

**EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (CHARGES FOR DRUGS AND
APPLIANCES) REGULATIONS 2015.**

2015 No. 570

1. This explanatory memorandum has been prepared by Department of Health and is laid before Parliament by Command of Her Majesty.
2. **Purpose of the instrument**
 - 2.1 These Regulations consolidate with amendments the National Health Service (Charges for Drugs and Appliances) Regulations 2000 (S.I. 2000/620) (“the 2000 Regulations”) and subsequent amendments to them.
 - 2.2 These Regulations provide for charges to be made and recovered for the supply as part of the National Health Service in England of certain drugs, appliances, wigs and fabric supports, and provides for certain exemptions from charging in prescribed circumstances.
 - 2.3 These Regulations increase prescription and other charges payable under them from the amounts that were specified in the 2000 Regulations. The charges for certain wigs and fabric supports are increased by approximately 1.6% and charges for drugs and other appliances by approximately 1.9%. However, the charges for pre-payment certificates are unchanged.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None.
4. **Legislative Context**
 - 4.1 The 2000 Regulations set out a scheme for charges for drugs, appliances and some other items supplied to NHS patients in England, and the arrangements for exemption from those charges in prescribed circumstances.
 - 4.2 The 2000 Regulations were made under provisions of the National Health Service Act 1977 (“the 1977 Act”), that subsequently were included, essentially, in Part 9 of the 2006 Act (“the 2006 Act”).
 - 4.3 Section 1(4) of the 2006 Act provides that services that are provided as part of the NHS must be provided free of charge, except in so far as the making and recovery of charges is expressly provided for in legislation. Part 9 of the 2006 Act provides for the overarching framework for the charges that are to be levied under the 2006 Act, including the charges to be levied in respect of drugs, appliances and similar items supplied as part of the NHS. These Regulations are the Regulations that include those charges.

4.4 There are different legislative arrangements for charging for NHS dental services, for providing free NHS sight tests and for making NHS payments towards ophthalmic appliances – and special additional charging arrangements for overseas visitors in other Regulations.

5. Territorial Extent and Application

5.1 These Regulations apply to England only.

6. European Convention on Human Rights

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

7. Policy background

7.1 This instrument consolidates with amendments the 2000 Regulations and subsequent amendments to them. As part of the consolidation exercise, some changes have been made to clarify the drafting and intention of the provisions, and to produce greater consistency in the wording of the provisions. Also, generally, amendments have been made to clarify the relationship between the exemptions that are provided for by virtue of section 173 of the 2006 Act and those that are created in the Regulations.

7.2 Prescription Charges: These Regulations set out the amount of the charge for an NHS prescription item and certain other appliances supplied by the NHS, the circumstances in which a charge must, or must not, be made and the patients who are exempt from prescription charges are set out in these Regulations. The changes made in these Regulations to the amounts specified in the 2000 Regulations increase the current single prescription charge in respect of drugs and appliances by 15p, an increase of 1.9%. This increase produces an overall increase in prescription charge revenue of 1.46%. This decision balances the importance of maintaining the contribution charges make to NHS funding with the need to constrain the impact of charges on personal incomes. The charge for elastic hosiery will increase in line with the prescription charge.

7.3 Prescription pre-payment certificates: These are available to everyone and three month certificates can be purchased directly from some pharmacists. Three and twelve month certificates can be purchased from the NHS Business Services Authority by phone, online or by post. A twelve month prescription pre-payment certificate can be purchased by ten direct debit instalments. They will save people money if they need four prescription items or more in a three month period, or 13 items or more in a year. Prescription prepayment 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. As indicated above, the fee payable for these certificates is being frozen to support those with long term conditions. An amendment is also made to clarify that pre-payment certificates do not cover wigs and fabric supports.

The basic charge per item and the charges for pre-payment certificates are in table 1 below.

7.4 Wigs and fabric supports: Charges are made for these items supplied by hospitals or by other bodies through contracts. Charges for these items will be increased by around 1.6%, balancing the need to protect NHS funding with the impact of charges on personal incomes. The current and new charges are in table 2 below. These Regulations make transitional provision in respect of an order given for supply given before the Regulations come into force.

Table 1: Prescription charges

	2014/15	2015/16	Increase
Single Charge per item	£8.05	£8.20	£0.15
3-month prescription pre-payment certificate	£29.10	£29.10	£0.00
12-month prescription pre-payment certificate	£104.00	£104.00	£0.00

Table 2: Wigs and fabric supports

	2014/15	2015/16	Increase
Surgical brassiere	£27.05	£27.45	£0.45
Abdominal or spinal support	£40.85	£41.50	£0.65
Stock modacrylic wig	£66.70	£67.75	£1.05
Partial human hair wig	£176.65	£179.45	£2.80
Full bespoke human hair wig	£258.35	£262.45	£4.10

7.5 Exemption for Medicines to Treat a Sexually Transmitted Disease: The Regulations address an problem with the alignment between the primary legislation and the secondary legislation regarding the exemption for treatment for sexually transmissible diseases (STDs).

The 1977 Act provided an exemption from charges for the supply of medicines to treat STDs in all care settings. The 2006 Act introduced a proviso, which allows for regulations to be made that would allow for charges for drugs for STD treatments in primary care settings if the supply is in the provision for primary medical services or in accordance with local pharmaceutical services contracts. However, the wording of the proviso, in practice, only has limited effect.

However, the 2000 Regulations did not reflect the position in primary legislation which meant charges were levied that should not have been. Rather than make a special case for supply under local pharmaceutical services contracts – which currently, in practice, include the only dispensing arrangements that could be affected by regulations under the proviso but which are relatively small in number – regulation 10(2) of these Regulations now provides a general exemption from charging for any drugs for the treatment of sexually transmitted disease.

7.6 Exemption from charges for medicines where there are risks to public health: This instrument combines two previously separate provisions for the exemption from charges for the supply of medicines during a public health emergency. As before, the provision can only be triggered by the Secretary of State making arrangements, or approving an NHS Body to make arrangements, to supply medicines free of charge. The arrangements would specify (a) which patients, (b) which medicines and (c) the route of supply.

For the purposes of future-proofing this provision, reference to brand names, specifically Relenza and Tamiflu, that were in the 2000 Regulations have been removed. The changes will allow for use of new antivirals which may come on to the market and may be required. The provision will continue to provide the flexibility to respond appropriately to treat any condition that may arise in the event of an emergency that threatens, is causing or has caused serious damage to public health.

8 Consolidation outcome

8.1 These regulations consolidate the 2000 Regulations and subsequent amendments.

Consultation outcome

8.2 The Department of Health is not required to consult on these Regulations.

9. Guidance

9.1 Relevant health care professionals and the public will be advised of the increase to charges for, prescriptions, wigs and fabric supports, by way of a patient information leaflet, the Drug Tariff, the NHS Choices website, and the gov.uk website. The Department will request the NHS Commissioning Board to provide notification via email bulletins for dissemination to staff.

9.2 Operational arrangements to ensure medicines to treat a sexually transmitted disease are supplied free through an NHS prescription form will be communicated to patients and health care professionals through the above routes in due course. Specific guidance will be provided to health care professionals and service commissioners.

10. Impact

10.1 An Impact Assessment has not been prepared for these Regulations. No impact on business, charities or voluntary bodies is foreseen. There is minimal cost to the public sector. The National Health Service Business Services Authority will need to amend their systems to reflect the increased level of the charges provided for in the Regulations and to accommodate supply through an NHS prescription form for medicines to treat sexually transmitted disease.

11. Regulating small business

11.1 NHS charges for drugs, appliances and other items do all impact upon arrangements for the remuneration of NHS services provided by small businesses that are not part of the public sector, including firms employing up to 20 people. However, these charges relate to aspects of the remuneration of NHS service providers that it would not be practical or appropriate to vary for companies of different sizes. This is to ensure the application of agreed nationwide NHS terms of service, where this is in the interests of both contractors and patients. Accordingly, the arrangements set out in these Regulations are exempt from the Small Firm Impact Test.

12. Monitoring & review

12.1 The charges imposed by these Regulations are reviewed annually, to consider what, if any, change in the amounts of such charges should be made.

13. Contact

13.1 Eleanor Shenton at the Department of Health Tel: 02079722923 or email: eleanor.shenton@dh.gsi.gov.uk can answer any queries regarding the instrument.