DIRECTIONS

NATIONAL HEALTH SERVICE, ENGLAND

The Primary Medical Services (Directed Enhanced Services) (No.2) Directions 2020

The Secretary of State for Health and Social Care, in exercise of the powers conferred by sections 98A(3), 272(7) and (8) and 273(1) of the National Health Service Act 2006(**a**), gives the following Directions.

Citation and commencement

- **1.**—(1) These Directions may be cited as the Primary Medical Services (Directed Enhanced Services) (No.2) Directions 2020 and come into force on 4th September 2020.
 - (2) These Directions are given to the Board.

Interpretation

2. In these Directions—

"the Act" means the National Health Service Act 2006;

"the Board" means the National Health Service Commissioning Board(b);

"child" has the same meaning as in regulation 3 of the National Health Service (General Medical Services Contracts) Regulations 2015(**c**);

"core hours" has the same meaning as in regulation 3 of the National Health Service (General Medical Services Contracts) Regulations 2015;

"CRP" means the Contractor Registered Population as defined in Annex A of the Statement of Financial Entitlements;

"financial year" means the twelve months ending on 31st March;

"general practitioner" means a medical practitioner whose name is included in the medical performers list prepared and maintained by the Board in accordance with regulation 3(1)(a) of the National Health Service (Performers Lists) (England) Regulations 2013(d) (performers lists);

"GMS contract" means a general medical services contract;

"GMS contractor" means a person with whom the Board is entering, or has entered into, a GMS contract:

⁽a) 2006 c.41. Section 98A of the National Health Service Act 2006 ("the Act") was inserted by section 49(1) of the Health and Social Care Act 2012 (c.7) ("the 2012 Act"). By virtue of section 271(1) of the Act, the powers conferred by these sections are exercisable by the Secretary of State only in relation to England.

⁽b) The National Health Service Commissioning Board (known as "NHS England") is established by section 1H of the Act. Section 1H is inserted into the Act by section 9(1) of the 2012 Act.

⁽c) S.I. 2015/1862, as amended by S.I. 2016/211, 481, 696, 875 and 1077; S.I. 2017/908; S.I. 2018/844 and 1114, S.I. 2019/248, 593, 1094 and 1137 and S.I. 2020/226 and 351.

⁽d) S.I. 2013/335, amended by S.I. 2013/1869, 2015/362 and 1862, S.I. 2016/686, S.I. 2017/960, S.I. 2018/378, S.I.2019/248 and S.I. 2020/411.

"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) (The Professional Standards Authority for Health and Social Care);

"out of hours services" has the same meaning as in regulation 3 of the National Health Service (General Medical Services Contracts) Regulations 2015;

"PMS agreement" means a section 92 arrangement(**b**) with a person which requires the provision by that person of primary medical services;

"PMS contractor" means a person with whom the Board is entering, or has entered into, a PMS agreement;

"practice" means the business operated by a primary medical services contractor for the purpose of delivering services under the primary medical services contract;

"primary care network" means a network of primary medical services contractors and other providers of services which has been approved by the Board, serving an identified geographical area(\mathbf{c})

"primary medical services" means medical services to which the provisions of Part 4 of the Act (medical services) apply;

"primary medical services contract" means—

- (a) a GMS contract;
- (b) a PMS agreement; or
- (c) contractual arrangements for the provision of primary medical services under section 83(2) of the Act(**d**) (primary medical services);

"primary medical services contractor" means—

- (a) a GMS or PMS contractor; or
- (b) a person with whom the Board is making, or has made, contractual arrangements for the provision of primary medical services under section 83(2) of the Act;

"registered patient" means-

- (a) a person recorded by the Board as being on a primary medical services contractor's list of patients; or
- (b) a person whom a primary medical services contractor has accepted for inclusion on its list of patients whether or not notification of that acceptance has been received by the Board and who has not been notified by the Board as having ceased to be on that list;

"Statement of Financial Entitlements" means the General Medical Services Statement of Financial Entitlements Directions 2013(e); and

⁽a) 2002 c.17; section 25(3) was amended by paragraph 17 of Schedule 10 to, the Health and Social Care Act 2008 (c.14), paragraph 15 of Schedule 15 to the Health and Social Care Act 2012 (c.7), paragraph 2 of Schedule 4 to the Children and Social Work Act 2017 (c.16) and article 68 of, and paragraph 10(1) and (2) of Schedule 4 to, S.I. 2010/231.

⁽b) Section 92 is amended by section 55(1) of, and paragraph 36 of Schedule 4 to, the 2012 Act. See section 92(8) of the Act.

⁽c) The Network Contract Directed Enhanced Service Contract Specification covering primary care networks is available at https://www.england.nhs.uk/gp/gpfv/investment/gp-contract/ or hard copies are available from the Primary Care Strategy and NHS Contracts team, NHS England, Area 2D, Skipton House, 80 London Road, London, SE1 6LH.]

⁽d) Section 83 is amended by section 55(1) of, and paragraph 30 of Schedule 4 to, the 2012 Act.

⁽e) Those Directions were signed on 27th March 2013 and were amended by the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2013, which were signed on 18th September 2013; the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2014, which were signed on 28th March 2014; the General Medical Services Statement of Financial Entitlements (Amendment No.2) Directions 2014, which were signed on 30th September 2014; the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2015, which were signed on 23rd March 2015; the General Medical Services Statement of Financial Entitlements (Amendment No.2) Directions 2015, which were signed on 28th September 2015; the General Medical Services Statement of Financial Entitlements (Amendment No.3) Directions 2015, which were signed on 6th October 2015; the General Medical Services Statement of Financial Entitlements (Amendment No.4) Directions 2015, which were signed on 4th December 2015; the General Medical Services Statement of Financial Entitlements (Amendment No.2) Directions 2016, which were signed on 9th May 2016; the General Medical Services Statement of Financial Entitlements (Amendment No.2) Directions 2016, which were signed on 24th November 2016; the General Medical Services Statement of Financial Entitlement (Amendment No.3) Directions 2016, which were signed on 24th November 2016; the General Medical Services Statement of Financial Entitlements (Amendment Directions 2016, which were signed on 24th November 2016; the General Medical Services Statement of Financial Entitlements (Amendment Directions 2016, which were signed on 24th November 2016; the General Medical Services Statement of Financial Entitlements (Amendment Directions 2017, which were signed on 31st March 2017; the General Medical Services

"working day" has the same meaning as in regulation 3 of the National Health Service (General Medical Services Contracts) Regulations 2015.

Establishment etc. of directed enhanced services schemes

- **3.**—(1) The Board must, in exercising its functions under section 83(1) of the Act, establish, operate and, as appropriate, revise the following schemes—
 - (a) a Network Contract Directed Enhanced Service Scheme, to integrate care by the formation and continued operation of primary care networks ("PCNs") in order to deliver care in a more personalised way;
 - (b) a Learning Disabilities Health Check Scheme, to encourage primary medical services contractors to—
 - (i) identify registered patients aged 14 and over who are known to the local authority social services department primarily because of their learning disabilities, and
 - (ii) offer and provide such patients with an annual health check;
 - (c) a Childhood Immunisation Scheme, to ensure that patients—
 - (i) who have attained the age of 2 years but who are not yet 3 years are able to benefit from the recommended immunisation courses (that is those that have been recommended in England and by the World Health Organisation(a)) for protection against—
 - (aa) diphtheria, tetanus, poliomyelitis, pertussis and Haemophilus influenzae type B (HiB) and Hepatitis B,
 - (bb) measles/mumps/rubella, and
 - (cc) Meningitis C, or
 - (ii) who have attained the age of 5 years but who are not yet 6 years are able to benefit from the recommended reinforcing doses (that is those that have been recommended in England and by the World Health Organisation) for protection against diphtheria, tetanus, pertussis and poliomyelitis;
 - (d) an Influenza and Pneumococcal Immunisation Scheme, to ensure that patients in the primary medical services contractor's area who are at risk of influenza (and certain other categories of patient) or pneumococcal infection are offered immunisation against these infections;
 - (e) a Violent Patients Scheme, to ensure that there are sufficient arrangements in place to provide primary medical services to patients who 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, to ensure that a wide range of minor surgical procedures are made available as part of the primary medical services provided throughout England.

Statement of Financial Entitlements (Amendment) (No.2) Directions 2017, which were signed on 30th October 2017; the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2018, which were signed on 29th March 2018; the General Medical Services Statement of Financial Entitlements (Amendment) (No.2) Directions 2018, which were signed on 23rd October 2018, the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2019 which were signed on 29th March 2019, the General Medical Services Statement of Financial Entitlements (Amendment) (No.2) Directions 2019, which were signed on 30th September 2019, the General Medical Services Statement of Financial Entitlements (Amendment) Directions 2020, which were signed on 26th February 2020 and the General Medical Services Statement of Financial Entitlements (Amendment)(No.2) Directions 2020, which were signed on 31st March 2020. Copies of the aforementioned Directions are available at: https://www.gov.uk/government/publications/nhs-primary-medical-services-directions-2013 or a hard copy from the Primary Care team, Department of Health and Social Care, 4th Floor, 39 Victoria Street, London SW1H 0EU.

(a) Information on such recommended immunisation courses is available from NHS England, PO Box 16738, Redditch, B97 7PT or can be accessed on the following website: http://www.who.int/immunization/policy/immunization_tables/en/.

- (2) The Board must not enter into arrangements with a primary medical services contractor as part of one of the schemes mentioned in paragraph (1) unless the Board is satisfied that the contractor—
 - (a) is capable of meeting its obligations under those arrangements (including under any agreed plan); and
 - (b) in particular, has the necessary facilities, equipment and properly trained and qualified general practitioners, health care professionals and staff to perform those obligations.

Network Contract Directed Enhanced Service Scheme

- **4.**—(1) As part of the Network Contract Directed Enhanced Service Scheme (referred to in this direction as "the Scheme"), the Board will have—
 - (a) offered to each primary medical services contractor (referred to in this Direction as a "contractor") an opportunity to enter into, during the relevant period, arrangements under the Scheme in accordance with the Board's Network Contract Directed Enhanced Services Specification(a) (referred to in this Direction as the "Specification");
 - (b) offered to contractors who wish to enter into arrangements under the Scheme but who are not part of an Approved PCN, an opportunity to apply to register, during the relevant period, a new PCN; and
 - (c) allowed contractors to apply to alter the membership of a new or Approved PCN during the relevant period.
- (2) The Board must only approve the registration of a new PCN or continue to approve an Approved PCN where each contractor forming part of the PCN has—
 - (a) signed a Network Agreement in accordance with the Specification;
 - (b) agreed upon and nominated one contractor to receive payments from the Board on their behalf, to be known as the "nominated payee";
 - (c) put in place suitable arrangements to enable the sharing of data to support the delivery of services and business administration, prior to the start of any service delivery under the Scheme, in accordance with the Network Agreement and the Specification; and
 - (d) complied with any additional applicable requirement in the Specification.
 - (3) Where the Board is satisfied there are exceptional circumstances it may allow—
 - (a) a contractor to enter into arrangements under the Scheme outside of the relevant period;
 - (b) contractors to apply to the Board to register a new PCN outside of the relevant period; or
 - (c) contractors to apply to the Board to alter the membership of a new or Approved PCN outside of the relevant period.
- (4) The arrangements that the Board enters into with a contractor under the Scheme must include—
 - (a) a requirement that the contractor agrees to continue to have arrangements under the Scheme in respect of each financial year until 31st March 2024, unless the contractor gives notice in accordance with the Specification to terminate its arrangements or the Board terminates the contractor's arrangements in accordance with the Specification;
 - (b) a requirement that the contractor agrees to alter the membership of the PCN, of which it is a member, to include a contractor notified by the Board, in circumstances where the Board has first engaged with a local medical committee;
 - (c) details of the contractor's obligations under the Scheme in accordance with the Specification;

⁽a) Specification at: https://www.england.nhs.uk/gp/gpfv/investment/gp-contract/

- (d) a requirement that the contractor is accountable, on a collective basis with the other contractors which are members of the same PCN, for complying with any obligations which are specified to be those of the PCN in the Specification;
- (e) details of the consequences of any breach of the contractor's obligations under the Scheme and of any obligations specified to be those of the PCN in the Specification;
- (f) details of the arrangements for the monitoring of the arrangements by the Board;
- (g) a requirement that the contractor provides the Board with such information as the Board may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the arrangements;
- (h) details of the arrangements for the provision of information to the Board by the contractor; and
- (i) the payment arrangements for the contractor.
- (5) The Board must, if necessary, vary the contractor's primary medical services contract so that the Scheme comprises part of the contractor's contract or agreement and the arrangements under the Scheme are conditions of the contract or agreement.
 - (6) In this direction—
 - (a) "Approved PCN" means a PCN approved in the period 1st July 2019 to 31st March 2020;
 - (b) "local medical committee" means a committee recognised by the Board under section 97 of the 2006 Act(a);
 - (c) "member" or "membership" refers to Core Network Practice(b) members which are contractors with responsibility for meeting the obligations specified to be those of the PCN in the Specification;
 - (d) "relevant period" means the period between 1st April 2020 and 31st May 2020; and
 - (e) "Specification" has the meaning given in direction 4(1)(a).

Learning Disabilities Health Check Scheme

- **5.**—(1) As part of its Learning Disabilities Health Check Scheme (referred to in this direction as "the Scheme"), the Board will have offered to—
 - (a) each GMS contractor which entered into a GMS contract before 1st April 2019 and which subsisted on 1st April 2020;
 - (b) each PMS contractor for which it holds a list of registered patients, which entered into a PMS agreement before 1st April 2019 and which subsisted on 1st April 2020;
 - (c) each GMS contractor which entered into a GMS contract between 1st April 2020 and 3rd September 2020; and
 - (d) each PMS contractor for which it holds a list of registered patients which entered into a PMS agreement between 1st April 2020 and 3rd September 2020,

an opportunity to enter into arrangements under the Scheme in respect of the financial year ending on 31st March 2021.

- (2) Subject to paragraph (3), the Board must offer to—
 - (a) each GMS contractor which enters into a GMS contract on or after 4th September 2020; and
 - (b) each PMS contractor for which it holds a list of registered patients and which enters into a PMS agreement on or after 4th September 2020,

an opportunity, after that date, to enter into the arrangements under the Scheme for the remainder of the financial year.

⁽a) Section 97 was amended by paragraph 41 of Schedule 4(4) to the Health and Social Care Act 2012 (c.7).

⁽b) See paragraph 2.2f of the Board's Network Contract Directed Enhanced Services Specification.

- (3) The Board must only enter into an arrangement under the Scheme after 31st December 2020 if—
 - (a) two or more GMS contracts or PMS agreements (under at least one of which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) merge and—
 - (i) as a result, two or more patient lists are combined, resulting in either a new or varied GMS contract or PMS agreement, and
 - (ii) the contractor who is a party to such a new or varied contract or agreement wishes to enter into new arrangements referred to in paragraph (1); or
 - (b) a GMS contract or PMS agreement (under which arrangements under the Scheme referred to in paragraph (1) had previously been entered into) splits and—
 - (i) as a result, the contractor's patient list is divided between two or more GMS or PMS contractors, resulting in either new or varied GMS contracts or PMS agreements, or a combination of both, and
 - (ii) a contractor who is a party to such a new or varied contract or agreement wishes to enter into a new arrangement as referred to in paragraph (1).
- (4) If the Board enters into a new arrangement under the Scheme, it must do so before the expiry of the period of 28 days beginning with the date of the merger or the split as the case may be.
 - (5) The Board must—
 - (a) consider any proposals put forward by a GMS or PMS contractor which wishes to enter into arrangements under the Scheme referred to in paragraphs (1) and (2) with a view to agreeing them;
 - (b) not delay any such consideration unreasonably; and
 - (c) not withhold its agreement unreasonably.
- (6) The Board may consider and reach a decision in respect of entering into any arrangements under the Scheme if a GMS or PMS contractor has failed to provide written proposals in response to the Board's offer to enter into such arrangements within 42 days beginning with the date of the offer.
- (7) The arrangements that the Board enters into with a GMS or PMS contractor as part of the Scheme must include—
 - (a) a requirement that the contractor compile a "health check learning disabilities register" from the coded information held on a registered patient's medical record for the purpose of identifying those of its registered patients aged 14 years or over with learning disabilities who are to be invited for an annual health check under the arrangement(a);
 - (b) a requirement that the contractor review any learning disabilities register it has already set up under Quality and Outcomes Framework arrangements under its contract or agreement and ensure that such learning disabilities register includes all those registered patients that have been identified for inclusion in the health check learning disabilities register;
 - (c) a requirement that the contractor takes reasonable steps to keep the health check learning disabilities register up to date throughout the period of the arrangement by removing and adding registered patients as appropriate;
 - (d) a requirement that the contractor provides the Board with such information as the Board may reasonably require to demonstrate that it has robust systems in place to maintain such register accurately;
 - (e) a requirement that the contractor must offer an annual health check to each patient on its health check learning disabilities register;

⁽a) Details of the learning disabilities health check scheme can be found in the 2020/21 Learning Disabilities Health Check Scheme Enhanced Service Specification at: https://www.england.nhs.uk/gp/investment/gp-contract/. Hard copies of this guidance are available from NHS England, PO Box 16738, Redditch B97 7PT.

- (f) a requirement that, if the patient consents, or if a person consents on a patient's behalf, the health check provided under the arrangement is to involve any carer, support worker or other person considered appropriate by either the patient, the person consenting on behalf of the patient or the contractor;
- (g) a requirement that any health check provided under the arrangement must, as a minimum, include—
 - (i) a review of the patient's physical and mental health that includes—
 - (aa) the provision of relevant health promotion advice,
 - (bb) a chronic illness and system enquiry(a),
 - (cc) a physical examination,
 - (dd) a consideration of whether the patient suffers from epilepsy,
 - (ee) a consideration of the patient's behaviour and mental health, and
 - (ff) a specific syndrome check(**b**),
 - (ii) the production of a health action plan for all patients with a learning disability who are aged 14 years and over,
 - (iii) a check on the appropriateness of any prescribed medicines,
 - (iv) a review of coordination arrangements with secondary care, and
 - (v) where appropriate, a review of any transitional arrangements which took place on the patient attaining the age of 18;
- (h) a requirement that in carrying out any health check provided under the arrangements the contractor must use—
 - (i) the "Cardiff" health check protocol which is available through the Royal College of General Practitioners' website(c) or a similar protocol agreed with the Board, or
 - (ii) the National Electronic Health Check (Learning Disabilities) Template(d);
- (i) a requirement that, before undertaking any health check under the arrangements, the contractor must arrange a training session, if it has not already done so, for its staff which meets the following requirements—
 - (i) the training session must be attended by such members of the contractor's staff as are agreed between the contractor and the Board, which must include as a minimum—
 - (aa) the lead general practitioner and the lead practice nurse, and
 - (bb) either the practice manager or the senior receptionist, if the contractor's staff include staff with those designations, or where the contractor's staff does not include staff with those designations, either of the members of the contractor's staff who have analogous roles,
 - (ii) the training session must consist of a multi-professional education session approved by the Board, and
 - (iii) the training session must include instruction on overcoming any attitudinal barriers of the staff with a view to improving their communication with patients with learning disabilities:

⁽a) A systems enquiry is a check of respiratory, cardiovascular and other functions in the body which may not currently present as being subject to chronic illness or disease.

⁽b) A syndrome check is a bodily check for certain syndromes known to cause learning disabilities which are associated with increased morbidity.

 ⁽c) The website can be found at http://www.rcgp.org.uk/learningdisabilities/. Hard copies of the protocol are available from the Primary Care team, Department of Health and Social Care, 4th Floor, 39 Victoria Street, SW1H 0EU.
(d) The National Electronic Health Check (Learning Disabilities) Template is an interactive code-based tool which has been

⁽d) The National Electronic Health Check (Learning Disabilities) Template is an interactive code-based tool which has been available on GP IT systems from 1st April 2017. The purpose of the tool is to help GPs assess the health needs of those with learning disabilities in a systematic way and to generate a Health Check Action Plan which is tailored towards the needs of individual patients. Further information about the template can be obtained from NHS England, PO Box 16738, Redditch, B97 7PT.

- (j) a requirement that the contractor makes relevant entries in the patient's medical record, including any refusal to take up the offer of a health check;
- (k) a requirement that, before 30th April 2021, the contractor informs the Board, in writing (to include by way of electronic mail), of the number of registered patients on the health check learning disabilities register who have received a health check undertaken by the contractor under the arrangement referred to in paragraph (1) in respect of the twelve month period ending on 31st March 2021;
- (l) details of the arrangements for the provision of information by the Board and by the contractor in addition to any information the contractor is required to provide in accordance with sub-paragraph (m);
- (m) details of the arrangements for the monitoring of the arrangements by the Board; and
- (n) 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 Board must have regard to the amounts of payments under Section 9 of the Statement of Financial Entitlements.
- (8) The Board must, if necessary, vary the contractor's GMS contract or PMS agreement so that the Scheme comprises part of the contractor's contract or agreement and the arrangements under the Scheme are conditions of the contract or agreement.

Childhood Immunisation Scheme

- **6.**—(1) As part of its Childhood Immunisation Scheme (referred to in this direction as "the Scheme"), the Board must, each financial year, offer the opportunity to enter into arrangements under the Scheme to each GMS or PMS contractor, 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 immunisation and pre-school boosters additional service under its general medical services contract.
- (2) The arrangements under paragraph (1) must, in respect of each financial year to which those arrangements relate, 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, or offer to provide, childhood immunisation and pre-school booster services (irrespective of whether or not those children may have already been immunised, or offered immunisation, by the contractor or otherwise),
 - (ii) proactively offers the recommended immunisations referred to in direction 3(c) in respect of the children on its Childhood Immunisation Scheme Register (with the aim of maximising uptake in the interests of patients, both individually and collectively and meeting any public health targets), by adopting robust call and reminder systems, and
 - (iii) records the information that it has in its Childhood Immunisation Scheme Register using any applicable national clinical codes(a);
 - (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

⁽a) The clinical codes that support the relevant enhanced service and vaccination programmes, are available on the Health and Social Care Information Centre website at: http://digital.nhs.uk.QOF/qofesextractspecs or in hard copy form from The Health and Social Care Information Centre, 1 Trevelyan Square, Boar Lane, Leeds, LS1 6AE.

- (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 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 immunisation,
 - (ii) where an offer of immunisation was accepted—
 - (aa) details of the consent to the vaccine or immunisation where a person has consented on a child's behalf (and 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 vaccine, and
 - (ff) any adverse reactions to the vaccine;
- (d) a requirement that the contractor ensures that any health care professional who is involved in administration of the vaccine has—
 - (i) the 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 the Board with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the arrangements;
- (g) arrangements for an annual review of the arrangements which must 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 PMS contractors, the payment arrangements for the contractor, which must comprise target payments to the contractor where the contractor—
 - (i) meets its obligations under the Scheme, 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 Board must disregard any personalised care adjustment in its calculation of target payments),

and in determining the appropriate level of those target payments, the Board must have regard to the target payments and the targets rewarded under Section 11 of the Statement of Financial Entitlements (childhood immunisations).

- (3) The Board must, if necessary, vary the contractor's GMS contract or PMS agreement so that the Scheme comprises part of the contractor's contract or agreement and the arrangements under the Scheme are conditions of the contract or agreement.
- (4) In this direction, "personalised care adjustment" has the same meaning as paragraph 4.14(a) of the Statement of Financial Entitlements.

Influenza and Pneumococcal Immunisation Scheme

- 7.—(1) As part of its Influenza and Pneumococcal Immunisation Scheme, the Board may enter into arrangements with any primary medical services contractor, and if it does so, the arrangements must, in respect of each financial year to which those arrangements relate, include—
 - (a) a requirement that the contractor develops and maintains a register (its "Influenza and Pneumococcal Immunisation 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) morbidly obese,
 - (cc) suffering from chronic respiratory disease (including asthma), chronic heart disease, chronic kidney disease, chronic liver disease, chronic neurological disease, Asplenia or dysfunction of the spleen, immuno-suppression due to disease or treatment, or diabetes mellitus, or
 - (dd) living in long-stay residential or nursing homes or other long-stay health or social care facilities, or
 - (ii) pneumococcal infection if they are—
 - (aa) aged 65 or over at the end of that financial year,
 - (bb) suffering from Asplenia or dysfunction of the spleen, chronic respiratory disease, chronic heart disease, chronic kidney disease, chronic liver disease, diabetes mellitus, immuno-suppression due to disease or treatment, or
 - (cc) if they have a cochlear implant or a cerebrospinal fluid leak;
 - (b) a requirement that the contractor undertakes to offer immunisation against influenza to patients identified by the contractor as falling into the following categories—
 - (i) health or social care staff employed by a registered residential care home, registered nursing home or registered domiciliary care provider,
 - (ii) health or care staff employed by a voluntary managed hospice provider,
 - (iii) a personal assistant,
 - (iv) a household contact of an individual on the Shielded Patient List(a),
 - (v) a carer,
 - (vi) a locum general practitioner,
 - (vii) diagnosed as pregnant; or
 - (viii) any person not falling within sub-paragraph (a)(i)(bb) to (dd) or paragraphs (i) to (vii), who is aged between 50 and 64 years and whose particular age group has been identified and announced as eligible to receive immunisation against influenza in accordance with the process to commence immunisation of this cohort in the Specification(b);
 - (c) a requirement that the contractor undertakes to offer immunisation against influenza and pneumococcal infection to those patients who are at risk, in addition to immunisation against influenza for patients identified pursuant to sub-paragraph (b), and—
 - (i) in the case of immunisation against influenza infection—

⁽a) The Shielded Patient List can be found at: https://digital.nhs.uk/coronavirus/shielded-patient-list. The Shielded Patient List includes patients who are immuno-compromised.

⁽b) https://www.england.nhs.uk/publication/directed-enhanced-service-specification-seasonal-influenza-and-pneumococcal-polysaccharide-vaccination-programme-2020-21/

- (aa) makes that offer before the end of the financial year, and in the case of patients identified pursuant to sub-paragraph (b), as soon as possible following that identification,
- (bb) concentrates the immunisation programme during the period from 4th September to 30th November in that financial year, and
- (cc) uses the influenza vaccines specified in guidance(a) produced by the Board;
- (ii) in the case of immunisation against pneumococcal infection, offers and delivers such immunisations throughout the financial year, and
- (iii) save in the case of those patients identified pursuant to sub-paragraph (b), records the information that it has in its Influenza and Pneumococcal Immunisation Scheme Register using any applicable national clinical codes(b);
- (d) a requirement that the contractor develops a proactive and preventative approach to offering these immunisations, save in relation to patients identified pursuant to subparagraph (b), by adopting robust call and reminder systems to contact at-risk patients, with the aims of—
 - (i) maximising uptake, and
 - (ii) meeting any public health targets in respect of such immunisations;
- (e) a requirement that the contractor takes all reasonable steps to ensure that the lifelong medical records held by the general practitioner of an at-risk patient and one identified pursuant to sub-paragraph (b) are kept up-to-date with regard to their immunisation status, and in particular include—
 - (i) any refusal of an offer of immunisation,
 - (ii) where an offer of immunisation was accepted—
 - (aa) details of the consent to the vaccine or immunisation (where a person has consented on behalf of an at-risk patient, or on behalf of a patient identified pursuant to sub-paragraph (b), that person's relationship to the 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 vaccine, and
 - (ff) any adverse reactions to the vaccine;
- (f) a requirement that the contractor ensures that any health care professional who is involved in the administration of the vaccine has—
 - (i) the 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;
- (g) 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;

⁽a) Guidance at: https://www.england.nhs.uk/gp/gpfv/investment/gp-contract/

⁽b) The clinical codes that support the relevant enhanced service and vaccination programmes, are available on the Health and Social Care Information Centre website at: https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/quality-and-outcomes-framework-qof/quality-and-outcome-framework-qof--business-rules/enhanced-services-es-vaccination-and-immunisation-vi-and-core-contract-components-2019-2020 or in hard copy form from The Health and Social Care Information Centre, 1 Trevelyan Square, Boar Lane, Leeds, LS1 6AE.

- (h) a requirement that the contractor supply the Board 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.
- (2) The Board must, where necessary, vary the primary medical services contractor's primary medical services contract so that the Scheme comprises part of the contractor's contract or agreement and the arrangements under the Scheme are conditions of the contract or agreement.
 - (3) In this direction—

"carer" means an individual in receipt of Carer's Allowance(a) or an individual who cares for an elderly or disabled person whose welfare might be at risk if the carer was unable to care for that person due to illness;

"household contact" means an individual, aged 6 months or over, who shares or expects to share living accommodation with an individual on the Shielded Patient List for part or all of the seven month period of September through to March";

"personal assistant" means a health or social care worker employed by means of one or a combination of health or social care Direct Payments(**b**), or a Personal Health Budget(**c**), or a Personal Budget(**d**), to provide domiciliary care;

"registered" means in relation to, a residential care home, nursing home or domiciliary care provider, being registered with the Care Quality Commission pursuant to the requirements of the Health and Social Care Act 2008(e) and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014(f);

"Specification" means the Directed Enhanced Service Specification for seasonal influenza and pneumococcal polysaccharide vaccination programme 2020/21(g); and

"voluntary managed" means managed by a charitable organisation.

Violent Patients Scheme

- **8.**—(1) The Board must consult the local medical committee (if any) for the area in which a primary medical services contractor which wishes to enter into arrangements in respect of a Violent Patients Scheme (referred to in this direction as "the Scheme") provides primary medical services about any proposals it has to establish or revise the Scheme.
 - (2) Where the Board enters into arrangements under the Scheme, the Board must—
 - (a) as part of those arrangements, make provision for the payment arrangements for the contractor agreeing and meeting its obligations under the Scheme in respect of each financial year to which those arrangements relate; and
 - (b) if necessary, vary the primary medical services contractor's contract or agreement so that the Scheme comprises part of the contractor's contract or agreement and the arrangements under the Scheme are conditions of the contract or agreement.
- (3) In this direction "local medical committee" has the same meaning as given in direction 4(6)(b).

⁽a) See section 70 of the Social Security Contributions and Benefits Act 1992 c.4.

⁽b) Direct Payments made pursuant to section 12A of the National Health Service Act 2006 C.41 (see also S.I. 2013/1617) and those made pursuant to sections 31 and 32 of the Care Act 2014 C.23 (see also S.I.2014/2871).

⁽c) https://www.england.nhs.uk/personal-health-budgets/what-are-personal-health-budgets-phbs/

⁽d) See section 26 of the Care Act 2014.

⁽e) 2008 C.14.

⁽f) S.I. 2014/2936 as amended by S.I. 2015/64, 643 and 664; S.I. 2016/765 and S.I. 2019/1094.

 $⁽g) \quad https://www.england.nhs.uk/publication/directed-enhanced-service-specification-seasonal-influenza-and-pneumococcal-polysaccharide-vaccination-programme-2020-21/\\$

Minor Surgery Scheme

- **9.**—(1) As part of its Minor Surgery Scheme (referred to in this Direction as "the Scheme"), the Board may enter into arrangements with any primary medical services contractor.
- (2) Where the Board enters into arrangements under the Scheme, those arrangements must, in respect of each financial year to which those arrangements relate, include—
 - (a) which minor surgical procedures are to be undertaken by the contractor and for which category of patients, and for these purposes, the minor surgical procedures that may be undertaken are any minor surgical procedures that the Board 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 for 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 the contractor considers there are clinically 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 Board may stipulate—
 - (i) the use of sterile packs from the local Central Sterile Service Department(a), disposable sterile instruments, or approved sterilisation procedures, and
 - (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 Scheme;
 - (h) a requirement that the contractor supplies the Board with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the Scheme; and
 - (i) the payment arrangements for the contractor.

⁽a) The local Central Sterile Services Department is the provider of equipment sterilisation facilities in the local health economy.

(3) The Board must, where necessary, vary the contractor's primary medical services contract or agreement so that the Scheme comprises part of the contractor's contract or agreement and the arrangements under the Scheme are conditions of the contract or agreement.

Revocations and savings

- **10.**—(1) Subject to paragraph (2), the Primary Medical Services (Directed Enhanced Services Directions) 2020 are revoked.
- (2) Notwithstanding the revocation provided for in paragraph (1), the Primary Medical Services (Directed Enhanced Services) Directions 2020 as in force immediately before 4th September 2020 are to continue to apply 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 and Social Care



Sarah Gravenstede Member of the Senior Civil Service Department of Health and Social Care

Date 3rd September 2020