EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CHARGES FOR DRUGS AND APPLIANCES) (AMENDMENT) REGULATIONS 2024

2024 No. 456

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 His Majesty.

2. Declaration

- 2.1 The Rt Hon Andrea Leadsom MP, Parliamentary Under Secretary of State for Public Health, Start for Life and Primary Care at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 2.2 Gila Sacks of Medicines at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Carol Walker at the Department of Health and Social Care, telephone: 0113 2546384 or email: prescribingpolicy@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

- 4.1 The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570) ("the 2015 Regulations") 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. This instrument amends the 2015 Regulations to increase prescription and other charges payable under them.
- 4.2 This instrument also amends the 2015 Regulations to:
 - Allow medical and maternity exemption certificates to be revoked when issued in error or due to fraud.
 - Allow third party applications for a 3 and 12 month prescription prepayment certificate (PPC)
 - Remove the requirement for PPCs that have been refunded to be returned.
 - Remove the requirement to collect a patient signature when a prescription charge is paid, where the supply is made via a Patient Group Direction (PGD) or Treatment Protocol (TP).
- 4.3 This instrument will increase all charges by 2.59% subject to rounding to the nearest 5 pence which is convention. The detail of the changes in the prescription charge and the other amendments to the 2015 Regulations are set out at Section 5, below.

4.4 To support the implementation of the new Pharmacy First service this instrument will remove the requirement for a signature to be collected where a charge is generated and paid i.e. where the patient is not otherwise exempt.

Where does the legislation extend to, and apply?

- 4.5 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.
- 4.6 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England.

5. Policy Context

What is being done and why?

- 5.1 The 2015 Regulations provide the amount of the charge for an NHS prescription item and certain other appliances supplied by the NHS, the circumstances in which the charge must, or must not, be made and the patients who are exempt from prescription charges. The amendments to the 2015 Regulations made in this instrument increase all prescription charges; the single charge, PPCs, HRT PPC, wigs and fabric supports. The single prescription charge will increase by 25 pence, to £9.90. Wigs and fabric supports will also increase by 2.58% on average. Charges are made for wigs when supplied by hospitals or by other bodies through contracts. This instrument makes transitional provision in respect of an order for supply given before this instrument comes into force. The basic charge per item and the charges for PPCs are set out in Table 1.
- 5.2 Changes to the 2015 Regulations will also amend regulations to align with NHS Business Services Authority (BSA) processes which have been modernised to reflect digital developments, as follows:
 - 5.2.1 Allow medical and maternity exemption certificates to be revoked when issued in error or due to fraud. The NHS BSA have requested this change to enable them to cancel a certificate if fraudulent activity is detected. There is no provision for this under the current regulations, but administrative processes have been out of alignment with this expectation. This was identified following an audit of maternity and medical exemption certificates.
 - 5.2.2 Allow third party applications for a 3 or 12-month Prescription Prepayment Certificate (PPC). The Charges regulations currently only allow the applicant named on the certificate to apply for a 3 or 12-month PPC. In practice the NHS BSA has found that applications for PPCs are often made on behalf of a patient This change would require a new statutory gateway to ensure appropriate data protection arrangements are in place and would allow for a person other than the patient to apply and pay for a PPC, and would support, for example, applications made by the public sector on behalf of care leavers or asylum seekers/refugees; as well as applications made by carers.
 - 5.2.3 Remove the requirement for PPCs that have been refunded to be returned. This is not possible for the majority of PPCs because over 98% are now issued digitally. PPCs can be refunded when a patient becomes exempt from charge, and so would show as being exempt on the real time exemption checking (RTEC) system, used by a majority of pharmacies.
- 5.3 The changes proposed regarding the new Pharmacy First service are aimed mainly at supporting community pharmacy contractors to implement that service they are

supported by NHSE and Community Pharmacy England (CPE). The proposal will remove what would otherwise be an administrative burden. The removal of the requirement for the patient to sign a form where a prescription charge is paid by the patient for supply via PGD or TP will remove an administrative burden on community pharmacy contractors and also support Distance Selling Pharmacies (DSPs) to deliver the service. It will also affect patients positively, making the patient journey less confusing.

5.4 Furthermore, it will have cost, carbon and time saving benefits across the system – with less paper, less transportation, quicker processes and fewer forms to securely destroy, and helps align Pharmacy First with the paperless pharmacy agenda.

Table 1: Prescription, Prescription Prepayment Certificate, Fabric Support and Wigs Charges for 2023-24, and the new charges for 2024-25 with effect from 1 May 2024.

	2023-24 (£)	2024- 25 (£)	increase (£)
Single prescription charge	9.65	9.90	0.25
Prescription Prepayment Certificate (3 month)	31.25	32.05	0.80
Prescription Prepayment Certificate (12 month)	111.60	114.50	2.90
Hormone replacement therapy prescription			
prepayment certificate	19.30	19.80	0.50
Surgical bra	31.70	32.50	0.80
Abdominal or spinal support	47.80	49.05	1.25
Stock modacrylic wig	78.15	80.15	2.00
Partial human hair wig	207.00	212.35	5.35
Full bespoke human hair wig	302.70	310.55	7.85

- 5.5 Prescription prepayment certificates (PPCs) are available to everyone and can be purchased directly from most pharmacies, or the from the NHS BSA, by phone, online or by post. A 12-month PPC is available to purchase in ten monthly direct debit instalments. PPCs will save people money if they need four or more items in a three-month period, or 12 items or more in a year. Certificate holders pay no further charge at the point of dispensing. There is no limit to the number of items the holder may obtain using the certificate.
- 5.6 The HRT PPC was introduced on 1 April 2023 and allows people requiring listed HRT medication to save money on their HRT NHS prescription costs. The HRT PPC cost is twice the single charge and is valid for a period of 12 months. Since launch, over 500,000 people have obtained the HRT PPC to help them manage their HRT medicine costs.

What was the previous policy, how is this different?

- 5.7 The previous policy set the prices shown in Table 1, above.
- 5.8 The previous regulations did not allow medical and maternity exemption certificates to be revoked when issued in error or due to fraud; did not allow third party applications for a 3 or 12-month Prescription Prepayment Certificate (PPC); and required that PPCs that have been refunded had to be returned to NHS BSA.
- 5.9 Under current legislation a contractor should collect a signature every time a supply is made via a PGD or TP. These changes will remove the requirement to collect a signature where a charge is levied and collected. When the outcome of a new

Pharmacy First service consultation is the supply of a medicine, the legal vehicle supply for that supply is a PGD or TP. The same exemptions will apply as elsewhere and the removal of the requirement to collect the signature in this scenario will remove one administrative burden for contractors and simplify the care pathway for patients.

6. Legislative and Legal Context

How has the law changed?

- 6.1 The changes made by this instrument increase prescription charges, excluding the costs of the 3-month and 12-month Prescription Prepayment Certificates. The other changes are listed below:
- Allow medical and maternity exemption certificates to be revoked when issued in error or due to fraud. The NHS BSA have requested this change to enable them to cancel a certificate if fraudulent activity is detected. There is no provision for this under the current regulations, but administrative processes have been out of alignment with this expectation. This was identified following an audit of maternity and medical exemption certificates.
- 6.3 Allow third party applications for a 3 or 12-month Prescription Prepayment
 Certificate (PPC). The Charges regulations currently only allow the applicant named
 on the certificate to apply for a 3 or 12-month PPC. In practice the NHS BSA has
 found that applications for PPCs are often made on behalf of a patient. This change
 would require a new statutory gateway to ensure appropriate data protection
 arrangements are in place and would allow for a person other than the patient to apply
 and pay for a PPC, and would support, for example, applications made by the public
 sector on behalf of care leavers or asylum seekers/refugees; as well as applications
 made by carers.
- Remove the requirement for PPCs that have been refunded to be returned. This is not possible for the majority of PPCs because over 98% are now issued digitally. PPCs can be refunded when a patient becomes exempt from charge, and so would show as being exempt on the real time exemption checking (RTEC) system, used by a majority of pharmacies.
- Remove the requirement to collect a signature from the patient where a supply is made via PGD or TP and a prescription charge is collected from the patient. This will decrease the paperwork that has to be filled out if a supply is made in that way, it doesn't affect the duty to pay a prescription charge if you are required to.

Why was this approach taken to change the law?

6.6 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 DHSC is not required to consult on the 2015 Regulations.

8. Applicable Guidance

8.1 Pharmacies, relevant health care professionals and the public will be advised of the increase to charges for prescriptions, the HRT PPC, wigs and fabric supports by way of patient information leaflets, the Drug Tariff, the NHS website and the gov.uk

website. DHSC will request NHS England to provide notification via email bulletins for dissemination to staff. Notifications of the price revisions will be shared with health departments in Wales, Scotland and Northern Ireland to assist with cross border dispensed prescriptions.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

- 9.1 A full Impact Assessment has not been prepared for this instrument because of low impact on the public sector and this being an increase that takes place annually.
- 9.2 A full Impact Assessment has not been prepared for the other changes as they modernise regulations to reflect digitisation that has already taken place to improve the customer experience relating to medical, maternity and prescription prepayment certificates.
- 9.3 A full Impact Assessment has not been produced for the Pharmacy First amendments.

Impact on businesses, charities and voluntary bodies

- 9.4 There is no, or no significant, impact on business, charities or voluntary bodies because the prescription charge increase has a low impact on businesses, charities and voluntary bodies.
- 9.5 The legislation does impact small or micro businesses. As this instrument concerns 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.
- 9.6 This instrument places no new requirements on small businesses. In respect of charges levied it merely changes the amount the patient pays. The amendments on medical, maternity and prescription prepayment certificates will save pharmacies time as the changes align with digitisation of services.
- 9.7 Pharmacy First funding is additional funding (on top of global sum) for community pharmacies. These changes will have a positive impact on those pharmacy businesses (c95%) that opt into delivering the service by reducing the amount of administration required to deliver the service and therefore making it easier to generate extra income. Beyond those businesses the changes will have no, or no significant, impact on other business, charities or voluntary bodies as it relates only to a decrease in the amount of administration required to be undertaken by the community pharmacy when supplies are made via PGDs and TPs.
- 9.8 The impact on the public sector is minimal. To accommodate the increase to the prescription charges the NHS Business Services Authority will need to amend their systems to reflect the increased level of the charges. Hospitals and other bodies supplying wigs and fabric supports will need to revise arrangements to reflect the new charges.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

- 10.1 The approach to monitoring this legislation is the charges for drugs and appliances and other items supplied by the NHS under the 2015 Regulations are monitored by NHS England and DHSC and are reviewed annually. This is to consider what, if any, change in the amounts of such charges should be made.
- 10.2 A statutory review clause is included in the instrument.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

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

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").