



*Local Pharmaceutical
Services*

Guidance Notes

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Local Pharmaceutical Services

Guidance Notes

The purpose of this document is to provide information on Local Pharmaceutical Services (LPS), to outline key components of the Health and Social Care Act 2001 and to give details of the issues which will need to be addressed by those interested in participating in LPS pilots.

All PCTs will need to decide quickly how they are going to respond to any proposals which they may receive from third parties for LPS pilots.

The Health and Social Care Act provides a means of contracting at local level for pharmaceutical services and other services within the same contract.

Throughout the document reference is made to Primary Care Trusts (PCTs). Subject to Parliament, the functions conferred on Health Authorities will generally be conferred directly on Primary Care Trusts but in the meantime the Secretary of State will require Health Authorities to delegate their functions relating to Local Pharmaceutical Pilots to PCTs.

The first wave of pilots will take place in 2002/03. Under the Act participation in the new arrangements is voluntary and Primary Care Trusts will, in the first instance, need to decide whether they wish to use the flexibility provided by the Act.

For those who wish to develop proposals for pilots, a brief outline of activities to be completed is set out below:

1. Process to decide on whether to use LPS	Timescale set locally by PCT
2. If yes, process to develop and select ideas	
3. Preparation of detailed proposals, including consultation and assessment	
4. Submission to the Secretary of State for approval	28th June 2002 or 1 November 2002
5. Notification of approval by the Secretary of State	
6. Completion of local arrangements	
7. Implementation	By agreement but usually three months after approval

Introduction

1. The NHS Plan sets out an ambitious and radical plan to bring about a modern NHS in which the involvement of all stakeholders is valued and used to encourage and support continuous improvement. It sets out a vision for a whole-system service that is patient focussed and inclusive. It encourages innovative and more flexible working practices to make better use of staff skills in the provision of high quality healthcare.
2. The opportunities and challenges posed by this ambitious plan extend to all parts of the NHS including pharmacy. Those challenges were recognised in the pharmacy programme *Pharmacy in the Future – Implementing the NHS Plan*, published in September 2000. This sets out how pharmacy can play a full part in delivering the vision of the new NHS. It identifies three major areas of challenge:-
 - Meeting the changing needs of patients
 - Responding to the changing environment
 - Enhancing public confidence in the professionand lays out a programme of work to meet those challenges.
3. The programme includes a number of key objectives which taken together will ensure that pharmacy can give patients the right care at the right time in the right way and of the right quality. Key objectives are:-
 - Better access to services - building on the strengths of pharmacy
 - Helping patients get the most from their medicines
 - Re-designing services around patients – getting the structures right
 - Ensuring high quality services, getting the most from staff
4. The current nationally determined arrangements under which community pharmacy services are provided limit the opportunities for tailoring the provision of these services to meet local needs (although a number of innovative local schemes have been introduced as additions to the national arrangements). Local Pharmaceutical Services (LPS) will provide an opportunity to develop integrated local arrangements which address local priorities and meet local needs and which reward service providers in a manner and at a level agreed by the PCT and the LPS provider.

5. The new arrangements provide an alternative legal framework for the provision of pharmaceutical services, under locally agreed contracts. It is unlikely that any two LPS contracts will be identical. LPS will first be provided under pilot schemes which are intended to develop and demonstrate innovative ways of providing high quality, cost effective services to patients.
6. The primary legislation for Local Pharmaceutical Services (LPS) is set out in the Health and Social Care 2001. The Act enables Health Authorities, working with patients and providers, to develop and pilot new ways of contracting for and delivering pharmaceutical services. In addition it allows provision, within the LPS contract, of a broader range of services than are traditionally associated with pharmacy. Subject to Parliament, the functions conferred on Health Authorities will be conferred directly on Primary Care Trusts (PCTs). Meantime, the Secretary of State will require Health Authorities to delegate their functions relating to LPS to PCTs.

Key characteristics of Local Pharmaceutical Services (LPS)

7. Local Pharmaceutical Services pilots will be effected through contracts made at local level between Primary Care Trusts and LPS providers.
8. LPS pilots
 - must be approved by the Secretary of State
 - may include arrangements for the provision of services under Part 1 of the NHS Act 1977 whether or not of the kind usually provided by pharmacies
 - may include arrangements for the provision of training and education (including training and education for persons who are or may become involved with LPS). Training and education in this context refers to the type of training and education usually undertaken by the NHS.
 - must include dispensing services whether to general and/or specific groups of patients
 - may not combine LPS with Personal Medical Services or Personal Dental Services although a separate contract may be held alongside either.
 - may not include dispensing by general practitioners

- will be reviewed (individually) at least once in a three year period beginning from the date on which piloted services commence
9. Participation in LPS pilots is voluntary. There will be a right of return, to a pharmaceutical services (PhS) contract, for current pharmacy contractors who switch to an LPS contract. For pharmacy contractors not interested in piloting new approaches, the current national contract arrangements under Part II of the NHS Act 1977 remain.
 10. The first wave of LPS pilots will begin in 2002/03. There will be two opportunities to submit proposals to the Secretary of State, for approval. The deadline for receipt of completed proposals is,
 - 28th June 2002
 - 1 November 2002

Further waves will follow in future years and details of submission dates will be announced later.

Objectives and benefits of LPS

11. The main objectives of LPS Pilots are to use the flexibilities on offer to secure improved health outcome through:
 - local contracts designed to deliver local healthcare priorities
 - designing services around patients
 - making better use of pharmacists' skills
 - providing opportunities for pharmacists to work within contracts which they help to design
12. Many PCTs will recognise that pharmacists' skills, particularly in community pharmacy, are not optimally used under the current national contract and that the current system of paying community pharmacies focuses on dispensing volume, whilst having very limited regard to the quality of the service provided. They will also recognise that because of its unique place in the community, pharmacy can be a resource for the delivery of a wider range of services. In designing services to meet key priorities identified, whether to specific groups of patients or within defined geographic areas, PCTs may now look to pharmacy for help in their delivery. LPS provides a mechanism to make local contracts tailored to met local requirements.

13. LPS may appeal to pharmacists who find the national pharmacy contract too rigid in that it does not provide an incentive to use their skills to the full. This may have deterred some pharmacists from widening their work in the community. Changes in the wider NHS may have highlighted the need to work in new ways and many pharmacists welcome an opportunity to explore this. The opportunity to work closely with their local PCT and help design the contract within which they work will appeal to many people. LPS contracts may also provide opportunities to lead an integrated team of health professionals or to work as part of such a team, thus reducing or ending the 'isolation' felt by some community pharmacists.
14. The benefits of LPS to patients include access to services that have been designed with their needs in mind. Many patients regard pharmacists as professionals who are both knowledgeable and easily accessible. They welcome the opportunity to benefit from the pharmacist's expertise especially in getting more help with their medicines. For others, LPS may mean that, in addition to pharmaceutical services, a broader range of care is available to them locally. This is likely to be especially appreciated by those with reduced mobility.

General Information

15. The Health and Social Care Act 2001 introduced the term 'Local Pharmaceutical Services'. Precisely what that term means is left to regulations to define, but they have to be the same types of pharmaceutical services as are currently provided under section 41 or by virtue of section 41A of the NHS Act 1977. They must not include practitioner dispensing services i.e. dispensing by medical or dental practitioners. We do not intend to introduce any further restrictions on the types of pharmaceutical services which may be provided as local pharmaceutical services.
16. This does not mean that every LPS pilot will have to cover the whole range of services, but it does mean that every LPS pilot must include something which would currently be provided as part of Part II pharmaceutical services. Indeed, since the prime purpose of LPS is to provide an alternative way of contracting for pharmaceutical services, the Secretary of State will only approve schemes which include some element of the services set out in section 41 – in other words they must include dispensing whether to patients generally or specific groups of patients or a combination of both.

17. Some contracts will concentrate purely on pharmaceutical services. Others may use the flexibility LPS affords to provide a broader range of services such as:
 - services which are not pharmaceutical services but which are of a kind that may be provided under Part I of the NHS Act 1977. This could include, for example, diagnostic testing or therapeutic monitoring
 - provision of training and education. Training and education in this context must be of a type usually provided for or in the NHS
18. The flexibility to include either or both of these services in addition to pharmaceutical services offers a means to broaden the range of services by and through pharmacy contracts. It also offers a way of linking together associated services for particular health problems/conditions to provide a holistic service for the patient. An example of a type of service which might be provided under Part I of the NHS Act 1977 and complement other services offered through an LPS contract would be where pharmaceutical services included provision for a special service for diabetes patients. In addition to diagnostics and health promotion services, optometry and chiropody services might also be provided at the same premises for those patients, as part of the LPS contract.
19. Association of healthcare services relevant to particular patient needs, within a single contract, will often add value to the core service provision as well as using resources efficiently in meeting patient need.
20. The range and mix of services which may be provided as part of an LPS contract is very wide and it is likely that no two LPS schemes will be identical.

Terms of Service

21. The purpose of LPS is to provide an alternative to the current arrangements under Part II of the NHS Act 1977. Clearly, therefore, the terms of service for pharmacies set out in Part II of Schedule 2 to the NHS (Pharmaceutical Services) Regulations 1992 will not apply to LPS pilots. However, PCTs will need to consider those terms of service and decide whether they wish to incorporate, expand or set specific criteria to be met as part of the contract applicable to an LPS pilot. In considering proposals for LPS pilots, the Secretary of State will wish to ensure that

- nothing in LPS affects what can be prescribed on a prescription form (for example, the list of appliances which may be prescribed and of medicines and other items which may not), though this does not exclude other arrangements being made locally
 - point of dispensing checks on evidence of exemption from prescription charges will continue
 - there is no reduction in existing standards relating, for example, to the standards of medicines dispensed
 - the provisions of the Medicines Act 1968 will be complied with
22. It is intended to make directions regarding arrangements for establishment and operation of a procedure to deal with complaints, that largely reflect the current rules. The complaints procedure will apply to complaints made in relation to any matter reasonably connected with the pilot's provision of LPS.

Prescription Charges

23. Arrangements for prescription charges under LPS will be the same as those which apply in relation to Part II services (and indeed to certain services provided under Part I, such as the supply of medicines under Patient Group Directions) People who are exempt or who otherwise are not required to pay prescription charges, will receive free prescriptions whether they use an LPS pilot scheme or a Part II provider.
24. Similarly, there will be no difference in the level of prescription charges, or the cost of pre-payment certificates. Such certificates will be valid for both services interchangeably.
25. Regulations will secure that any charges in respect of LPS will be the same as those which would apply had the service been provided under Part II of the NHS Act 1977.

“Control of entry” regulations and “Rural dispensing” regulations

26. The regulations governing the admission of pharmacies to pharmaceutical lists (the control of entry regulations, and the rural dispensing regulations) do not apply to LPS pilot schemes. This will allow PCTs to make use of LPS to provide services in specific geographic areas or to particular patient groups thus targeting services where they

are most needed. PCTs will, however, have to assess the likely effect of the proposed pilot scheme on existing pharmaceutical services and general and personal medical services. Where any significant adverse effect is predicted, the Secretary of State will need to be convinced that the benefits of approving the scheme outweigh the disadvantages.

27. Regulations will, however be made which will mean that, in considering applications for inclusion in pharmaceutical lists and dispensing doctors lists, under section 41 of the NHS Act 1977, account will need to be taken of premises providing services under LPS pilots in the same way as account is taken of premises providing services under section 41. Where services provided under LPS are limited (for example to particular groups of patients or particular times) that will, of course, be a relevant factor in deciding, for example, whether a proposed new pharmacy is necessary or desirable.

Right of return

28. Regulations will be made providing that pharmacy contractors who leave the current 'PhS contract' and provide services under LPS from existing or nearby premises, will be able to revert to PhS status when the LPS contract ends or in certain cases where an LPS scheme is terminated by the PCT with approval of the Secretary of State.
29. When an LPS provider, who was previously a PhS contractor within the area in which LPS is to be provided, is replaced (for example, where the business is sold) and is not returning to PhS contractor status in the area in which LPS has been provided, it is intended that the replacement provider would also have a preferential right to acquire PhS contractor status in respect of the premises in which LPS was provided. However it is not intended that other new LPS providers will have a right to become a PhS contractor, other than as a result of applying to join the pharmaceutical list in the usual way.
30. The terms under which LPS providers may revert will be clear to each potential LPS provider before the original contract is signed and, where appropriate before variations to the original contract are agreed.
31. It is proposed to make regulations preventing the provision of LPS pilot scheme services from the same premises as pharmaceutical services under Part II of the NHS Act 1977 except in situations where the Secretary of State is satisfied that there is no risk of the provider (or providers) abusing the co-location, for example by presenting prescriptions for payment under whichever contractual arrangements are most beneficial financially.

32. Where LPS and pharmaceutical services under Part II of the NHS Act 1977 are provided from the same premises, there will not be a need for a right of return since the contract for provision of services under Part II of the NHS Act 1977 has not been abandoned.

Number of pilots

33. There is no national, regional or local limit on the number of LPS pilots. However all LPS pilots must
- include dispensing services
 - meet local priorities/needs
 - be supported by all parties to the contract, in particular the PCT and the LPS provider
 - satisfy the legal requirements and policy objectives of LPS pilot schemes

Commissioning LPS

34. All LPS pilot schemes are commissioned by PCTs. Details of pilot schemes, as approved by the Secretary of State, are to be embodied in contracts between the PCT and the LPS provider. Where subsequent changes and developments arise, they will need to be agreed as variations, as and when they arise.
35. Legislation is currently before Parliament which would prevent PCTs from themselves being LPS providers. In the meantime, the Secretary of State will not approve schemes under which PCTs would themselves be LPS providers. However, PCTs can work up proposals for preliminary approval by the Secretary of State before they identify an LPS provider with whom to contract for provision of the services approved by the Secretary of State. In such cases the full proposal, which had been given preliminary approval, will need to be re-submitted together with details of the LPS provider for full approval.
36. LPS contracts will be monitored in the same way as other contracts that the PCT might make for provision of services. The Department will require contracts to include arrangements for termination, dispute resolution, handling complaints, governance and standards, including clinical governance.

LPS providers

37. LPS provider in this context means the contract- holder for LPS. The individuals actually providing the day-to-day services stipulated in the LPS contract may be different to the named contract holder.
38. Any individual or body corporate (other than a PCT) can be an LPS provider. However, because LPS pilots must include dispensing, contract holders must ensure that they are in a position to meet the requirements of Section 52 of the Medicines Act 1968 either themselves or that they employ a pharmacist as part of the contract to meet the requirements of the Act.
39. LPS providers will be contracted to provide a service in the same way as a PCT might contract for the provision of any service. An LPS contract does not make the contract holder or individuals providing services under the contract an 'employee' or sub-contractor of the commissioning PCT. In some instances the LPS provider will employ individual(s) to deliver all or some of the services specified within the contract. Such individuals will be employees or sub-contractors of the LPS contract holder.
40. It should be noted that all proposals submitted for approval must include provision for any participant other than the PCT to withdraw from the scheme.

Proposal and Approval Process

41. This section provides information on
 - preparatory work
 - procedure for making and processing outline proposals
 - procedure for making full proposals or proposals to be put forward for preliminary approval
 - areas to be considered in the proposal including requirements for local consultation
 - funding including for the preparation costs for proposals

Initial preparatory work required

42. Local Pharmaceutical Services pilot schemes are entered into on a voluntary basis on the part of the purchaser (PCT) and the provider. No PCT can be compelled to use LPS nor can any provider be compelled to provide services under LPS. . Indeed, it is likely that a number of PCTs may wish to continue the provision of pharmaceutical services under the current national contract but make arrangements to introduce ‘additional services’ depending on local needs and opportunities.
43. Each PCT will, however, need to take a decision about whether it wishes to use LPS or not, since the starting point for LPS pilots may be either the PCT taking the initiative or a potential LPS provider making a request to the PCT in the form of an outline proposal which it wishes the PCT to consider. It would not be right to allow potential LPS providers to spend time and money working up outline proposals only for them to discover that the PCT has no intention, or no immediate intention, of putting forward any LPS pilot schemes to the Secretary of State for approval.
44. Most NHS organisations, as part of their governance arrangements, will have procedures for policy-making decisions already laid down and these should be followed. As with any decision, it is vital that the decision making process regarding LPS is transparent and commands confidence. It is therefore important that PCTs have in place a robust process by which they make a decision so that decisions are taken in the light of information available on the subject, and that those decisions are clearly reasonable.
45. The Board should have the opportunity of a full discussion and the Board’s decision recorded in the minutes of the meeting. If it is the decision of the Board that the use of Local Pharmaceutical Services should be deferred, a process and date for review of this decision should be set. It would certainly be wise to review the decision as and when the Department announces further waves of LPS pilots.
46. If the Board recommends the use of LPS, there are a number of tasks and processes which flow from that decision. PCTs which have decided to use LPS will recognise the need to make arrangements to provide the necessary resources, both human and financial to implement such decision. One of the first tasks is to identify a lead person to take the work forward.

47. The next task is to devise a process to ensure that the requirements of the scheme can be met. This process must equally aim to be transparent and command confidence. This is particularly so with LPS, which appeals to a wide number of stakeholders. Where decisions are to be taken or selections made on proposals, it is important that panels making such decisions are appropriately representative, bearing in mind the area under consideration. In other words, where decisions are being taken on matters relating to provision of pharmacy in the community, it is expected that panels would include not only the Pharmaceutical Advisor but representatives of community pharmacy, public health and patients, amongst others.

Stages of development of LPS proposals

48. For those PCTs that have taken a decision to use LPS, there are five stages in the development of full proposals, as follows:-
- (i) Outline proposals
 - (ii) Scrutiny and selection of outline proposals
 - (iii) Sign-off of decision by the PCT Board
 - (iv) Working up of full proposals and/or proposals for preliminary approval
 - (v) Submission of full proposal for approval or preliminary approval by Secretary of State

Outline proposals

49. The Health and Social Care Act 2001 provides that PCTs may make pilot schemes either on their own initiative or in response to a request from those wishing to participate in a scheme.
50. Regulations will be made providing that requests must take a certain form and include information under specific headings (see **Annex A**) and be submitted by a date, specified by the PCT. This is called the **outline proposal stage**.
51. PCTs may, if they wish, include additional headings on the outline proposal form for which information must be provided.

52. PCTs will need to ensure that it is clear from the outset i.e. as part of the decision to use LPS, whether the PCT is going to consider requests (outline proposals) or whether it is only going to put forward proposals on its own initiative. If it is only going to put forward proposals, it would probably be advisable at this early stage in the development of LPS for the proposals to be in the form of applications for preliminary approval. If a PCT is considering putting forward full proposals on its own initiative (i.e. proposals which include details of a proposed LPS provider) it will need to be confident that the process by which that provider has been selected is robust, and demonstrably achieves value for money.
53. If a PCT is going to consider outline proposals, it will need to make clear on what basis decisions will be taken as to which outline proposals will be taken forward for development as full proposals. This information should be available to all applicants as it encourages transparency and aids applicants' understanding of the requirements of the scheme. It will be much easier for PCTs to justify decisions not to take proposals forward if they can show that they have been assessed against previously agreed criteria.
54. Outline proposals are intended to
 - identify ideas which may be worked up to full proposal stage and
 - ensure that the ideas fall within the scope of the pilots.
55. By testing proposals at this stage, it may save time and effort in the long run. Outline proposals do not represent commitment either to work up a full application or to proceed to a pilot. More detailed work and information will be needed by all concerned before that stage can be reached.
56. Any outline proposals received by the PCT will need to be processed and a decision made on which, if any, proposals should be taken forward for development as full proposals. It is important that the selection process is undertaken by a panel and that applications are fully considered. Recommendations should then be made to the Board on which proposals should be taken forward.
57. The PCT Board will then need to discuss the panel's recommendations and make a decision on which applications, if any, should be taken forward for further development.

58. It should be noted that while PCTs should consider all outline proposals, unlike PMS, there is no requirement on them to put forward all outline proposals that they receive for further development and approval.
59. The Secretary of State has the power to call for summaries of all proposals received. PCTs should record details of each outline proposal received and document its progress through the selection process. The Department of Health may require sight of such records.

Full proposals or proposals for approval in principle

60. There are two types of proposal which may be submitted for approval, as follows:-
 - (a) Full proposals. These are proposals for which the LPS provider is known
 - (b) Proposals for preliminary approval. In this case the PCT works up the full proposal but has not identified the LPS provider
61. Once outline proposals have been selected for development as full proposals, PCTs may wish to identify any areas earmarked for LPS but for which no proposals were received or if received were not selected for further development. If such areas are identified, a decision as to whether to work up a proposal for preliminary approval will need to be made. . Of course, a PCT could decide from the outset that it wished to work up a proposal for preliminary approval rather than looking at outline proposals. In either event, if it is decided to take this course then all of the processes and actions pertaining to development of full proposals for submission, referred to at (a) above, will apply.
62. The objective of tasks in this stage is to ensure that a robust scheme is designed and put together which will be capable of delivering its objectives, if approved by the Secretary of State and implemented. The objectives of any LPS scheme are determined at local level by PCTs.

Local Consultation

63. It is an established principle that health services and care should take account of the views of those who will be affected. As LPS proposals will vary in size, scope and degree of innovation, it will be for PCTs to determine who should be consulted and how, in addition to the local groups listed below who must be consulted:-

- Local Pharmaceutical Committee
- Local Medical Committee
- Community Pharmacy contractors in the geographic area to which the proposal(s) refer
- Dispensing Doctors in the geographic area to which the proposal(s) refer
- CHC

Designation

64. The Health and Social Care Act 2012 provides for designation of neighbourhoods, premises or description of premises for the purposes of LPS. This would allow the Health Authority to defer consideration of Part II applications, apart from changes of ownership, relating to the neighbourhood, premises or description of premises that have been designated. (Under current legislation, the responsibility for considering Part II applications remains with Health Authorities. Legislation currently before Parliament would transfer this function to PCTs.) PCTs may choose whether or not to use designation depending on the local circumstances. Regulations are currently being drafted to set out the circumstances in which designations may be made, maintained or cancelled. This will be the subject of separate guidance.

Assessment of impact of LPS

65. All proposals submitted for approval, whether full proposals or proposals for preliminary approval, will be required to include an assessment by the PCT of the likely effect of the implementation of proposals on the following services:
- (a) Pharmaceutical services, within the meaning of section 41 of the NHS Act 1977 (note that this includes dispensing by doctors as well as by pharmacies and appliance contractors)
 - (b) Local pharmaceutical services provided under existing LPS pilots (obviously this will not apply to the first tranche of LPS pilots since there will be no LPS pilots in existence)
 - (c) General medical services provided under arrangements made under section 29(1) of the NHS Act 1977

- (d) Personal medical services provided under arrangements made under section 28C of the NHS Act 1977 or under pilot schemes made under section 1 of the National Health Service (Primary Care) Act 1997(c46) (All PMS schemes are currently pilot schemes.)
66. If it appears to a PCT that the proposals would, if implemented, affect any of the services mentioned above provided in the area of another PCT, they must consult that other PCT about the proposals before submitting them for approval or preliminary approval.
67. A PCT consulted in the above circumstances must prepare an assessment of the likely effect of the implementation of the proposals on those services ((a) – (d) above) and supply it to the PCT which consulted it.
68. A PCT consulted in the above circumstances must prepare an assessment of the likely effect of the implementation of the proposals on those services ((a) – (d) above) and supply it to the PCT that consulted it. This function may, if the second PCT agrees, be carried out on its behalf by the first PCT.

Information to be included in full proposals for approval or proposals for preliminary approval.

69. Proposals must be submitted (hard copy) on the form available for download at www.doh.gov.uk/localpharmaceuticalservices/index.htm
70. The form requests basic details on both the PCT and the LPS provider in applications other than those for preliminary approval.
71. The main body of the application form is designed to allow a full description of the LPS proposal including the aims and background, features, benefits, patient groups served, monitoring arrangements funding and contingency arrangements – full details in **Annex B**.
72. All applications submitted for approval or preliminary approval must attach a letter signed by the Chair and Chief Executive of the PCT addressing the following issues:-
- Support of the Board for the application
 - Confirmation of due process
 - Confirmation that resources will be made available as indicated on the application and the pilot implemented as planned.

Approval Process

73. Applications which are submitted by the deadline date will be considered firstly by a regional level panel. They will then be examined by the Department of Health before submission to the Secretary of State.
74. There will be four such panels largely based on the present geographic areas covered by the four Directorates of Health and Social Care. Membership of each panel includes the following:
 - Regional level Pharmacist
 - Individual with Performance Management & Improvement responsibility at Strategic HA level
 - Public Health Consultant from Regional Office of Government
 - Strategic HA Finance Director
 - Individual with responsibility for Performance Management &/or Improvement at PCT level
 - Community Pharmacy Contractor
 - Patient representative or non executive member of a PCT Board
 - PCT Pharmaceutical Adviser
75. The function of panels is to scrutinise proposals and make recommendations on their suitability or otherwise as LPS pilots.
76. Criteria which all proposals will be required to meet in order to be recommended for approval include:
 - Meet legal and policy requirements
 - Meet patient and service needs identified by the PCT
 - Have advantages which outweigh any adverse effect on existing services
 - Require the use of LPS (i.e. could not be achieved simply as “add-ons” to Part II arrangements)
 - Are innovative in their use of resources to be transferred from non-discretionary funding

- Demonstrate capacity to assure probity
 - Provide value for money
77. The Secretary of State may approve proposals as submitted; approve proposals subject to modification or reject them. The Secretary of State's decisions will be notified to PCTs concerned and they in turn must, without delay, notify the LPS provider. There is no right of appeal against approval, modification or rejection.

Preparation costs

78. Allocations of national funding to support LPS preparatory costs, totalling £0.6m, were distributed between all PCTs in 2001/02. It is planned to make further limited funding available for the current year 2002/03.
79. Preparatory work means work which is reasonable for a person to undertake
- in the preparation of a proposal for submission for approval or preliminary approval
 - in preparing to implement an LPS pilot, once approval has been given
80. It is intended that PCTs will handle all claims for funding of preparatory work and have power to set out the conditions under which such funding may be applied for and given bearing in mind that national funds for preparatory work are limited.
81. Funding will not be available for preparation of outline proposals since these simply require an outline of the proposal and are designed to test ideas before any expenditure has been incurred.
82. It is planned to allocate funding in two stages, as follows
- on submission of proposals for approval
 - upon receipt of approval

83. Regulations will provide that PCTs may only make payments of financial assistance for preparatory work undertaken by a person in connection with preparing of proposals for the provision of LPS if
- the applicant specifies the purposes for which it is intended to use the payment
 - the PCT has notified the applicant in writing that it is willing to make a payment of financial assistance for the purposes specified and the maximum amount of the payment which it is willing to make
 - the PCT is satisfied that the actual costs incurred are not less than those claimed and were incurred in the relevant period. Relevant period in this case means the period
 - (i) to date of submission of full proposal for approval or notification of the claimant by the PCT that they will not be putting a full proposal forward (note that, if a proposal is not put forward, it is unlikely that any central funding will be available)
 - (ii) after proposal has been approved but before actual date of implementation of the pilot.
84. Where two or more persons apply together for financial assistance, payment may be made to one of them on behalf of all.
85. All applications for funding of preparatory work must comply with any conditions specified by PCTs. Where a PCT discovers that an applicant has not complied with the conditions, if any, imposed it may demand repayment of any payment or part-payment made.

Pilot costs/ Funding

86. Central funding for LPS pilots will be provided from an annual transfer of funds from PhS non-discretionary provision. In supporting the development of full proposals, PCTs will want to ensure that proposals are fully costed. In addition, PCTs themselves should clearly identify the planned sources of funding available and be able to demonstrate that schemes offer value for money. Planned sources of funding, apart from the Department's contribution, will need to be outlined in the proposal. Prospective LPS providers and PCTs should also take account of long term funding implications of pilots.

87. In considering affordability, PCTs should note that transfer from non-discretionary funds will be based on a calculation, which the PCT will be required to put forward in the first instance, of the level of remuneration that the predicted level of dispensing would have attracted had it been calculated under the terms of the national contract.
88. In making their calculations, PCTs should include the full range of fees and allowances including, where the conditions would be met, the professional allowance and payments under the 'Essential Small Pharmacies scheme'. However, calculations should not include the cost of drugs, appliances, chemical reagents or containers.
89. Details of the calculation should be included in applications for approval. Accordingly, it is important that the basis of the calculation is clear, including any assumptions made and data sources used, as this will require to be checked as part of the approval process.
90. It is recognised that it will be difficult to predict accurately the level of dispensing likely in the first year of pilots particularly those which include provision of a dispensing service to a group of patients or in an area not previously served. Funding in future years will be uplifted in line with increases in the remuneration due to be paid to Part II contractors. If it becomes apparent in the light of experience that dispensing volumes in any particular pilot scheme are significantly in excess of those predicted (uplifted as necessary for any general increase in dispensing volumes) the Department will consider proposals for increased funding. Conversely, if it becomes apparent that dispensing volumes in any pilot scheme are significantly below those predicted (or below what might have been expected after taking account of any general increase in dispensing volumes) the Department reserves the right not to uplift funding to the extent set out in this paragraph. In either event, there will be no formulaic link between dispensing volumes and the level of Departmental funding – the objective will be to take account of significant discrepancies between what has been predicted and what has happened in reality. Nor will there be any "clawback" of funds already committed (or any additional payment in respect of past workload). The aim is to adjust future allocations if necessary in the light of experience.
91. Allocation to PCTs from non-discretionary provision will be made after the LPS pilot has been approved and implemented. Unless there are exceptional circumstances, adjustments to this allocation would not be made until twelve consecutive months of data becomes available.

92. No central funds will be provided for the on-going management support of LPS pilots. This is a matter for agreement between the PCT and the LPS provider. When considering what, if any, management costs should be allowed for within the agreed contract price, PCTs will want to ensure that they treat all pilots fairly, taking account of resources available.
93. It should be noted that the position for re-imburement of drug costs will be calculated in the same way as currently and is not different for LPS. LPS pilots will be registered separately with the PPA. Where medicines and appliances are dispensed against a prescription, the forms will therefore need to be submitted to the Prescription Pricing Authority (PPA) in the usual way. The PPA will arrange for re-imburement of those costs.

Preparation for implementation

94. PCTs are required to implement proposals in the form approved by the Secretary of State. This is important in guaranteeing that the scrutiny of the aims, scope and nature of a pilot scheme, carried out prior to approval is not undermined by subsequent unauthorised changes.
95. Contracts may be NHS contracts or ordinary contracts. The Health and Social Care Act 2012 enables a pilot scheme to apply to become a health service body for the purpose of entering NHS contracts. Experience with PMS has demonstrated clearly that there are advantages to NHS contract arrangements for both the providers of services and for the PCT. Entering NHS contracts enables bureaucracy to be kept to a minimum without sacrificing security for contractors. It is therefore likely that some LPS pilot providers approved by the Secretary of State will wish to be recognised as health service bodies.
96. If an LPS provider becomes a health service body the contractual arrangement with another health service body (such as a PCT) will be considered an NHS contract. Any dispute between health service bodies can be put to the Secretary of State for resolution avoiding costly and time-consuming recourse to the courts.
97. If a contractual dispute has been resolved in this way, the court will be able to enforce the Secretary of State's Directions as to payment. Although this mechanism is unlikely to be used in practice, it is a useful fail-safe, which will provide additional security for both sides.
98. Both parties in an NHS or other contract are strongly advised to set out, in advance of signing the contract, their arrangements for settling such disputes at an internal arbitration stage.

99. In order to become a health service body the LPS provider will need to submit an application, in writing, to the Secretary of State and copy it to the relevant PCT. The application should specify the pilot scheme it relates to and include the name and address of each applicant and that it wishes to be an NHS body for the purpose of LPS pilots. In granting an application, the Secretary of State will specify when the health service body status will come into effect. Any contract with another health service body entered into after that date will be an NHS contract.
100. If a pilot scheme comes to an end for any reason then the body will cease to have health service body status. If a pilot scheme wishes to cease to have that status during the pilot period, all the members of the body should agree this in writing and inform the Secretary of State and the PCT of their decision. The pilot will cease to have health service body status on the date specified by the members. This will have no effect on existing NHS contracts but contracts subsequently entered into will have a separate legal status.
101. Applications for health service body status can be made at any stage but it would be desirable if pilots were to apply at the earliest possible opportunity. This would enable contract negotiations between the pilot and PCT to go ahead as soon as possible and on the correct footing. However, approval of applications for health service body status cannot be granted until the pilots themselves have been given approval.

Payments to LPS providers

102. PCTs and LPS providers have considerable flexibility in determining the scope, form and value of the agreement negotiated between them. In all cases contracts must include an agreed total value, based on the services to be provided. PCTs and LPS providers should also agree the monthly payment schedule. Once the contract has been signed, PCTs must submit the payment schedule to the PPA.
103. In addition to re-imburement referred to in point 92, the PPA will provide a payment service for LPS pilot contracts which PCTs will be able to use if they wish. The PPA will not, however, be able to calculate LPS contract payments. This will be the responsibility of the PCT. The PPA will simply pay each month the amount that is notified to them, on the monthly payment schedule, by the PCT as being due to the LPS provider.

Publication of details of LPS schemes

104. As soon as practicable after implementing proposals for a pilot scheme, the PCT concerned must (in accordance with directions to be made) publish details of the scheme.

Review of pilot schemes

105. The Health and Social Care Act specifies that

- At least one review of the operation of each pilot scheme must be conducted by the Secretary of State
- The review must occur within a period of three years from the date on which services are first provided under the pilot scheme
- PCTs and LPS providers will be given an opportunity to provide comments on matters relevant to the review

Evaluation

106. A national evaluation of LPS pilots will be undertaken. LPS pilots and their PCTs will be required to participate in the evaluation and provide information, if required. The framework for evaluation is currently being developed and full details will be issued at a future date.

Annex A

Information required on outline proposals submitted by prospective LPS provider

- a request that the proposal be considered as an outline proposal for LPS
- Signature of authorised person and their position in relation to the outline proposal. Where relevant, position in the company e.g. chief executive, superintendent pharmacist, should be stated.
- If more than one, the name(s) of prospective provider(s), if known, their respective roles and the proposed legal relationship (if any) between them
- Address(es)/location(s) from which it is intended to provide service(s) under LPS pilot
- Is/Are the proposed location(s) registered retail pharmacy premises (under Part IV of the Medicines Act 1968) already included in the PhS list
- Broad aims of the LPS pilot
- Patient needs and service issues/problems to be addressed and how these were identified, if appropriate
- How the pilot intends to tackle these issues and main features of the proposed pilot
- Outline of the contractual arrangements proposed
- Benefits to patients
- Contribute to the delivery of local priorities/needs and health improvement, as appropriate
- Any views emerging from initial discussions which may already have taken place with HA and/or key stakeholders.
- Estimated cost including cost of dispensing element.

Additional information may be requested by PCTs, as required.

Annex B

1. Basic Details

- PCT name and contact details
- Name of PCT LPS Lead contact
- Statement as to whether this is an application for final approval or an application for preliminary approval
- LPS Provider details i.e. name, title and contact details – to be included in applications other than those for preliminary approval.
- If more than one provider, the name, contact details and role of each.
- Name of locality/neighbourhood in which LPS will be located
- Location(s) (specific address, if known) from which service(s) will be provided
- Is/Are the proposed location(s) registered retail pharmacy premises (under Part IV of the Medicines Act 1968) already included in the PhS list. If not, give details (including timescale) of plans for proposed location of registered retail pharmacy premises.

2. The LPS proposal

Aims and background

1. Proposals should firstly, set out the broad aims of the scheme. This should be followed by a brief description of the background and/or context in which the pilot was developed, highlighting any particular features that were important in leading to a decision to proceed with this particular scheme. Information on discussion, if any, with other interests in the wider health services/community should also be given.

Justification

2. Information should be provided on patient needs and service issues to be addressed by the LPS and their importance within local PCT priorities or healthcare improvement plans.

3. It is important that some indication is given at this point as to the PCT's vision for the pilot and how success would be capitalised on
 - in the context of how it fits with local needs/issues
 - how pilots, if successful, would be integrated into local mainstream delivery of healthcare in the future
 - roll out

Please describe how the proposed pilot will meet patient and carer interests and their involvement, if any, in the formation of the proposed pilot.

Details

4. Proposals should set out the objectives of the proposed pilot and then describe the scheme in full, including such points as
 - main features of the scheme
 - specific activity/activities and services to be undertaken as part of the pilot and access arrangements (e.g. times, days etc.)
 - specialist service provision, if any
 - patient group(s) targeted
 - access to other services
 - new or innovative configurations of services or access to wider services
 - any other relevant information

Monitoring/measuring progress

5. As with any scheme it is important to have targets and to be able to measure progress to and achievement of those targets, using either qualitative or quantitative measures/methods. Please describe the main targets of the scheme and how you will measure progress towards their achievement. It is important to be specific about how you will know a target has been achieved particularly in relation to pivotal and/or core targets where achievement is vital to the success of the pilot. In addition, please provide information on any incentives to be provided in relation to activity. Please also indicate how value for money is measured and monitored.

Probity

6. All pilots will need to describe how probity will be assured and what steps will be taken to monitor this on an on-going basis.

Funding

7. Describe arrangements for how funding will flow and highlight any new or unique attributes of the arrangement. Specific details should be provided under the headings shown on the proposal form.

General

8. Date it is proposed to implement the pilot, if approval is given by SofS. It should be noted that all proposals must include satisfactory arrangements for any participant other than the PCT withdrawing from the pilot scheme. Please therefore describe your arrangements for this contingency and also describe what arrangements are proposed in the event of:-
 - Termination in the event of unsatisfactory performance
 - Dispute resolution

3. Accompanying documentation

Copy of

- (i) Responses to consultation
- (ii) assessment(s) of impact on services

