Annex E

Summary: Intervention & Options

Department /Agency: Department of Health	Title: Impact Assessment of new arrangements under Part IX of the Drug Tariff for the provision of stoma, urology and other appliances	
Stage: Implementation	Version: 5	Date: 23 November 2009
Related Publications: "Proposed new arrangements under Part IX of the Drug Tariff for the provision of stoma and urology appliances – and related services –in Primary Care" June 2008		

Available to view or download at:

http://www.

Contact for enquiries: primaryandacute.part9@dh.gsi.gov.uk **Telephone:**

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

The current arrangements have remained largely unchanged for 20 years. The Department believes that the arrangements do not work in a way that means the NHS achieves value for money. Further, the Regulatory Terms of Service under which dispensing appliance and pharmacy contractors operate are out of step in relation to aspects of clinical governance and quality; the service specification is insufficiently defined to ensure effective standards for patient care; and dispensing appliance contractors and pharmacy contractors are not remunerated in an equitable way for equivalent services.

What are the policy objectives and the intended effects?

We aim to: maintain, and where applicable improve, the current quality of care to patients and provide a consistent level of care; ensure equitable payment to dispensing appliance contractors and pharmacists for equivalent services; achieve clear transparency between what is paid for services and what is reimbursed for items; secure value for money for the NHS; work in partnership to deliver fair prices for the NHS and reasonable returns for suppliers and contractors; facilitate the introduction of innovative solutions; maintain local choice in the provision of services.

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

1. The Current arrangement: Maintaining the current situation for reimbursement and remuneration under Part IX of the Drug Tariff has been considered along with various options.

2. The Department's decision on arrangements reduces the reimbursement for item prices by 2% and specifies services in terms of two types ('essential' and 'advanced'). This decision has been made after several consultations and discussion with stakeholders since 2005 refining the orginal proposals in response to industry and user/patient concenrs while still meeing Government objectives.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? Policy operation will be monitored by the Department and Prescription Pricing Division of the NHS BSA, and will be formally reviewed 3 years after implement (2013/14) or earlier as appropriate.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister: ..... Date:

Summary: Analysis & Evidence

Policy Option: 2	Description: This includes the summary impact of the Department's decision in terms of arrangements for both service remuneration and item reimbursement

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 0.9m	1
Average Annual Cost (excluding one-off)	
£ 15.2m	

Description and scale of **key monetised costs** by 'main affected groups' The decision results in an annual increase in remuneration for services of £19.7m. This decision also results in a reduction of item prices of £4.5m. Subsequently, the net cost to the public sector (NHS) for services and fees, relative to the current arrangements, is £15.2m after implementation of the new arrangements.

A one-off increase of 4.4% to the on-cost scale payable to appliance contractors under the current arrangements, for the six months prior to implementation of the new arrangements, will cost £0.9m.

Total Cost (PV)	**£ 15.2m**

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

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ N/A	
Average Annual Benefit (excluding one-off)	
£ 0	

Description and scale of **key monetised benefits** by 'main affected groups' As described above, the public sector realises a cost in payment of contractors for service provision regarding Part IX appliances. The key benefits under the Departments decision are significant and included under non-monetised benefits.

Total Benefit (PV)	**£ 0**

Other **key non-monetised benefits** by 'main affected groups' Remuneration for specific services will generate transparency for the NHS. Standards will improve regulation and quality. Contractors will be remunerated equitably. Opening the market for services under Part IX will improve competition, choice and subsequent offerings and value.

Key Assumptions/Sensitivities/Risks The analysis is sensitive to likely take-up of advanced services proposed by different contractor groups. The estimates for the impact of introducing the price/fee increase mechanisms for services and products are sensitive to assumptions about growth, the forecast values for the GDP deflator and staff salary increases

Price Base Year 2010/11	Time Period Years 1	**Net Benefit Range** (NPV) **£ N/A**	**NET BENEFIT** (NPV Best estimate) **£ -15.2m**

What is the geographic coverage of the policy/option?			England only	
On what date will the policy be implemented?			April 2010	
Which organisation(s) will enforce the policy?			PCTs	
What is the total annual cost of enforcement for these organisations?			£ 28k	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			N/A	
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?			Yes	
Annual cost (£-£) per organisation (excluding one-off)	Micro **N/A**	Small **N/A**	Medium **N/A**	Large **N/A**
Are any of these organisations exempt?	Yes	Yes	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)					(Increase - Decrease)
Increase of	£ negligible	Decrease of	£ negligible	**Net Impact**	**£** negligible

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Contents

Tables

Background

1. The Department of Health ('the Department') has been consulting with interested parties since October 2005 on the arrangements under Part IX of the Drug Tariff for the provision of dressings, chemical reagents, stoma appliances and incontinence appliances, and where applicable, related services to Primary Care.

2. The first phase concentrated on the provision of dressings and chemical reagents and on information gathering relating to the provision of stoma and incontinence appliances. The review of the arrangements for some dressings and chemical reagents concluded in October 2006. Since that date, the review has continued and has focussed on stoma and incontinence appliances and related services.

3. The Department has been looking at two distinct but related areas of policy reform:

- The Terms of Service that govern the arrangements under which dispensing appliance contractors and pharmacy contractors operate and the remuneration for those services. The governing terms are incorporated in:

    1. National Health Service (Pharmaceutical Services) Regulations 2005 (Statutory Instrument 2005 No. 641); and
    2. The National Health Service Act 1977, The Pharmaceutical Services (Advanced and Enhanced Services)(England) Directions 2005.

- The classification of – and reimbursement for – Part IX prescription products dispensed.

4. The first consultation was initiated in November 2006, with a second round of consultation in September 2007. In particular, responses to the latter highlighted two key requirements: that patient care must be maintained and that any new proposals should have been more affordable than those put forward in the September 2007 consultation. Both requirements were in line with our stated aims. In view of these responses and of discussions held with interested parties in early 2008, the Department published a further consultation entitled "Proposed new arrangements under Part IX of the Drug Tariff for the provision of stoma and urology appliances – and related services – to Primary Care" in June 2008.

5. This final consultation sought views on a number of revised proposals relating to the arrangements under Part IX of the Drug Tariff for the provision of stoma and urology appliances and related services to Primary Care by dispensing appliance contractors and pharmacy contractors. In general, respondents to the June 2008 consultation believed that the proposals reflected the fact that the Department had listened to stakeholders' concerns about the maintenance of patient care and were more affordable to industry. The final views expressed on the last consultation, as with all views to date, have shaped the new arrangements, the standards and requirements of service provision, the remuneration systems, and the regulatory frameworks where applicable.

6. Given the views expressed by industry and user/patient groups, the Department has made a policy decision as set out in this Impact Assessment.

Case for intervention

7. In Primary Care, stoma and incontinence appliances are usually provided to users by a prescription written by their GP or a prescribing nurse. This prescription is then dispensed by one of the following who provide NHS Pharmaceutical Services: a dispensing appliance contractor, a pharmacy contractor or a dispensing doctor.

8. Parts IX A, B and C of the Drug Tariff list appliances that can be prescribed and how much dispensing contractors will be reimbursed for dispensing them. Part IX A lists catheters and non-catheter appliances (such as tracheostomy and laryngectomy appliances, elastic hosiery, irrigation solutions, etc.), Part IX B lists incontinence related appliances (such as incontinence sheaths, tubing and bags, and urinal systems) and Part IX C lists stoma appliance (such as stoma bags and caps and ostomy systems).

9. The Drug Tariff lists over 5,000 different urinary catheters, incontinence and stoma appliances and related products. The broad split by NIC[1] related to total Part IXA, B, C prescription items dispensed by both dispensing appliance contractors and pharmacy contractors is: Part IX A-catheter (3%), Part IX A-non catheter (78%), Part IX B (7%), and Part IX C (12%).

10. Part IX of the Drug Tariff sets out what these contractors will be reimbursed for an appliance. In the case of dispensing appliance contractors (DACs) and pharmacy contractors (PCs), the Tariff also sets out what they will be paid for services. Dispensing doctors dispense NHS prescriptions in accordance with The Statement of Financial Entitlements made in section 28T of the National Health Service Act 1977 signed on 30 March 2005 as amended; we do not propose to change their current arrangements with this announcement.

The Current Arrangement

11. The analysis in this Impact Assessment compares the impact of the Department's decision against the current arrangements under which dispensing appliance contractors and pharmacy contractors operate in providing stoma and urology appliances and related services to Primary Care.

12. The arrangements for reimbursing these products and remunerating services have remained largely unchanged for 20 years. The Department believes that the arrangements do not work in such a way that the NHS achieves value for money, and users of appliances know what services are available to them – and that such services are provided to the same standard. Currently, for instance:

- The Terms of Service under which dispensing contractors operate are particularly generic ill-defined? in relation to aspects of clinical governance and quality;
- The service specification is insufficiently defined to ensure consistent standards for patient care; and
- Dispensing appliance contractors and pharmacy contractors are not remunerated in an equitable way for equivalent services.

13. The previous mechanism for item price increases has been suspended since April 2006.

[1] The NIC (Net Ingredient Cost) is the overall value that a dispensing appliance contractor or a pharmacy receives for dispensing a drug or an appliance before discounts. The NIC is obtained by multiplying the number of prescription items dispensed by the price listed in the Drug Tariff for each of the items dispensed.

The Aims of the Department

14. The Department's policy announcement seeks to:

- maintain, and where applicable improve, the current quality of care to patients – and provide a consistent level of care;
- ensure equitable payment to dispensing appliance contractors and pharmacists for equivalent services;
- achieve clear transparency between what is paid for services and what is reimbursed for items;
- secure value for money for the NHS;
- work in partnership to deliver fair prices for the NHS - and reasonable returns for suppliers and contractors;
- facilitate the introduction of innovative solutions;
- maintain local choice in the provision of services; and
- keep administration arrangements to the necessary minimum.

15. In particular, the Department's policy announcement seeks to open up the market for services. For example, by extending payment to pharmacy contractors for similar services in relation to Part IX appliances, the Department is potentially opening up services to more than 10,000 contractors. Improved competition will likely benefit innovation, service quality, and cost. The greater volume of suppliers of services will benefit the NHS and users of appliances providing greater choice and value.

16. The new arrangements further aim to advance the quality of services by defining standards and regulations. The current service expectations and specifications need to be better defined and the current terms of service are particularly generic and ill-defined in relation to aspects of clinical governance and quality required by dispensing contractors. Revised arrangements are required which clearly delineate the essential services and advanced (optional) services when providing Part IX appliances, and the Regulations and Directions should define the standards, content, and regulatory framework in providing the fees. The new arrangements should aim to ensure a standard of quality, and thus improve the equality of services across postcodes, and further define benchmarks to which contractors are accountable.

17. The Department's decision is described below.

The Department's decision

18. Over the course of the consultation process which started in 2006, the Department has presented a number of proposals.

19. The key factors of the Department's decision on arrangements are related to two strands of policy and are set out as follows.

20. On *service remuneration*, the following policies relate to dispensing appliance contractors and pharmacies only. What dispensing doctors will be paid for related services is set out in The Statement of Financial Entitlements made section 28T of the National Health Service Act 1977 signed on 30 March 2005 as amended. The Department does not propose to change this arrangement with this announcement.

- The on-cost allowance and all fees that dispensing appliance contractors (DACs) receive currently will be replaced by new arrangements – arrangements that create

greater transparency between remuneration for services and reimbursement for items;

- The current service remuneration structure for pharmacies will be maintained, with a few additions;
- Funding for the remuneration of services provided by DACs and pharmacies in relation to the dispensing of Part IX appliances will be increased by c. £19.7 million;
- In the normal course of their business, both DACs and pharmacies will dispense Part IX prescription items as an essential service as part of their terms of service. They will receive a 90p professional dispensing fee for each Part IX prescription item dispensed.
- As an additional dispensing service, both DACs and pharmacies will provide home delivery for qualifying items in Part IXA[2] and all items in Part IXB and Part IXC of the Drug Tariff, if so requested by the user. DACs and pharmacies will also provide, where necessary, a reasonable supply of complimentary wipes and disposal bags for the categories of prescription items in Part IX A, Part IX B and Part IX C listed in the Drug Tariff at the time of implementation. For the provision of these services, DACs and pharmacies will receive £3.40 for every Part IXA (qualifying items), Part IXB and Part IXC item dispensed. In dispensing Intermittent Self Catheters (ISCs), contractors will receive a total postage allowance at a rate of £9.44 per prescription item;
- Fees for dispensing elastic hosiery and trusses that require measurement and/or fitting, currently paid to pharmacies, will also be paid to DACs. The fee will be £2.60 per prescription item for all contractors;
- The fee per Part IXC prescription item for stoma customisation will not be subject to a cap but will only be paid for items that are actually customisable and the fee will be £4.32 per item;
- Appliance Use Reviews (AUR) – formerly known as specialist nurse visits – may be carried out at either the patient's home or at the DAC's or pharmacy's premise;
- Remuneration for each AUR carried out at the patient's home will be £54 and £27 for each AUR carried out at the DAC's or pharmacy's premise.
- The number of AURs declared in any year (April to March) must not be greater than one for every 35 Part IXA (qualifying items), Part IXB or Part IXC prescription items dispensed in that year;
- A mechanism similar to that used for fees paid to pharmacies will be introduced (related to the GDP deflator,[3] NHS efficiency targets and salary increases) which allows fees to be reviewed on an annual basis; and
- A new infrastructure payment system will be introduced for dispensing appliance contractors, which pays a fee according to a banded payment structure, without cap, based on the volume of all Part IX prescription items they dispense. The bands and fees are as follows:

[2] Selected items under Part IXA that qualify for the home delivery fee include: catheter, laryngectomy and tracheostomy, catheter accessories, catheter maintenance solutions, anal irrigation system, vacuum pumps and constrictor rings for erectile dysfunction, and wound drainage pouches. Throughout this document, "Part IXA(qualifying items)" will refer to this list of items.

[3] GDP deflator is a publicly available index that is a measure of inflation. It is published by HM Treasury.

Table 1: Infrastructure payment fees

Band Identifier	Number of Part IX prescription items dispensed in one month	Infrastructure Payment fee (Band A fixed payment, Band B, C, D fee per item)
A	1 – 10	£150.00 (fixed)
B	11 – 1,000	£13.60/item
C	1,000 – 35,000	£2.40/item
D	>35,000	£2.30/item

This payment system was designed to support the contractor's overhead costs, accommodate the changes and demands from the new arrangements, and allow continuation of the provision of services without disruption to patients. Since dispensing appliance contractors currently vary widely in regards to size, service model, existing infrastructure, etc., the new infrastructure payment system has been designed using inputs from several consultations and discussions with stakeholders. This system has been broadly accepted as fair and equitable.

- An expensive prescription fee, currently paid to pharmacy contractors, will be extended to dispensing appliance contractors and applied to all Part IX prescription items with a NIC value greater than £100.[4] The fee will be a rate of 2% of the prescription item NIC value.

21. The related amendments to Regulatory Terms of Service for dispensing appliance and pharmacy contractors are set out in The NHS (Pharmaceutical Services) (Appliances) (Amendment) Regulations 2009. The changes to services to include advanced services such as stoma customisation and Appliance Use Review are set out in The Pharmaceutical Services (Advanced Services) (Appliances) (England) Directions 2009.

22. With regards to *product reimbursement*:

- Reimbursement for all Part IXA (catheter) , Part IXB and Part IXC items listed in the Drug Tariff will be reduced by 2%;
- Companies with a combined NIC – including Part IXA (catheter), Part IX B and Part IXC items – of less than £5.6 million per annum may apply to the Prescription Pricing Division (PPD) for an exemption from this reduction;
- An annual pricing increase mechanism will be introduced six months from the date that any new arrangements come into effect; and
- The item price increase mechanism will be related to the GDP deflator minus Factor X, where Factor X is set to 0.75 and subject to review.

23. With regards to *implementation* of service remuneration and the Terms of Service, existing dispensing appliance contractors and pharmacy contractors will have six months to comply with the new regulations from the time that the arrangements come into force, unless they choose to participate in the new directed services. If contractors opt to provide advanced services as regulated in the Directions, then they must be in compliance with the Directions prior to initiating those services.

24. With regards to *implementation* of item reimbursement, any new arrangements relating to reimbursement for items will come into effect at the same time as the changes to the Regulations.

[4] Expensive item fees are paid on each prescription item with a NIC value greater than £100, not on each prescription form dispensed.

25. The following sections of this Impact Assessment set out the benefits, cost, assumptions and risks related to the two key strands of the Department's decision – service provision and remuneration, and product reimbursement – compared to the current arrangements. This analysis is based on discussion and responses received through the course of consultations.

Service Remuneration

The Current arrangements

26. The Department's decision changes the Terms of Service as laid out in the National Health Service (Pharmaceutical Services) Regulations 2005 and arrangements for remuneration of services relating to appliances in Part IX of the Drug Tariff. In essence, this entails that the Department will move to a 'payment for service' and away from a general mark-up or 'on-cost' allowance on the Net Ingredient Cost of products provided by dispensing appliance contractors.

27. Pharmacy contractors and dispensing appliance contractors are included within the scope of this announcement, whilst dispensing doctors are not included.

28. Dispensing appliance contractors have been remunerated for service provision via a mark-up on the cost of appliances dispensed from Part IX of the Drug Tariff and a number of relatively small service fees:

- The mark-up, or 'on-cost' allowance, is based upon a sliding scale of the number of products dispensed, but generally averaging 17% of the Net Ingredient Cost of the products.[5] The 'on-cost' totalled around £37.0m in 2007/08 across Part IXA, Part IXB and Part IXC products. Of note, as the 'on-cost' allowance is applied regardless of the type of item dispensed, contractors may receive payments for service they do not provide.
- Contractors receive a small dispensing fee as contribution to costs of 2p per Part IX item dispensed; and
- They may also receive a number of relatively small service fees – for example, a small fee that varies from 5p to 78p for elastic hosiery and trusses – but these contributions are also negligible.[6]

Subsequently, for the range of services provided by dispensing appliance contractors, the bulk of remuneration is derived from the on-cost allowance of £37.0m.

29. Pharmacy contractors currently do not support the extent of services in relation to Part IX appliances. However, for the services they do currently provide, they are paid per item, rather than through on-cost. For example:

- Pharmacy contractors currently dispense Part IX appliances. They receive a professional dispensing fee of 90p for each prescription item dispensed from the Drug Tariff.[7]
- They receive a fee per expensive prescription dispensed;
- They also receive fees for elastic hosiery and trusses that varies between 128p and 197p; and
- They receive support for infrastructure (which may support service provision for Part IX appliances) via Establishment and Practice Payments, for example.

30. Under current arrangements then, both pharmacists and dispensing appliance contractors dispense Part IX appliances and provide some services. Table 2 below emphasises the disparity in how the different contractors are paid in the current payment system.

[5] See Table at Part VIB ("On cost Allowance" scale) of the Drug Tariff
[6] The remuneration of small fees for appliance contractors (e.g. dispensing fees, hosiery and truss) in 2007/08 totalled c. £80k.
[7] See clause 6A in Part II of the Drug Tariff

Table 2: Current sources of remuneration for different contractors

Source of Remuneration	Dispensing Appliance Contractors	Pharmacy Contractors
On-cost allowance	√	-
Professional dispensing	negligible	√
Fees for other individual services in relation to Part IX appliances	negligible	negligible
Expensive Prescription Fee	-	√
Infrastructure Payment	-	√

31. As pharmacy contractors do not receive the 'on-cost' allowance and dispensing appliance contractors receive a lower-value dispensing and hosiery fee (and no expensive prescription fee), this means that payments to dispensing appliance contractors and pharmacy contractors in relation to services are not made on a consistent basis. Moreover, although some industry-wide, voluntary service standards exist (such as developed by Patients Industry Professionals [PiPs] Forum), no detailed mandatory service standards exist. This means that one user may receive different services or a different standard of service from another user for the same prescription.

Coverage of the Department's decision

32. The Department announces two levels of provision: 'essential' services that dispensing appliance contractors and pharmacy contractors must provide, and 'advanced' services which these contractors may choose to provide.

33. Every dispensing appliance contractor and pharmacist in England must provide several 'essential' services:

- A dispensing service;
- A repeat prescription service;
- A dispensing referral;
- Home delivery and complementary supplies of disposal bags and wipes; and
- Provision of expert advice to improve the patient's knowledge and use of the specified appliance.

34. Dispensing contractors may choose to provide two 'advanced' services:

- The customisation of stoma appliances; and
- Appliance Use Reviews – formerly referred to as *specialist nurse visits*.

35. The fee for home delivery and complementary supplies of disposal bags and wipes will be extended to include Part IXA (qualifying items) as well as Part IXB and Part IX C items.

36. In the consultation documents published in November 2006, September 2007 and June 2008, we proposed that remuneration should be linked directly to service provision – and that dispensing appliance contractors and pharmacists should receive similar levels of payment for the provision of similar services. This objective remains unchanged and the new approach can be summarised as follows:

- Dispensing appliance contractors: replace the ‘on cost’ allowance and all fees with alternative arrangements.
- Pharmacies: maintain the current service remuneration structure with a few additions to the current professional dispensing fee.

37. Under the Department’s decision ‘essential’ services fees will be available on equal terms for both dispensing appliance and pharmacy contractors, to include:

- the professional dispensing fee, applied to all Part IXA, Part IXB and Part IXC prescription items,
- an additional dispensing fee to remunerate for the cost of home delivery and complementary supplies, applied to Part IXA (qualifying items), and all Part IXB and Part IXC prescription items; the Department also introduces an allowance for postage of Intermittent Self Catheters,
- an essential service fee for dispensing elastic hosiery and trusses that require measurement and/or fitting, which is currently paid to pharmacies and will be paid to DACs also, and
- an expensive prescription fee, which is currently paid to pharmacies and will be paid to DACs also.

38. Separate fees are introduced for each of the ‘advanced’ services:

- stoma customisation (largely flange cutting, but also extended to stoma caps and protectors), and
- Appliance Use Reviews as set out in this document which are extended to Part IX A (qualifying items), Part IXB and Part IXC prescription items.

39. Furthermore, dispensing appliance contractors will receive an additional payment – intended to cover elements of essential service provision which are not directly linked to dispensing a prescription item; for instance, operating within a clinical governance framework. This payment will be known as an ‘infrastructure payment’.

40. We are aware that there are a number of other services provided to a comparatively small percentage of the user population, such as an emergency holiday delivery service. We do not propose to include these services in contractors’ Regulatory Terms of Service, but would expect them to continue to be provided since the Department considers these types of services to be ‘differentiators’ for individual contractors within the market, intended to encourage customer loyalty to a particular contractor.

Costs/benefits to users relative to the current arrangements

41. The Department’s decision aims to provide a fairer and more consistent method of remunerating services to users. It will ensure payments are made for specific, defined services valued by users. Moreover, by bringing the payments made by dispensing appliance contractors and pharmacy contractors onto the same basis, the Department aims to ensure equitable payment for equivalent services.

42. All services, both ‘essential’ and ‘advanced’, as described above, will be provided within a clinical governance framework to ensure consistency and quality in service provision as announced under the modified Regulatory Terms of Service. These can be found in The NHS (Pharmaceutical Services) (Appliances) (Amendment) Regulations 2009 and the Pharmaceutical Services (Advanced Services) (Appliances) (England) Directions 2009 ; overall the changes in service specifications are perceived as a benefit to the NHS and appliance users.

43. Enforcing the clinical governance framework may also result in a monetised cost. Though the Terms of Service focus on authorising the Primary Care Trusts to regulate service provision, the new arrangement do not dictate the means or frequency of regulation and audit, and as such, the cost to PCTs under this framework will be variable. Further, many PCTs currently already have such regulatory arrangements in place for each pharmacy contractor which provides services. Subsequently, implementing the new arrangements will likely only result in a small cost relative to the value of improved transparency and oversight. Assuming the additional cost of an annual review[8] of each of the approximately 130 dispensing appliance contractor facilities, all PCTs in totality may incur approximately £28k in additional costs.

44. The Department believes that the announced policies will: maintain the quality of care to users/patients; widen the choice through which users/patients can seek services and products; provide equal treatment for services provided independently of contractor type; and create value for money for the NHS by specifying and remunerating for the types of service provision valued by users.

Costs/benefits due to changes in remuneration relative to the current arrangements

45. Discussions to date have highlighted that the previous consultation proposals to remunerate for services could imply that dispensing appliance contractors may receive less fees for services than they currently receive from the 'on cost' arrangements. It has been central to the consultation discussions that the overall level and structure of remuneration for services remains appropriate for contractors to continue to provide sufficient patient care and that the Terms of Service remain flexible enough to ensure the viability of services provided by different types of contractors.

46. The new arrangements revise the current arrangements (visualised in Table 2) by removing the on-cost payments for dispensing appliance contractors and introducing a more transparent fee-for-service system; the new arrangements also open up additional services (with equitable remuneration) for both dispensing appliance contractors and pharmacy contractors. The new arrangements can be visualised in Table 3. The Department estimates that the total amount of remuneration provided by the NHS for services for dispensing appliance contractors and pharmacy contractors will rise from current levels by £19.7m.

47. Under plans to devolve the global sum to PCTs then all costs will be met from PCT budgets, and since the estimate of remuneration will rise by £19.7m, this will be the budgetary impact on the PCTs. This is offset by the benefit of the 2% item price reduction, which is estimated to deliver a saving for the NHS of approximately £4.5m per annum relative to the current arrangements depending on the number of small companies seeking an exemption. Lastly, the new arrangements will increase value in terms of equality, transparency, choice and improved standards and regulation of service – delivering additional significant benefits to the NHS and users alike.

48. Whilst the vast majority of contractors will be affected, those noticing the most change will be dispensing appliance contractors (of which there are approximately 130) primarily due to the restructuring of their cost allowances. Pharmacy contractors (of which there are around 11,000) would see increased revenues for the services they provide, as a result of this proposal.

[8] Based on the day rate of an NHS employee at Band 7 (PSSRU, 2007) of £154 per day. Calculations assume approximately 130 DAC premises inspections and approximately 40% additional costs.

49. Given that the new arrangements will not commence until April 2010, a one-off increase of 4.4% in the on-cost payment was given to DACs from October 2009 to March 2010. This recognises that as the previous price increase mechanism has been suspended since April 2006, the on-cost that DACs currently receive has also been frozen – as it is calculated on the total reimbursement they receive for items. The 4.4% equates to the payments that DACs would have received if the new arrangements for essential services had been implemented in October 2009 rather than April 2010.

50. Table 3 provides a breakdown of the estimated remuneration provided by types of contractor and types of service the Department has specified. It can be seen that there is an increase in the overall remuneration relative to the current arrangements for both dispensing appliance contractors and pharmacy contractors.

Table 3: Breakdown of the spend estimated for remunerating services under the Department's decision on arrangements.

Type of service	Service	Remuneration (£m)		
		Dispensing Appliance Contractors	**Pharmacy Contractors**	**All Contractors**
Essential	Infrastructure Payment	20.1	N/A	20.1
	Professional dispensing	4.2	*	4.2
	Additional dispensing	12.8	9.9	22.7
	Expensive prescription	2.8	*	2.8
	Hosiery and Trusses	0.1	0.3	0.4
Advanced	Stoma customisation	4.8	1.0	5.8
	Appliance Use Review	4.6	2.7	7.2
Total under the new arrangements		49.5	13.8	63.3
(Current arrangements)		(43.4)	(0.1*)	(43.4)
Difference relative to the current arrangements		+6.1	+13.7	**+19.7**

* For Pharmacy Contractors, only the aspects of Part IX that will change under the new arrangements are shown. Therefore, the current arrangements figure for Pharmacy Contractors only includes the costs for hosiery and trusses, because the fee for this will change under the new arrangements. The level of remuneration available to pharmacy contractors thorough the dispensing fee and expensive prescription fee will remain unchanged and therefore is not included in this table.

51. For dispensing appliance contractors, examples of remuneration to different sized firms are included in the sections on competition and small firms.

Assumptions underlying the analysis

52. A number of assumptions have been made in calculating the service remuneration fees listed in Table 3. The key assumptions are listed in Table 4.

Table 4: Assumptions underlying the service remuneration fees

Assumption	Source
General	
Volumes of Part IX items and its individual parts will increase in future years at the rate seen in the last three years of available data (5.4% per annum).	Latest available data (up to November 2008) for items dispensed provided by PPD (NHS BSA).
Delivery cost fee	
Delivery cost is based on Royal Mail postage of £3.08	Based on packet tariff (L>353m, W>250m, D>25mm) for weight range 501g to 750g; first class
Complimentary supplies cost assumed to be £0.17 (disposable bags) and £0.29 (disposable wipes).	Based on industry data
95% of qualifying Part IX A, B, and C products require home delivery	Based on industry data
A fee of £3.40 should remunerate home delivery with complimentary supply	£3.40 = (£3.08 x 95%) + £0.17 + £0.29
Delivery of ISC items requires a higher total fee of £9.44	Based on Royal Mail standard parcel tariff £9.44 for a 6kg package
Stoma Customisation fee	
49.3% of Part IX C items dispensed by appliance contractors and 21.8% of Part IX C items dispensed by pharmacy contractors are customisable	Based on industry data.
There is an average of 60 bags per Part IXC prescription item	Based on data provided from NHS BSA PPD
A standard customisation rate is 90 bags per hour	Based on industry data. The assumed rate is the weighted average that takes into account rates of manual cutting (lower weight applied in the calculation) and of semi-automated customisation (higher weight in the calculation)
A work day is 8 hours per day	Based on industry norms
There are 240 working days per year	Based on industry norms
Annual salary of employee performing customisation is £15,400	Based on industry research
The cost of stoma customisation per Part IX C customisable prescription item is £4.32	90bags/hr x 8hrs/d x240d/yr = 172,800bags/yr; £15,400 salary /(172,800bags/yr) = £0.09/bag; £0.09/bag x 60bags/item x 80% = £4.32 per customisable prescription item
Trusses & Hosiery	
Time required for measurement is 10 minutes and fitting is 10 minutes	Based on industry research
Annual salary of employee performing measurement and fitting is £15,400	Based on industry research
The cost of measuring and fitting should be £2.60 per item	1 item/20min x (60min/hr x 8hrs/d x 240d/yr) = 5,760items/year

	£15,400 salary / (5,760items/year) = £2.60/item
Appliance Use Reviews	
Assume 1.5 hours spent per visit including travel time	Based on industry research
Hours and working day assumptions as per customisation calculation	Based on industry norms
Gross annual salary of nurse conducting the visit at £48,000	Based on data for Grade 8A nurse from the Royal College of Nursing
90% of PCs are assumed to provide AUR visits, of which half are provided at the patients' homes and half at the PC premises	Prudent assumption base on industry research
90% of dispensing appliance contractors are assumed to provide AURs, all of which are assumed to be provided at the patients' home	Prudent assumption base on industry research
Travel and administrative costs are £12	Per responses received to the September 2007 consultation
Cost per home visit approximates £54	• (240d/yr x 8hrs/day)/1.5hrs = 1,280 visits/yr • £48,000 salary/1,280 visits = £38/visit • £38/visit + £12 overhead = £50
Cost per visit on the contractor's premises is set at £27	Based on current remuneration for MURs (Medicine Use Review)

53. The Department will introduce an annual fee increase mechanism for elements of the service that are to be remunerated, as stated in the June 2008 consultation document. The annual fee increase mechanism will not be introduced until twelve months after the arrangements related to this consultation come into effect.

54. The overall budget for the service remuneration fees will be increased annually by the value of the GDP deflator plus the increases in staff salaries in excess of the GDP deflator levels[9] and less an efficiency assumption, which assumes contractors' ability to make efficiencies and is consistent with efficiency targets in the NHS as a whole. This is in keeping with current arrangements for the total contract sum for pharmacy contractors.

Risks and mitigation

55. A key policy risk is whether the level of remuneration is appropriate to allow contractors to provide sufficient levels and quality services under the new arrangements. Over the course of discussions with key stakeholders, including user/patient groups, the Department has sought to appreciate the various policy risks. Particular risks were expressed in relation to:

- The proposed level of the additional dispensing fee in terms of covering the full range of delivery costs (e.g. increased Royal Mail costs and the supplemental costs of ISCs);
- Additional dispensing fees not covering users of laryngectomy and tracheostomy products currently receiving home deliveries and the requirement to deliver other

[9] The index that will be used is the LNMM – whole economy NSA including bonuses, used by the Office of National Statistics. The same index is used with the pharmacy contractors.

items (catheter accessories, catheter maintenance solutions, etc.) out of patient necessity or convenience;
- The effect of the cap on stoma customisation in terms of patient care or the requirement to customise other items such as stoma caps and protectors;
- The increased time actually required to measure and fit hosiery and trusses;
- The effect of the cap on AURs to the patients in terms of patient care;
- The proposed fee to remunerate AURs, which should also take into account additional costs such as travel and administrative costs;
- The infrastructure payment structure, specifically the fee structure and the existence of the cap;
- The lack of expensive prescription fee for DACs;
- The lack of a fee increase mechanism for services; and
- The need for sufficient time for contractors to prepare for the new arrangements after such arrangements had been made public.

56. Following evaluation of responses to the last several consultation documents and discussions with stakeholders, the Department has sought to address those policy risks by:

- Increasing the additional dispensing fee to £3.40;
- Extending home deliveries to include Part IX A (qualifying items) as well as all products in Part IXB and Part IXC;
- Removing the cap on stoma customisation fees and extending the fee to customisable stoma caps and protectors;
- Extending the hosiery and truss fee to DACs and increasing the rate to £2.60 per item requiring fitting;
- Extending the AURs to additional qualifying items and lowering the AURs cap to one review for every 35 Part IXA (qualifying items), Part IXB and Part IXC prescription items dispensed in a financial year;
- Increasing the fee for reviews at the patient's home to £54;
- Modifying the infrastructure payments and removing the cap. This is reflected in the positive overall impact of the Department's decision relative to the current arrangements as highlighted in Table 3;
- Extending the expensive prescription fee to DACs, applied to all Part IX prescription items with a value greater than £100, at a rate of 2% of the prescription item value;
- Introducing an annual price review mechanism for elements of the service that are to be remunerated; and
- Introducing a transition period of 6 months following the announcement that will be provided to allow companies to prepare for the necessary changes before implementation of any changes takes place.

57. A general risk over the medium to long term is that the level of service remuneration may be different to that which has been estimated by the Department if there is significant change in demand for Part IX products. In order to evaluate and, if appropriate, react to significant changes in demand, the operation of the policy will be monitored by the Department and the Prescription Pricing Division (PPD) of the NHS BSA, and will be formally reviewed by the Department 3 years after implementation. This does not preclude the possibility of earlier review if there are significant unintended consequences which appear as a result of the policy changes.

Item Reimbursement

The Current arrangements

58. Part IX of the Drug Tariff sets out what dispensing appliance contractors, pharmacy contractors and dispensing doctors will be reimbursed for an appliance supplied against an NHS prescription.

The Department's decision

59. The Department's decision on arrangements includes the following:

- All Part IX A (catheter), Part IX B and Part IX C products will be subject to a 2% price reduction.
- Small companies with an annual NIC value of up to £5.6m per annum may make a voluntary application for exemption or waiver from the implementation of the 2% saving adjustment being applied to their products to the PPD NHS BSA.
- The annual price increase mechanism will not be introduced until 6 months following implementation of the announcement related to this consultation.

.

Costs/benefits due to changes in reimbursement relative to the current arrangements

60. The Department believes that the current level of reimbursement for these products may not represent best value for money for the NHS. Consequently, the Department believes that it is appropriate to reconsider the reimbursement prices in order to deliver an appropriate level of savings benefiting the NHS, whilst reflecting the concerns expressed by industry. To reflect responses received to the consultations to date, as well as discussions with industry, user/patient groups and nurses, we announced a 2% price reduction, which is estimated to deliver a saving for the NHS of circa £4.5m in 2010/11 relative to the current arrangements.

61. The decision results from consultation with stakeholders. Following several consultations and discussions with stakeholders, various areas were explored in order to ascertain how to minimise any potential negative impact of reducing item reimbursement:

- First, regarding the 12% discount proposed in the September 2007 consultation, concerns were expressed in relation to the affordability to companies. These concerns related to companies being able to afford to make available all products that are currently contained within Part IX of the Drug Tariff.
- In addition, the impact of such savings on small companies[10] also needed to be taken into account.

In response to the June 2008 consultation, the majority of respondents appreciated the significant reduction in the discount to only 2% and agreed with the proposal.

62. The Department recognises that the previous agreement regarding the formula for price rises of products listed in Part IX of the Drug Tariff, expired in April 2006.

[10] Small and medium sized enterprises are defined in terms of NIC received as a proxy for turnover. The threshold is defined under "The Companies Act 1985 (Accounts of Small and Medium-Sized Enterprises and Audit Exemption) (Amendment) Regulations 2004" (available at http://www.opsi.gov.uk/si/si2004/20040016.htm) as £5.6m of less for small companies.

63. The Department will introduce a mechanism for price increases. The annual price increase mechanism will not be introduced until 6 months after the arrangements related to this consultation come into effect.

64. The annual price increase mechanism will see an increase in item prices over time by just under general inflation in the economy, defined by the GDP deflator. The decision is to remove the NHS efficiency target and increase price by (GDP minus Factor X), where Factor X is set to 0.75 and subject to review. It is estimated that this should equate to increased reimbursement of approximately £2.2m in the first year and £7.1m in the second year for the first two years of implementation.

Risks and mitigation

65. A key policy risk highlighted over the course of consultations is whether item price savings are affordable to companies. If discounts available in the supply chain decrease as a result of the announced changes, wholesalers may decrease the number of products that they choose to stock, impacting on the speed at which dispensers can obtain products for patients and pharmacy contractor procurement costs. Through discussions with industry the Department believes that the level of item pricing savings decided upon should not have a significant impact on discounts available to dispensing appliance contractors through the supply chain.

66. Small companies with an annual NIC value of up to £5.6m per annum (based on the Companies Act classification 20 of small companies by turnover, where, in this case, NIC is used as the most reasonable proxy for turnover) may make a voluntary application for exemption or waiver from the implementation of the 2% saving adjustment being applied to their products.

Competition Impact

The Current arrangements – current market structure

67. Market price does not play a major role in the primary care market; rather, the role of factors such as innovation and marketing are relatively more important for competition.[11] This is largely explained by the lack of price sensitivity of General Practitioners and continence care professionals, which means that suppliers have little ability to increase sales through lower prices. Thus, whilst on price, the Drug Tariff provides some control over remuneration and reimbursement in the market, this framework has not been reformed for some years despite development in the marketplace.

68. Furthermore, under the current system, the route to market through dispensing appliance contractors differs from the one through pharmacy contractors.

- Dispensing appliance contractors receive as remuneration for services:
  - A mark-up on the cost of the Part IX appliance – known as an 'on cost' allowance. This averages at 17% of the Net Ingredient Cost; and
  - A small fee; this varies between 5p and 78p for elastic hosiery and trusses, and 2p for all other appliances listed in Part IX A, B and C of the Drug Tariff.[12]

- Pharmacists receive as remuneration for services:
  - A professional fee of 90p for dispensing each of the prescription products listed in the Drug Tariff;
  - Additional fees for the measurement and fitting of hosiery and trusses; and
  - A series of payments, notably: establishment payments, practice payments, protected professional allowance payments, repeat dispensing payments, transitional payments and electronic transmission of prescriptions allowances.

69. Some dispensing appliance contractors are run as a combined nursing service and dispensing appliance businesses. In general, dispensing appliance contractors no longer fulfil their original function of supplying a fitting service. They now serve mainly as specialist suppliers of ostomy and continence care appliances. They may employ sales teams, use databases or engage in other types of direct marketing. Some dispensing appliance contractors employ nurses to visit patients in their home and others have now focused on mail order to dispense products. The vast majority of products dispensed by dispensing appliance contractors are ostomy/stoma products and many that concentrate on ostomy are owned by manufacturers; a supplier of continence care or ostomy products derives particular advantages from ownership of a dispensing appliance contractor.

70. The purpose of the new arrangements has been to maintain and sufficiently remunerate home delivery and other services that are valued by patients whilst achieving balance and equity in the system for remunerating services provided by contractors.

71. The current inequality in funding arrangements between pharmacy contractors and dispensing appliance contractors has been recognised by the Competition Commission and the Office of Fair Trading[13] who have both stated that the current remuneration structure for dispensing appliance contractors and community pharmacies

[11] Competition Commission (2002) Coloplast A/S and SSL International plc: A report on the merger situation.
[12] Details of the small fees received by dispensing appliance contractors in dispensing Part IX products are described in Part III of the Drug Tariff.
[13] The Office of Fair Trading (2004), Assessing the impact of public sector procurement on competition.

has made it financially advantageous for a manufacturer to supply products through their own vertically integrated appliance contractor, leading to distortion in the distribution of certain appliances.

72. The prescribing of proprietary products combined with the relative low responsiveness of demand to price (because products are prescribed according to individual clinical need) could in the long term drive up costs for the NHS if the mechanism for remunerating for service and products is not sufficiently transparent.

The Department's decision

73. The Department's decision aims to provide transparency in the method of pricing products and related services. The level of remuneration and reimbursement across pharmacy contractors and dispensing appliance contractors is intended to ensure the supply chain for these products is protected whilst generating savings for the NHS were appropriate.

74. As Table 3 shows, the impact of the Department's decision across contractor groups in terms of service remuneration is broadly positive relative to the current arrangements. Whilst the vast majority of contractors will be affected, those noticing the most change will be dispensing appliance contractors, primarily due to the restructuring of their cost allowances. Pharmacy contractors will see increased revenues for the services, especially if they choose to provide 'advanced' services. The impact on pharmacies' total remuneration is illustrated in Table 3 on the basis of the assumptions outlined in Table 4.

75. The decision aims to provide a more equitable and consistent method of remunerating services to users. It should ensure payments are made for specific, defined services valued by users. Moreover, by bringing the payments made by dispensing appliance contractors and pharmacy contractors onto the same basis, the Department aims to ensure equitable payment for equivalent services and thus enhance competition between contractors.

76. With regards to other competition issues, control of entry is outside the scope of this consultation, but we would ask you to note the following:

- The pharmacy White Paper '*Pharmacy in England - Building on Strengths, Delivering the Future*' published in April 2008 set out a range of proposals and actions the Government will take forward to develop pharmaceutical services. These include proposals for appliance contractors in relation to current control of entry arrangements. These flow from the review Anne Galbraith conducted in 2007 reviewing contractual arrangements which heard evidence from dispensing appliance contractors.
- The Galbraith report draws attention to problems new appliance contractor entrants can face. The White Paper consultation, which closed at the end of November 2008, outlined possible options to be considered further.

'Commercial arrangements'

77. A key aspect of the consultation responses with respect to the impact on competition relates to various arrangements made between contractors. Currently, the different payment structure between pharmacies contractors and dispensing appliance contractors has led to the creation of relationships whereby prescriptions for products are transferred between pharmacy contractors and dispensing appliance contractors. The amendments to the Terms of Service provides that the pharmacy contractors and dispensing appliance contractors must not accept or receive inducements, such as

financial awards, for merely transferring prescription forms to another contractor where no additional service is provided.

78. One of the key strengths of the pharmacy network is its accessibility both in terms of geography and opening hours. Therefore, in order to access a large specialist inventory of stoma and incontinence products the next working day, commercial arrangements may be used by a large number of community pharmacies which is to the benefit of the end-user as it provides greater patient choice.

79. The Department seeks to ensure that the Terms of Service allow flexibility for both pharmacies and dispensing appliance contractors to pass a prescription form to another organisation – including another dispensing contractor – with the patient's consent if they cannot dispense the prescription item.

80. The amendments to the Terms of Service are sufficiently flexible to enable one contractor to retain the prescription form transferred and submit that form to the PPD for the purpose of remuneration.

81. In addition, some pharmacies might not have the level of expert knowledge required to deliver services such as telephone care line information (which has been identified as an important service to patient quality of life). In these circumstances, the amendments to the Terms of Service do not prohibit pharmacies to be able to outsource this care line information aspect of the service to a generic stoma patient care line in order to meet patient service needs.

82. Further, as stated in the pharmacy White Paper, the Government will discuss with representatives of appliance contractors what further action may be needed so that their contractual requirements ensure service delivery is both professional and to high standards and quality.[14]

Marketing and innovation

83. Marketing and innovation are a key part of competition in the market, particularly in the absence of strong price sensitivity among consumers and prescribers. Marketing and new product innovation is an essential part of running an ostomy and/or continence care business. In addition to contact with care advisers, marketing takes the form of free samples to clinics and hospitals, promotional pamphlets, advertising in nursing publications, presence at continence exhibitions and educational visits. Brand names also factor into the marketing of products. Judging by the breadth and strength of the marketing initiative, it appears to be an important part of how firms compete with each other.

84. It is part of the Department's policy considerations that the incentive to introduce new products is not stymied, and remains consistent with wider policy on innovation in the NHS.[15] This concern was raised through recent consultation responses from industry and also patient/user groups. As part of the Department's decision, the mechanism for introducing new and innovative products will not change. Manufacturers are free to inform the PPD of new products that they consider should demand a premium price on the Drug Tariff. Availability of specialist and innovative products has been identified as important to quality of life through discussions with patient groups. If a company can demonstrate the innovation then it can negotiate through the current mechanism a price which is cost effective for the NHS and provides a fair return to industry.

[14] ibid, page 100, paragraph 7.55
[15] Innovation for Health: making a difference" Strategic Implementation Group, DH, March 2007

Small Firms Impact

85. Micro, small and medium-sized enterprises are socially and economically important, since they represent 99% of all enterprises in the EU and provide around 65 million jobs and contribute to entrepreneurship and innovation. However, they face particular difficulties which the EU and national legislation try to address by granting various advantages to smaller firms.[16] Overall, the Department's preferred option has a relatively beneficial impact on smaller firms.

86. Regarding the proposals for service remuneration, the vast majority of small businesses impacted by this change are pharmacists. The impact on pharmacists as a group is illustrated in Table 3. In addition, the exemption of small businesses from the 2% price adjustment ensures any adverse impact on small businesses is minimised and in some cases eliminated.

87. Table 5 illustrates the various service remuneration amounts received by typical businesses of differing sizes in terms of the amount of products dispensed. The last row shows that the level of remuneration per item tends to be higher for smaller contractors. This, however, is a stylised illustration of the levels of remuneration expected.

88. Examples 1 to 8 show the impact by size of business in terms of levels of dispensing. Examples 9 and 10 are variations on examples 3 and 4, intended to illustrate the impact of dispensing higher or lower proportions of stoma products.

[16] European Commission (2003) SME User Guide explaining the new SME definition, available at http://ec.europa.eu/enterprise/enterprise_policy/sme_definition/index_en.htm.

Table 5: Stylised examples of annual impact for single-license contractors

	Example	1	2	3	4	5	6	7	8	9	10
	Indicative business size	**Micro**	**Micro**	**Small**	**Small**	**Medium**	**Medium**	**Large**	**Large**	**Small**	**Small**
Volumes	**Total lines dispensed of qualifying[17] Part IX A, B and C items, annual**	**900**	**7,000**	**15,000**	**60,000**	**200,000**	**400,000**	**700,000**	**1,000,000**	**15,000**	**60,000**
	% of Part IXC customisable items	**75%**	**75%**	**75%**	**75%**	**75%**	**75%**	**75%**	**75%**	**25%**	**25%**
	Part IXC customisable items	**675**	**5,250**	**11,250**	**45,000**	**150,000**	**300,000**	**525,000**	**750,000**	**3,750**	**15,000**
Fees Remunerated[19]	**Number of Appliance Use Reviews (AUR) remunerated[18]**	**25**	**200**	**428**	**1,714**	**5,714**	**11,428**	**20,000**	**28,571**	**428**	**1,714**
	Professional Dispensing fee [rate £0.90 per Part IX item]	**£810**	**£6,300**	**£13,500**	**£54,000**	**£180,000**	**£360,000**	**£630,000**	**£900,000**	**£13,500**	**£54,000**
	Additional dispensing fee [rate £3.40 per qualified item]	**£3,060**	**£23,800**	**£51,000**	**£204,000**	**£680,000**	**£1,360,000**	**£2,380,000**	**£3,400,000**	**£51,000**	**£204,000**
	Supplemental postage allowance[20] [£5.90 more per ISC, for total £9.30]	**£432**	**£3,357**	**£7,194**	**£28,775**	**£95,915**	**£191,830**	**£335,703**	**£479,576**	**£7,194**	**£28,775**
	AUR fee[21] [£54 per home visit]	**£1,350**	**£10,800**	**£23,112**	**£92,556**	**£308,556**	**£617,112**	**£1,080,000**	**£1,542,834**	**£23,112**	**£92,556**
	Customisation fee [£4.32 per customisable item]	**£2,916**	**£22,680**	**£48,600**	**£194,400**	**£648,000**	**£1,296,000**	**£2,268,000**	**£3,240,000**	**£16,200**	**£64,800**
	Infrastructure payment (£)	**£12,408**	**£95,368**	**£170,568**	**£278,568**	**£614,568**	**£1,094,568**	**£1,786,568**	**£2,476,568**	**£170,568**	**£278,568**
	Expensive prescription fee[22] [2% of the NIC of items >£100]	**£540**	**£4,200**	**£9,000**	**£36,000**	**£120,000**	**£240,000**	**£420,000**	**£600,000**	**£9,000**	**£36,000**
	TOTAL, annual (£)	**£21,516**	**£166,505**	**£322,974**	**£888,299**	**£2,647,039**	**£5,159,510**	**£8,900,271**	**£12,638,978**	**£290,574**	**£758,699**
	Total per item (£)	**£23.91**	**£23.79**	**£21.53**	**£14.80**	**£13.24**	**£12.90**	**£12.71**	**£12.64**	**£19.37**	**£12.64**

89. Overall, the Department's decision has a modestly favourable impact on the remuneration and reimbursement received by smaller companies.

[17] These examples consider contractors dispensing an annual volume of Part IX A (qualifying items) as well as all products in Part IXB and Part IXC. For the purpose of the examples, we assume that all dispensed Part IX A items are "qualifying" items.
[18] Assumes execution of 1 AUR for every 35 of the Part IX (qualifying items), Part IXB and Part IXC items.
[19] The hosiery and trusses fee has been left out intentionally due to relatively negligible volumes and impact.
[20] In2007/08 there were 224,184 ISCs dispensed by DACs, resulting in a generic rate of 7.94% of all items qualifying for supplemental postage allowance of £6.04 per item. The *total* delivery fee for ISCs is £9.44, but in these examples, since £3.40 is already paid under the additional dispensing fee, this amounts to supplementing £6.04 *more* per ISC, where £3.40 + £6.04 = £9.44.
[21] Assumes all AURs are conducted at home (the assumption made for DACs) at the rate of £54/visit
[22] In 2007/08, the total NIC of items with NIC over £100 dispensed by appliance contractors was £120,445,202. Based on the 2% fee of the NIC value, this would have resulted in a £2.4m/yr spend. This equates to a generic rate of an additional fee of £0.60 per item dispensed.

Health Impact

90. Stoma and incontinence care is an essential health service for patients in England who have a stoma or have become incontinent, typically through cancer, multiple sclerosis, bowel disease or other serious illness or accidents. Over 450,000 patients are currently using stoma or incontinence appliances.

91. The character of the patient population (examined further in the 'Equality Impact' section) is that many face a long-term condition which often implies that:

- These patients are the most intensive users of the most expensive services;
- Numbers are increasing due to factors such as an ageing population, health inequalities and certain lifestyle choices that people make; and
- These patients are not just high users of primary and specific acute services, but also social care and community services and urgent and emergency care.

92. It is likely that the number of items related to Part IXA (catheter), Part IXB and Part IXC of the Drug Tariff and level of dependency will increase with the ageing of the population. Maintaining, and where possible improving, the quality of care to the patients is a key objective of the Department's decisions.

Incontinence/urology conditions and their implications for patients

93. It is estimated that over three million people in the UK have some degree of incontinence or other urological conditions. Although urinary incontinence becomes more common as people get older, it does not only affect older people. It is twice as common in women as men and is more common in women who have had children. There are various types of incontinence – stress incontinence generally being the most common. Reported prevalence rates of urinary incontinence for older people in acute care are scant but have remained constant at 30 to 40 per cent.[23] Prevalence in long-term care is identified at 60 per cent by the Royal College of Physicians.[24]

94. Some of the possible causes of urinary incontinence are:

- Physical disabilities or mobility issues that prevent patients getting to the toilet in time.
- Side effects of drugs patients are taking, particularly drugs that cause them to produce or retain more urine or blood pressure drugs that relax the sphincter.
- Constipation (a full rectum can affect bladder function by direct pressure).
- Untreated diabetes.
- Having surgery in the pelvic area including hysterectomy.
- Having a tumour or lump in the pelvic area.

95. Some of the possible causes of stress incontinence are:

- Damage to muscles around pregnancy.
- Being overweight, which consequently puts stress on the muscles.
- Injuring or straining the area when giving birth to a child or children.
- The weakening of the muscles as one ages, especially after the menopause.

[23] Fasing, 1996; Mason and Tully, 2002
[24] Royal College of Physicians (1995) audit

96. Some of the possible causes of urge incontinence are:

- Infections of the bladder or urinary tract, including cystitis.
- Sphincter disorders or neurological disorders that affect the nerves including stroke, Parkinson's disease, brain tumours, Multiple sclerosis, spinal cord injury.
- Forms of dementia such as Alzheimer's disease.
- Blockages caused by bladder stones or very occasionally tumours.
- An irritable or unstable bladder where the bladder muscle tightens from time to time, pushing out a little urine into the top of the urethra where the sphincter helps to keep the tube closed. The pressure of urine at this point causes a strong desire to relax the sphincter and pass urine.
- Overflow incontinence occurs when the bladder fills but because of an obstruction such as an enlarged prostate gland, it cannot be emptied normally. Once full, the bladder overflows and leaks small amounts of urine on an almost continuous basis.

97. Incontinence can thus affect every aspect of life. Those affected often feel anxious, ashamed, inadequate or embarrassed. It is essential that when those with incontinence seek help, there are sufficient pathways for them to receive support, followed by the necessary steps to receive further consultation and investigations appropriate for their individual needs.

Stoma/ostomy conditions and their implications

98. Stomas are commonly necessary in sufferers of inflammatory bowel disease, including Crohn's disease and ulcerative colitis. They are also formed during operations for bowel cancer, bladder cancer, familial adenomatous polyposis, diverticular disease and after accidental damage to the bowel wall or trauma. Urostomies are not common and are performed if there is a problem that prevents urine produced by the kidneys from reaching the outside of the body. Such problems can arise because of cancer, or pelvic or abdominal surgery.

99. Stoma surgery itself represents a major change in the patient's life. The patient is in a position where they have to cope with a complex 'roller-coaster' of emotional, social and physical problems associated with a newly formed stoma.[25] The critical period after an operation may involve a number of challenges:

- Choosing an appliance/brand can be difficult, as well as dealing with new products.
- There is a need to gain confidence and for family/carers to adjust in order to promote true self-care and independent living, if possible.
- Caring and maintaining an appliance requires learning and time, as well as nursing support, general advice on technique, as well as in selecting appropriate accessory products. There is a certain level of trial and error involved in the process.

100. Most stoma problems are seen in the first year post stoma formation.[26] It is important that patients are informed of any potential problems; these might include leakage, bleeding, diarrhoea and constipation, retraction of stoma, prolapse, herniation and stenosis.[27] Accidents can and do inevitably happen and patients need to be educated in order to prepare for any eventuality. Leakages are generally related to the change in stoma size, shape and function as well as changes in abdominal contours as the patient recovers from their surgery. Weight gain or loss post surgery also has attributing factors. Each stoma problem needs to be assessed as more often than not the problem is found to be

[25] Williams, 2005
[26] Wade, 1989
[27] Taylor, 1999; Black, 2000; Breckman, 2005; Johnson and Porrett, 2005

made up of several associated problems.[28] Each of these can contribute to the overall problem and therefore these need to be considered before appropriate advice and help can be offered. Associated problems might include basic stoma management technique, stoma sizing and diet.

101. Generally, there are a number of issues related to caring and maintaining a stoma and appliances. It may take several months, or even a year, before a patient gets used to the stoma pouch/appliance. Thus, the importance of advice and support, and where possible from family or carers, is important in the first couple of months after operation, particularly as there may be a settling down period of stoma function and the length of this period will vary by type of operation, condition and whether other treatment is required, e.g. chemotherapy.

Department's policy development

102. The health impact of the Department's decision depends on the level of overall remuneration being sufficient to ensure continued provision from dispensing appliance contractors and pharmacy contractors. We believe that the levels of money invested into services under the decision safeguard patient care.

103. In addition, the specification of service fees in terms of 'essential' and 'advanced' services should ensure there are clear standards and transparency in the remuneration provided to contractors.

104. In terms of item price reimbursement, the level of savings being sought by the NHS should not have a significant adverse impact on the commercial viability of contractors and indeed, as outlined in the 'Small Firms Impact' section, the overall thrust of the policy on both service remuneration and item reimbursement favours, in relative terms, smaller contractors. This should ensure patient care is maintained where smaller contractors provide services.

105. The decision aims to provide equity and transparency in the arrangements for reimbursing contractors and consistency in service standards. As stated as part of the 'Competition Impact' section, it is envisaged that pharmacy contractors would benefit by better aligning remuneration with the service they provide, while the amendments to the Terms of Service will provide sufficient flexibility for pharmacies to outsource services to other contractors where this is appropriate in order to maintain patient choice, for example, for the provision of care line services. According to a survey of patients,[29] over 80% of all products received are through home delivery, and half have received telephone care line advice. Two-thirds of users of complimentary supplies and half using telephone care line advice regarded them as 'extremely important to their quality of life'.

106. In the normal course of their business, every dispensing appliance contractor and pharmacy contractor in England should be required to provide expert advice, either at a contractor's premise or via a telephone care line.

107. According to the same patient survey, one-third of those patients receiving appliances also had a nurse visit. Furthermore, of those receiving visits, two-thirds regarded them as 'extremely important to their quality of life.' Unlike in stoma care, few continence nurses are sponsored by appliance manufacturers, therefore changes to the remuneration arrangements are unlikely to have a major adverse impact on the provision of nursing care to these patients. Under the Department's new policy arrangements, as Appliance Use Reviews are intended to complement the care provided by healthcare

[28] Breckman, 2005
[29] Patient's Industry Professional Forum Survey, submitted to the consultation, March 2007

professionals working in the NHS, the specialist nurse – working on behalf of the dispensing appliance contractor or pharmacy – or pharmacist will have to maintain close contact with the NHS healthcare professional looking after the patient. Subject to the outcome of these new arrangements, the Department will wish to reassure itself that a suitable number of dispensing appliance contractors and pharmacy contractors are providing ‘advanced’ services.

Equality Impact

108. This equality impact assessment considers the possible impact of the Department's policy on people according to their gender, race, disability, age, sexual orientation, religion or belief and deprivation. It is clear that incontinence and stoma conditions have a strong association with:

- **Gender** – where prevalence of incontinence is greater amongst women, particularly women who have had children.
- **Disability** – where incontinence and stoma conditions can seriously influence the physical, psychological and social well being of those affected as well as appearing as a symptom of other conditions, including neurological diseases.
- **Age** – where the prevalence of incontinence in particular tends to increase with age.

109. The new arrangements are of potential significance to disabled people insofar as some users of Part IX products may wish to define themselves in some sense as having a physical impairment that has a substantial and long-term adverse effect on his or her ability to carry out normal day-to-day activities if not for the Primary Care service being offered.

110. Patients living with incontinence and stomas have complex needs, with patients experiencing a range of physical, social and emotional problems. Indeed, this policy sits within the Department's wider agenda on long-term conditions. The long-term (Neurological) conditions National Service Framework (NSF) launched in March 2005 aims to ensure the way health and social care services support people to live with long term neurological conditions. Key themes are independent living, care planned around the needs and choices of the individual, easier, timely access to services and joint working across all agencies and disciplines involved.

111. Equally, the NSF for older people[30] centres upon ensuring that services are person-centred and in ensuring older people are treated with respect and dignity. The Department is committed to improving the health and well-being of the population through a health and social care system which: offers a personal service which is person-centred and supports independent living; provides dignity; has sufficiently increased capacity to enable choice; and is fair in providing access to care.[31]

Patient characteristics

112. Incontinence can affect individuals of all ages but is a particular problem in older people and the elderly or those with a mental illness, who may require carer and other support in accessing pharmaceutical services, for example where patients are housebound.

113. In addition, incontinence can be a common symptom of other conditions. For example, bladder/bowel dysfunction problems are estimated to occur in: 40,000 people with Spinal Cord Injury; those with Traverse Myelitis or Cauda Equina Syndrome; those with Spina Bifida (one in a thousand births); three quarters of people with Multiple Sclerosis, half of people following Stroke; some of the 120,000 people with Parkinson's Disease; people with Diabetic Neuropathy; children with congenital urinary tract abnormalities; and women with Fowler's syndrome.[32] Other people will develop continence difficulties due to urogynaecological or urological conditions including cancers in the pelvic

[30] DH (2001) National Service Framework for Older People
[31] DN (2007) About Dignity in Care; DH (2000) Good practice in continence services
[32] Incontact submission to the November 2006 consultation document

region. Many others with continence problems may have an unrelated disability/condition arising with age, such as arthritis or poorer manual dexterity or eyesight. A significant proportion of these patient groups will require, at some stage, the use of Part IX products.

114. Regarding ostomy, a recent multi-national study involving 4,739 patients found that the key factors that affected quality of life in patients with a permanent stoma were length of time after surgery, level of satisfaction with the care provided; confidence in self-care; and a trusting and therapeutic relationship with their stoma care nurse.[33]

115. Table illustrates the various 'equality groups' (e.g. gender, age etc.) considered as part of the equality impact of the consultation proposals and the prevalence of urology and ostomy conditions for these groups.

116. In order to understand these issues further over the course of the consultation, the Department has had meetings with patient/user groups on a number of occasions as well as evaluated responses received to the consultation documents.

[33] Marquis P, Marrel A, Jambon B. Quality of life in patients with stomas: The Montreux study. Ostomy Wound Manage. 2003;49(2):48–55

Table 6: Prevalence of urology and ostomy conditions by 'equality group'

Equality Group	Prevalence and impact on equality groups
Gender (including Trans)	On the whole, there does not seem to be a significant gender related trend in terms of those with stomas. There may, however, be a correlation insofar certain gender groups may experience conditions or diseases (e.g. certain cancers) that can result in an ostomy operations and a resulting stoma. With regards to urology, women are more susceptible; and the incidence increases with age. Figures are difficult to quote with certainty, particularly since there is a level of under-reporting due to stigma. Some studies cite that among 15-64 year-olds, about 3% of males, and up to 10% of women suffer from incontinence. However, in a UK community study, the prevalence of urinary incontinence known to the health and social service agencies was 0.2% in women aged 15-64 years and 2.5% in those aged 65 and over.[34] A concurrent postal survey showed a prevalence of 8.5% in women aged 15-64 and 11.6% in those aged 65 and over. Incontinence was described as 'moderate' or 'severe' in one-fifth of those who reported it and, even among these, fewer than one-third were receiving health or social services for the condition. A survey of women aged over 20 years shows that slight to moderate urinary incontinence is more common in younger women, while moderate and severe urinary incontinence affects the elderly more often.[35] Pregnancy and childbirth can also affect urology conditions. Trans people may have particular needs and sensitivities, especially regarding the way devices are chosen and fitted and the labelling on the products. Trans people may also require temporary continence support following gender reassignment surgery. Healthcare workers may need extra training to be able to support trans people appropriately.
Race	There is little direct evidence of potential impact by race. Although, economic and culturally determined behaviours can impact on patient preferences as well as their ability and support in handling their condition, e.g. social stigma, lack of home support, language barriers. The policy changes are not deemed to impact on current access in terms of race. There may be a risk to access in certain ethnic groups depending on cultural factors, but these ongoing risks would not seem to be exacerbated by the policy change. It will be for the PCTs to ensure that at local level reasonable support in terms of information and services is provided based on the character of the local population.
Disability	Patients typically facing urology conditions tend to suffer from other conditions/injuries creating complex needs, for example: spinal injury (15%); multiple sclerosis (15%); spina bifida (4%); stroke (5%); other neurological diseases, e.g. Parkinson, diabetes (10%); stricture (10%);

[34] Thomas TM, Plymat KR, Blannin J, et al. Prevalence of urinary incontinence. *British Medical Journal* 1980;281(6250):1243–5. From NICE guidelines CG40 (2006)

[35] Hannestad YS, Rortveit G, Sandvik H, et al. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. Sandvik H, Hunskaar S, Seim A, et al. Validation of a severity index in female urinary incontinence and its implementation in an epidemiological survey. From NICE guidelines CG40 (2006)

	BPH/enlarged prostate (15 to 20%).[36] Stomas are commonly necessary in sufferers of inflammatory bowel disease, including Crohn's disease and ulcerative colitis. They are also formed during operations for bowel cancer, bladder cancer, familial adenomatous polyposis, diverticular disease and after accidental damage to the bowel wall or trauma. Therefore, stoma appliance users may typically face a range of other conditions that could imply a need for other types of care support.
Age	Notwithstanding the sizeable number of younger users, both incontinence and stoma appliance users tend to be older. A key issue is that decreasing manual dexterity or eyesight arising in older age can exacerbate the challenges of living with and using various Part IX products. For urology users, this can be an issue of ensuring sufficient cleansing to avoid infection. For stoma appliance users, this can be an issue of ensuring sufficient integrity of the skin around the stoma. The prevalence of incontinence tends to rise with age, since it is correlated with other health conditions (see above). In addition, continence issues can be quite common in children. It has been estimated that over half a million children are affected by continence problems, largely as a result of slow development, congenital problems, spinal injuries or learning disabilities. Older people with dementia and other mental health conditions often have trouble recognising when they need to pass stools or urine. For stoma appliance users, there is greater prevalence with age given the interaction with other diseases (e.g. cancers). However, one should not detract from the prevalence among younger age groups, arising, for example, from a congenital condition. For laryngectomy, the majority of patients are over 50 years and living within community. For tracheostomy, the patient group is difficult to size, but it is clear that there is a very large secondary care/temporary patient population. These types of patients are prone to infection – resulting in high drug dependency.
Sexual Orientation	No impact is anticipated for sexual orientation as a result of policy change.
Religion or belief	No impact is anticipated for religion or belief as a result of policy change. However, one should note the points made under “Race” above. There may be an impact by religious groups if, for example, they are characterised by frequent fasting or other practices that affect diet.
Deprivation	There is considerable evidence that social and economic deprivation leads to low status. In addition, physical and irregular work is a contributing factor in acquiring goods and services in general. There is therefore a need to ensure services are physically accessible to all income groups at a local level.

Meeting general needs

[36] The percentages in parentheses are approximations based on information provided by the BHTA to the consultation, April 2007.

117. The diversity of conditions affecting patients of primary care in this area means that specific medical needs are specialised, but patients in general may seek:

- **Advice on products.** This is particularly the case for stoma patients in the first couple of months after operation where issues around choosing, maintaining and dealing with problems around an appliance are most common. Advice and support is therefore important. This is in addition to the large amounts of valuable information provided by the industry in leaflet and electronically and by family and carers.
- **Care line advice** had been considered very important from survey evidence.
- Availability of **specialist and innovative products** are important to users' quality of life, and product availability needs to meet varying life style differences between patients as well as changes in needs over an individual user's life.
- **Delivery** is a key service given that many products are likely to be bulky or weighty. Patients facing urology conditions typically tend to suffer from other conditions/injuries accounted in Table above. Consequently, many may be frail or housebound. It will be difficult for post operative patients to carry continence/urology products in the first months. Without an essential home delivery service many would require the support of social services, community nurses, home helps and friends and family to visit the pharmacy.
- In addition to the physical aspect of delivery, any form of continence or stoma condition carries with it a huge social stigma. For many customers, **delivery discreetly and directly** to their home is important for social and psychological reasons.
- **Reliability of delivery** of products has been highlighted in consultations.
- Care that is **personalised**. This, of course, arises from a need to be measured and fitted in privacy, giving patients confidentiality and convenience.
- **Ongoing support for some patients** due to changes in body size and shape and those who have recently become patients (e.g. growing children and adolescents, patients with large changes in body weight, twisted pelvis, severe muscle wasting). In these cases, a patient may require more frequent and active support and advice.

118. In addressing these general needs, the Department has developed the policy through consultation and in discussion with industry and patient groups.

The Department's policy development

119. The Department's decision seeks to ensure there is appropriate specification and transparency in the reimbursement for 'advanced' services (including appliance user reviews, stoma customisation) as well as specifying that home delivery, complimentary supplies of disposable bags and wipes and expert advice should be classified as 'essential' and remunerated appropriately.

120. Remunerating home delivery and customisation (where appropriate) sufficiently is a key aspect of the Department's decision and ensuring policy is sensitive to the impact on disabled or vulnerable groups. Accordingly, the Department has modified its policy to increase the fee for additional dispensing and to remove the cap on stoma customisations.

121. The nursing service on many occasions saves patients from needing further overnight hospital admission and/or day case treatment. By the nurse seeing the patient at home for assessment/care/training, there is a saving on secondary care cost and waiting times. These nurses fit the correct products alleviating wastage. Patients are measured and fitted in privacy. Consequently, the patient is given a much improved quality of life. The Department's policy includes two fees to contractors – one fee (£54) for Appliance Use Reviews taking place at the patient's home and another fee (£27) for those conducted at

the contractor’s premises. The Department believes the changes would not seriously affect patients’ ability to access expert nurses or pharmacists who fit surgical products for people with continence problems, but would allow fees to reflect the differences in the underlying cost of the service being provided.

122. Given the importance of availability of specialist and innovative products, the mechanism for companies to invest in and introduce innovative products, which would demand a premium, will not change. If a company can demonstrate the innovation then it can negotiate through the normal mechanism a price which is cost-effective for the NHS and provides a fair return to industry.

123. The operation of the policy will be monitored by the Department and the Prescription Pricing Division (PPD) of the NHS BSA, and will be formally reviewed by the Department 3 years after implementation. The post-implementation review will comprise an evaluation of the service provided by dispensing contractors and consider the possible impact on patient care, including in terms of equality to ensure the policy is not discriminating against any particular patient groups. This does not preclude the possibility of earlier review if there are significant unintended consequences which appear as a result of the policy changes.

Enforcement, monitoring and sanctions

124. The decisions regarding service provision and remuneration will require changes to the systems within the Prescription Pricing Division (PPD) of the NHS BSA.

125. As part of any future system, prescriptions will be transmitted electronically. This should allow efficiency and accuracy in data transmission over the long run. It was decided that dispensing appliance contractors should receive an allowance that will allow them to access and operate the electronic prescription service. This is in line with arrangements already agreed with the pharmacy contractors.

126. The Electronic Prescription Service has been deployed in phases with two releases (Release 1 and Release 2) of ETP Compliant pharmacy systems. The proposed payments are an initial allowance of £2,600 that contributes to: IT systems being in place that have been accredited by NHS Connecting for Health; appropriate network connectivity; and staff training and registration. It is deemed that this is appropriate allowance to compensate for the administrative cost of transition to electronic prescription transmission in the near term. A further allowance of £1,000 will be paid linked to the contractor deploying Release 2 of the Electronic Prescription Service.

127. In addition, an ongoing payment of £200 per month for ongoing operation of the electronic prescription service will be paid.

128. Notwithstanding the changes to IT systems, in terms of overall impact on administrative burden on businesses, it is deemed that this would be negligible. The PPD will remunerate PCs and DACs in the normal way and the information provided for that to take place will only marginally change. Table 7 lists the activities to be conducted by contractors and whether these would change due to the new arrangements.

129. It will be for PCs and DACs to 'maintain records'[37] and for PCTs to conduct 'inspections and access information'.[38] PCTs will wish to consider whether/how they modify their individual compliance strategies in order to meet local needs and to ensure that inspections and information access are consistent with Hampton principles.[39]

[37] See http://www.opsi.gov.uk/si/si2005/20050641.htm#8c
[38] See http://www.opsi.gov.uk/si/si2005/20050641.htm#37a and http://www.opsi.gov.uk/si/si2005/20050641.htm#24c
[39] The Hampton Review (2005) on effective inspection and enforcement laid down principles that "all regulatory activity should be on the basis of a clear, comprehensive risk assessment."

Table 7: Changes in activities and administrative burdens

Service	Activities to be conducted by Contractors		Change in administrative burden on contractor businesses
	Dispensing appliance contractor	Pharmacy contractor	
Professional dispensing	• Record total number of Part IX A, B and C products dispensed • Enter information on monthly electronic return form (FP34) • Submit prescription to PPD monthly along with relevant FP10 forms		No change on current activities
Additional dispensing	Covered within the requirements of the step above		No change on current activities (Automatic payment based on the number of Part IXA (qualifying items), Part IXB and Part IXC prescription items submitted to the PPD, and on number of ISCs dispensed)
Infrastructure payment	Covered within the steps above	Not applicable	No change on current activities
Hosiery & Trusses fee	• Endorse prescriptions relative to hosiery and trusses measured and fitted		Small change for appliance contractors
Expensive prescription fee	Covered within the requirements of the step above		No change on current activities
Stoma customisation	• Declares intent to offer ‘advanced’ services to PPD and PCT • Covered within the requirements of the step above		• Payment effected once contractor declares intent to offer ‘advanced’ services to the PPD and the relevant PCT. • Automatic payment based on the number of customisable Part IXC prescription items submitted to the PPD
Appliance Use Reviews (AURs)	• Declares intent to offer ‘advanced’ services to PPD and PCT • Record number of AURs per month • Enter information on monthly electronic return form (FP34) • Submit form to PPD		Contractors would fill in one box on the FP34C to declare the number of AURs conducted on the contractors premises and the number at the patient’s home.

130. An additional administrative burden will be due to the fact that appliance contractors will now have to comply with governance frameworks (in line with what is already required of pharmacy contractors). Conversely, the PCTs will have the right to access and inspect appliance contractors’ premises. PCTs will wish to consider whether/how they modify their individual compliance strategies in order to meet local needs.

131. The operation of the policy will be monitored by the Department and the Prescription Pricing Division (PPD) of the NHS BSA, and will be formally reviewed by the Department 3 years after implementation. The post-implementation review will comprise an evaluation of the

service provided by dispensing contractors and consider the possible impact on patient care, including in terms of equality to ensure the policy is not discriminating against any particular patient groups. This does not preclude the possibility of earlier review if there are significant unintended consequences which appear as a result of the policy changes.

Rural Proofing

132. Some patients live in rural areas which necessitate a bus trip to the local town to collect supplies. There is evidence that carers prefer to have the home delivery service as this relieves them of the additional task of having to collect from a pharmacy. The Department seeks to ensure the level of remuneration is sufficient to protect home delivery. With respect to dispensing doctors, which provide an important service in rural areas, arrangements will not change with this announcement.

133. PCTs should ensure there is sufficient information and guidance to ensure policy changes are understood for those contractors and businesses affected in rural areas.

Human rights

134. The Department does not envisage any adverse human rights impacts.

Contacts Details

135. Further information on this announcement is set out on the DH website and contact details are primaryandacute.part9@dh.gsi.gov.uk

References

- Black P (2000) Holistic Stoma Care. Bailliere Tindall, Edinburgh
- Breckman B (2005) Problems in stoma management. In Breckman B ed Stoma Care and rehabilitation Churchill Livingstone, Edinburgh
- Cabinet Office (2007) Impact Assessment guidance
- Competition Commission (2002) 'Coloplast A/S and SSL International plc: A report on the merger situation'
- DH (2000) 'Good practice in continence services' DH, 19 April 2000
- DH (2003) 'Infection Control – prevention of healthcare associated infection in primary and community care' NICE, June 2003
- DH (2005) 'Creating a patient centred NHS – delivering the NHS improvement plan' – March 2005
- DH (2006) 'Our Health, our care, our say; a new direction for community services' – January 2006
- DH (2007) 'A recipe for Care: not a single ingredient' - January 2007.
- DH (2007) 'About Dignity in Care' DH, 13 March 2007
- DH (2007) 'Framework for Fairness – Proposals for a Single Equality Bill for Britain' a Govt consultation paper, DCLG, June 2007
- DH (2007) 'Innovation for Health: making a difference' Strategic Implementation Group, March 2007
- DH (2007) 'Our NHS Our future: NHS next stage review - interim report' DH, October 2007
- DH (2007) General Pharmaceutical Services (Annual Bulletin) 2006/07.
- DH (2007) Single Equality Scheme 2007-2010
- DH/HM Government White Paper (2008) 'Pharmacy in England Building on strengths – delivering the future', April 2008
- Dingwall (2008) 'Promoting effective continence care for older people: a literature review' British Journal of Nursing, Vol. 17, Iss. 3, 14 Feb 2008, pp 166 - 172
- Fasing S (1996) Assessment and treatment of urinary incontinence in the hospitalized adult. J Wound Ostomy Continence Nurs 23(5): 269–72
- Johnson A and Porrett T (2005) Discharge planning and supporting patient selfcare. In Porrett T and McGrath A, eds Stoma Care–essentials clinical skills for nurses. Blackwell Publishing, Oxford
- Mason M, Tully S (2002) Urinary incontinence in the older adult care population: effects of knowledge, attitudes and beliefs of nurses on continence management. Perspectives 26(3): 4–9
- Marquis P, Marrel A, Jambon B. Quality of life in patients with stomas: The Montreux study. Ostomy Wound Manage. 2003;49(2):48–55
- National Institute for Health and Clinical Excellence (2006) NICE clinical guideline 40 – Urinary incontinence, the management of urinary incontinence in women
- National Minimum Standards for Care Homes
- National Occupational Standards for health and social care
- National Service Framework for Children, Young People and Maternity Services (Every Child Matters – Change for Children), DH 15 Sept 2004
- National Service Framework for Long Term Conditions (published March 2005)
- National Service Framework for Older People, DH 27 March 2001
- The NHS and Social Care Long Term Conditions Model
- The Office of Fair Trading (2004) 'Assessing the impact of public sector procurement on competition'
- Personal Social Services Research Unit (PSSRU) (2007) Unit Costs of Health and Social Care 2007. University of Kent, Canterbury. http://www.pssru.ac.uk/pdf/uc/uc2007/uc2007.pdf
- Royal College of Physicians (1995) Incontinence. Causes, management and provision of services. A working party of the Royal College of Physicians
- Royal College of Physicians (2005 and 2006) Report of the National Audit of Continence Care for Older People (65 years and above) in England, Wales & Northern Ireland. RCP, London

- Taylor P (2003) Community aspects of stoma care. In: Elcoat, ed. Stoma Care Nursing. Hollister Ltd, Berkshire
- Thomas TM, Plymat KR, Blannin J, et al. Prevalence of urinary incontinence. British Medical Journal 1980;281(6250):1243–5
- Wade B (1989) A stoma is for life. Scutari press, Middlesex
- Williams (2007) ‘Stoma care nursing: what the community nurse needs to know’ British Journal of Community Nursing, Vol. 12, Iss. 8, 03 Aug 2007, pp 342 – 346
- Williams J (2005) Psychological issues in stoma care. In Porrett T and McGrath A eds Stoma Care–essentials clinical skills for nurses. Blackwell Publishing, Oxford

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	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	Yes	No
Rural Proofing	Yes	No

Annexes

< Click once and paste, or double click to paste in this style.>