

EXPLANATORY MEMORANDUM TO

**THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES,
CHARGES AND PRESCRIBING) (AMENDMENT) REGULATIONS 2018**

2018 No. 1114

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 amends the following sets of Regulations relating to the provision of community pharmaceutical services, primary medical services and NHS charges:

- 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 (Charges for Drugs and Appliances) Regulations 2015 (SI 2015/570, as amended) (the Charges Regulations) which provide for charges to be made and recovered for the supply of certain drugs, appliances, wigs and fabric supports, and provide for certain exemptions from charging in prescribed circumstances.
- 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.

2.2 The amendments will:

- Enable phase 4 of the Electronic Prescription Service (EPS) to be piloted and rolled out across England, which will allow for much greater flexibility in the dispensing of electronic prescriptions.
- Introduce real-time exemption checking (RTEC) to allow dispensing contractors to confirm eligibility for free prescriptions.
- Implement some of the recommendations from the Department's statutory post-implementation review of the PLPS regulations.
- Include paramedics in definition of a "prescriber" in the PLPS and Charges Regulations, and ensure that prescription forms written by paramedic independent prescribers can be dispensed and the dispensing contractor reimbursed for the dispensed items.
- Provide a statutory gateway for the sharing of prescription data between NHS contractors, commissioners and the NHS Business Services Authority (NHS BSA).

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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 Arrangements for the delivery of primary medical services in England (most commonly, the provision of General Practitioner (GP) services) and for the delivery of pharmaceutical services in England (at the core of which are dispensing services delivered most commonly by retail pharmacy businesses, known as pharmacy contractors, but also by dispensing doctors and dispensing appliance contractors) are governed in the main by three sets of Regulations:

- NHS pharmaceutical services in England are provided on the basis of four sets of standard arrangements which are set out in the PLPS Regulations; and
- The GMS Contracts Regulations and the PMS Agreements Regulations contain the mandatory contractual terms that must be contained in two of the three types of primary medical services agreements made between the NHS England (also known as the NHS Commissioning Board in legislation) and GPs (the third type of agreement is covered by statutory directions)

6.2 Section 1(4) of the National Health Service Act 2006 requires that NHS services provided in England must be provided for free of charge, except in so far as legislation expressly provides otherwise. One of the most important exceptions is prescription charging, and this is essentially what is covered in the Charges Regulations. Prescriptions in England that attract a charge are most commonly dispensed under the arrangements set out in the PLPS Regulations, but there are also other NHS settings where a prescription charge is payable and these are set out in the Charges Regulations.

6.3 Importantly, the Charges Regulations also include a number of exemptions from the requirements to pay a prescription charge. The exemption categories based on age are generally automatic (the patient's age being printed on the prescription form or being recorded in the EPS), but the other exemption categories require the patient to have a valid exemption certificate or a prepayment certificate, and for a declaration of entitlement to be made by or on behalf of the patient when the prescription is

collected. It is hoped that, over time, RTECs will allow much more of the prescription charge exemption process to be digitised.

7. Policy background

What is being done and why

A requirement in respect to the use of the Electronic Prescription Service

- 7.1 The EPS is the NHS IT system used in England as the means to generate, transmit and receive NHS electronic prescriptions in primary care. Patients are currently asked whether they are content for their prescription to be sent electronically and which dispensing contractor they want it sent to (known as nominating a pharmacy). Until now, patients who did not wish to nominate a pharmacy still had to receive paper prescriptions and would not be able to use EPS.
- 7.2 The proposed amendments introduce three important changes. Firstly, they will require all eligible prescriptions to be sent electronically where the new arrangements are in place, subject to limited exceptions. Secondly, patients will no longer have to nominate a dispensing contractor, although the option of nomination will remain available and encouraged. Currently when a prescription for a patient is transmitted via the EPS, the patient receives a paper “prescription” token which looks very similar to current FP10 paper prescriptions and includes both patient and product information. A key part of this change is that patients who want to use a nominated a dispensing contractor will no longer receive a paper token (although they are entitled to ask for and receive a written record of their prescription).
- 7.3 Thirdly, for a patient who has not nominated a dispensing contractor or who does not want to use their nominated dispensing contractor on a particular occasion, the prescriber will need to give the patient a token similar to that currently used. However, crucially this token (an “EPS token”) will now include a barcode to allow any dispensing contractor with the necessary access to the EPS (in the most common case, a community pharmacy) to retrieve the electronic prescription. Implementing these changes, initially as part of a pilot scheme, is expected to increase EPS utilisation and generate incremental efficiencies for the NHS.
- 7.4 For circumstances where EPS cannot be used, for example cross-border healthcare or if a GP practice is unable to use EPS because of technical or other difficulties, then patients will receive paper prescriptions. The proposed amendments will also allow for a paper prescription to be issued where the welfare of the patient is at risk and an exceptional request is made for a paper prescription; this will be on a per prescription basis based on the professional judgement of the prescriber.

Real Time Exemption Checking (RTEC) for prescription charges

- 7.5 RTEC will allow a pharmacist to confirm a patient’s eligibility for free NHS prescriptions. There is currently no technical solution for a dispenser to check a patient’s active prescription exemption status. Exemptions are not always declared correctly prior to medication being dispensed for a patient – this can be due to genuine patient error or deliberate fraud. Implementing RTEC would ensure prescription charge exemptions are applied correctly, thereby reducing prescription fraud in England, which currently stands at an estimated £256.1 million a year. It would also help to reduce genuine patient error. There are a number of potential benefits from RTEC:

- The NHS, as a whole, benefits from the reduced cost of prescription fraud due to a decrease in fraudulent prescription claims.
- In time, it will remove the burden and time taken to manage numerous exemption certificates within the care environment.
- It supports an initiative known as Paperless 2020 (through patients no longer needing to sign a paper declaration of entitlement if they are digitally shown to be exempt from prescription charges).
- Pharmacies will benefit from more efficient exemption status checks due to digitising the process.
- It should mean less confrontation between patients and dispensers thereby reducing stress to both groups.

7.6 While RTEC covers mainly back office functions, there are a number of potential benefits for patients specifically:

- Patients will benefit from fewer penalty charge notices caused by accidental/erroneous prescription charge exemption claims.
- Patients will benefit by not paying for prescriptions when they didn't realise they were exempt from charges. They could then be signposted to check the details of their actual exemption with the NHS BSA. This information may then prompt the individual to investigate other possible benefits to which they may be eligible e.g. Healthy Start vouchers, free school meals etc.
- A pharmacist will no longer know the reason for a patient's prescription charge exemption automatically, ensuring privacy, although the patient is free to share further information.
- It should mean less confrontation between patients and dispensers thereby reducing stress to the patient.

Recommendations from a Post Implementation Review of the PLPS Regulations

7.7 On 30th March 2018, the Department published a statutory review of the PLPS Regulations¹. Following consultation, evidence gathering and analysis, this review identified a number of potential unintended consequences. Four of the amendments set out within this instrument seek to address issues highlighted by the post-implementation review. These amendments are as follows:

- Regulation 69 is amended to clarify the requirements for local dispute resolution processes to be undertaken before a breach notice can be served by NHS England to contractors. This seeks to resolve an unintended consequence of the Regulations by requiring NHS England to make a reasonable effort to communicate with a contractor before serving a breach notice, if the suspected breach relates to a contractor's opening hours. It was not intended that action by NHS England should be automatic in these circumstances.
- Regulations 70 and 71 are amended to introduce a provision allowing NHS England to repeal breach or remedial notices. This seeks to address an unintended consequence of the Regulations whereby breach notices issued to contractors in error cannot be rescinded by NHS England. Outstanding breach

¹ <https://www.gov.uk/government/publications/nhs-pharmaceutical-and-local-pharmaceutical-services-regulations-2013-post-implementation-review>

and remedial notices can prevent contractors from gaining local services contracts.

- Schedule 3 Paragraph 8 is amended to resolve an unintended consequence of the Regulations, whereby interested parties were required to submit a formal request for attendance at oral hearings, even if they have previously made representations and would naturally be expected to attend.

Paramedic prescribers

- 7.8 The Human Medicine Regulations 2012 were amended with effect from 1st April 2018 to include paramedics as a profession which could train to become independent prescribers. Paramedics join other professions with independent prescribing responsibilities such as nurses, midwives, physiotherapists and pharmacists. These Regulations include paramedics in the definition of a “prescriber” in the PLPS and Charges Regulations, and ensure that prescription forms written by paramedic independent prescribers can be dispensed under the PLPS Regulations and the dispensing contractor appropriately reimbursed for the dispensed items.

Processing of prescription data

- 7.9 The amendments to the Charges Regulations provide a statutory gateway for the sharing of prescription data between NHS contractors, commissioners and the NHS BSA for three purposes:
- The invoicing and reimbursement/remuneration of contractors;
 - Post exemption checking and enforcement action to minimise fraud;
 - Limited management functions.
- 7.10 Providing statutory authority for this processing places existing arrangements on a secure statutory footing, within the terms of the Data Protection Act 2018, and the new statutory gateway will also ensure that staff processing prescription data have an appropriate confidentiality obligation.

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 Charges Regulations, similarly, were consolidated in 2015. There are also no plans to consolidate the PLPS Regulations.

10. Consultation outcome

Amendments to the GMS Contracts and PMS Agreements Regulations

- 10.1 There is no statutory requirement to consult on proposals to amend the GMS Contracts or PMS Agreements Regulations. However, the Department has referred a draft of the proposed amendments to the British Medical Association (BMA), who are the recognised representatives of GPs for these purposes. The Department also met

with the BMA and NHS Employers to discuss the policy and the detail of the draft Regulations, beginning discussions in May 2018. We have responded to the comments from the BMA and made appropriate changes to the Regulations.

Amendments to the PLPS and Charges 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 met with these bodies to discuss the policy changes and draft Regulations, and responded to their comments, making changes to the Regulations where appropriate. The Department has also sought the views of the Association of British HealthTech Industries (ABHI) in relation to changes relevant to Dispensing Appliance Contractors (DACs).

11. Guidance

Electronic Prescription Service

- 11.1 Once these Regulations are in place, NHS Digital will begin an initial stage of deployment, a first of type, to inform its approach to future national deployment. As part of this initial stage, it will assess:
- the operational impact on prescribing staff and dispensing staff,
 - the volume impact on systems – prescribing, dispensing, the NHS Spine & NHS BSA, and
 - the patient experience.
- 11.2 Sites will be selected for the first of type deployment based on the need to understand the full range of prescribing and dispensing scenarios. Guidance materials, including on communications, will be tested during this initial stage of deployment ahead of final guidance being produced to support national deployment.

Real Time Exemption Checking (RTEC) for prescription charges

- 11.3 Relevant guidance for the pilot will be developed by NHS Digital and the NHS BSA. Following the pilot, further guidance will be developed if a decision is taken to roll out RTEC across England and will consider any learning from the pilot stage.

Recommendations from a Post Implementation Review of the PLPS Regulations

- 11.4 These amendments introduce minor changes to the PLPS Regulations. Therefore, accompanying guidance is not considered necessary for implementation.

Paramedic prescribers

- 11.5 These amendments follow the earlier changes to Human Medicines Regulations 2012 (as set out in paragraph 7.8). NHS England publicised the amendments to the Human Medicines Regulations 2012 when they were made and is working with the professional bodies for paramedics and Health Education England to provide information about training and practice arrangements for paramedic prescribers.

Processing of prescription data

- 11.6 The new statutory gateway is primarily to support existing activities of the NHS BSA who have been involved in the development of these Regulations. Review of their existing processes will be a matter for the Authority to take forward.

12. Impact

- 12.1 An Impact Assessment has not been prepared for this instrument. The EPS amendments are enabling and facilitative in that, principally, they will remove restrictions around the use of electronic prescriptions. The other regulatory changes are also, essentially, enabling and facilitative, and do not create or impose significant costs on business, charities or voluntary bodies. There is also no significant impact on the public sector.
- 12.2 The generally beneficial nature of these instruments means that no adverse impacts are foreseen in the context of the discharge of the Secretary of State's Public Sector Equality Duty or his general duties under the National Health Service Act 2006. In particular, these changes will support the continuous improvement in the quality of NHS services, as mentioned in section 1A of the 2006 Act.

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.
- 13.3 As the GMS Contracts, PMS Agreements and PLPS Regulations concern the provision of NHS 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 practices in the provision of such services as part of the nationally determined contractual frameworks.
- 13.4 GP practices are exempt from the Small Firm Impact Test as they are considered part of the public sector due to their provision of primary medical services for the NHS. Public sector organisations are exempt from this test.

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 and PLPS Regulations, has regular discussions with interested parties including the NHS and contractors' representatives mentioned in paragraph 10.1 and 10.2 above on any problems identified.
- 14.2 Monitoring of GMS Contracts and PMS Agreements is the responsibility of the NHS England. However, the Secretary of State has responsibility for the terms of contracts contained in Regulations and for the consolidation of those Regulations.

15. Contact

- 15.1 Catherine Fiegehen at the Department of Health and Social Care Telephone: 020 7210 5992 or email: catherine.fiegehen@dh.gsi.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Jeannette Howe, Head of Pharmacy at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Steve Brine, Parliamentary Under Secretary of State for Public Health and Primary Care at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.