1. Purpose

This paper represents the conclusions drawn by the Scottish Government following the meetings of the review group established to review the arrangements for the provision of stoma care appliances to patients in the community introduced in April 2006. This paper has been drafted by the Scottish Government (SG) Primary Care Division as a summary of the review group’s discussions.

2. Background

In April 2006, new arrangements were introduced relating to the provision of stoma care products to patients in the community. These involved:

- Establishment of a new service for the provision of stoma care products outwith the traditional Pharmaceutical Services contractual arrangements.
- Introduction for the first time of service standards for all contractors.
- A unitary funding regime for all contractors i.e. previous dispensing appliance contractors and community pharmacists involving a single dispensing fee for all products.
- A formal procurement process to establish specific Scottish reimbursement prices to replace the direct link with English Tariff prices.
- Establishment of specific Scottish procedure before new items are added to the list of the products which may be prescribed.
- Abolition of practice of company employment or company sponsoring of specialist stoma nurses operating within NHS Scotland and their transfer into direct NHS employment.
- Temporary transitional funding from industry to help NHS Boards adapt to the new regime.
- Continued patient access to the service through existing prescription arrangements.
- Patient choice of appliance as selection of prescribed item remains at the clinical discretion of the Clinical Nurse Specialist (CNS).
- Introduction of local implementation groups.
- Establishment of national audit arrangements of patient satisfaction with the service provided.
- Discontinued ad hoc provision of samples and replaced this with the introduction of formal procurement arrangements for purchasing samples in the secondary sector.

3. Review Group Meetings

A review group involving key stakeholders including patient groups, manufacturers, service contractors, community pharmacists, NHS Boards, NHS
National Services Scotland and SG Primary Care Division was established under the chairmanship of Mr Terry Findlay of NHS Greater Glasgow and Clyde. The remit of the group was to:

- Monitor ongoing stoma supply arrangements;
- Review patient experience of the stoma service being provided, using the output from the audit toolkit;
- Provide a forum to discuss issues and concerns; and
- Consider future developments.

The review group met on 7 occasions between November 2006 and January 2009. Minutes of the meetings may be accessed from http://www.sehd.scot.nhs.uk/appliance_contractors/

Mr Findlay left NHS Greater Glasgow and Clyde after the last review group meeting of 2008. The Scottish Government invited Mr David Thomson also of NHS Greater Glasgow and Clyde to be acting Chairman for the review group’s final meeting in January 2009.

In addition to the larger review group meetings, Scottish Government officials met with stakeholders in a series of bilateral meetings between April and June 2009 to focus on the key issues for each group. The meetings were held with patients’ groups, contractors and Board representatives/Clinical Nurse Specialists (CNS’s). A summary of the key issues discussed at these meetings and the Scottish Government’s response is provided as an Appendix.

**Summary of Conclusions**

The Scottish Government has concluded that:

- Patient choice and meeting the clinical needs of patients is at the core of the service. The review group process clarified that there would be no changes to aspects of the service which are fundamental to patients. Review group members want to continue to see improvements to the service delivery arrangements introduced in 2006 but would not welcome further changes to the service. There is therefore no requirement for a formal consultation on service changes.
- There is a need for both local and national audit arrangements. A national audit process will be developed in partnership with all key stakeholders.
- The review process clarified that:
  - The hospital formulary is optional and that no patient would be forced to change from products that work for them to products which are on the formulary.
  - There will be no change to the customisation service.
  - A right to review for patients will be introduced but will be flexible to suit patient needs – it will be optional for patients whether they choose to have a review.
  - The service standards contractors are required to meet in delivery timescales and the provision of accessories will be reinforced and monitored through audit processes.
- There is a need for improved communication and partnership working to monitor service delivery and resolve issues at Board level. This report concludes that
Local Implementation Groups are replaced by more forward looking Stoma Forums which bring together all key stakeholders.

- There is a need to ensure improved value for money. Work will be taken forward with contractors as part of the 2010 tendering process. Where changes are proposed there will be a formal consultation prior to changes being made.

A full set of conclusions can be found at pages 17-20.
SECTION 1
DEVELOPMENTS SINCE THE INTRODUCTION OF NEW ARRANGEMENTS IN APRIL 2006

4. Publication of NHS QIS Audit

In February 2008, NHS QIS published the results of an audit commissioned by the Scottish Stoma Nurses Group to assess the impact of the new stoma contract on the quality of the service on patients and CNS’s and assess patient satisfaction with the service. The full report is available at http://www.nhshealthquality.org/nhsqis/4319.html.

The Executive Summary of the report states that:

"It was reassuring to find that there were no significant differences in the responses to the patient questionnaire between those patients seen before 1st April 2006 and those seen after 1st April 2006. In both years the overall feedback from patients was very positive about the quality of the service they received from the CNS's."

'I have had excellent care and attention from stoma nurse, giving me confidence to accept my condition.'

In addition, the majority of CNS’s said that they felt there had been no change to the quality of service they provided to patients. However, the nurse questionnaire highlighted issues with the new service:

- Concern that patient's choice of appliances was being limited through lack of samples within acute care
- Time spent with patients had reduced
- Reduction in time available for training and education

The results indicate that whilst CNS’s have maintained the standard of the service provided to patients their role has been affected. A third of the CNS’s said that they felt that if they cannot maintain their specialist knowledge and keep up to date with new appliances, then patients could be affected in the long term.

While the audit was helpful, the review group generally felt a more robust national audit was necessary to ensure that the services standards are being fully met. Further mention of audit is at paragraph 8.3. For conclusions see paragraph 10 Improvement in Value for Money.

5. Product Procurement Arrangements August 2008 Onwards

During Spring 2008, National Procurement Scotland completed negotiations with manufacturers of stoma care appliances on prices to apply in respect of items prescribed during 2008-9. These revised reimbursement prices came into force from August 2008. National Procurement have advised that although some cost efficiencies have been achieved as part of this process a number of other
manufacturers/wholesalers did not offer improved prices to NHS Scotland citing a combination of unwillingness to pre-empt the results of the consultation in England and intentions to maintain income following the move to the Scottish unitary dispensing fee. For conclusions see paragraph 10 Improvement in Value for Money.

6. Introduction of Optional Hospital Formulary

An optional national formulary for stoma products was introduced in 2007 and provides for the first time a single national focus for the development of CNS knowledge about prescribable items. The arrangements for this are published at: [http://www.sehd.scot.nhs.uk/appliance_contractors/addproducts.htm](http://www.sehd.scot.nhs.uk/appliance_contractors/addproducts.htm).

The optional formulary is advisory and is used only for new patients in hospitals. The optional formulary provides:

- An objective framework for the assessment of new patients
- A Scotland wide formulary avoids the need for 14 different local NHS Board versions but allows local flexibility in use
- The potential for Boards to standardise and improve the availability of samples of recommended products for patients
- An appropriate balance between product quality and value for money
- Motivation to manufacturers to offer attractive pricing to NHS Scotland
- Greater consistency of prescribing practice by GPs advised by CNS’s as patients progress into the community

Some Boards however already had formularies and they tend to apply the new formulary in different ways. The optional formulary is subject to regular review allowing items to be added or removed as appropriate. A representative group of CNS’s participate in the review and development of the optional formulary and advise National Procurement on the relative suitability and quality of individual products.

A number of review group members raised concerns that the formulary has placed restrictions on the products available to patients. The patient groups were concerned that CNS’s may focus on a limited number of products and not be aware of new products. In addition, they were also concerned that patients may not know that they could access products outwith the formulary. CNS’s confirmed that they were aware that they could order products not on the optional formulary particularly where this met patients’ clinical needs. The Scottish Government confirmed its position that the choice of product for the patient should continue to be a matter of clinical judgement for the clinician specifying the items to be prescribed and that the optional formulary provides a supportive framework for that decision for new patients in hospitals. That decision will continue to be informed by the patient’s view as to which products are most suitable for their particular needs.

Some CNS’s said that not all products are available for prescription, however, it was not possible to provide a clear evidence base for these instances. The availability of products outside the formulary should be emphasised. The Scottish Government agreed to discuss with National Procurement colleagues how often
the products should be reviewed. Community Pharmacy Scotland (CPS) reported that they were comfortable with the concept of working with an optional formulary as this was common practice for community pharmacies.

There were strong concerns amongst some group members that the optional formulary would result in patients being forced to change from their existing products if those products were not on the formulary. There was a call for reassurance that this would not be the case. The Scottish Government confirmed that no patient has been or will be forced to change their products because the products are not on the optional formulary. The CNS continues to be able to prescribe/recommend the prescribing of an alternative product to meet the clinical needs of the patient.

**Conclusion 1** The Scottish Government has concluded that the impending new tenders should confirm the procedures used for the establishment of the optional formulary and for the consideration of new stoma products which manufacturers may wish to offer in addition to the list of items which may be ordered in hospitals or prescribed in the community. See paragraph 10 Improvement in Value for Money.

7. **Consultation on changes to arrangements in England relating to provision of stoma care and other appliances**

A further consultation relating to the provision of appliances to patients in England was launched in June 2008 and closed in September 2008. This consultation extended to a wider range of appliances including continence products and catheters, than is the subject of the current Scottish review.

On 1 April 2009, Department of Health Ministers announced the outcome of their consultation and their intention to put in place new arrangements from April 2010. In summary, their new arrangements look to:

- Define and standardise the services that both dispensing appliance contractors (DACs) and pharmacy contractors provide in the normal course of their business when dispensing Part IX A (catheter), Part IX B and Part IX C appliances. Essential services that must be provided include services such as a repeat prescription service, appropriate advice and a home delivery service - if the Patient requests it. Advanced services, which (DACs) and pharmacy contractors may choose to provide, include stoma appliance customisation and appliance use reviews
- Require appliance contractors to operate within a similar clinical governance framework to pharmacy contractors
- Replace appliance contractor remuneration 'on-cost' arrangements with fees and allowances, which will be laid out in the Drug Tariff;
- Introduce a funding uplift mechanism for remuneration for Part IX related services that is similar to arrangements in place within the community pharmacy contract framework
• Apply a uniform reimbursement price reduction of 2% to the reimbursement prices of all items listed as of 31 March 2010 in the following sections of Part IX of the Drug Tariff:
  - Part IXA catheters: urinary and urethral
  - all items listed in Part IXB, which lists incontinence appliances
  - all items listed in Part IXC, which lists stoma appliances
• Allow manufacturers whose products have a combined net ingredient cost of less than £5.6 million a year to apply for an exemption from this reduction
• Introduce a reimbursement price increase mechanism for appliances supplied six months after the new arrangements come into effect.

See also paragraph 10 Improvement in Value for Money.

SECTION 2
SUMMARY OF ISSUES ARISING FROM REVIEW GROUP PROCESS

Since the new arrangements were introduced in 2006 the review group has considered the need for continuous improvement to service delivery. In some cases issues raised have not always been unanimously acknowledged as problems requiring resolution. In addition, some issues raised have been more appropriate for a particular Board or Boards to address rather than for action at a national level. This section of the report summarises the issues identified and the conclusions identify national or local action required.

Conclusion 2 The Scottish Government has concluded that the new service delivery arrangements introduced in 2006 have bedded in. All key stakeholders expressed a wish to improve the service and concluded that changes to the service would not be welcomed. A formal consultation on service changes is therefore not required. This report proposes a number of ways in which key stakeholders can continue to work in partnership locally and nationally to secure service improvements.

8. Review of Patient Service Standards

8.1 Provision of accessories

The introduction of patient service standards has generally been regarded as positive. The review group considered a recurring area of concern with regards to varying arrangements for the provision of wipes and accessories such as disposal bags. The patient groups were of the view that accessories are complimentary and provided by the suppliers rather than as prescription items. CNS’s said that whilst DACs provide accessories as complimentary items, patients supplied by community pharmacies are provided with only the accessories on the prescription form which may mean that accessories are sometimes not provided as intended.

The service standards do state that the supply of disposal bags and wipes are to be automatic with each delivery.
8.2 Timescales for Delivery of Appliances

Concerns were also expressed that the service standard for delivery of appliances within two working days is not always being met, although the extent of instances of this and the impact on patients was not clear. The existing standards also state that delivery within 2 days is only a requirement when so required by the patient.

That said, suppliers need to understand the compulsory contractual nature of the service they have to provide. It may be necessary to make it explicit that non-compliance may result in action being taken.

Community Pharmacy Scotland (CPS) identified difficulties for community pharmacies in both sourcing certain items at the listed price and incurring additional handling charges. This impacts on the timescale for delivery of products to patients as well as resulting in additional costs for community pharmacies. CPS feared that this could mean that some community pharmacy contractors may choose not to be a stoma appliance provider in future. The Scottish Government has asked the British Healthcare Trades Association (BHTA) and CPS to cooperate on supply chain improvements to prevent delays for patients.

Conclusion 3 The Scottish Government has concluded that:
- All contractors should be reminded of their obligations as a service provider in relation to provision of accessories
- New audit arrangements will monitor delivery
- Small order handling charges should be made transparent – see conclusion 10.

8.3 Audit of contractor performance against standards

After initial teething issues there has not been any evidence of patient dissatisfaction with particular suppliers presented to the Scottish Government. The discussions about audit arrangements was an area of difference in review group discussions and there was some difficulty in reaching a shared understanding of objectives for the audit process.

The former Chair and Acting Chair suggested that audit of suppliers should be an issue for individual NHS Boards as it is Boards who are the customers of DACs and community pharmacies and it is a requirement for contractors to meet the required service standards. The patient groups did not agree that Boards should be responsible for auditing their services and held the view that a national audit should be conducted to establish a baseline. BHTA thought an audit should be carried out to check service quality against the national standards and CNS’s also wanted to be assured that a check on standards was in place.

The Scottish Government’s view was that a national process for future audit and monitoring should be built into new arrangements from April 2010. The final responsibility for auditing and ensuring that contractors are delivering an appropriate service in their area will however remain with Boards. The Scottish Government considers that Boards should continue to be able to make such supplementary
checks as considered necessary to address local concerns including patient complaints about service provision. The Scottish Government concluded that there is an opportunity for National Procurement, NHS Boards including CNS's and patient groups to work in partnership to design a national audit programme. To support local audit of contractor services, a volunteer from a Board could also be invited to provide a template audit tool which other Boards could benefit from.

Conclusion 4 The Scottish Government has concluded that:
- The impending new tenders should be conducted in such a way as to build in arrangements for a formal national audit of service suppliers to be carried out within the currency of the new contracts
- These arrangements should be developed through a partnership of National Procurement, NHS Boards including CNS's, patient groups and other stakeholders as appropriate drawing on existing audit tools which may be available in individual Boards
- Boards should continue to be able to make such supplementary checks as they think necessary to address specific local issues including patient complaints about service provision.

8.4 Provision of customised cutting service

Customised cutting is an essential and valued service for many patients, particularly new patients, and is a core service already included in the service standards and therefore should currently be being offered by all DACs and community pharmacies. CNS's use their clinical judgement as to when it is necessary for an individual patient to access this service.

Some comments expressed by the review group that the customised cutting service is offered as a competitive advantage by some suppliers. An independent assessment would provide a definitive view on the scale of need for this service. However it is not intended to proceed with an independent assessment, but views may be taken from patients as part of new service audit arrangements to monitor their ongoing experience of customisation. The Scottish Government would not wish to take any action that would compromise patients' access to customisation services.

Conclusion 5 The Scottish Government has concluded that:
- There is a continuing need for product customisation for certain patients
- The proposed new national audit should monitor patients' views as to the value of customisation
- Remuneration should in future reflect the level of service provided by service suppliers with differential arrangements for supply only and customised supplies.

8.5 Provision of samples

Some CNS nurses advised that the withdrawal of samples has resulted in a lack of opportunity for them to trial and assess a product. They claimed that instead of individual samples they currently must purchase full product boxes which can be
costly. CNS’s would find it helpful to have access to samples of products they know are likely to be needed by patients. However, the review was not able to present any clear evidence to suggest that any patients in the community are having difficulty in obtaining samples from suppliers, but a number of review group members maintained there was a real issue at local level. To support resolution of this issue at a national level, National Procurement has agreed to work with selected Boards including those identifies as having good practice plus those where CNS report ongoing difficulties to help find solutions. It will, however, continue to be for individual Boards to implement optimum arrangements for obtaining samples.

The Scottish Government continues to believe that the procedure for the provision of samples should be formal i.e. through the issue of formal orders, to maintain the integrity of the purchasing process.

**Conclusion 6** The Scottish Government has concluded that:
- It is the responsibility of each NHS Board to have in place robust arrangements for the ready provision of samples for use by new patients and those who the CNS considers might benefit from a change of appliance
- National Procurement will work with both Boards with good practice and those where CNS’s report ongoing difficulties to level up standards of service to help ensure national consistency of service delivery
- Manufacturers will be given the opportunity to make recommendations as to how samples formally ordered by Boards could be made available more effectively in terms of speed and cost during the 2010 tender preparations.

8.6 Introduction of patient right to a regular Care Review with a CNS and of a protocol for consideration of amendments to a patient’s prescribed items

The review group considered a proposal made by the Scottish Government to introduce a formal right to a regular review with a CNS for all patients. It was suggested that this would enhance the general level of patient service and may help to address some of the problems raised during the review group process.

A care review would also provide an opportunity to:
- Provide patients with the opportunity to access appropriate clinical advice
- Ensure that the patient’s care remains optimal
- Discuss whether any change to a patient’s prescribed items or their formulations is indicated

Review group members expressed a range of concerns. Some welcomed the proposal whilst others expressed concerns about CNS’s workloads in undertaking reviews. There was also concern that rather than enhancing the service, an annual review could place a burden on patients. Some CNS’s added that where patients experience problems with products, patients contact them to seek immediate resolution rather than waiting for a review.

The Scottish Government clarified that the review would be a formal right ensuring those who wish to have a review are entitled to it. Patients would not be required to
have an annual review. The method used to conduct the review would be flexible to make it easier for both patient and CNS to have a discussion – the review could take place by phone, by questionnaire or in person depending on the wishes of the patient. Importantly, reviews would not be linked to restricted product choice or used as an opportunity to steer patients towards other products that they did not want.

The Scottish Government felt that it would be helpful when considering the issue of the review to clarify how this links with the issue of responsibility for specifying appliances which may then be prescribed. The Scottish Government suggested that this might be done by introduction of a formal protocol which would ensure a common understanding is in place with all participants aware of their respective roles and responsibilities. It was suggested by a Board representative that the protocol should make clear how a patient will be assisted to change to a new and appropriate product.

The review group accepted that the majority of patients will not want to change their product once established with it and most changes will be due to a change in stoma size.

**8.7 Prescribing**

It was noted in review group meetings that only a small number of CNS’s have undertaken training on prescribing to date. The Scottish Government’s preferred approach for the future is that the CNS should be the prescriber responsible for stoma appliance prescriptions. Until then the CNS should continue to be responsible for advising the patient’s GP or other prescriber in the practice on what to prescribe.

In the longer term, with an increasing number of nurses qualifying as prescribers, it is expected that CNS’s will play a greater role in effective management of prescribing. To manage workload and minimise any delay in accessing the service, it was discussed whether this function could be carried out by an appropriately trained district nurse if the patient’s condition is stable. Boards advised that some district nurses already prescribe for continuity of care. However, CNS’s thought it important that where district nurses are involved in prescribing stoma care products, they should only prescribe the patient’s usual items and not change or add any items without first consulting the CNS.

The issue of inappropriate prescribing by GPs and the fact this can have major cost implications was raised by one Board. SGPC representatives commented that GPs are commonly asked to prescribe stoma appliances without sufficient knowledge of the products and are not in the best position to identify the best products for patients. They supported prescribing training for specialist nurses for stoma products.

There was general agreement that any developments in the way that prescriptions are processed should not result in any inconvenience for patients.
Conclusion 7 The Scottish Government has concluded that the service standards should be updated to include a new patient's right to a regular review with a CNS. It has also concluded that the arrangements for such reviews should be transparent, and should operate within the following framework:

- All patients should be advised of their right to a care review
- Patients will decide whether he/she wishes to have a care review however, where a change of appliance is sought a clinical assessment by the CNS would always be required
- A care review may be conducted either in person or remotely, for example, by telephone, which ever is most appropriate for the patient
- The timetabling of advice to patients of their right to a care review would be a matter for NHS Boards
- The frequency of the care review would depend on the clinical circumstances of each patient and be agreed between the CNS and patient
- A protocol should apply where a review does take place and alternative appliances to those currently in use are to be considered. In such cases the CNS should exercise his/her clinical judgement as to what is suitable for the patient including advice available from the optional formulary in force, any appliance suggested by the patient and other clinically appropriate and comparable value for money alternatives
- The optional formulary used in the hospital setting, should be available to inform any product review conducted in the community but with the understanding that patients will not be required to change from a product with which they are satisfied
- Clinicians such as GPs or nurse prescribers or pharmacy prescribers in the community should in all but exceptional circumstances only prescribe those items specified by the CNS
- Where District Nurses are prescribing stoma care products, they should only prescribe the patient's usual items and not change or add any items without first consulting the CNS.

These arrangements reflect the underlying principle that patient choice is at the core of the service. This means that the patient should be able to access the product which is most suitable for his/her circumstances with the selection of product from the list developed and maintained by National Procurement in conjunction with CNS representatives of all products which may be prescribed. The selection of the appropriate item should continue to be a clinical one for the CNS in partnership with the patient concerned.

8.8 Maintenance of patient confidentiality
To eliminate fear of unauthorised persons accessing patient records with a view to amending prescriptions, there should be a re-statement of NHS policies on working with clinical suppliers that should be followed by all staff. Payment Verification and Counter Fraud Services have specific roles in relation to contactors and service standards in the NHS.

Conclusion 8 The Scottish Government has concluded that the 2010 tender should remind contractors of the requirement to observe all relevant provisions relating to maintaining confidentiality of patient data so that prior patient consent is obtained before data is shared with third parties.
9. Partnership Working to Improve Stoma Service

Members of the review group from areas with Local Implementation Groups (LIGs) appeared to appreciate the groups and found that the meetings provided a helpful forum to discuss and resolve issues locally. There was however concern from some group members that in some areas LIGs had not met recently and an opportunity to monitor arrangements was being lost. There was a strength of opinion from the review group that there is a need for local groups to support dialogue and that the LIG arrangements need to be reinvigorated.

In reaching conclusions about ensuring good arrangements are in place for local partnership working, the Scottish Government considered that LIGs now need to be revitalised. Given that the new service arrangements were put in place in 2006, the Scottish Government concluded that rather than focusing on implementation, the focus needs to be about monitoring and resolving issues and that a forum is more appropriate for that purpose.

**Conclusion 9** The Scottish Government has concluded that:

- Each Board should establish a local stoma care forum (as a successor to the original LIG established in 2006) including Board managers, CNS's and patient representatives.
- Where appropriate that Boards, for instance Island Boards with relatively few patients, should consider joining with neighbouring Boards to establish regional arrangements for this purpose.

10. Improvements in Value for Money

The new arrangements have impinged negatively on NHS Board budgets for two main reasons.

i. Additional costs now being fully borne by NHS Boards following the transfer of company employed and/or sponsored specialist nurses into Board employment have not been balanced by compensating aggregate reductions in tendered appliance prices.

ii. Prescription volume is now significantly in excess of that originally forecast when the new regime was introduced and the current dispensing fee set.

10.1 Alternatives to a single dispensing fee regime

There remains a view amongst some review group members that having a single dispensing fee to cover the provision of both customised and non-customised appliances may not appropriately reward the activity of the contractor providing the service. A base fee with an extra payment for customisation may be more appropriate.
However, there was a concern that a higher fee for customisation in itself may act as a perverse incentive for the provision of this service even when not actually required by the patient.

An alternative point of view is that customisation is written into the service standards so should always be provided free of charge. There was also a suggestion that some suppliers might recommend extra items in order to generate extra income.

10.2 Resetting of the dispensing fee

There was a suggestion particularly favoured by some NHS Boards that the dispensing fee should be reset in order to rebalance the aggregate cost to what was originally intended. However, it was not favoured by patient groups or contractors.

10.3 Reduction of the number of potential service providers

Some review group members consider that the current practice of allowing all fit and proper providers to act as service providers whilst providing a choice for patients does not necessarily deliver optimal arrangements that fully exploit the potential economies of scale.

The current arrangements which leave the choice of service contractor to the patient are also regarded by some review group members as inefficient in that CNS’s, GPs and NHS Boards have no formal locus to recommend any particular service supplier (as opposed to product manufacturer).

National Procurement advises that within NHS Scotland there are some clinical areas that require the services of a home delivery company to support the care package of the patient and, in most of these, the NHS Board and the provider work very closely in supporting the patient with the service being monitored to ensure support is optimised. This is achieved through the careful selection of a limited number of provider(s) with regular meetings to review performance at NHS Board level. It is recognised that stoma care is a specialist service and there are no plans to reduce patients ability to choose which service provider they wish to use.

NHS Greater Glasgow & Clyde had identified a wish to improve the process of helping patients making informed choices about which supplier they use to provide their stoma service/products. Consequently the Board recently advertised that it was seeking to appoint (a) preferred service provider(s). The Board advised that it is it’s intention that patients will still be able to choose a supplier from the national list and that that local stakeholders have been fully engaged in discussions on their proposal.

Several members of the review group remained concerned that this initiative may inhibit a patient’s choice of supplier and that the Scottish Government would seek to roll out the approach taken by NHS Greater Glasgow & Clyde nationally. Scottish Government confirmed that it has no plans to roll out this approach. We would hope that the new 2010 tender arrangements may be more supportive of the needs of individual NHS Boards to ensure that services are being provided effectively.
The Scottish Government considered that the question of the implication on value for money for the NHS of having multiple service suppliers should be addressed in discussions on remuneration and reimbursement with contractors' representative groups on the 2010 tender arrangements and that local arrangements within the national framework are a matter for each NHS Board. They have therefore developed a list of factors which they wish to discuss further with contractor representatives before 2010 tender arrangements are finalised. These appear in the conclusions below.

**Conclusion 10** The Scottish Government has concluded that value for money aspects of supply arrangements should be explored as commercial issues within preliminary discussions with contractor representatives prior to the launch of any national tenders for 2010 including:

- How to ensure that NHS Scotland receives equivalent value in its stoma item purchases to the support provided by the industry in England and Wales to sponsor/employ nurses
- How to achieve transparency within the 2010 tender for product to ensure that discounts paid to service providers by manufacturers are fully factored into the overall funding package
- What can be learned from the recent renegotiation of service funding in England and Wales
- How the national tender for service suppliers might be best constructed to enable the NHS to benefit from economies of scale whilst maintaining patient choice of service supplier.

The Scottish Government has also concluded that service supplier contracts from 2010 onwards should:

- Maintain on cost effective terms a list of contractors who can demonstrate their fitness to provide a service on a single national tariff
- Underpin a national audit of the way suppliers meet the published service standards (the details of which would be developed in partnership with patient representatives and other stakeholders, and general arrangements for which would be published within the new contract)
- Be supportive of the needs of individual NHS Boards to ensure that services are being provided effectively.

Product supply contracts from 2010 onwards should:

- Formalise initiatives introduced since the new arrangements were introduced in 2006, such as the optional hospital formulary and arrangements for adding items to the list of those which may be ordered in hospital or prescribed in the community
- Support the target that individual samples ordered by the CNS are delivered within 48 hours and that urgent requirements from service suppliers are met by manufacturers in a way that is cost effective for the NHS with small order charges made transparent
- Ensure ongoing value for money for NHS Scotland taking into account all relevant factors including changes to service delivery arrangements in England and Wales taking effect in April 2010 and announced during the Scottish review group process.
10.4 Transparency in Arrangements

Product manufacturers have pressed for clarity in how decisions are taken on the addition of items to formulary. Patient groups have similarly requested that the methodology for the scoring of products for inclusion in the voluntary national formulary be publicised. These were made available to the Group by National Procurement and were published at [http://www.sehd.scot.nhs.uk/appliance_contractors/addproducts.htm](http://www.sehd.scot.nhs.uk/appliance_contractors/addproducts.htm)

**Conclusion 11** The Scottish Government has concluded that the 2010 tender should be explicit in respect of (a) the optional formulary arrangements and (b) the process of review of requests by manufacturers to add products to the list of prescribable items.

11. Continuous Professional Development for Clinical Nurse Specialists

The QIS survey highlighted that a number of nurse specialists are concerned that they have insufficient dedicated time to enable them to maintain and develop their product knowledge. Some CNS's on the review group reiterated this concern however they indicated there were no issues around access to continuous professional development opportunities. Both patient groups and CNS's stressed the importance for nurses to be kept up to date about all products available, not just those within the formulary. Other training issues raised in the QIS audit appear to have been addressed.

The development of the optional national formulary concept provides for the first time a single national focus for the development of CNS knowledge about prescribable items. It is also highly desirable that CNS development programmes include nurse prescribing training thus eliminating the undesirable situation whereby prescriptions are written by GPs who are not specifying the product the patient clinically needs and who are vulnerable to requests from third parties for prescriptions to be amended and/or for new prescriptions to be issued.

There is an opportunity to put in place a national approach to meet this essential requirement. NHS National Education Scotland (NES) have a responsibility to provide access to appropriate training material and courses for NHS staff. As staff Knowledge and Skills Frameworks (KSFs) are developed then ongoing training requirements would be embedded in the individual Personal Development Plans (PDPs). The Scottish Government will engage with both NHS NES and National Procurement to determine options for training.

**Conclusion 12** The Scottish Government has concluded that NHS NES should develop a framework to ensure appropriate training and development opportunities are put in place to support product knowledge for CNS and NHS staff.
Conclusions

Conclusion 1 Introduction of optional hospital formulary – p.6

• The impending new tenders should confirm the procedures used for the establishment of the optional formulary and for the consideration of new stoma products which manufacturers may wish to offer in addition to the list of items which may be ordered in hospitals or prescribed in the community.

Conclusion 2 Summary of issues arising from review group process – p.7

• The new service delivery arrangements introduced in 2006 have bedded in. All key stakeholders expressed a wish to improve the service and concluded that changes to the service would not be welcomed. A formal consultation on service changes is therefore not required. This report proposes a number of ways in which key stakeholders can continue to work in partnership locally and nationally to secure service improvements.

Conclusion 3 Timescale for delivery of appliances – p.8

• All contractors should be reminded of their obligations as a service provider in relation to provision of accessories
• New audit arrangements will monitor delivery
• Small order handling charges should be made transparent – see conclusion 10.

Conclusion 4 Audit – p.9

• The impending new tenders should be conducted in such a way as to build in arrangements for a formal national audit of service suppliers to be carried out within the currency of the new contracts
• These arrangements should be developed through a partnership of National Procurement, NHS Boards including CNS’s, patient groups and other stakeholders as appropriate drawing on existing audit tools which may be available in individual Boards
• Boards should continue to be able to make such supplementary checks as they think necessary to address specific local issues including patient complaints about service provision.

Conclusion 5 Provision of customised cutting service – p.9

• There is a continuing need for product customisation for certain patients
• The proposed new national audit should monitor patients’ views as to the value of customisation
• Remuneration should in future reflect the level of service provided by service suppliers with differential arrangements for supply only and customised supplies.
Conclusion 6 Provision of samples – p.10

- It is the responsibility of each NHS Board to have in place robust arrangements for the ready provision of samples for use by new patients and those who the CNS considers might benefit from a change of appliance
- National Procurement will work with both Boards with good practice and those where CNS's report ongoing difficulties to level up standards of service to help ensure national consistency of service delivery
- Manufacturers will be given the opportunity to make recommendations as to how samples formally ordered by Boards could be made available more effectively in terms of speed and cost during the 2010 tender preparations.

Conclusion 7 Care review with a CNS – p.12

The service standards should be updated to include a new patient's right to a regular review with a CNS. It has also concluded that the arrangements for such reviews should be transparent, and should operate within the following framework:

- All patients should be advised of their right to a care review
- Patients will decide whether he/she wishes to have a care review however, where a change of appliance is sought a clinical assessment by the CNS would always be required
- A care review may be conducted either in person or remotely, for example, by telephone, which ever is most appropriate for the patient
- The timetabling of advice to patients of their right to a care review would be a matter for NHS Boards
- The frequency of the care review would depend on the clinical circumstances of each patient and be agreed between the CNS and patient
- A protocol should apply where a review does take place and alternative appliances to those currently in use are to be considered. In such cases the CNS should exercise his/her clinical judgement as to what is suitable for the patient including advice available from the optional formulary in force, any appliance suggested by the patient and other clinically appropriate and comparable value for money alternatives
- The optional formulary used in the hospital setting, should be available to inform any product review conducted in the community but with the understanding that patients will not be required to change from a product with which they are satisfied
- Clinicians such as GPs or nurse prescribers or pharmacy prescribers in the community should in all but exceptional circumstances only prescribe those items specified by the CNS
- Where District Nurses are prescribing stoma care products, they should only prescribe the patient's usual items and not change or add any items without first consulting the CNS.

These arrangements reflect the underlying principle that patient choice is at the core of the service. This means that the patient should be able to access the product which is most suitable for his/her circumstances with the selection of product from the list developed and maintained by National Procurement in conjunction with CNS
representatives of all products which may be prescribed. The selection of the appropriate item should continue to be a clinical one for the CNS in partnership with the patient concerned.

Conclusion 8 Maintenance of patient confidentiality – p.12

- The 2010 tender should remind contractors of the requirement to observe all relevant provisions relating to maintaining confidentiality of patient data so that prior patient consent is obtained before data is shared with third parties.

Conclusion 9 Partnership Working to Improve Stoma Service – p.13

- Each Board should establish a local stoma care forum (as a successor to the original LIG established in 2006) including Board managers, CNS's and patient representatives.
- Where appropriate that Boards, for instance Island Boards with relatively few patients, should consider joining with neighbouring Boards to establish regional arrangements for this purpose.

Conclusion 10 Improvements in Value for Money – p.15

Value for money aspects of supply arrangements should be explored as commercial issues within preliminary discussions with contractor representatives prior to the launch of any national tenders for 2010 including:

- How to ensure that NHS Scotland receives equivalent value in its stoma item purchases to the support provided by the industry in England and Wales to sponsor/employ nurses
- How to achieve transparency within the 2010 tender for product to ensure that discounts paid to service providers by manufacturers are fully factored into the overall funding package
- What can be learned from the recent renegotiation of service funding in England and Wales
- How the national tender for service suppliers might be best constructed to enable the NHS to benefit from economies of scale whilst maintaining patient choice of service supplier.

That service supplier contracts from 2010 onwards should:

- Maintain on cost effective terms a list of contractors who can demonstrate their fitness to provide a service on a single national tariff
- Underpin a national audit of the way suppliers meet the published service standards (the details of which would be developed in partnership with patient representatives and other stakeholders, and general arrangements for which would be published within the new contract)
- Be supportive of the needs of individual NHS Boards to ensure that services are being provided effectively.

That product supply contracts from 2010 onwards should:
• Formalise initiatives introduced since the new arrangements were introduced in 2006, such as the optional hospital formulary and arrangements for adding items to the list of those which may be ordered in hospital or prescribed in the community
• Support the target that individual samples ordered by the CNS are delivered within 48 hours and that urgent requirements from service suppliers are met by manufacturers in a way that is cost effective for the NHS with small order charges made transparent
• Ensure ongoing value for money for NHS Scotland taking into account all relevant factors including changes to service delivery arrangements in England and Wales taking effect in April 2010 and announced during the Scottish review group process.

Conclusion 11 Transparency in Arrangements – p.16

• The 2010 tender should be explicit in respect of (a) the optional formulary arrangements and (b) the process of review of requests by manufacturers to add products to the list of prescribable items.

Conclusion 12 CPD for Nurses – p.16

• NHS NES should develop a framework to ensure appropriate training and development opportunities are put in place to support product knowledge for CNS and NHS staff.

Scottish Government Health Directorate
Primary and Community Care Directorate| Primary Care Division.
November 2009
APPENDIX

KEY ISSUES AND SCOTTISH GOVERNMENT RESPONSE DISCUSSED AT BILATERAL MEETINGS WITH PATIENT GROUPS, CONTRACTORS AND BOARD REPRESENTATIVES/CNS’s

Separate bilateral meetings were held with stakeholder groups to offer the opportunity for each group to fully air their views on comments on the arrangements for the provision of stoma products in the community. The bilateral meetings were held on the following dates:

30 April 2009 – meeting with patient representative groups
9 June 2009 – Meeting with Contractors (BHTA and CPS)
11 June 2009 - Meeting with Board representatives including CNS’s

<table>
<thead>
<tr>
<th>Key issues of concern</th>
<th>Who</th>
<th>Scottish Government response</th>
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<tbody>
<tr>
<td>Patient choice of product – concerns that proposed changes would lead to a reduction of choice.</td>
<td>CNS’s, patient groups and BHTA.</td>
<td>The choice of product for the patient should continue to be a matter of clinical judgement for the clinician specifying the items to be prescribed. That decision will continue to be informed by the patient’s view as to which products are most suitable for their particular needs. The acute formulary will continue to be optional and offers products based on the best clinical evidence. No reduction in patient/clinician choice of product or service is intended and patients would still be able to access products outwith the formulary where the clinician views it appropriate.</td>
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<tr>
<td>Availability of accessories – free accessories need defining as they are different to those accessories in the Drug Tariff. Appliance suppliers should provide disposal bags as a matter of course and wipes on patients’ request.</td>
<td>CNS’s, patient groups</td>
<td>Want to confirm that it is a formal responsibility for the service supplier to meet reasonable needs for items such as wipes and other accessories without the need for a prescription.</td>
</tr>
<tr>
<td>Customisation – concerns about restrictions on customisation. Also the issue of wipes and disposal bags which are not prescription items but complimentary items supplied by contractors.</td>
<td>Patient groups</td>
<td>There are no plans to restrict customisation. Want to make it a formal responsibility for the service supplier to meet reasonable needs for items such as wipes and other accessories without the need for a prescription.</td>
</tr>
<tr>
<td>Patient choices of service provider and delivery</td>
<td>Patient groups, CNS’s contractors (BHTA and CPS)</td>
<td>Do not intend to reduce patients ability to choose which service provider they wish to use.</td>
</tr>
<tr>
<td>Access to samples and new products – patient reps concerned that stoma nurses do not have access to new products so cannot test them or let patients try them. Patients should be able to</td>
<td>Patient groups, CNS’s, Boards</td>
<td>No evidence that there are difficulties in nurses accessing samples – Boards were asked if they had any procurement issues preventing nurses obtaining samples and there was no indication that this is the case.</td>
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<td>Topic</td>
<td>Group/Source</td>
<td>Scottish Government's Perspective/Action</td>
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<td>Make decisions about new products themselves</td>
<td>CNS's, patient groups, Boards</td>
<td>This does not appear to be an issue for most Boards. Would like to see evidence to understand the scale of the problem in Boards where nurses deem this to be a problem. National Procurement has agreed to provide a monitoring tool for CNS's to record where issues arise.</td>
</tr>
<tr>
<td>Difficulties in CNS's accessing product samples—only patients can get samples; CNS's can get them only for named patients.</td>
<td>BHTA. Patients and CNS's also have concerns re formulary</td>
<td>As above - formulary is optional and would offer products based on the best clinical evidence. The Scottish Government is not aware of any evidence that suggests Boards are not allowing CNS's appropriate discretion.</td>
</tr>
<tr>
<td>BHTA has concerns about formulary and says it is NOT optional in the Acute Trusts</td>
<td>BHTA</td>
<td>Scottish Government believes that the methodology used was fair and transparent and followed legal advice. BHTA invited to send feedback to Paul Hornby at National Procurement.</td>
</tr>
<tr>
<td>CPS of view that optional formulary could help pharmacy contractors source certain products and facilitate availability of samples. CPS also suggested including sample packs in Drug Tariff.</td>
<td>BHTA</td>
<td>Wish to explore how views from patients can be obtained when considering products for the formulary and Drug Tariff.</td>
</tr>
<tr>
<td>Methodology of scoring products for formulary seen as flawed</td>
<td>Patient groups</td>
<td>Glasgow model is a pilot and Scottish Government will be interested to see results. Their intention is to have (a) preferred supplier(s). Patients will still be able to use any supplier of their choice.</td>
</tr>
<tr>
<td>Patient buy-in to product evaluation process</td>
<td>Patient groups</td>
<td>Would like to see specific evidence of cases of this. Happy to raise this with CPS if this is an issue. Have asked BHTA and CPS to cooperate on supply chain improvements to prevent delays for patients.</td>
</tr>
<tr>
<td>NHS Greater Glasgow &amp; Clyde arrangements—concerns around a single supplier, different preferred suppliers in different Boards, postcode prescribing/lottery. CPS suggest accreditation for suppliers as an alternative to Boards having preferred suppliers. BHTA say there should be national product choice not varied from Board to Board.</td>
<td>CPS, BHTA</td>
<td></td>
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<tr>
<td>Service standards not always being met e.g. community pharmacies not meeting delivery of appliances within 2 working days.</td>
<td>CNS's</td>
<td></td>
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<tr>
<td>Training—formulary could lead to more limited product training for CNS's</td>
<td>BHTA have concerns. Patients have related concerns about CNS access to products and samples.</td>
<td>CNS's had advised at a recent meeting that there are no issues around access to training. Scottish Government is willing to discuss any concerns with the CNS group.</td>
</tr>
<tr>
<td>Evidence of one company continuing to sponsor or employ CNS's</td>
<td>BHTA</td>
<td>Agreed with contractors that this is no longer an issue.</td>
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<tr>
<th>Annual review not necessary for all patients and would change way CNS's work. Not enough CNS's in some areas to be able to deal with increased workload from annual reviews.</th>
<th>CNS's, patient groups, Boards</th>
<th>Patients would have a right to have a regular review. Regular reviews would be optional, not compulsory. This is intended as a benefit to the patient, not a burden. It would not need to be a formal appointment and the precise approach could be customised to local circumstances. Acknowledge this needs to be made clearer and also need to tell patients they should contact CNS straight away with any problems rather than wait until their next scheduled review.</th>
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<tr>
<td>Prescribing - role of GP/CNS as gatekeeper. Also lack of progress on CNS prescribing and risk that CNS's with these skills would not be able to use them. Only NHS Borders has CNS prescribing and this is with extra resources.</td>
<td>Patient groups and CNS's</td>
<td>Preferred approach for the future is that CNS is the prescriber responsible for prescriptions or as at present is responsible for advising the patient's GP and/or practice/community nurses on what to prescribe. District Nurses may also prescribe in consultation CNS's.</td>
</tr>
<tr>
<td>Inappropriate prescribing - GPs not understanding products has major cost implications.</td>
<td>Boards</td>
<td>See response above – preferred approach for future is that the CNS is responsible for what is prescribed.</td>
</tr>
<tr>
<td>Some CNS's concerned they have insufficient time to maintain and develop their specialist knowledge, including product knowledge. Also issue of training of suppliers.</td>
<td>CNS's</td>
<td>Wish to encourage CNS's to maintain and develop their knowledge of products.</td>
</tr>
<tr>
<td>Protocol - concern GPs will not agree to this unless enhanced funding provided to pay for practice nurses. Protocol should cover what happens if patient wants to change to a new product and clarify how they will be assisted.</td>
<td>Boards</td>
<td>Scottish Government to discuss this further with NHS Grampian colleagues who had raised this.</td>
</tr>
<tr>
<td>Complaints procedures – patients more likely to complain to suppliers than their community pharmacy</td>
<td>Patient groups</td>
<td>There is an established NHS complaints procedure in place. Scottish Government would not wish to discourage patients from contacting suppliers with problems but need to look at collecting information and sharing it with Boards. Will raise this at meetings with suppliers and Boards.</td>
</tr>
<tr>
<td>Provision of a level playing field for contractors - difficulties for community pharmacies in sourcing certain items at the listed price. The number of suppliers has fallen and not all products stocked on a regular basis by wholesalers. Pharmacy contractors sometimes asked to pay a</td>
<td>CPS</td>
<td>Scottish Government has asked CPS and BHTA to work together to look at these issues. BHTA to find out from their manufacturer members if there is a consistent approach to dealing with special orders.</td>
</tr>
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<td>significant handling charge</td>
<td>CPS</td>
<td>Scottish Government wishes to work with contractors in developing a new model. A draft is being prepared and will be offered for discussion probably during August.</td>
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<td>More relevant price monitoring is required - not clear whether the prices negotiated and fees set originally were realistic.</td>
<td>CPS</td>
<td>As above.</td>
</tr>
<tr>
<td>Improvements in value for money – new arrangements do not deliver some of the expected financial benefits, both relating to remuneration and reimbursement</td>
<td>CNS's, patient groups, Boards and BHTA.</td>
<td>An audit was conducted by NHS QIS and published in February 2008 and overall feedback from patients was positive. It reported issues around 1) lack of wipes and other accessories and 2) delays in the supply chain which are currently being pursued. A process for future audit and monitoring will be built into new arrangements from April 2010.</td>
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