
WELSH STATUTORY INSTRUMENTS

2016 No. 90 (W. 43)

NATIONAL HEALTH SERVICE, WALES

**The National Health Service (Primary Medical Services
and Primary Dental Services) (Wales) (Amendment
and Transitional Provision) Regulations 2016**

<i>Made</i>	- - - -	<i>26 January 2016</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>29 January 2016</i>
<i>Coming into force</i>	- -	<i>1 March 2016</i>

The Welsh Ministers, in exercise of the powers conferred by sections 46(2), 47, 61, 66 and 203(9) and (10) of the National Health Service (Wales) Act 2006(1), make the following Regulations:

PART 1

General

Title, commencement and application

1.—(1) The title of these Regulations is the National Health Service (Primary Medical Services and Primary Dental Services) (Wales) (Amendment and Transitional Provision) Regulations 2016 and they come into force on 1 March 2016.

(2) These Regulations apply in relation to Wales.

Interpretation

2. In these Regulations—

“the Act” (“*y Ddeddf*”) means the National Health Service (Wales) Act 2006;

“the GDS Regulations” (“*Rheoliadau GDS*”) means the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(2);

(1) 2006 c. 42.

(2) S.I. 2006/490 (W. 59).

“the GMS Contracts Regulations” (“*Rheoliadau Contractau GMS*”) means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004⁽³⁾;

“the GMS Prescription of Drugs Regulations” (“*Rheoliadau Rhagnodi Cyffuriau GMS*”) means the National Health Service (General Medical Services Contracts) (Prescription of drugs etc) (Wales) Regulations 2004⁽⁴⁾; and

“the PDS Regulations” (“*Rheoliadau PDS*”) means the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006⁽⁵⁾.

PART 2

Amendment of the GMS Contracts Regulations

Amendment of regulation 2 of the GMS Contracts Regulations

3. In regulation 2(1) of the GMS Contracts Regulations (interpretation), after the definition of “approved medical practice” insert—

““armed forces of the Crown” means the forces that are “regular forces” or “reserve forces” within the meaning given in section 374 of the Armed Forces Act 2006⁽⁶⁾(definitions applying for the purposes of the whole Act);”.

Amendment of regulation 10 of the GMS Contracts Regulations

4. In regulation 10 of the GMS Contracts Regulations (health service body status), for paragraph (7)(b) substitute—

“(b) paragraph (5), where it or the Local Health Board—

- (i) has referred any matter to the NHS dispute resolution procedure before it ceases to be a health service body, or
- (ii) refers any matter to the NHS dispute resolution procedure, in accordance with paragraph 98(1) of Schedule 6, after it ceases to be a health service body,

the contractor is to continue to be regarded as a health service body (and accordingly the contract is to continue to be regarded as an NHS contract) for the purposes of the consideration and determination of the dispute;”.

Insertion of a new paragraph 15A into Schedule 6 to the GMS Contracts Regulations

5. In Schedule 6 to the GMS Contracts Regulations (other contractual terms), after paragraph 15 (application for inclusion in a list of patients), insert—

“Inclusion in list of patients: armed forces personnel

15A.—(1) The contractor may, if its list of patients is open, include a person to whom sub-paragraph (2) applies in that list for a period of up to two years and paragraph 25(1)(b) does not apply in respect of any person who is included in the contractor’s list of patients by virtue of this paragraph.

(2) This sub-paragraph applies to a person who is—

(3) S.I. 2004/478 (W. 48).

(4) S.I. 2004/1022 (W. 119).

(5) S.I. 2006/489 (W. 58).

(6) 2006 c. 52; a relevant amendment to section 374 was made by section 44(3) and (4) of the Defence Reform Act 2014 (c. 20).

- (a) a serving member of the armed forces of the Crown who has received written authorisation from Defence Medical Services⁽⁷⁾ to receive primary medical services from the contractor's practice; and
 - (b) living or working within the contractor's practice area during the period in respect of which that written authorisation is given.
- (3) Where the contractor has accepted a person to whom sub-paragraph (2) applies onto its lists of patients, the contractor must—
- (a) obtain a copy of the patient's medical record, or a summary of that record, from Defence Medical Services; and
 - (b) provide regular updates to Defence Medical Services, at such intervals as are agreed with Defence Medical Services, about any care and treatment which the contractor has provided to the patient.
- (4) At the end of the period of two years, or on such earlier date as the contractor's responsibility for the patient has come to an end, the contractor must—
- (a) notify Defence Medical Services of the fact that the contractor's responsibility for the patient has come to an end; and
 - (b) update the patient's medical record, or summary of that record, and return it to Defence Medical Services.
- (5) In this paragraph, "primary medical services" means the medical services which are provided by the contractor's practice under the contract to which Part 4 of the Act applies."

Amendment of paragraph 25 of Schedule 6 to the GMS Contracts Regulations

6. In Schedule 6 to the GMS Contracts Regulations (other contractual terms), in paragraph 25 (removals from the list of patients absent from the United Kingdom etc), for sub-paragraph (1)(b) substitute—

- "(b) is in the armed forces of the Crown (except in the case of a patient to which paragraph 15A applies);"

Amendment of paragraph 67 of Schedule 6 to the GMS Contracts Regulations

7. In Schedule 6 to the GMS Contracts Regulations (other contractual terms), in paragraph 67, sub-paragraph (2) (appraisal and assessment), for the words "United Kingdom Armed Forces of Her Majesty" substitute "armed forces of the Crown".

Amendment of paragraph 98 of Schedule 6 to the GMS Contracts Regulations

8. In Schedule 6 to the GMS Contracts Regulations (other contractual terms), in paragraph 98 (dispute resolution: non-NHS contracts), for sub-paragraph (1) substitute—

- "(1) In the case of a contract that is not an NHS contract, any dispute arising out of or in connection with the contract, except matters dealt with under the procedures for notifying concerns or making complaints pursuant to Part 5A and 6 of this Schedule, may be referred for consideration and determination to the Welsh Ministers—
 - (a) if it relates to a period when the contractor was treated as a health service body, by the contractor or by the Local Health Board; or
 - (b) in any other case, by the contractor or, if the contractor agrees in writing, by the Local Health Board."

(7) Defence Medical Services is an umbrella organisation within the Ministry of Defence responsible for the provision of medical, dental and nursing services in the United Kingdom to members of the armed forces of the Crown.

PART 3

Amendment of the GMS Prescription of Drugs Regulations

Amendment of Schedule 2 to the GMS Prescription of Drugs Regulations

9. In Schedule 2 to the GMS Prescription of Drugs Regulations (drugs or medicines to be ordered only in certain circumstances)—

- (a) in column 1 of the table (drugs) in the entry relating to drugs for the treatment of erectile dysfunction—
 - (i) omit “Apomorphine Hydrochloride”, “Moxisylyte Hydrochloride” and “Thymoxamine Hydrochloride”; and
 - (ii) after “Alprostadil” insert “Avanafil”;
- (b) in column 2 of the table (patient) in the entry relating to the drug Oseltamivir (Tamiflu) for the treatment of influenza omit the wording “who is aged 1 year or over and” in each place it appears; and
- (c) at the end of the table in the interpretation provision—
 - (i) omit the definitions of “at-risk” and “child”; and
 - (ii) in the appropriate alphabetical order, insert—
 - ““at-risk” means in relation to a patient, a patient who—
 - (a) has chronic respiratory disease (including asthma and chronic obstructive pulmonary disease);
 - (b) has significant cardiovascular disease, excluding a patient who has hypertension only;
 - (c) has chronic renal disease;
 - (d) is immunocompromised;
 - (e) has diabetes mellitus;
 - (f) has chronic liver disease; or
 - (g) has chronic neurological disease;”.

PART 4

Amendment of the GDS Regulations

Amendment of regulation 9 of the GDS Regulations

10. In regulation 9(7) of the GDS Regulations (health body status) for sub-paragraph (b) substitute the following sub-paragraph—

- “(b) paragraph (5), where it or the Local Health Board—
 - (i) has referred any matter to the NHS dispute resolution procedure before it ceases to be a health service body, or
 - (ii) refers any matter to the NHS dispute resolution procedure, in accordance with paragraph 54(1)(a) of Schedule 3, after it ceases to be a health service body, the contractor is to continue to be treated as a health service body (and accordingly the contract is to continue to be regarded as an NHS contract) for the purposes of the consideration and determination of the dispute; or”.

Amendment of Schedule 3 to the GDS Regulations

11. In Schedule 3 to the GDS Regulations (other contractual terms), after paragraph 13 (telephone services), insert—

“13B. – Cost of relevant calls

(1) The contractor must not enter into, renew or extend a contract or other arrangement for telephone services unless it is satisfied that, having regard to the arrangement as a whole, persons will not pay more to make relevant calls to the practice than they would to make equivalent calls to a geographical number.

(2) Where a contractor is party to an existing contract or other arrangement for telephone services under which persons making relevant calls to the practice call a number which is not a geographical number, the contractor must comply with sub-paragraph (3).

(3) The contractor must—

- (a) before 1 March 2017, review the arrangement and consider whether, having regard to the arrangement as a whole, persons pay more to make relevant calls than they would to make equivalent calls to a geographical number; and
- (b) if the contractor so considers, take all reasonable steps, including in particular considering the matters specified in sub-paragraph (4), to ensure that, having regard to the arrangement as a whole, persons will not pay more to make relevant calls than they would to make equivalent calls to a geographical number.

(4) The matters referred to in sub-paragraph (3)(b) are—

- (a) varying the terms of the contract or arrangement;
- (b) renegotiating the terms of the contract or arrangement; and
- (c) terminating the contract or arrangement.

(5) If despite taking all reasonable steps referred to in sub-paragraph (3)(b), it has not been possible to ensure that, having regard to the arrangement as a whole, persons will not pay more to make relevant calls to the practice than they would to make equivalent calls to a geographical number, the contractor must consider introducing a system under which if a caller asks to be called back, the contractor will do so at the contractor’s expense.

(6) In this paragraph—

- (a) “existing contract or other arrangement” means a contract or arrangement that was entered into prior to 1 March 2016 and which remains in force on 1 March 2016;
- (b) “geographical number” means a number which has a geographical area code as its prefix; and
- (c) “relevant calls” means calls—
 - (i) made by patients to the practice for any reason related to services provided under the contract, and
 - (ii) made by persons, other than patients, to the practice in relation to services provided as part of the health service.”.

Amendment of paragraph 54 of Schedule 3 to the GDS Regulations

12. In paragraph 54 of Schedule 3 to the GDS Regulations (contractual terms-dispute resolution: non-NHS contracts), for sub-paragraph (1) substitute the following sub-paragraph—

“(1) In the case of a contract that is not an NHS contract, any dispute arising out of or in connection with the contract, except matters dealt with under the procedures for notifying

concerns or making complaints pursuant to Parts 5A or 6 of this Schedule, may be referred for consideration and determination to the Assembly—

- (a) if it relates to a period when the contractor was a health service body, by the contractor or by the Local Health Board; or
- (b) in any other case, by the contractor or, if the contractor agrees in writing, by the Local Health Board.”.

Amendment of paragraph 65 of Schedule 3 to the GDS Regulations

- 13.—(1) Schedule 3 (other contractual terms), is amended as follows—
- (2) In paragraph 65 (termination on the death of an individual dental practitioner)—
 - (a) in sub-paragraph (1) substitute “seven days” with “28 days”; and
 - (b) in sub-paragraph (1)(a), substitute “not exceeding three months” with “not exceeding six months”.
 - (3) In paragraph 65 (termination on the death of an individual dental practitioner) in sub-paragraph (2), substitute “the three month period referred to in sub-paragraph (1)(a)” with “the six month period referred to in sub-paragraph (1)(a)”.

PART 5

Amendment of the PDS Regulations

Amendment of regulation 9 of the PDS Regulations

14. In regulation 9(7) (health service body status) for sub-paragraph (b) substitute the following sub-paragraph—

- “(b) paragraph (5), where it or the Relevant Body –
- (i) has referred any matter to the NHS dispute resolution procedure before it ceases to be a health service body, or
 - (ii) refers any matter to the NHS dispute resolution procedure, in accordance with paragraph 54(1)(a) of Schedule 3, after it ceases to be a health service body,
- the contractor is to continue to be treated as a health service body (and accordingly the contract is to continue to be regarded as an NHS contract) for the purposes of the consideration and determination of the dispute; or”.

Amendment of Schedule 3 to the PDS Regulations

15. In Schedule 3 to the GDS Regulations (other contractual terms), after paragraph 14 (telephone services), insert—

“14A. – Cost of relevant calls

(1) The contractor must not enter into, renew or extend a contract or other arrangement for telephone services unless it is satisfied that, having regard to the arrangement as a whole, persons will not pay more to make relevant calls to the practice than they would to make equivalent calls to a geographical number.

(2) Where a contractor is party to an existing contract or other arrangement for telephone services under which persons making relevant calls to the practice call a number which is not a geographical number, the contractor must comply with sub-paragraph (3).

- (3) The contractor must—
- (a) before 1 March 2017, review the arrangement and consider whether, having regard to the arrangement as a whole, persons pay more to make relevant calls than they would to make equivalent calls to a geographical number; and
 - (b) if the contractor so considers, take all reasonable steps, including in particular considering the matters specified in sub-paragraph (4), to ensure that, having regard to the arrangement as a whole, persons will not pay more to make relevant calls than they would to make equivalent calls to a geographical number.
- (4) The matters referred to in sub-paragraph (3)(b) are—
- (a) varying the terms of the contract or arrangement;
 - (b) renegotiating the terms of the contract or arrangement; and
 - (c) terminating the contract or arrangement.
- (5) If, despite taking all reasonable steps referred to in sub-paragraph (3)(b), it has not been possible to ensure that, having regard to the arrangement as a whole, persons will not pay more to make relevant calls to the practice than they would to make equivalent calls to a geographical number, the contractor must consider introducing a system under which if a caller asks to be called back, the contractor will do so at the contractor’s expense.
- (6) In this paragraph—
- (a) “existing contract or other arrangement” means a contract or arrangement that was entered into prior to 1 March 2016 and which remains in force on 1 March 2016;
 - (b) “geographical number” means a number which has a geographical area code as its prefix; and
 - (c) “relevant calls” means calls—
 - (i) made by patients to the practice for any reason related to services provided under the contract, and
 - (ii) made by persons, other than patients, to the practice in relation to services provided as part of the health service.”.

Amendment of paragraph 54 of Schedule 3 to the PDS Regulations

16. In paragraph 54 of Schedule 3 of the PDS Regulations (contractual terms - dispute resolution: non-NHS contracts), for sub-paragraph (1) substitute the following sub-paragraph—

“(1) In the case of a contract that is not an NHS contract, any dispute arising out of or in connection with the contract, except matters dealt with under the procedures for notifying concerns or making complaints pursuant to Parts 5A or 6 of this Schedule, may be referred for consideration and determination to the Assembly—

- (a) if it relates to a period when the contractor was a health service body, by the contractor or by the Local Health Board; or
- (b) in any other case, by the contractor or, if the contractor agrees in writing, by the Local Health Board.”.

Amendment of paragraph 63 of Schedule 3 to the PDS Regulations

17.—(1) Schedule 3 of the PDS Regulations (other contractual terms), is amended as follows—

(2) In paragraph 63 (termination on the death of an individual) at sub-paragraph (1)—

- (a) substitute “seven days” with 28 days”; and
- (b) in paragraph (a), substitute “not exceeding three months” with “not exceeding six months”.

(3) In paragraph 63 (termination on the death of an individual) at sub-paragraph (2), substitute “the three month period referred to in sub-paragraph (1)(a)” with “the six months period referred to in sub-paragraph (1)(a)”.

PART 6

Transitional Provision

Transitional provision relating to disputes in respect of which legal proceedings have commenced before 1 March 2016

18.—(1) Paragraph (2) applies as regards any dispute which relates to matters arising before 1 March 2016 under—

- (a) a general medical services contract;
- (b) a general dental services contract; or
- (c) an arrangement under section 64 of the Act,

which is or are not an NHS contract.

(2) If legal proceedings relating to the dispute have commenced before 1 March 2016, the provisions amended by—

- (a) regulations 4 and 8 (in the case of a dispute relating to a general medical services contract);
- (b) regulations 10 and 12 (in the case of a dispute relating to a general dental services contract);
or
- (c) regulations 14 and 16 (in the case of a dispute relating to an arrangement under section 64 of the Act),

are to have effect in relation to that dispute as if those provisions had not come into force.

26 January 2016

Mark Drakeford,
Minister for Health and Social Services, one of
the Welsh Ministers

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (General Medical Service Contracts) (Wales) Regulations 2004 (S.I. 2004/478, as amended) (“the GMS Contracts Regulations”), the National Health Service (General Medical Service Contracts) (Prescription of Drugs Etc) (Wales) Regulations 2004 (S.I. 2004/1002, as amended) (“the GMS Prescription of Drugs Regulations”), the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006 (S.I. 2006/490, as amended) (“the GDS Regulations”), and the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006 (S.I. 2006/489, as amended) (“the PDS Regulations”).

Providers of services under the contracts or agreements in respect of which provision is made by the GMS Contract Regulations, the GDS Regulations and the PDS Regulations may choose to be a “health service body” and so for their contract to be an NHS contract. Providers who choose to be a health service body may also choose to cease to be such a body and for their contract to cease to be an NHS contract. Where a contractor chooses to cease to be a health service body, the amendments made by regulations 4, 8, 10, 12, 14 and 16 have the effect of providing that all disputes relating to the period when the contract was an NHS contract are to be dealt with under the NHS dispute resolution procedure. Transitional provision is made in regulation 18 which provides that if a dispute is already the subject of legal proceedings before these Regulations came into force, that dispute is to be determined in accordance with the relevant legislation as it applied at that time.

Regulation 5 inserts a new paragraph 15A into Schedule 6 to the GMS Contracts Regulations. This enables a contractor to accept a member of Her Majesty’s armed forces as a patient for a maximum period of two years if that person has been authorised in writing by Defence Medical Services to receive medical services under the contract at the contractor’s practice and the contractor is satisfied that the person is living or working within the contractor’s practice area.

Regulation 3 inserts a definition of “armed forces of the Crown” into regulation 2(1) of the GMS Contracts Regulations.

Regulations 6 and 7 make amendments to paragraph 25 and 67 of Schedule 6 to the GMS Contracts Regulations which are consequential to the amendments made by regulations 3 and 5.

Regulation 9 amends Schedule 2 to the GMS Prescription of Drugs Regulations. Regulation 9 makes amendments to the table in Schedule 2 which restricts the circumstances in which certain drugs or medicines may be ordered for specified categories of patients for specified purposes. The entry in the table relating to certain drugs which may only be ordered for the treatment of erectile dysfunction in restricted circumstances has been amended so as to remove Apomorphine Hydrochloride, Moxisylyte Hydrochloride, and Thymoxamine Hydrochloride and to include Avanafil. The entry in the table relating to the drug Oseltamivir (Tamiflu) for the treatment of flu is amended so as to remove the restriction on prescribing the drug to infants under 1 years of age. Regulation 9 also amends the definition of what is meant by “at-risk” in Schedule 2.

Regulations 11, 13, 15 and 17 amend Schedule 3 to the GDS Regulations and Schedule 3 to the PDS Regulations in relation to other contractual terms which a GDS contract and PDS agreement must contain. Regulations 11 and 15 insert new provision in respect of the use of certain telephone numbers which charge patients more than the equivalent cost of calling a geographical number. Regulations 13 and 17 make amendments in respect of the contractual terms in relation to the termination of a dental contract on the death of an individual practitioner. The effect of the amendments is to extend the period within which the estate of a contract holder has to confirm to the

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health board that they wish to continue to hold the contract after the death of the contract holder to 28 days. The time period the estate then has to arrange the continuation of services is also extended to six months.