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WELSH STATUTORY INSTRUMENTS

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**2022 No. 1314 (W. 264)**

**NATIONAL HEALTH SERVICE, WALES**

**The National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2022**

<i>Made</i>	- - - -	<i>11 December 2022</i>
<i>Laid before Senedd Cymru</i>		<i>13 December 2022</i>
<i>Coming into force</i>	- -	<i>6 January 2023</i>

The Welsh Ministers make the following Regulations in exercise of the powers conferred on them by sections 80(2), 88(6), (8A)(a) and (c), (8B)(b) and (8D), and 203(9) and (10) of the National Health Service (Wales) Act 2006(1).

At the time these Regulations are made, the Welsh Ministers consider, for the purposes of section 88(8A)(c) of that Act, coronavirus to be a pandemic disease.

**Title and commencement**

1. The title of these Regulations is the National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2022 and they come into force on 6 January 2023.

**Amendment of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020**

2. The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020(2) are amended in accordance with regulations 3 and 4.

**Amendment of regulation 2**

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

““coronavirus” (“*coronafeirws*”) has the meaning given in section 1(1) of the Coronavirus Act 2020(3) (meaning of “coronavirus” and related terminology);”.

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(1) 2006 c. 42. See section 206(1) of the National Health Service (Wales) Act 2006 (“the Act”) for the definitions of “prescribed” and “regulations”, which are relevant to the powers being exercised. Section 80 has been amended by the Health and Social Care Act 2012 (c. 7), sections 220(8) and 213(7). Section 88 has been amended by the Health Service Medical Supplies (Costs) Act 2017 (c. 23), section 2 and the Health and Care Act 2022 (c. 31), section 161(2).

(2) S.I. 2020/1073 (W. 241).

(3) 2020 c. 7.

## New regulation 55A

4. After regulation 55 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors) insert—

### **“Zero or nominal product reimbursement for coronavirus vaccines, coronavirus antivirals and influenza virus vaccines**

**55A.**—(1) In the case of the drugs or medicines to which paragraph (2) applies, determining authorities must ensure that determinations under section 88 of the 2006 Act (remuneration for 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 the purposes of the Drug Tariff, 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,
- (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, or
- (c) a drug or medicine which is used for vaccinating or immunising people against an influenza virus (“an influenza vaccine”), if the conditions set out in paragraph (5) are satisfied.

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

- (a) either the Welsh Ministers have or the Secretary of State has purchased coronavirus vaccines for supply as part of the health service,
- (b) the Welsh Ministers have made arrangements for all or part of the stock of coronavirus vaccines, purchased as mentioned in sub-paragraph (a), to be supplied to NHS pharmacists, whether directly or via an intermediary, at no cost to the NHS pharmacists,
- (c) a Local Health Board has made arrangements for the administration of coronavirus vaccines from the stock mentioned in sub-paragraph (b) in accordance with any directions given to them by the Welsh Ministers under section 12 of the 2006 Act (functions of Local Health Boards), and
- (d) the coronavirus vaccine in question is from that stock and administered as part of the health service.

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

- (a) either the Welsh Ministers have or the Secretary of State has purchased coronavirus antivirals of a particular type for supply as part of the health service,
- (b) the Welsh Ministers have made arrangements for all or part of the stock of that particular type of coronavirus antiviral, purchased as mentioned in sub-paragraph (a), to be supplied to NHS pharmacists, whether directly or via an intermediary, at no cost to the NHS pharmacists, 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 under the arrangements mentioned in sub-paragraph (b).
- (5) The conditions set out in this paragraph are—
  - (a) either the Welsh Ministers have or the Secretary of State has purchased influenza virus vaccines for supply as part of the health service,
  - (b) the Welsh Ministers have made arrangements for all or part of the stock of influenza virus vaccines, purchased as mentioned in sub-paragraph (a), to be supplied to NHS pharmacists, whether directly or via an intermediary, at no cost to the NHS pharmacists,
  - (c) a Local Health Board has made arrangements for the administration of influenza virus vaccines from the stock mentioned in sub-paragraph (b) in accordance with any directions given to them by the Welsh Ministers under section 12 of the 2006 Act (functions of Local Health Boards), and
  - (d) the influenza virus vaccine in question is from that stock and administered as part of the health service.
- (6) For the purposes of paragraph (4), the Welsh Ministers may characterise the particular type of coronavirus antivirals that are available at no cost to NHS pharmacists 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).
- (7) For the avoidance of doubt, determinations under section 88 of the 2006 Act that, in accordance with this regulation—
  - (a) do not provide for or permit any 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 in the course of which the drug or medicine is supplied or administered.
- (8) In this regulation—
  - (a) “nominal reimbursement” means, in the case of a drug or medicine that has been provided at no cost to a NHS pharmacist, payment of an amount that is paid in place of the amount that the NHS pharmacist would ordinarily make from the difference between—
    - (i) the amount that they paid for the drug or medicine when they purchased it, and
    - (ii) the amount that they are paid by the relevant Local Health Board 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 services, and
  - (b) “health service” has the meaning given in section 206(1) of the 2006 Act.”

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**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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11 December 2022

*Eluned Morgan*  
Minister for Health and Social Services, one of  
the Welsh Ministers

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (S.I. 2020/1073 (W. 241)) (“the Pharmaceutical Regulations”). The Pharmaceutical Regulations govern the provision of pharmaceutical services as part of the National Health Service in Wales under Part 7 of the National Health Service (Wales) Act 2006 (“the Act”).

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.

Regulation 4 inserts new regulation 55A into the Pharmaceutical Regulations which provides that, where the Welsh Ministers or the Secretary of State have centrally purchased coronavirus vaccines, coronavirus antivirals or influenza vaccines, and those products are made 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.

The Welsh Ministers’ Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.