

THE NATIONAL HEALTH SERVICE ACT 2006

The Primary Medical Services (Directed Enhanced Services) (England) Directions 2008

The Secretary of State gives the following directions in exercise of the powers conferred by sections 8 and 272(7) and (8) of the National Health Service Act 2006(a):

Citation, commencement and application

1.—(1) These Directions may be cited as the Primary Medical Services (Directed Enhanced Services) (England) Directions 2008 and shall come into force on 2nd September 2008.

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

Interpretation

2. In these Directions—

“the Act” means the National Health Service Act 2006;

“bank holiday” has the same meaning as in the National Health Service (General Medical Services Contracts) Regulations 2004(b);

“clinical session” means a fixed period of time made available for clinical consultations with patients and where, unless the context otherwise requires, the health care professional who is available for such clinical consultations is a general practitioner ;

“core hours” has the same meaning as in the National Health Service (General Medical Services Contracts) Regulations 2004;

“CRP” means the Contractor Registered Population as defined in the Statement of Financial Entitlements;

“financial year” means the twelve months ending with 31st March;

“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 Lists) Regulations 2004(c);

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

(a) 2006 c.41.

(b) 2004/291 as amended by S.I. 2004/2694, 2005/893 and 3315, 2006/1501, 2007/289 and 3491 and 2008/528, 1514 and 1700.

(c) S.I. 2004/585 as amended by S.I. 2004/2694, 2005/502, 893 and 3491, 2006/635, 1914 and 3185 and 2008/1187.

“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^(a);

“out of hours services” has the same meaning as in the National Health Service (General Medical Services Contracts) Regulations 2004;

“PMS contractor” means a person with whom a Primary Care Trust is entering or has entered into section 92 arrangements^(b) which require the provision by that person of primary medical services;

“primary medical services contract” means—

- (a) a general medical services contract;
- (b) section 92 arrangements which require the provision of primary medical services; or
- (c) contractual arrangements for the provision of primary medical services under section 83(2)(b) of the Act (primary medical services);

“primary medical services contractor” means—

- (a) a GMS or PMS contractor; or
- (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 83(2)(b) of the Act;

“registered patient” has the same meaning as in the National Health Service (General Medical Services Contracts) Regulations 2004;

“relevant Strategic Health Authority” has the same meaning as in the National Health Service (General Medical Services Contracts) Regulations 2004;

“Statement of Financial Entitlements” means any directions given by the Secretary of State under section 87 of the Act (GMS contracts: payments); and

“working day” has the same meaning as in the National Health Service (General Medical Services Contracts) Regulations 2004.

Establishment etc. of directed enhanced services schemes

3.—(1) Each Primary Care Trust must exercise its functions under section 83 of the Act 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 Extended Hours Access Scheme, the underlying purpose of which is to enable patients to consult a general practitioner, face to face, at times other than during the core hours specified in the contractor’s primary medical services contract, as agreed with the Primary Care Trust;
- (b) 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

(a) 2002 c.17.

(b) See section 92(8) of the Act.

been recommended nationally and by the World Health Organisation) for protection against—

- (aa) diphtheria, tetanus, poliomyelitis, pertussis and Haemophilus influenzae type B (HiB),
 - (bb) measles/mumps/rubella, and
 - (cc) Meningitis C, 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, pertussis and poliomyelitis;
- (c) 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;
- (d) 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
- (e) a Minor Surgery Scheme, the underlying purpose of which is 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 paragraph (1), 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 those arrangements including under any plan agreed under 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 Primary Care Trust to enter into such arrangements with a contractor if it has not been able to satisfy itself in this way about the contractor.

Extended Hours Access Scheme

4.—(1) As part of its Extended Hours Access Scheme, each Primary Care Trust must, subject to paragraphs (3) and (6), offer, within the time limits set out in paragraph (2), to each GMS contractor in its area, and each PMS contractor in its area for which it holds a list of registered patients, the opportunity to enter into arrangements in respect of the period up to and including 31st March 2010, thereby affording the contractor a reasonable opportunity to participate in the scheme during the period up to and including 31st March 2010.

(2) The time limits referred to in paragraph (1) are—

- (a) in the case of a contractor that is providing services on 2nd September 2008, on or before the expiry of the period of 28 days beginning with 2nd September 2008; and
- (b) in the case of a contract that commences after 2nd September 2008, on or before the expiry of the period of 28 days beginning with the date the contract starts.

(3) A Primary Care Trust is not required to offer to enter into arrangements with any GMS or PMS contractor if it has, prior to the coming into force of these Directions, entered into any arrangement with that GMS or PMS contractor the purpose of which was the same or broadly similar to the purpose set out in paragraph 3(1)(a), and which the Primary Care Trust, having consulted the contractor, is satisfied meets the same or broadly similar standards and objectives as the scheme the Primary Care Trust must offer under these Directions.

(4) If a Primary Care Trust has entered into arrangements with a contractor as set out in paragraph (3), it must, before 2nd November 2008, complete a review of those arrangements and, subject to the agreement of the contractor, vary the terms of the agreement relating to those arrangements so that—

- (a) if the arrangements would otherwise terminate before 31st March 2010, the terms of the agreement are extended to 31st March 2010;
- (b) if the arrangements would otherwise extend beyond 31st March 2010, the terms of the agreement are reduced to 31st March 2010;
- (c) if the financial terms are less favourable than those that would be available under the scheme made available under these Directions and the Statement of Financial Entitlements, the financial terms are equivalent, as regards the period between the date the review is concluded and 31st March 2010, to the financial terms that would apply to a scheme made available under these Directions and the Statement of Financial Entitlements; and
- (d) if the requirements imposed on either the Primary Care Trust or the contractor are not equivalent to those that would be imposed under a scheme made available under these Directions and the Statement of Financial Entitlement, the requirements impose requirements of an equivalent standard,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the terms of any agreement revised in accordance with the requirements of this paragraph comprise part of the contractor's contract and the requirements of the agreement revised in accordance with the requirements of this paragraph are conditions of the contract.

(5) Where a Primary Care Trust determines, in accordance with paragraph (3), that it is not required to offer to enter into arrangements in accordance with paragraph (1), it shall record the name of the contractor and its reasons for so determining and it shall send to the relevant Strategic Health Authority a list of such contractors and the associated reasons no later than 11th November 2008.

(6) A Primary Care Trust is not required to enter into any arrangements under paragraph (1) after 31st December 2009.

(7) A Primary Care Trust must—

- (a) consider any proposals put forward by a GMS or PMS contractor which wishes to enter into arrangements under paragraph (1) with a view to agreeing them;

- (b) not delay any such consideration unreasonably;
- (c) not withhold its agreement unreasonably; and
- (d) in making a decision as to whether to agree to any proposals, have regard to any relevant local circumstances, any known patient preferences and any relevant guidance issued by the Secretary of State.

(8) A Primary Care Trust is not required to consider and reach a decision on any proposals in accordance with paragraph (7) if the GMS or PMS contractor has failed to provide any information requested by the Primary Care Trust that the Primary Care Trust reasonably requires in order to ascertain whether the proposals meet its requirements.

(9) The arrangements that a Primary Care Trust enters into with a GMS or PMS contractor for Extended Hours Access must be in writing and must include—

- (a) a written obligation by the contractor to implement the agreed arrangements in so far as they place obligations upon it;
- (b) details of the arrangements the contractor proposes to make in order to enable patients to consult a general practitioner, face to face, at times other than during the core hours specified in the contractor's primary medical services contract; and those arrangements must comply with the following provisions—
 - (i) the arrangements must include the provision of a clinical session or sessions, provided by a general practitioner or practitioners, on a regular basis each week from the contractor's practice premises which are held at times other than during the core hours specified in the contractor's primary medical services contract;
 - (ii) any clinical session or sessions provided must be in addition to the contractor's normal provision of clinical sessions during core hours;
 - (iii) the additional period of the clinical session or sessions provided must, as a minimum, equate to a period of time calculated as follows—
 - (aa) first, divide the contractor's CRP at the time the arrangements are agreed by 1000;
 - (bb) then, multiply the figure obtained from the calculation made under sub-paragraph (aa) by 30;
 - (cc) then, convert the figure obtained from the calculation made under sub-paragraph (bb) into hours and minutes, rounded to the nearest quarter hour;
 - (iv) the agreed period of time of any additional clinical session or sessions must be provided in full and may not be met by a clinical session or sessions consisting of concurrent appointments which, when added together, provide the equivalent of the agreed period of time, unless, having regard to any relevant local circumstances and to any relevant guidance issued by the Secretary of State, the Primary Care Trust, at its absolute discretion, agrees otherwise;
 - (v) any clinical session or sessions provided must be provided in continuous periods of at least 1 and a half hours unless, having regard to any relevant local circumstances, to any relevant guidance issued by the Secretary of

State and to the views of the contractor's patients, the Primary Care Trust, at its absolute discretion, agrees to alternative arrangements;

- (c) a requirement that the contractor co-operate with the Primary Care Trust in any review of the arrangements designed to establish whether the pattern of additional hours provided under the arrangements is meeting the requirements of the contractor's registered patients;
- (d) where the contractor provides out of hours services to its patients, a requirement that the contractor will not limit access to any additional clinical session or sessions it provides under the agreement to those patients that it would in any event have been obliged to see in accordance with its obligations in providing that out of hours service;
- (e) the arrangements for the provision of information by the Primary Care Trust and by the contractor;
- (f) the arrangements for the monitoring of the arrangements by the Primary Care Trust;
- (g) the arrangements for changing the pattern of, or for cessation of, agreed extended opening times, including an agreed notice period for any such changes or cessation;
- (h) the arrangements to be made by the contractor and the Primary Care Trust for informing the contractor's patients about the additional clinical session or sessions being made available under these arrangements; and
- (i) in the case of PMS contractors, the amount of the payments to be made to the contractor for meeting its obligations under the arrangements and in determining the appropriate level of those payments the Primary Care Trust must have regard to the amounts of payments under section 7G of the Statement of Financial Entitlements and may only make such payment in respect of the period during which services under the arrangements are provided and may not make any payment in respect of any period prior to the commencement of the provision of any such services ,

and the Primary Care Trust must, where necessary, and subject to the provisions of paragraph (10), vary the primary medical services contractor's primary medical services contract so that the arrangements comprise part of the contractor's contract and the requirements of the arrangements are conditions of the contract.

(10) No variation of the contract to incorporate any Extended Hours Access arrangements shall provide—

- (a) in the case of a contractor that does not provide out of hours services, that any obligation under the contract to attend on a patient outside practice premises (in accordance with the provisions of paragraph 3 of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004 or paragraph 4 of Schedule 5 to National Health Service (Personal Medical Services Agreements) Regulations 2004(a)) applies in respect of any additional period during which the contractor is providing services in accordance with the Extended Hours Access arrangements; or

(a) 2004/627 as amended by S.I. 2004/2694, 2005/893 and 3315, 2006/1501, 2007/289 and 3491 and 2008/528, 1514 and 1700.

- (b) that Saturday is to be considered a “working day” for the purpose of any calculation of a period of time required under the contract where such calculation is defined with reference to “working day”.

Childhood Immunisation Scheme

5.—(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—

- (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(b) 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 its 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 those target 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

6. 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—

- (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 they are—
 - (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 they are 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 their 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

7.—(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—

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

Minor Surgery Scheme

8. 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—

- (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

9. The Primary Medical Services (Directed Enhanced Services) (England) Directions 2007 are hereby revoked, save to the extent necessary to assess any entitlement to payment in respect of services provided under arrangements made in accordance with those Directions.

Signed by authority of the Secretary of State for Health

A handwritten signature in black ink, appearing to read 'Richard Armstrong', written over a horizontal line.

1st September 2008

Richard Armstrong
Department of Health
A member of the Senior Civil Service