

# THE NATIONAL HEALTH SERVICE ACT 1977

## THE PRIMARY MEDICAL SERVICES (DIRECTED ENHANCED SERVICES) (ENGLAND) DIRECTIONS 2004

The Secretary of State for Health, in exercise of the powers conferred upon him by sections 17 and 126(4) of the National Health Service Act 1977(a), and of all other powers enabling him in that behalf, hereby gives the following Directions:—

### Citation, commencement and application

1.—(1) These Directions may be cited as the Primary Medical Services (Directed Enhanced Services) (England) Directions 2004 and shall come into force on 1st April 2004.

(2) These Directions are given to Primary Care Trusts in England and apply in relation to England only.

### Interpretation

2. In these Directions—

“the Act” means the National Health Service Act 1977;

“general practitioner” means a medical practitioner whose name is included in a medical performers list prepared by a Primary Care Trust under regulation 3 of the National Health Service (Performers List) Regulations 2004(b);

“GMS contractor” means a person with whom a Primary Care Trust is entering or has entered into a general medical services contract;

“health care professional” means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(c);

“PMS contractor” means a person with whom a Primary Care Trust is entering or has entered into section 28C arrangements which require the provision by that person of primary medical services;

“primary medical services contract” means—

- (a) a general medical services contract;
- (b) section 28C arrangements which require the provision of primary medical services; or
- (c) contractual arrangements for the provision of primary medical services under section 16CC(2)(b) of the Act (primary medical services); and

“primary medical services contractor” means—

- (a) a GMS or PMS contractor; or

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(a) 1977 c.49. Section 17 of the 1977 Act is as substituted by the Health Act 1999 (c.8) (“the 1999 Act”), section 12(1), and thereafter amended by the Health and Social Care Act 2001 (c.15), Schedule 5, paragraph 5(3), and the National Health Service Reform and Health Care Professions Act 2002 (c.17) (“the 2002 Act”), Schedule 1, paragraph 7. Section 126(4) of the 1977 Act was amended by the National Health Service and Community Care Act 1990 (c.19), section 65(2). As regards Wales, the functions of the Secretary of State under the 1977 Act were transferred to the National Assembly for Wales by virtue of article 2 of, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672), as amended by section 66(5) of the 1999 Act and as read with section 40(1) of the 2002 Act.

(b) S.I. 2004/ .

(c) 2002 c.17.

- (b) a person with whom a Primary Care Trust is making or has made contractual arrangements for the provision of primary medical services under section 16CC(2)(b) of the Act (primary medical services).

### **Establishment etc. of directed enhanced services schemes**

3.—(1) Each Primary Care Trust must exercise its functions under section 16CC of the Act (primary medical services) of providing primary medical services within its area, or securing their provision within its area, by (as part of its discharge of those functions) establishing (if it has not already done so), operating and, as appropriate, revising the following schemes for its area—

- (a) an Improved Access Scheme, the underlying purpose of which is to improve patient access to primary medical services, and which may comprise or include—
  - (i) arrangements for ensuring that patients requiring routine appointments will, on request, be able to see face-to-face, by the end of—
    - (aa) the first normal working day after the day on which the request was made, a health care professional, and
    - (bb) the second normal working day after the day on which the request was made, a general practitioner; and
  - (ii) arrangements to address specific local health needs or requirements in respect of access to primary medical services locally;
- (b) a Quality Information Preparation Scheme in respect of GMS and PMS contractors (which is to come to an end on 31st March 2005), the underlying purpose of which is to summarise and improve the quality of medical records held by GMS or PMS contractors in its area;
- (c) a Childhood Immunisation Scheme, the underlying purpose of which is to ensure that patients in its area—
  - (i) who have passed their second birthday but not yet their third are able to benefit from the recommended immunisation courses (i.e. those that have been recommended nationally and by the World Health Organisation) for protection against—
    - (aa) diphtheria, tetanus and poliomyelitis,
    - (bb) pertussis,
    - (cc) measles/mumps/rubella, and
    - (dd) Haemophilus influenzae type B, or
  - (ii) who have passed their fifth birthday but not yet their sixth birthday are able to benefit from the recommended reinforcing doses (i.e. those that have been recommended nationally and by the World Health Organisation) for protection against diphtheria, tetanus, acellular pertussis and poliomyelitis;
- (d) an Influenza and Pneumococcal Immunisation Scheme, the underlying purposes of which is to ensure that patients in its area who are at-risk of influenza or pneumococcal infection are offered immunisation against these infections;
- (e) a Violent Patients Scheme, the underlying purpose of which is to ensure that there are sufficient arrangements in place to provide primary medical services to patients that have been subject to immediate removal from a patient list of a primary medical services contractor because of an act or threat of violence; and
- (f) a Minor Surgery Scheme, the underlying purpose of which to ensure that a wide range of minor surgical procedures are made available as part of the primary medical services provided within the Primary Care Trust's area.

(2) Before entering into any arrangements with a primary medical services contractor as part of one of the Schemes mentioned in this direction, a Primary Care Trust must satisfy itself that the contractor with which it is proposing to enter into those arrangements—

- (a) is capable of meeting its obligations under the plan setting out those arrangements; and

- (b) in particular, has the necessary facilities, equipment and properly trained and qualified general practitioners, health care professionals and staff to carry out those obligations,

and nothing in these directions shall be taken as requiring a PCT to enter into such arrangements with a contractor if it has not been able to satisfy itself in this way about the contractor.

### **Improved Access Scheme plans**

4.—(1) As part of its Improved Access Scheme, each Primary Care Trust must, each financial year, offer to enter into arrangements with each GMS or PMS contractor in its area (unless it already has such arrangements with the contractor in respect of that financial year), thereby affording the contractor a reasonable opportunity to participate in the Scheme during that financial year.

(2) The plan setting out the arrangements that a Primary Care Trust enters into, or has entered into, with a GMS or PMS contractor as part of its Improved Access Scheme must, in respect of each financial year to which the plan relates, include—

- (a) any agreed arrangements for meeting and maintaining the access targets in direction 3(a)(i)(aa) and (bb);
- (b) any agreed arrangements for collecting data—
  - (i) for monitoring achievement of those access targets, or
  - (ii) relating to occasions when those access targets may be in jeopardy (and any arrangements for warning the Primary Care Trust when those access targets may be in jeopardy);
- (c) any contingency plans to cover circumstances when those access targets may be in jeopardy;
- (d) any improvements to the arrangements for the access to primary medical services provided by the contractor which—
  - (i) the Primary Care Trust and the contractor consider appropriate to address specific health needs or requirements of the population served by the contractor, and
  - (ii) are to be carried out in that financial year; and
- (e) in the case of PMS contractors, the amount of the payments to the contractor for agreeing and meeting its obligations under the plan, and those payments must comprise—
  - (i) an implementation payment, payable once those obligations have been agreed, and
  - (ii) a reward payment, payable where the contractor has fulfilled its obligations under its plan,

and in determining the appropriate level of payments, the Primary Care Trust must have regard to the amounts of payments under Section 6 of the Statement of Financial Entitlements,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the plan comprises part of the contractor's contract and the requirements of the plan are conditions of the contract.

### **Quality Information Preparation Scheme plans**

5.—(1) As part of its Quality Information Preparation Scheme, each Primary Care Trust must offer to enter into arrangements with each GMS or PMS contractor in its area in respect of the financial year 2004 to 2005 (unless it already has such arrangements with the contractor in respect of that financial year), thereby affording the contractor a reasonable opportunity to participate in the Scheme during that financial year.

(2) The plan setting out the arrangements that a PCT enters into, or has entered into, with any GMS or PMS contractor as part of its Quality Information Preparation Scheme must, in respect of the financial year 2004 to 2005, include—

- (a) a project for summarising the medical records held by the contractor, which must include—
  - (i) a protocol for how the summarising is to be done, to be agreed if the contractor is a partnership by all the partners in the partnership, and
  - (ii) arrangements for the on-going maintenance of the summarising project;
- (b) where necessary, provision for fully trained summarisers, who—
  - (i) must not take medical records away from practice premises,
  - (ii) must have appropriate access to general practitioners when they have queries,
  - (iii) must sign a confidentiality agreement, and
  - (iv) must be appropriately supervised; and
- (c) in the case of PMS contractors, the amount of the payment for the contractor agreeing its obligations under the plan in respect of the financial year 2004 to 2005 (and in determining the appropriate amount, the Primary Care Trust must have regard to the potential amounts of payments under Section 7 of the Statement of Financial Entitlements),

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the plan comprises part of the contractor's contract and the requirements of the plan are conditions of the contract.

### **Childhood Immunisation Scheme plans**

6.—(1) As part of its Childhood Immunisation Scheme, each Primary Care Trust must, each financial year, offer to enter into arrangements with each GMS or PMS contractor in its area, unless—

- (a) it already has such arrangements with the contractor in respect of that financial year; or
- (b) in the case of a GMS contractor, the contractor is not providing the childhood immunisations and pre-school boosters additional service under its general medical services contract,

thereby affording the contractor a reasonable opportunity to participate in the Scheme during that financial year.

(2) The plan setting out the arrangements that a Primary Care Trust enters into, or has entered into, with any primary medical services contractor as part of its Childhood Immunisation Scheme must, in respect of each financial year to which the plan relates, include (unless, in the case of a PMS contractor, prior to 1st March 2004 the Primary Care Trust already had an alternative plan in place with it in respect of that financial year)—

- (a) a requirement that the contractor—
  - (i) develops and maintains a register (its "Childhood Immunisation Scheme Register", which may comprise electronically tagged entries in a wider computer database) of all the children for whom the contractor has a contractual duty to provide childhood immunisation and pre-school booster services (who may already have been immunised, by the contractor or otherwise, or to whom the contractor has offered or needs to offer immunisations),
  - (ii) undertakes to offer the recommended immunisations referred to in direction 3(c) to the children on its Childhood Immunisation Scheme Register (with the aim of maximising uptake in the interests of patients, both individually and collectively), and
  - (iii) undertakes to record the information that it has in Childhood Immunisation Scheme Register using any applicable national Read codes;
- (b) a requirement that the contractor—

- (i) develops a strategy for liaising with and informing parents or guardians of children on its Childhood Immunisation Scheme Register about its immunisation programme with the aim of improving uptake, and
- (ii) provides information on request to those parents or guardians about immunisation;
- (c) a requirement that the contractor takes all reasonable steps to ensure that the lifelong medical records held by a child's general practitioner are kept up-to-date with regard to the child's immunisation status, and in particular include—
  - (i) any refusal of an offer of vaccination,
  - (ii) where an offer of vaccination was accepted—
    - (aa) details of the consent to the vaccination or immunisation (where a person has consented on a child's behalf, that person's relationship to the child must also be recorded),
    - (bb) the batch number, expiry date and title of the vaccine,
    - (cc) the date of administration of the vaccine,
    - (dd) where two vaccines are administered in close succession, the route of administration and any injection site of each vaccine,
    - (ee) any contraindications to the vaccination or immunisation,
    - (ff) any adverse reactions to the vaccination or immunisation;
- (d) a requirement that the contractor ensures that any health care professional who is involved in administering a vaccine has—
  - (i) any necessary experience, skills and training with regard to the administration of the vaccine, and
  - (ii) training with regard to the recognition and initial treatment of anaphylaxis;
- (e) a requirement that the contractor ensures that—
  - (i) all vaccines are stored in accordance with the manufacturer's instructions, and
  - (ii) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken from that thermometer on all working days;
- (f) a requirement that the contractor supply its Primary Care Trust with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan;
- (g) arrangements for an annual review of the plan which shall include—
  - (i) an audit of the rates of immunisation, which must also cover any changes to the rates of immunisation, and
  - (ii) an analysis of the possible reasons for any changes to the rates of immunisation; and
- (h) in the case of contractors that are not GMS contractors, the payment arrangements for the contractor, which must comprise target payments to the contractor where the contractor—
  - (i) meets its obligations under the plan, and
  - (ii) meets, in respect of the children on the contractor's Childhood Immunisation Scheme Register, immunisation levels designed to ensure adequate protection, both for individual patients and for the public, against the infectious diseases against which immunisation is being offered (and the Primary Care Trust must take no account of exception reporting in its calculations of target payments),

and in determining the appropriate level of payments, the Primary Care Trust must have regard to the target payments and the targets rewarded under Section 8 of the Statement of Financial Entitlements,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the plan comprises part of the contractor's contract and the requirements of the plan are conditions of the contract.

## **Influenza and Pneumococcal Immunisation Scheme plans**

7. As part of its Influenza and Pneumococcal Immunisation Scheme, each Primary Care Trust may enter into arrangements with any primary medical services contractor, but where it does so, the plan setting out the arrangements that a Primary Care Trust enters into, or has entered into, with the primary medical services contractor must, in respect of each financial year to which the plan relates, include (unless, in the case of a PMS contractor, prior to 1st March 2004 the Primary Care Trust already had an alternative plan in place with it in respect of that financial year)—

- (a) a requirement that the contractor develops and maintains a register (its “Influenza and Pneumococcal Scheme Register”, which may comprise electronically tagged entries in a wider computer database) of all the at-risk patients to whom the contractor is to offer immunisation against influenza or pneumococcal infection, and for these purposes a patient is at risk of—
  - (i) influenza infection if he is—
    - (aa) aged 65 or over at the end of that financial year,
    - (bb) suffering from chronic respiratory disease (including asthma), chronic heart disease, chronic renal disease, immuno-suppression due to disease or treatment, or diabetes mellitus,
    - (cc) living in long-stay residential or nursing homes or other long-stay health or social care facilities, or
  - (ii) pneumococcal infection if he is—
    - (aa) aged 75 or over at the end of that financial year, or
    - (bb) from 1st April 2005, aged 65 or over at the end of the financial year;
- (b) a requirement that the contractor undertakes—
  - (i) to offer immunisations against those infections to those at risk patients, and with immunisations against influenza infection—
    - (aa) to make that offer during the period from 1st August to 31st March in that financial year, but
    - (bb) to concentrate the immunisation programme during the period from 1st September to 31st January in that financial year, and
  - (ii) to record the information that it has in its Influenza and Pneumococcal Immunisation Register using any applicable national Read codes;
- (c) a requirement that the contractor develops a proactive and preventative approach to offering these immunisations by adopting robust call and reminder systems to contact at-risk patients, with the aims of—
  - (i) maximising uptake in the interests of at-risk patients, and
  - (ii) meeting any public health targets in respect of such immunisations;
- (d) a requirement that the contractor takes all reasonable steps to ensure that the lifelong medical records held by an at-risk patient’s general practitioner are kept up-to-date with regard to his immunisation status, and in particular include—
  - (i) any refusal of an offer of vaccination,
  - (ii) where an offer of vaccination was accepted—
    - (aa) details of the consent to the vaccination or immunisation (where a person has consented on an at-risk patient’s behalf, that person’s relationship to the at-risk patient must also be recorded),
    - (bb) the batch number, expiry date and title of the vaccine,
    - (cc) the date of administration of the vaccine,
    - (dd) where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine,
    - (ee) any contraindications to the vaccination or immunisation,

- (ff) any adverse reactions to the vaccination or immunisation;
- (e) a requirement that the contractor ensures that any health care professional who is involved in administering a vaccine has—
  - (i) any necessary experience, skills and training with regard to the administration of the vaccine, and
  - (ii) training with regard to the recognition and initial treatment of anaphylaxis;
- (f) a requirement that the contractor ensures that—
  - (i) all vaccines are stored in accordance with the manufacturer's instructions, and
  - (ii) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken from that thermometer on all working days;
- (g) a requirement that the contractor supply its Primary Care Trust with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan; and
- (h) the payment arrangements for the contractor,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the plan comprises part of the contractor's contract and the requirements of the plan are conditions of the contract.

#### **Violent Patient Scheme consultation and plans**

**8.**—(1) Each Primary Care Trust must consult the local medical committee (if any) for its area about any proposals it has to establish or revise a Violent Patients Scheme.

(2) As part of its Violent Patients Scheme, each Primary Care Trust may enter into arrangements with any primary medical services contractor, but where it does so, the plan setting out those arrangements must provide, in respect of each financial year to which the plan relates, for the payment arrangements for the contractor agreeing and meeting its obligations under the plan.

#### **Minor Surgery Scheme plans**

**9.** As part of its Minor Surgery Scheme, each Primary Care Trust may enter into arrangements with any primary medical services contractor, but where it does so, the plan setting out the arrangements that a Primary Care Trust enters into, or has entered into, with the primary medical services contractor must, in respect of each financial year to which the plan relates, include (unless, in the case of a PMS contractor, prior to 1st March 2004 the Primary Care Trust already had an alternative plan in place with it in respect of that financial year)—

- (a) which minor surgical procedures are to be undertaken by the contractor and for which patients, and for these purposes, the minor surgical procedures that may be undertaken are any minor surgical procedures that the Primary Care Trust considers the contractor competent to provide, which may include—
  - (i) injections for muscles, tendons and joints,
  - (ii) invasive procedures, including incisions and excisions, and
  - (iii) injections of varicose veins and piles;
- (b) a requirement that the contractor takes all reasonable steps to provide suitable information to patients in respect of whom they are contracted to provide minor surgical procedures about those procedures;
- (c) a requirement that the contractor—
  - (i) obtains written consent to the surgical procedure before it is carried out (where a person consents on a patient's behalf, that person's relationship to the patient must be recorded on the consent form), and
  - (ii) takes all reasonable steps to ensure that the consent form is included in the lifelong medical records held by the patient's general practitioner;

- (d) a requirement that the contractor ensures that all tissue removed by surgical procedures is sent for histological examination, unless there are acceptable reasons for not doing so;
- (e) a requirement that the contractor ensures that any health care professional who is involved in performing or assisting in any surgical procedure has—
  - (i) any necessary experience, skills and training with regard to that procedure; and
  - (ii) resuscitation skills;
- (f) a requirement that the contractor ensures that it has appropriate arrangements for infection control and decontamination in premises where surgical procedures are undertaken, and for these purposes, the Primary Care Trust may stipulate—
  - (i) the use of sterile packs from the local Central Sterile Service Departments, disposable sterile instruments, or approved sterilisation procedures,
  - (ii) the use of particular infection control policies in relation to, for example, the handling of used instruments and excised specimens, and the disposal of clinical waste;
- (g) a requirement that the contractor ensures that all records relating to all surgical procedures are maintained in such a way—
  - (i) that aggregated data and details of individual patients are readily accessible for lawful purposes, and
  - (ii) as to facilitate regular audit and peer review by the contractor of the performance of surgical procedures under the plan;
- (h) a requirement that the contractor supplies its Primary Care Trust with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan; and
  - (i) the payment arrangements for the contractor,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the plan comprises part of the contractor's contract and the requirements of the plan are conditions of the contract.

### **Revocations**

**10.—**(1) Articles 3(b) and 5 shall cease to have effect on 1st April 2005 unless revoked with effect from an earlier date.

(2) The Improved Access, Quality Information Preparation and Violent Patients Schemes (England) Directions 2003 are hereby revoked.

Signed by authority of the Secretary of State for Health

Rob Webster

Department of Health

A member of the Senior Civil Service

5 March, 2004