

## EXPLANATORY MEMORANDUM TO

### THE NATIONAL HEALTH SERVICE (CORONAVIRUS) (CHARGES AND FURTHER AMENDMENTS RELATING TO THE PROVISION OF PRIMARY CARE SERVICES DURING A PANDEMIC ETC.) REGULATIONS

2020 No. 885

#### 1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

#### 2. Purpose of the instrument

- 2.1 This instrument makes pandemic-related changes to some of the Regulations that set the regulatory framework for primary care in England, and to the Regulations that provide for prescription charging in England in a range of care settings.
- 2.2 The amendments relating to prescription charging, the provision of primary dental services and the provision of primary ophthalmic services are essentially to deal with the filling in and signing of forms, and allow for revised arrangements that, in practice, should help to reduce cross-infection risks.
- 2.3 The amendments relating to pharmaceutical services are to delay the production of pharmaceutical needs assessments by Health and Wellbeing Boards of local authorities, and to allow new pharmacy and appliance contractor premises, that are, or have been, in the pipeline, a longer period in which to open.

#### 3. Matters of special interest to Parliament

##### *Matters of special interest to the Joint Committee on Statutory Instruments*

- 3.1 None.

##### *Other matters of interest to the House of Commons*

- 3.2 As the instrument is subject to the negative resolution procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

#### 4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is only to England.
- 4.2 The territorial application of this instrument is only to 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 National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570, as amended) (“the Prescription Charges Regulations”) provide for charges to be levied and recovered in England for the supply of certain drugs, appliances, wigs and fabric supports, and provide for certain exemptions from charging in prescribed

circumstances. Some of those exemptions require the production of exemption certificates.

- 6.2 The National Health Service (Dental Charges) Regulations 2005 (S.I. 2005/3477, as amended) (“the Dental Charges Regulations”) provide for charges to be levied and recovered in England for the provision of dental treatment, including urgent and orthodontic treatment, for the supply and replacement of dental appliances, for courses of treatment provided as part of primary dental services, and for exemptions from those charges. The standard contractual arrangements for the provision of primary dental services are set out in the National Health Service (General Dental Services Contracts) Regulations 2005 (S.I. 2005/3361, as amended) and the National Health Service (Personal Dental Services Agreements) Regulations 2005 (S.I. 2005/3373, as amended). Under the Dental Charges Regulations, a declaration of entitlement to an exemption has to be made – and evidence provided, where this is required, and under the standard contractual arrangements, contractors are required to ensure patients sign dental treatment plans.
- 6.3 The National Health Service (Optical Charges and Payments) Regulations 2013 (S.I. 2013/461, as amended), the Primary Ophthalmic Services Regulations 2008 (S.I. 2008/1186, as amended) and the General Ophthalmic Services Contracts Regulations 2008 (2008/1185, as amended) (together referred to as “the Ophthalmic Services Regulations”) provide the framework which govern the arrangements in England for the provision of primary ophthalmic services. These include free NHS sight tests, help with the cost of private sight tests, vouchers to help with the cost of optical appliances and repair and replacement of optical appliances. Patients are required to complete forms, sign declarations and provide evidence of eligibility in order to access these services.
- 6.4 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Pharmaceutical Services Regulations”) govern the arrangements in England, under Part 7 of the National Health Service Act 2006 for the provision of pharmaceutical and local pharmaceutical services. They include a pharmaceutical list system, which is a list of approved community pharmacies and dispensing appliance contractors who are entitled to dispense NHS prescriptions. Routine applications to join these lists are mostly assessed against a local plan known as a pharmaceutical needs assessment (“PNA”). Successful applicants to join these lists have only limited opportunity after the grant of their application to do so.

## 7. Policy background

### *What is being done and why?*

- 7.1 **Form filling and provision of evidence** – Under the Prescription Charges Regulations, the Dental Charges Regulations, the Regulations for the standard contractual arrangements for primary dental services and the Ophthalmic Services Regulations, there are various requirements relating to the filling in and signing of forms, alongside patients being asked to provide evidence to support exemption requirements – for example, showing pharmacists an exemption certificate to receive free prescriptions. In the case of filling in forms, it is common practice for pens to be lent to patients for this purpose, and both that sort of interaction, and the handling of the paperwork on which the present primary care system still largely relies, creates a potential cross infection risk both for patients and service provider staff. Although there have been some practical work-arounds, it is appropriate to place any revisions

to the statutory arrangements on a secure statutory footing rather than relying on this type of non-statutory decision-making.

- 7.2 **Pharmaceutical Needs Assessments (PNAs)** - The Pharmaceutical Services Regulations require Health and Wellbeing Boards of local authorities (HWBs) to publish PNAs every three years or sooner. PNAs were last published in 2018. This instrument amends the Pharmaceutical Services Regulations to suspend the publishing of revised PNAs, due by 1st April 2021, until no later than 1st April 2022. This instrument further requires any HWB that needs to publish its first PNA to do so by 1st April 2022. These measures will help reduce the immediate burden on HWBs, who are currently prioritising delivery to other urgent services during the COVID-19 pandemic, from undertaking a consultative process for a further 12 months. In the interim, HWBs may continue to issue updates to their PNA known as supplementary statements, where appropriate.
- 7.3 **Opening a community pharmacy premises.** The Pharmaceutical Services Regulations allow community pharmacy contractors and dispensing appliance contractors six months to open new premises following the successful grant of an application. Beyond this, a discretionary three-month further extension may also be granted. This instrument amends the Pharmaceutical Services Regulations to change the statutory time frame for opening. This is to mitigate against adverse effects on service providers who were due to open new premises but, because of the COVID-19 pandemic, have not been able to, or are unlikely to be able to do so, within the current statutory timeframe.
- 7.4 This instrument enables additional extensions within the following circumstances:
- I. Where a six-month opening period expires after this instrument comes into force, there would be an automatic extension to 12 months;
  - II. Where a three-month discretionary extension expires after this instrument comes into force, there would be an automatic extension so that it ends six months after this instrument comes into force; and
  - III. Where a three-month discretionary extension expired in the six months before this instrument came into force, once this instrument comes into force (but not before), the statutory time frame for opening is treated as not having ended and it is extended so that it ends six months after this instrument comes into force.
- 7.5 Scenario III ensures that businesses that have recently been prejudiced by the strict time limits in the Regulations will no longer be so, once this instrument comes into force, which will ensure that all businesses affected by this issue are treated equitably.
- 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 / trigger the statement requirements under the European Union (Withdrawal) Act
- 9. Consolidation**
- 9.1 There are no plans to consolidate the Regulations amended by this instrument in the near future, but this will be kept under review.

## **10. Consultation outcome**

- 10.1 The Department is not statutorily required to consult on any of the Regulations amended by this instrument and does not generally consult on changes to the Prescription Charges Regulations. It does generally consult the Pharmaceutical Services Negotiating Committee (PSNC) on changes to the Pharmaceutical Services Regulations and did so on this occasion. The PSNC agreed the proposals.
- 10.2 The Department also consulted with the British Dental Association, the Optical Confederation and NHS England and Improvement on the provisions relating to the suspension of signatures on dental and eye care forms. All welcomed and were content with the provisions.

## **11. Guidance**

- 11.1 The Department will issue guidance to the relevant health care professionals, covering the suspension of signatures on prescription, dental and eye care forms. The Department will request NHS England to provide notification via email bulletins for dissemination to NHS contractors.

## **12. Impact**

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies specifically from these measures but they take effect in the general context of the COVID-19 pandemic on primary care contractors, the impact of which at the moment is impossible to quantify. Generally, these measures should make life easier for patients and service providers – and as indicated above in paragraphs 7.1 and 7.2, they should potentially also ease the administrative burdens on the NHS Business Services Authority and HWBs.
- 12.2 There is, potentially, a small risk of increased fraud by contractors and/or patients where patient signatures are not collected to confirm payment or entitlement to exemption from charges. Whilst it is not, in the circumstances, possible to estimate the level of this potential increase, a 1% increase would equate to a loss of around £2.5m per annum (less over a shorter period). To mitigate against this risk the guidance will ask contractors to confirm patients' eligibility and annotate the forms on the patients' behalf. Patients will also continue to be asked to produce evidence of entitlement to services.
- 12.3 A proportionate Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the [legislation.gov.uk](https://www.legislation.gov.uk) website. It found that the net impact of the easements are small and likely to provide a net benefit to the UK in terms of managing its response to the pandemic; patient access to medicines, dentistry, ophthalmology services and wider pharmaceutical services; and ensuring businesses are not unfairly prevented from opening as a result of the pandemic.

## **13. Regulating small business**

- 13.1 The legislation applies to activities that are undertaken by small businesses, including firms employing up to 20 people. As these Regulations principally concern the provision of NHS primary care services in England on the basis of nationally determined terms of service, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed nation-wide standards and practice in the provision of such services as part of a nationally determined contractual framework.

13.2 This instrument places no new requirements on small businesses.

**14. Monitoring & review**

14.1 The changes will be in place for a period of time as specified above.

**15. Contact**

15.1 Jonathan Gill at the Department of Health and Social Care, telephone: 0113 254 6994 or email: [Jonathan.gill@dhsc.gov.uk](mailto:Jonathan.gill@dhsc.gov.uk), can be contacted with any queries regarding this instrument.

15.2 Elizabeth Woodeson, Director of Medicines and Pharmacy at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Matt Hancock, Secretary of State for the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.