STATUTORY INSTRUMENTS

2022 No. 930

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022

Made - - - -	*1st September 2022*
Laid before Parliament	*2nd September 2022*
Coming into force - -	*1st October 2022*

The Secretary of State for Health and Social Care, in exercise of the powers conferred by sections 126(2), 129, 130(1), 164(6), (8A)(a) and (c), (8B)(b) and (8D) and 272(7) and (8) of the National Health Service Act 2006(**1**), makes the following Regulations:

At the time these Regulations are made, the Secretary of State for Health and Social Care considers, for the purposes of section 164(8A)(c) of that Act, coronavirus to be a pandemic disease.

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2022.

(2) These Regulations come into force on 1st October 2022.

(3) These Regulations extend to England and Wales and apply in relation to England only.

Amendment of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

2. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**2**) are amended in accordance with regulations 3 to 8.

(**1**) 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, paragraph 30 and 47(j), and the Health and Care Act 2022 (c. 31) ("the 2022 Act"), Schedule 1, paragraph 1. Section 129 has been amended by: the Health Act 2009 (c. 21), 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, paragraphs 120 and 121; the 2022 Act, Schedule 1, paragraph 1: and S.I. 2010/231. Section 164 has been amended by: the Health and Social Care Act 2008 (c. 14), section 141(1) and Schedule 15, Part 4; the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 89(3); the Health Service Medical Supplies (Costs) Act 2017 (c. 23), section 1; and the 2022 Act, section 161(1), and 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.

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

Amendment of regulation 2

3. In regulation 2(**3**) (interpretation), in paragraph (1), at the appropriate place in the alphabetical order insert—

> ""coronavirus" has the meaning given in section 1(1) of the Coronavirus Act 2020(**4**) (meaning of "coronavirus" and related terminology);".

Amendment of regulation 10

4.—(1) In regulation 10(**5**) (pharmaceutical lists and EPS lists)—

(a) omit paragraphs (4) and (5); and

(b) in paragraph (6), omit "and any EPS lists".

(2) Omit "and EPS lists" from the heading of regulation 10.

New regulation 91A

5. After regulation 91 (remuneration of NHS chemists: instruments of appointment of NHS England) insert—

"**Zero or nominal product reimbursement for coronavirus vaccines and antivirals**

91A.—(1) In the case of the drugs or medicines to which paragraph (2) applies, determining authorities must ensure that determinations under section 164 of the 2006 Act(**6**) (remuneration of persons providing pharmaceutical services) in respect of pharmaceutical remuneration that relates to the supply or administration of those drugs or medicines either—

(a) do not provide for or permit any reimbursement to be paid for the cost of the drug or medicine (and so the basic price of the drug or medicine, for Drug Tariff purposes, is zero); or

(b) only provide for or permit nominal reimbursement to be paid for the cost of the drug or medicine.

(2) This paragraph applies to—

(a) a drug or medicine which is used for vaccinating or immunising people against coronavirus ("a coronavirus vaccine"), if the conditions set out in paragraph (3) are satisfied; or

(b) an antiviral drug or medicine which is used for preventing or treating coronavirus ("a coronavirus antiviral"), if the conditions set out in paragraph (4) are satisfied.

(3) The conditions set out in this paragraph are—

(a) the Secretary of State (references to whom in this regulation encompass both the Secretary of State for Health and Social Care and other Secretaries of State) has purchased coronavirus vaccines for supply as part of the health service;

(b) the Secretary of State has made arrangements for all or part of the Secretary of State's stock of coronavirus vaccines, purchased as mentioned in sub-

(**3**) Amended by S.I. 2015/137, 570, 1862 and 1879, 2016/696 and 1077, 2018/1114, 2019/593, 990 and 1094, 2020/351 and 1126, 2021/169 and 1346 and 2022/634.
(**4**) 2020 c. 7.
(**5**) Amended by S.I. 2016/1077.
(**6**) Section 164 of the National Health Service Act 2006 (c. 41) has been amended by: the Health and Social Care Act 2008 (c. 14), section 141(1) and Schedule 15, Part 4: the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 89(3); the Health Service Medical Supplies (Costs) Act 2017 (c. 23), section 1; and the Health and Care Act 2022 (c. 31), section 161(1), and Schedule 1, paragraph 1.

paragraph (a), to be supplied to NHS pharmacists and LPS chemists, whether directly or via an intermediary, at no cost to the NHS pharmacists or LPS chemists;

(c) NHS England has made arrangements for the administration of coronavirus vaccines from the stock mentioned in sub-paragraph (b) as part of an enhanced service; and

(d) the coronavirus vaccine in question is from that stock and administered as part of that service.

(4) The conditions set out in this paragraph are—

(a) the Secretary of State has purchased coronavirus antivirals of a particular type for supply as part of the health service;

(b) the Secretary of State has made arrangements for all or part of the Secretary of State's stock of that particular type of coronavirus antiviral, purchased as mentioned in sub-paragraph (a), to be supplied to NHS pharmacists and LPS chemists, whether directly or via an intermediary, at no cost to the NHS pharmacists or LPS chemists; and

(c) the coronavirus antiviral in question—

(i) is from that stock, or

(ii) is not from that stock but is nevertheless of the particular type of coronavirus antiviral that is available at no cost to NHS pharmacists and LPS chemists under the arrangements mentioned in sub-paragraph (b).

(5) For the purposes of paragraph (4), the Secretary of State may characterise the particular type of coronavirus antivirals that are available at no cost to NHS pharmacists and LPS chemists solely by reference to the presentation of the drug or medicine (as well as by reference to its active ingredient, strength or any, or a combination of any, other distinguishing characteristics).

(6) For the avoidance of doubt, determinations under section 164 of the 2006 Act that, in accordance with this regulation—

(a) do not provide for or permit reimbursement to be paid for the cost of a drug or medicine (and so the basic price of the drug or medicine, for Drug Tariff purposes, is zero); or

(b) only provide for or permit nominal reimbursement to be paid for the cost of a drug or medicine,

may nevertheless provide for or permit remuneration to be paid for any service provided by a NHS pharmacist or LPS chemist, in the course of which the drug or medicine is supplied or administered.

(7) In this regulation, "nominal reimbursement" means, in the case of a drug or medicine that has been provided at no cost to a NHS pharmacist or LPS chemist, payment of an amount that is paid in place of the amount that the NHS pharmacist or LPS chemist would ordinarily make from the difference between—

(a) the amount that they paid for the drug or medicine when they purchased it; and

(b) the amount that they are paid by NHS England in respect of the cost of that drug or medicine (most commonly the basic price listed in the Drug Tariff), if they supply or administer that drug or medicine under arrangements for the provision of pharmaceutical or local pharmaceutical services.".

Amendment of Schedule 2

6.—(1) Schedule 2 (applications in respect of pharmaceutical lists and the procedures to be followed) is amended as follows.

(2) In Part 1 (information to be included in routine and excepted applications), after paragraph 5 (fitness information that has already been provided under pharmaceutical or local pharmaceutical services) insert—

"**Updating of information about or relating to a superintendent**

5A.—(1) Where, in the case of a body corporate making an application for inclusion in a pharmaceutical list, there is a change to the superintendent of the body corporate before the applicant is included in a pharmaceutical list or the application cannot be further proceeded with, the applicant must update the application as soon as is reasonably practicable with—

(a) the details about that superintendent that the applicant would have been required to submit under paragraph 3; and

(b) the details about any other body corporate that the applicant would have been required to submit under paragraph 4 because of that superintendent being that other body corporate's superintendent,

had the superintendent been in post at the time the application was submitted.

(2) If—

(a) the application has been determined by NHS England but—

(i) there are proceedings relating to the application that have not yet reached their final outcome, or

(ii) in the case of an application that has been granted, there are no such proceedings but the applicant has not yet been included in a pharmaceutical list; and

(b) NHS England is satisfied, on the basis of the information provided or required to be provided under sub-paragraph (1), that there are grounds for refusing the application under regulation 33 or imposing a condition under regulation 35,

NHS England may redetermine the application, but only for the purpose of refusing it under regulation 33 or imposing a condition under regulation 35 (so there may still be a purpose to any proceedings that have not yet reached their final outcome).".

(3) In Part 3 (notification of certain applications), in paragraph 19(**7**) (notification procedure for notifiable applications), in sub-paragraph (4), after "given to them" insert ", or within 30 days in the case of applications pursuant to regulation 26A".

Amendment of Schedule 3

7. In Schedule 3 (appeals to the Secretary of State), in Part 3 (determination of appeals), in paragraph 7 (flexibility with regard to the manner or determining appeals), after sub-paragraph (3) insert—

"(4) Where an application for inclusion in a pharmaceutical list has been updated in accordance with paragraph 5A of Schedule 2, the Secretary of State may, on an application from NHS England, defer the Secretary of State's decision in relation to the application on any ground that NHS England could have relied on for deferring the application pursuant to regulation 34 until—

(**7**) To which there is an amendment not relevant to these Regulations.

(a) the reason for the deferral no longer exists; or

(b) the outcome of the cause of the deferral is known and NHS England has—

(i) decided, in the light of that outcome, whether or not to redetermine the application, and

(ii) redetermined the application, if it is to be redetermined.

(5) Where NHS England redetermines an application in accordance with paragraph 5A(2) of Schedule 2 and refuses it, the Secretary of State may direct that the proceedings relating to the appeal are to be brought to an end without a determination of the matter under paragraph 9.".

Amendment of Schedule 4

8.—(1) Schedule 4 (terms of service of NHS pharmacists) is amended as follows.

(2) In Part 3 (hours of opening), in paragraph 23 (pharmacy opening hours: general), in sub-paragraph (7)(b)—

(a) in sub-paragraph (ii), after "core opening hours)" insert ", if that change reduces the total number of any supplementary opening hours";

(b) in sub-paragraph (iii), after "supplementary opening hours" insert ", unless that change relates to an increase in the total number of supplementary opening hours"; and

(c) in the full-out words at the end, after "3 months" insert ", or 5 weeks in the case of changes pursuant to sub-paragraph (ii) or (iii), ".

(3) In Part 4 (other terms of service), in paragraph 28(**8**) (clinical governance and the promotion of healthy living), in sub-paragraph (2)—

(a) in paragraph (a), omit sub-paragraph (iv); and

(b) in paragraph (e), after sub-paragraph (iii) insert—

"(iiia) a requirement that P undertakes an approved workforce survey annually, in an approved manner,".

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

James Morris
Parliamentary Under Secretary of State
Department of Health and Social Care

1st September 2022

(**8**) Amended by S.I. 2015/528, 2016/1077, 2020/1126 and 2021/1346.

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 Act"), for the provision of pharmaceutical and local pharmaceutical services.

The scheme for paying for pharmaceutical and local pharmaceutical services in Part 7 of the Act is predicated on the basis that the determining authorities for pharmaceutical remuneration will ordinarily include, in the payments for those services, an amount which is in respect of (but ordinarily slightly more than) the price paid by service providers when they purchased the prescription items that they supply or administer to NHS patients. However, there are powers in Part 7 to enable alternatives to these ordinary remuneration arrangements in some circumstances.

A new regulation 91A is included in the PLPS Regulations which provides that, where the Government has centrally purchased coronavirus vaccines or coronavirus antivirals and makes those products available to community pharmacies at no cost, the determining authorities for pharmaceutical remuneration are to set a zero or nominal NHS reimbursement price for those products, if certain conditions are met. However, this does not prevent the determining authorities from paying community pharmacies for the services (such as professional services) that they provide in conjunction with the supply or administration of those vaccines or antivirals (regulations 3 and 5).

These Regulations also make a small number of relatively minor amendments to the PLPS Regulations.

Applicants for inclusion in a pharmaceutical list (the basis on which most community pharmacies and all dispensing appliance contractors provide pharmaceutical services) are required to provide updates of the fitness to practise information about their superintendents up until they are actually included on such a list or the application can no longer be proceeded with (for example, because an application has been refused and the time for bringing an appeal has expired) – and consequential amendments are made to provide for the redetermination of applications where this becomes necessary on fitness grounds (regulations 6(2) and 7). The requirement for NHS England to keep lists of service providers that use the Electronic Prescription Service is removed (regulation 4). The consultation period in relation to applications to consolidate services onto a particular site is reduced (regulation 6(3)). The notice period where a community pharmacy on a pharmaceutical list wants to reduce its supplementary hours, which are ordinarily the hours it is open above 40 hours per week, is reduced – and the notification requirement is removed altogether where the pharmacy wants to increase its supplementary hours (regulation 8(2)). There is a new requirement for community pharmacies on pharmaceutical lists to undertake an annual workforce survey as part of its clinical governance obligations, but the existing requirement to undertake a patient satisfaction survey as part of those obligations is removed (regulation 8(3)).

A full impact assessment has not been undertaken in relation to this instrument as 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.