# Chief Medical Officer Directorate

Pharmacy and Medicines Division



Dear Colleague

# ADDITIONAL PHARMACEUTICAL SERVICES – NALOXONE EMERGENCY SUPPLY SERVICE

## **Summary**

1. This Circular advises that a naloxone emergency supply service will be added to the community pharmacy Public Health Service from 30 October 2023.

## **Background**

- 2. The <u>Drug Death Taskforce report</u> published in July 2022 contains the following action: *All community pharmacies should hold naloxone for administration in an emergency and should be able to supply take home naloxone (THN) to people who use drugs, families and anyone likely to witness an opioid overdose.*
- 3. By holding a supply of naloxone, the community pharmacy network will support increased access so that it can be used to reverse the effects of an opioid overdose.
- 4. <u>Circular PCA(P)(2023) 22</u> provided details of payments made to community pharmacy contractors for preparatory work, including purchase of two naloxone kits to be held in stock for emergency use.

#### **Details**

5. The Scottish Government and Community Pharmacy Scotland have agreed that a new national service will be implemented to provide **emergency access to supplies of naloxone**. The service is due to start on **30 October 2023** and pharmacy teams are asked to familiarise themselves with the arrangements. Take Home Naloxone (THN) via pharmacies will be a later phase.

12 September 2023

#### Addresses

For action

Chief Executives. NHS Boards

#### For information

NHS Directors of Pharmacy Director of Practitioner Services, NHS NSS

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### **Service Specification and Directions**

- A service specification for naloxone emergency supply is attached to this circular as Annex A.
- 7. The 2021 Directions for the Public Health Service are amended by the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2023 which enable community pharmacies to supply and, where necessary, administer naloxone for emergency use. The Directions will come into force on 30 October 2023 and are attached to this Circular as Annex B.
- Community pharmacy contractors and pharmacy teams should ensure they are 8. familiar with the new arrangements as detailed below. A PGD is not required for this service.

### **Training**

- Community pharmacy contractors should ensure that pharmacy teams complete the e-learning module for naloxone emergency supply, now available on the NES TURAS Learn website at: Community Pharmacy Emergency Naloxone Holding Service | Turas | Learn (nhs.scot) A Frequently Asked Questions (FAQs) resource has also been developed and is available at the same web link.
- In addition, webinars to support the implementation of the service will be held on Wednesday 4 October and Tuesday 14 November at 19:30. Details of how to register can be found at on Turas Learn at Pharmacy Naloxone Emergency Supply Service | Turas | Learn (nhs.scot). The webinar will be recorded and made available.

### IT roll-out

All Patient Medication Record (PMR) suppliers have confirmed that pharmacy IT software will support pharmacy teams to deliver naloxone emergency supply from the launch date of 30 October 2023. A new universal claim framework (UCF) module will be available for claims when naloxone kits are supplied or expire.

## Reimbursement arrangements

- NHS Circular PCA(P)(2023)22, issued on 24 May 2023 advised of funding 12. issued to community pharmacy contractors for preparatory work ahead of the service formally commencing. That payment is specifically to be used as a contribution towards training and for the purchase of two naloxone kits by each pharmacy contractor to be held for emergency use.
- As the initial two naloxone kits have already been funded, claims for 13. reimbursement of those two kits **must not be submitted**. However, all subsequent supplies of kits, and any expired kits that are being withdrawn from stock, should be claimed for reimbursement using the UCF module. Payment verification and counterfraud checks will be determined as appropriate by National Services Scotland (NSS).







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The content of this Circular has been agreed with Community Pharmacy Scotland.

### Action

15. Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists, GPs, Health and Social Care Partnerships, Area Pharmaceutical Committees and Alcohol and Drug Partnerships (ADPs).

Yours sincerely,

**Alison Strath** 

Chief Pharmaceutical Officer Pharmacy & Medicines Division





# National Community Pharmacy Emergency Naloxone Holding Service Specification

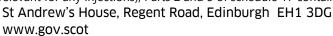
### 1. Service Aim

- 1.1 To contribute to a reduction in drug related deaths within Scotland by providing overdose awareness training for community pharmacy teams, and naloxone for immediate emergency supply and emergency administration from community pharmacies across Scotland. Immediate emergency supply of naloxone will be made from the pharmacy premises while emergency administration may occur within or out with pharmacy premises.
- 1.2To ensure naloxone is stocked and available for emergency use in every community pharmacy across Scotland.

### 2. Service Outline & Standards

- 2.1 Legally, naloxone can be given in an emergency for the purpose of saving a life. [The Human Medicines Regulations 2012 (legislation.gov.uk)] <sup>1</sup>
- 2.2A standard operating procedure should be in place within the pharmacy which covers all aspects of the service.
- 2.3 The community pharmacy contractor will ensure that each supply of naloxone is recorded via Universal Claims Framework (UCF). Products held for this service that become out of date should be disposed and also recorded via the UCF.
- 2.4 Where possible, a note recording supply or administration should be made on the patient's medication record (PMR).
- 2.5 The pharmacy contractor must ensure that there are enough staff, suitably trained to provide this service during the pharmacy's normal opening hours.
- 2.6 The pharmacy contractor must make arrangements to ensure each community pharmacy holds at least two naloxone kits for emergency use. This can be naloxone in injection or nasal form or a combination of both.

<sup>&</sup>lt;sup>1</sup> Regulation 238 and schedule 19 provide exemption from the usual rules about who can parenterally administer (relevant for any injections); Parts 2 and 5 of schedule 17 contain exemptions relevant for supply.









- 2.7 The specific products that may be used for this service are:
- Prenoxad 2mg/2ml Pre-filled Syringe for Intramuscular Injection. (first line option) Prenoxad is licensed from 16 years.
- Nyxoid 1.8mg intra-nasal spray (second line option). Nyxoid is licensed from 14 years.
- 2.8 Any suspected adverse events should be reported using the MHRA Yellow Card Scheme (Yellow Card Centre Scotland – Making medicines safer).
- 2.9 The service is provided according to any required regulatory and professional standards.

# 3. Training

- 3.1 All community pharmacists and pharmacy staff should complete the overdose awareness and naloxone training associated with this service, available via NES Turas Learn module: Community Pharmacy Emergency Naloxone Holding Service | Turas | Learn (nhs.scot)
- 3.2 The community pharmacy contractor should ensure that staff are provided with the opportunity to undertake the training module and within timescales given by the Scottish Government.
- 3.3 Staff should note that if they have not yet completed the training module, using clinical judgement they can still supply or administer in an emergency situation.
- 3.4 The community pharmacy contractor should ensure that staff are provided with any updates or changes to the service. It is recommended that annual refresher training is undertaken.

#### 4. Service Procedure

- 4.1 In the event of suspected opioid overdose, the process outlined in the overdose awareness and naloxone training module should be followed to respond as appropriate to the situation.
- 4.2 No pharmacy label is required for the naloxone product to be supplied or administered in an immediate emergency.
- 4.3 Submit claim via Universal Claim Work to PSD in the usual manner. Expired naloxone stock for this service should be claimed for by following the same process.
- 4.4 Replenishment stock should be ordered to ensure arrangements are in place for at least two naloxone kits to be held in the pharmacy.







# 5. Monitoring and evaluation

5.1 It is a requirement of the service that appropriate records are kept via UCF submission for naloxone use or expiry for internal and external audit, evaluation, and monitoring purposes.

# 6. Payment

- 6.1 A payment was made in May 2023 (Circular PCA (P)(2023)22) to enable pharmacy contractors to purchase two naloxone kits and to provide support towards the cost of training. The contractor should use the Universal Claim Framework (UCF) to claim the reimbursement cost of purchasing subsequent kits following administration or supply made from the original stock or if existing stock for this service expires.
- 6.2 Details of reimbursement are set out in the Scottish Drug Tariff.



## NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

# HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (PUBLIC **HEALTH SERVICE) (SCOTLAND) DIRECTIONS 2023**

The Scottish Ministers give the following Directions in exercise of the powers conferred by sections 2(5), 27A, 27B, 28A and 105(7) of the National Health Service (Scotland) Act 1978<sup>2</sup>, and all other powers enabling them to do so.

#### 1. **Citation and commencement**

1.1 These Directions may be cited as the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2023 and come into force on 30 October 2023.

#### 2. **Interpretation**

2.1 In these Directions, unless the context otherwise requires:

"the Act" means the National Health Service (Scotland) Act 1978;

"the 2009 Regulations" means the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009<sup>3</sup>;

"Public Health Service" or "PHS" has the meaning ascribed in paragraph 3.1.

- 2.2 Other words and phrases used in these Directions have the same meaning as they have in the Act and in the 2009 Regulations.
- 2.3 Any reference in these Directions
  - to a numbered paragraph, is a reference to a paragraph bearing that number in (i) these Directions,
  - (ii) to a numbered Schedule, is a reference to the Schedule to these Directions bearing that number, and
  - (iii) to a numbered paragraph of a numbered Schedule, is a reference to a paragraph bearing that number in the Schedule bearing that number.

<sup>&</sup>lt;sup>2</sup> 1978 c.29; section 2(5) was amended by the National Health Service and Community Care Act 1990 (c.19), section 66(1); section 27A was inserted by the National Health Service (Primary Care) Act 1997 (c.46) ("the 1997 Act"), section 27(2); section 28A was substituted by the Health Act 1999 (c.8) ("the 1999 Act"), section 57, and amended by the Primary Medical Services (Scotland) Act 2004 (asp 1) ("the 2004 Act"), section 8, and schedule 1, paragraph 1; section 105(7) was amended by the Health Services Act 1980 (c.53), Schedule 6, paragraph 5(1) and Schedule 7, the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 9, Part I, paragraph 24 and the 1999 Act, Schedule 4, paragraph 60. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).







#### 3. **Description of the Public Health Service**

- 3.1 The Public Health Service (PHS) is a service that:
  - promotes the pro-active involvement of community pharmacists and their staff in supporting self-care,
  - offers suitable interventions to promote healthy lifestyles,
  - involves participating in national and local health campaigns,
  - provides a health promoting environment across the network of community pharmacies.
  - provides smoking cessation support which comprises advice and supply of smoking cessation products in order to help smokers successfully stop smoking,
  - provides sexual health support which comprises the supply of emergency hormonal contraception (EHC), bridging contraception and related advice,
  - provides prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccinations as clinically appropriate, and
  - supplies and, where necessary, administers naloxone for emergency use as clinically appropriate.
- The component elements of PHS are specified in Schedule 1, paragraphs 1 and 2. 3.2

#### 4. Health Board duty to arrange for a Public Health Service

4.1 Subject to paragraph 2 of Schedule 1 and until otherwise directed, Health Boards have a duty to arrange for the provision of a Public Health Service (PHS) for persons in their area as an additional pharmaceutical service.

#### 5. Persons authorised to provide the Public Health Service

- 5.1 Health Boards may only enter into arrangements for the provision of PHS with:
  - a person who is a registered pharmacist; or (a)
  - a person other than a registered pharmacist who, by virtue of section 69 of the Medicines Act 1968<sup>4</sup>, is taken to be a person lawfully conducting a retail pharmacy business in accordance with that section;

and, in the case of both (a) and (b) who is on the pharmaceutical list maintained by the Health Board in terms of regulation 5 of the 2009 Regulations<sup>5</sup>.

5.2 The supply of medicines or appliances is to be performed by or under the direct supervision of a pharmacist.

<sup>&</sup>lt;sup>5</sup> Regulation 5 was amended by S.I. 1997/696, S.S.I. 1999/57, S.S.I. 2004/39, S.S.I. 2006/143, S.S.I. 2011/32 and S.S.I. 2014/148.







<sup>&</sup>lt;sup>4</sup> 1968 (c.67) section 69 was amended by the Pharmacy Act 1954 (c.61), Schedule 16, the Pharmacists (Fitness to Practise) Act 1997 (c.19), section 1 and Schedule paragraph 4, and the Statute Law Repeals Act 1993 (c.50), and by SI 2007/289.

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- 5.3 A pharmacist providing PHS in accordance with this paragraph must not be one who:
  - (a) has been disqualified under section 29B (2) of the Act;
  - (b) is suspended by direction of the Tribunal, or
  - (c) is the subject of a corresponding decision in England, Wales or Northern Ireland.

#### 6. **Compliance and Conditions**

6.1 The arrangements made by a Health Board in accordance with paragraphs 4 and 5 shall include the terms and conditions specified in Schedules 1, 2 and 3, with which the provider of a PHS shall be obliged to comply.

#### 7. Payment for the provision of a Public Health Service

- 7.1 Remuneration for the provision of a PHS will be paid at nationally negotiated rates as set out in the Drug Tariff and in accordance with Schedule 3 of these Directions.
- 7.2 The prices and methodology for calculating reimbursements to a PHS provider for any drugs, medicines or listed appliance that the provider may supply to patients in connection with providing PHS will be in accordance with the provisions set out in Part 1 of the Drug Tariff.

#### 8. Revocations

8.1 These Directions revoke and supersede the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Directions 2015 and the Health Board Additional Pharmaceutical Services (Public Health Service) (Scotland) Amendment Directions 2021.

> Signed by Alison Strath A member of staff of the Scottish Ministers

St Andrew's House, Edinburgh 8 September 2023







## NATIONAL HEALTH SERVICE (SCOTLAND) ACT 1978

# HEALTH BOARD ADDITIONAL PHARMACEUTICAL SERVICES (PUBLIC **HEALTH SERVICE) (SCOTLAND) DIRECTIONS 2023**

#### **SCHEDULE 1**

### SERVICES TO BE PROVIDED AS A PUBLIC HEALTH SERVICE

- 1. A Public Health Service (PHS) comprises the following services:
  - the provision of advice to patients or members of the public on healthy living (a) options and promotion of self-care in circumstances where in the professional opinion of the pharmacist it is appropriate to do so or by request from a patient or member of the public;
  - (b) making available for use by patients and members of the public a range of NHS or NHS approved health improvement campaign materials and other health improvement information and support material;
  - participation in health improvement campaigns, each campaign being on (c) display and visible within a pharmacy for a set period, determined nationally by Scottish Ministers following consultation with a body deemed to be representative of community pharmacy contractors;
  - where agreed between a PHS provider and the Health Board, participation in (d) locally agreed health improvement campaigns in the intervals between the national campaigns referred to under sub-paragraph (c);
  - (e) the provision of smoking cessation support comprising advice and supply of smoking cessation products as indicated in the service specification and NHS Board guidance, in order to help smokers successfully stop smoking;
  - the provision of sexual health support comprising the supply of emergency (f) hormonal contraception (EHC), bridging contraception and related advice;
  - the provision of prophylactic antipyretic (paracetamol) in advance of or (g) following childhood meningitis B vaccination and other childhood vaccinations as clinically appropriate; and
  - (h) the supply and, where necessary, administration of naloxone for emergency use as clinically appropriate.
- 2. Where a PHS provider decides not to supply emergency hormonal contraception (EHC) or bridging contraception according to subparagraph 1 (f) above, they should give notice in writing to the Health Board and advise the Agency of their decision and ensure prompt referral of patients to another provider who they have reason to believe provides that service.
- 3. For the provision of the services listed at subparagraphs 1 (c) and (d) a PHS provider shall make available space in a window of the pharmacy or, only in the absence of any suitable window, another space within the pharmacy. Such space should be made







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available for the full duration of the campaigns unless by agreement with the relevant Health Board because of unforeseen or special circumstances.



#### **SCHEDULE 2**

# TERMS AND CONDITIONS OF THE PROVISION OF THE PUBLIC HEALTH SERVICE

- 1. For the purposes of PHS the 'patient medication record' is a pharmacy retained electronic record that as a minimum must include:
  - (aa) the patient's date of birth;
  - (a) the name and address of the patient;
  - (ba) the patient's sex;
  - (b) the patients' CHI number where available;
  - (c) name and address of the patient's GP practice;
  - (d) the dates of all dispensing episodes;
  - (e) the items dispensed.

# **Provisions**

- 2. In providing the PHS service, PHS providers will be required to:
  - (a) use materials, including leaflets and posters, provided or approved by Scottish Ministers or Health Boards;
  - (b) use the display equipment, including display stands and other devices, made available by Scottish Ministers or Health Boards, which display equipment may not be used for any commercial purpose, and make appropriate space available within the pharmacy to hold such display equipment;
  - (c) undertake smoking cessation support, sexual health support, the provision of prophylactic antipyretic (paracetamol) in advance of or following childhood meningitis B vaccination and other childhood vaccination as clinically appropriate, and the supply and administration of naloxone for emergency use as clinically appropriate, as components of PHS in accordance with service specifications provided by Scottish Ministers.
- 3. In providing PHS a PHS provider and pharmacist must:
  - (a) have regard to and, where required, comply with, stated standards and administrative guidance that is from time to time produced by Scottish Ministers and disseminated by Health Boards to PHS providers as soon as possible after they are received;
  - (b) conform with the standards generally accepted by both the NHS and the pharmaceutical profession; and
  - (c) have completed the required training to enable them to offer patients requiring smoking cessation, sexual health and naloxone services.
- 4. In providing a PHS, a PHS provider is agreeing to the following:

- (a) that it takes responsibility for the veracity of any payment claims submitted to the Agency;
- (b) that its payment claims will be authenticated from appropriate records held by the provider or at the Agency;
- (c) that payments will be subject to Payment Verification and the PHS provider undertakes to co-operate fully with this process; and
- (d) that the PHS provider will provide documentary evidence to support payment claims.
- 5. The requirement for a complaints procedure under paragraphs 12 and 13 of Schedule 1 to the 2009 Regulations applies to the provision of a PHS.
- 6. The requirement for record keeping under paragraph 14 of Schedule 1 to the 2009 Regulations apply to the provision of a PHS.

#### **SCHEDULE 3**

#### PAYMENT FOR THE PUBLIC HEALTH SERVICE

- 1. The payments for providing the Public Health Service (PHS) are set out in the Drug Tariff.
- 2. Payments for providing the PHS under Schedule 1, Paragraph 1(d) will be at rates agreed between the NHS Board and the PHS providers.
- 3. Health Boards will be entitled to take such reasonable steps as are necessary to ensure that providers are:
  - (a) providing appropriate advice and support to patients and members of the public;
  - (b) making available a range of NHS or NHS approved health improvement campaign materials and information and support materials;
  - (c) displaying the agreed national campaigns, for the set periods;
  - (d) participating in locally agreed health improvement campaigns, where agreed with the Health Board; and
  - (e) providing the services and components named under Schedule 1.
- 4. Payments made to providers for providing a PHS will be subject to post payment verification checks and investigation by the Agency.
- 5. Where after suitable investigation a Health Board is satisfied that a PHS provider is not providing the services listed in Schedule 1 but is receiving payment under paragraph 1 of that Schedule and the Drug Tariff, it may (without prejudice to any other action which may be open to it):
  - (a) write to the provider advising of the conclusion reached by the investigation;
  - (b) inform the provider that the payments will be stopped with immediate effect; and
  - (c) recover any payments made to the provider in respect of any period(s) when the provider was not providing the services specified in Schedule 1.