EXPLANATORY MEMORANDUM TO

THE NHS (PHARMACEUTICAL SERVICES AND LOCAL PHARMACEUTICAL SERVICES) AMENDMENT REGULATIONS 2010

2010 No. 914

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations make amendments to the framework Regulations which govern the provision of NHS community pharmaceutical services. The amendments give effect to the provisions in the National Health Service Act 2006 which require Primary Care Trusts (PCTs) to develop and publish pharmaceutical needs assessments. The amendments also make some unrelated technical changes to the framework Regulations, including correcting an error which allowed a PCT, in certain circumstances, to grant dispensing rights to a doctor when that surgery is within 1.6km of an existing pharmacy.

3. Matters of Special Interest to the Joint Committee on Statutory Instruments

3.1 These Regulations are the first use of the powers conferred by section 128A of the NHS Act 2006 as inserted by Section 25 of the Health Act 2009.

4. Legislative Context

4.1 The great majority of community pharmaceutical services in England are provided on the basis of one of two sets of standard arrangements with Primary Care Trusts. Arrangements for the provision of "pharmaceutical services" are governed by the National Health Service (Pharmaceutical Services) Regulations 2005 (S.I. 2005/641, as amended) ("the PS Regulations"). Arrangements for the provision of "local pharmaceutical services" are governed by the National Health Service (Local Pharmaceutical Services etc) Regulations 2006 (S.I. 2006/552, as amended) ("the LPS Regulations").

4.2 The PS Regulations set out the statutory terms of service of the majority of retail pharmacy outlets providing "pharmaceutical services". The companies responsible for these outlets have to be on a pharmaceutical list, kept by the local PCT. Two additional categories of people may provide "pharmaceutical services". First, dispensing doctors, who are general practitioners able to dispense to patients who live in designated rural areas a distance away from pharmacies. Second, appliance contractors, who dispense appliances (for example, incontinence aids, dressings, bandages etc.) but not medicines. Generally, all these providers of pharmaceutical services are known as "contractors", and are referred to in this memorandum as such, even though they do not have a formal contract with their PCT.

4.3 The LPS Regulations contain an alternative, less prescriptive set of arrangements for the provision of community pharmaceutical services. This is a contractual framework, and most of the terms of the contracts are for local negotiation. However, there are also some common standard terms and conditions set out in the LPS Regulations. The LPS Regulations also contain a scheme for designating areas where the PCT is to make arrangements for the provision of services on the basis of the LPS Regulations rather than the PS Regulations.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

As the Instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 The amendments made in these Regulations can be grouped as follows:

7.1.1 amendments which flow from the Government White Paper *Pharmacy in England – Building on Strengths, Delivering the Future* published in April 2008 and consultation on regulatory changes in 2009/10 based on the powers inserted in the National Health Service Act 2006 by Section 25 of the Health Act 2009; and

7.1.2 further amendments to improve the working of the PS and LPS Regulations that have been identified since but which were not part of that consultation.

7.2 These Regulations achieve the following changes which were the subject of full consultation.

7.2.1 The Regulations will require PCTs to develop and publish a pharmaceutical needs assessment (PNA) by 1 February 2011. A PNA is the statement of the assessment each PCT must make of the needs in its area for community pharmaceutical services provided as part of the NHS. The PNA must describe the population profiles and local characteristics as well as providing an assessment of unmet needs. The services to be covered by the PNA and the information which must be included are set out. When developing its PNA the PCT must have regard to prescribed matters including the local Joint Strategic Needs Assessment, the demography of the locality, the needs of different patient groups and different localities and the benefits from having reasonable choice. It is very important that PCTs involve and consult local people on changes to health services, and the Regulations therefore specify the minimum local consultation requirements PCTs are required to meet.

7.2.2 This is the first stage of a threefold plan to implement the pharmacy provisions which were included in the Health Act 2009. The second stage will involve changing the way contractors are included on pharmaceutical list. The "control of entry" test will be replaced with a new market entry test which will enable PCTs to determine entry by reference to PNAs. PNAs will therefore become the essential tool for local planning of pharmaceutical services. The benefits that this type of planning should bring are covered in the Impact Asssessment referred to in paragraph 10.1.

7.2.3 The final element of the plan is to reform the arrangements for market exit. PCTs are to be given new powers to take action where there are concerns about the quality of services provided by or performance of pharmacy contractors. It is anticipated that stages two and three will be included in Regulations that will come into force in 2011.

Further minor amendments to the PS and LPS Regulations have been made which were not subject to full consultation. These are essentially improvements to correct problems that have been identified. The changes are:

7.2.4 Changes consequential upon the abolition of the Family Health Services Appeal Authority.

7.2.5 Correcting an error in the PS Regulations which allowed a PCT, in certain circumstances, to grant dispensing rights to a doctor when that surgery is within 1.6km of an existing pharmacy.

7.2.6 Requiring the dates of birth and professional registration numbers of directors and superintendents of bodies to be included when their details are required as part of making applications to enter or vary any entry on a pharmaceutical list.

7.2.7 Removing references to two forms which are no longer in use for claiming repayment of NHS charges.

7.2.8 Clarifying in the LPS Regulations that the scheme for designations under designation of priority neighbourhoods and premises does not require a designation to be in place in respect of all pharmacy premises from which local pharmaceutical services are, or are to be, provided.

7.2.9 Correcting a numbering error.

- ***Consolidation***

7.3 There are no immediate plans to consolidate any of the Regulations amended by these Regulations. The Department proposes, as outlined in paragraphs 7.2.2 and 7.2.3 above but subject to further consultation, to replace the PS Regulations with a new set of Regulations as part of further work to reform the current market entry requirements contained in the National Health Service Act 2006. This replacement is anticipated to take place in 2011.

8. Consultation outcome

8.1 The proposals in paragraph 7.2.1 were devised with the support of the Advisory Group on the NHS (Pharmaceutical Services) Regulations. Members comprise representatives of patient groups, the NHS and pharmaceutical contractors. Papers for the Group's work are available on the Department's website at www.dh.gov.uk. The proposals were subject to full consultation from 1 December 2009 to 28 February 2010. There were 68 written responses. Respondents supported the regulatory requirements and the Department concluded that, with one minor correction, no further specific measures were needed. The correction was to substitute the use of the word "immediate" in respect of pharmaceutical needs with "current" where appropriate. The minimum information requirements were generally considered to be adequate, with some suggestions being made for inclusion of additional information. A number of PCTs who responded called for a longer consultation period on draft PNAs. Although there is a minimum requirement for a 60 day consultation period, PCTs can determine locally whether they wished to extend this to, say, 90 days. There was some concern expressed about PCT capacity to undertake robust PNAs. The Department will discuss further with the NHS how it can best support PCTs in this work during 2010. Comprehensive guidance (see Section 9) to accompany these Regulations will be published and a series of implementation workshops held later this Spring to support PCT work.

8.2 The proposals in paragraphs 7.2.4 – 7.2.9 were not subject to a general public consultation. However, the Department has sought views from the NHS, the PSNC and representatives of dispensing doctors and dispensing appliance contractors and they have agreed the amendments.

9. Guidance

9.1 The Department in partnership with the NHS also developed draft Guidance which accompanied the consultation. Revised guidance for the NHS and contractors drawing on comments received following consultation is scheduled for publication, if possible, shortly after the Regulations are made.

10. Impact

10.1 The final Impact Assessment estimates a net benefit of compiling and revising PNAs over 10 years of £100million. The Impact Assessment can be found on the Department's website at www.dh.gov.uk.

10.2 There is no negative impact on equality issues.

11. Regulating small business

11.1 The Regulations amended by these Regulations apply to small businesses, including firms employing up to 20 people. As the PS and LPS Regulations concern the provision of NHS pharmaceutical services, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed universal standards and practices in the provision of such services.

12. Monitoring and review

12.1 The Department monitors the implementation of the Regulations and has regular discussions with interested parties including the NHS and contractors' representatives on any problems identified in their operation. The Department expects to review the changes included in these Regulations within 2 years of their coming into operation.

13. Contact

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Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	Impact Assessment to require PCTs to devise and to publish Pharmaceutical Needs Assessments (PNAs)	
Stage: Implementation	Version: 1.7	Date: March 2010
Related Publications: White Paper *Pharmacy in England: Building on strengths - delivering the future.* Health Bill 2009 Consultation document: *Proposals for legislative change* (Autumn 2008)		

Available to view or download at: http://www.dh.gov.uk

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What is the problem under consideration? Why is government intervention necessary?

The Pharmacy White Paper published April 2008 identified (paras 8.20 and 8.21) that there was considerable variation in the scope, depth and breadth of PCT pharmaceutical needs assessments (PNAs). The structure of and data requirements for PNAs required review and strengthening to ensure they are an effective and robust commissioning tool to meet the pharmaceutical needs of their local populations. Following consultation in Autumn 2008, government intervention is necessary as the provision of NHS pharmaceutical services is governed by the NHS Act 2006. The Government's legislative proposals were contained in the Health Bill 2009, now the Health Act 2009. This IA develops the IA on PNAs and NHS market entry published as part of the papers for that Bill.

What are the policy objectives and the intended effects? The policy objective has two stages. First, PCTs will be required to devise and to publish PNAs assessing pharmaceutical needs of their local communities. This will provide an objective measure against which PCTs commission pharmaceutical services. This IA only concerns this first stage. Second, PNAs will then be used to determine NHS market entry, replacing the current "control of entry" system. The intended outcomes are greater PCT control over pharmaceutical services locally, a fairer and more equitable system for market entry, improved access to and choice of pharmaceutical services for patients, improved confidence for businesses to invest, a more efficient use of PCT and NHS resources and a regime which encourages closer partnership working.

What policy options have been considered? Please justify any preferred option.

Option 1: No change in existing policies.

Option 2: Devise Regulations to bring the provisions in the Health Bill 2009 requiring PCTs to devise and to publish PNAs into force.

Preferred Option: Option 2, as it delivers the policy objectives and supports world-class commissioning of pharmaceutical services which reflect local needs.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

Within 24 months of implementation.

Ministerial Sign-off for final proposal/implementation stage Impact Assessments

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Mike O'Brien.....Date: ***16th March 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: Regulations requiring PCTs to devise and to publish PNAs.

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' **Exchequer Costs**
One-off (Transition)		Cost of PNAs: £8.6mn (year 1); Average admin cost £1.6mn (from year 2). Cost of additional services: £0.6mn (year 1) £0.7mn (year 2 onwards)
£0.1mn		Costs of programme evaluation: £0.1mn (one-off in year 2).
Average Annual Cost (excluding one-off)		
£3mn	10yrs	**Total Cost** (PV) **£27mn**

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'
One-off	**Yrs**	Improved health outcomes for patients: £30mn (Year 2) and £32mn (Year 3+).
£ -		
Average Annual Benefit (excluding one-off)		
£ 28mn	10	**Total Benefit** (PV) **£ 264mn**

Other **key non-monetised benefits** by 'main affected groups'

Increased scope for business planning by pharmacies.

Key Assumptions/Sensitivities/Risks Conservative estimates used for all costs and benefits. For patient benefits, the "Stop Smoking" enhanced service has been used as a proxy measure to estimate benefits. It is assumed that commissioning of such services would improve under robust PNAs. Evaluation is assumed to improve the programme. Opportunity costs are 2.4 times exchequer costs.

Price Base Year 2008	Time Period Years 10	**Net Benefit Range** (NPV) **£ (-64mn) to 200mn**	**NET BENEFIT** (NPV Best estimate) **£ 100mn**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?				
Which organisation(s) will enforce the policy?			PCTs	
What is the total annual cost of enforcement for these organisations?			£ n/a	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ n/a	
What is the value of changes in greenhouse gas emissions?			£ n/a	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits:** **(Net) Present**

Evidence Base (for summary sheets)

1. Introduction

Following consultation in autumn 2008, the Government set out in the Health Bill 2009 (published on 16th January) its proposals first, to create a legislative duty for each PCT to make and to publish an assessment of needs for pharmaceutical services in its area, in accordance with regulations and then to use this as the basis for commissioning pharmaceutical services and for determining entry to the NHS pharmaceutical market. This would replace the current system known as "control of entry". Further information on the control of entry system was contained in the Explanatory Notes and Impact Assessment for these measures accompanying the Health Bill. The Bill received Royal Assent on 12 November 2009 and is now the Health Act 2009.

This Impact Assessment only concerns the first stage of this process – the duty on PCTs to devise and to publish a pharmaceutical needs assessment (PNA) in accordance with regulations. Most PCTs already have PNAs, and whilst each PNA will be specific to each PCT, depending on local priorities, their consistency, breadth and depth have been judged as variable and justify Government intervention to promote consistency and ensure PCTs have an objective basis against which to commission services.

Costing assumptions for this Impact Assessment are set out in the Annexes. These are based on best estimates and reasonable assumptions and have been informed by views of an Advisory Group, chaired by Paul Burns, which has assisted in advising on and devising the draft Regulations to implement this requirement.

2. Purpose and Intent

The key aim of strengthening the role of PNAs is to better inform commissioning. This, in turn, will improve health outcomes, contribute to wider developments in primary care provision and reduce health inequalities, by facilitating better access to pharmaceutical services appropriate for population needs. Using PNAs, PCTs' decisions concerning pharmaceutical services provision will also be more transparent and consistent.

Evidence also indicates that there is currently significant variation in the provision of enhanced pharmaceutical services in England. Whilst it is possible that some of these services may be provided by other providers, the variation does not always reflect the needs of the local population.

3. Background

The White Paper *Pharmacy in England: Building on strengths - delivering the future* (chapter eight) [1] identified a number of shortcomings with the current framework governing the system which determines whether a contractor can provide NHS pharmaceutical services. These are inconsistent with the direction of NHS reforms and the desire to give PCTs more responsibility to secure effective commissioning of adequate services which address local priorities. Such shortcomings were also reinforced by the broad themes in *High Quality Care for All* – the NHS Next Stage Review final report, published on 30 June 2008.[2]

The White Paper endorsed, as part of the World Class Commissioning Programme, the need to strengthen commissioning. The aim is for continuous service improvement through evidence-based commissioning using local PNAs.

Guidance to support PCTs in developing their PNAs has already been published in stages by NHS Employers and DH.

The first element of this programme – Guidance for PCTs on pharmaceutical needs assessments – was published by NHS Employers on 7 January 2009. It is available at www.nhsemployers.org/PNAguidance. The guidance shows how PNAs can be used to support, and extend, existing pharmaceutical services to deliver benefits to local patients.

In March 2009 the Department published guidance for PCTs on commissioning pharmaceutical services *Improving Pharmaceutical Services* as part of the World Class Commissioning in Primary Care programme. It is available at www.dh.gov.uk/en/Managingyourorganisation/Commissioning/PolicyGuidanceandtoolkits/index/htm.

In July 2009, NHS Employers published a toolkit for PCTs *Developing Pharmaceutical Needs Assessments – a practical guide* giving detailed advice on the information PNAs should contain. The toolkit is structured around five steps:

- Getting the engagement right
- Identifying local needs
- Mapping current provision
- Shaping the future
- Action planning

together with a series of individual supporting guides (for example, on involving patients and the public, timetable for the PNA process, national and local data sources, minimum data for PNAs, mapping service need to provision).

[1] Paragraphs 8.2 – 8.17

[2] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825

Together, this suite of guidance, reflecting good NHS practice, sets the context for PNAs, provides information on how the needs of the population should be identified and how to commission pharmaceutical services. It supports all PCTs in creating and implementing effective PNAs, to help improve health outcomes in their area.

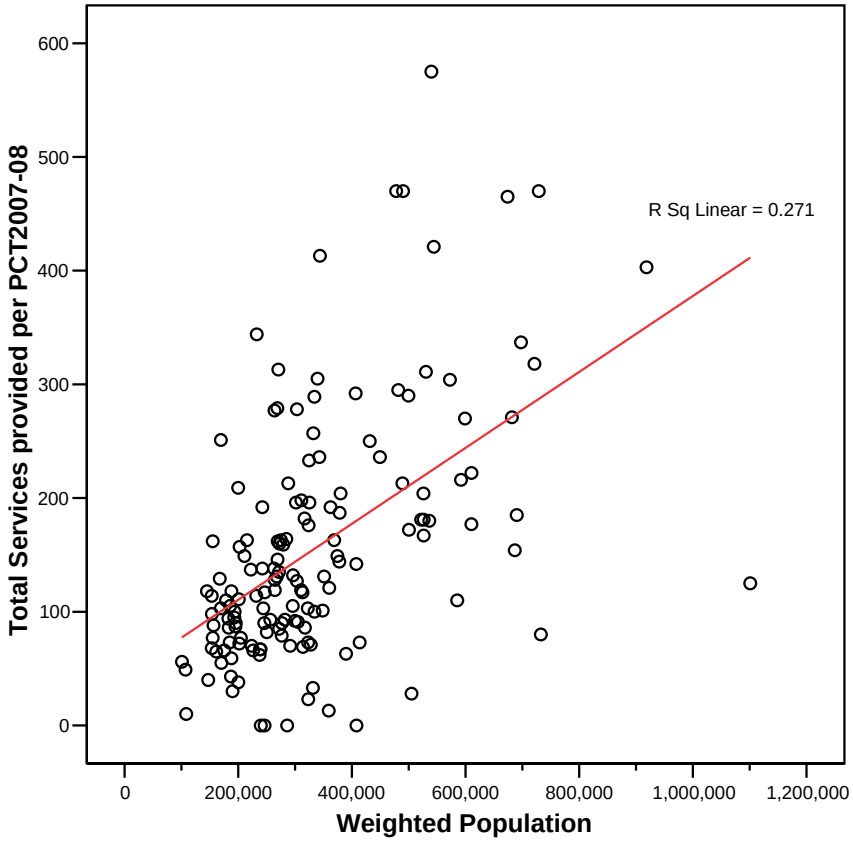
The Regulations to give effect to the new legislative duty therefore take account of this existing guidance. However, to support PCTs further, the Department has prepared with interested stakeholders information on how PCTs should proceed to implement the requirements for PNAs in accordance with those Regulations.

Evidence of variability in service provision

There is evidence to indicate that PCTs' current PNAs and the "control of entry" system may not be meeting the needs of local populations. A simple regression analysis of local needs of the population[3] and pharmacy enhanced services (from General Pharmaceutical Services England and Wales 2007-08, published by The Information Centre for health and social care) indicates significant variation in service provision among PCTs (see Figure 1 below). While there is likely to be a number of reasons for this, including that some services are provided by other providers, it is reasonable to conclude, at least in part, that this variation can be explained by institutional factors, such as PCT commissioning decisions not reflecting the needs of the local populations. Therefore, a system based on PNAs has the potential to target specific local needs and focus PCT commissioning decisions on local priorities. PNAs should in time reduce this variation in service delivery and make local services more reflective of local needs.

[3] Weighted population measure of local need used to allocate PCT funding. The formula takes into account age-sex factors, mortality, local deprivation, market forces factors and other factors that have been shown to affect demand. (For more detail, see http://www.dh.gov.uk/en/Managingyourorganisation/Financeandplanning/Allocations/DH_4104471).

Figure 1: Variation in the provision of PCT commissioned Local Enhanced Services[4]



Note: The numbers of Local Enhanced Services (for example, stop smoking services, minor ailments services, supervised administration of methadone) at PCT level was regressed against the PCT population, which was weighted for need (weighted populations from PCT allocation formula. See footnote 3 for more detail). The results of the regression were robust (no heteroscedasticity, independent errors and constant variance), and showed that the needs-weighted population was a significant determinant of the numbers of enhanced services (coefficient 0.521, significant at less than 1%). However, the results show that there is significant variation in service provision that cannot be explained local needs. The R-squared of the regression (0.271) indicates that only 27% of the service provision is currently explained by needs of the local population, as measured by this index. We hypothesise that at least a part of the remaining variation is explained by institutional factors, such as PCT commissioning decisions. The results clearly indicate that there is scope to make PCT commissioning decisions more reflective of local needs.

PCT commissioning of pharmaceutical services based on PNAs should achieve a better balance between the needs of PCTs as commissioners and the certainty pharmaceutical services providers want to invest to provide services. Importantly, the legislative regime should encourage stronger relationships between commissioner and contractor as well as stimulating competition whilst not undermining the collaboration between professionals which helps ensure safe and consistent patient care.

[4] Details of PCT commissioned local enhanced services are published in the annual Information Centre statistical bulletin on NHS pharmaceutical services – for more information see www.ic.nhs.uk

4. Rationale for Government intervention

Government intervention is necessary as the provision of NHS pharmaceutical services is governed by the NHS Act 2006. Current practice around PNAs is erratic and the services commissioned by PCTs have been shown not to fully meet the needs of local populations. Placing a duty on PCTs to devise and to publish PNAs to minimum national requirements should lead to evidential, consistent identification of these population needs and the commissioning of necessary services to meet those needs. The Government has therefore concluded that PCTs should be required to devise and to publish effective and robust PNAs which assess pharmaceutical needs of their local populations.

5. Options

Two options have been identified:

Option 1: No change in existing policies.

Option 2: Requiring PCTs to devise and to publish PNAs in accordance with legislation.

A third option of gradual introduction through piloting was discussed but rejected in the IA accompanying the original proposals in the Health Bill.

Preferred option: Option 2. It better secures the purpose and intent as described in section 2 above. Introducing PNAs across all PCTs at the same time would secure consistency and avoides delay to the benefit realisation.

6. Consultation

A consultation on the draft Regulations, draft guidance and consultation impact assessment took place over a twelve-week period between 1 December 2009 and 28 February 2010. Also, in January 2010, six half-day listening events were held in three locations throughout England, mainly aimed at PCT staff, where the draft regulations and guidance were explained and comments received. A total of 68 written responses to the consultation were received, mainly from providers of pharmaceutical services or their representation organisations.

Those respondents who commented on the Impact Assessment, in particular providers of pharmaceutical services and their representative organisations, felt that the costs to pharmacy contractors and LPCs had been understated. A reasonable amount should be factored into developmental costs to fully fund meetings between the LPCs and PCT staff and to cover the amount of time spent by LPCs collaborating with PCTs. NHS respondents noted that costs for some PCTs may be higher where, for example, they have large geographic areas to cover or where they support contractor involvement.

In the Government's response to the consultation, we noted the comments made and stated that by convention, only impacts on government spending are accounted as costs. Local representative committees source their funding from a levy on the fees invoiced by individual contractors in a PCT. It is therefore open to these committees to revise their estimates of any costs in 2010/11 that might arise. In addition, PCTs are able to support

local patients, groups and contractors and their staff as part of the consultation if they deem it appropriate. We promised to reflect these comments in the revision to the Impact Assessment for these Regulations. However, no data were supplied to help us quantify how often this would occur or the extent of such additional costs, and therefore this is an unknown potential extra cost. When considered across all PCTs, we do not think the impact should be so significant as to affect our overall assessment of the total costs and net benefits.

7. Benefits and costs

Benefits

Option 1 – No change in existing policies
Without any action, there would be no change in the current practise of completing PNAs, commissioning pharmaceutical services would remain variable around patient need (as evidenced above). The current level of health benefit is maintained. There are no additional benefits with this option.

Option 2 – Requiring PCTs to devise and to publish PNAs in accordance with legislation.

PNAs devised in accordance with legislation will provide a universally applicable, objective and robust assessment of needs which are sufficiently flexible to take account of local health circumstances. This in turn will enable services to be commissioned which better meet such needs, enabling PCTs to target services which have the potential to secure improved health outcomes for patients, whilst not adversely impacting on overall provision.

8. Costs

Option 1 – No change in policy
Without any action, there would be no change in the current practise of completing PNAs. There would be no change in costs that are currently incurred, either to PCTs or pharmacies.

Option 2 – Requiring PCTs to devise and to publish PNAs in accordance with legislation

There would be costs for PCTs from having to undertake and to publish PNAs, or from having to bring their existing PNAs up to agreed minimum requirements. If PNAs lead to the commissioning of further services, there will be costs to PCTs in funding such services. The costs of this option are quantified in Annex C.

There will be ongoing costs to PCTs to ensure that PNAs are maintained and reflect the changing needs of the PCT’s population.

9. Risks

The following risks have been identified:

PCTs have insufficient resources to complete the new regulatory requirements to time: In addition to the comprehensive suite of guidance already available to PCTs, further guidance has been prepared as part of this current consultation to accompany the draft Regulations. The Department will also consider with the NHS and other stakeholders what further support needs to be offered to PCTs to ensure they are able to complete their PNAs on schedule.

PCTs complete PNAs on time but are insufficient or inadequate: In addition to the support programme above, the Regulations will require PCTs to report on consultation and what steps have been taken to address views and comments received. They will also set out the circumstances under which a PCT is to undertake a new assessment.

The Department also intends to undertake a comprehensive evaluation within 24 months of implementation to identify lessons learnt and best practice in addressing any problems encountered. For more information on this evaluation, please see Section 13.

Summary of Benefits, Costs and Risks

Option	Benefits	Costs	Risks
Option 1 – No change in policy	-	-	-
Option 2 – Requiring PCTs to devise and to publish PNAs in accordance with legislation	PNAs devised in accordance with legislation will provide a universally applicable, objective and robust assessment of needs which are sufficiently flexible to take account of local health circumstances. Services will be commissioned which better meet such needs, enabling PCTs to target services which have the potential to secure improved health outcomes for patients, whilst not adversely impacting on overall provision. Patients will benefit from services tailored to their needs.	Administrative costs for PCTs. These are highest in producing the first PNA or bringing an existing PNA up to standard. Thereafter whilst there will be costs for further revisions, these are expected to be reduced. Costs to PCTs in paying for an expert stakeholder group to advise the PCT on pharmaceutical needs in the PCT's area. Costs of evaluating the programme in year 2, although this should yield improved benefits in time. Costs of funding additional services	PCTs have insufficient resources to complete the new regulatory requirements to time. PCTs complete PNAs to time but the PNAs are insufficient or inadequate. Risks mitigated by support programme for PCTs, by requiring PCTs to report on consultation and by setting out the circumstances under which a PCT is to undertake a new assessment in the regulations.

	Early programme evaluation could increase benefits from Year 2. Overall, the benefits justify costs	identified through the PNA process.	

10. Competition Assessment

We have not identified any significant competition impacts as the requirement to produce PNAs falls largely on PCTs. The final PNA will apply to all NHS contractors. It is worth noting, however, that there is no price competition at present for the majority of services provided by pharmaceutical contractors. This is because NHS pharmaceutical services, which can for example represent the bulk (80% or more) of a pharmacy contractor's income, are provided free of charge or by nationally set charges (e.g. prescription charges). Therefore, any increase in competition would be based on the quality of service provision rather than its cost.

11. Small Firms Impact Assessment

Small firms (independent community pharmacies and pharmacies with five or fewer chains) are responsible for the provision of a significant proportion (39%) of pharmaceutical services in the UK, though this number has gradually declined from around two-thirds in the early 1990s.

There are also Dispensing Appliance Contractors, dispensing around 0.5% of prescription items. These tend to be small firms, providing an important niche service to the local population.

We have not identified any greater significant impact on small firms than on larger firms in terms of devising PNAs as the chief impact falls on PCTs. Larger firms will however have more resources to be able to devote to helping develop the PNA. At seminars for small businesses held in October 2008 as part of the original White Paper consultation, concern was expressed that revising PNAs will carry higher costs for smaller businesses although these have not been quantified at this stage.

The set up costs for the provision of commissioned services (particularly if they are specialist services) are likely to be more burdensome for smaller firms, who may have less capital to invest to set up adequate facilities. Regardless of any potential government subsidy towards training and administration costs, costs of training (both financial and time costs) are also likely to be larger for smaller firms. Nevertheless, it is possible that a smaller contractor could be more responsive to local needs than a national chain and better tailor service delivery to the PCT's commissioning requirements.

The potential benefits of using community contractors to deliver services derived from the PNAs may not be realised, because smaller businesses will not make adequate money nor be able to "scale-up" in a way that is necessary. Nevertheless, a properly designed

and funded programme could use pharmacists to deliver extremely cost-effective services.

The Department considers that whilst there may be some impact on small businesses from the new proposals for commissioning services, it is not clear that such an impact would be disproportionate. However, the Department will continue to assess this impact and any mitigating measures would be considered as part of a comprehensive evaluation of the proposals once introduced.

12. Health Impact Assessment

As set out above, the impact of these proposals on health is expected to be positive, as pharmaceutical service provision will better reflect the needs of the local communities to be served and thereby have a positive impact on health inequalities. This would give PCTs greater control over the services commissioned against those needs and raise standards for NHS patients. At this stage, no specific impacts have been identified on the wider determinants of health or on lifestyle behaviours.

13. Equality Impact Screening and Report

Attached as Annexes A+B

14. Review

It is intended that Option 2 would be subject to a comprehensive evaluation within 2 years of implementation. This will enable the Department to make any amendments necessary to legislation or to PCT guidance to ensure that best practice is observed.

The Department would evaluate through a sample of PCTs, quantifying the costs and benefits, and qualitatively assessing the differences in PCTs' application of PNAs.

It is reasonable to assume that post evaluation, benefits to patients would increase and there would be cost savings to PCTs as best practice could be adopted more widely through the Department amending regulations and/or guidance.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	***Results in Evidence Base?***	***Results annexed?***
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

ANNEX A - EQUALITY SCREENING PROFORMA

Screening

Question 1

For each of the six equality categories, ask the questions in the table below.

	Age	Disability	Race	Religion and	Gender	Sexual Orientati
1.a) Do different groups have different needs, experiences, issues and priorities in relation to the proposed policy?	✓	X	✓	X	X	X
1.b) Is there potential for or evidence that the proposed policy will promote equality of opportunity for all and promote good relations between different groups?	✓	✓	✓	✓	✓	✓
1.c) Is there potential for or evidence that the proposed policy will affect different population groups differently (including possibly discriminating against certain groups)?	X	X	X	X	X	X
1.d) Is there public concern (including media, academic, voluntary or sector specific interest) in the policy area about actual, perceived or potential discrimination against a particular population group or groups?	X	X	X	X	X	X
1.e) Is there doubt about answers to any of the above questions (for instance there is not enough information to draw a conclusion)?	X	X	X	X	X	X

ANNEX B – EQUALITY IMPACT REPORT

Introduction

Access to NHS pharmaceutical services, advice and supply of medicines and health consumables is an integral part of primary care in the NHS and, as such, should be available equally to all people in England.

The general principles underpinning the proposal to require PCTs to devise and to publish PNAs are to promote equality of access to fair, personalised, safe and effective NHS services for all groups in society and to reduce health inequalities. As such, it is intended to benefit all the population, with particular emphasis on supporting disadvantaged groups (e.g. those in poverty or not registered with GPs), those groups currently adversely affected by either specific conditions or the way services are delivered and those groups with long-term conditions (LTCs).

Related policy areas are Delivering Race Equality, Care Programme Approach, Valuing People, Healthy Weight Healthy Lives and the PSA Target on Life Expectancy.

General Equality Issues

Research conducted for the Pharmacy White Paper found there are around 1.6 million visits daily to a pharmacy, of which 1.2 million are for health-related reasons[5]. Pharmacies are mainly used to enable prescribed medicines to be dispensed and to purchase supplies of over-the-counter medicines. Around 1 in 10 people get health advice from their pharmacy but very few use a pharmacy to obtain urgent advice or to make use of other services, such as regular monitoring and screening.

Other key findings from this research were that:

- The majority of adults use pharmacies with 84% of adults visiting a pharmacy at least once a year and 78% visiting a pharmacy for health related reasons at least once a year.
- Adults in England visit pharmacies on average 14 times per year and on average of 11 visits per year specifically for health related reasons.
- Frequent users of pharmacies include females, those aged over 35 and those with a long term health condition or disability (LTC). Those working full time visit pharmacies less frequently than other groups.
- If gender and age are considered together, the highest frequency pharmacy users are females aged 35-74 and males aged over 55. Males aged 16-24 use pharmacies the least.

[5] Cited on page 71 - Community pharmacy use; market research report: http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_083815

- Gender, age, speaking English as a main language and having a long term condition or disability are all key drivers of pharmacy usage, in that order.

It is recognised that, proportionately, some groups are adversely affected by either conditions or service delivery which impact on their health outcomes. Some examples are Pakistani, Bangladeshi and Irish males who smoke, gay men and all women with depression, as well as older people who require access to medicines management and compliance aids.

Beyond this, we have not identified any factors arising from this proposal which significantly impact on any of the equality categories discussed below. It is likely that any impact would be positive as robust and high quality PNAs are likely to lead to services being commissioned that reflect differing local health needs in terms of ethnicity, age, gender, disability or other specific health needs.

The draft Regulations place a specific requirement on PCTs, when making their assessments of pharmaceutical needs, to have specific regard to the different needs of members of different groups in its area who share a common attribute in respect of any of the following equality issues:

- Age
- Disability
- Gender, including proposed, commenced or completed gender reassignment
- Race
- Religion or belief; and
- Sexual orientation.

The Government asked in its consultation from consultees, particularly from those representing affected communities, whether key equality issues have been raised and addressed within this Impact Assessment. The majority of those who responded to this question in the consultation, felt that there were no further matters to be included in the Equality Impact Assessment. However, some patient/public respondents felt there needs to be caution in the element of collection as collecting the data might become more important rather than the quality of patient experience and that some groups will be prevented by geographical location from accessing services unless special provision is made. The homeless, travellers and prisoners also warrant special consideration. We will ensure this is also reflected in the final Guidance.

B1 – The public

Race Equality impact assessment

There is no strong evidence that the proportion of people from ethnic minorities who make use of pharmaceutical services differs significantly compared to the population as a whole.

However, it is likely that where ethnic minorities have a higher incidence of a particular health problem than the population as a whole they are more likely to have increased requirements for regular access to such services to help meet their health needs. The research referred to earlier identified that there is very low use of other health related services offered by some pharmacies such as regular monitoring of current health conditions and health screening for conditions

which may be of particular benefit to people from ethnic minorities where such incidence is higher.

While the health complications of increasing obesity affect all ethnic groups in society, two have particular impact on specific groups. These are Type 2 diabetes for people of Indian, Pakistani, Bangladeshi or Black Caribbean origin, where NHS figures show prevalence is 2 - 4 times higher than in the general population and Black Caribbean men who have the highest prevalence of hypertension. The policy proposals requiring a PCT to have particular regard to the needs of their local populations according to their race will promote equality by increasing access to locally targeted and culturally appropriate services.

Similarly, men in Pakistani, Bangladeshi and Irish groups are more likely to report smoking than men in the general population. Both Black Caribbean women and Irish women showed a slightly higher prevalence of smoking than among women in the general population (Health Survey for England, 2004). Local, easily accessible, culturally appropriate and targeted services in local high street community pharmacies will help reduce inequality and promote equality.

Data on ethnicity are not recorded for teenage pregnancy, but the 2001 census showed higher rates of motherhood in young Mixed, Other Black and Black Caribbean groups than in the general population. In 2004, NHS data showed that Black Caribbean and African women presented for 9% of terminations, while accounting for 3% of the population. Local, culturally appropriate health promotion and services providing easily accessible contraception services within community pharmacies would help reduce unplanned pregnancy and this inequality.

PNAs can also help identify and deficiencies in local service provision and promote such better access including where they do not have English as a first language. For example, 495 pharmacies were in contract with their PCT in England as at 31 March 2008 to provide language services to people whose first language is not English. Special language services at pharmacies are likely to encourage attendance and improve access to services for people who might encounter language barriers. The proportion of people from ethnic minorities is higher in urban areas, where such pharmacies tend to be located, than rural areas.

At this stage, the Department believes that the introduction of PNAs will have a positive effect on the three parts of the race equality duty i.e. to eliminate unlawful racial discrimination; to promote equal opportunities or to promote good relations between people from different racial groups. Respondents to the consultation held in autumn 2008 (which included a number of national pharmaceutical and professional representative organisations) and delegates at the national listening events held to support the consultation, did not identify any adverse impact.

It is important that, subject to Parliamentary processes, the Department continues to consider any such impacts as the regulations to introduce the proposals set out here are finalised for implementation and subsequently evaluated.

Disability impact assessment

It is a requirement that community pharmacy contractors, in fulfilling their responsibility to provide a range of essential services under the current contractual framework, comply with the requirements of the Disability Discrimination Act 1995. This applies to pharmacies who would be commissioned to provide services based on PNAs.

Pharmacy contractors as service providers have a duty to make reasonable adjustments to enable someone with a disability to utilise the service. Reasonable adjustment may include the provision of an auxiliary or compliance aid to enable a person, who is disabled, to take their medicines. In determining what is reasonable, consideration needs to be given to the individual circumstances of the patient and the pharmacy, and a judgement made by the service provider, the pharmacy. As such, it is not appropriate to determine and specify the nature of "reasonable adjustment" nationally, nor to set out different types of intervention and associated payments. Instead, the Department has made specific funding available within the overall contractual settlement as a contribution to pharmacy contractors meeting the requirements of the Act.

Gender impact assessment

Research has indicated that women aged 35 – 74 and men over 55 tend to be higher users of pharmaceutical services. This can be expected as people tend to have need for more medicines as they get older – for example as a result of long-term conditions which require regular access to medicines. Whilst male users aged 16 – 24 are the lowest users, it is likely that their need to access general pharmaceutical services will be less than the population as a whole. On this basis, a full gender assessment is not indicated at this stage.

However, the prevalence of chlamydia is 10% in young people who are screened (Health Protection Agency 2007) with the under 24s particularly at risk. Development of appropriate screening services in community pharmacies can provide a more anonymous setting than general practice and also more easily accessible than genito-urinary clinics will help this group access advice and treatment and reduce health inequality.

Other equality issues

Pharmaceutical services are available to any patients regardless of age, religious belief and sexual orientation; and the eligibility to provide pharmaceutical services covers any applicant regardless of age, religious belief and sexual orientation.

Older people are more likely to be regular users of pharmaceutical services. In addition to the research referred to earlier, a study conducted for the Office of Fair Trading in 2002 found that 22% of the sample of 1,434 households who had pharmacies make their prescriptions up were aged between 60 and 70, and 17% were over the age of 70, compared with 10% and 11% of the UK population generally.

Human Rights

The requirement on PCTs to devise and to publish a pharmaceutical needs assessment has been considered in the context of the European Convention on Human Rights. The Department is satisfied that these provisions are compatible with the Convention.

Rural proofing

Option 2 is likely to benefit patients living in more rural areas as PCTs would need to assess local service provision to ensure that access to pharmaceutical services meets the needs of the local patient population in such areas and is proportionate and adequate in relation to the overall needs of the PCT's population as a whole.

B2 – The profession

Race Equality impact assessment

From the Royal Pharmaceutical Society of Great Britain's (RPSGB) 2008 register of pharmacists, a greater proportion of pharmacists are from black and ethnic minority backgrounds (30%) than for the general population as a whole (8%), (drawing on 2001 Population and Census data). 20% are Asian, 4% Chinese, 4% black and 2% other or mixed race with 70% white.

It is important that, subject to Parliamentary processes, the Department continues to consider any such impacts as the regulations to introduce the proposals set out here are finalised for implementation.

Disability impact assessment

The RPSGB started collecting disability data in March 2007. To date, the Department is not aware that any pharmacists have registered as disabled with the RPSGB.

Gender impact assessment

Women are well represented in the pharmacy workforce. According to the Royal Pharmaceutical Society's register, at 1st August 2009, there were 50,023 pharmacists in Great Britain, of whom 28,730 (57%) were women. There are 38,356 pharmacists in England (21,642 women and 16,714 men) of whom 34,519 are practising.

The Department does not consider the proposals set out here would have any disproportionate impact on businesses owned or run by women. A full gender assessment is therefore not indicated.

Other equality issues

Over two-thirds of pharmacists in the 2006 register were aged 49 or less. A higher proportion of female pharmacists are in the younger age groups.

ANNEX C – QUANTIFICATION OF COSTS AND BENEFITS (OPTION 2)

Discounting

All costings are for a period of 10 years and all costs are discounted at 3.5%. QALYs are discounted at 1.5%.

Methodology

The proposed legislation will give PCTs broad powers to devise and publish PNAs against the requirements of the regulations and guidance to support those regulations. The costings in this impact assessment are based on reasonable estimates of the costs and benefits of what is intended to be achieved from introducing PNAs. It is not possible to evaluate the full programme costs in greater detail as the nature of the policy of requiring PCTs to devise PNAs which are then used to commission service provision will depend on the determination of local needs relevant to each PCT. Only the costs and benefits of new services are considered in this Impact Assessment.

Overall, the net benefit is calculated by taking the difference between the discounted benefits and the discounted opportunity costs. The discount rate is 3.5% per annum. Opportunity costs are estimated as 2.4 times the exchequer costs, as per current DH guidance.

The scale of the costs determines the rounding of figures. This can lead to discrepancies in summing costs.

Where costs involve salaried individuals, the salary is pro-rated for the given time. It is assumed there are 225 working days for the individual and 22 working days in a month. When valuing an individual's contribution, their annual salary is used. Due to the variability of on-costs, these are not included in the evaluation.

EXCHEQUER COSTS

Exchequer costs are only costs that fall on PCTs, and so ultimately, the Exchequer.

Research[6] commissioned by the Department of Health to evaluate the implementation of PNAs, indicated that 90% of PCTs had completed a PNA, 85% of which had used one or more resources to assist with the process of undertaking a PNA. Local community pharmacists were engaged in the process in most PCTs (92%). There are no national standards on PNAs at present, which means that the quality and scope of them can be variable. Responses to the consultation held in Autumn 2008 highlighted concerns that the quality of PNAs is highly dependent on local skills. At that time, there was perceived to be a significant gap between how PNAs were presented and what they will need to look like in future.

[6] University of Manchester, 2006.

For costing purposes, we have assumed that the remaining 10% of PCTs would now complete PNAs, and the 90% of PCTs who already have PNAs would have to revise their PNAs to ensure consistency, quality and meeting the regulatory requirements. Therefore, all PCTs would incur the cost of performing a PNA, either because they have yet to do so, or because they would now have to revise their existing PNA to comply with the regulations and to mitigate any variation in the depth and rigour of PNAs, especially where amalgamations of PCTs have taken place.

Costs include the PCT costs for:

- writing the PNA;
- reviewing the PNA on an annual basis; and
- commissioning extra services as a result of the PNA; and
- programme evaluation.

To account for higher costs in rural PCTs, 50% of PCTs are assumed to have costs that are 10% higher than non-rural PCTs. This is applied to all PCT costs.

Cost of writing PNAs for PCTs

The costs for PCTs in completing the PNAs have a net present value of £20mn. Whilst the initial costs of completing a PNA is £8.6mn, these are expected to fall by 50% when PCTs come to fundamentally review their PNA, 3-years after the original was written. This reduction is due to PCTs becoming more aware of the processed involved in completing a PNA.

Average cost for one PCT to complete a PNA for the first time using guidance is estimated at £61,000, or £8.6mn for all 152 PCTs. This involves administration costs to PCTs of completing the PNA (£47,000), the cost of compensating stakeholder groups for their input (£9,000) and, sometimes, the cost of revising a PNA (£6,000) where consultation reveals poor PNA coverage in an area.

Administration Costs

The burden of completing PNAs falls on PCTs. Administration costs are based on informal estimates from a range of PCTs. We assume that completing or reviewing a PNA would require input from PCTs in the form of one senior manager for 2 days a week for 12 months, assumed to be 90 working days, after taking holidays into account, equating to £24,000 (90/225*£60,000=£24,000). An administrative support person is assumed to assist for two full months (44/225*£20,000=£4,000). It is also assumed that each PCT would need additional senior management input, costing £14,000. There are also costs of the PEC and Board for each PCT, costing £1,000. It is further assumed that a PCT would publicise each PNA through three public meetings, adding a total of £1,500 to costs. All of the costs are assumed to apply to all 152 PCTs, with adjustments for a PCT in a rural location.

Stakeholder Group

Although there is currently no formal requirement for a stakeholder steering group, PCTs might want to consider local expertise and consult a local steering group when devising their PNAs. For this impact assessment it has been assumed that each PCT would involve a number of patients, pharmaceutical contractors, GPs and representatives from the local authority. A PCT is assumed to pay participants according to their salary. Recompensing travel costs was considered as too small to have any effect on costs, and so was excluded from the calculations.

Total costs for PCTs in paying for a stakeholder group are £9,000 per PCT. We have assumed that three people from each group would be involved in a hypothetical stakeholder steering group. Each steering group would meet for three days to help each PCT to prepare each PNA. Patient time is evaluated at UK median earnings (£25,000 per annum), GP time is evaluated at average GP salary (£114,000 per annum) as estimated by the Personal Social Services Research Unit (PSSRU), pharmacist time is evaluated at average pharmacist earnings (£42,000 per annum, from PSSRU) and Local Authority personnel's time has been estimated at £35,000 per annum. The costs to all PCTs from engaging a Stakeholder group is £1.4mn for each PNA written.

Revising a PNA

As part of the process, a PCT is expected to consult its local area when a PNA is ready for publication. If a consultation results in new information brought to the attention of the PCT, it is possible that a PNA could be improved by further revision. This could take 10 days of senior management time (10/225*£60,000=£2,700) and 2 days of administrative support time (2/225*£20,000=£180). Board approval for the new PNA would cost £500, and the stakeholder group consulted for a further half day, costing £1,400. There is also additional consultation to ensure the revisions now meet the needs of the population, costing £500. Estimated costs of having to revise a PNA are £6,000 per PCT that needs to revise.

It is assumed that not all PCTs would need to revise their PNA, and that the proportion would fall as PCTs learn best practise. It is unknown how many PCTs would have to revise, but assumed as 15% for the first writing of a PNA, then falling to 10%, then 5%, then a constant 2% for every subsequent fundamental review of the PNA.

Annual Review of a PNA

In addition to a fundamental review every three years, we have assumed that PCTs would do a small-scale update of their PNAs every year, with a net present cost of £1.5mn. This is to ensure that PNAs are maintained and kept up to date, in order for their best use. For each PCT, the review is estimated to cost £1,900, with 5 days of senior management time (5/225*£60,000=£1,300) and 5 days of administrative support (5/225*£20,000=£400).

Increased costs to PCTs from additional services

Under PNAs, PCTs would be able to influence the quality of service provision and patient access by commissioning services in locations of greatest need. Therefore, PNAs could result in PCTs commissioning more services from existing providers as well from new entrants to the

market. It is not possible to estimate the numbers of new contractors that would enter the market as a result of PNAs. It is also not possible to estimate at this stage the benefits to patients who have easier access to pharmaceutical services.

For this impact assessment, costs and benefits have been estimated by constructing a hypothetical scenario based on variation in the delivery of Local Enhanced Services. To arrive at a conservative net benefit estimate, we have assumed that the delivery of Enhanced Services, where necessary, will reflect the pharmaceutical needs of the local population. Thus, assuming that a robust PNA would lead to a further commissioning of services to meet the needs of the local population, there would be costs to the PCTs to provide these services.

In 2007/08 there were 23,551 local enhanced services provided in England. This equates to 155 services per PCT on average. The most common enhanced service provided was a 'Stop Smoking' service (20% of all services). Statistics on Stop Smoking services for England indicate that the expenditure on Stop Smoking services was £74mn in April 2008 – March 2009. Evidence from NHS IC Stop Smoking Services (2008/9) states that 17% of smokers who set a quit date did so through a Stop Smoking Service provided at a pharmacy. Therefore, £13mn (0.17*£74mn) is assumed to be channeled through pharmacies.

Taking Stop Smoking services as an example for all PCT services, the extra cost of commissioning services as a result of PNAs is £629,000, incurring from year 2. To ensure a conservative net benefit estimate, it has been assumed that 90% of PCTs who have PNAs, are to at least some degree meeting the local pharmaceutical needs for such services. It is assumed that of the 10% of PCTs that do not have PNAs at present, half would now commission new services that would not have otherwise have been commissioned. This leads to extra costs of service provision of £629,000 (0.05*£13mn) for all PCTs from year 2. 'Stop Smoking' service has been taken as a representative service, and has been evaluated for health benefits (see below under Benefits).

Costs of programme evaluation

The Department intends to evaluate the costs and benefits of this option within two years of implementation. This process is intended to promote best practise amongst PCTs, thus reducing costs to PCTs in terms of the time taken to undertake a full PNA. This has an estimated net present value to PCTs of £117,000, where 20 PCTs are included in the evaluation. It is estimated the evaluation would require 20 days of a PCT's senior manager's time (20/225*£60,000=£5,300) and 5 days of administrative support (5/225*£20,000=£400). This will be a one-off cost incurred by PCTs in the second year of implementation.

The results of the programme evaluation are expected to improve the PNA guidance for PCTs, making it easier and quicker for PNAs to be completed, with improved assessment of the local population needs for pharmaceutical services. It is valued as decreasing costs to PCTs of completing PNAs by 5%, due to decreased time taken to complete PNAs. It is also expected to identify best practise at recognising health needs in the population. This is valued as increasing service provision by 5%.

Whilst having tried to estimate total costs in implementing this option, it is possible that further costs could be incurred by PCTs, especially in the commissioning of extra pharmaceutical services. Therefore, costs are a conservative estimate.

PRIVATE BENEFITS

While there are no data to prove conclusively that pharmaceutical needs are not at present met in England, the Department's analysis indicates that variation in service provision is significant and that there is scope to expand enhanced services in some areas, and that the local population would be likely to benefit from those services. It is also reasonable to assume that, at least in the case of the 10% of the PCTs that do not have PNAs, local pharmaceutical services could be better tailored to reflect the needs of their local populations.

For the purposes of this Impact Assessment, and to arrive at a conservative benefit estimate, we have assumed that the delivery of Enhanced Services, where necessary, will contribute to meeting the pharmaceutical needs of the local population. The benefit to patients from one enhanced service has been evaluated, and it has been assumed that this is lost for half of the 10% of PCTs that do not perform PNAs. The benefit from PCTs commissioning pharmaceutical services based on PNAs is the improvement in patient health outcomes for the local population. To achieve a conservative net benefit estimation, we have assumed that for the 90% of PCTs currently performing PNAs there is no additional positive effect in terms of improved health outcomes that could be gained by improving the quality of the PNAs.

As described earlier, a Stop Smoking Service was the most common enhanced service provided by pharmacies in 2006/07 and 2007/08. The benefits in terms of health outcomes are extrapolated from the QALY benefits of people quitting smoking as a result of the service. According to statistics on NHS Stop Smoking Services April 2008 – March 2009 (published August 2009), 671,259 patients set a quit date through the NHS stop smoking service and 337,054 patients had quit smoking.[7] Pharmacy services helped 116,212 (17%) to set a quit date. The life-time quit rate associated with stop-smoking services is around 7% (taking into account of those who would have quit regardless of a stop-smoking service), and we have assumed this is also the case for patients accessing pharmacy-led services.[8]

[7] Number of patients self-reporting they have successfully quit at 4-weeks from setting a quit date.
[8] The life-time quit rate is estimated from NICE costing template (http://www.nice.org.uk/guidance/index.jsp?action=download&o=35946) and Yudkin et al (2003) 'Abstinence from smoking eight years after participation in randomised controlled trial of nicotine patch', BMJ pp. 327.

The health benefits for each adult who decides to stop smoking are significant. The health benefits are measured in discounted life-years and were calculated by first apportioning quitters into five different age bands (<35, 35-44, 45-54,55-64, 65+). For each age band, the share of smokers quitting in the band, was multiplied by the life year penalty associated with each quit age band. The penalty from smoking is larger for older people, due to larger damage done to the body. The numbers of life years lost if a smoker were to quit today were subtracted from the values of the number of life years lost from smoking at a given age. This gives the number of life years that could be reclaimed if the smoker were to stop smoking at their current age. Valuing a life-year at £60,000, the benefit for adult men from quitting smoking at their current age is £82,000 (1.36 extra life years), and for adult women £67,000 (1.12 extra life years). This is likely to be a conservative benefit estimate as it does not take into account other externalities that smoking causes (NHS and private expenditure). It also assumes that no harm is incurred by smoking before the age of 35, or benefit from quitting after the age of 65.

The gain to individuals from extra Stop Smoking Services commissioned as a result of PNAs is valued at £30mn taking effect from year 2, since it takes time for services to be commissioned and health benefits to be realized. This takes the average of the life years gained for men and women (1.24 QALYS), and valuing it at £60,000 per QALY. Assuming that 5% of PCTs (half of 10% that have not completed PNAs) now commission Stop Smoking Services, this will increase the number of people accessing Stop Smoking Services by 5%, thereby increasing the number of individuals successfully quitting by 5%. This leads to 400 extra people quitting per annum, saving 500 QALYs (1.24*400), valued at £30mn (500*£60,000).

After the programme is evaluated in Year 2, it is estimated that there would be an increase in benefits of 5% through better targeting of services. This would result in benefits of £32mn per annum from Year 3 onwards (£30mn*1.05), assuming it takes 1 further year for the commissioning of services to be put in practice and health benefits are realized

We have not evaluated the potential benefits from the number of other enhanced services that pharmacies provide, and have made conservative assumptions on the benefits of stop smoking services. It was also assumed that service provision could only be partially improved by those PCTs that do not commission services based on PNAs. The quality and robustness of the PNAs that the PCTs currently base their commissioning decisions on was not taken into account, and it was assumed that local needs are already being met. For these reasons, this benefit estimate is likely to be conservative.

Summary of costs and benefits

		Impact	Value (£/year)	PV 10 years (£)
Benefits	Non-monetised benefits	Robust and effective PNAs will support greater PCT control over pharmaceutical services locally, improved access to and choice of pharmaceutical services for patients as services are more responsive to local needs and a more efficient use of PCT and NHS resources.	-	-
	Improved health outcomes	Patient health outcomes could improve (example of stop smoking services).	Year 2: £30mn Year 3+: £32mn	£264mn
Total Valued Benefits				**£264mn**
Costs	PCT costs for completing PNAs	PCTs to complete PNAs or improve existing PNAs, including costs of revising PNAs when better analysis is available. Also includes Stakeholder group costs.	Year1: £8.6mn Year 4: £4.8mn Years 7 and 10: £4mn	£20mn
	Costs to PCTs of reviewing PNAs	Annual reviews of PNAs are needed whenever a PCT is not completing a PNA in the given year.	Years 2,3,5,6,8,9: £0.3mn	£1.5mn
	Additional service costs.	Costs of providing additional services (example of stop smoking services).	Year 2 £0.6mn Year 3+ £0.7mn	£5mn
	Evaluation of changes	Costs of supporting evaluation will be met by the NHS	One-off: £0.1mn	£0.1mn
Total Valued Costs				**£27mn**
Net monetised benefit- with opportunity cost ratio of 2.4 for all PCT costs				**£200mn**