STATUTORY INSTRUMENTS

2021 No. 331

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2021

Made - - - -	*at 12.30 p.m. on 17th March 2021*
Laid before Parliament	*at 3.00 p.m. on 17th March 2021*
Coming into force - -	*1st April 2021*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 85, 89(1) and (2)(a), 94(1) and 272(7) and (8) of the National Health Service Act 2006(**a**).

Citation, commencement, extent, application and interpretation

1.—(1) These Regulations may be cited as the National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2021.

(2) These Regulations come into force on 1st April 2021.

(3) These Regulations extend to England and Wales.

(4) These Regulations apply in relation to England only.

(5) In these Regulations—

"the GMS Contracts Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2015(**b**);

"the PMS Agreements Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2015(**c**).

Amendment of the GMS Contracts Regulations

2. Schedule 1 contains amendments to the GMS Contracts Regulations.

Amendment of the PMS Agreements Regulations

3. Schedule 2 contains amendments to the PMS Agreements Regulations.

(**a**) 2006 c. 41. Section 94 was amended by section 28 of, and paragraph 38 of Schedule 4 to, the Health and Social Care Act 2012 (c. 7) and by paragraph 52 of Schedule 9 to the Crime and Courts Act 2013 (c. 22). There are amendments to sections 89 and 272 but none is relevant to these Regulations. "Prescribed" and "regulations" are defined in section 275 of the National Health Service Act 2006.

(**b**) S.I. 2015/1862; relevant amending instruments are S.I. 2019/1137 and 2020/226.

(**c**) S.I. 2015/1879; to which there are amendments not relevant to these Regulations

Signed by authority of the Secretary of State for Health and Social Care.

Jo Churchill
Parliamentary Under-Secretary of State
Department of Health and Social Care

At 12.30 p.m. on 17th March 2021

SCHEDULE 1

Regulation 2

Amendment of the GMS Contracts Regulations

General

1. The GMS Contracts Regulations are amended as follows.

Essential Services

2.—(1) Regulation 3 (interpretation) is amended as follows.

(2) The existing text becomes paragraph (1).

(3) In paragraph (1)—

(a) in the definition of "additional services" omit paragraphs (a) and (c) to (f);

(b) for the definition of "cervical screening services" substitute—

""cervical screening services" has the meaning given in paragraph (2);";

(c) for the definition of "child health surveillance services" substitute—

""child health surveillance services" has the meaning given in paragraph (3);";

(d) omit the definition of "childhood vaccines and immunisations";

(e) for the definition of "maternity medical services" substitute—

""maternity medical services" has the meaning given in paragraph (4);";

(f) after the definition of "therapeutic radiographer independent prescriber" insert—

""vaccine and immunisation services" has the meaning given in paragraph (7);".

(4) After paragraph (1) insert—

"(2) "Cervical screening services" means the following services—

(a) providing necessary information and advice to assist women who are identified by the Board as recommended nationally for a cervical screening test in making an informed decision as to their participation in the NHS Cervical Screening Programme(**a**);

(b) performing cervical screening tests on women who have agreed to participate in that programme;

(c) ensuring that test results are followed up appropriately;

(d) where a cervical screening test is performed on a woman, recording in the patient's record—

(i) the carrying out of the test,

(**a**) Further information about the NHS Cervical Screening Programme is available at https://www.gov.uk/guidance/cervical-screening-programme-overview or in hard copy form from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

(ii) the result of the test, and

(iii) any clinical follow up requirements.

(3) "Child health surveillance services" means the following services—

(a) monitoring the health, well-being and physical, mental and social development ("development") of a patient who has not attained the age of five years (a "relevant patient") with a view to detecting any deviations from normal development—

(i) by the consideration of information concerning the relevant patient received by or on behalf of the contractor, and

(ii) on any occasion when the relevant patient is examined or observed by or on behalf of the contractor (whether by virtue of sub-paragraph (c) or otherwise);

(b) offering to the parent of the relevant patient an examination of the relevant patient at the frequency that has been agreed with the Board in accordance with the nationally agreed evidence based programme set out in the fifth edition of "Health for all Children"(**a**);

(c) where any offer of an examination under sub-paragraph (b) is accepted, carrying out the examination of the relevant patient;

(d) maintaining, in the relevant patient's record, an accurate record of the development of the patient whilst under the age of five years, which is compiled as soon as reasonably practicable following the first examination of the relevant patient and, where appropriate, amended following each subsequent examination;

(e) recording in the relevant patient's record the response (if any) to any offer of an examination under sub-paragraph (b).

(4) "Maternity medical services" means the following services—

(a) providing to expectant mothers all necessary relevant services throughout the antenatal period;

(b) providing to mothers and their babies (if relevant) all necessary relevant services throughout the postnatal period other than neonatal checks;

(c) inviting each mother who gives birth to a child to attend a maternal postnatal consultation;

(d) where the invitation is accepted, providing the mother with such a consultation—

(i) otherwise than at the same time as any consultation at which the physical health of the baby is reviewed (if relevant), and

(ii) wherever possible, within the postnatal consultation period;

(e) providing all necessary relevant services to patients whose pregnancy has terminated as a result of miscarriage or abortion.

(5) For the purposes of paragraph (4)(c) "child" includes a still-born child within the meaning of the Births and Deaths Registration Act 1953(**b**) (see section 41(1) of that Act).

(6) For the purposes of paragraph (4)—

"antenatal period" means the period beginning with the start of the pregnancy and ending with the onset of labour;

"maternal postnatal consultation" means a consultation with a general medical practitioner, at which the physical and mental health and well-being of the mother is reviewed;

"postnatal consultation period" means the period which—

(a) begins six weeks after the conclusion of the delivery of the baby, and

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(**a**) "Health for all Children" revised fifth edition by Alan Emond was published by Oxford University Press on 28th February 2019.

(**b**) 1953 c. 20. The definition of "still-born child" was amended by Still-Birth (Definition) Act 1992 (c. 29).

(b) ends—

(i) eight weeks after the conclusion of the delivery, or

(ii) if the mother has not been discharged from secondary care services before the end of that period, eight weeks after the mother's discharge from secondary care services;

"postnatal period" means the period which—

(a) begins with the later of—

(i) the conclusion of the delivery of the baby, and

(ii) the mother's discharge from secondary care services, and

(b) ends eight weeks after the conclusion of the delivery;

"relevant services"—

(a) in relation to a patient (other than a baby), means all primary medical services relating to pregnancy, excluding intra partum care;

(b) in relation to a baby, means any primary medical services necessary in their first eight weeks of life.

(7) "Vaccine and immunisation services" means the following services—

(a) offering to administer or provide to patients all vaccines and immunisations of the type, and in the circumstances which are, specified in the GMS Statement of Financial Entitlements;

(b) providing appropriate information and advice to patients and, where appropriate, to the parents of patients, about such vaccines and immunisations;

(c) in relation to patients other than children and taking into account the individual circumstances of the patient, considering whether—

(i) immunisation ought to be administered by the contractor or by another health care professional, or

(ii) a prescription form ought to be provided for the purpose of self-administration by the patient of the immunisation;

(d) recording in the patient's record any refusal of the offer mentioned in sub-paragraph (a);

(e) where—

(i) the offer mentioned in sub-paragraph (a) is accepted, and

(ii) in case of a patient who is not a child, the immunisation is to be administered by the contractor or another health care professional,

administering the immunisations and recording the immunisation information in the patient's record, using codes agreed by the Board for this purpose;

(f) where—

(i) the offer mentioned in sub-paragraph (a) is accepted, and

(ii) in the case of a patient who is not a child, the immunisation is not to be administered by the contractor or another health care professional,

issuing a prescription form for the purposes of self-administration by the patient.

(8) For the purposes of paragraph (7)—

"immunisation information" means—

(a) either—

(i) the patient's consent to immunisation, or

(ii) where another person consents to immunisation on behalf of the patient, the name of the person who gave that consent and their relationship to the patient;

(b) the batch number, expiry date and title of the vaccine;

(c) the date of administration of the vaccine;

(d) where two vaccines are administered by injections, in close succession, the route of administration and the injection site of each vaccine;

(e) any contraindications to the vaccine; and

(f) any adverse reactions to the vaccine.

(9) For the purposes of paragraphs (2) to (7) "a patient's record" means the record which is kept in relation to a patient in accordance with regulation 67.".

3. In regulation 5 (conditions relating solely to medical practitioners), in paragraph (6) after "maternity medical services" insert "(except the services mentioned in regulation 3(4)(c) or (d))".

4. In regulation 17 (essential services)—

(a) in paragraph (6), in the words after sub-paragraph (b) for "contraceptive services" substitute "the services specified in paragraph (6A)";

(b) after paragraph (6) insert—

"(6A) The services mentioned in paragraph (6) are—

(a) cervical screening services;

(b) child health surveillance services;

(c) contraceptive services;

(d) maternity medical services; and

(e) vaccine and immunisation services.";

(c) omit paragraphs (12) to (15).

5. In Schedule 1 (additional services) omit paragraphs 2 and 4 to 7.

New Part 9A (vaccines and immunisations)

6. After Part 9 insert—

"PART 9A

Vaccines and immunisations

Vaccines and immunisations: duty of co-operation

66A.—(1) The contractor must co-operate, in so far as is reasonable, with relevant persons—

(a) to understand the current uptake, and barriers to uptake, of offers to provide or administer vaccines and immunisations of the type specified in the GMS Statement of Financial Entitlements ("relevant vaccines and immunisations") to patients, and

(b) to develop (if necessary) a strategy for improving the contractor's immunisation programme.

(2) For the purposes of paragraph (1) "relevant persons" means—

(a) other persons who administer relevant vaccines and immunisations to patients;

(b) the Board;

(c) the Secretary of State;

(d) local authorities.

Vaccines and immunisations: appointments

66B.—(1) A contractor must ensure that they have in place a system for delivering appointments at which relevant vaccines or immunisations are administered to patients ("immunisation appointments") which meets the Vaccines and Immunisations Standards.

(2) In this regulation—

"relevant vaccine or immunisation" means a vaccine or immunisation which is of a type specified in the GMS Statement of Financial Entitlements other than—

(a) an influenza vaccine,

(b) a vaccine or immunisation for the purposes of travel which is not overseas travel, or

(c) a vaccine or immunisation which is offered in response to a local outbreak;

"the Vaccines and Immunisations Standards" means the standards determined by the Board and which a contractor is required to meet in relation to the following matters—

(a) the invitation of patients for immunisation appointments when they first become eligible for relevant vaccines or immunisations ("newly eligible patients");

(b) the steps to be taken if no response is received to an invitation falling within sub-paragraph (a);

(c) the provision of immunisation appointments to newly eligible patients;

(d) the steps to be taken if a newly eligible patient does not attend an immunisation appointment;

(e) requests for relevant vaccines or immunisations made by patients who are eligible for them but have not previously received them for any reason;

(f) the identification of gaps in the vaccination records of registered patients, and the offer, and provision of, immunisation appointments to those patients.

Vaccines and immunisations: catch-up campaigns

66C.—(1) The contractor must participate in a manner reasonably required by the Board in one vaccine and immunisations catch-up campaign in each financial year.

(2) In this regulation "vaccine and immunisations catch-up campaign" means a campaign which is aimed at maximising the uptake of a particular vaccine or immunisation by patients who are eligible for it but have not received that vaccine or immunisation for any reason (other than a decision to refuse the vaccine or immunisation).

Vaccines and immunisations: additional staff training

66D.—(1) The contractor must ensure that all staff involved in the administration of vaccines and immunisations are trained in the recognition and initial treatment of anaphylaxis.

(2) This regulation does not affect the contractor's obligations under Part 7.

Vaccines and immunisations: nominated person

66E.—(1) The contractor must nominate a person (a "V & I lead") who is to have responsibility for—

(a) overseeing the provision of vaccine and immunisation services by the contractor,

(b) carrying out, on behalf of the contractor, any of the contractor's functions under regulation 66A, and

(c) overseeing compliance with the requirements of regulations 66A to 66D.

(2) The contractor must ensure that the V & I lead—

(a) has regard to all guidance issued by the Board which is relevant to that role, and

(b) if they are not a health care professional, is directly supervised in that role by a healthcare professional.

Vaccines and immunisations: exception for private arrangements

66F. Nothing in this Part applies in relation to the offer or administration of any vaccine or immunisation to a patient under a private arrangement.".

SCHEDULE 2

Regulation 3

Amendment of the PMS Agreements Regulations

Insertion of new Part 10A (vaccines and immunisations)

1. In the PMS Agreements Regulations, after Part 10 insert—

"PART 10A

Vaccines and immunisations

Part 10A: interpretation

59A. In this Part—

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

"vaccine and immunisations services" has the meaning given in regulation 3(7) of the General Medical Services Contracts Regulations.

Vaccines and immunisations: duty of co-operation

59B.—(1) The contractor must co-operate, in so far as is reasonable, with relevant persons—

(a) to understand the current uptake, and barriers to uptake, of offers to provide or administer vaccines and immunisations of the type specified in the GMS Statement of Financial Entitlements ("relevant vaccines and immunisations") to patients, and

(b) to develop (if necessary) a strategy for improving their immunisation programme.

(2) For the purposes of paragraph (1) "relevant persons" means—

(a) other persons who administer relevant vaccines and immunisations to patients;

(b) the Board;

(c) the Secretary of State;

(d) local authorities.

Vaccines and immunisations: appointments

59C.—(1) A contractor must ensure that they have in place a system for delivering appointments at which relevant vaccines or immunisations are administered to patients ("immunisation appointments") which meets the Vaccines and Immunisations Standards.

(2) In this regulation—

"relevant vaccine or immunisation" means a vaccine or immunisation which is of a type specified in the GMS Statement of Financial Entitlements other than—

(a) an influenza vaccine,

(b) a vaccine or immunisation the purposes of travel other than overseas travel, or

(c) a vaccine or immunisation which is offered in response to a local outbreak.

"the Vaccines and Immunisations Standards" means the standards determined by the Board and which a contractor is required to meet in relation to the following matters—

(a) the invitation of patients for immunisation appointments when they first become eligible for relevant vaccines or immunisations ("newly eligible patients");

(b) the steps to be taken if no response is received to an invitation falling within sub-paragraph (a);

(c) the provision of immunisation appointments to newly eligible patients;

(d) the steps to be taken if a newly eligible patient does not attend an immunisation appointment;

(e) requests for relevant vaccines or immunisations made by patients who are eligible for them but have not previously received them for any reason;

(f) the identification of gaps in the vaccination records of registered patients, and the offer, and provision of, immunisation appointments to those patients.

Vaccines and immunisations: catch-up campaigns

59D.—(1) The contractor must participate in a manner reasonably required by the Board in one vaccines and immunisations catch-up campaign in each financial year.

(2) In this regulation "vaccines and immunisations catch-up campaign" means a campaign which is aimed at maximising the uptake of a particular vaccine or immunisation by patients who are eligible for it but have not received that vaccine or immunisation for any reason (other than a decision to refuse the vaccine or immunisation).

Vaccines and immunisations: additional staff training

59E.—(1) The contractor must ensure that all staff involved in the administration of vaccines and immunisations are trained in the recognition and initial treatment of anaphylaxis.

(2) This regulation does not affect the contractor's obligations under Part 8.

Vaccines and immunisations: nominated person

59F.—(1) The contractor must nominate a person (a "V & I lead") who is to have responsibility for—

(a) overseeing the provision of vaccine and immunisation services by the contractor,

(b) carrying out, on behalf of the contractor, any of the contractor's functions under regulation 59B, and

(c) overseeing compliance with the requirements of regulations 59B to 59E.

(2) The contractor must ensure that the V & I lead—

(a) has regard to all guidance issued by the Board which is relevant to that role, and

(b) if they are not a health care professional, is directly supervised in that role by a healthcare professional.

Vaccines and immunisations: exception for private arrangements

59G. Nothing in this Part applies in relation to the offer or administration of any vaccine or immunisation to a patient under a private arrangement.".

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (General Medical Services Contracts) Regulations 2015 (S.I. 2015/1862) ("the GMS Contracts Regulations") and the National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/1879) ("the PMS Agreements Regulations"), which make provision in respect of services provided under a general medical services contract and a personal medical services agreement made pursuant to Part 4 of the National Health Service Act 2006 (c. 41). They apply to England only.

The GMS Contracts Regulations are amended so as to make the following services "essential services":

(a) cervical screening services;

(b) child health surveillance services;

(c) maternity medical services (including the offer and provision of a maternal postal natal consultation);

(d) vaccine and immunisations services (including childhood vaccines and immunisations)

(see paragraph 2 of Schedule 1).

The maternity medical services are also amended so that the postnatal period, during which relevant services are to be provided to mothers or their babies (where relevant), is extended from two to eight weeks.

These Regulations also amend the GMS Contracts Regulations and the PMS Agreements Regulations to impose additional duties on contractors in connection with the provision of vaccine and immunisations services under a general medical services contract or personal medical services agreement (see paragraph 6 of Schedule 1 and paragraph 1 of Schedule 2).

These are:

(a) a duty of cooperation with other persons who administer vaccines and immunisations, the Board, Secretary of State, local authorities,

(b) a requirement to comply with certain standards when offering appointments for recommended vaccines and immunisations,

(c) a requirement to take part in catch-up campaigns, and

(d) a requirement to appoint a vaccines and immunisations coordinator to oversee the provision of these services by the contractor.

These Regulations also make various consequential amendments to the GMS Contracts Regulations.

A full Impact Assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

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