

EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (AMENDMENTS RELATING TO THE PROVISION OF PRIMARY CARE SERVICES DURING A PANDEMIC ETC.) REGULATIONS 2020

2020 No. 351

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 sets of Regulations by including new provisions relating to the provision of primary care services by GPs, chemists and dentists during a pandemic or where one is imminent:
 - The National Health Service (General Medical Services Contracts) Regulations 2015 (SI 2015/1862) (“GMS Contracts Regulations”) which set out the framework for General Medical Services (GMS) contracts.
 - 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.
 - The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (SI 2013/349, as amended) (“the PLPS Regulations”) which set out the framework for dispensing contractors’ terms of service.
 - The National Health Service (General Dental Services Contracts) Regulations 2005 (“the GDS Contracts Regulations”) which set out a framework for General Dental Services contracts.
 - The National Health Service (Personal Dental Services Agreements) Regulations 2005 (“the PDS Agreements Regulations”) which set out a framework for Personal Dental Services agreements.
- 2.2 The amendments will enable NHS England and Improvement (NHS E&I) with the agreement of Secretary of State for Health and Social Care during a pandemic (or where one is imminent) to implement the following:
 - suspend the enforcement of particular terms of service of primary care contractors. In these circumstances, the contract term will remain in place, but the contractor will not need to comply with it. The fact that a contractor did not comply with it would not prevent the NHS continuing to pay the contractor – because we could at the same time suspend the payment conditions that required performance of the requirement.
 - temporarily remove particular terms of service of a primary care contractor from their arrangements with NHS E&I. If we decide to remove a term

temporarily, the expectation is that contractors would not perform the requirement even if they could and wanted to.

- Require that each GP contractor adjust the minimum number of appointments they accept from direct bookings by NHS 111 or a service accessed via NHS 111.
- Vary core hours for GP contractors to include Good Friday and bank holidays, for an area and period specified in an announcement, in order to assist in the management of the serious risk or potentially serious risk to human health.
- Require from each dispensing contractor (pharmacies and dispensing doctors), as part of their dispensing services, that they provide a home delivery option to eligible patients.
- Vary core and supplementary opening hours for the community pharmacies that have statutory terms of service, for a period specified in an announcement, in order to assist in the management of the serious risk or potentially serious risk to human health.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 These Regulations breach the convention that a Statutory Instrument should not come into force until 21 days have elapsed after it has been laid before Parliament. They will come into force the day after the day on which they are laid. The reason for this is that the Regulations are a mitigation to help primary care focus immediately on the Covid-19 pandemic, by enabling NHS E&I, with the agreement of Secretary of State for Health and Social Care, to stop certain services and prioritise delivery of other more essential services. This instrument will also enable pharmacies and dispensing doctors to begin immediately to make arrangements for the delivery of medicines to eligible patients who have been advised to stay away from pharmacy and dispensing premises. They will also enable NHS E&I, with the agreement of the Secretary of State, to require GP practices to work on Good Friday and Easter bank holiday Monday, if need be.

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 the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders 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.
- 4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

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

6. Legislative Context

- 6.1 Primary care services in England – the NHS services provided by GPs, dentists, opticians, pharmacists and dispensing appliance contractors – are provided under arrangements made with NHS E&I under Parts 4 to 7 of the National Health Service Act 2006. As regards the core NHS services that each of these groups of providers provide, the majority do so under contractual arrangements where the terms relating to core service provision are set out in Regulations – or (in the case of most community pharmacies and of dispensing appliance contractors) on the basis of statutory terms of service set out in Regulations. Those statutory arrangements function in a similar way to contractual arrangements, and so generally, all these groups of primary care providers are referred to as contractors.
- 6.2 These Regulations do not apply to opticians but otherwise apply to all types of provider of primary care. Some GPs provide core services under contracts provided for in Directions rather than the GMS Contracts Regulations or the PMS Agreements Regulations. The Department’s intention is to amend the relevant Directions in parallel with the amendments being made by these Regulations.

7. Policy background

What is being done and why?

- 7.1 As a consequence of a disease being or in anticipation of a disease being imminently pandemic and a serious risk or potentially a serious risk to human health, such as Covid 19, NHS E&I may need to ask primary care contractors to prioritise delivery of particular NHS services. The new powers will enable NHS E&I with the agreement of Secretary of State for Health and Social Care, to suspend enforcement of particular terms of service, or temporarily remove particular terms of service, in the manner described in paragraph 2.2 above.
- 7.2 Both powers can be limited geographically to particular areas of England, or applied across England, but must be used in a way that is time limited.
- 7.3 The triggers for using both powers are:
- a disease (not necessarily Covid-19) must be or must be about to become a pandemic;
 - that disease must represent a serious or potential serious risk to human health (the first two conditions are based on reg.226 of the Human Medicines Regulations 2012);
 - NHS E&I must, with the agreement of the Secretary of State for Health and Social Care, make an announcement in respect of the prioritisation of the services to be provided as part of the NHS;
 - that prioritisation must be in order to assist in the management of the serious risk or potentially serious risk to human health; and
 - as part of that announcement NHS E&I must, with the agreement of the Secretary of State for Health and Social Care, say which terms of service contractors won’t be enforced, or are not to be complied with, for the specified period.
- 7.4 These measures are part of a suite of measures being enacted to deal with the Covid 19 outbreak. They are expressed in terms that would enable them to deal with other

pandemics so that they could help DHSC to deal with other similar outbreaks in the future. The experience of dealing with the Covid 19 outbreak has already shown that NHS service prioritisation is an essential part of the emergency response, so that the NHS can focus on Covid 19 patients.

- 7.5 In the present circumstances, NHS E&I may need to ask GP contractors to change their core opening hours to include Good Friday and bank holidays, in order to assist in the management of the Covid 19 outbreak. This change is being made to address the particular potential need for additional GP services in April 2020. However, the change would also allow the powers to be used later in a similar emergency.
- 7.6 Covid 19 patients are generally being triaged via the NHS 111 service. In the sort of pandemic situation that we already find ourselves in, NHS E&I may need to ask GP practices to accept more directly booked appointments from NHS 111, or a service linked to NHS 111 on behalf of patients who have been through NHS 111 triage. This is a practical measure designed to support this fast developing triaging service.
- 7.7 In order to deal with the Covid 19 pandemic, although the change could potentially be used in a later pandemic, we will be able to require from each dispensing contractor (pharmacies and dispensing doctors, who are a sub-category of GP practice that provides dispensing services to at least some of their patients) as part of their essential services, that they must ensure that a home delivery option is in place for delivery of prescription items to eligible patients. Generally, this will require adhering to the following hierarchy:
- using the home delivery option that the eligible patient themselves has put in place (for example, a relative, neighbour, or volunteer collecting the prescription).
 - the pharmacy delivering the items itself;
 - the pharmacy finding another pharmacy who will deliver it, the first pharmacy having dispensed it; or
 - the pharmacy sending the prescription form to another pharmacy, that does do deliveries, for them to dispense and deliver the item.
- 7.8 Dispensing doctors may also be asked provide home delivery services, using a similar approach. In the case of pharmacies, there is likely to be directions under section 127 of the National Health Service Act 2006 providing more detail about the actual delivery arrangements.
- 7.9 Home delivery will support the “shielding” strategy that is key to limiting the spread of Covid 19.
- 7.10 As another part of the current emergency response, but potentially available in the event of any pandemic, NHS E&I with the agreement of Secretary of State for Health and Social Care, will be able to vary core and supplementary opening hours for community pharmacies on statutory terms of service for a period specified in an announcement. This would enable NHS E&I to arrange, for example, for a pharmacy to close for a certain amount of time to the public so that it could focus on dispensing, and another pharmacy to be open for longer to deal with the reduced capacity in the locality.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 The GMS Contracts Regulations and the PMS Agreements Regulations were consolidated in December 2015. The Department does not consider that there is a current need to further consolidate these Regulations.

9.2 The consolidation of the GDS and PDS regulations will be considered as part of any further work to develop a new NHS dental contractual system.

9.3 There are no plans to consolidate the PLPS Regulations.

10. Consultation outcome

Amendments to the GMS Contracts and PMS Agreements Regulations

10.1 Customarily the Department and NHS E&I would seek views of the British Medical Association's General Practitioners Committee on changes to the GMS Contracts and PMS Agreements Regulations. The Department and NHS E&I has been able to discuss the policy changes and draft regulations with these bodies and has responded to their comments, making changes to the Regulations where appropriate.

Amendments to the PLPS Regulations

10.2 Customarily, the Department seeks the views of the Pharmaceutical Services Negotiating Committee (PSNC), the BMA and the Dispensing Doctors' Association (DDA) on changes to the PLPS Regulations. The Department has been able to discuss the policy changes and draft Regulations, and responded to their comments, making changes to the Regulations where appropriate.

Amendments to the GDS Contracts and PDS Agreement Regulations

10.3 There have been also discussions with the British Dental Association on the proposed changes to the GDS Contracts and PDS Agreements Regulations, and changes made to the package, as appropriate, in the light of those discussions.

11. Guidance

Amendments to the GMS Contracts and PMS Agreements Regulations

11.1 NHS E&I has issued guidance, and will issue further guidance, on what services and they would like GP contractors to cease to undertake in order to focus on the response to a pandemic.

Amendments to the PLPS Regulations

11.2 NHS E&I will issue guidance on what services and in what order they would like pharmacy contractors to cease to undertake in order to focus on the response to a pandemic.

11.3 If there are separate directions as mentioned in paragraph 7.8 above, then NHS E&I will issue a service specification outlining what is required of the contractors in respect of the service.

Amendments to the GDS Contracts and PDS Agreement Regulations

- 11.4 NHSE & I will issue guidance on what services they would like NHS dental contractors to cease to undertake, in order to focus on the response to a pandemic.

12. Impact

- 12.1 A high-level Impact Assessment was conducted, setting out the rationale for intervention and describing the main impact of the proposed legislation in comparison to taking no action. Since it is not possible to say which service or statutory duties will be deprioritised or what services or interventions put in their place the impacts of the proposed legislation have not been formally quantified.
- 12.2 The proposed legislation is aimed at giving the NHS the flexibility to divert resources away from relatively less urgent uses so that they can be redeployed to more effective management of the Covid-19 outbreak. Decisions about what services or duties to deprioritise will be made on the basis of those in which any adverse impact in the short term is minimised and redeployed to uses in which the management of the Covid 19 pandemic is maximised. It is therefore assumed that the health benefit to patients of prioritised services will significantly outweigh the health cost to patients of deprioritised services. To mitigate against the risk that such decisions do not produce the intended net gain in effectiveness, decisions will be kept under regular review and reassessment. The high-level Impact Assessment describes how this legislation will enable more effective prioritisation of resources, transparency and certainty for the system about the lawfulness of national, local, and individual (contractor) decisions.
- 12.3 There is no, or no significant, impact on business, charities or voluntary bodies specifically as a consequence of these measures, which are enabling, but they take effect in the context of the general impact of the Covid 19 pandemic on primary care contractors, the impact of which at this stage is impossible to quantify.
- 12.4 There is no, or no significant, impact on the public sector specifically as a consequence of these measures, which are enabling, but they take effect in the context of the general impact of the Covid 19 pandemic on NHS commissioners, the impact of which at this stage is impossible to quantify. In reprioritising their resources, service providers may incur some set-up and transitional costs though we expect these to be relatively low.
- 12.5 The Impact Assessment has not been published alongside this instrument because of the enabling nature of the measures and given the urgency with which it they have had to be prepared. However, before any of these powers will be used, if the circumstances so permit, we will discuss doing so with the representative bodies of the affected contractors.

13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

- 14.1 The Department monitors the implementation and efficient operation of all the Regulations amended by this instrument, and in the case of the changes to the PMS Agreements, GMS Contracts, PLPS Regulations and the GDS Contracts and PDS

Agreement Regulations, has regular discussions with interested parties including the NHS and contractors' representatives on any problems identified.

15. Contact

- 15.1 Christie Silk at the Department of Health and Social Care. Telephone: 020 7210 6082 or email: Christie.Silk@dhsc.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Ed Scully, Deputy Director for Primary Care, at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 The Secretary of State for Health and Social Care, Matt Hancock at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.