Contract and IT

June 2018

PSNC Briefing 034/18: Information and disclosure regulations

The Health Service Products (Provision and Disclosure of Information) Regulations 2018 (the Regulations) come into force on 1 July 2018 and give the Department of Health and Social Care (DHSC) greater powers to request information about the prices and costs associated with the distribution and supply of medicines and other products for the NHS in England.

The Regulations apply to those involved in the medicines supply chain for the NHS; this briefing is directed at NHS community pharmacy contractors in England (contractors) but also includes brief details on the requirements relating to wholesalers, as some community pharmacies have wholesale dealer's licences.

Contractors will be affected in two main ways:

1. Keep, record and provide information on price and volume

Contractors must record and keep relevant information on the price and volume of medicines, appliances and borderline substances dispensed for the NHS and provide this to the DHSC in response to a written request.

Smaller contractors (those with NHS pharmaceutical services remuneration of £5 million or less) will only be required to provide invoices or existing documents. For details on how to determine whether you are a small contractor, see later in this briefing.

Larger contractors must provide the requested information via the NHS Digital online gateway unless DHSC provide an electronic spreadsheet for this purpose.

The DHSC has indicated that its intention is to continue with the current Margin Survey.

The new regulations will provide a stronger legal basis for the Margin Survey and, therefore, any failure to provide the information requested (after DHSC has issued a compliance notice) may lead to a financial penalty.

Further information about contractors' responsibilities is in Appendix A.

2. Provide information on costs

Contractors must provide any relevant information on the costs of distributing or supplying a medicine or appliance associated with NHS dispensing, in response to an information notice from the DHSC.

The DHSC may not require any information which you could not reasonably be expected to keep and record for understanding your own costs.

The DHSC has indicated that such requests are likely to be infrequent but may be made where it has no 'visibility' over costs in the supply chain.

info@psnc.org.uk psnc.org.uk 0203 1220 810

Any failure to provide the information requested in response to an information notice may lead to a financial penalty.

Further information about contractors' responsibilities is in Appendix A.

Background to the Regulations

The Regulations are made under the Health Service Medical Supplies (Costs) Act 2017, which established a new framework for the DHSC to manage the costs of health service medicines, appliances and borderline substances, by obtaining comprehensive information about costs in the supply chain.

The statutory purposes for collecting such information in relation to community pharmacy, is to ensure that adequate health service medicines, appliances and borderline substances are available and that the terms on which they are available represent value for money (now section 264A (3) of the NHS Act 2006).

Smaller Contractors

In relation to Point 1 above (Record, keep and provide information on price and volume), smaller community pharmacy contractors may provide any information requested by the DHSC in the form of an invoice or other existing document.

A smaller community pharmacy contractor (referred to in the Regulations as a 'small UK producer') is one with:

- Total NHS remuneration in the last full year ending on 31 March of £5 million or less (this can be determined from your FP34 Schedule of Payments);

  And

- Either (a) does not have a wholesaler dealer's licence;

  Or (b) has a wholesaler dealer's licence and a net wholesale income of £5 million or less.

PSNC estimates that approximately 120 contractors will **not** be smaller contractors, based on the 2017/18 financial year ending on 31 March 2018.

The relevant provisions are contained within Part 4 of the Regulations, specifically regulation 24 and Schedule 2.

Enforcement

The DHSC may issue a compliance notice if a contractor does not provide the information requested in relation to Point 1 above (Keep, record and provide information on price and volume) following a written request.

You may have only 7 days to respond to a compliance notice in relation to Point 1, for example, the Margin Survey. Time starts on the working day the notice is given to you, or the first working day after it is given (see the glossary, annex C, for the meaning of working day).

The DHSC may demand a financial penalty in a compliance notice (the penalty is applied after the additional time you are given in the compliance notice to provide the information).

The DHSC may demand a financial penalty in relation to Point 2 (Provide information on costs), if information has not been provided in response to an information notice (the penalty is applied after the end of the time to comply given in the information notice).

Appeals

You may appeal any information notice or compliance notice, any requirement to pay a financial penalty or the amount of the financial penalty (collectively these are known as enforcement decisions).

Written requests for information, such as those used for the Margin Survey cannot be appealed.

The appeal procedure is determined by the Health Services Medicines (Price Control Appeals) Regulations 2000 https://www.legislation.gov.uk/uksi/2000/124/pdfs/uksi_20000124_en.pdf which sets out the procedure for appeals and includes sending a formal notice of appeal and additional material to the tribunal within 28 days of the enforcement decision.

Penalties

The financial penalties are calculated on a daily basis.

For smaller contractors the daily penalty is £250 on the day of the contravention and for each of the following 13 days that the contravention occurs; and after this £500 a day.

For other contractors, the financial penalty depends on turnover and is as follow:

Turnover	Financial Penalty
more than £5 million and less than £20 million	daily fine for the first 14 days is £500 and thereafter £1,000
more than £20 million and less than £50 million	daily fine for the first 14 days is £1,000 and thereafter £2,000
more than £5o million and less than £100 million	daily fine for the first 14 days is £2,500 and thereafter £5,000
more than £100 million	daily fine for the first 14 days is £5,000 and thereafter £10,000

Regulations

The Regulations – the Health Service Products (Provision and Disclosure of Information) Regulations 2018 – are available https://www.legislation.gov.uk/ by entering the year '2018' and the number of the Regulations '677'.

If you have queries on this PSNC Briefing, or you require more information, please contact Gordon Hockey, Director of Operations and Support.

Appendix A

1. Record, keep and provide information on price and volume

Contractors will be used to keeping records for products they dispense, and many will have previously submitted this type of information as part of the Margin Survey.

For medicines, appliances and borderline substances contractors dispense for the NHS they must:

Record and keep for 4 years:

- the purchase invoice;
- the name of the person from whom they were purchased (e.g. the wholesaler);
- the quantity by pack size purchased;
- a statement of any discounts, payments, payments or benefits in kind given in connection with the purchase that are not included in the invoice;
- the terms on which any discounts etc. were given;
- *For appliances, food and dermatological products only*, the name of the person to whom those discounts, etc. were given if that was not you; and
- the net purchase amount or a reasonable estimate of the net purchase amount paid for the purchase.

The relevant provisions are contained within Part 4 of the Regulations, specifically regulation 19 and 22.

The DHSC may make a written request for any of the retained information, which you must provide within 28 days of the day on which you are given the request.

If you are a smaller contractor, you may provide the DHSC with existing invoices and documents. Other contractors must provide the requested information via the NHS Digital online gateway unless DHSC provide an electronic spreadsheet for this purpose.

The relevant provisions are contained within Part 4 of the Regulations, specifically regulations 23 and 24.

If a reasonable estimate of the purchase price is used the DHSC may also request ….

(a) the reasons for which the producer [i.e. the pharmacy contractor] provided the original information in the form, or on the basis, of a reasonable estimate, rather than an actual amount, and

(b) the method used by the producer to calculate the reasonable estimate.

…. which must be provided within 7 days of the day on which you are given the request. (Explanations of reasonable estimates also apply to smaller contractors.)

The relevant provisions are contained within Part 7 regulation 30.

2. Provide information on costs

These provisions relate to any medicine or appliance contractors dispense for the NHS.

The DHSC must request the information by an 'information notice' which may be appealed.

Relevant costs include: '… *any costs (including, for example, manufacturing costs, supply costs, distribution costs, research costs, research and development cost, capital costs and business costs) other than costs which relate to any transaction between the producer and a UK producer for the relevant health service product*'.

The DHSC may also request in writing more general information about the manufacturing and distribution costs of medicines or appliances contractors dispense for the NHS.

The relevant provisions are contained within Part 4 of the Regulations, specifically regulations 25 and 26.

Appendix B

Wholesaling

Wholesalers – those with a wholesale dealers licence from the Medicines and Healthcare products Regulatory Agency (MHRA) – and others are subject to additional requirements under the Regulations.

Wholesalers and others are subject to quarterly reporting of relevant information about - unbranded generic, special and imported special - health service medicines (generally those listed in the Drug Tariff).

Quarterly reporting for unbranded generic medicines starts following the period 1 July to 30 September 2018 (and for the other two categories following the period 1 August 2018 to 31 October 2018).

Relevant information must be provided via the NHS digital online gateway unless the DHSC provide a spreadsheet to be completed. Wholesalers and others have 28 days to provide the information following the end of the period.

The four quarterly periods for unbranded generic health service medicines and the submission deadlines are:

Quarterly period	**Submission deadline**
1 July to 30 September	28 October
1 October to 31 December	28 January
1 January to 31 March	28 April
1 April to 30 June	28 July

The quarterly periods and submission deadlines for special and imported special health service medicines are different.

Wholesalers are also subject to provisions in the Regulations to provide relevant information relating to shortages of medicines, and similar requirements to provide information in relation to health service medicines to which community pharmacy contractors are subject and have been discussed already.

Wholesalers should seek more detailed information on the Regulations, particularly since there are transitional arrangements for members of 'Scheme W' and others.

Appendix C

Glossary

There are various words and phrases that have specific meanings in the Regulations, for example:

Discount means a trade or other discount (however named) and includes a settlement discount or a rebate.

UK health service medicine means, for the purposes of England means a health service product or other related product required for the purposes of the health service in England (S. 264A (14) of the NHS Act 2006).

Unbranded generic health service medicine means a health service medicine the labelling of which includes the common name of the product (usually the non-proprietary name); but does not include an invented name.

Net purchase amount means for any health service product, the amount paid, including any delivery or supply charge (however named) and after the deduction of any discounts or payments or the value of any payments or benefits in kind received in connection with the purchase.

Pharmaceutical services remuneration in relation to a community pharmacy contractor means remuneration for the provision of pharmaceutical or local pharmaceutical services provided under Part 7 of the NHS Act 2006.

Working day means a day that is not a Saturday, Sunday, Christmas day or Good Friday or a bank holiday (Easter Monday; the last Monday in May; the last Monday in August; 26th December, if it be not a Sunday; and 27th December in a year in which 25th or 26th December is a Sunday)

Net wholesale income means the total income excluding VAT and after deduction of all discounts and payments and the value of all payments and benefits in kind given in connection with the wholesale supplies.

info@psnc.org.uk psnc.org.uk 0203 1220 810