

2021 No. 302

NATIONAL HEALTH SERVICE

**The National Health Service (General Medical Services and
Primary Medical Services Section 17C Agreements) (Scotland)
Amendment Regulations 2021**

Made - - - - *3rd September 2021*

Laid before the Scottish Parliament *7th September 2021*

Coming into force - - *18th October 2021*

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 9(6), 17E, 17N and 105(7) of the National Health Service (Scotland) Act 1978(a), and all other powers enabling them to do so.

Citation and Commencement

1. These Regulations may be cited as the National Health Service (General Medical Services and Primary Medical Services Section 17C Agreements) (Scotland) Amendment Regulations 2021 and come into force on 18 October 2021.

Amendments to the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018

2. The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018(b) are amended in accordance with regulations 3 to 10.

3. In regulation 3(1) (interpretation)—

- (a) in the definition of “additional services” omit “paragraphs (c) and (d),
- (b) omit the definition of “childhood vaccinations and immunisations”,
- (c) in the definition of “enhanced services”—
 - (i) in paragraph (a)—
 - (aa) for “or” where it first appears substitute “;”,
 - (bb) after “additional services” insert “or vaccination services”,

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- (a) 1978 c. 29. Section 9 was relevantly amended by section 29(5) of the National Health Service and Community Care Act 1990 (c. 19) and paragraph 43 of schedule 4 of the Health Act 1999 (c. 8). Section 17E was inserted by section 22(2) of the National Health Service (Primary Care) Act 1997 (c. 46) and was relevantly amended by section 65 and schedules 4 and 5 of the Health Act 1999 (c. 8), section 2(4) of the Primary Medical Services (Scotland) Act 2004 (asp. 1) and S.I. 2003/1250. Section 17N was inserted by the Primary Medical Services (Scotland) Act 2004 (asp. 1). Section 105(7) was relevantly amended by section 25(3), paragraph 5 of schedule 6 and schedule 7 of the Health Services Act 1980 (c. 53), section 29 and paragraph 24 of schedule 9 of the Health and Social Services and Social Security Adjudications Act 1983 (c. 41) and, section 65 and paragraph 60 of schedule 4 of the Health Act 1999 (c. 8).
- (b) S.S.I. 2018/66. Relevantly amended by paragraphs 422 to 425 of schedule 19 of the Data Protection Act 2018 (c. 12), S.S.I. 2018/94, S.S.I. 2019/336 and S.S.I. 2019/284, and S.I. 2019/1094.

- (ii) in paragraph (b)—
 - (aa) at the beginning insert “in respect of”,
 - (bb) for “or” where it appears a second time substitute “, ”,
 - (d) after the definition of “the Tribunal” insert—
 - ““vaccination services” means one or more of the services described in schedule 2A;”,
 - and
 - (e) omit the definition of “vaccinations and immunisations”.
4. After regulation 20 (opt outs of additional services) insert—

“Requirement to provide vaccination services

20A.—(1) A contract must include terms which have the same effect as paragraph 1 of schedule 2A.

- (2) A contract which includes the provision of any vaccination services must—
 - (a) in relation to all such services, contain a term which has the same effect as that specified in paragraph 2 of schedule 2A; and
 - (b) in relation to each such service which the contractor is required to provide, contain terms which have the same effect as those specified in schedule 2A which are relevant to that service.”

5. After regulation 33 (out of hours) insert—

“Transitional arrangements for vaccination and immunisation services

33A.—(1) Where on 17 October 2021 a contract included a requirement to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services in accordance with schedule 1—

- (a) the Health Board may serve notice to the contractor requiring the contractor to continue to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services, for a period specified in the notice;
- (b) despite the revocation of paragraphs 4 and 5 of schedule 1, where the Health Board has given notice under sub-paragraph (a), paragraphs 4 and 5 of schedule 1 continue to have effect in relation to that contract on and after 18 October 2021 as they had effect immediately before that date, until the end of the period specified in the notice; and
- (c) where the Health Board has given notice under sub-paragraph (a), in relation to that contract, the definition of “additional services” in regulation 3(1) is to be read as including “vaccinations and immunisations” and “childhood vaccinations and immunisations”.

- (2) A notice served by the Health Board under paragraph (1)(a) must—

- (a) be served not later than 1 December 2021; and
- (b) specify a period which ends no later than 1 April 2022.

(3) A notice served by the Health Board under sub-paragraph (1)(a) must list all of the vaccinations and immunisations which the contractor is required to provide as a consequence of the notice, as of the date of the notice.(4) A letter stating that the contractor is to continue to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services, for a period specified in the letter, which is sent by the Health Board to the contractor’s official correspondence address (specified in accordance with regulation 14) before the coming into force of this regulation is deemed to have the same effect as a notice under paragraph (1)(a), if it complies with the requirements of this regulation.

(5) The Health Board may reduce the duration of the period specified in a notice served under paragraph (1)(a) by serving the contractor with a further notice.

(6) Where the contractor is required to provide vaccination services in accordance with schedule 2A, the contractor's obligation to provide services in accordance with a notice served under paragraph (1)(a) will end on the date on which the contractor's obligation to provide vaccination services begins.

(7) Subject to paragraph (9), prior to the contractor's duty to provide vaccination and immunisation services under this regulation ceasing the Health Board and the contractor must discuss how to inform patients of the change to how vaccinations and immunisations will be delivered to them.

(8) Subject to paragraph (9), if the Health Board requests it, the contractor must inform the contractor's patients of the change to how vaccinations and immunisations will be delivered to them by—

- (a) placing a notice in the practice's waiting room; and
- (b) including the information in the practice leaflet.

(9) Paragraphs (7) and (8) do not apply where the contractor is ceasing to provide the vaccinations and immunisations services under this regulation but will immediately begin providing vaccination services in accordance with schedule 2A."

6. In schedule 1 (additional services) omit paragraphs 4 and 5.

7. After schedule 2 (opt outs of additional services) insert—

“SCHEDULE 2A VACCINATION SERVICES

Regulation 20A

Requirement to provide vaccination services

1.—(1) Subject to the provisions of this paragraph, where the Health Board is satisfied that by reason of distance, inadequacy of means of communication, or other exceptional circumstances, the Health Board will have serious difficulties in delivering any vaccination service to the contractor's patients, the Health Board may require the contractor to provide those services to the contractor's patients until further notice.

(2) The Health Board may not require a contractor to deliver services in accordance with sub-paragraph (1) unless it has first consulted the area medical committee regarding the matter.

(3) The Health Board may not require a contractor to deliver a vaccination service in accordance with sub-paragraph (1) unless the contractor was, immediately prior to the Health Board notifying the contractor of the requirement, offering that particular vaccination service to the contractor's patients as part of an additional service, an enhanced service or as part of a transitional arrangement under regulation 33A.

(4) Nothing in sub-paragraph (3) prevents the contractor and the Health Board from agreeing that the contractor will deliver a vaccination service in accordance with this schedule.

(5) The Health Board must give a contractor reasonable notice that the contractor is required to provide a vaccination service and must, if the contractor is no longer to be required to provide a service, give reasonable notice that the requirement to provide the service is to be discontinued.

(6) A notice served by the Health Board under sub-paragraph (1) must list all of the vaccinations and immunisations which the contractor is required to provide as a consequence of the notice, as of the date of the notice.

(7) A contractor which is required to provide a vaccination service may request that the Health Board reviews that requirement.

(8) A review request under sub-paragraph (7) may not be made by a contractor—

- (a) unless the contractor has been providing the vaccination service for a period of not less than 6 months; and
- (b) the contractor has not made a review request in respect of the service in the 6 months prior to its present review request.

(9) Where it receives a review request, the Health Board must—

- (a) acknowledge the review request within 30 days,
- (b) consider any comments which the contractor has provided to accompany the review request;
- (c) within 3 months of receiving the review request, provide the contractor with either—
 - (i) a written statement of reasons as to why the contractor is required to continue to provide the vaccination service; or
 - (ii) a written plan for the discontinuation of the requirement that the contractor provide the vaccination service which includes the date on which the requirement will end.

(10) When considering whether it will have serious difficulty in delivering a vaccination service or serving notice under sub-paragraph (1) or when considering a review request submitted under sub-paragraph (7), the Health Board must comply with any directions given by the Scottish Ministers in relation to these matters.

(11) For the purposes of this paragraph, a “vaccination service” comprises—

- (a) offering and administering to patients all doses necessary to complete the recommended course of vaccination for a single disease, or in the case of a combination vaccine which protects the patient against multiple diseases, all doses necessary to complete the recommended course of vaccination for all of the diseases for which that combination vaccine provides protection; and
- (b) providing appropriate information and advice to patients regarding the course of vaccination offered.

Conditions which apply to all vaccination services

2. The contractor must, in relation to each vaccination service which they provide, provide such facilities and equipment as are necessary to enable it to properly perform that service.

Vaccinations and immunisations

3.—(1) A contractor who is required in accordance with paragraph 1 to provide vaccinations and immunisations to their patients must comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor must—

- (a) offer to provide to patients all vaccinations and immunisations (excluding childhood vaccinations and immunisations) of a type and in the circumstances for which a fee is provided for in directions given under section 17M of the Act;
- (b) where a patient has informed the contractor that the patient intends to travel outside of the United Kingdom, offer to provide the patient with all vaccinations and immunisations of a type and in circumstances for which a fee is provided for in directions given under section 17M of the Act;
- (c) provide appropriate information and advice to patients about such vaccinations and immunisations;

- (d) record in the patient's record kept in accordance with paragraph 68 of schedule 6 any refusal of the offers referred to in sub-paragraph (a) and (b);
 - (e) where an offer referred to in sub-paragraphs (a) and (b) is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 68 of schedule 6—
 - (i) the patient's consent to vaccination or immunisation, or the name of the person who gave consent to the vaccination or immunisation and that person's relationship to the patient;
 - (ii) the batch numbers, expiry date and title of the vaccine;
 - (iii) the date of administration;
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
 - (v) any contraindications to the vaccination or immunisation; and
 - (vi) any adverse reactions to the vaccination or immunisation.
- (3) The contractor must ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Childhood vaccinations and immunisations

4.—(1) A contractor who is required in accordance with paragraph 1 to provide childhood vaccinations and immunisations to their patients must comply with the requirements in sub-paragraphs (2) and (3).

- (2) The contractor must—
- (a) offer to provide to children all vaccinations and immunisations of a type and in the circumstances for which a fee is provided for in directions given under section 17M of the Act;
 - (b) where a patient has informed the contractor that the patient intends to travel outside of the United Kingdom, offer to provide the patient with all vaccinations and immunisations of a type and in circumstances for which a fee is provided for in directions given under section 17M of the Act;
 - (c) provide appropriate information and advice to patients and, where appropriate, their parents, about such vaccinations and immunisations;
 - (d) record in the patient's record kept in accordance with paragraph 68 of schedule 6 any refusal of the offers referred to in sub-paragraph (a) and (b);
 - (e) where an offer referred to in sub-paragraphs (a) and (b) is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 68 of schedule 6—
 - (i) the patient's consent to vaccination or immunisation, or the name of the person who gave consent to the vaccination or immunisation and that person's relationship to the patient;
 - (ii) the batch numbers, expiry date and title of the vaccine;
 - (iii) the date of administration;
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
 - (v) any contraindications to the vaccination or immunisation; and
 - (vi) any adverse reactions to the vaccination or immunisation.
- (3) The contractor must ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Supplementary vaccinations and immunisations

5.—(1) Where directions given under section 17M have provided for a fee to be payable for the provision of a vaccination or immunisation of a specified type in specified circumstances, but those directions have not specified that the vaccination or immunisation is to form part of the vaccinations and immunisations described by paragraph 3 or the childhood vaccinations and immunisations described by paragraph 4, that vaccination or immunisation is to be considered a “supplementary vaccination and immunisation”.

(2) Subject to paragraph 1, a Health Board may require a contractor to provide to their patients any of the supplementary vaccinations and immunisations.

(3) A contractor who is required to provide supplementary vaccinations and immunisations to their patients must comply with the requirements in sub-paragraphs (4) and (5).

(4) The contractor must—

- (a) offer to provide to patients all such vaccinations and immunisations which the Health Board may specify;
- (b) provide appropriate information and advice to patients about such vaccinations and immunisations or, where appropriate, if the patient is a child, provide this information and advice to their parents;
- (c) record in the patient’s record kept in accordance with paragraph 68 of schedule 6 any refusal of the offer referred to in sub-paragraph (a);
- (d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient’s record kept in accordance with paragraph 68 of schedule 6—
 - (i) the patient’s consent to vaccination or immunisation, or the name of the person who gave consent to the vaccination or immunisation and that person’s relationship to the patient;
 - (ii) the batch numbers, expiry date and title of the vaccine;
 - (iii) the date of administration;
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
 - (v) any contraindications to the vaccination or immunisation; and
 - (vi) any adverse reactions to the vaccination or immunisation.

(5) The contractor must ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.”.

8. In paragraph 1(l) of schedule 3 (minimum standards for practice premises) before “fittings” insert “premises,”.

9. In schedule 6 (other contractual terms)—

- (a) after paragraph 7 (storage of vaccines) insert—

“Anaphylaxis training

7A. The contractor must ensure that all registered medical practitioners and registered nurses routinely employed or engaged by the contractor are trained in the recognition and initial treatment of anaphylaxis.”.

- (b) in paragraph 9 (duty of co-operation in relation to additional and enhanced services)—
 - (i) for the words “and enhanced services” where they appear in the heading substitute “, enhanced services and vaccination services”,
 - (ii) in sub-paragraph (1)—
 - (aa) after “a particular additional service” omit “or”,

- (bb) after “a particular enhanced service;” insert—
 - “or
- (c) a particular vaccination service;” and
- (c) in paragraph 10 (duty of co-operation in relation to additional and enhanced services)—
 - (i) for the words “and enhanced services” where they appear in the heading substitute “, enhanced services and vaccination services”,
 - (ii) after “a particular additional service” omit “or”,
 - (iii) after “a particular enhanced service;” insert—
 - “or
 - (c) a particular vaccination service;” and,
- (d) in paragraph 94(1) (variation of a contract: general)—
 - (i) for “regulation 31” substitute “regulations 31 and 33A”, and
 - (ii) after “schedule 2” insert “, paragraph 1 of schedule 2A”.

10. In schedule 8 (information to be included in practice leaflets) after paragraph 19 insert—

“**19A.** The details of the arrangements for the delivery of vaccinations and immunisations (and childhood vaccinations and immunisations) to the contractor’s patients.”

Amendments to the National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018

11. The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018(a) are amended in accordance with regulations 12 to 20.

12. In regulation 3(1) (interpretation)—

- (a) in the definition of “additional services” omit paragraphs (c) and (d).
- (b) omit the definition of “childhood vaccinations and immunisations”,
- (c) in the definition of “enhanced services”—
 - (i) in paragraph (a)—
 - (aa) omit “or” where it first appears,
 - (bb) after “additional services” insert “or vaccination services”,
 - (ii) in paragraph (b)—
 - (aa) at the beginning insert “in respect of”,
 - (bb) for “or” where it appears a second time substitute “,”,
- (d) after the definition of “the Tribunal” insert—
 - ““vaccination services” means one or more of the services described in schedule 3A;”,
 - and
- (e) omit the definition of “vaccinations and immunisations”.

13. In regulation 12(1) (primary medical services and content of agreements) after “paragraphs” insert “5, 5A,”.

(a) S.S.I. 2018/67. Relevantly amended by paragraphs 426 to 429 of schedule 19 of the Data Protection Act 2018 (c. 12), S.S.I. 2018/94, S.S.I. 2019/336 and S.S.I. 2019/284, and S.I. 2019/1094.

14. After regulation 14 (additional services and content of agreements) insert—

“Requirement to provide vaccination services

14A.—(1) An agreement must include terms which have the same effect as paragraph 1 of schedule 3A.

- (2) An agreement which includes the provision of any vaccination services must—
- (a) in relation to all such services, contain a term which has the same effect as that specified in paragraph 2 of schedule 3A; and
 - (b) in relation to each such service which the provider is required to provide, contain terms which have the same effect as those specified in schedule 3A, which are relevant to that service.”.

15. After regulation 28 (out of hours) insert—

“Transitional arrangements for vaccination and immunisation services

28A.—(1) Where on 17 October 2021 an agreement included a requirement to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services in accordance with schedule 3—

- (a) the Health Board may serve notice to the provider requiring the provider to continue to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services for a period specified in the notice;
- (b) despite the revocation of paragraphs 4 and 5 of schedule 3, where the Health Board has given notice under sub-paragraph (a), paragraphs 4 and 5 of schedule 3 continue to have effect in relation to that agreement on and after 18 October 2021 as they had effect immediately before that date, until the end of the period specified in the notice; ;
- (c) where the Health Board has given notice under sub-paragraph (a), in relation to that agreement, the definition of “additional services” in regulation 3(1) is to be read as including “vaccinations and immunisations” and “childhood vaccinations and immunisations”.

(2) A notice served by the Health Board under paragraph (1)(a) must—

- (a) be served no later than 1 December 2021; and
- (b) specify a period which ends no later than 1 April 2022.

(3) A notice served by the Health Board under sub-paragraph (1)(a) must list all of the vaccinations and immunisations which the provider is required to provide as a consequence of the notice, as of the date of the notice.(4) A letter stating that the provider is to continue to provide the vaccinations and immunisations additional service, the childhood vaccinations and immunisations additional service, or both services, for a period specified in the letter, which is sent by the Health Board to the provider’s official correspondence address (specified in accordance with regulation 15) before the coming into force of this regulation is deemed to have the same effect as a notice under paragraph (1)(a), if it complies with the requirements of this regulation.

(5) The Health Board may reduce the duration of the period specified in a notice served under paragraph (1)(a) by serving the provider with a further notice.

(6) Where the provider is required to provide vaccination services in accordance with schedule 3A, the provider’s obligation to provide services in accordance with a notice served under paragraph (1)(a) will end on the date on which the provider’s obligation to provide vaccination services begins.

(7) Subject to paragraph (9), prior to the provider’s duty to provide vaccination and immunisation services under this regulation ceasing, the Health Board and the provider

must discuss how to inform patients of the change to how vaccinations and immunisations will be delivered.

(8) Subject to paragraph (9), if the Health Board requests it, the provider must inform the provider's patients of the change to how vaccinations and immunisations will be delivered to them by—

- (a) placing a notice in the practice's waiting room;
- (b) including the information in the practice leaflet.

(9) Paragraphs (7) and (8) do not apply where the provider is ceasing to provide vaccination and immunisation services under this regulation but will immediately begin providing vaccination services in accordance with schedule 3A.”.

16. In schedule 1—

- (a) after paragraph 5 (storage of vaccines) insert

“Anaphylaxis training

5A. The provider must ensure that all registered medical practitioners and registered nurses routinely employed or engaged by the provider are trained in the recognition and initial treatment of anaphylaxis.”.

- (b) in paragraph 7 (duty of co-operation in relation to primary medical services) in sub-paragraph (1)—
 - (i) after “a particular additional service” omit “or”,
 - (ii) after “a particular enhanced service” insert—
 - “or
 - (d) a particular vaccination service;”
- (c) in paragraph 8 (duty of co-operation in relation to primary medical services)
 - (i) after “a particular additional service omit “or”, and
 - (ii) after “a particular enhanced service; or” insert—
 - “(d) a particular vaccination service;” , and
- (d) in paragraph 61(1) (variation of an agreement: general)—
 - (i) for “regulation 25” substitute “regulations 25 and 28A”; and
 - (ii) after “this schedule” insert “, paragraph 1 of schedule 3A”.

17. In schedule 3 (agreements to provide additional services) omit paragraphs 4 and 5.

18. After schedule 3 insert—

“SCHEDULE 3A

Regulation 14A

VACCINATION SERVICES

Requirement to provide vaccination services

1.—(1) Subject to the provisions of this paragraph, where the Health Board is satisfied that by reason of distance, inadequacy of means of communication, or other exceptional circumstances, the Health Board will have serious difficulties in delivering any vaccination service to the provider's patients, the Health Board may require the provider to provide those services to the provider's patients until further notice.

(2) The Health Board may not require a provider to deliver services in accordance with sub-paragraph (1) unless it has first consulted the area medical committee regarding the matter.

(3) The Health Board may not require a provider to provide a vaccination service in accordance with sub-paragraph (1) unless the provider was, immediately prior to the Health Board notifying the provider of the requirement, offering that particular vaccination service to the provider's patients as part of an additional service, an enhanced service or as part of a transitional arrangement under regulation 28A.

(4) Nothing in sub-paragraph (3) prevents the provider and the Health Board from agreeing that the provider will deliver a vaccination service in accordance with this schedule.

(5) The Health Board must give a provider reasonable notice that the provider is required to provide a vaccination service and must, if the provider is no longer required to provide a service, give reasonable notice that the requirement to provide the service is to be discontinued.

(6) A notice served by the Health Board under sub-paragraph (1) must list all of the vaccinations and immunisations which the provider is required to provide as a consequence of the notice, as of the date of the notice.

(7) A provider which is required to provide a vaccination service may request that the Health Board reviews that requirement.

(8) A review request under sub-paragraph (7) may not be made by the provider—

- (a) unless the provider has been providing the vaccination service for a period of not less than 6 months; and
- (b) the provider has not made a review request in respect of the service in the 6 months prior to its present review request.

(9) Where it receives a review request, the Health Board must—

- (a) acknowledge the review request within 30 days;
- (b) consider any comments which the provider has provided to accompany the review request;
- (c) within 3 months of receiving the review request, provide the provider with either—
 - (i) a written statement of reasons as to why the provider is required to continue to provide the vaccination service; or
 - (ii) a written plan for the discontinuation of the requirement that the provider provide the vaccination service which includes the date on which the requirement will end.

(10) When considering whether it will have serious difficulty in delivering a vaccination service or serving notice under sub-paragraph (1), or when considering a review request submitted under sub-paragraph (7), the Health Board must comply with any directions given by the Scottish Ministers in relation to these matters.

(11) For the purposes of this paragraph a “vaccination service” comprises—

- (a) offering and administering to patients all doses necessary to complete the recommended course of vaccination for a single disease, or in the case of a combination vaccine which protects the patient against multiple diseases, all doses necessary to complete the recommended course of vaccination for all of the diseases for which that combination vaccine provides protection; and
- (b) providing appropriate information and advice to patients regarding the course of vaccination offered.

Conditions which apply to all vaccination services

2. The provider must—

- (a) in relation to each vaccination service which they provide, provide such facilities and equipment as are necessary to enable the provider to properly perform that service; and

- (b) provide each vaccination service which they provide, within core hours as is appropriate to meet the reasonable needs of their patients.

Vaccinations and immunisations

3.—(1) A provider who is required in accordance with paragraph 1 to provide vaccinations and immunisations to their patients must comply with the requirements in sub-paragraphs (2) and (3).

(2) The provider must—

- (a) offer to provide to patients all vaccinations and immunisations (excluding childhood vaccinations and immunisations) of a type and in the circumstances for which a fee is provided for in directions given under section 17M of the Act;
- (b) where a patient has informed the provider that the patient intends to travel outside of the United Kingdom, offer to provide the patient with all vaccinations and immunisations of a type and in circumstances for which a fee is provided for in directions given under section 17M of the Act;
- (c) provide appropriate information and advice to patients about such vaccinations and immunisations;
- (d) record in the patient's record kept in accordance with paragraph 36 of schedule 1 any refusal of the offers referred to in sub-paragraphs (a) and (b);
- (e) where an offer referred to in sub-paragraphs (a) and (b) is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 36 of schedule 1—
 - (i) the patient's consent to vaccination or immunisation, or the name of the person who gave consent to the vaccination or immunisation and that person's relationship to the patient;
 - (ii) the batch numbers, expiry date and title of the vaccine;
 - (iii) the date of administration;
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
 - (v) any contraindications to the vaccination or immunisation; and
 - (vi) any adverse reactions to the vaccination or immunisation.

(3) The provider must ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Childhood vaccinations and immunisations

4.—(1) A provider who is required in accordance with paragraph 1 to provide childhood vaccinations and immunisations to their patients must comply with the requirements in sub-paragraphs (2) and (3).

(2) The provider must—

- (a) offer to provide to children all vaccinations and immunisations of a type and in the circumstances for which a fee is provided for in directions given under section 17M of the Act;
- (b) where a patient has informed the provider that the patient intends to travel outside of the United Kingdom, offer to provide the patient with all vaccinations and immunisations of a type and in circumstances for which a fee is provided for in directions given under section 17M of the Act;
- (c) provide appropriate information and advice to patients and, where appropriate, their parents, about such vaccinations and immunisations;

- (d) record in the patient's record kept in accordance with paragraph 36 of schedule 1 any refusal of the offers referred to in sub-paragraph (a) and (b);
- (e) where an offer referred to in sub-paragraph (a) and (b) is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 36 of schedule 1—
 - (i) the patient's consent to vaccination or immunisation, or the name of the person who gave consent to vaccination or immunisation and that person's relationship to the patient;
 - (ii) the batch numbers, expiry date and title of the vaccine;
 - (iii) the date of administration;
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
 - (v) any contraindications to the vaccination or immunisation; and
 - (vi) any adverse reactions to the vaccination or immunisation.

(3) The provider must ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

Supplementary vaccinations and immunisations

5.—(1) Where directions given under section 17M have provided for a fee to be payable for the provision of a vaccination or immunisation of a specified type in specified circumstances, but those directions have not specified that the vaccination or immunisation is to form part of the vaccinations and immunisations described by paragraph 3 or the childhood vaccinations and immunisations described by paragraph 4, the vaccination or immunisation is to be considered a “supplementary vaccination and immunisation”.

(2) Subject to paragraph 1, a Health Board may require a provider to provide to their patients any of the supplementary vaccinations and immunisations.

(3) A provider who is required to provide any supplementary vaccination and immunisation to their patients must comply with the requirements in sub-paragraph (4) and (5).

(4) The provider must—

- (a) offer to provide to patients all such vaccinations and immunisations which the Health Board may specify;
- (b) provide appropriate information and advice to patients about such vaccinations and immunisations or, where appropriate, if the patient is a child, provide this information and advice to their parents;
- (c) record in the patient's record kept in accordance with paragraph 36 of schedule 1 any refusal of the offered referred to in sub-paragraph (a);
- (d) where the offer is accepted, administer the vaccinations and immunisations and include in the patient's record kept in accordance with paragraph 36 of schedule 1—
 - (i) the patient's consent to vaccination or immunisation, or the name of the person who gave consent to the vaccination or immunisation and that person's relationship to the patient;
 - (ii) the batch numbers, expiry date and title of the vaccine;
 - (iii) the date of administration;
 - (iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
 - (v) any contraindications to the vaccination or immunisation; and
 - (vi) any adverse reactions to the vaccination or immunisation.

(5) The provider must ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.”.

19. In schedule 4 (minimum standards for practice premises) in paragraph 12 before “fittings” insert “premises,”.

20. In schedule 6 (information to be included in practice leaflets) after paragraph 21 insert—

“**21A.** The details of the arrangements for the delivery of vaccinations and immunisations (and childhood vaccinations and immunisations) to the provider’s patients.”.

St Andrew’s House,
Edinburgh
3rd September 2021

HUMZA YOUSAF
A member of the Scottish Government

EXPLANATORY NOTE

(This note is not part of the Regulations)

The National Health Service (General Medical Services Contracts) Regulations 2018 (the “principal GMS regulations”) set out for Scotland the framework for general medical services contracts into which Health Boards may enter under section 17J of the National Health Service (Scotland) Act 1978 (the “1978 Act”). Regulations 2 to 10 of these Regulations make amendments to the principal GMS regulations to remove “vaccinations and immunisations” and “childhood vaccinations and immunisations” from the classification of “additional services” such that vaccinations no longer form a core element of the contract which all contractors must provide, unless they have specifically opted out using the process in Schedule 2 of the principal GMS regulations. These Regulations place “vaccinations and immunisations” and “childhood vaccinations and immunisations” in a new classification, “vaccination services” which contractors are only required to provide in certain circumstances. These Regulations make provision as to those circumstances. These Regulations also make consequential and transitional provision in relation to this change of classification.

These Regulations correct one drafting error in the principal GMS regulations in relation to the minimum standards for practice premises which are used by contractors.

The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2018 (the “principal PMS regulations”) set out for Scotland the framework for primary medical services agreements which Health Boards may make under section 17C of the 1978 Act. Regulations 11 to 20 of these Regulations make amendments to the principal PMS regulations which are equivalent to those amendments made for the principal GMS regulations.

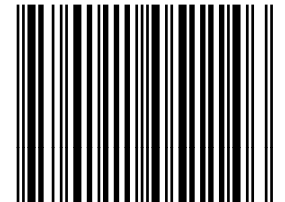
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