STATUTORY INSTRUMENTS

2024 No. 894

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) (No. 2) Regulations 2024

Made - - - - *2nd September 2024*

Laid before Parliament *3rd September 2024*

Coming into force in accordance with regulation 1(2) and (3)

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 126(2), 129(1)(a), (2)(b), (2C) and (6), 164(8A)(a), (8B)(b) and (8D) and 272(7) and (8) of, and paragraph 3(1) and (3)(c) and (d) of Schedule 12 to, the National Health Service Act 2006(**a**).

Citation, commencement, extent, application and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) (No. 2) Regulations 2024.

(2) These Regulations, apart from this regulation and regulations 2 and 3, come into force on 1st January 2025.

(3) This regulation and regulations 2 and 3 come into force on the twenty-eighth day after the day on which these Regulations are laid before Parliament.

(4) These Regulations extend to England and Wales and apply in relation to England only(**b**).

(5) In these Regulations, "the PLPS Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**c**).

(**a**) 2006 c. 41. Section 126 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; the Children and Social Work Act 2017 (c. 16), Schedule 5, paragraphs 30 and 47; and the Health and Care Act 2022 (c. 31) ("the 2022 Act"), Schedule 1, paragraph 1. Section 129(1)(a) has been amended by the 2022 Act, Schedule 1, paragraph 1. Section 129(2)(b) has been amended by the 2022 Act, Schedule 1, paragraph 1. Section 129(2C) was inserted by the Health Act 2009 (c. 21) ("the 2009 Act"), section 26(3), and amended by the 2012 Act, section 207(6), and the 2022 Act, Schedule 1, paragraph 1. Section 129(6) has been amended by: the 2009 Act, section 26(7) and 27, and Schedule 6; the 2012 Act, section 207(8)(a) to (c), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraphs 120 and 121; the 2022 Act, Schedule 1, paragraph 1; and S.I. 2010/231. In section 164, subsections (8A) to (8E) were inserted by the Health Service Medical Supplies (Costs) Act 2017 (c. 23), section 1, and subsections (8A) and (8D) were thereafter amended by the 2022 Act, section 161(1)(a) to (c). Paragraph 3 of Schedule 12 has been amended by: the 2009 Act, section 29(13) to (15); the 2012 Act, Schedule 4, paragraph 93(4); the Crime and Courts Act 2013 (c. 22), Schedule 9, paragraph 52(1)(b) and (2); and the 2022 Act, Schedule 1, paragraph 1. *See* section 275(1) of the National Health Service Act 2006 for the meanings given to "prescribed" and "regulations" which are relevant to the powers being exercised.

(**b**) *See* section 271(1) of the National Health Service Act 2006, by virtue of which the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England.

(**c**) S.I. 2013/349, as amended.

Amendment of regulation 91A of the PLPS Regulations

2.—(1) Regulation 91A of the PLPS Regulations(**a**) (zero or nominal product reimbursement for vaccines and antivirals) is amended as follows.

(2) In paragraph (2)—

(a) omit "or" at the end of sub-paragraph (ab); and

(b) after sub-paragraph (ab) insert—

"(ac) a drug or medicine which is used for vaccinating or immunising people against pertussis (whooping cough), if the conditions set out in paragraph (3) are satisfied; or".

(3) In paragraph (3A), for "to (ab)" substitute "to (ac)".

Amendment of Schedule 2 to the PLPS Regulations and transitional provisions

3.—(1) Schedule 2 to the PLPS Regulations (applications in respect of pharmaceutical lists and the procedures to be followed) is amended in accordance with paragraphs (2) and (3).

(2) In Part 1 (information to be included in routine and excepted applications), in paragraph 3 (fitness information about individuals: routine and excepted applications for inclusion in a pharmaceutical list)(**b**), omit sub-paragraph (8).

(3) In Part 4 (determination and deferral of applications), in paragraph 23 (additional matters for consideration in relation to applications for inclusion in a pharmaceutical list)(**c**), in sub-paragraph (1), omit paragraph (c).

(4) Where, before the day on which this regulation comes into force, it was necessary to include information in an application for inclusion in a pharmaceutical list by virtue of paragraph 3(8) of Schedule 2 to the PLPS Regulations—

(a) if that information was not provided before that day, or the obligation to provide that information was only partially discharged before that day, it is no longer necessary for the applicant to provide that information, or the rest of that information, pursuant to that paragraph 3(8); but

(b) if the applicant or a referee has provided or does provide information in the form of a reference or details of a referee either prior to or notwithstanding the revocation of paragraphs 3(8) and 23(1)(c) of Schedule 2 to the PLPS Regulations, NHS England may—

(i) have regard to that information for the purposes of its consideration of the application, and

(ii) request further information or documentation from the applicant pursuant to paragraph 11 of Schedule 2 to the PLPS Regulations(**d**) (relevant information or documentation), which it considers to be missing relevant information or documentation as a consequence of its consideration of that information.

Amendment of Schedule 4 to the PLPS Regulations

4. In Part 2 of Schedule 4 to the PLPS Regulations (terms of service of NHS pharmacists – essential services), in paragraph 8 (providing ordered drugs or appliances)(**e**), after sub-paragraph (2) insert—

"(2A) Subject to sub-paragraphs (2B) to (2E) and without prejudice to sub-paragraphs (10) and (11), for the purposes of sub-paragraph (1)(b), a drug is provided in accordance

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(**a**) Regulation 91A was inserted by S.I. 2022/930 and has been amended by S.I. 2024/838.
(**b**) Paragraph 3 has been amended by S.I. 2023/479 and 1071.
(**c**) The relevant amending instrument is S.I. 2023/1071.
(**d**) Amended by S.I. 2023/1071.
(**e**) Paragraph 8 has been amended by S.I. 2019/775 and 990, 2020/1126 and 2021/169 and 1346.

with the order on a prescription form or repeatable prescription if (in addition to where the provision is exactly in accordance with the order)—

(a) a different quantity is provided to that ordered on the prescription form or repeatable prescription in order to allow for the provision of the drug in its manufacturer's original outer packaging; and

(b) the provision is otherwise in accordance with the order.

(2B) In the case of an order for a prescription only medicine, sub-paragraph (2A) only applies if sub-paragraph (8) applies or one of the following applies—

(a) the provision is in accordance with regulation 217B(1) to (3) of the Human Medicines Regulations 2012(**a**) (original pack dispensing), and accordingly, regulation 217B(1) to (3) of those Regulations is expressly applied to such supplies; or

(b) the medicine must be provided in the manufacturer's original outer packaging in order to comply with regulation 217C of the Human Medicines Regulations 2012(**b**) (original pack dispensing: medicinal products containing a relevant substance).

(2C) In the case of an order for a drug that is not a prescription only medicine, sub-paragraph (2A) only applies if sub-paragraph (8) applies or the provision of a different quantity to that ordered on the prescription is in circumstances where—

(a) the different quantity is no more than 10% greater or no more than 10% less than the quantity ordered; and

(b) the registered pharmacist carrying out or directly supervising the provision does not consider, in the exercise of their professional skill and judgement, that the provision of a different quantity to that ordered may mean that the patient does not, or is not able to, follow the medication regimen as intended by the prescriber.

(2D) Where P may, pursuant to sub-paragraph (2A) and sub-paragraph (2B)(a) or (2C)(a) and (b), provide a different quantity of a drug to that ordered on a prescription form or a repeatable prescription, P must consider, in the exercise of their professional skill and judgement, whether it is reasonable and appropriate to do so, having regard to the benefits to patients where they are provided with drugs in their manufacturer's original outer packaging.

(2E) Sub-paragraphs (2B)(a) and (2C)(a) and (b) do not apply to the provision of any drug which is—

(a) for the time being specified in Schedules 2 to 4 of the Misuse of Drugs Regulations 2001(**c**) (which relate to controlled drugs excepted from certain provisions under the Regulations); or

(b) a special medicinal product for the purposes of regulation 167 of the Human Medicines Regulations 2012 (**d**)(supply to fulfil special patient needs).".

Amendment of Schedule 7 to the PLPS Regulations

5. In Schedule 7 to the PLPS Regulations (mandatory terms for LPS schemes), in paragraph 6 (providing ordered drugs or appliances)(**e**), after sub-paragraph (1) insert—

"(1A) Subject to sub-paragraphs (1B) to (1E) and without prejudice to sub-paragraphs (8) and (9), for the purposes of sub-paragraph (1)(b), a drug is provided in accordance with the order on a prescription form or repeatable prescription if (in addition to where the provision is exactly in accordance with the order)—

(**a**) Inserted by S.I. 2023/1015.
(**b**) Inserted by S.I. 2023/1015.
(**c**) S.I. 2001/3998, as amended.
(**d**) S.I. 2012/1916; amended by S.I. 2017/715 and 2019/775.
(**e**) Paragraph 6 has been amended by S.I. 2019/775 and 990 and 2021/1346.

(a) a different quantity is provided to that ordered on the prescription form or repeatable prescription in order to allow for the provision of the drug in its manufacturer's original outer packaging; and

(b) the provision is otherwise in accordance with the order.

(1B) In the case of an order for a prescription only medicine, sub-paragraph (1A) only applies if sub-paragraph (6) applies or one of the following applies—

(a) the provision is in accordance with regulation 217B(1) to (3) of the Human Medicines Regulations 2012(**a**) (original pack dispensing), and accordingly, regulation 217B(1) to (3) of those Regulations is expressly applied to such supplies; or

(b) the medicine must be provided in the manufacturer's original outer packaging in order to comply with regulation 217C of the Human Medicines Regulations 2012(**b**) (original pack dispensing: medicinal products containing a relevant substance).

(1C) In the case of an order for a drug that is not a prescription only medicine, sub-paragraph (1A) only applies if sub-paragraph (6) applies or the provision of a different quantity to that ordered on the prescription is in circumstances where—

(a) the different quantity is no more than 10% greater or no more than 10% less than the quantity ordered; and

(b) the registered pharmacist carrying out or directly supervising the provision does not consider, in the exercise of their professional skill and judgement, that the provision of a different quantity to that ordered may mean that the patient does not, or is not able to, follow the medication regimen as intended by the prescriber.

(1D) Where C may, pursuant to sub-paragraph (1A) and sub-paragraph (1B)(a) or (1C)(a) and (b), provide a different quantity of a drug to that ordered on a prescription form or a repeatable prescription, C must consider, in the exercise of their professional skill and judgement, whether it is reasonable and appropriate to do so, having regard to the benefits to patients where they are provided with drugs in their manufacturer's original outer packaging.

(1E) Sub-paragraphs (1B)(a) and (1C)(a) and (b) do not apply to the provision of any drug which is—

(a) for the time being specified in Schedules 2 to 4 of the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain provisions under the Regulations); or

(b) a special medicinal product for the purposes of regulation 167 of the Human Medicines Regulations 2012 (supply to fulfil special patient needs).".

Signed by authority of the Secretary of State for Health and Social Care

Stephen Kinnock
Minister of State
Department of Health and Social Care

2nd September 2024

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 PLPS Regulations"). The PLPS Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006 ("the 2006 Act"), for the provision of pharmaceutical and local pharmaceutical services.

(**a**) Inserted by S.I. 2023/1015.
(**b**) Inserted by S.I. 2023/1015.

The scheme for paying for NHS pharmaceutical and local pharmaceutical services is predicated on the basis that pharmaceutical remuneration that relates to prescription items will ordinarily include an amount which is in respect of (but ordinarily slightly more than) the price that a service provider paid when they purchased a prescription item that they go on to supply or administer. However, there are powers in Part 7 of the 2006 Act to enable alternatives to these ordinary remuneration arrangements in some circumstances. These Regulations amend the alternative arrangements that already allow a zero or nominal NHS reimbursement price to be set for centrally purchased coronavirus, respiratory syncytial virus and measles, mumps and rubella vaccines so that they also apply to centrally purchased pertussis (whooping cough) vaccines (regulation 2).

The PLPS Regulations include the terms of service on which community pharmacies that are on pharmaceutical lists held by NHS England, or that have local pharmaceutical services contacts with NHS England, provide NHS pharmaceutical services. Those terms of service are amended to allow a community pharmacy to provide a different quantity of a prescription item to that ordered on an NHS prescription, provided it is no more than 10% greater or less than the quantity ordered, subject to exceptions (regulations 4 and 5).

The applications process for inclusion on a pharmaceutical list of authorised providers – either as a community pharmacy or as a dispensing appliance contractor – is changed so that references no longer need to be provided in respect of specified pharmacists – and thereafter taken up and checked. There is a transitional provision for applications submitted before the new arrangements come into force, which amongst other matters allows NHS England to continue to have regard to references already received and to base requests for further information on such references (regulation 3).

An assessment of the effect of this instrument was undertaken and it was deemed that a full impact assessment would not be proportionate. These Regulations are not expected to have a significant impact on the public and voluntary sectors, and only a limited impact on the private sector, below the threshold for undertaking a full impact assessment.

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