

A national framework for the provision of secondary care within general practice

Executive summary

1. This document requires Health Authorities to establish and operate new arrangements for authorizing the provision by GPs of certain secondary care services in a primary care setting, and to ensure the safe and effective provision of those services.
2. Any provision of these Guidelines which imposes a requirement on a Health Authority has effect as directions given under Section 17 of the National Health Service Act 1977.
3. From 1 April 1996 provision of secondary care services by GPs will require Health Authority approval whether these services are purchased by:
 - i. Health Authorities;
 - ii. GP fundholders using the fund to pay GPs or other primary care professionals; or
 - iii. GP fundholders using the fund to pay for their own services.

This circular sets out the relevant guidance.

4. From 1 April 1996 Regulations allow GP Fundholders to receive payment from the fund for providing procedures contained in the Approved List of Goods and Services for their own patients, subject to each GP intending to carry out the relevant procedures receiving the appropriate approval from their Health Authority. HSG(93) 14, which covers the provision of secondary care by GP fundholding practices, has been cancelled. These guidelines direct Health Authorities to establish appropriate approval procedures. Details of transitional arrangements are included at paragraph 13.
5. GPs will be expected to honour their normal GMS commitments. Minor surgery as defined by paragraph 42 of the Statement of Fees and Allowances is separate from, and not covered by, these new arrangements. These arrangements do not apply to procedures which are usually carried out by consultants in outreach clinics or to GPs working as clinical assistants in Trusts.

Background

6. The guidelines have been produced in collaboration with the medical profession via a working group established by the Chief Medical Officer which reported in November 1995. The group recognised that the provisions of HSG(93) 14 were in some instances inappropriately restrictive and that the introduction of a consistent approval process which applied to all GPs was important in the effective development of a primary care led NHS and to ensure value for money for the NHS. The group recognised that a significant number of GPs are fully competent to perform a wider range of services than are included within GMS or covered by HSG(93)14. An important consideration, therefore, was to enable competent GPs to carry out relevant procedures in a consistent framework which both protected and furthered patient interests.

Key Principles

7. These arrangements form part of the development of a Primary Care led NHS with movement of services from secondary care to the primary care sector where this is appropriate; ie where this is more convenient for patients, cost-effective, safe and of a recognised standard. The change provides an important opportunity, in appropriate circumstances, to allow the skills of suitably qualified and experienced individuals to be fully utilised to the benefit of patients in the NHS.
8. In future GPs who are appropriately qualified and experienced will be able to perform certain secondary care procedures in appropriate primary care settings. It is expected that provision of such services will be in addition to, and complementary to, those services normally provided by the GP under GMS. Health Authorities will be expected to operate approval processes which are fair and open and follow the procedures outlined in this document. Health Authority approval processes will be subject to performance monitoring by NHS Executive Regional Offices. Health Authorities may wish to consider establishing joint advisory panels with neighboring Authorities to keep administrative costs to a minimum.
9. For these purposes "procedure" does not refer exclusively to-surgical procedures but should be interpreted more widely to include other activities normally performed in a secondary care setting. Individual applications may include details of one or more "procedures" for which approval is sought.

The Application

10. GPs who wish to undertake procedures traditionally provided in a secondary care setting, either under contract to the Health Authority or through payment from the fund, must have approval from their local Health Authority. Each GP is required to submit a formal application to the Health Authority containing details of:
- i. the procedure(s) for which approval is sought;
 - ii. the person who will carry out the procedures, including details of relevant training and experience, and details of any support to be provided by other health care professionals (including nurses);
 - iii. the premises where the procedure will be carried out and supporting infrastructure.
 - iv. details of proposed costings

Procedures requiring general anesthesia should not be approved.

11. Health Authorities should not purchase community nursing services (ie health visiting and district nursing services) from GP providers: nor should approval be given under these new approval procedures to applications from GPs to provide such services.
12. Health Authorities (either on their own or in conjunction with neighboring Authorities) shall be responsible for local approval systems, to include an expert advisory panel to provide full and expert advice to the Health Authority on each application. To ensure high quality and equal standards the panel should advise on clinical issues which take account of: relevant guidance from the medical Royal Colleges; expert bodies; existing practice in local provider units; and health & safety advice. They are required to take account of the considerations set out in Annex B to this circular.
13. Following the recommendations by the expert advisory panel the Health Authority shall be responsible for granting or refusing a particular application, with reasons, in writing. The letter should set out the period within which approval will be reviewed. This should normally not be more than 5 years.

Purchasing Decisions

14. The determination of a GP's application by a Health Authority has no implication for its own purchasing intentions. In deciding whether to purchase from a GP that Health Authority (or any Health Authority considering purchasing from a GP accredited by another Health Authority) must take account of value for money considerations and the delivery of a high quality service to the patient. Health Authorities when reviewing contracts with providers may wish to consider how effectively GPs could deliver services. Fundholding GPs will also be required to make their own decisions about whether to purchase or directly provide secondary care procedures for which they have received approval and make a judgement about whether this constitutes an "effective and efficient" use of the fund. Intentions to provide procedures should be contained in the annual practice plan. The Secretary of State through the NHS Executive Regional Offices will retain a performance management overview of the whole process to ensure that the framework is applied fairly, openly and equitably.

Patient Interests

15. Services to patients must be of a high quality and cost effective. Patient interests must be protected by ensuring that the procedures delivered are safe, clinically necessary and provided by approved experienced and qualified personnel in appropriate environments. Where appropriate patients should be offered a choice as to whether they receive treatment in a local primary care or more traditional hospital setting. It follows, therefore, that information should be made available to patients to enable them to make this choice.
16. Where it becomes clear that services are not being delivered to a standard that benefits patients, then, following discussions with the GP concerned, conditions may be imposed or approval may be withdrawn.

costs

17. The full cost of providing the procedure, including costings for any necessary additional professional, clerical and administrative staff, disposable etc should be included in the price. Costs already reimbursed through GMS arrangements must not be included in the costings, though where staff provide both GMS and HCHS services, reimbursement should be given for the portion of time spent on HCHS work. Health Authorities should take into account whether the price provides value for money when considering whether to give approval.

18. GP Fundholders will be required to assess whether delivery of the proposed procedures represents good value for money (using full cost comparisons) when set against the current (or alternative) arrangements and taking account of the potential benefits to patients and to briefly set out this assessment in their annual practice plan. Health Authorities will be required to make similar value for money judgments in respect of contracts they set with GPs. NHS Executive Regional Offices will look at value for money considerations as part of their performance management role. The rate of remuneration should in all cases be reasonable. All individual GPs will be expected to meet in full their contracted GMS commitments.

Transitional Arrangements

19. Approvals already given by virtue of HSG(93) 14, or contracts granted to GPs by Health Authorities, prior to 1 April 1996 may continue until there is a material change in circumstances which affects the approval given. Any new contracts agreed between HAs and GPs would then be subject to the approval arrangements. Health Authorities should discuss with GPs who have received approvals under HSG(93) 14 when a review would be appropriate.
20. Health Authorities may wish to develop joint approval systems as an interim or longer term measure. In the short term NHS Executive Regional Offices may wish to assist Health Authorities in establishing local systems. Health authorities are expected to have established an approval system which meets the requirements of this framework by 30 November 1996.

Annexes

21. Further details about the application and the approval process, and more detailed operational points are included in the annexes to this guidance.

Action

22. Health Authorities are required to establish appropriate approval systems within six months of the date of this circular.
23. Health Authorities are required to bring this document to the attention of all GPs
24. Regional Offices should monitor the establishment of local approval systems and maintain a performance management overview of the whole process to ensure that the framework is applied fairly, openly and equitably.

Enquiries

25. Enquiries about the contents of this circular should be addressed to Paul Betts, NHS Purchasing Branch, Room 3W30, Quarry House, Quarry Hill, Leeds, LS2 7UE.

Addressees

For action:

Health Authority Directors of Purchasing
 Health Authority Directors of Public Health
 General Practitioners (*Health Authorities please note that you have been sent sufficient copies of this HSG to distribute to GPs in your area*)

For information:

Health Authority Chief Executives
 NHS Trust Chief Executives
 Regional Directors of Performance Management

Regional Directors of Public Health
Regional Postgraduate Deans
Regional Advisors in General Practice

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ANNEX A

RELEVANT RESPONSIBILITIES WITHIN THE PROCESS

GPs - GENERAL

- 1, GPs are responsible for making an application to their Health Authority which as a minimum contains ~ details of: the procedure(s) to be performed; the premises/supporting infrastructure (including equipment and support staff) to be used; and, the person who will perform the procedures. Health Authorities may require other supporting information also. In all cases applications should be detailed and specific about the procedure or procedures to be performed. Costings for procedures should in all cases be reasonable and fully justifiable and should be based on standard costing and pricing principles.
2. GPs are responsible for ensuring only those procedures for which application has been made and approval has been given are performed and in accordance with any conditions set by the Health Authority. Part of the approval process will be that GPs should carry out regular and relevant clinical audit of procedures. Where a significant change occurs in the circumstances of the GP following initial approval the GP should seek re-approval. GPs have a duty to inform their patients about the range of choices available to them in respect of treatment.

GPs CONTRACTING WITH HEALTH AUTHORITIES

3. The fact that an individual Health Authority does not wish to place a contract with a GP does not preclude an application being made nor approval being given to that GP to carry out the procedure being given (on the basis that the GP may wish to contract with other purchasers).

GP FUNDHOLDERS

4. Approval for standard fundholding GPs who wish to receive payment from the fund for particular services may only be granted in respect of procedures which are included in the Approved List of Goods and Services. Community fundholders are not covered by this guidance except to the extent that they may wish to provide services under contract with Health Authorities.
5. Fundholding GPs are required to use their fund effectively and efficiently for the benefit of patients and will need to make reasonable judgments about whether to provide a specific service against the background of this responsibility. They should also ensure that the decision making process is clear for audit purposes.

HEALTH AUTHORITY

6. The Health Authority is required to receive and make a decision on each application and in doing so will need to establish local approval mechanisms in line with this guidance. Health Authorities either individually or jointly, should establish an expert advisory panel to which applications may be referred for advice and guidance. The Health Authority should normally set time limits for the approval or rejection of applications. Formal appeal mechanisms are not required, though Health Authorities would normally wish to provide review procedures through which the reasons for refusal of an application can be explained to applicants. When establishing local approval processes, Health Authorities would normally wish to consult relevant interests locally. Health Authorities will be responsible for meeting the costs and expenses of the expert advisory panel.

7. It is recommended that advisory panels are established according to the following principles:
- they have some constant membership eg the chairman;
 - they have access to relevant expert advice;
 - that the number of members is kept to a minimum but is fully representative of key interests (e.g relevant specialties, GP advisers, nursing input, medical education and training, patient interests).
8. Following the recommendation of the expert advisory group the Health Authority is responsible for granting or refusing a particular application, with reasons, in writing. The letter should set out the period within which approval will be reviewed. This should not be more than 5 years. In doing so the Health Authority must keep separate its considerations as a purchaser and its responsibility for the approval process.

THE EXPERT ADVISORY PANELS

9. The expert advisory panel is responsible for giving full and impartial advice to the Health Authority on all applications referred to it. The panel should comment on the application as a whole and in particular on:
- i) The procedure(s) including appropriateness, suggested activity levels and the need to adhere to relevant clinical guidelines.
 - ii) The premises and infrastructure, including the suitability of the premises and equipment, back-up facilities (including resuscitation facilities where relevant), health and safety requirements, safe use and storage of substances, storage and disinfection of equipment.
 - iii) The person(s) to be approved, including relevant experience, qualifications, competence, appropriateness and currency of training and education; also details of appropriately skilled and qualified support staff including nursing support, giving details of relevance of experience.
10. In some instances the advisory group may wish to visit the GP and/or premises before arriving at its recommendation. The advisory group will also wish to consult relevant clinical guidelines and protocols issued by the relevant Royal Colleges and other expert bodies. Because there is no prescriptive list of allowable procedures, the Royal Colleges have helpfully agreed to produce guidelines on commonly performed procedures within 6 months of a request being received. The advisory group should in general advise on individual procedures only and not complete service areas.
11. In some circumstances the recommendation of the advisory group may be conditional on certain further criteria being satisfied, eg premises improvements, additional or continuing training. The advisory group should also make recommendations on periods for re-approval which will depend on a number of factors eg levels of activity, anticipated rapid development and change in a particular service area. In general re-approval will be appropriate at least every 5 years, or more regularly where there has been a significant change of circumstances since the application or most recent re-approval. The information provided by regular audit and peer review will play an important role in the process of re-approval.

NHS EXECUTIVE REGIONAL OFFICE

12. The NHS Executive Regional Office will have overall responsibility for performance management of Health Authorities through its responsibility for purchaser performance

and ensuring compliance with national policy. Regional Offices will ensure: a) approval processes are in place; b) approval processes are functioning fairly & effectively; and, c) details of the number and results of applications are received.

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ANNEX B

CHECKLIST OF KEY POINTS FOR GPs WHEN APPLYING FOR APPROVAL (AND WHICH SHOULD BE TAKEN INTO ACCOUNT BY THE HEALTH AUTHORITY)

- 1) The GP(s) has the experience and qualifications to undertake the procedure and all personnel providing the service are competent to provide those aspects of the service for which they are responsible and will keep their skills up to date.
- 2) Equipment and facilities are suitable for the purpose, and are subject to proper maintenance, decontamination and calibration, as appropriate.
- 3) The quality standards are at least equal to those written into other contracts placed by the Health Authority for the same service.
- 4) Staff and premises costs already reimbursed by Health Authorities (e.g expenses reimbursed through GMS) should not be included in costings nor should they be charged to the contract or recovered through the contract price. The price of the service contracted for should offer at least equal value for money as the same service provided by other local providers, taking into account benefits for patients. In all cases normal NHS costing principles should apply and full cost basis and VFM comparisons should be made.
- 5) The GP carrying out the service will be expected to fulfil his or her existing GMS commitments before undertaking additional procedures. The relevant Gp should ensure that all partners are in agreement.
- 6) All personnel providing the service through the contract have appropriate indemnity cover to meet in full claims made against them as individuals.
- 7) Adequate back-up arrangements and an agreed emergency procedure are in place. All health and safety legislation requirements are to be fulfilled.
- 8) Patients should be provided with appropriate information and, where appropriate, a patient consent form should be completed for each procedure. The normal procedure in dealing with any patient complaints should be followed.
- 9) The practice undertakes to maintain records for clinical audit purposes, of: names and numbers of patients; entry in patients' clinical records and details of complications, misdiagnose and outcome. The result of any audit (suitably anonymised) be made available to the Health Authority Medical Adviser and MAAG on request.
- 10) The practice undertakes to review annually the provision of the service and to inform the Health Authority in its annual report of the extent of use of the service, and of any material changes from the information previously supplied.
- 11) For fundholders the service contracted for is a legitimate charge to the fund ie it is listed in the Approved List of Goods and Services.

Protocols and Quality Issues

- 12) In general, protocols should be kept for sterilisation, maintenance and/or calibration of equipment. For pathology, the advice in the document "Guidelines for the Implementation of Near Patient Testing" developed with the support of the Association of Clinical Biochemists and the Royal College of Pathologists should be used as guidance. Arrangements made for diagnostic pathology testing must be in accord with Health & Safety guidelines and Code of Substances Hazardous to Health Regulations.

- 13) Similarly for tests of liver function and electrolytes, both internal and external quality assurance procedures should be described. A link with a local provider unit will be required, so that the results can be assessed against the National Quality Control Scheme standards.
- 14) Where procedures require local anaesthesia and/or sedation, the Royal College of Surgeons booklet "Guidelines for Sedation by Non-Anaesthetists" should be used as guidance.
- 15) All patients to whom services are offered will need to be assessed as to their suitability for undergoing an operative procedure in the practice setting. This is particularly relevant when intravenous sedation is needed. There should be a protocol for such an assessment.
- 16) A protocol for resuscitation must be available and both the operator and the assistant(s) must be fully conversant with it. For all investigations involving endoscopes, a protocol for decontamination should be submitted with the application. For vasectomies, a protocol indicating how it is intended to ensure successful occlusion has been achieved should accompany the application.
- 17) For ENT, general surgery, and gynecology, links with specialists at a local provider unit to ensure back-up facilities will be necessary.