



**Spinal Injuries Association (SIA)'s
response to consultation on -
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

RESPONSE TEMPLATE

Closing date for responses: 9 September 2008

Please send to: ***Primaryandacute.part9@dh.gsi.gov.uk***

Alternatively, they can be posted to:

Part IX Consultation
 Department of Health
 5th Floor
 New King's Beam House
 22 Upper Ground
 London SE1 9BW

Note: Before submitting your response to the Department, please make sure that it has been saved in a name that will make it easier for us to track. Many thanks.

Respondent Details (Please provide the details of a single point of co-ordination for your response)

Title	Mr
Full Name	John Mansfield
Organisation	Spinal Injuries Association (SIA)
Your Role	Consultation Development Officer (Public Affairs)
Address (including postcode)	SIA House 2 Trueman Place Oldbook Milton Keynes MK6 2HH
Email Address	cfc@spinal.co.uk
Phone Contact	0845 – 678 - 6633

If you are replying on behalf of a group of respondents or a number of organisations, please complete the following information:

Organisations represented within this response	
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Response details

Date of response: 28.8.08	Closing date: 5pm on 9 September 2008
<p>Confidentiality: Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).</p> <p>If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information that you have provided to be confidential. If we receive a request for disclosure of the information we will take full account of your request, but we cannot give an assurance that confidentiality can be maintained. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.</p> <p>The Department will process your personal data in accordance with the DPA and, in the majority of circumstances; this will mean that your personal data will not be disclosed to third parties.</p>	

Views are sought on the following:

A. Proposals regarding Service Provision and Remuneration

- A fee of 90p per Part IXA, Part IXB and Part IXC prescription item dispensed should be paid to DACs.

SIA is of the opinion – as indicated in our response to previous consultation in September 2007 - that all Part IX prescribed items should be reimbursed at a level sufficient for dispensing appliance contractors to cover their costs and guarantee the future level of services on which users depend.

- Additional dispensing fee should be extended to all Part IXA (laryngectomy and tracheostomy) prescription items, in addition to Part IXA (catheter), Part IXB and Part IXC prescription items; the additional dispensing fee should be £3.40 for all those prescription items.

See response to Q 1 (above)

- DACs and pharmacy contractors should provide, where necessary, a reasonable supply of complimentary wipes and disposal bags in relation to the Part IXA (catheter, laryngectomy and tracheostomy), Part IXB, and Part IXC item categories listed in Annexes C2, C3 and C4.

SIA supports this proposal

- A fee should be paid to DACs for dispensing elastic hosiery requiring measurement and/or fitting and trusses requiring measurement and/or fitting, respectively of £1.28 and of £1.97 per prescription item.

SIA has no comments on this issue.

- A new infrastructure payment should be paid to DACs, mainly based on a fee per item system and with a higher cap, resulting in an overall increase in the remuneration level as compared to the proposals set out in September 2007.

SIA welcomes the proposed increase in the remuneration level of fees paid to DACs, for the reasons given in our response to Q 1 (above). We are however concerned that the proposed remuneration for service provision may be inadequate for some DACs to maintain their current level and quality of support provided to users.

- A fee for stoma customisation of £4.32 for every Part IXC prescription item that can be customised should be paid to DACs and pharmacy contractors, and there should be no cap on the number of items eligible to receive the fee.

SIA has no comments on this issue.

- Appliance Use Reviews (AURs) should be conducted, in relation to Part IXA (catheter), Part IXB or Part IXC prescription items, by a specialist nurse – working on behalf of the DAC or pharmacy contractor that dispensed the appliance – or by a pharmacist.

SIA is of the opinion that it is essential that all users of continence and stoma care products should be enabled to have access on a regular basis to professional advice and support on continence management, as well as information on new products and the opportunity to test the usage of such products. This could include an overall assessment /review of the management of their condition as well as testing usage of specific appliances. SIA supported the proposal, in the previous consultation in September 2007, to extend home visits by specialist nurses to all users of Part IX items. We are however concerned at the proposal to include pharmacists in AURs as not all pharmacists will have the required knowledge, skills or experience in continence management to be able to fully provide appropriate support and advice for users of continence supplies and appliances.

- AURs may take place at the patient's home or at the DAC's or pharmacy contractor's premises and should be paid respectively £54 and £27.

SIA is concerned that holding AURs at pharmacy contractor's premises would not always provide an appropriate venue for confidential discussions relating to continence issues. Not all pharmacies will have appropriate facilities to enable demonstrations of continence appliances to take place discretely and in reasonable comfort to ensure the dignity and privacy of service users. Despite disability discrimination legislative requirements, not all pharmacy premises have suitable accommodation, including changing, examination and WC facilities, which are accessible by wheelchair users.

- The total number of AURs that a DAC or pharmacy contractor may claim for should be limited to one for every 35 Part IXA (catheter excluding any catheter accessory and maintenance solution), Part IXB and Part IXC prescription items dispensed in a year (April to March).

SIA is of the opinion that the frequency of AURs should be based on clinical need. The priority should be the needs of the service user and not the cost of the AUR. For the reasons given in considerable detail in SIA's responses to previous consultations on this issue, ongoing assessment and review is an essential component of continence management.

- Specialist nurses and pharmacists conducting appliance use reviews on behalf of a DAC or pharmacy contractor will have to maintain close contact with the NHS healthcare professional looking after the user.

SIA supports this proposal and suggests that following each AUR a summary of the outcome of the review with recommended action, including any changes to prescribed items, is sent to the service user and to their general medical practitioner and/or consultant.

- A fee increase mechanism should be introduced and be as proposed

SIA is of the opinion that linking future changes to prices to NHS efficiency targets through the GDP deflator may result in some products becoming too expensive for manufacturers to produce. This could impact most significantly on the most innovative and technologically advanced products which, whilst more expensive than other products, have enabled users to improve their independence, freedom and quality of life. We therefore support the removal of this proposed link to NHS efficiency targets.

- In regard to the electronic prescribing service, provision should be made in the Drug Tariff for DACs to be able to claim allowances similar to those already agreed with pharmacy contractors

SIA has no comments on this issue.

B. Proposed amendments to Regulatory Terms of Service

- The proposed amendments to the National Health Service (Pharmaceutical Services) Regulations 2005 Regulations and the revised draft Pharmaceutical Services (Advances Services)(Appliances)(England) Directions 2009 capture what the Department is trying to achieve in relation to the services provided by DACs and pharmacy contractors in relation to the dispensing of Part IXA (catheter, laryngectomy and tracheostomy), Part IXB and Part IXC prescription items.

SIA has no comments on this issue.

- It should no longer a requirement that in the case of an urgent supply of an appliance, the prescriber is personally known to the pharmacy contractor or DAC.

SIA has no comments on this issue.

- A DAC or pharmacy contractor should provide home delivery as an essential service to users of Part IXA (laryngectomy and tracheostomy), in addition to originally proposed Part IXA (catheter), Part IXB and Part IXC items.

SIA supports the proposal to extend home delivery to users of all Part IX items.

- A pharmacy contractor or a DAC should not receive rewards solely in return for providing names of alternative dispensing contractors or solely for the referral of the prescription.

SIA has no comments on this issue.

- PCT's inspections should include the auditing, monitoring and analysing of arrangements which a dispensing contractor may have made with another contractor.

SIA has no comments on this issue.

- Expert clinical advice should mean advice given, in respect of appliances listed in Part IX A (catheters), Part IX B and Part IX C of the Drug Tariff, at the dispensing contractor's premise or through a telephone care line, by a person who is suitably trained and who has the relevant experience in respect of the specified appliances.

SIA supports the proposal for persons providing advice to be suitably trained and have relevant experience in continence management, but this should also include clinical advice given during home visits.

- A location for stoma customisation should be a suitable area which is designated for the volume of appliances which may be customised there at any given time.

SIA is of the opinion that such venues should be accessible for wheelchair users and have appropriate changing, examination and WC facilities.

- The possibility to conduct AURs should be extended to any nurse employed or engaged by a pharmacy contractor or a DAC for the purposes of conducting such reviews as well as to a pharmacist.

SIA supports the proposal – as indicated in Q 18 (above) – that clinical advice is only provided by persons with suitable training and relevant experience in the management of continence. We are however concerned - as indicated in our response to Q 7 (above) - that without such training and expertise, not all pharmacists may have the required knowledge, skills or experience in continence management to be able to fully provide appropriate support and advice for users of continence supplies and appliances.

- The AURs can take place also at the contractor's premise, provided the consultation area at that premise is a clearly designated area for confidential consultation which is distinct from the general public area and is an area where both the patient and the pharmacist or specialist nurse can sit down together and talk at normal speaking volumes without being overheard by other visitors to that premise.

SIA is of the opinion that the dignity and privacy of patients must be maintained and supports this proposal. However we note that – as indicated in our response to Q 8 (above) - holding AUR s at pharmacy contractor's premises would not always provide an appropriate venue for confidential discussions relating to continence issues. Not all pharmacies will have appropriate facilities to enable demonstrations of continence appliances to take place discretely and in reasonable comfort to ensure the dignity and privacy of service users. Despite disability discrimination legislation, not all pharmacy premises have suitable accommodation, including changing and WC facilities, which are accessible by wheelchair users.

- The number of total reviews that a dispensing appliance contractor or pharmacy contractor may claim for should be limited to one for every 35 Part IX A (catheter excluding any catheter accessory and maintenance solution), Part IXC and C prescription items dispensed in a year (April to March).

SIA's opinion – as indicated in our response to Q 9 (above) – is that the frequency of AUR s should be based on clinical need. The priority should be the needs of the service user and not the cost of the AUR. For the reasons given in considerable detail in SIA's responses to previous consultations on this issue, ongoing assessment and review is an essential component of continence management and this is defined by the Department of Health (*Good Practice in Incontinence Services DH 2000*) as follows:-

“All patients should have a periodic review of their initial assessment to monitor the effectiveness of their treatment/management plan and to ensure there is adequate clinical improvement.”

C. Reimbursement for items and Classification

- The level of adjustment to the reimbursement for all catheters listed in Part IXA and for items listed in Part IXB and Part IXC should be 2%

SIA is of the opinion – as indicated in our response to previous consultation in September 2007 - that all Part IX prescribed items should be reimbursed at a level sufficient for dispensing appliance contractors to cover their costs and guarantee the future level of services on which users depend.

- Manufacturers whose products have a combined NIC ¹ of less than £5.6 million a year may apply for an exemption from the proposed 2% price adjustment

SIA has no comments on this issue.

- The price increase mechanism should be as proposed

SIA is of the opinion that linking future changes to prices to NHS efficiency targets through the GDP deflator may result in some products becoming too expensive for manufacturers to produce. This could impact most significantly on the most innovative and technologically advanced products which, whilst more expensive than other products, have enabled users to improve their independence, freedom and quality of life. We therefore support the removal of this proposed link to NHS efficiency targets.

- The proposed classification - in particular, the classification groupings and sub category headings:
 - please use the template which can be found in Annex F to highlight any factual errors that the proposed classification may contain, particularly in reference to ‘specialised’ products such as urinal systems in urology and First Generation appliances.

SIA has no specific expertise in respect of the classification of continence products. However, as indicated in our response to the previous consultation, spinal cord injured people are extensive users of and rely upon safe, effective and reliable continence care products to maintain their independence and quality of life. Whilst in the past urological complications, including urinary tract infections, could often lead to hospitalisation and increase the risk of premature death, innovations in continence product design have led to improved standards of health and well being for thousands of spinal cord injured. As indicated in our detailed response to the previous consultation, SIA would seek an assurance that the specific innovative features of individual continence products are fully recognised in any re-classification.

¹ *Net Ingredient Cost (NIC) on stoma and incontinence products dispensed in England in the 12 months preceding the announcement of any new arrangements*

D. Timetable for implementation

- The timetable for implementation for all new arrangements, as proposed.

SIA believes that the implementation date would need to allow six months from the announcement /publication of the decision. Increased resources will be required to ensure communication of any changes to all stakeholders. The DH must ensure the extra funding; personnel and infrastructure are in place to cover the increase in NHS health professionals' workloads, resulting from the implementation of these proposals. If the DH cannot ensure and make provisions for this, the consultation's objectives will be completely contradicted, by a severe reduction in the quality and level of care supplied to the users of these products. It will also significantly reduce patient choice and their quality of life, which is unacceptable.

General comments

Do you have any other comments you would like to make in relation to this consultation?

SIA is concerned, as stated in our previous responses, that this extensive consultation has primarily focussed on issues of cost, rather than considering how services for the users of continence and stoma products can be improved. SIA fully supports the aim of seeking to get the best value for money within the NHS. However, if as a result of a reduction in the level of remuneration companies are forced to either reduce - or even worse - withdraw products or services because they become commercially non-viable, this could cause considerable hardship for many spinal cord injured people and others, who rely on such products and services.

Although we are pleased with many of the improvements made to the latest proposals and commend the DH for addressing many of our previous concerns, we are still worried that certain changes, namely those suggested under Service Provision, will still impact negatively on users.

SIA fully agrees with the views expressed in the Urology User Group Position Statement (July 2008) that, whilst the revised proposals have come a long way to address many of our previous concerns, we still believe that more consideration needs to be given in the specific area of service provision and remuneration, to ensure that choice, quality and consistency of care is maintained for all users.