



# Clinical Community Pharmacy Service

Service specification for the Clinical Community Pharmacy Service in Wales

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1.3	<p>Inclusion of strong encouragement of submission of daily reports of service availability to support collaborative working with other service providers (section 4)</p> <p>Updated to clarify restrictions around provision of services to individuals with a close personal relationship (clause 6.1)</p> <p>Addition of explicit requirement for equipment and connectivity in the consultation area to allow access to the Choose Pharmacy system (Clause 9.2.7)</p>	27 Mar 2022

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# Overarching requirements

## 1. Interpretation

- 1.1. The definitions set out in The Pharmaceutical Services (Clinical Services) (Wales) Directions 2022 (or subsequent iterations of this document) apply to this specification.
- 1.2. *All Wales Pharmacy Database* means the database held by the NHS Wales Shared Services Partnership that contains details of the clinical services that each Pharmacy is commissioned to provide and of the services that individual Service Providers are accredited to provide. This definition includes any subsequent databases that replace the AWPDP in the future.
- 1.3. *Bridging Contraception* means desogestrel tablets, supplied following a supply of emergency contraception to provide contraceptive cover until a regular supply can be arranged.
- 1.4. *CCPS* means the Clinical Community Pharmacy Service, or one of the component services included within it.
- 1.5. *Choose Pharmacy* means the software system developed and managed by Digital Health and Care Wales, where clinical records for this service are maintained, with consultation records being used to generate data for service payment.
- 1.6. *Clinical Supervisor* means a Healthcare Professional acting in the capacity of a clinical supervisor, as defined by the current national protocol for inactivated influenza vaccine (where one has been issued).
- 1.7. *Contractor* means a person lawfully conducting a retail pharmacy business.
- 1.8. *GP Practice* means a provider of General Medical Services contracted essential services.
- 1.9. *Local Health Board (LHB)* means the Local Health Board that the pharmacy in which the service is being provided is located.
- 1.10. *National Extended Services Management Board (NESMB)* means the Board that has been established by LHBs to facilitate national discussion around community pharmacy extended services. In the event that the name of this board changes, this definition will be taken to mean the replacement board.
- 1.11. *National Clinical Services Accreditation (NCSA)* system means the section of the Health Education and Improvement Wales (HEIW) website where training requirements and packages are made available to individuals working in community pharmacies.
- 1.12. *Patient* means any person in receipt of one or more components of the service.

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- 1.13. *Pharmacist* means a person who is listed in Part 1 of the Register of Pharmacists held by the General Pharmaceutical Council under the Pharmacists and Pharmacy Technicians Order 2007.
- 1.14. *Pharmacist Independent Prescriber* means a Pharmacist who is listed in the NHS Wales approved list of Pharmacist Independent Prescribers.
- 1.15. *Pharmacy* means any premises included on a health board pharmaceutical list where a Pharmacist provides drugs or services as part of pharmaceutical services.
- 1.16. *Pharmacy Staff* means any person or persons employed or engaged by a Contractor, who provides, or has an ancillary role in respect of, any part of the service.
- 1.17. *Pharmacy Technician* means a person listed in Part 1 of the Register of Pharmacy Technicians held by the General Pharmaceutical Council under the Pharmacists and Pharmacy Technicians Order 2007
- 1.18. *Protocol or National Protocol* means a document issued by Welsh Government in times of pandemic disease that permits vaccination to be carried out by a wider range of individuals who work under the supervision of a competent Clinical Supervisor.
- 1.19. *QuickStart Contraception* means desogestrel tablets, supplied on request to provide contraceptive cover until a regular supply can be arranged.
- 1.20. *Relevant Prescriber* means - a doctor, dentist, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber, or Pharmacist independent prescriber registered in the UK or an EEA or Swiss doctor or dentist.
- 1.21. *Service Availability Tool* means a nationally agreed reporting system that allows pharmacies to report the availability of key components of CCPS and PIPS in their premises
- 1.22. *Service Provider* means a suitably trained individual providing any component of this service.
- 1.23. *Temporary Resident* means a patient who is away from home and temporarily resident in Wales for at least the next 24 hours and needs to access one or more components of this service.
- 1.24. *Unprotected Sexual Intercourse (UPI)* means sexual intercourse where no contraception was used, or the contraceptive method used failed (e.g. split condom).

## 2. Scope

- 2.1. This service specification relates to provision of the Common Ailments Service (incorporating Sore Throat Test and Treat), Emergency Medicines Supply, Emergency Contraception, Bridging and QuickStart Contraception, and Seasonal Influenza Vaccination components of the Clinical Community Pharmacy Service.

## 3. Service Aims

- 3.1. To deliver prudent healthcare using a 'community pharmacy first' model of care, for patients who can be appropriately managed in the community pharmacy setting, thereby reducing the number of patients consulting their GP or other health services provider.
- 3.2. To help tackle health inequalities through increasing access (both temporally and geographically) to services that meet patient need for unplanned care, contraception, advice on sexually transmitted infections, or vaccination against influenza.
- 3.3. To maximise influenza immunisation for patients included in nationally and locally agreed at-risk groups.

## 4. Service Availability

- 4.1. Contractors, and their teams, are **strongly encouraged** to report the availability (or otherwise)<sup>1</sup> of the EMS, EC, and CAS components of the service (including sore throat test and treat) via the national Service Availability Tool on each day that the pharmacy is open.

## 5. Eligibility

- 5.1. Patients resident (including Temporary Residents and those of no fixed abode), or registered with a GP practice located, in Wales.<sup>2</sup>
- 5.2. Patients may self-refer to the service, or be referred to the service by a member of staff in the pharmacy, or another healthcare provider.

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<sup>1</sup> In this context, 'available' means that the pharmacy are able to receive referrals from other providers, or can provide the service to a walk-in patient within a reasonable timeframe (see clause 9.11).

<sup>2</sup> In exceptional circumstances, where the pharmacist is satisfied that the patient would be unable to access care in a timely manner, the service may be provided to other patients who entitled to NHS services.

## 6. General Principals

- 6.1. Except in exceptional circumstances,<sup>3</sup> Service Providers will not provide any component(s) of this service to themselves, members of their family, or others with whom they have a close personal relationship that would impact on their ability to provide safe and effective care.<sup>4</sup>
- 6.2. Where the patient's clinical circumstances are outside of the scope of the relevant component of this service, the Service Provider will provide an alternative service in the pharmacy, or refer patients to an appropriate service provider who is able to meet their needs.
- 6.3. All care will be as part of NHS Wales and all consultations and any products supplied under the terms of this service shall be made at no cost to the patient.
- 6.4. The Contractor and individuals employed or engaged by them will offer a user-friendly, non-judgmental, patient-centred, and confidential service.
- 6.5. All care provided to patient who are less than 16 years of age will be provided in accordance with Fraser Guidance and any other relevant guidance issued by the Welsh Government.
- 6.6. Service Providers must be aware of and responsive to the needs of young people accessing the service and follow Young Person Friendly guidelines when providing this service, available here:  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/216350/dh\\_127632.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216350/dh_127632.pdf).

## 7. Consultation records

- 7.1. Details of all consultations provided under this service will be recorded immediately in the relevant module of the Choose Pharmacy system. Where the Choose Pharmacy system is temporarily unavailable, details of the consultation will be recorded on paper forms and transferred to the relevant module as soon as possible, and not normally later than the next working day.

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<sup>3</sup> This would include circumstances where non-provision would mean it would be likely that the patient would be unable to access care via a reasonable route, or care would be delayed by a clinically meaningful time

<sup>4</sup> In line with best practice guidance, service providers should consider the appropriateness of providing care to any individual that they have a close personal relationship before offering to assess, advise, or treat that individual.



## Section: Overarching Requirements

- 7.2. With the exception of Emergency Contraception consultations, an electronic summary will be automatically forwarded to the patient's GP following each entry consultation that is entered in the Choose Pharmacy system. However, where this is not possible (such as where the patient is registered with a GP in England), details of the consultation must be printed and forwarded as soon as practicable and in all cases within 5 working days to the person with whom the patient is registered for General Medical Services.

## 8. Training and accreditation requirements

- 8.1. Before providing any component of this service, Service Providers will ensure that they:
  - 8.1.1. have completed the required modules set out on the HEIW National Clinical Services Accreditation (NCSA) platform for each of the service components they are providing, including any requirements for refresher training; and
  - 8.1.2. have successfully completed the Disclosure and Barring Service (DBS) check process with NHS Wales Shared Services Partnership; and
  - 8.1.3. have their name included in the All Wales Pharmacy Database for the relevant component(s) of the service; and
  - 8.1.4. Meet any additional requirements listed under the relevant service component below.
- 8.2. Service Providers must be competent to assess a patient's capacity to understand the nature and purpose of the treatment they will be offered/receive and that they have the capacity to give or refuse consent to treatment.

## 9. Contractor responsibilities

- 9.1. Contractors wishing to provide this service will indicate this through submission of a Premises Listing Form to the NHS Wales Shared Services Partnership available from: <https://nwssp.nhs.wales/ourservices/primary-care-services/our-services/pharmacy-services/all-wales-pharmacy-database/>.
- 9.2. Other than with prior agreement of their Local Health Board, the Contractor will ensure that the service is provided from a consultation area of the pharmacy which:
  - 9.2.1. is a clearly designated area for confidential discussion which is distinct from the general public areas of the pharmacy; and
  - 9.2.2. is an area where both the patient receiving the service and the Service Provider can sit down together and talk at normal speaking volumes without being overheard by any person, including Pharmacy Staff; and
  - 9.2.3. is an area which ensures the dignity and privacy of the patient is maintained; and

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- 9.2.4. is of an appropriate size and layout to facilitate the provision of all aspects of the service being provided in accordance with accepted standards of safe clinical practice including the management of any potential adverse effect, including provision of basic life support and anaphylaxis management where relevant;<sup>5</sup> and
  - 9.2.5. has suitable facilities to ensure adequate hand hygiene can be maintained; and
  - 9.2.6. has suitable arrangements in place with their Local Health Board for the safe disposal of sharps and clinical waste; and
  - 9.2.7. has appropriate equipment and connectivity to allow access to the Choose Pharmacy system.
- 9.3. Where clinically appropriate, the service may be provided remotely to a patient, via a telephone or video consultation conducted by the Service Provider. In such cases, the Service Provider must ensure that they cannot be overheard by any person, including Pharmacy Staff.
  - 9.4. The Contractor will ensure that Pharmacy Staff involved in delivery of this service have knowledge of, and/or relationships with, other appropriate Service Providers such that patients with ongoing needs can be referred effectively.
  - 9.5. Notwithstanding exceptional circumstances where the system is not available, the Contractor will ensure that the Choose Pharmacy system is accessible to all Service Providers, such that they can maintain contemporaneous records for each consultation.
  - 9.6. The Contractor must ensure that appropriate infection prevention and control policies are in place, including cleaning between patients, where appropriate.
  - 9.7. The Contractor will ensure that appropriate indemnity insurance arrangements are in place for registered Pharmacists, registered pharmacy technicians, and other Pharmacy Staff providing the service, pursuant to their individual roles and responsibilities.
  - 9.8. The pharmacy Contractor will ensure that a standard operating procedure in place at the pharmacy for the provision of each component of the service.
  - 9.9. The Contractor will ensure that all standard operating procedures and any guidance or instructions issued align to the provisions in this service specification and that there are no additional restrictions, limits, or directions preventing Service Providers from exercising their professional autonomy in delivering this service.

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<sup>5</sup> Where the consultation area itself is not of a size or layout to allow BLS to be administered, arrangements must be in place to ensure that this can be done in the immediate vicinity of the consultation area, whilst considering the dignity and privacy of the Patient

## Section: Overarching Requirements

- 9.10. The Contractor will have appropriate business continuity arrangements in place to maintain service continuity and take all reasonable steps to ensure that patients are able to access this service in the event of temporary suspension of pharmaceutical services in the pharmacy (see clauses 9.11 and 9.12).
- 9.11. When a patient requests the Common Ailments Service (incorporating Sore Throat Test and Treat), Emergency Medicines Supply, Emergency Contraception, or Bridging and Quick Start Contraception components of this service:
  - 9.11.1. the service will be provided at a mutually agreeable time, normally within 24 hours of the request, but not more than 48 hours<sup>6</sup> after the request was made; and
  - 9.11.2. where the service cannot be provided within 48 hours of the request (e.g. no accredited Pharmacy Staff member available, insufficient capacity, etc.), the Pharmacy Staff will support the patient to access care at another pharmacy locally; and
  - 9.11.3. where there is no local pharmacy able to provide the service, the Pharmacy Staff will support the patient to access care via another Service Provider (e.g. GP practice, sexual health clinic, etc.).
  - 9.11.4. In this context, supporting the patient to access care will involve ensuring that any referral to another provider (whether a pharmacy or other Service Provider) is only done after the Pharmacy Staff have taken all reasonable steps to confirm that the service will be available from that provider to the patient within a reasonable timeframe, based on clinical need and urgency at the time of presentation.
- 9.12. Where a patient requests the Seasonal Influenza Vaccination service, it will be provided at time that is mutually agreeable to the patient and the Contractor during the current season.
- 9.13. All Pharmacy Staff will be fully informed and competent in relation to their involvement in the service.
- 9.14. The Contractor will have awareness of, and ensure the service is provided in accordance with, any relevant nationally or locally agreed standards this will specifically include, but not be limited to, having in place procedures for dealing with needle stick injuries, syncope and resuscitation.
- 9.15. The Contractor will participate in any reasonable publicity of the service required by the Local Health Board or Welsh Government.

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<sup>6</sup> Pharmacy Staff must consider the clinical implications of delayed access to any component of the service and, where this is potentially significant, take all reasonable steps to ensure the patient is able to access the service in a timely manner.

## Section: Overarching Requirements

- 9.16. Where publicity material not directly supplied by the Health Board or Public Health Wales is used to promote the service, such materials as are developed by a Contractor must state that the service is funded by NHS Wales, include the NHS Wales logo, and be approved by the Local Health Board before use.
- 9.17. Unless explicitly stated within the individual component details, Contractors are responsible for procuring all consumables and equipment required for service provision.
- 9.18. All equipment or tests used in provision of this service must be used in accordance with the manufacturer's instructions.
- 9.19. Where required, maintenance, and quality assurance/validation of equipment or tests must be undertaken in line with the manufacturer's instructions and all relevant statutory and regulatory requirements relating to equipment and tests must be adhered to.
- 9.20. Contractors, and Pharmacy Staff, will participate in any reasonable review of the service required by their Local Health Board, or Welsh Government.
- 9.21. Contractors will report any clinical incidents that occur through the provision of this service via the Once for Wales Concerns Management System (Datix Cymru).
- 9.22. Suspected adverse events will be reported using the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme, where appropriate.
- 9.23. Contractors will ensure that the service is provided only by Service Providers who meet the requirements specified in Section 8.

### **10. Service Provider responsibilities**

- 10.1. When conducting consultations, patients must be offered a chaperone in line with the Contractor's Chaperone Policy.
- 10.2. Pharmacists and Pharmacy Technicians providing the service will ensure that indemnity insurance is in place that covers their roles and responsibilities with respect to provision of the service.
- 10.3. Where necessary, Service Providers should take steps to confirm the identity of individuals wishing to register with a service.
- 10.4. Service Providers will use their professional judgement to consider and, where appropriate, act on any child protection and or safeguarding issues coming to their attention in the course of providing the service.

### **11. Monitoring and review**

- 11.1. Monitoring and review of service delivery will be undertaken during the Contract Monitoring Visits.

## Section: Overarching Requirements

- 11.2. Post Payment Verification (PPV) will also be undertaken by health board officers or its representatives as required to meet external audit requirements and ensure proper use of public funds.
- 11.3. Where such monitoring and review activity identifies discrepancies, further steps may be taken as set out in The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.

## **12. Fees**

- 12.1. Details of all fees payable under this service are given in the current Drug Tariff, available here: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-Contractors/drug-tariff>.

## Common Ailments Service

### 13. Legal authority to supply medicines

**13.1. *Supply of prescription only medicines, or medicines outside of their licensed indications, under this service component will only be offered where an authorised PGD suite has been issued by the Local Health Board in which the pharmacy is located, and the Service Provider has signed this PGD suite for that LHB area.***

### 14. Patient eligibility

- 14.1. Patients presenting with symptoms indicative of a condition listed in the current edition of the NHS Wales Common Ailments Formulary (<http://cas.inform.wales.nhs.uk/IndexAMG.aspx>) are eligible for the Common Ailments Service (CAS) component of this service.
- 14.2. Where a patient is willing and able to self-care for their ailment without advice, and indicates an intention to purchase medication over-the-counter, they should not be offered the service.

### 15. Patient Registration

- 15.1. Patients must register with a community pharmacy of their choice in order to receive advice and treatment under the CAS component.
- 15.2. Patients (or their representative, where under 16) must read and understand the Choose Pharmacy Information Governance leaflet before the Service Provider attempts to register them.
- 15.3. Individuals may register with only one pharmacy at any one time and registering at a (new) pharmacy will automatically withdraw the individual from the pharmacy where they were previously registered for CAS.
- 15.4. Individuals may transfer to another pharmacy at any time. Where they choose to do so, the patient will be required to register with the (new) pharmacy.
- 15.5. Patients who have not accessed the service for a period of 12 months will cease to be registered with any pharmacy until such a time as they access the service again.
- 15.6. Registration will only be undertaken at the time the service is being provided and patients must not be registered in advance of them requiring the service.
- 15.7. Patients will be registered by performing an NHS patient demographic database trace using patient details and their record annotated to confirm that they have consented to the service terms and conditions as set out in the Choose Pharmacy Information Governance leaflet.

## 16. Consultations

- 16.1. Care provided through the CAS component includes the presentation, assessment, and treatment of symptoms typical of common ailments.
- 16.2. Patients will normally present themselves (in person or via phone/video call) with symptoms seeking advice and/or treatment. Occasionally someone will present on behalf of someone else, for example, a parent or guardian may present with child, or a carer may present with someone that they care for.
- 16.3. Where the patient is acutely unwell, referral to other appropriate services for further assessment or care should be considered.
- 16.4. All patients must be assessed by a Service Provider, who then considers the most appropriate course of action, which may include:
  - 16.4.1. provision of advice and reassurance alone; or
  - 16.4.2. provision of advice and reassurance alongside medicines from the formulary (see section 19) which alleviate symptoms or address the underlying cause of illness; or
  - 16.4.3. provision of another service in the pharmacy that is more suited to the patient's needs; or
  - 16.4.4. referral to an alternative healthcare professional where indicated.
- 16.5. The Service Provider will assess the symptoms in order to determine the cause and severity of the presenting clinical circumstances.
- 16.6. Where it is appropriate to manage the ailment under the CAS, the Service Provider will advise the patient (or their parent, guardian or carer) of:
  - 16.6.1. the nature of the ailment that will be managed under the service; and
  - 16.6.2. any further symptoms, related to the ailment, that they may experience; and
  - 16.6.3. any requirement for follow up, including safety netting advice;<sup>7</sup> and
  - 16.6.4. any steps that can be taken to alleviate the symptoms; and
  - 16.6.5. how to care for themselves should the ailment reoccur.
- 16.7. Where it is not appropriate to manage the ailment under the CAS, the Service Provider will:
  - 16.7.1. arrange for an alternative service to be provided in the pharmacy; or
  - 16.7.2. support the patient to access care via an alternative Service Provider.

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<sup>7</sup> In this context, safety netting advice would include any red flag symptoms to watch out for and what action should be taken if these, or other symptoms develop, or if the patient deteriorates.

- 16.8. When a referral is indicated, this should be supported with written or verbal referral information, where appropriate.

### **17. Sore Throat Test and Treat – supply of antibiotics**

- 17.1. The Contractor must make available, to Service Providers who are trained to provide antibiotics for management of acute bacterial tonsillitis, a Rapid Antigen Point of Care Test with a minimum of 96% Sensitivity and Specificity.
- 17.2. Where appropriate, the Service Provider will offer a POCT to patients presenting with a sore throat whose FeverPAIN or Centor score indicates possible Streptococcus A infection.
- 17.3. Based on the Service Provider's clinical assessment of the patient and the outcome of any POCT, they will determine whether it is appropriate to supply an antibiotic, within the terms of the PGD.
- 17.4. Where the supply of an antibiotic is not appropriate, Service Providers should consider supply of symptomatic treatment under the CAS.

### **18. Supply of medication**

- 18.1. Where the Service Provider decides that a supply of one or more medicine(s) is indicated to manage the patient's ailment, medicine(s) supplied under this service will be selected from the national formulary (see section 19).
- 18.2. Where, during a CAS consultation, the patient expresses a preference for a product that is not listed in the formulary and the Service Provider considers that the medicine(s) would be appropriate, the Service Provider may sell the patient that product. In such circumstances, the consultation will still be considered to be within the terms of the CAS where a record of the consultation is made in line with this specification.
- 18.3. Where a medicine is supplied, it will be appropriately labelled and the Service Provider will counsel the individual regarding its safe and effective use.

### **19. Formulary**

- 19.1. The Common Ailments formulary includes selected Pharmacy (P) and General Sales List (GSL) and Prescription Only (POM) medicines and appliances from Part VIIIA and Part IXA of the Drug Tariff, where there is an evidence base for their use in management of the listed ailment.
- 19.2. The formulary can be accessed via the Choose Pharmacy application or via the following link <http://cas.inform.wales.nhs.uk/IndexAMG.aspx>.



## **20. Training and accreditation**

- 20.1. In addition to the requirements set out in clause 8.1, Service Providers of this component must submit a signed copy of the PGD suite for this service component to the NHS Wales Shared Services Partnership.

## Contraception Services: Emergency Contraception

### 21. Legal authority to supply medicines

- 21.1. *This component will only be provided where an authorised PGD has been issued by the Local Health Board in which the pharmacy is located, and the Service Provider has signed this PGD for that LHB area.***

### 22. Patient Eligibility

- 22.1. Patients aged 13 years or over who are of childbearing potential<sup>8</sup> and have had unprotected sexual intercourse in the past five days are eligible for the Emergency Contraception component of this service.
- 22.2. Where the patient is aged 13, 14, or 15 years of age, the service will be offered in accordance with Gillick competence, Fraser guidance and any guidance issued by the Welsh Government in relation to the provision of confidential sexual health advice and/or treatment for patients aged 13 years or over.

### 23. Service outline

- 23.1. On presentation in the pharmacy, the patient will be assessed by the Service Provider for the appropriateness of emergency contraception, based on the timing of UPSI, the date of the last menstrual period, the patient's usual cycle length, and the patient's BMI / weight. This assessment is to determine both the risk of adverse effects and the likely effectiveness of emergency hormonal contraception, or other methods of emergency contraception.
- 23.2. Where this assessment determines it is appropriate to supply emergency contraception, the relevant medicine will be supplied to the service user, via a patient group direction, for immediate consumption on the premises.
- 23.3. Where provided by the Local Health Board, condoms will be offered to service users where appropriate.
- 23.4. The Service Provider will provide advice on the avoidance of pregnancy including the use of contraception and will offer Bridging Contraception, or signpost patients to services that provide ongoing contraception support, to all patients using this service component.

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<sup>8</sup> We acknowledge in line with RCOG and FSRH that, in addition to women, other people (such as transgender men and non-binary people) may have childbearing potential. In this service specification, the gender-neutral term of 'patient' is used to denote any individual who accesses the service.

- 23.5. The Service Provider will provide advice on the prevention of STIs through safer sex and use of condoms, and will signpost patients to services that provide diagnosis and treatment for STIs, where appropriate.
- 23.6. Patients excluded from the PGD, or those for whom emergency hormonal contraception is unlikely to be effective will be referred to appropriate local NHS services that are able to meet their needs.
- 23.7. The Service Provider will be aware of local sexual health services to facilitate referrals, where appropriate.

#### **24. Pharmacists unwilling to provide this component of the service<sup>9</sup>**

- 24.1. The following considerations must be made where a Pharmacist is unwilling to provide emergency contraception component of this service for reasons of religion, personal values, or beliefs;
  - 24.1.1. Before arranging a locum booking or employing a Pharmacist, both the Contractor and Pharmacist who is unwilling to provide this service must consider the ease with which a user of the pharmacy would be able to access advice and emergency contraception from another Service Provider locally. For example, in locations that are more rural, or in pharmacies that are open in the evening, or at weekends, other services are less likely to be available and there is an increased risk that an individual requesting the service would not be able to access it in a timely manner.
  - 24.1.2. Pharmacists who receive a request for emergency contraception and are unwilling to supply must:
    - 24.1.2.1. treat the matter sensitively and non-judgementally; and
    - 24.1.2.2. support the patient to access an alternative source of supply, which is available within the timeframe for emergency contraception to be effective, in line with the requirements set out in clause 9.11.

#### **25. Training and accreditation**

- 25.1. In addition to the requirements set out in clause 8.1, Service Providers of this component must submit a signed copy of the PGD booklet for this service component to the NHS Wales Shared Services Partnership.

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<sup>9</sup> These clauses should be read in conjunction with the current guidance from the GPhC on [Religion, personal values and beliefs](#)

## Contraception Services: Bridging and QuickStart Contraception

### 26. Legal authority to supply medicines

**26.1. *This component will only be provided where an authorised PGD has been issued by the Local Health Board in which the pharmacy is located, and the Service Provider has signed this PGD for that LHB area.***

### 27. General Principles

27.1. The Service Provider will provide general advice and support to those seeking advice on contraception and signposting to specific services where appropriate. However, the Service Provider must be responsive to service users who do not fulfil the criteria for Bridging or QuickStart Contraception service and assist them in finding the correct service, e.g. General Practitioner or local Sexual Health clinic.

### 28. Patient eligibility

28.1. Patients aged 13 years to 54 years (inclusive) who are of childbearing potential<sup>10</sup> are eligible for the Bridging and Quick Start Contraception component of this service.

28.2. Where the patient is aged 13, 14, or 15 years of age, the service will be offered in accordance with Gillick competence, Fraser guidance, and any other guidance issued by the Welsh Government in relation to the provision of confidential sexual health advice and/or treatment for patients aged 13 years or over.

28.3. There are two modes through which this service can be offered

28.3.1. at the same time as a supply of Emergency Contraception (EC) is made (Bridging Contraception); or

28.3.2. on request from a Patient in order to provide contraceptive cover until a regular supply can be established (QuickStart Contraception).

### 29. Consultations

29.1. All consultations for Bridging or QuickStart Contraception will include:

29.1.1. measurement and assessment of blood pressure; and

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<sup>10</sup> It is acknowledged, in line with RCOG and FSRH that, in addition to women, other people (such as transgender men and non-binary people) may have childbearing potential. In this service specification, the gender-neutral term of 'patient' is used to denote any individual who accesses the service.

- 29.1.2. assessment of Body Mass Index; and
- 29.1.3. assessment of inclusion and exclusion criteria for the PGD to ascertain the appropriateness of supply.
- 29.2. As clinically appropriate, the Service Provider will:
  - 29.2.1. supply 84 desogestrel 75 microgram film-coated tablets, which is sufficient for 3 months' supply – where the Patient meets the inclusion and exclusion criteria of the PGD; and
  - 29.2.2. provide appropriate contraceptive information, including the advantages of long acting reversible contraception, and the role of condoms in preventing sexually transmitted infections; and
  - 29.2.3. Provide advice on sexually transmitted infections and associated health promotion advice/literature provided by the LHB or Public Health Wales. This will include information on other primary care providers, such as GPs and local sexual health services provided by the LHB; and
  - 29.2.4. signpost patients to services that provide diagnosis and treatment for STIs where appropriate.
- 29.3. Where Patients requesting the service are unable to have their needs met, they will be referred to appropriate local NHS services able to meet their needs.
- 29.4. The service will normally be provided as a confidential face-to-face consultation. However, the Service Provider may conduct a consultation by telephone call or remote consultation via Video Consultation Service (VCS), where they consider it is appropriate to do so and this would be in the Patient's best interest.
- 29.5. Where the Patient provides consent, the Patient's GP practice will be notified of a consultation under this service. Notification will either be via a summary of the consultation being electronically transferred via Choose Pharmacy (by selecting the relevant option within the module), or a paper copy will be printed by the Service Provider and sent to the GP practice.
- 29.6. Further information on 'QuickStart Contraception is available at <https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/>.

### **30. Supply of medication**

- 30.1. Where supply is made:
  - 30.1.1. the medicine will be appropriately labelled and the Service Provider will counsel the individual regarding its safe and effective use; and
  - 30.1.2. the supply recorded in the patient medication record; and

- 30.2. Supplies made under this service will be as a one-off 3-month supply. However, in exceptional circumstances, where a client has been unable to secure an ongoing supply in that first 3-month period the Service Provider may provide one further 3-month supply. A maximum of 6-month supply in total can be given to an individual patient under this service.

### **31. Pharmacists unwilling to provide this component of the service<sup>11</sup>**

- 31.1. The following considerations must be made where a Pharmacist chooses not to provide the Bridging and QuickStart contraception component of this service for reasons of religion, personal values, or belief must:

- 31.1.1. Before arranging a locum booking or employing a Pharmacist, both the Contractor and Pharmacist who is unwilling to provide this service must consider the ease with which a user of the pharmacy would be able to access advice and Bridging or QuickStart Contraception from another Service Provider locally. For example, in locations that are more rural, or in pharmacies that are open in the evening, or at weekends, other services are less likely to be available and there is an increased risk that an individual requesting the service would not be able to access it in a timely manner.
- 31.1.2. In addition, Pharmacists with these views who receive a request for Bridging or QuickStart contraception must:
- 31.1.2.1. treat the matter sensitively and non-judgementally; and
- 31.1.2.2. support the patient to access an alternative source of supply in a timely fashion, in line with the requirements set out in clause 9.11.

### **32. Training and accreditation**

- 32.1. In addition to the requirements set out in clause 8.1, Service Providers of this component must submit a signed copy of the PGD for this service component to the NHS Wales Shared Services Partnership.

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<sup>11</sup> These clauses should be read in conjunction with the current guidance from the GPhC on [Religion, personal values and beliefs](#)

# Emergency Medicines Supply

## 33. Legal authority to supply medicines

**33.1. *The Human Medicines Act 2012 remains the primary legislation governing the emergency supply of prescription only medication at the request of a patient and all supplies of prescription only medication made must be made in accordance with these regulations.***

## 34. Service provision

- 34.1. The Emergency Medicines Supply component will normally only be provided where the Service Provider believes that it would not be practicable for the patient to obtain the medicines they require in a clinically appropriate timeframe via the usual route.
- 34.2. The service should not be provided where a prescription is anticipated to be available in sufficient time to meet the needs of the patient, or where there is adequate time available for a prescription to be requested via the usual route.

## 35. Patient Eligibility

- 35.1. Patients who have had one or more medicines prescribed in the past by a relevant prescriber and who require an urgent supply of medication where no prescription is available are eligible for the Emergency Medicines Supply component of this service.

## 36. Service summary

- 36.1. This service relies on regulation 225 (and 226) of the Human Medicines Regulations (2012), which allows the emergency supply of medicines by Pharmacist: at patient's request.
- 36.2. In order to meet the requirements of this regulation and enable a legal supply of a prescription only medicine without a prescription, the Service Provider must interview the patient and be satisfied:
  - 36.2.1. that there is an immediate need for the medicine supplied; and
  - 36.2.2. that it is impracticable to obtain a prescription without undue delay; and
  - 36.2.3. that treatment with the medicine has on a previous occasion been prescribed by a relevant prescriber for the person requesting it; and
  - 36.2.4. as to the dose which in the circumstances it would be appropriate for that person to take.

## Section: Emergency Medicines Supply

- 36.3. Where the criteria in clause 36.2 have not been met, a supply cannot be made under this service and the patient should be advised to request a prescription for the medication via the usual route.
- 36.4. Where available, the Service Provider should access to the patient's Welsh GP record via the Emergency Medicines module of the Choose pharmacy system as an aid to establishing the medicines, dosage, and frequency that has previously been prescribed and to aid reaching satisfaction regarding clauses 36.2.1 to 36.2.4.
- 36.5. Where the Welsh GP record is not available (e.g. a patient registered in England), the Service Provider should take all reasonable steps to satisfy themselves of the appropriateness of a supply before considering referral to other services.
- 36.6. The Service Provider, having regard for the medicine being requested and its clinical indication, shall satisfy themselves that is advisable to supply the medicine given the likely clinical consequences of the dose(s) being delayed or omitted.
- 36.7. Where appropriate the Service Provider shall remind the patient of the importance of ordering medicines in a timely manner.
- 36.8. The Service Provider must not supply:
- 36.8.1. Any prescription only medicine, drug or other substance specified in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations 2001 as amended with the exception of phenobarbital or phenobarbital sodium supplied for use in the treatment of epilepsy; or
  - 36.8.2. Any prescription only medicine that consists or contains a substance specified in Schedule 18 to the Human Medicines Regulations 2012 as amended.
- 36.9. Where a request does not meet the requirements of regulations 225 or 226 (as set out in clause 36.2), the Service Provider will make a judgement as to the urgency of need for the medication and, where appropriate, refer the patient to their GP, or the NHS 111 service to obtain an urgent prescription.
- 36.10. The quantity of a medicine, detailed in column 1, to be supplied must not exceed that shown in column 2 for that medicine:

Column 1 - Medicine	Column 2 - Maximum quantity
A prescription only medicine that- (a) Is a preparation of insulin, an aerosol for the relief of asthma, an ointment or cream, and (b) Has been made up for sale in a package elsewhere than at the place of sale or supply	The smallest pack that the pharmacy has available for sale or supply. <i>e.g. For insulin cartridges the smallest pack constitutes 1 cartridge – not the outer of 5</i>
An oral contraceptive	A quantity sufficient for a single treatment cycle



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An antibiotic for oral administration in liquid form	The smallest quantity that will provide a full course of treatment
A controlled drug within schedule 1, 2 or 3 of the Misuse of Drugs Regulations 2001 (see phenobarbital below)	<b>No supply can be made</b>
A controlled drug within the meaning of Schedule 4 or 5 of the Misuse of Drugs Regulations 2001 or Schedule 4 or 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002.	Five days' treatment.
Phenobarbital or Phenobarbital sodium for the treatment of epilepsy	Five days' supply
Any other medicine that the Service Provider establishes is prescribed regularly for the patient.	A maximum of 30 days' supply

36.11. The quantity supplied shall be at the discretion of the Service Provider, by consideration of:

- 36.11.1. the potential benefits of supplying a medicine in its original pack; and
- 36.11.2. the cost of the medicine; and
- 36.11.3. the potential for the medicine to be misused or misdirected; and
- 36.11.4. any relevant national or local guidance.

### 37. Labelling

37.1. The Service Provider shall ensure that any medicine supplied is labelled with the following:

- 37.1.1. The date on which the medicine was supplied; and
- 37.1.2. The name, quantity and (unless apparent from the name) the pharmaceutical strength of the medicine; and
- 37.1.3. The dose and frequency that the medicine should be used; and
- 37.1.4. The name of the person requesting the medicine; and
- 37.1.5. The name and address of the registered pharmacy from which the medicines is supplied; and
- 37.1.6. The words "Emergency Supply".

### 38. Records

38.1. The Service Provider will ensure that an entry in respect of the emergency supply is made in the record that each pharmacy is required to keep of the supply of prescription only medicines in respect of regulation 253 of the Human Medicines Regulations 2012.

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38.2. The Service Provider shall ensure that the entry is made on the day of supply or if that is not reasonably practicable, on the following day, and that it contains the following:

- 38.2.1. The date on which the prescription only medicine was supplied; and
- 38.2.2. The name, quantity and (unless apparent from the name) the pharmaceutical form and strength of the prescription only medicine; and
- 38.2.3. The name and address of the person requiring the prescription only medicine; and
- 38.2.4. The nature of the emergency.

38.3. The Service Provider shall ensure that details of the supply are recorded in the pharmacy's Patient Medication Record system.

## **39. Provision of the service during a pandemic**

39.1. During periods when a disease is pandemic, or it is anticipated that a disease is imminently pandemic and there is a serious or potentially serious risk to human health, regulation 226 may be used to enable a supply. In such circumstances, the Pharmacist need only be satisfied that:

- 39.1.1. that treatment with the medicine(s) has on a previous occasion been prescribed by a relevant prescriber for the person to be treated with it; and
- 39.1.2. the dose(s), which in the circumstances it would be appropriate for that person to take.

# Seasonal Influenza Vaccination

## 40. Legal authority to supply medicines

**40.1. This component will only be provided where:**

- 40.1.1. an authorised PGD has been issued by the Local Health Board in which the pharmacy is located, and the Service Provider has signed this PGD for that LHB area; or**
- 40.1.2. a relevant National Protocol is in place; or**
- 40.1.3. an accredited Pharmacist Independent Prescriber has issued a PSD.**

## 41. General principles

- 41.1. The pharmacy Contractor will offer influenza immunisation at the pharmacy, or off-site venue, administered by an accredited Service Provider, to patients identified as eligible for vaccination by the Welsh Government.
- 41.2. The pharmacy Contractor shall promote influenza immunisation to eligible patients including providing information (which may be verbal or written) regarding the availability of influenza vaccination from their GP and from the pharmacy.
- 41.3. The Contractor should inform local GP practices as soon as possible that they intend to provide the Seasonal Influenza Vaccination (SIV) service during the relevant season.
- 41.4. Where patients indicate that they have already booked an appointment with their GP for vaccination, they should be encouraged to keep this appointment.

## 42. Patient eligibility

- 42.1. Patients aged 18 years or over who meet one or more of the criteria set out for influenza vaccination in the current season in formal communications from Welsh Government or Local Health Board are eligible for the SIV component of this service.

## 43. Consultations

- 43.1. All patients requesting vaccination under this component of the service will be assessed for their eligibility (see 41.1) and the clinical appropriateness of the selected vaccination before the vaccine is administered.
- 43.2. The Service Provider will only vaccinate a patient where they have a valid legal authority in place for vaccination of that patient. This may be through one of:

- 43.2.1. A Patient Group Direction – this option is only available to Pharmacists, who have signed the relevant PGD.
- 43.2.2. A Patient Specific Direction – this option can only be used where:
  - 43.2.2.1. the patient has been individually assessed as suitable for vaccination by a competent<sup>12</sup> Pharmacist Independent Prescriber; and
  - 43.2.2.2. the Pharmacist Independent Prescriber is present at the time of vaccination); and
  - 43.2.2.3. the registration number of Pharmacist Independent Prescriber who has authorised the administration is recorded within the Choose Pharmacy record for each patient.
- 43.2.3. A National Protocol – this option can only be used where:
  - 43.2.3.1. A National Protocol is in place as part of a national response to a Pandemic; and
  - 43.2.3.2. there is a competent<sup>13</sup> Clinical Supervisor present at the time of vaccination; and
  - 43.2.3.3. the Service Provider has completed a vaccinator competency assessment tool with a competent<sup>13</sup> Healthcare Professional and has been considered competent; and
  - 43.2.3.4. been authorised by name as an approved person under the current terms of the protocol; and
  - 43.2.3.5. the registration number of the Clinical Supervisor in place at the time of vaccination is recorded within the Choose Pharmacy record for each patient.
- 43.3. When providing vaccination in the pharmacy, or off-site, the Contractor shall ensure that the service is only provided from an area that meets the criteria set out in clause 9.2.
- 43.4. When providing vaccinations off-site, the Contractor must ensure that each of the points listed in section 46 are considered. Further, they must ensure that there are appropriate procedures in place to enable the safe transfer of vaccines (including maintenance of the cold chain), patient records, and clinical waste and sharps between the pharmacy and the premises where the service is provided.

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<sup>12</sup> In order to be considered competent in this respect, the Pharmacist must have met the criteria set out in clause 8.1 and have submitted a signed copy of the PGD for the health board in which they are operating to the NHS Wales Shared Services Partnership

<sup>13</sup> For the purposes of this specification, the Clinical Supervisor must be a Pharmacist that has met the criteria set out in clause 8.1 and submitted a signed copy of the PGD for the health board in which they are operating to the NHS Wales Shared Services Partnership

- 43.5. To facilitate the provision of “flu clinics” by pharmacy Contractors, the service may be provided in the pharmacy or off-site, outside of normal pharmacy opening hours. In all cases, the standards for service provision remain as laid out in this document.
- 43.6. The Contractor will ensure that all Pharmacy Staff involved in providing this component of the service have been offered vaccination against Hepatitis B.

#### **44. Pharmacists with needle phobia**

- 44.1. The following considerations must be made where a Pharmacist has needle phobia:
  - 44.1.1. Before arranging a locum booking/employment, both the Contractor and Pharmacists with needle phobia must consider the ease with which a user of the pharmacy would be able to access advice influenza vaccination from another Service Provider locally if it were not to be available in this pharmacy. For example, in locations that are more rural, other services are less likely to be available and there is an increased risk that an individual requesting the service would not be able to access it in a timely manner.
  - 44.1.2. Pharmacists with a needle phobia may consider completing training and becoming accredited for the service in order to support other Pharmacy Staff to actually administer vaccines under clauses 43.2.2 and 43.2.2.3

#### **45. Training and accreditation**

- 45.1. In addition to the requirements set out in clause 8.1, Service Providers of this component must submit one of the following to the NHS Wales Shared Services Partnership:
  - 45.1.1. signed copy of the PGD for this service (Pharmacists ONLY); or
  - 45.1.2. a copy of the Declaration for Service Providers of the Seasonal Influenza Vaccination.

#### **46. Vaccination off premises**

- 46.1. When providing vaccination services away from the pharmacy premises the Contractor must ensure that information governance, infection prevention and control, and clinical governance are carefully considered to ensure the safe and effective delivery of the service. In particular, the following must be in place:
  - 46.1.1. Appropriate transportation arrangements to maintain the vaccine cold chain in line with the requirements of the relevant Summary of Product Characteristics; and
  - 46.1.2. Immunisation will be carried out by a Service Provider meeting the accreditation requirements set out in Sections 8 and 45; and

## Section: Seasonal Influenza Vaccination

- 46.1.3. Appropriate hygiene and infection prevention measures will be in place; and
- 46.1.4. Appropriate personal protective equipment will be available; and
- 46.1.5. Appropriate arrangements are in place for clinical record documentation; and
- 46.1.6. Appropriate arrangements for the management of anaphylaxis will be in place, including adrenaline and emergency telephone access; and
- 46.1.7. Appropriate arrangements for the management of clinical waste will be in place (including transportation back to the pharmacy) and that these are in line with relevant hazardous waste regulations; and
- 46.1.8. Suitable indemnity insurance arrangements will be in place; and
- 46.1.9. Information is provided to the patients GP in a timely fashion; and
- 46.1.10. Choose Pharmacy flu vaccination records are updated on the same or, where Choose Pharmacy cannot be used at the off-site location, no later than the next working day following vaccination.