## 2019 No. 1137

## NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (General Medical Services Contracts and Personal Medical Services Agreements)
(Amendment) Regulations 2019

Made - - - - 17th July 2019

Laid before Parliament 18th July 2019

Coming into force - - 1st October 2019

The Secretary of State for Health and Social Care, in exercise of the powers conferred by sections 85(1), 89(1) and (2)(a), 94(1) and (3)(a) and 272(7) and (8) of the National Health Service Act 2006(a), makes the following Regulations.

## PART 1

#### General

#### Citation, commencement 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 2019.
  - (2) They come into force on 1st October 2019.
  - (3) In these Regulations—
    - (a) "the GMS Contracts Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2015(**b**); and
    - (b) "the PMS Agreements Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2015(c).

<sup>(</sup>a) 2006 c.41. The National Health Service Act 2006 ("the Act") was amended by the Health and Social Care Act 2012 (c.7) and relevant amendments to section 89 were made by section 202(2). There are no relevant amendments to section 94. *See* section 275(1) of the Act for the meaning given to "prescribed" and "regulations". The powers exercised in making these Regulations are exercisable by the Secretary of State in relation to England only by virtue of section 271(1) of the Act.

<sup>(</sup>b) S.I. 2015/1862, as amended by S.I. 2016/211, 481, 696, 875 and 1077, 2017/908, 2018/844 and 2018/1114.

<sup>(</sup>c) S.I. 2015/1879, as amended by S.I. 2016/211, 481, 696, 875 and 1077, 2017/908, 2018/844 and 2018/1114.

## PART 2

## Amendment of the GMS Contracts Regulations

## Amendment of regulation 3 of the GMS Contracts Regulations

- 2. In regulation 3 of the GMS Contracts Regulations (interpretation)(a)—
  - (a) in the definition of "additional services" omit paragraph (b);
  - (b) for the definition of "contraceptive services", substitute—
    - ""contraceptive services" means the following services—
    - (a) the giving of advice about the full range of contraceptive methods;
    - (b) where appropriate, the medical examination of patients seeking such advice;
    - (c) the treatment of such patients for contraceptive purposes and the prescribing of contraceptive substances and appliances (excluding the fitting and implanting of intrauterine devices and implants);
    - (d) the giving of advice about emergency contraception and, where appropriate, the supplying or prescribing of emergency hormonal contraception;
    - (e) the giving of advice and referral in cases of unplanned pregnancy including advice about the availability of free pregnancy testing in the contractor's practice area;
    - (f) the giving of initial advice about sexual health promotion and sexually transmitted infections; and
    - (g) the referral as necessary to specialist sexual health services, including tests for sexually transmitted infections;";
  - (c) after the definition of "practice premises" insert—
    - "practice website" means any website through which the contractor advertises the primary medical services it provides;";
  - (d) after the definition of "primary medical services" insert—
    - ""private services" means the provision of any treatment which would amount to primary medical services if it were provided under or by virtue of a contract or agreement to which the provisions of Part 4 of the Act apply;"; and
  - (e) for the definition of "repeatable prescription", substitute—
    - ""repeatable prescription" means—
    - (a) a form provided by the Board, a local authority or Secretary of State for the purpose of ordering a drug, medicine or appliance which is in the format required by the NHS Business Services Authority and which—
      - (i) is issued, or is to be issued, by a repeatable prescriber to enable a chemist or person providing dispensing services to receive payment for the provision of repeat dispensing services,
      - (ii) indicates, or is to indicate, that the drug, medicine or appliance ordered may be provided more than once, and
      - (iii) specifies, or is to specify, the number of occasions on which the drug, medicine or appliance may be provided; or
    - (b) in the case of an electronic prescription to which regulation 57 applies, data created in an electronic form for the purpose of ordering a drug, medicine or appliance, which—
      - (i) is signed, or is to be signed, with a prescriber's advanced electronic signature,

<sup>(</sup>a) The definition of repeatable prescription was amended by S.I. 2018/1114.

- (ii) is transmitted, or is to be transmitted, as an electronic communication to a nominated dispenser or via an information hub by the Electronic Prescription Service, and
- (iii) indicates, or is to indicate, that the drug, medicine or appliance ordered may be provided more than once and specifies, or is to specify, the number of occasions on which the drug, medicine or appliance may be provided;".

#### Amendment of regulation 17 of the GMS Contracts Regulations

- **3.** In regulation 17 of the GMS Contracts Regulations (essential services), for paragraph (6) substitute—
  - "(6) The services described in this paragraph are the provision of appropriate ongoing treatment and care to all of the contractor's registered patients and temporary residents taking into account their specific needs including—
    - (a) advice in connection with the patient's health and relevant health promotion advice; and
    - (b) the referral of a patient for services under the Act,

together with the provision of contraceptive services.".

## Amendment of regulation 20 of the GMS Contracts Regulations

- **4.** In regulation 20 of the GMS Contracts Regulations (services: general), after paragraph (5) insert—
  - "(6) A contract must specify that where the contractor proposes to provide private services in addition to primary medical services, to persons other than its patients the provision must take place—
    - (a) outside of the hours the contractor has agreed to provide primary medical services;
    - (b) on no part of any practice premises in respect of which the Board makes any payments pursuant to the National Health Service (General Medical Services Premises Costs) Directions 2013(a) save where the private services are those specified in regulation 24(2B).".

#### Amendment of regulation 24 of the GMS Contracts Regulations

- **5.** In regulation 24 of the GMS Contracts Regulations (fees and charges), after paragraph (2) insert—
  - "(2A) The contractor must not, either itself or through any other person, demand or accept from any of its patients a fee or other remuneration for its own benefit or for the benefit of another person, for the completion, in relation to the patient's mental health, of—
    - (a) a mental health evidence form; or
    - (b) any examination of the patient or of the patient's medical record in order to complete the form,

the purpose of which is to assist creditors in deciding what action to take where the debtor has a mental health problem.

<sup>(</sup>a) These directions were signed on the 28th March 2013 and came into force on the 1st April 2013. They were amended by the National Health Service (General Medical Services - Premises Costs) (Amendment) Directions 2013, which came into force on the 19th November 2013. These directions are published at https://www.gov.uk/government/publications/nhs-primary-medical-services-directions-2013. A hard copy can be obtained by writing to the GP Policy Team, Fourth Floor, 39 Victoria Street, London SW1H 0EU.

- (2B) The contractor must not, either itself or through any other person, demand or accept from anyone who is not a patient of the contractor, a fee or other remuneration for its own benefit or for the benefit of another person, for either of the following services provided on practice premises to which regulation 20(6)(b) applies, unless those services are provided outside of core hours—
  - (a) for treatment consisting of an immunisation for which the contractor receives no remuneration from the Board when provided to its patients and which is requested in connection with travel abroad; or
  - (b) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.".

## Amendment of regulation 55 of the GMS Contracts Regulations

- **6.** In regulation 55 of the GMS Contracts Regulations (prescribing: general), for paragraph (2) substitute—
  - "(2) In regulations 56, 57 and 59 to 63, a reference to "drugs" includes contraceptive substances and a reference to "appliances" includes contraceptive appliances."

## Insertion of new regulation 60A of the GMS Contracts Regulations

7. After regulation 60 of the GMS Contracts Regulations (repeatable prescriptions), insert—

#### "Electronic repeat dispensing services

- **60A.**—(1) Subject to regulations 56, 57, 59 and 60(2)(b) to (4), where a prescriber orders a drug, medicine or appliance by means of an electronic repeatable prescription, the prescriber must issue the prescription in a format appropriate for electronic repeat dispensing services where—
  - (a) it is clinically appropriate to do so for that patient on that occasion; and
  - (b) the patient consents.
  - (2) For the purposes of paragraph (1)—

"electronic repeat dispensing services" means pharmaceutical services or local pharmaceutical services which involve the provision of drugs, medicines or appliances by a nominated dispenser in accordance with an electronic repeatable prescription which has a specified number of identical issues of drugs, medicines or appliances associated with it for dispensation over a period of time up to but not exceeding 12 months."

#### Amendment of regulation 71 of the GMS Contracts Regulations

- 8. In regulation 71 of the GMS Contracts Regulations (patient online services)(a)—
  - (a) for paragraph (3) substitute—
    - "(3) A contractor must when complying with the requirements in paragraph (1)(a)—
      - (a) ensure that a minimum of 25% of its appointments per day during core hours are made available for online booking, whether or not those appointments are booked online, by telephone or in person, to include all appointments which must be made available for direct booking by NHS 111(**b**) in accordance with paragraph 11B of Part 1 of Schedule 3 to these Regulations(**c**); and

<sup>(</sup>a) Amended by S.I. 2018/844.

<sup>(</sup>b) NHS 111 is a service available online and by telephone for urgent medical help.

<sup>(</sup>c) This provision provides that a minimum number of appointments must be available for NHS 111 staff to book directly online depending upon the number of registered patients.

- (b) consider whether it is necessary, in order to meet the needs of its registered patients, to increase the proportion of appointments which are available for its registered patients to book online and, if so, increase that number.
- (3A) In the case of appointments required to be made available for direct booking by NHS 111, in accordance with paragraph 11B of Part 1 of Schedule 3 to these Regulations, those appointments can be released to be booked by a contractor's registered patients by any means in the two hour period within core hours prior to the appointment time, or such other period agreed pursuant to a local arrangement, if they have not been booked by NHS 111 prior to this time."
- (b) omit paragraphs (4) and (6);
- (c) after paragraph (5) insert—
  - "(5A) In addition to complying with the requirements in paragraphs (1) and (5), a contractor must offer to its newly registered patients, the facility to access online all information entered onto the patient's medical record on or after 1st October 2019 in so far as its computerised clinical systems and redaction software allow, unless—
    - (a) in the reasonable opinion of the contractor, access to such information would not be in the patient's best interests because it is likely to cause serious harm to—
      - (i) the patient's physical or mental health, or
      - (ii) the physical or mental health of any other person; or
    - (b) the information includes a reference to any third party who has not consented to its disclosure."; and"
- (d) for paragraph (9) substitute—
  - "(9) In this regulation—
    - (a) "local arrangement" means an arrangement between the contractor and the Board as to the timeframe within which appointments not booked by NHS 111 can be released for booking by the contractor's registered patients; and
    - (b) "newly registered patient" means a person who becomes a registered patient on or after 1st October 2019.".

## Omission of regulation 74A of the GMS Contracts Regulations

**9.** Omit regulation 74A(a) of the GMS Contracts Regulations (provision of information: GP access data).

## Amendment of regulation 74C of the GMS Contracts Regulations

**10.** For the table in regulation 74C(**b**) of the GMS Contracts Regulations (information relating to indicators no longer in the Quality and Outcomes Framework), substitute—

#### "Table

Quality and Outcomes Framework – indicators no longer in the Quality and Outcomes Framework

Indicator ID	Indicator Description
Clinical domain CHD003	The percentage of patients with coronary heart disease whose last measured cholesterol (measured in the preceding 12 months) is 5 mmol/l or less

<sup>(</sup>a) Inserted by 2016/875. Contractors already provide this data via their monthly returns to the Board reporting on the Clinical Commissioning Groups Improving Access Framework.

**<sup>(</sup>b)** Inserted by S.I. 2017/908.

**CKD002** The percentage of patients on the CKD register in whom the last blood pressure reading (measured in the preceding 12 months) is 140/85 mmHg or less The percentage of patients on the CKD register whose notes have a **CKD004** record of a urine albumin: creatinine ratio (or protein: creatinine ratio) test in the preceding 12 months **NM84** The percentage of patients on the CKD register with hypertension and proteinuria who are currently treated with renin-angiotensin system antagonists The percentage of patients diagnosed with hypertension (diagnosed CVD-PP002 after or on 1st April 2009) who are given lifestyle advice in the preceding 12 months for: smoking cessation, safe alcohol consumption and healthy diet DM005 The percentage of patients with diabetes, on the register, who have a record of an albumin: creatinine ratio test in the preceding 12 months The percentage of patients with diabetes, on the register, who have a DMO11 record of retinal screening in the preceding 12 months EP002 The percentage of patients 18 or over on drug treatment for epilepsy who have been seizure free for the last 12 months recorded in the preceding 12 months EP003 The percentage of women aged 18 or over and who have not attained the age of 55 who are taking antiepileptic drugs who have a record of information and counselling about contraception, conception and pregnancy in the preceding 12 months The percentage of patients on the learning disability register with LD002 Down's syndrome aged 18 or over who have a record of blood TSH in the preceding 12 months The percentage of patients aged 40 or over with schizophrenia, bipolar MH004 affective disorder and other psychoses who have a record of total cholesterol: hdl ratio in the preceding 12 months The percentage of patients aged 40 or over with schizophrenia, bipolar MH005 affective disorder and other psychoses who have a record of blood glucose or HbA1c in the preceding 12 months The percentage of patients with schizophrenia, bipolar affective MH007 disorder and other psychoses who have a record of alcohol consumption in the preceding 12 months The percentage of women aged 25 or over and who have not attained MH008 the age of 65 with schizophrenia, bipolar affective disorder and other psychoses whose notes record that a cervical screening test has been performed in the preceding 5 years The percentage of patients with peripheral arterial disease in whom the **PAD002** last blood pressure reading (measured in the preceding 12 months) is 150/90 mmHg or less **PAD003** The percentage of patients with peripheral arterial disease in whom the last measured total cholesterol (measured in the preceding 12 months) is 5 mmol/l or less PAD004 The percentage of patients with peripheral arterial disease with a record in the preceding 12 months that aspirin or an alternative anti-platelet is being taken **RA003** The percentage of patients with rheumatoid arthritis aged 30 or over and who have not attained the age of 85 who have had a cardiovascular risk assessment using a CVD risk assessment tool adjusted for RA in the preceding 12 months

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The percentage of patients aged 50 or over and who have not attained the age of 91 with rheumatoid arthritis who have had an assessment of

fracture risk using a risk assessment toll adjusted for RA in the

**RA004** 

	preceding 24 months
SMOK001	The percentage of patients aged 15 or over whose notes record smoking status in the preceding 24 months
STIA005	The percentage of patients with a stroke shown to be non-
	haemorrhagic, or a history of TIA whose last measured total cholesterol
	(measured in the preceding 12 months) is 5 mmol/l or less
THY001	The contractor establishes and maintains a register of patients with
	hypothyroidism who are currently treated with levothyroxine
THY002	The percentage of patients with hypothyroidism, on the register, with
	thyroid function tests recorded in the preceding 12 months"

## Insertion of new regulation 74G of the GMS Contracts Regulations

**11.** After regulation 74F of the GMS Contracts Regulations (information relating to overseas visitors), insert—

## "Medicines and Healthcare products Regulatory Agency Central Alerting System

#### **74G.** A contractor must—

- (a) provide to the Medicines and Healthcare products Regulatory Agency ("the MHRA")(a) on request, an electronic mail address which is registered to the contractor's practice;
- (b) monitor that address:
- (c) if that address ceases to be registered to the practice, notify the MHRA immediately of its new electronic mail address; and
- (d) provide to the MHRA on request, one or more mobile telephone numbers for use in the event that the contractor is unable to receive electronic mail.".

## Omission of paragraph 3 of Schedule 1 to the GMS Contracts Regulations

**12.** In Schedule 1 to the GMS Contracts Regulations (additional services), omit paragraph 3 (contraceptive services).

## Insertion of new paragraph 11B to Part 1 of Schedule 3 to the GMS Contracts Regulations

**13.** After paragraph 11A(**b**) of Part 1 of Schedule 3 to the GMS Contracts Regulations (NHS e Referral Service), insert—

## "Direct booking by NHS 111

- **11B.**—(1) A contractor must ensure that as a minimum the following number of appointments during core hours for its registered patients are made available per day for direct booking by NHS 111—
  - (a) one, where a contractor has 3,000 registered patients or fewer; or
  - (b) one for each whole 3,000 registered patients, where a contractor has more than 3,000 registered patients.
  - (2) The requirements in sub-paragraphs (1) and (3) do not apply where—
    - (a) the Board has agreed to a request from the contractor to suspend the requirements for operational reasons; or

<sup>(</sup>a) The Medicines and Healthcare products Regulatory Agency is an Executive Agency of the Department of Health and Social Care

<sup>(</sup>b) Inserted by S.I.2018/844.

- (b) the contractor does not have access to computer systems and software which would enable it to offer the service described in sub-paragraph (1).
- (3) A contractor must—
  - (a) configure its computerised systems to allow direct booking by NHS 111;
  - (b) monitor its booking system for appointments booked by NHS 111;
  - (c) assess the Post Event Message received from NHS 111 in order to decide whether an alternative to the booked appointment should be arranged, such as a telephone call to the patient or an appointment with another healthcare professional and where appropriate, make those arrangements; and
  - (d) co-operate with the Board in its oversight of direct booking by NHS 111 by providing any information relating to direct booking by NHS 111 which is reasonably required by the Board.
- (4) In this paragraph, "Post Event Message" means the electronic message which is sent to a contractor at the end of a telephone call to NHS 111.".

## Amendment of paragraph 15 to Part 1 of Schedule 3 to the GMS Contracts Regulations

**14.** In paragraph 15(1)(b) of Part 1 of Schedule 3 to the GMS Contracts Regulations (duty of cooperation), after "enhanced service" insert ", except in relation to one provided under the Network Contract Directed Enhanced Service Scheme which is a scheme provided for by direction 5 of the Primary Medical Services (Directed Enhanced Services) Directions 2019(a)".

## Insertion of a new paragraph 15A to Part 1 of Schedule 3 to the GMS Contracts Regulations

**15.** After paragraph 15 of Part 1 of Schedule 3 to the GMS Contracts Regulations (duty of cooperation), insert—

## "Duty of co-operation: Primary Care Networks

**15A.**—(1) A contractor must comply with the requirements in sub-paragraph (2) where it is—

- (a) signed up to the Network Contract Directed Enhanced Service Scheme ("the Scheme"); or
- (b) not signed up to the Scheme but its registered patients or temporary residents, are provided with services under the Scheme ("the services")(**b**) by a contractor which is a member of a primary care network.
- (2) The requirements specified in this sub-paragraph are that the contractor must—
  - (a) co-operate, in so far as is reasonable, with any person responsible for the provision of the services:
  - (b) comply in core hours with any reasonable request for information from such a person or from the Board relating to the provision of the services;
  - (c) have due regard to the guidance published by the Board(c);
  - (d) participate in primary care network meetings, in so far as is reasonable;

<sup>(</sup>a) The Primary Medical Services (Directed Enhanced Services) Directions 2019 were signed on the 29th March 2019. These directions are available at: https://www.gov.uk/government/publications/gp-contract-directions-2019-to-2020 and hard copies may be obtained by writing to the GP Policy Team, Fourth Floor, 39 Victoria Street, London SW1H 0EU.

<sup>(</sup>b) The Network Contract Directed Enhanced Service Contract Specification is available at: https://www.england.nhs.uk/gp/gpfv/investment/gp-contract/. Hard copies are available from New Business Models team, NHS England, Area 2D, Skipton House, 80 London Road, London, SE1 6HL.

<sup>(</sup>c) The Board's guidance is published at https://www.england.nhs.uk/publication/network-contract-directed-enhanced-service-des-guidance-2019-20/. Hard copies may be obtained by writing to New Business Models team, NHS England, Area 2D, Skipton House, 80 London Road, London, SE1 6HL.

- (e) take reasonable steps to provide information to its registered patients about the services, including information on how to access the services and any changes to them; and
- (f) ensure that it has in place suitable arrangements to enable the sharing of data to support the delivery of the services, business administration and analysis activities.
- (3) For the purposes of this paragraph, "primary care network" means a network of contractors and other providers of services which has been approved by the Board, serving an identified geographical area with a minimum population of 30,000 people."

## Amendment of the heading to Part 6 of Schedule 3 to the GMS Contracts Regulations

**16.** For the heading to Part 6 of Schedule 3 to the GMS Contracts Regulations (provision of information: practice leaflet), substitute—

"Provision of information: practice leaflet, use of NHS primary care logo, marketing campaigns and advertising private services".

# Insertion of new paragraphs 48A, 48B and 48C to Part 6 of Schedule 3 to the GMS Contracts Regulations

**17.** After paragraph 48 of Part 6 of Schedule 3 to the GMS Contracts Regulations (information to be included in practice leaflets), insert—

## "Use of NHS primary care logo

**48A.** Where a contractor chooses to apply the NHS primary care logo to signage, stationery, leaflets, posters, its practice website or to any other form of written representation relating to the primary care services it provides, it must have regard to guidance concerning use of the NHS primary care logo produced by the Board(a).

## **Marketing campaigns**

**48B**. The contractor must participate in a manner reasonably requested by the Board in up to 6 marketing campaigns in each financial year.

#### Advertising private services

**48C.** The contractor must not advertise the provision of private services, either itself or through any other person, whether the contractor provides the services itself or they are provided by another person, by any written or electronic means where the same are used to advertise the primary medical services it provides.".

## PART 3

## Amendment of the PMS Agreements Regulations

#### Amendment of regulation 3 of the PMS Agreements Regulations

- **18.** In regulation 3 of the PMS Agreements Regulations (interpretation), after the definition of "primary medical services" insert—
  - (a) after the definition of "practice premises" insert—

<sup>(</sup>a) The Board's guidance is published at: https://www.england.nhs.uk/nhsidentity/identity-guidelines/primary-care-logo/. Hard copies can be obtained from: New Business Models team, NHS England, Area 2D, Skipton House, 80 London Road, London SE1 6HL.

- ""practice website" means any website through which the contractor advertises the primary medical services it provides;"; and
- (b) after the definition of "primary medical services" insert—

""private services" means the provision of any treatment which would amount to primary medical services if it was provided under or by virtue of a contract or agreement to which the provisions of Part 4 of the Act apply;".

## Amendment of regulation 13 of the PMS Agreements Regulations

- **19.** In regulation 13 of the PMS Agreements Regulations (agreements: general), after paragraph (3) insert—
  - "(4) An agreement must specify that where the contractor proposes to provide private services in addition to primary medical services, to persons other than its patients the provision must take place—
    - (a) outside of the hours the contractor has agreed to provide primary medical services;
       and
    - (b) on no part of any practice premises in respect of which the Board has agreed with that contractor to make payments in relation to the costs of those premises save where the private services are those specified in regulation 18(2B).".

## Amendment of regulation 18 of the PMS Agreements Regulations

- **20.** In regulation 18 of the PMS Agreements Regulations (fees and charges), after paragraph (2) insert—
  - "(2A) The contractor must not, either itself or through any other person, demand or accept from any of its patients a fee or other remuneration for its own benefit or for the benefit of another person, for the completion, in relation to the patient's mental health, of—
    - (a) a mental health evidence form; or
    - (b) any examination of the patient or of the patient's medical record in order to complete the form,

the purpose of which is to assist creditors in deciding what action to take where the debtor has a mental health problem.

- (2B) The contractor must not, either itself or through any other person, demand or accept from anyone who is not a patient of the contractor, a fee or other remuneration for its own benefit or for the benefit of another person, for either of the following services provided on practice premises to which regulation 13(4)(b) applies, unless those services are provided outside of core hours—
  - (a) for treatment consisting of an immunisation for which the contractor receives no remuneration from the Board when provided to its patients and which is requested in connection with travel abroad; or
  - (b) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.".

## Amendment of regulation 48 of the PMS Agreements Regulations

- **21.** In regulation 48 of the PMS Agreements Regulations (prescribing: general), for paragraph (2) substitute—
  - "(2) In regulations 49, 50 and 52 to 56, a reference to "drugs" includes contraceptive substances and a reference to "appliances" includes contraceptive appliances.".

## Insertion of new regulation 53A of the PMS Agreements Regulations

22. After regulation 53 of the PMS Agreements Regulations (repeatable prescriptions), insert—

## "Electronic repeat dispensing services

**53A.**—(1) Subject to regulations 49, 50, 52 and 53(2)(b) to (4), where a prescriber orders a drug, medicine or appliance by means of an electronic repeatable prescription, the prescriber must issue the prescription in a format appropriate for electronic repeat dispensing services where—

- (a) it is clinically appropriate to do so for that patient on that occasion; and
- (b) the patient consents.
- (2) For the purposes of paragraph (1)—

"electronic repeat dispensing services" means pharmaceutical services or local pharmaceutical services which involve the provision of drugs, medicines or appliances by a nominated dispenser in accordance with an electronic repeatable prescription which has a specified number of identical issues of drugs, medicines or appliances associated with it for dispensation over a period of time up to but not exceeding 12 months."

## Amendment of regulation 64 of the PMS Agreements Regulations

- 23. In regulation 64 of the PMS Agreements Regulations (patient online services)(a)—
  - (a) for paragraph (3) substitute—
    - "(3) A contractor must when complying with the requirements in paragraph (1)(a)—
      - (a) ensure that a minimum of 25% of its appointments per day during core hours are made available for online booking, whether or not those appointments are booked online, by telephone or in person, to include all appointments which must be made available for direct booking by NHS 111(b) in accordance with paragraph 16B of Part 2 of Schedule 2 to these Regulations(c); and
      - (b) consider whether it is necessary, in order to meet the needs of its registered patients, to increase the proportion of appointments which are available for its registered patients to book online and, if so, increase that number.

(3A) In the case of appointments required to be made available for direct booking by NHS 111, in accordance with paragraph 16B of Part 2 of Schedule 2 to these Regulations, those appointments can be released to be booked by a contractor's registered patients by any means in the two hour period within core hours prior to the appointment time, or such other period agreed pursuant to a local arrangement, if they have not been booked by NHS 111 prior to this time.".

- (b) omit paragraph (4) and (6);
- (c) after paragraph (5) insert—

"(5A) In addition to complying with the requirements in paragraphs (1) and (5), a contractor must offer to its newly registered patients, the facility to access online all information entered onto the patient's medical record on or after 1st October 2019 in so far as its computerised clinical systems and redaction software allows unless—

- (a) in the reasonable opinion of the contractor, access to such information would not be in the patient's best interests because it is likely to cause serious harm to—
  - (i) the patient's physical or mental health, or
  - (ii) the physical or mental health of any other person; or
- (b) the information includes a reference to any third party who has not consented to its disclosure.";

<sup>(</sup>a) Amended by S.I. 2018/844.

<sup>(</sup>b) NHS 111 is a service available online and by telephone for urgent medical help.

<sup>(</sup>c) This provision provides that a minimum number of appointments must be available for NHS 111 staff to book directly online depending upon the number of registered patients.

- (d) for paragraph (9) substitute—
  - "(9) In this regulation—

"Table

- (a) "local arrangement" means an arrangement between the contractor and the Board as to the timeframe within which appointments not booked by NHS 111 can be released for booking by the contractor's registered patients; and
- (b) "newly registered patient" means a person who becomes a registered patient on or after 1st October 2019.".

## Omission of regulation 67A of the PMS Agreements Regulations

**24.** Omit regulation 67A(a) of the PMS Agreements Regulations (provision of information: GP access data).

## Amendment of regulation 67C of the PMS Agreements Regulations

**25.** For the table in regulation 67C(**b**) of the PMS Agreements Regulations (information relating to indicators no longer in the Quality and Outcomes Framework), substitute—

Quality and Outcomes Framework – indicators no longer in the Quality and Outcomes Framework

Indicator ID Indicator Description	
maicaioi 1D	таксиот Безсприон
Clinical domain	
CHD003	The percentage of patients with coronary heart disease whose last measured cholesterol (measured in the preceding 12 months) is 5 mmol/l or less
CKD002	The percentage of patients on the CKD register in whom the last blood pressure reading (measured in the preceding 12 months) is 140/85 mmHg or less
CKD004	The percentage of patients on the CKD register whose notes have a record of a urine albumin: creatinine ratio (or protein: creatinine ratio) test in the preceding 12 months
NM84	The percentage of patients on the CKD register with hypertension and proteinuria who are currently treated with renin-angiotensin system antagonists
CVD-PP002	The percentage of patients diagnosed with hypertension (diagnosed after or on 1st April 2009) who are given lifestyle advice in the preceding 12 months for: smoking cessation, safe alcohol consumption and healthy diet
DM005	The percentage of patients with diabetes, on the register, who have a record of an albumin: creatinine ratio test in the preceding 12 months
DMO11	The percentage of patients with diabetes, on the register, who have a record of retinal screening in the preceding 12 months
EP002	The percentage of patients 18 or over on drug treatment for epilepsy who have been seizure free for the last 12 months recorded in the preceding 12 months
EP003	The percentage of women aged 18 or over and who have not attained the age of 55 who are taking antiepileptic drugs who have a record of information and counselling about contraception, conception and pregnancy in the preceding 12 months

<sup>(</sup>a) Inserted by S.I. 2016/875.

<sup>(</sup>b) Inserted by S.I. 2017/908.

LD002	The percentage of patients on the learning disability register with Down's syndrome aged 18 or over who have a record of blood TSH in
MH004	the preceding 12 months  The percentage of patients aged 40 or over with schizophrenia, bipolar affective disorder and other psychoses who have a record of total cholesterol: hdl ratio in the preceding 12 months
MH005	The percentage of patients aged 40 or over with schizophrenia, bipolar affective disorder and other psychoses who have a record of blood glucose or HbA1c in the preceding 12 months
MH007	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of alcohol consumption in the preceding 12 months
MH008	The percentage of women aged 25 or over and who have not attained the age of 65 with schizophrenia, bipolar affective disorder and other psychoses whose notes record that a cervical screening test has been performed in the preceding 5 years
PAD002	The percentage of patients with peripheral arterial disease in whom the last blood pressure reading (measured in the preceding 12 months) is 150/90 mmHg or less
PAD003	The percentage of patients with peripheral arterial disease in whom the last measured total cholesterol (measured in the preceding 12 months) is 5 mmol/l or less
PAD004	The percentage of patients with peripheral arterial disease with a record in the preceding 12 months that aspirin or an alternative anti-platelet is being taken
RA003	The percentage of patients with rheumatoid arthritis aged 30 or over and who have not attained the age of 85 who have had a cardiovascular risk assessment using a CVD risk assessment tool adjusted for RA in the preceding 12 months
RA004	The percentage of patients aged 50 or over and who have not attained the age of 91 with rheumatoid arthritis who have had an assessment of fracture risk using a risk assessment toll adjusted for RA in the preceding 24 months
SMOK001	The percentage of patients aged 15 or over whose notes record smoking status in the preceding 24 months
STIA005	The percentage of patients with a stroke shown to be non-haemorrhagic, or a history of TIA whose last measured total cholesterol (measured in the preceding 12 months) is 5 mmol/l or less
THY001	The contractor establishes and maintains a register of patients with hypothyroidism who are currently treated with levothyroxine
THY002	The percentage of patients with hypothyroidism, on the register, with thyroid function tests recorded in the preceding 12 months"

## Insertion of new regulation 67G of the PMS Agreements Regulations

**26.** After regulation 67F of the PMS Agreements Regulations (information relating to overseas visitors), insert—

"Medicines and Healthcare products Regulatory Agency Central Alerting System

67G. A contractor must—

- (a) provide to the Medicines and Healthcare products Regulatory Agency ("the MHRA")(a) on request, an electronic mail address which is registered to the contractor's practice;
- (b) monitor that address;
- (c) if that address ceases to be registered to the practice, notify the MHRA immediately of its new electronic mail address; and
- (d) provide to the MHRA on request, one or more mobile telephone numbers for use in the event the contractor is unable to receive electronic mail."

## Amendment of paragraph 10 to Part 1 of Schedule 2 to the PMS Agreements Regulations

**27.** In paragraph 10(1)(a) of Part 1 of Schedule 2 to the PMS Agreements Regulations (duty of co-operation), after "a particular service" insert ", except in relation to one provided under the Network Contract Directed Enhanced Service Scheme which is a scheme provided for by direction 5 of the Primary Medical Services (Directed Enhanced Services) Directions 2019(b)".

## Insertion of new paragraph 10A to Part 1 of Schedule 2 to the PMS Agreements Regulations

**28.** After paragraph 10 to Part 1 of Schedule 2 to the PMS Agreements Regulations (duty of cooperation), insert—

#### "Duty of co-operation: Primary Care Networks

**10A.**—(1) A contractor must comply with the requirements in sub-paragraph (2) where it is—

- (a) signed up to the Network Contract Directed Enhanced Scheme ("the Scheme"); or
- (b) not signed up to the Scheme but its registered patients or temporary residents, are provided with services under the Scheme ("the services")(c) by a contractor which is a member of a primary care network.
- (2) The requirements specified in this sub-paragraph are that the contractor must—
  - (a) co-operate, in so far as is reasonable, with any person responsible for the provision of the services:
  - (b) comply in core hours with any reasonable request for information from such a person or from the Board relating to the provision of the services;
  - (c) have due regard to guidance published by the Board(**d**);
  - (d) participate in primary care network meetings, in so far as is reasonable;
  - (e) take reasonable steps to provide information to its registered patients about the services, including information on how to access the services and any changes to them; and
  - (f) ensure that it has in place suitable arrangements to enable the sharing of data to support the delivery of the services, business administration and analysis activities.

<sup>(</sup>a) The Medicines and Healthcare products Regulatory Agency is an Executive Agency of the Department of Health and Social Care.

<sup>(</sup>b) The Primary Medical Services (Directed Enhanced Services) Directions 2019 were signed on the 29th March 2019 and came into force on 1st April 2019. These directions are available at: https://www.gov.uk/government/publications/gp-contract-directions-2019-to-2020 and hard copies may be obtained by writing to the GP Policy Team, Fourth Floor, 39 Victoria Street, London SW1H 0EU.

<sup>(</sup>c) The Network Contract Directed Enhanced Service Contract Specification is available at: https://www.england.nhs.uk/gp/gpfv/investment/gp-contract/. Hard copies are available from New Business Models team, NHS England, Area 2D, Skipton House, 80 London Road, London, SE1 6HL.

<sup>(</sup>d) The Board's guidance is published at https://www.england.nhs.uk/publication/network-contract-directed-enhanced-service-des-guidance-2019-20/. Hard copies may be obtained by writing to New Business Models team, NHS England, Area 2D, Skipton House, 80 London Road, London, SE1 6HL.

(3) For the purposes of this paragraph, "primary care network" means a network of contractors and other providers of services which has been approved by the Board, serving an identified geographical area with a minimum population of 30,000 people.".

## Insertion of new paragraph 16B to Part 2 of Schedule 2 to the PMS Agreements Regulations

**29.** After paragraph 16A of Part 2 of Schedule 2 to the PMS Agreements Regulations (NHS e Referral Service), insert—

## "Direct booking by NHS 111

- **16B.**—(1) A contractor must ensure that as a minimum the following number of appointments during core hours for its registered patients are made available per day for direct booking by NHS 111—
  - (a) one, where a contractor has 3,000 registered patients or fewer; or
  - (b) one for each whole 3,000 registered patients, where a contractor has more than 3,000 registered patients.
  - (2) The requirements in sub-paragraphs (1) and (3) do not apply where—
    - (a) the Board and the contractor have agreed to suspend the requirements for operational reasons; or
    - (b) the contractor does not have access to computer systems and software which would enable it to offer the service described in sub-paragraph (1).
  - (3) A contractor must—
    - (a) configure its computerised systems to allow direct booking by NHS 111;
    - (b) monitor its booking system for appointments booked by NHS 111;
    - (c) assess the Post Event Message received from NHS 111 in order to decide whether an alternative to the booked appointment should be arranged, such as a telephone call to the patient or an appointment with another healthcare professional and where appropriate, make those arrangements; and
    - (d) co-operate with the Board in its oversight of direct booking by NHS 111 by providing any information relating to direct booking by NHS 111 which is reasonably required by the Board.
- (4) In this paragraph, "Post Event Message" means the electronic message which is sent to a contractor at the end of a telephone call to NHS 111.".

## Amendment of the heading to Part 6 of Schedule 2 to the PMS Agreements Regulations

**30.** For the heading to Part 6 of Schedule 6 to the PMS Agreements Regulations (provision of information: practice leaflet), substitute—

"Provision of information: practice leaflet, use of NHS primary care logo, marketing campaigns and advertising private services".

# Insertion of new paragraphs 44A, 44B and 44C to Part 6 of Schedule 2 to the PMS Agreements Regulations

**31.** After paragraph 44 of Part 6 of Schedule 2 to the PMS Agreements Regulations (information to be included in practice leaflets), insert—

#### "Use of NHS primary care logo

**44A.** Where a contractor chooses to apply the NHS primary care logo to signage, stationery, leaflets, posters, its practice website or to any other form of written

representation relating to the primary care services it provides, it must have regard to guidance concerning use of the NHS primary care logo produced by the Board(a).

## Marketing campaigns

**44B.** The contractor must participate in a manner reasonably requested by the Board in up to 6 marketing campaigns in each financial year.

#### Advertising private services

**44C.** The contractor must not advertise the provision of private services, either itself or through any other person, whether the contractor provides the services itself or they are provided by another person, by any written or electronic means where the same are used to advertise the primary medical services it provides.".

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

Seema Kennedy
Parliamentary Under-Secretary of State,
Department of Health and Social Care

17th July 2019

#### **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 the 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) (medical services). They apply to England only.

Part 2 of the Regulations amends the GMS Contracts Regulations.

Regulation 2 amends regulation 3 (interpretation) to omit paragraph (b) in the definition of "additional services" as "contraceptive services", which is defined, will cease to be an additional service under Schedule 1 of the GMS Contract Regulations and will become an essential service. It also substitutes a definition of "repeatable prescription". Two definitions are added, "practice website" and "private services". The latter refers to medical services, which are akin to primary medical services provided under Part 4 of the Act, but which are provided on a private fee-paying basis to persons other than a contractors' patients.

Regulation 3 adds the provision of contraceptive services to essential services.

Regulation 4 amends regulation 20 (services: general) by adding a provision which requires a contract to specify that where a contractor intends to provide private services in addition to the primary medical services it provides that provision must take place in certain circumstances only.

Regulation 5 amends regulation 24 (fees and charges) by adding a provision requiring the contract to contain a term that the contractor cannot charge its patients for completion of a mental health evidence form and a term setting out the limited circumstances in which a contractor can provide

<sup>(</sup>a) The Board's guidelines are published at:https://www.england.nhs.uk/nhsidentity/identity-guidelines/primary-care-logo/. Hard copies can be obtained from: New Business Models team, NHS England, Area 2D, Skipton House, 80 London Road, London SE1 6HL.

treatment privately to persons other than its patients from premises which are funded by the Board as referred to in regulation 20(6)(b).

Regulation 6 amends regulation 55 (prescribing: general) to make clear that a reference to "drugs" in regulations 56 (orders for drugs, medicines and appliances), 57 (electronic prescription), 59 (repeatable prescribing services), 60 (repeatable prescriptions), 61 (restrictions on prescribing by medical practitioners), 62 (restrictions on prescribing by supplementary prescribers) and 63 (bulk prescribing), includes contraceptive substances and a reference to "appliances" includes contraceptive appliances.

Regulation 7 inserts a new regulation 60A (electronic repeat dispensing services) which requires a prescriber to issue an electronic repeatable prescription in a format that will enable a nominated dispenser to provide electronic repeat dispensing services with the aim of increasing uptake in the use of electronic repeat dispensing, where this is clinically appropriate for the patient and the patient has agreed to be issued with an electronic repeatable prescription.

Regulation 8 amends regulation 71 (patient online services) to require a contractor to offer the facility to book a minimum percentage of daily appointments online (provided the practice's computer systems and software allow this), to include the appointments which must be made available to NHS 111 in accordance with the provision concerning direct booking by NHS 111 inserted by regulation 13. Regulation 8 omits paragraphs (4) and (6) which are no longer relevant. It also adds a new provision paragraph 5A, which provides that patients newly registered on or after 1st October 2019 should have online access to all information entered onto their medical record unless specified exemptions apply.

Regulation 9 omits regulation 74A (provision of information: GP access data) which is no longer relevant.

Regulation 10 substitutes a new table in regulation 74C (information relating to indicators no longer in the Quality and Outcomes Framework). The new table is an update of the indicators which are no longer in the Quality and Outcomes Framework but in respect of which the Health and Social Care Information Centre (NHS Digital) can extract information from a contractor's computerised system.

Regulation 11 inserts a new regulation 74G (Medicines and Healthcare products Regulatory Agency Central Alerting System) to require a contractor to provide (and notify any changes to) its email address and at least one telephone number to the Medicines and Healthcare products Regulatory Agency for the purpose of receiving safety alerts.

Regulation 12 omits paragraph 3 (contraceptive services) in Schedule 1 (additional services) to reflect that contraceptive services are no longer additional services under the GMS Contracts Regulations.

Regulation 13 inserts a new paragraph 11B (direct booking by NHS 111) to Part 1 of Schedule 3 to the GMS Contracts Regulations to ensure that in certain circumstances a number of appointments are made available to be booked directly by the NHS 111 service. The contractor must also monitor the booking system and assist the Board in its oversight of direct booking by NHS 111. The requirements do not apply if the Board has agreed to suspend them for operational reasons or the contractor does not have the computer systems or software to enable it to comply.

Regulation 14 amends paragraph 15(1)(b) (duty of co-operation) to Part 1 of Schedule 3 to the GMS Contracts Regulations to exempt services provided under the Network Contract Directed Enhanced Scheme ("the Scheme") from the duty to co-operate under paragraph 15 as this is provided for under the new paragraph 15A.

Regulation 15 inserts a new paragraph 15A (duty of co-operation: primary care networks) to Part 1 of Schedule 3 to the GMS Contracts Regulations to ensure that where either a contractor is signed up to the scheme or is not signed up but its registered patients or temporary patients receive services from a member of a primary care network, it must cooperate with that network. In doing so, it must comply with reasonable requests for information, must have regard to guidance issued

by the Board, in addition to participating in meetings, providing information to its registered patients and sharing data.

Regulation 16 inserts a new heading for Part 6 of Schedule 3 to the GMS Contracts Regulations, to reflect that this part also deals with use of the NHS primary care logo, marketing campaigns and advertising private services.

Regulation 17 inserts new paragraph 48A (use of NHS primary care logo) to Part 6 of Schedule 3 which requires a contractor to follow guidance produced by the Board when using the logo.

Regulation 17 also inserts a new paragraph 48B (marketing campaigns) to Part 6 of Schedule 3 which requires a contractor to participate in up to six marketing campaigns in each financial year.

Regulation 17 also inserts a new paragraph 48C (advertising private services) to Part 6 of Schedule 3 which provides that a contractor must not advertise the provision of private services through certain means which are used to advertise the primary medical services it provides.

Part 3 of the Regulations makes amendments to the PMS Agreements Regulations which correspond to the amendments made to the GMS Contracts Regulations by regulations 2(c) and (d), 4 to 11 and 13 to 17.

Regulation 18 amends regulation 3 (interpretation) by adding two new definitions of "practice website" and "private services". The latter refers to medical services, which are akin to primary medical services provided under Part 4 of the Act, but which are provided on a private fee-paying basis to persons other than a contractors' patients.

Regulation 19 amends regulation 13 (agreements: general) by adding a provision which requires a contract to specify that where a contractor intends to provide private services in addition to the primary medical services it provides that provision must take place in certain circumstances only.

Regulation 20 amends regulation 18 (fees and charges) by adding a provision requiring the contract to contain a term that the contractor cannot charge its patients for completion of a mental health evidence form and a term setting out the limited circumstances in which a contractor can provide treatment privately to persons other than its patients from premises which are funded by the Board as referred to in regulation 13(4)(b).

Regulation 21 amends regulation 48 (prescribing: general) to make clear that a reference to "drugs" in regulations 49 (orders for drugs, medicines and appliances), 50 (electronic prescription), 52 (repeatable prescribing services), 53 (repeatable prescriptions), 54 (restrictions on prescribing by medical practitioners), 55 (restrictions on prescribing by supplementary prescribers) and 56 (bulk prescribing), includes contraceptive substances and a reference to "appliances" includes contraceptive appliances.

Regulation 22 inserts a new regulation 53A (electronic repeat dispensing services) which requires a prescriber to issue an electronic repeatable prescription in a format that will enable a nominated dispenser to provide electronic repeat dispensing services with the aim of increasing uptake in the use of electronic repeat dispensing, where this is clinically appropriate for the patient and the patient has agreed to be issued with an electronic repeatable prescription.

Regulation 23 amends regulation 64 (patient online services) to require a contractor to offer the facility to book a minimum percentage of daily appointments online, to include the appointments which must be made available to NHS 111 in accordance with the provision concerning direct booking by NHS 111 inserted by regulation 29. Regulation 23 also omits paragraphs (4) and (6) of regulation 64 which are no longer relevant. It also adds a new provision paragraph 5A, which provides that patients newly registered on or after 1st October 2019 should have online access to all information entered onto their medical record, in so far as their computer systems and redaction software allow, unless specified exemptions apply.

Regulation 24 omits regulation 67A (provision of information: GP access data) which is no longer relevant.

Regulation 25 replaces the table in regulation 67C (information relating to indicators no longer in the Quality and Outcomes Framework). The new table is an update of the indicators which are no longer in the Quality and Outcomes Framework but in respect of which the Health and Social Care Information Centre (NHS Digital) can extract information from a contractor's computerised system.

Regulation 26 inserts a new regulation 67F (Medicines and Healthcare products Regulatory Agency Central Alerting System) to require a contractor to provide (and notify any changes to) its email address and at least one telephone number to the Medicines and Healthcare products Regulatory Agency for the purpose of receiving safety alerts.

Regulation 27 amends paragraph 10(1)(b) (duty of co-operation) of Part 1 of Schedule 2 to the PMS Agreements Regulations to exempt services provided under the Network Contract Directed Enhanced Scheme ("the Scheme") from the duty to co-operate under paragraph 10 as this is provided for under the new paragraph 10A.

Regulation 28 inserts a new paragraph 10A (duty of co-operation: primary care networks) of Part 1 of Schedule 2 to the PMS Agreements Regulations to ensure that where either a contractor is signed up to the scheme or is not signed up but its registered patients or temporary patients receive services from a member of a primary care network, it must cooperate with that network. In doing so, it must comply with reasonable requests for information, must have regard to guidance issued by the Board, in addition to participating in meetings, providing information to its registered patients and sharing data.

Regulation 29 inserts a new paragraph 16B (direct booking by NHS 111) of Part 2 of Schedule 2 to the PMS Agreements Regulations to ensure that in certain circumstances a number of appointments are made available to be booked directly by the NHS 111 service. The contractor must also monitor the booking system and assist the Board in its oversight of direct booking by NHS 111. The requirements do not apply if the Board has agreed to suspend them for operational reasons or it does not have the computer systems or software to enable it to comply

Regulation 30 inserts a new heading to Part 6 of Schedule 2 (provision of information: practice leaflets) of the PMS Agreements Regulations to reflect that this part also deals with use of the NHS primary care logo, marketing campaigns and advertising private services.

Regulation 31 inserts a new paragraph 44A (use of NHS primary care logo) to Part 6 of Schedule 2 which requires a contractor to follow guidance produced by the Board when using the NHS logo.

Regulation 31 also inserts a new paragraph 44B (marketing campaigns) to Part 6 of Schedule 2 which requires a contractor to participate in up to six marketing campaigns in each financial year.

Regulation 31 also inserts a new paragraph 44C (advertising private services) to Part 6 of Schedule 2 which provides that a contractor must not advertise the provision of private services through certain means which are used to advertise the primary medical services it provides.

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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