EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES CONTRACTS AND PERSONAL MEDICAL SERVICES AGREEMENTS) (AMENDMENT) REGULATIONS 2021

2021 No. 331

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (DHSC) and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 This instrument amends the following Regulations relating to the provision of primary medical services in England:
 - i. the National Health Service (General Medical Services Contracts) Regulations 2015 (SI 2015/1862) (the "GMS Contracts Regulations") which set out the framework for General Medical Services (GMS) contracts; and
 - ii. the National Health Service (Personal Medical Services Agreements)
 Regulations 2015 (SI 2015/1879) (the "PMS Agreements Regulations"),
 which set out the framework for Personal Medical Services (PMS)
 agreements.
- 2.2 Every individual or partnership of GPs must hold an NHS GP contract to run an NHS-commissioned general practice. The contract sets out mandatory requirements and services for all general practices, as well as making provisions for several types of other services that practices may also provide, if they so choose. There are three different types of GP contract arrangements in England: General Medical Services (GMS), Personal Medical Services (PMS) and Alternative Provider Medical Services (APMS). All types of contract are managed by the NHS commissioner (either NHS England and NHS Improvement, (NHSE/I), the operating name of the NHS Commissioning Board (the Board), or Clinical Commissioning Groups (CCGs)).
- 2.3 The amendments in this instrument implement part of the agreement between NHSE/I and the General Practitioners Committee (GPC) of the British Medical Association (BMA) on changes to primary medical services (GP) contracts made in February 2020.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The Department regrets that this instrument breaches the rule that statutory instruments subject to the negative resolution procedure should normally be laid 21 days before the instrument comes into force ("the 21 day rule"). It has been agreed with NHSE/I and the GP Committee of the BMA that this instrument will come into force on 1st April 2021. Any delay to this commencement would cause significant operational and legal issues for NHSE/I and contractors. NHSE/I's payment systems

have already been changed to account for the reclassification of services on that date as provided for in this instrument. If commencement of this instrument were to be delayed beyond 1st April 2021, interim arrangements in legislation and guidance would need to be negotiated with the GP Committee of the BMA and made at speed, to ensure continuity of service obligations (in particular vaccinations and immunisations) and allow the GP contracts and payment mechanisms to operate as intended. This includes reflecting these interim payment arrangements in the forthcoming General Medical Services Statement of Financial Entitlement Directions and the Primary Medical Services (Directed Enhanced Services) Directions, to lapse when the instrument comes into force. Any legislation we put in place to enable this would breach the 21 day rule further, and we cannot confirm that the legislation and guidance could be prepared at sufficient pace, given the timelines. These arrangements would subsequently need to be replaced when this instrument came into force.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As this instrument is subject to the negative resolution procedure there are no matters relevant to Standing Order Nos. 83P and 83T of the Standing Orders of the House of Commons relating to public business at this stage.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is England and Wales.
- 4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

5.1 As this instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 Part 4 of the National Health Service Act 2006 (c. 41) requires NHSE/I to secure the provision of primary medical services in England. It makes provision for regulations to be made to govern the terms of contracts under which primary medical services are provided.
- 6.2 This instrument is being made to amend existing regulations to reflect the terms which will form part of the GP contract. Such amendments are usually made twice a year.
- 6.3 Agreement was reached in February 2020 between NHSE/I and the GPC on changes to be made to the primary medical services contracts for 2020-21 (see the *Update to the GP contract agreement 2020/21 2023/24*, published by NHSE/I and the BMA on 6th February 2020 at: https://www.england.nhs.uk/wp-content/uploads/2020/03/update-to-the-gp-contract-agreement-v2-updated.pdf).
- Various amendments were made to existing regulations to reflect these changes for 2020-21 (see the NHS (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2020 (S.I. 2020/226), the NHS (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) (No. 2) Regulations 2020 (S.I. 2020/911) and the NHS (General Medical Services Contracts and Personal Medical Services Agreements)

- (Amendment) (No. 3) Regulations 2020 (S.I. 2020/1415)). However, it was not possible to implement all of the agreed amendments for 2020-21 in those regulations.
- 6.5 This instrument is, therefore, being made to amend existing regulations to implement some of the remaining amendments which were agreed and made public in 2020 (detailed in paragraphs 7.3 7.13 of this explanatory memorandum) but not implemented in those earlier regulations. In addition, following the most recent negotiating round between NHSE/I and the GPC, this instrument reclassifies Cervical Screening Services as an essential service (detailed in paragraph 7.2) see the NHSE/I letter to the primary care sector of 21st January 2021 at: https://www.england.nhs.uk/wp-content/uploads/2021/01/C1054-supporting-general-practice-in-21-22.pdf.
- 6.6 The amendments made by this instrument will apply from 1st April 2021.

7. Policy background

What is being done and why?

7.1 The following amendments are made by this instrument to GP contracts:

Reclassification of Cervical Screening Services as an essential service

7.2 This amendment to the GMS Contracts Regulations will help to standardise delivery and funding of cervical cancer screening services, by reclassifying these from additional services (which practices can opt out of delivering) to essential services (which all practices must deliver). This is part of a general process of moving additional services into essential services to simplify the contract, where this is appropriate. In practice, almost all contractors currently provide Cervical Screening Services, so the clinical and financial impact of moving them from additional to essential services is expected to be minimal. A link to new DHSC guidance has also been added; these provide an overview of the cervical screening programme which would be useful for commissioners and general practices – see: https://www.gov.uk/guidance/cervical-screening-programme-overview.

Reclassification of Child Health Surveillance (CHS) and Maternity Medical Services (MMS) as essential services

7.3 This amendment to the GMS Contracts Regulations will reclassify CHS and MMS as essential services which contractors are required to provide – removing the opportunity for contractors to opt out of providing either. This is intended to help standardise the delivery and funding of these services and will reflect the fact that the vast majority of practices provide these services already. To improve care to new mothers, this amendment will extend the definition of the post-natal period from two to eight weeks. This is in line with the National Institute for Health and Clinical Excellence's (NICE) clinical guideline [CG37] *Postnatal care up to 8 weeks after birth*, (see: https://www.nice.org.uk/guidance/cg37) which considers eight weeks after birth to be an appropriate period in which general practices can treat emerging issues.

Reclassification of the Vaccines and Immunisation additional service and the Childhood Vaccines and Immunisation additional service as essential services

7.4 These amendments to the GMS Contracts Regulations will reclassify these as essential services which contractors are required to provide – removing the opportunity for contractors to opt out of providing them.

New duties related to vaccine and immunisation services

- 7.5 This instrument also amends the GMS Contracts Regulations and the PMS Agreements Regulations to introduce a set of core operational standards and criteria that contractors must adhere to in relation to vaccines and immunisations (other than those which are offered to patients under private arrangements).
- 7.6 Contractors will be required, as far as reasonable, to co-operate with 'relevant persons' (including the Board, the Secretary of State, local authorities, and others who administer vaccines and immunisations within and without of their primary care network) to: understand current uptake, and barriers to uptake, of 'the vaccines and immunisations' specified in the GMS Statement of Financial Entitlement Directions; and develop, if necessary, a strategy for improving the contractor's immunisation programme.
- 7.7 Contractors will be required to have a system in place for delivering appointments for administering these vaccines and immunisations which meets the 'Vaccines and Immunisations Standards' determined by the Board. These standards (see paragraph 7.11 of this explanatory memorandum) will cover, amongst other things, when patients are to be invited for appointments, how missed appointments are to be followed up and the steps contractors are to take to identify, and address, gaps in patients' immunisation records.
- 7.8 Contractors will be required to participate in one vaccine and immunisations catch-up campaign every financial year. This aims to maximise the uptake of a particular vaccine or immunisation by those patients who are eligible for but have not yet received it, unless they have already decided to refuse it.
- 7.9 Contractors will continue to be required to ensure all their staff involved in administering vaccines and immunisations are trained in the recognition and initial treatment of anaphylaxis, in addition to other training requirements already required in the regulations.
- 7.10 Contractors will be required to nominate a vaccinations and immunisations lead responsible for overseeing the provision of their vaccine and immunisation services and overseeing compliance with the requirements outlined in this section.
- 7.11 Associated guidance agreed with the BMA (entitled Vaccinations and Immunisations: Guidance for 2021/2022 in England) is due to be published by NHSE/I by 1st April 2021: this will provide contractors with more information on what they need to do to meet these requirements in the 2021-22 financial year.
- 7.12 Changes to the related Alternative Provider Medical Services Directions will be made separately to come into effect from 1st April 2021.
- 7.13 The changes detailed in paragraphs 7.4 to 7.10 adhere to the recommendations made in a 2019 NHSE/I review of current contracting arrangements entitled *Interim findings of the Vaccinations and Immunisations Review September 2019*; (see: https://www.england.nhs.uk/publication/interim-findings-of-the-vaccinations-and-immunisations-review-september-2019/).
- 8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union
- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 The GMS Contracts Regulations and the PMS Agreements Regulations from 2015 were consolidating instruments. Both sets of Regulations have since been amended; however, DHSC does not consider there to be a current need to further consolidate these Regulations.

10. Consultation outcome

10.1 There is no statutory requirement to consult on proposals to amend the GMS
Contracts Regulations or PMS Agreements Regulations. However, it is custom and
practice that contractual changes are negotiated with the GP Committee of the BMA.
DHSC referred a draft of these proposed amendments to the GP Committee of the
BMA, who are the recognised representatives of GPs for these purposes, and to
NHSE/I for their consideration and comment.

11. Guidance

- Details of the GP contract agreed to date for England in 2020/21 were published by NHSE/I and the BMA on 6th February 2020 see: https://www.england.nhs.uk/wp-content/uploads/2020/03/update-to-the-gp-contract-agreement-v2-updated.pdf.
- 11.2 Details of the GP contract agreed to date for England in 2021/22 were laid out by NHSE/I in a letter to the primary care sector dated 21st January 2021 see: https://www.england.nhs.uk/publication/supporting-general-practice-in-2021-22/. NHSE/I will publish guidance concerning vaccinations and immunisations by 1st April 2021 (see paragraph 7.11 of this explanatory memorandum).

12. Impact

- 12.1 This instrument has no, or no significant, impact on business, charities or voluntary bodies
- 12.2 This instrument has no, or no significant, impact on the public sector.
- 12.3 A full Impact Assessment has not been prepared for this instrument as no, or no significant impact, on the private, voluntary or public sector is foreseen.

13. Regulating small business

13.1 Although many general practices are small businesses, they are nevertheless exempt from the Small Firm Impact Test. This is because they are considered as part of the public sector due to their provision of primary medical services for the NHS.

14. Monitoring & review

- 14.1 The approach to monitoring of this instrument is the responsibility of NHSE/I. However, the Secretary of State has responsibility for the terms of contracts contained in regulations and for the consolidation of those regulations.
- 14.2 This instrument does not include a statutory review clause.

15. Contact

15.1 Grant Hibberd, GP Legislation Policy and Parliamentary Business officer at the Department of Health and Social Care, can be contacted with any queries regarding

- these Amending Regulations and this explanatory memorandum. Please email: generalpracticemailbox@dhsc.gov.uk.
- 15.2 Sarah Gravenstede, Deputy Director for Primary Care at the Department of Health and Social can confirm that this explanatory memorandum meets the required standard.
- 15.3 Jo Churchill MP, Parliamentary Under Secretary of State for Prevention, Public Health and Primary Care at the Department of Health and Social Care, can confirm that this explanatory memorandum meets the required standard.

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