STATUTORY INSTRUMENTS

2016 No. 296

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2016

Made - - - - *3rd March 2016*

Laid before Parliament *10th March 2016*

Coming into force in accordance with regulation 1(1)

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 126, 129 and 272(7) and (8) of, and paragraph 3 of Schedule 12 to, the National Health Service Act 2006(**a**).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2016 and—

(a) apart from regulations 4(2) and 5(2), come into force on 1st April 2016;

(b) regulations 4(2) and 5(2) come into force on 1st July 2016.

(2) In these Regulations, "the principal Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**b**).

Amendment of regulation 75 of the principal Regulations

2.—(1) Regulation 75 of the principal Regulations (voluntary and automatic removal of listings: change of ownership, relocation, temporary provision and voluntary closure) is amended as follows.

(2) In paragraph (2)—

(a) in sub-paragraph (a), for "regulation 67(4)(b)" substitute "regulation 67(4)"; and

(b) in sub-paragraph (b)(ii), for regulation 67(4)(a)(ii), substitute "regulation 67(4)".

(**a**) 2006 c.41. Section 126 of the National Health Service Act 2006 ("the 2006 Act") has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63. Section 129 of the 2006 Act has been amended by: the Health Act 2009 (c. 21) ("the 2009 Act"), sections 26 and 27, and Schedule 6; the 2012 Act, section 207(1) to (9), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 121; and S.I. 2010/231. Paragraph 3 of Schedule 12 to the 2006 Act has been amended by: the 2009 Act, section 29(14) and (15); and the 2012 Act, Schedule 4, paragraph 93(4). By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England. *See also s*ection 275(1) of the 2006 Act, which contains definitions of "prescribed" and "regulations" that are relevant to the powers being exercised.

(**b**) S.I. 2013/349.

Substitution of regulation 121 of the principal Regulations

3. For regulation 121 of the principal Regulations (review of these Regulations) substitute the following—

"Review of these Regulations

121.—(1) The Secretary of State must, in accordance with paragraphs (2) to (4)—

(a) carry out reviews of these Regulations;

(b) set out the conclusions of each review in a report; and

(c) publish each report.

(2) Each report must in particular—

(a) set out the objectives intended to be achieved by these Regulations;

(b) assess the extent to which those objectives have been achieved;

(c) assess whether those objectives remain appropriate; and

(d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(3) The first report under this regulation must be published before the end of 31st August 2017.

(4) Each subsequent report must be published before the end of the period of five years beginning on the day on which the previous report was published.".

Amendment of Schedule 4 to the principal Regulations

4.—(1) Schedule 4 to the principal Regulations(**a**) (terms of service of NHS pharmacists) is amended as follows.

(2) In paragraph 7 (preliminary matters before providing ordered drugs or appliances), after sub-paragraph (3) insert the following sub-paragraph—

"(3A) In any case where no satisfactory evidence, as required by sub-paragraph (3), is produced to P, P must ensure before the drugs or appliances are provided that the person who was asked to produce that evidence is advised, in appropriate terms, that checks are routinely undertaken to ascertain entitlement to—

(a) exemption under the Charges Regulations(**b**); or

(b) remission of charges under the Remission of Charges Regulations(**c**),

where such entitlement has been claimed, as part of the arrangements for preventing or detecting fraud or error in relation to such claims.".

(3) After paragraph 29 (professional standards), insert the following paragraph—

"Accessing summary care records

29A.—(1) If an NHS pharmacist (P) is providing pharmaceutical services to or in respect of a patient and has access to the summary information that comprises a summary care record of that patient, P must access that summary information where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

(a) in P's clinical judgment it is in the best interests of the patient to do so; and

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(**a**) Relevant amendments have been made by S.I. 2015/570.
(**b**) These are the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570).
(**c**) These are the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003 (S.I. 2003/2382).

(b) in doing so P is acting in accordance with the guidance known as "The NHS Care Record Guarantee", published in the document entitled "The Care Record Guarantee – Our Guarantee for NHS Care Records in England" that was published by the National Information Governance Board for Health and Social Care in January 2011(**a**).

(3) In this paragraph, a "summary care record" and "summary information" mean a summary care record and summary information within the meanings given in—

(a) regulation 68 of the GMS Regulations(**b**) (summary care records); and

(b) regulation 61 of the PMS Regulations(**c**) (summary care records).".

Amendment of Schedule 7 to the principal Regulations

5.—(1) Schedule 7 to the principal Regulations(**d**) (mandatory terms for LPS schemes) is amended as follows.

(2) In paragraph 5 (preliminary matters before providing ordered drugs or appliances), after sub-paragraph (3) insert the following sub-paragraph—

"(3A) In any case where no satisfactory evidence, as required by sub-paragraph (3), is produced to C, C must ensure before the drugs or appliances are provided that the person who was asked to produce that evidence is advised, in appropriate terms, that checks are routinely undertaken to ascertain entitlement to—

(a) exemption under the Charges Regulations(**e**); or

(b) remission of charges under the Remission of Charges Regulations(**f**),

where such entitlement has been claimed, as part of the arrangements for preventing or detecting fraud or error in relation to such claims.".

(3) After paragraph 13 (professional standards), insert the following paragraph—

"Accessing summary care records

13A.—(1) If an LPS chemist (C) is providing local pharmaceutical services to or in respect of a patient and has access to the summary information that comprises a summary care record of that patient, C must access that summary information where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

(a) in C's clinical judgment or the clinical judgement of a registered pharmacy technician employed or engaged by C, it is in the best interests of the patient to do so; and

(b) in doing so C or the registered pharmacy technician is acting in accordance with the guidance known as "The NHS Care Record Guarantee", published in the document entitled "The Care Record Guarantee – Our Guarantee for NHS Care Records in England" that was published by the National Information Governance Board for Health and Social Care in January 2011(**g**).

(**a**) This guidance is available at http://systems.hscic.gov.uk/rasmartcards/strategy/nhscrg. Hard copies may be obtained by writing to the Department of Health, Wellington House, 133-155 Waterloo Road, London SE1 8UG. The National Information Governance Board for Health and Social Care is no longer in existence. Its role in monitoring and seeking to improve information governance practices was taken over by a National Information Governance Committee of the Care Quality Commission, which is at 151 Buckingham Palace Road, London SW1W 9SZ.

(**b**) These are the National Health Service (General Medical Services Contracts) Regulations 2015 (S.I. 2015/1862).

(**c**) These are the National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/1879).

(**d**) Relevant amendments have been made by S.I. 2015/570.

(**e**) These are the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570).

(**f**) These are the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003 (S.I. 2003/2382).

(**g**) This guidance is available at http://systems.hscic.gov.uk/rasmartcards/strategy/nhscrg. Hard copies may be obtained by writing to the Department of Health, Wellington House, 133-155 Waterloo Road, London SE1 8UG. The National Information Governance Board for Health and Social Care is no longer in existence. Its role in monitoring and seeking to

(3) In this paragraph, a "summary care record" and "summary information" mean a summary care record and summary information within the meanings given in—

(a) regulation 68 of the GMS Regulations(**a**) (summary care records); and

(b) regulation 61 of the PMS Regulations(**b**) (summary care records).".

Signed by authority of the Secretary of State for Health.

Alistair Burt
Minister of State,
Department of Health

3rd March 2016

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations"). The 2013 Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006, for the provision of pharmaceutical services and local pharmaceutical services.

Regulation 2 corrects two typographical errors in the 2013 Regulations.

Regulation 3 substitutes the review provision in the 2013 Regulations with a new provision that requires further reviews after the first review (which previously had been provided for), sets out in greater detail what the reports following each review are to include, and sets a five year maximum interval between reviews.

Regulations 4 and 5 amend the terms of service of chemists that provide NHS community pharmaceutical services.

Before providing a drug or appliance that has been ordered on an NHS prescription, if entitlement to non-payment of an NHS prescription charge is being claimed, the chemist must ask for evidence of that entitlement. If evidence is not supplied, the chemist is now required, before the drug or appliance is supplied, to advise the person who was asked to produce that evidence that checks are routinely undertaken to ascertain entitlement to non-payment of NHS prescription charges, where this is claimed, as part of the relevant arrangements for preventing or detecting fraud or error (regulations 4(2) and 5(2)).

Some chemists have access to NHS patients' summary care records, which are electronic records under the management of the Health and Social Care Information Centre. If chemists do have this access, they are required to access those records when they are providing NHS community pharmaceutical services, where it is in the best interests of a patient to do so and doing so accords with the guidance known as "The NHS Care Record Guarantee" (regulations 4(3) and 5(3)).

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improve information governance practices was taken over by a National Information Governance Committee of the Care Quality Commission, which is at 151 Buckingham Palace Road, London SW1W 9SZ.

(**a**) These are the National Health Service (General Medical Services Contracts) Regulations 2015 (S.I. 2015/1862).

(**b**) These are the National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/1879).

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