- LPS contract variation, and
- Termination.
- Low Volume Pharmacies

A model LPS contract template will shortly be available separately at this site.

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Section 1

Chapter 1
Commissioning LPS services

Introduction

1. **This document provides a template for PCTs which, if they are considering commissioning LPS services, they may wish to adopt. PCTs are not constrained from using other commissioning processes, however all LPS schemes must comply with the appropriate legislation.**

2. In this document there are references to:
   - the NHS Act 1977;
   - the Medicines Act 1968 as amended;
   - the NHS & Community Care Act 1990
   - the Health and Social Care Act 2001;
   - Patients' Forum (Functions) Regulations 2003;[1]
   - the NHS (Pharmaceutical Services) Regulations 2005 (SI 2005/641) as amended (see paragraph 7 below) referred to as "the Pharmaceutical Services Regulations" except where stated otherwise
   - the NHS Act 2006;
   - the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (SI 2006/552) referred to as "the LPS Regulations 2006" except where stated otherwise.

LPS – wider context

3. The NHS Plan, published in July 2000, set out an ambitious and radical plan to bring about a modern NHS. It envisaged a whole-system service that is patient focussed and inclusive, encouraging innovative and more flexible working practices to make better use of staff skills in the provision of high quality healthcare.

4. "Pharmacy in the Future – Implementing the NHS Plan", published in September 2000, included a number of objectives to support the key role of pharmacy in the delivery of healthcare, as follows:

   - better access to services - building on the strengths of pharmacy

[1] It is proposed that these regulations will be replaced with the Local Involvement Networks Regulations 2008 which have been made and are expected to come into force on 1 April 2008. It is also proposed that a number of other regulations will be made which provide a right of entry to an individual authorised by a Local Involvement Network.

- helping patients get the most from their medicines
- ensuring high quality services, getting the most from staff
- re-designing services around patients – getting the structures right

5. The White Paper "Our health, our care ,our say" published in January 2006, encourages increasing use of community pharmacy in support of better use of skills, improved provision and access to healthcare. LPS schemes have a key part in this and provide PCTs with an important commissioning instrument.

Provision of Community Pharmacy Services

6. Community pharmaceutical services are generally provided on the basis of statutory terms and conditions, which are negotiated nationally and set out in regulations, which apply nationally. The National Health Service (Pharmaceutical Services) Regulations 2005 (SI 2005/641) set out the legal requirements in full, as amended by S.Is: 2005/641, 2005/1015; 2005/1501; 2005/3315; 2006/913; 2006/1501; 2006/3373 and 2007/674.

Alternative arrangements for provision through Local Pharmaceutical Services

7. The Health and Social Care Act 2001 (these provisions are now consolidated in the National Health Service Act 2006) introduced the possibility of alternative arrangements to be known as local pharmaceutical services arrangements (referred to in this document as "LPS" arrangements). LPS arrangements permit pharmaceutical services to be delivered on the basis of locally negotiated contracts, which must include a dispensing service and certain terms of service (see paragraph 73 et seq.). Beyond those required terms, the content of the contract and the range of services to be provided under LPS arrangements are a matter for local negotiation.

Introduction of LPS Permanence arrangements

8. LPS arrangements were piloted from 2002 to 2006. Following a national evaluation, conducted by the School of Pharmacy & Pharmaceutical Sciences at the University of Manchester, LPS changed from pilot to permanence status from 1 April 2006. This gives a PCT the power to make LPS schemes locally within regulations, without requiring approval from the Secretary of State for each scheme. The main regulations, governing LPS permanence are contained in the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (SI 2006/552) referred to subsequently as "the LPS Regulations 2006".

9. All services currently provided through national arrangements may be provided through LPS in addition to services not traditionally associated with pharmacy. Training and education may also be provided through LPS contracts including training and education for those who are or may become involved in the provision of LPS.

10. LPS is likely to be immediately useful where national arrangements do not permit a specific configuration of services which may be required by a PCT or where current providers are unable or unwilling to provide certain services. This does not preclude a variety of other circumstances in which LPS may be used.

11. LPS schemes may also be co-located in premises with national arrangements, for instance, to address the needs of a particular patient group.

Differences between LPS and national pharmaceutical services arrangements

12. LPS puts PCTs in the driving seat. It is for the PCT to decide when and in what circumstances it wishes to enter an LPS contract. LPS provides the PCT with flexibility to decide not just where it might wish to locate LPS schemes but also the mix of services within any given scheme.

- The LPS contract may provide for such combination of services as the parties between them agree.
- The level of remuneration for services provided under LPS contracts is decided locally between parties to the contract and not nationally.
- LPS is not subject to Pharmaceutical Services 'control of entry' regulations, therefore, an LPS scheme may be located in any part of a PCT's geographic area and is not required to meet the provision of the Pharmaceutical Services regulations 'necessary and expedient' test.
- PCTs have power to "designate" neighbourhoods, premises or descriptions of premises (see paragraph 19 etc.) while deciding whether to develop and/or implement an LPS scheme. This has the effect of deferring consideration of any applications to the pharmaceutical list, whether under Regulation 12 ('necessary or desirable') or 13 ('exempt') of the Pharmaceutical Services regulations, in the area under designation (see "Designation of priority neighbourhoods or premises" for further details), and
- Exemptions to the "necessary or expedient" test under regulation 13 of the Pharmaceutical Services regulations do not apply to applications in a neighbourhood in which LPS are (are to be) provided.

Benefits Of LPS

13. LPS is an important local commissioning tool that provides flexibility to build local contracts, which support local delivery of improved health services through:

- local contracts designed to address local healthcare priorities, specific or unique situations without restriction on location
- better use of pharmacies to increase access to a broader range of health services
- provision or reconfiguration of services designed around patients or specific groups of patients

- better use of pharmacists' skills especially in extending clinical services in local areas
- providing opportunities for LPS providers to work within contracts which they help to design
- pharmacists working more closely with other health professionals e.g. leading integrated teams of health professionals or working as part of such a team
- providing PCTs with the flexibility to participate in health promoting schemes in a wider context, for example, local regeneration projects.

14. Benefits of LPS to patients include:

- access to services that have been designed with their needs in mind
- the opportunity to benefit from the pharmacist's expertise
- access to a broader range of care, facilitated by the local pharmacy
- locally based services that offer easy access especially to those with reduced mobility.

Chapter 2

LOCAL PHARMACEUTICAL SCHEME COMMISSIONING

Preparatory Phase

1. This section outlines the wider context to the development of LPS arrangements, especially as part of local pharmaceutical needs assessment and wider consultation on the provision of pharmacy services. The use of "designation" to mitigate the potentially adverse impact of the introduction of additional national arrangements in an area where the development or implementation of an LPS scheme is underway is also discussed.

2. This section also examines the specific requirements which potential providers of LPS services are required to meet and outlines some of the services which might be included in an LPS contract.

Establishing the requirement for pharmaceutical services within the PCT area

3. In determining arrangements for provision of pharmaceutical services for their population, PCTs may take into account arrangements made under LPS schemes. PCTs should be aware of the provisions of sections 242 (1) to (5) (Public Involvement and Consultation) and 244 (1) to (4) (Overview and Scrutiny Committees) of the Health Act 2006.

Communicating a PCT decision not to commission LPS services

4. A PCT may decide whether or not it wishes to use LPS. This decision may refer to a specified period, e.g. the current year or for the foreseeable future. In any case, it is recommended that the decision is publicly communicated, along with an indication of when the decision will be revisited. This will avoid unnecessary effort on the part of those who might wish to develop LPS proposals.

5. It is recommended, at the minimum, that the Local Pharmaceutical Committees be informed about any changes to the PCT's policy on the commissioning of LPS schemes.

Designation of priority neighbourhoods or premises.

6. The LPS Regulations (SI 2006/552, Regulation 4) provides for designation of priority neighbourhoods or premises. This has the effect of allowing PCTs to defer consideration of applications to join the pharmaceutical list (PhS applications) in the area under designation. In addition, for the life of a designation, applications to be included in the pharmaceutical list, under "exemption" provisions, within the Pharmaceutical Regulations, may also be deferred.

7. It is proposed that LPS Regulations will provide that certain PhS applications will be excluded from deferral by the PCT (bringing LPS arrangements into line with Pharmaceutical Services Regulation 25(2)). The PhS applications are:

- for changes of ownership
- from a nominated person for temporary inclusion to provide services, in place of a pharmacist who has been suspended
- to exercise the right of return after ceasing to provide LPS
- where preliminary consent had already been granted and certain conditions are satisfied, or
- for inclusion in the pharmaceutical list received more than 30 days prior to the date of designation where the applications relate to the neighbourhood, premises or description of premises that has been designated until such time as the designation is cancelled or expires.

8. LPS Regulation 4(2) allows PCTs to defer consideration of all other Part 2 applications if they decide to do so. However, in certain cases e.g. applications for minor relocations, PCTs may choose not to defer.

9. PCTs may choose to use the power of designation, depending on local circumstances. The aim of a designation is to allow time for an LPS proposal to be worked up, processed or implemented. Designation therefore allows PCTs to mitigate the potentially adverse impact of any new community pharmacy beginning to operate in an area where the development or implementation of an LPS scheme is underway. This may be a critical factor where in some cases the PCT has to plan and commit to a longer-term development, e.g. commissioning and building new community health centre premises.

10. PCTs may wish to note that designations are subject to review and cancellation, particularly where an LPS scheme proposal has not been submitted to the PCT approval process within twelve months, beginning with the date of the original designation, or if the LPS application is rejected. More detailed guidance is given in the following paragraphs.

11. LPS Regulations 2006 (SI 2006/552 Part 2) provide that a PCT may designate neighbourhoods, premises or descriptions of premises in or at which local pharmaceutical services are to be provided under:

    - a proposal for an LPS scheme, or
    - a scheme (or schemes) that has been approved. (Note. there is no time limit on designation in the period between approval and implementation – so that, provided a scheme has been approved, designation may continue for more than one year, subject to the necessary reviews, for example, if construction of new premises is required before implementation).

    (Note neither "locality" or "neighbourhood" are defined in the NHS Act, Pharmaceutical Services Regulations or LPS Regulations)

12. A designation must:

    - be made in writing and dated
    - include a map showing the location
    - specify details of the services to be provided under the relevant scheme to which it refers

13. Once a designation has been made the PCT must notify:

    - the Local Pharmaceutical Committee for the area
    - the Local Medical Committee for the area
    - any person whose name is included on the pharmaceutical list of that PCT or of a neighbouring PCT that is likely be affected by the designation
    - any person who provides services under LPS arrangements or an LPS scheme in the locality of the PCT.
    - any person whose name is included in the dispensing doctor list of the PCT or of a neighbouring PCT who, in the opinion of the PCT is likely to be affected by the designation
    - any Patients Forum serving the locality of the designating PCT or of a neighbouring PCT that is likely to be affected by the designation.

14. A PCT must make available for inspection at its offices, copies of all designations that it has made including any variations to such designations.

Variation of designation

15. A PCT may vary a designation that it has made, where the designation relates to:

    - a neighbourhood and the services to be provided under the scheme are to be provided from part only of that neighbourhood;

- a premises and the services to be provided under the scheme are to be provided from a part only of that premises;
- a description of premises and the services to be provided under the scheme are to be provided from certain parts only of the premises described.

16. A variation to a designation may only reduce the area previously designated. There is no provision for increasing the area of designation under an existing designation.

17. A designation as varied must:

- be made in writing and dated
- include a map showing the location
- specify the details of the services to be provided under the scheme to which it refers

18. Notice of the variation must be given to those who were sent notification of the original designation.

Increasing the designated area

19. If a PCT finds that the area it has designated is less than that which it now wishes to designate, it can consider separately designating an additional area. This should be treated as a new designation and the PCT should take this forward in accordance with the designation process as set out in the previous paragraphs.

Review of designation

20. A PCT must regularly review a designation which it has made. It must conduct a review before the end of a period of six months beginning with the date of designation or the date of the last review, as the case may be. When conducting a review, it must take into account representations made by:

- the Local Pharmaceutical Committee for the area
- the Local Medical Committee for the area
- any person whose name is included on the NHS pharmaceutical list of the designating PCT or of a neighbouring PCT that is likely to be affected by the designation
- any person who provides services under LPS arrangements or an LPS scheme in the locality of the PCT
- any person whose name is included in the dispensing doctor list of the PCT or of a neighbouring PCT who, in the opinion of the PCT is likely to be affected by the designation
- any Patients Forum serving the locality of the designating PCT or of a neighbouring PCT that is likely to be affected by the designation.

21. The PCT must notify those listed above of the outcome of the review.

Cancellation of designation

22. A PCT may at any time cancel a designation which it has made. However, it must cancel a designation in the following situations:
    - if required to do so by a direction given by the Secretary of State
    - if, within a period of twelve months beginning with the date of designation, an application for an LPS scheme that relates to the designation has not been submitted to a PCT for approval (Note - A PCT may continue a designation where it has started the process of examining an LPS proposal. The designation may remain in place for the interval between approval and commencement of the scheme);
    - if the only (or only remaining) application for an LPS scheme that relates to the designation has been rejected; or
    - if there is a significant change to a neighbourhood in which, or the premises from which, the LPS services are to be provided other than a change which leads to a variation as described in the paragraphs on 'variation of designation' above. In this case, the twelve month period will continue to run from the original date of designation.

23. A PCT must give notice of cancellation of designation to:

    - the Local Pharmaceutical Committee for the area
    - the Local Medical Committee for the area
    - any person whose name is included on the NHS pharmaceutical list of the designating PCT or of a neighbouring PCT that is likely to be affected by the designation
    - any person who provides services under LPS arrangements or an LPS scheme in the locality of the PCT
    - any person whose name is included in the dispensing doctor list of the PCT or of a neighbouring PCT who, in the opinion of the PCT is likely to be affected by the designation
    - any Patients Forum serving the locality of the designating PCT or of a neighbouring PCT that is likely to be affected by the designation.

24. Where a PCT has cancelled a designation, it may not designate the same neighbourhood, premises or description of premises within a period of six months beginning with the date of cancellation. This does not apply where the reason for the cancellation of the designation was the rejection of an application for an LPS scheme. In such cases a new designation can be made immediately following the decision to reject.

LPS provider(s)

25. The range of possible LPS providers is broad. However, to the extent that an LPS contract must include the provision of dispensing, in practice it may only be entered into by a provider who can arrange to meet the requirements of section 52 of the Medicines Act 1968 relating to that activity. (In summary, section 52 of the Medicines Act requires that Prescription Only Medicines ("POMs") and Pharmacy ("P") medicines may only be dispensed from a registered retail pharmacy, by or under the supervision of a pharmacist. A pharmacy may only register as a retail pharmacy if it complies with the statutory requirements set out in the Medicines Act.)

26. Potential LPS providers will need to be able to convince the PCT that they can provide the range of skills and experience necessary to provide the required services and meet wider contractual obligations associated with LPS contracts.

27. LPS schemes may **not** be combined with any of the other contractual arrangements for providing primary care medical services or dental services although a separate contract may be held alongside either. For PMS contracts - see Section 92(4) of NHS Act 2006; for PDS contracts - see section 107(4) NHS Act 2006). For GMS, APMS or PCTMS contracts - see paragraph 4 of Schedule 12 to the NHS Act 2006. Furthermore, LPS may not include dispensing by medical practitioners. See NHS Act 2006, Part 7, Chapter 2 section 134(7) "local pharmaceutical services" means such services of a kind which may be provided under section 126 of that Act [Arrangements for pharmaceutical services] or by virtue of section 127 of that Act [Arrangements for additional pharmaceutical services] (other than practitioner dispensing services).

28. Participation in LPS schemes is voluntary on the part of the provider and the PCT. There will normally be a right of return to a pharmaceutical services (PhS) contract, where pharmacy providers move from providing services under a PhS contract ('national' contract) to an LPS contract (see "right of return" for more information).

29. A PCT may enter into an LPS scheme with:

- an individual, provided the individual is not disqualified within the provisions of paragraph 7(2) – (4) in Part 3 of LPS Regulations (SI 2006/552) but note paragraph 36,

- two or more individuals, practising in partnership, if each of those individuals does not fall within the provisions of paragraph 7(2) – (4) in Part 3 of LPS Regulations (SI 2006/552), or

- A body corporate, if (a) the body corporate or (b) any director, chief executive, superintendent pharmacist or company secretary of the body corporate does not

fall within the provisions of paragraph 7(2) – (4) in Part 3 of LPS Regulations (SI 2006/552).

Provision of LPS services by a PCT

30. There is no provision for a PCT to be a provider of LPS services within its own PCT or another PCT. (Schedule 12 paragraph 1(2)(c) of the Health Act 2006).

Health Body Status for LPS Providers

31. An LPS provider will be treated as a health services body for the purposes of section 4 (NHS contracts) of the NHS & Community Care Act 1990, from the date the LPS contract commences, unless a provider indicates otherwise by giving notice to the PCT of a wish to opt out. Further details of health service body status provisions may be found in **Annex A**.

Right of return to national contractual arrangements

32. It is recommended that the PCT should publish the principles (which may be amended from time to time) by which it will make right of return determinations. Details of the guiding principles used by the Department in making determinations during the pilot phase of LPS are set out in **Annex E**.

What services may be included in an LPS contract?

33. Dispensing is a 'core' service and all LPS contracts must include an element of dispensing. There is no floor or ceiling on the level of dispensing, i.e. the volume of dispensing in an LPS scheme is not specified and will be different from scheme to scheme.

34. Although dispensing is a core aspect of LPS, it does not have to be provided for the whole population generally. An LPS scheme could dispense for a section of the population only, for example, patients with diabetes and over 75 years of age.

35. LPS schemes may include the provision of drugs or appliances in accordance with a repeatable prescription. The provision of repeat dispensing may not be appropriate in certain schemes and in these cases, the PCT should specify in the contract whether or not repeat dispensing is to be included as part of the LPS scheme.

36. Contracts for service provision in respect of specific groups may include services not traditionally associated with community pharmacy. For example, in the case of patients with diabetes, the LPS contract may include access to services such as podiatry, optometry, signposting to or provision of further services and support on managing the condition. In this way, services may be designed with particular focus on patient need while at the same time reducing the contracting burden through commissioning all appropriate services within one contract.

37. Examples of combinations of services possible in LPS are contained in **Annex B**.

Chapter 3
INITIATING AN LPS SCHEME

1. Proposals for LPS schemes may come from a PCT itself (for instance the PCT may have identified service requirements which it wishes to address through an LPS contract) or may be put forward from outside the PCT, for example, an individual or body may put forward a proposal to address a service gap.

2. Where a PCT wishes to consider LPS proposals and has communicated this intention, these might be initiated by:

   - the PCT specifying services or location and other details of an LPS scheme it wishes to commission and invite prospective providers to come forward, or
   - a prospective LPS provider/provider or any other person putting forward a proposal for a scheme. (Note. where such an application is received, the information in that application should be treated as confidential, until such time as it is appropriate to make the information public).

3. It should be noted that a PCT may use either or both of the above to develop LPS schemes. Whichever way an LPS scheme is initiated, the PCT, if it proposes to use LPS, must have in place a process by which schemes are examined and processed. This process must be transparent and command confidence. For example, it is recommended there should be a process for declarations of interest by any party to the decision making process.

4. It should be noted that there is no obligation on the PCT to commission a particular service though an LPS scheme even where the PCT policy is to use LPS. Likewise, there no obligation on an individual or body to become an LPS provider.

5. Any prospective LPS provider must supply information with their LPS proposal as to whether any relevant person, or in the case of a partnership, the partners in the partnership, or where the person is a body corporate, the body corporate, or any of its directors, its chief executive, its company secretary or its superintendent pharmacist, falls within the provisions outlined in **Annex C** relating to suitability and fitness to practise.

6. Where a home PCT receives information about “fitness to practise” it must consider that information and decide whether the information raises questions about the:

   - provider’s suitability to be a contractor
   - fitness to practise.

Procurement process

7. This guidance is issued by the Department of Health to assist PCTs in the implementation of LPS contracts. PCTs should note that this guidance does not seek to provide guidelines in respect of the procurement process. PCTs are strongly advised to ensure that they obtain expert advice on public procurement and ensure that their procurement exercises are compatible with the general principles of public procurement law and Council Directive 2004/18/EC. Failure to do so could expose a PCT to challenge by way of judicial review, which could involve substantial costs for the PCT concerned. PCTs are directed to the NHS Purchasing and Supply Agency (PASA) website (http://www.pasa.nhs.uk). PASA provide strategic guidance on procurement to the NHS where procurement is taking place at a regional or local level. PASA also provides practical guidance, education and training to those involved in procurement throughout the NHS.

8. The process for awarding an LPS contract is the standard procurement process. Where the value of the contract exceeds the level currently set by EU Regulations the tendering process must comply with EU Regulations. Where the value of the contract falls below this level, a transparent process of procurement should still be followed. This should apply even in cases where a potential provider has submitted a proposal for an LPS scheme to the PCT. The contract for the scheme should still be tendered, even though this may result in the potential provider not being awarded the contract.

9. Any technical specifications required by the PCT should be drafted clearly and precisely and should be easily understood by potential providers. All of the technical specifications required should be included in the contract documents.

10. As with the commissioning of any contract, the process for decision-making should ensure that decisions are taken in the light of information available, and that those decisions are clearly reasonable. This is important since there is no right of appeal in LPS. Those dissatisfied with decisions may put forward a legal challenge in the form of a judicial review.

11. As part of good practice, PCTs are encouraged to place as much information as possible in the public domain. This includes not just details of the services to be provided under LPS but also the criteria to be used in selecting either proposals for further development or selection of LPS providers, as the case may be. In this way those considering whether to put forward proposals or to respond to any call for LPS providers will be in a better position to make a judgement about what is required.

12. There is no specified model commissioning-process for LPS schemes. However, PCTs will be informed by experience of the commissioning processes for other services. Experience from the LPS pilot phase indicates that having specific

documents for use at each stage of the process helps to avoid confusion and encourages the provision of information in a standardised format. For example, having a form to be completed by those who wish to put forward ideas for LPS schemes will help to capture outline details and help all sides to be clear about the information supplied, the source of the information and the date on which information was put forward. This will then aid further processing. A link to a selection of template forms used in the pilot phase of LPS is given in **Annex D**, for information.

13. Where decisions are to be taken or selections made on proposals, it is important that decision-makers are appropriately representative, bearing in mind the area under consideration. In the case of LPS schemes, this may include not only a PCT Pharmaceutical Advisor and representatives of community pharmacy, but also patients, public health and primary care advisors, among others. As mentioned earlier, it is recommended that there should be a process for declarations of interest by any party to the decision making process.

LPS proposals - notification

14. It is proposed that regulations will provide that notification of LPS proposals, which have been selected for further development, must be made to:

- the Local Pharmaceutical Committee for the area
- the Local Medical Committee for the area
- any person whose name is included on the NHS pharmaceutical list of the designating PCT or of a neighbouring PCT that is likely be affected by the designation
- any person who provides services under LPS arrangements or an LPS scheme in the locality of the PCT
- any person whose name is included in the dispensing doctor list of the PCT or of a neighbouring PCT who, in the opinion of the PCT is likely to be affected by the designation
- any Patients Forum serving the locality of the designating PCT or of a neighbouring PCT that is likely to be affected by the designation[2].

There will be nothing to prevent a PCT from consulting a wider range of stakeholders than those specified. It is also proposed that regulations will provide that any person so notified may, within 45 days of the notification, make representations to the PCT.

Developing an LPS scheme for “low volume” dispensing pharmacies

15. As part of its service provision arrangements, a PCT may wish to take account of changes in pattern and volume of dispensing in its established pharmacies. LPS

[2] It is proposed that these regulations will be replaced with the Local Involvement Networks Regulations 2008 which have been made and are expected to come into force on 1 April 2008. It is also proposed that a number of other regulations will be made which provide a right of entry to an individual authorised by a Local Involvement Network.

contracts may be a useful means to ensure the continued provision of services in areas where provision under national contractual arrangements might be uneconomic, for example, areas served by low-volume pharmacies. Further material on low-volume pharmacies is presented in Section 2 of this guidance.

Chapter 4

DEVELOPMENT OF LOCAL PHARMACEUTICAL SERVICE CONTRACTS

1. This section provides guidance on development of the contract for LPS services. It includes advice on the co-location within the same premises of LPS arrangements with national pharmaceutical service arrangements; the right of LPS providers to return to national arrangements; payments to LPS providers; terms and conditions and restrictions.

Preparatory payments during LPS scheme development

2. PCTs may make payments of financial assistance in respect of the development of LPS schemes (preparatory payments). It is for PCTs to decide the level and circumstances in which payments, if any, are made.

Co-location of PhS and LPS contracts

3. Existing pharmacy contractors are among those who may provide LPS services. LPS contracts may be co-located at the same premises, for example, a pharmacy contractor might provide services under the terms of the national contract and provide an out-of-hours service under an LPS contract. Another example might be that of a pharmacy providing services generally under the national contract but providing a specific service for patients with a long term condition under an LPS contract. The PCT should satisfy itself that the arrangements are auditable and that there is no movement of prescriptions between contracts, for example, presentation of prescriptions for payment under whichever contractual arrangements are most beneficial financially.

Right of return to national pharmaceutical services arrangements

4. A right of return in this case means a right to return to provision of pharmaceutical services under the national contractual arrangements. The only LPS providers eligible to be considered for right of return are those who moved from a PhS contract under which services were provided under national arrangements, to providing services wholly though LPS.

5. In cases where an existing pharmacy contractor on the pharmaceutical list of the PCT moves across to an LPS contract, i.e. ceases to provide services under national

arrangements, the LPS Regulations 2006 (SI 2006/552 Regulation 15(1)) require the PCT to determine, before entering into an LPS scheme, whether the contractor is to be given a right of return to the PCT's pharmaceutical list after ceasing to provide services under LPS.

6. Before an LPS contract is varied to permit the provision of services from different or additional premises, a PCT will need to consider the impact by reference to the principles it has adopted for 'right of return'.

7. A PCT may at any time make a determination or vary a determination about an LPS provider by reference to the principles it has adopted for 'right of return', if requested by an LPS provider.

8. If the LPS contract is terminated due to the provider no longer meeting the fitness to practise provisions, the provider might make an application to return to national contractual arrangements. However, the provider would be required to make a declaration of fitness to practise before entering onto the PCTs pharmaceutical list and the provisions of Regulation 19 (fitness to practise grounds) of the Pharmaceutical Services Regulations (S.I 2005/641) would apply.

9. If a provider wishes to sell the business but the LPS contract was being terminated on grounds of poor performance, the PCT will need to consider in the normal way, any application by the new provider to join the pharmaceutical list where the application is based on the 'right of return' which could have been exercised by the original contractor.

10. The PCT must notify the following of any determination made in regard to right of return:
    - Contractors providing local pharmaceutical services in its locality
    - Any person included in the pharmaceutical list, i.e. all persons, not just those persons who may be significantly affected by the determination
    - the Local Pharmaceutical Committee for the area
    - the Local Medical Committee for the area
    - any PCT or (where the LPS will be situated near the border) the appropriate Welsh or Scottish Primary Care Organisation, any part of whose locality is within two kilometres of the premises of the relevant provider; and
    - any Patient's Forum serving the locality of the PCT.[3]

11. Different determinations may be made with respect to different providers providing services under LPS schemes. This may be appropriate in situations where a group of

[3] It is proposed that these regulations will be replaced with the Local Involvement Networks Regulations 2008 which have been made and are expected to come into force on 1 April 2008. It is also proposed that a number of other regulations will be made which provide a right of entry of an individual authorised by a Local Involvement Network.

contractors who previously provided services under the national contractual arrangements, come together to provide services under a single LPS contract.

LPS Terms and conditions

12. Specified terms relating to the provision of dispensing or other pharmaceutical services are set out in Schedule 2 of the LPS Regulations 2006 and these must be incorporated in the LPS contract although PCTs may expand or add to the specified terms listed. PCTs may also include additional terms of service, relating to any services to be provided as part of the LPS contract.

13. A number of the terms relating to dispensing and other pharmaceutical services, for example, conditions and standards, are similar to those for PhS contractors. General provisions are that the provider must comply with all relevant legislation including the provisions of the LPS Regulations (SI 2006/552) and must, in accordance with Patients' Forum (Functions) Regulations 2003, allow entry and inspection of premises where LPS is provided.[4]

14. LPS providers (as service providers) will also need to comply with any other general legislation, as appropriate, e.g. Health and Safety at Work, etc. Act 1974, Disability Discrimination Acts 1995 & 2005.

15. In all cases, a provider must provide the services agreed and exercise any professional judgement in connection with the provision of such services and in conformity with the standards generally accepted in the pharmaceutical profession.

16. The provider must also:
    - comply with the relevant provisions of the Drug Tariff; and
    - have regard to all relevant guidance issued by the PCT, the relevant Strategic Health Authority and/or the Secretary of State.

17. Where a registered pharmacist is engaged in connection with the provision of local pharmaceutical services, the LPS provider (whether an individual or body corporate) must ensure compliance with the relevant requirements by that pharmacist.

18. An LPS provider must ensure that the PCT is provided with an up to date record of the services he /she provides under LPS and the days and times at which those services are provided.

[4] It is proposed that these regulations will be replaced with the Local Involvement Networks Regulations 2008 which have been made and are expected to come into force on 1 April 2008. It is also proposed that a number of other regulations will be made which provide a right of entry of an individual authorised by a Local Involvement Network.

19. The contract terms must require an LPS provider to provide information about fitness to practise matters as they arise (paragraphs 16 and 17 of Schedule 2 to the LPS Regulations (SI 2006/552).

Clinical Governance

20. Paragraphs 12 and 13 of Schedule 2 to the LPS Regulations (SI 2006/552) requires LPS providers to participate in a system of clinical governance in the manner reasonably required by the PCT. A "system of clinical governance" is defined as a framework through which the provider endeavours to improve continuously the quality of services, and safeguards high standards of care, by creating an environment in which clinical excellence can flourish.

Complaints

21. Paragraph 25 of Schedule 2 to the LPS Regulations require a provider to have arrangements for dealing with complaints which are "essentially the same" as those set out in Part II of the Complaints Regulations 2004 (SI 2004/1768) which has been amended by the NHS (Complaints) Amendment Regulations 2006 - SI 2006/2084. Regulation 7 of the 2006 regulations amends this requirement to increase the time limit to 25 working days. The complainant may agree to a longer time period.

Restrictions within individual LPS contracts

22. Where an LPS scheme is limited, for example, to:
    - the provision of dispensing of specified drugs or appliances, or
    - the provision of services to a particular class of person, or
    - services to persons in a specified geographic area;

    a provider must not provide LPS services outside those limits.

23. Dispensing of prescriptions whether electronic or non-electronic is subject to the same standards and conditions and restrictions as dispensing by pharmacies operating under national arrangements.

24. An LPS provider may refuse to provide the drugs or appliances ordered on a prescription in certain circumstances, where he/she:
    - does not believe the prescription is genuine;
    - thinks there is an error in the prescription or
    - that making the supply would be contrary to their clinical judgement; or
    - is subjected to or threatened with violence by the person presenting the prescription (paragraph 7(1)(c) of Schedule 2 to the LPS Regulations (SI 2006/552).

Similar provisions apply to repeatable prescriptions where they are dispensed as part of the LPS arrangements, as apply in the national pharmaceutical arrangements.

25. An LPS provider must refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is a prescription only medicine that the prescriber is not entitled to prescribe.

26. An LPS provider must ensure that appropriate advice is given to patients relating to utilisation, storage and return of unwanted drugs or appliances. In addition, a provider must provide the patient with a written note of any 'owings' and inform them when it is expected that the item(s) will become available.

27. An LPS provider must keep and maintain records of drugs and appliances provided and, in appropriate cases, of advice given or any interventions or referrals made. Additionally, a provider must provide a written record of the drugs or appliances ordered on an electronic prescription, if the patient requests it and the number of occasions on which it can be dispensed.

28. An LPS provider or his / her staff must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of his:

    - presenting an order for drugs or appliances on a non-electronic prescription form or non-electronic repeatable prescription; or
    - nominating the provider as dispensing provider (or one of them) in his NHS Care Record.

29. Promising, offering or providing an auxiliary aid in relation to the supply of drugs or a home delivery service is not a gift or reward.

Prescription Charges

30. Prescription charges or exemption arrangements apply to LPS prescriptions in the same way as prescriptions dispensed by pharmacies operating under national arrangements. People who are exempt or who otherwise are not required to pay prescription charges, will receive free prescriptions whether they use a pharmacy operating under LPS or national arrangements.

31. There is also no difference in the level of prescription charges, or the cost of pre-payment certificates. Such certificates are valid in pharmacies operating under LPS as well as national arrangements. Similarly, prescription charge refunds should also be administered by LPS providers, in the same way as national pharmaceutical services providers, i.e. the paid refund claim form (FP57) should be submitted with prescriptions for pricing to the NHS Business Authority's Prescription Pricing Division who will credit the LPS provider with the amount refunded to the patient.

32. Prescription charges regulations apply to any primary care service supplying medicines or appliances whether through an FP10 prescription form or under patient group directions (PGDs).

Payments to LPS providers under LPS contracts

Value of LPS contract

33. PCTs and LPS providers have considerable flexibility in determining the scope, form and value of a contract negotiated between them. Performance incentives may also be part of the contract. Once the total value of the contract has been agreed, parties should also agree a schedule of payments.

34. It should be noted that there is no automatic link between dispensing volume and levels of remuneration under an LPS agreement. In other words, there is no direct link to rates of remuneration (fees) set out in the Drug Tariff – this aspect is for negotiation between the parties to the contract in a similar way to any other service provided within the contract.

35. All LPS providers should be enabled to send and receive Electronic Prescription Service messages. It is proposed that regulations will provide for all LPS contracts to include the provision of an Electronic Prescription Service.

36. LPS contracts are local contracts and are funded from the PCT budget. The fact that all LPS contracts will have a dispensing element means that arrangements also have to be in place for the collection of data from prescriptions dispensed as well as for reimbursement of the cost of medicines.

37. For the most part the system for this mirrors the arrangements for the national arrangements, in that the NHS Business Services Authority's Prescription Pricing Division handles the processing of prescriptions to collect data and arranges reimbursement (direct to the LPS provider) for the cost of medicines and appliances in line with levels set out, from time to time, in the Drug Tariff, as provided for in regulations.

38. At present payment of remuneration for LPS contracts is made, on instruction by the PCT, using the services of the NHS Business Services Authority's Prescription Pricing Division. Payment intervals and levels will be those agreed in the payment schedule of the LPS contract, as appropriate. Further information relating to payments for dispensing is given in **Annex F.**

List of LPS providers

39. The PCT must publish lists of LPS providers in their area to include details of the services that each provides and the days and times on which such services are provided.

Overpayments

40. Paragraph 19 of Schedule 2 to the LPS Regulations (SI 2006/552) also require that an LPS agreement must include a provision to allow the PCT to recover any overpayment made to the LPS provider that should not have been made. The regulations also provide that such recovery of an overpayment is without prejudice to any investigation of an alleged breach of the LPS agreement.

Chapter 5
CONTRACT VARIATIONS

Changes in Circumstances

1. Where changes in circumstances are notified to the PCT by the LPS provider, decisions should be made in each case taking account of the specific circumstances. Where a change to the original contract is agreed between parties to the contract, this should be recorded in a formal contract variation document.

2. In certain circumstances the PCT can vary the contract without the provider's consent in order to comply with the NHS Act, and regulations or directions made under that Act. The PCT is required to notify the provider in writing, giving the proposed wording of the variation and the date on which it will take effect. Where it is reasonably practicable, the date on which the variation is to take effect should not be less than 14 days after the date on which notice is received by the LPS provider.

Minor re-locations

3. The LPS Regulations do not prevent parties to an LPS scheme varying the contract as regards minor relocations.

Change of ownership

4. Where the LPS contract is terminated in the case of a change of ownership and a right of return to national pharmaceutical service arrangements exists, it is usual that this right of return would be transferred to the new owner. PCTs may wish to make specific reference in the contract regarding whether the *right of return* would be transferable to a new provider as this will create certainty – see principles for determining right of return in Annex E.

Extending existing LPS schemes geographically by adding new providers

5. The action required to add new providers will depend on the design of the scheme at the outset. If the scheme originally included the localities where the new providers are based, and these were included in the consultation on the scheme, then new providers can be recruited to the scheme. However, if the original LPS proposal and consultation did not include localities where new providers are to be recruited, then the statutory requirements for setting up new LPS schemes must be met.

Changing the dispensing element on an LPS scheme.

6. All LPS contracts must have a dispensing "element" to provide dispensing services to all or some individuals or groups of individuals. Where the objective of the change in contract is to reduce the level of dispensing provided under the contract, this may be done through agreement between the parties to the contract. Where the objective of a

change to the LPS contract is to increase the dispensing activity or extend cover to other groups of patients, the PCTs will need to ensure that the increase in dispensing activity is within the scope of the scheme as tendered, in addition to any wider implications, for example, in terms of impact on other contractors. Any increase in activity not envisaged in the original tendering exercise may require a re-tendering exercise.

EXTENSION OR RENEWAL OF LPS CONTRACTS

7. It is usual for contracts to include provisions for the extension of a contract for a further defined period of time in certain circumstances. Unless this specific provision is made in either the original contract or the original tender document, the contract will terminate on the date agreed and the PCT must undertake a specific procurement exercise before a further contract may be agreed.

Renewal of an LPS contract

8. Where a contract has run its duration, the PCT will need to undertake a procurement process. This may result in a change of provider, although the LPS service provided may remain unchanged.

TERMINATION OF LPS CONTRACTS

9. The following paragraphs provide guidance on contract termination.

Termination by agreement.

10. Paragraph 27 of Schedule 2 to the LPS Regulations (SI 2006.552) provides that termination of the contract should be agreed between the parties to the contract subject to the requirement that:

- the PCT and the LPS provider may agree in writing to terminate the scheme; and
- if they so agree they must agree the date upon which termination should take effect.

Termination by notice

11. Paragraph 28 of Schedule 2 to the LPS Regulations (SI 2006/552) provides that an LPS provider or a PCT may terminate the arrangement by serving notice in writing on the other party of not less than six months. The scheme will then terminate on the expiry of the notice period. Where an LPS provider has a ‘right of return, it is important to note that this ‘right of return’ must be exercised before the expiry of the notice period.

Termination with immediate effect (fitness to practise, patient safety and provider financial situation)

12. A PCT may give notice in writing to an LPS provider terminating the LPS contract with immediate effect or from a specified date, if at any time the provider, whether an individual, group, body corporate or a director, chief executive, superintendent pharmacist or company secretary of a body corporate, is the subject of disqualification or suspension within the terms set out in paragraph 29 of Schedule 2 to the LPS Regulations (SI 2006/552).

13. A PCT may give notice of termination in accordance with paragraph 30 of Schedule 2 to the LPS Regulations (SI 2006/552) with immediate effect or with effect from a specified date where:

- an LPS provider has breached the terms of the LPS scheme resulting in a risk to the safety of patients served by the scheme; or
- a provider's financial situation is such that a PCT considers the PCT is at risk of material loss.

14. Paragraph 31 (1) of Schedule 2 to the LPS Regulations (SI 2006/552) provides that the "specified date" for scheme termination should not be less than 28 days after the date on which the PCT has served notice on the provider, except where the PCT is satisfied that less than 28 days is necessary in order to protect the safety of the provider's patients or to protect the PCT from financial loss.

Notification to be given to PPD of contract termination

15. A PCT must notify the NHS Business Services Authority's Prescription Pricing Division as soon as possible after the termination of an LPS contract, that the contract has been terminated.

NHS Dispute Resolution Procedure

16. If the NHS dispute resolution procedure referred to in Paragraph 22 of Schedule 2 to the LPS Regulations (SI 2006/552) is invoked, the contract can be terminated when:

- there has been a determination of the dispute and that determination permits the PCT to terminate; or
- the LPS provider ceases to pursue the resolution procedure; or
- before the conclusion of that procedure if the PCT concludes that it is necessary to do so, in order to protect the safety of the provider's patients, or to protect the PCT from financial loss, and confirms by written notice served on the provider, that the scheme will terminate on the date advised in the earlier notice (SI 2006/552 Schedule 2 paragraph 31(5)).

17. There is provision in the LPS regulations in paragraph 21 of Schedule 2 (SI 2006/552) in the case of a non NHS contract, that these contracts can be referred to the Secretary of State for resolution of disputes in certain circumstances.

Third party rights

18. An LPS contract will not create any right enforceable by any person not a party to it.

Section 2

Local Pharmaceutical Services for pharmacies dispensing low volumes of prescriptions

1. PSNC, NHS Employers and the Department of Health negotiated the terms of the new pharmacy contractual framework, which came into force on 1 April 2005. As part of the new arrangements, the threshold for certain payments, such as the professional allowance, is set at certain levels, updates of which are notified in the Drug Tariff and a package of measures for pharmacy contractors dispensing low volumes of prescriptions was agreed. These included:

   - Protected professional allowance payments, until 31 March 2008, for pharmacies that had been providing pharmaceutical services and were in receipt of payments for Additional Professional Services prior to 1 April 2005;
   - An exit payment, for those pharmacy contractors that decided to relinquish their NHS contract by 31 March 2006. (It should be noted that the exit payment was a one-off, and there is no scope for further exit payment arrangements.)

2. Separate arrangements were made through local pharmaceutical services for essential small pharmacies where certain conditions were met.

3. DH reminded all PCTs in a letter dated 2nd March 2007, of the need to consider whether any further action is required to secure the provision of adequate pharmaceutical services in areas served by pharmacies affected by the cessation of Protected Professional Allowance payments.

4. As the period for the protected arrangements for low-volume pharmacies is drawing to a close, PCTs may wish to consider using LPS arrangements to ensure pharmaceutical services provision remains adequate in areas now served by such pharmacies.

5. The basis of Local Pharmaceutical Services (LPS) contracts is quite different to pharmaceutical services provided under the national contractual arrangements although there are similarities in a small number of the terms of service. In LPS contracts, the level of remuneration is not tied to dispensing volumes but is based on the actual services to be provided. For this reason, pharmacies that do not meet the thresholds under the national arrangements may be better suited to an LPS contract. The range and mix of services in any LPS contract is a matter for agreement between the parties to the contract.

6. Local pharmaceutical services contracts do not come within 'control of entry' regulations and therefore provision under LPS may be located wherever the PCT requires. LPS therefore provides an opportunity for PCTs to strategically plan improvements to both the quality and range of local services using the ease of access afforded by pharmacies and pharmacist's knowledge and expertise.

7. In areas where there is currently a low volume of prescriptions, there may nevertheless be a need for a greater number of other services and LPS contracts are capable of addressing such situations. The balance between the dispensing element and the other services included in the contract will, in such cases, reflect the particular local requirements, as identified by the PCT.

8. For example, an LPS contract agreed with a low volume pharmacy might include the following:

- Dispensing and associated services (similar to the current category of essential services in the national contract). The proportion of activity on this aspect might be relatively small.
- A minimum number of Medicines Use Reviews, including for specific groups identified by the PCT
- Specific other services, if requested by the PCT to meet the needs of its patients
- Specific opening hours, to be agreed between the parties to the contract. (Under the national arrangements a pharmacy is able, within limits, to specify its own opening hours. Under an LPS contract, the PCT would be able to stipulate the hours it needs to meet the needs of its patients, and the remuneration for the LPS could reflect this greater obligation).

9. Another example might be an LPS contract, which includes an element of out-of-hours provision of specific services. Again, the mix of services and the times that they are available is easily accommodated through an LPS contract.

10. An LPS contract may also be agreed with a group of low volume pharmacies so that a broad range of services needed for patients are provided across the PCT area. In some such cases, the LPS scheme might be co-located with national contractual arrangements.

Annex A:

Health Services Body

1. LPS providers may be considered as health service bodies for the purposes of entering into an LPS contract. In turn, this allows the LPS contract to be considered as an NHS contract. An NHS contract is an arrangement between one health service body and another for the provision of goods and services. Entering into a NHS contract brings advantages to both contractor and PCT - bureaucracy is kept to a minimum but security is retained for contractors. Any disputes about the terms of a NHS contract may be resolved through the NHS disputes procedure thereby avoiding time consuming and costly recourse to the courts.

2. A provider shall be treated as a health service body for the purposes of section 4 of the NHS and Community Care Act 1990 from the date it makes an LPS scheme unless, prior to making the scheme, it objected in a written notice served on the Primary Care Trust with which it subsequently made the scheme.

3. Where a provider is to be treated as a health service body for the purposes of section 4 of the 1990 Act pursuant to paragraph (1) of this Annex, any change in the parties comprising the provider shall not affect the health service body status of the provider.

4. If, pursuant to paragraphs (1) or (4) of this Annex, a provider is to be treated as a health service body, that fact shall not affect the nature of, or any rights or liabilities arising under, any other scheme or contract with a health service body entered into by that provider before the date on which the provider is to be so regarded.

5. A provider may at any time request a variation of the LPS scheme to include or remove provision from the scheme that the scheme is an NHS contract, and if it does so:

   (a) the Primary Care Trust must agree to the variation; and
   (b) the procedure in paragraph 26 of Schedule 2 to the LPS Regulations (SI 2006/552) shall apply.

6. Where, pursuant to paragraph (4) of this Annex the Primary Care Trust agrees to a variation of the scheme, the provider shall—

   (a) be treated; or
   (b) subject to paragraph (7) of this Annex, cease to be treated, as a health service body for the purposes of section 4 of the 1990 Act from the date that variation takes effect.

7. Subject to paragraph (7) of this Annex, a provider that is to be treated as a health service body pursuant to paragraphs (1) or (4) above, as the case may be, shall cease to be treated as a health service body for the purposes of section 4 of the 1990 Act if the scheme is terminated.

8. Where a provider ceases to be treated as a health service body pursuant to—

   (a) paragraphs (5) or (6) of this Annex, it shall continue to be treated as a health service body for the purposes of being a party to any other NHS contract entered into after it was treated as a health service body but before the date on which the provider ceased to be treated as a health service body (for which purposes it ceases to be such a body on the termination of that NHS contract);

   (b) paragraph (5) of this Annex, it shall, if it or the Primary Care Trust has referred any matter to the NHS dispute resolution procedure before it ceases to be treated as a health service body, be bound by the determination of the adjudicator as if the dispute had been referred pursuant to paragraph 22 of Schedule 2 to the LPS Regulations (SI 2006.552); or

   (c) paragraph (6) of this Annex, it must continue to be treated as a health service body for the purposes of the NHS dispute resolution procedure where that procedure has been commenced—

      (i) before the termination of the scheme, or
      (ii) after the termination of the scheme, whether in connection with, or arising out of, the termination of the scheme or otherwise, for which purposes it ceases to be such a body on the conclusion of that procedure.

Annex B:

Examples of scenarios using LPS to address community pharmaceutical services needs

Examples where LPS contracts may be useful include:

- A PCT identifies a geographic area where it wishes to improve access to primary care services available through pharmacy. For example, it wishes to make better use of the pharmacist's knowledge and skills to provide services to specific patient groups, for example, patients over 75 years of age. It also wishes to include services such as testing and monitoring of certain conditions, for example, blood pressure, glucose levels and weight measurement. In addition, it wishes to put in place access to broader services, for example, podiatry and a referral pathway to services such as occupational therapy, social care services and local authority services.

- A PCT with a rising population of individuals with long-term conditions resident in the community. It wishes to have the pharmacy to provide a domiciliary service for provision of medicines and to act as an access point for advice and support on medicines and signposting for other agencies such as social care and other health professionals, for example, community nurses, working within the local community. As part of an LPS contract, it wishes to have the pharmacist provide training to support carers in helping patients with medicine taking.

- A PCT wishes to commission the provision of access to pharmaceutical services in specified out-of-hours periods covering certain geographic areas. It also wishes to include the provision of a pharmaceutical service to a residential care home within the LPS contract.

- A PCT wishes to provide a care pathway for certain categories of patients through an LPS contract; e.g.

    - those who may be exhibiting symptoms of depression and have otherwise not been identified. The PCT wishes to have a system whereby such patients, if identified by the pharmacist, are referred to the local community mental healthcare team.
    - those patients who have been prescribed medication for certain mental health conditions. In such cases, the contract will require the provision of support by the pharmacist to help such patients to take their medicines, especially in the case of those who are newly diagnosed with such conditions.

- A PCT wishes to set up a network of health promoting pharmacies through an LPS contract. It envisages that such service will extend to those suffering certain ill-health conditions that are ameliorated through sustained healthy lifestyle choices as well as a service for those who wish to maximise their health and well-being. Pharmacies providing this service will act as 'centres of excellence' and referrals to the service will be made by a broad range of health professionals working across the PCT.

- A PCT's pharmaceutical needs are currently met by existing contractors through a mix of PhS and LPS contracts but notes that amongst the PhS contractors are some 'low volume' providers. The PCT, in considering the impact of the ending of the fixed professional allowance for such providers may wish to consider the use of LPS as a contracting tool to assure itself that the pharmaceutical needs of its population continue to met.

Annex C:

Conditions relating to LPS providers (Regulation 7, LPS Regulations (SI 2006/552)

A provider (see "Who may be an LPS provider") may not enter into an LPS scheme with a PCT if he/she, and where applicable, in the case of a company, a director, chief executive, superintendent pharmacist or company secretary:

(i) is the subject of national disqualification,

(ii) is disqualified or suspended (other than by an interim suspension order or direction pending an investigation) from practising by any licensing or regulatory body anywhere in the world, unless the PCT is satisfied that the relevant disqualification or suspension does not render the provider unsuitable to enter into an LPS scheme,

(iii) has been removed or refused admission to a PCT list because of inefficiency, fraud or unsuitability by virtue of the NHS Act 2006 in the 5 years preceding the date on which the LPS scheme is to begin (or, to be signed if earlier date), unless there has been a subsequent inclusion in a PCT list,

(iv) has been convicted in the United Kingdom of murder, or a criminal offence other than murder, committed on or after 1st April 2006, and has been sentenced to a term of imprisonment of over six months,

(v) has been convicted elsewhere of an offence, committed on or after 1st April 2006, which in England and Wales would constitute murder or offence other than murder, where they were sentenced to a term of imprisonment of over six months, unless the PCT is satisfied that the relevant conviction does not render the provider unsuitable to enter an LPS scheme,

(vi) has been convicted of an offence, committed on or after 1 April 2006, referred to in Schedule 1 to the Children and Young Persons Act 1933,

(vii) has been convicted of an offence, committed on or after 1 April 2006, under Part 2 of the Sexual Offences Act 2003,

(viii) has been adjudged bankrupt or sequestration of the estate has been awarded, unless nullified in either case,

(ix) has been made the subject of bankruptcy restrictions order or an interim order under Schedule 4A to the Insolvency Act 1986,

(x) made a composition or arrangement with, or granted a trust deed for, his creditors which remains in force and in the case of a company, has been wound up,

(xi) there is an administrator, administrative receiver or receiver appointed in respect of him / her or there is an administration order made in respect of him / her under Schedule B1 to the Enterprise Act 2002, or

(xii) has within a period of five years prior to signing the LPS agreement or the start of the LPS scheme (whichever is earlier) been;

- removed as a charity trustee by the Charity Commissioners or the High Court on the grounds of misconduct or mismanagement for which he \ she was responsible or was aware of,
- removed from the management or control of any body under section 7 of the Law Reform (Miscellaneous Provisions)(Scotland) Act 1990,
- subject to a disqualification order under the Company Directors Disqualification Act 1986, or
- in the case where the PCT has concerns about the provider's ability to provide LPS services, has refused to comply with the PCT's request to undergo a medical examination, where appropriate.

Annex D:

Selection of forms used in the Pilot LPS process – for information only

Outline proposal form LPS1

Submission for full/preliminary approval LPS2

Final proposal LPS3

Determination or variation of determination of LPS right of return to primary care trust pharmaceutical list LPS10

Link to forms

Annex E:

Principles used to determine Right of Return in the Pilot Phase of LPS

The principles which guided the Secretary of State in making determinations as to whether a right of return would be granted were as follows:

1. Where a PhS contractor becomes an LPS provider and ceases to be a PhS contractor, that contractor will have a right of return in relation to those premises from which he was providing PhS services, so long as he continues to provide LPS from those premises.

2. Where an LPS provider who has been granted a right of return under principles 1 or 3 of this Annex, transfers the provision of LPS services to new premises within the same neighbourhood, that LPS provider will have a right of return in respect of the new premises only.

3. Where an LPS provider who has been granted a right of return under principle 1, 2 or 3 of this Annex transfers his business as a going concern to a new LPS provider who is continuing to provide LPS from those premises, the new LPS provider will have a right of return, so long as he continues to provide LPS from those premises, and the previous provider will lose his right of return.

4. The right of return set out in principle 2 above will not apply where a change of premises results in a significant change in the arrangements for the provision of pharmaceutical services or dispensing services (as defined in the NHS (Pharmaceutical Services) Regulations 1992 (the 1992 regulations)), in any part of a controlled locality (as defined in the 1992 regulations), and where the Secretary of State has, because he considers that the provision of general medical services or personal medical services is likely to be adversely affected, imposed conditions in the determination analogous to those which may be imposed under regulations 12(15) or 13(13)(b) of the 1992 regulations.

5. Where more than one PhS contractor joins together to provide LPS, whether as a single LPS provider or as multiple LPS providers, the number of rights of return will be limited to the number of premises from which PhS was provided. If the number of premises from which LPS is to be provided is less than the number of PhS contractors, or if there is to be any change of ownership of existing PhS premises on the move to LPS, the contractors will need to inform the Secretary of State as to the arrangements which they wish to see made as regards rights of return. Subject to it being clear that there is agreement on those arrangements, and to it being clear how any successors

to the original LPS provider or providers are to be treated as regards their potential right of return, the Secretary of State will endorse those arrangements.

6. Where an LPS provider who has been granted a right of return is unable to exercise that right in relation to the premises from which he is providing LPS services (for example, because the premises have been made available on condition that LPS is provided from them), that provider will be permitted to exercise that right in relation to other premises in the same neighbourhood.

7. In these principles "PhS contractor" refers to an entry on a pharmaceutical list. In other words, an individual or body corporate with more than one premises in an area will be counted as a separate PhS contractor for each premises.

8. Reference in these principles to a "right of return" will not override any regulations which may be made relating to refusal to grant an application for inclusion in a pharmaceutical list on efficiency, fraud or suitability grounds.

Annex F:

Funding for LPS dispensing activity

1. Reimbursement for dispensed items and dispensing fees for PhS contractors are generally covered by the Global Sum, which is currently managed centrally. On the basis that if LPS contracts did not exist, the prescriptions being dispensed as part of LPS schemes would be dispensed by PhS contractors, a sum is taken from the Global Sum and given to SHAs for distribution in proportion to the dispensing levels of LPS contracts held by their relevant PCTs.

2. Since the Global Sum covers PhS contractors as well as LPS, it is important to be fair to both sides, accordingly, calculation of amounts due for LPS are reconciled each year using data returns captured by PPD.

3. As an aid to determination of the appropriate transfer of funding from SHAs to PCTs, a calculator is available at: Calculator. This calculates the figure, which the corresponding level of dispensing would have cost had the dispensing taken place within the national contract. The part of the total appropriate to the Global Sum is indicated and it is this figure that a PCT might expect to be transferred from its SHA.

4. Each LPS scheme will differ in the level of its dispensing although evidence from pilot schemes suggests that as schemes mature and reach capacity the level seems to plateau.

Submission of prescriptions dispensed under LPS arrangements

5. The NHS Business Authority's Prescription Pricing Division (PPD) must be notified before the start of an LPS scheme, so that an LPS OCS code can be issued to the provider.

6. LPS schemes are registered separately with the PPD. A PCT must ensure the provider is aware of the importance of submitting LPS prescriptions to the PPD with a prescription submission document (FP34) specifically coded for the LPS scheme. This is essential for monitoring LPS dispensing activity and is of particular importance where a PhS contract is also in operation at the same premises. LPS prescriptions must be kept separate from PhS prescriptions. Failure to do so will result, among other things, in a loss of LPS dispensing data (PPD will be unable to disaggregate LPS prescriptions from PhS prescriptions) and may, depending on the terms, render the LPS contract void.

7. Separate from reimbursement of the cost of medicines dispensed through prescriptions, referred to above, the PPD will provide a payment service for LPS

contracts. The PPD will not, however, calculate the amount of the remuneration (payments agreed in the contract between the PCT and the LPS provider). This will be the responsibility of the PCT. The PPD will simply pay the amount that is notified to it each month or at a period agreed with a PCT. This amount will correspond to the payment schedule within the contract as agreed between a PCT and LPS provider.

Electronic Prescriptions Service (EPS)

8. In principle, all those providing pharmaceutical services should be in a position to operate an Electronic Prescription Service (EPS) (formerly ETP). Unlike for PhS contractors, EPS payments are not centrally funded (that is, are not part of the LPS allocation from the Global Sum) for LPS schemes. Accordingly, where EPS payments are to be made, a PCT must notify the PPD of the amount to be paid to a LPS provider.