

WG22-06

**THE NATIONAL HEALTH
SERVICE (WALES) ACT 2006**

**The Pharmaceutical Services
(Clinical Services) (Wales)
Directions 2022**

Made 4 March 2022

Coming into force 1 April 2022

The Welsh Ministers, in exercise of the powers conferred by sections 12(3), 81, 82 and 203(9) and (10) of the National Health Service (Wales) Act 2006(1), give the following Directions.

Title, commencement and application

1.—(1) The title of these Directions is the Pharmaceutical Services (Clinical Services) (Wales) Directions 2022.

(2) These Directions come into force on 1 April 2022.

(3) These Directions are given to Local Health Boards.

Interpretation

2.—(1) In these Directions—

“the Act” means the National Health Service (Wales) Act 2006;

“approved” means approved by the Welsh Ministers;

“Choose Pharmacy” means the electronic system used by NHS pharmacists to create a Choose Pharmacy Record;

“Choose Pharmacy Record” means the patient record kept by an NHS pharmacist who, in accordance with an arrangement made with a

Local Health Board, provides a service specified in these Directions;

“clinical management plan” means a written plan relating to the treatment of an individual patient that is agreed by—

- (a) the patient,
- (b) the doctor or dentist who is a party to the plan, and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

“drug misuser” means a person who misuses drugs by self-injection;

“enhanced criminal record certificate” means an enhanced criminal record certificate issued under section 113B(1) of the Police Act 1997⁽¹⁾ which includes, in such cases as are from time to time prescribed under section 113BA(1)⁴ of that Act, suitability information relating to children or vulnerable adults, and any relevant up-date information where such a certificate is subject to up-date arrangements;

“financial year” means a year ending with 31 March;

“gluten free foods” means only those gluten free foods that are specified in list A of Part XV (borderline substances) of the Drug Tariff;

“GMS contract essential services” means the services required to be provided by GMS contractors in accordance with regulation 15 of the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004⁽²⁾;

“Human Medicines Regulations” means the Human Medicines Regulations 2012⁽³⁾;

“independent prescriber” means a—

- (a) doctor or dentist who is a party to a clinical management plan with a supplementary prescriber,
- (b) dispensing doctor,
- (c) independent nurse prescriber,
- (d) nurse independent prescriber,
- (e) optometrist independent prescriber,
- (f) paramedic independent prescriber,
- (g) pharmacist independent prescriber,
- (h) physiotherapist independent prescriber,

(1) 1997 c. 50.
(2) S.I. 2004/478 (W. 48).
(3) S.I. 2012/1916.

- (i) podiatrist or chiropodist independent prescriber, or
- (j) therapeutic radiographer independent prescriber;

“NECAF” means the National Electronic Claim and Audit Form, the electronic system used by NHS pharmacists to submit claims for remuneration for the provision of NHS services;

“NHS body” has the meaning given by regulation 213 of the Human Medicines Regulations;

“notify” means to notify in writing and includes electronic communications;

“NWSSP” means NHS Wales Shared Services Partnership, established by the Velindre National Health Service Trust Shared Services Committee (Wales) Regulations 2012(1), which is responsible for exercising functions of Velindre University NHS Trust in relation to shared services, policy and strategy, and the management and provision of shared services to the health service in Wales;

“out of hours period” means, in relation to a pharmacy, the days and times at which the pharmacy is not obliged to remain open under paragraph 23 (pharmacy opening hours: general) of Schedule 5 to the Pharmaceutical Services Regulations;

“patient care record” means the patient records kept by the person who is providing the patient with GMS contract essential services, or their equivalent;

“pharmaceutical essential services” has the meaning given to “essential services” in regulation 2(1) of the Pharmaceutical Services Regulations;

“Pharmaceutical Services Regulations” means the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020(2);

“pharmacy technician” means a person registered in Part 2 of the General Pharmaceutical Council Register.

(2) Expressions used in these Directions and in the Pharmaceutical Services Regulations have the same meaning as in those Regulations.

General matters and pre-conditions for making arrangements

3.—(1) Where a Local Health Board makes arrangements with an NHS pharmacist for the provision of any of the clinical services specified in

(1) S.I. 2012/1261 (W. 156).

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

directions 4 to 8, the NHS pharmacist must satisfy the conditions set out in paragraphs (2) to (7).

(2) The first condition is that the NHS pharmacist has notified the Local Health Board of their intention to provide the relevant clinical service, in the manner approved⁽¹⁾ for that purpose, and provided the Local Health Board with a satisfactory enhanced criminal record certificate.

(3) The second condition is that the NHS pharmacist is satisfactorily complying with their obligations under Schedule 5 to the Pharmaceutical Services Regulations in connection with the provision of pharmaceutical services.

(4) The third condition is that—

- (a) if the NHS pharmacist is a registered pharmacist, they must complete all approved training required in order to provide the services which form part of the relevant clinical service;
- (b) if the NHS pharmacist is a registered pharmacist and they intend to employ or engage a registered pharmacist or pharmacy technician to provide services which form part of a clinical service, that registered pharmacist or pharmacy technician must complete all approved training required in order to provide the services which form part of the relevant clinical service; or
- (c) if the NHS pharmacist is a body corporate or partnership, any registered pharmacist or pharmacy technician they intend to employ or engage to provide any services which form part of a clinical service must complete all approved training required in order to provide services as part of the relevant clinical service.

(5) The fourth condition is that—

- (a) if the NHS pharmacist is a registered pharmacist, they must complete [in the approved manner the approved form] warranting that they are competent to provide the services which form the relevant clinical service;
- (b) if the NHS pharmacist is a registered pharmacist and they intend to employ or engage a registered pharmacist or pharmacy technician to perform services which form part of a clinical service, that registered pharmacist or pharmacy technician must

(1) The approved forms for the clinical services can be accessed at:
<http://www.wales.nhs.uk/ourservices/directory/LocalHealthBoards>

complete in the approved manner the approved form warranting that they are competent to provide those services; or

- (c) if the NHS pharmacist is a body corporate or partnership, any registered pharmacist or pharmacy technician they intend to employ or engage to provide any services which form part of a clinical service must complete in the approved manner the approved form warranting that they are competent to provide those services.

(6) The fifth condition is that the NHS pharmacist has in place, at the pharmacy at, or from, which services which form part of the relevant clinical service are to be provided, a standard operating procedure for the delivery of the service—

- (a) which has been notified to all pharmacy staff,
- (b) which explains the clinical service, its eligibility criteria and the roles that pharmacy staff may be required to perform as part of its delivery, and
- (c) about which pharmacy staff have received appropriate training, if there is any role that they may be required to perform as part of the service.

(7) The sixth condition, subject to paragraph (8), is that the clinical services provided under any arrangement are provided at an acceptable location, and in this direction, “acceptable location” means an area for confidential consultations at the NHS pharmacist’s pharmacy premises, which is—

- (a) clearly designated as an area for confidential consultations,
- (b) distinct from the general public areas of the pharmacy premises, and
- (c) is an area where both the person receiving services and the registered pharmacist or pharmacy technician providing those services are able to sit down together and talk at normal speaking volume without being overheard by any other person (including other pharmacy staff).

(8) A registered pharmacist or pharmacy technician who is, or who is employed or engaged by, the NHS pharmacist may provide services other than at the acceptable location at the NHS pharmacist’s pharmacy premises if that registered pharmacist or pharmacy technician does so—

- (a) by telephone, or video call or in person at a location other than the pharmacy premises in order to provide services to a particular patient on a particular occasion,

- (b) with the agreement of that patient, that patient having expressed a preference for that contact to be by telephone, or video call or at a location other than the pharmacy premises on that occasion, and
- (c) in circumstances where—
 - (i) the registered pharmacist or pharmacy technician is at the NHS pharmacist’s pharmacy, and
 - (ii) the conversation cannot be overheard (except by someone who the patient wants to hear the conversation, for example, a carer); or
 - (iii) the provision of services takes place in a location other than the NHS pharmacy premises, with the consent of the Local Health Board.

The Discharge Medicines Review Service

4.—(1) Each Local Health Board must make arrangements for the provision of a discharge medicine review (“DMR”) service, for persons within and outside its area, with NHS pharmacists included in its pharmaceutical list who—

- (a) wish to enter into such arrangements and notify the Local Health Board of their intention to provide the DMR service in accordance with direction 3(2), and
- (b) satisfy the conditions set out in direction 3, paragraphs (3) to (7) inclusive, and
- (c) agree to provide the DMR service in accordance with the relevant specification⁽¹⁾.

(2) The underlying purpose of the DMR service is, with the patient’s agreement, to contribute to a reduction in risk of medication errors and adverse drug events by, in particular—

- (a) increasing the availability of accurate information about a patient’s medicines,
- (b) improving communication between health care professionals and others involved in the transfer of patient care, and patients and their carers,
- (c) increasing patient involvement in their own care by helping them to develop a better understanding of their medicines, and
- (d) reducing the likelihood of unnecessary duplicated prescriptions being dispensed, and reducing wastage of medicines.

(1) <https://nwssp.nhs.wales/ourservices/primary-care-services/our-services/pharmacy-services/all-wales-pharmacy-database/>

5.—(1) Prior to entering into arrangements with an NHS pharmacist for the provision of the DMR service under direction 4, a Local Health Board must satisfy itself those arrangements provide that—

- (a) only a registered pharmacist or pharmacy technician, who has completed in the approved manner the approved form warranting that they are competent to provide Part 1 and Part 2 services as part of the DMR service, is to provide those services;
- (b) Part 1 and Part 2 services provided as part of the DMR service are to be provided at an acceptable location at the NHS pharmacist's pharmacy premises, within the meaning given by direction 3(7) except in the circumstances provided for by direction 3(8);
- (c) the NHS pharmacist may only offer the provision of the DMR service—
 - (i) to persons who have been discharged from one care setting to another within the previous 4 weeks,
 - (ii) for whom the pharmacy has received a copy of an advice note regarding the patient's medicines issued by the care setting from which the patient has been discharged, and—
 - (aa) a change has occurred to the patient's medicines prior to the patient being discharged,
 - (bb) the patient is taking 4 or more medicines,
 - (cc) the patient requires a reasonable adjustment to be made to the presentation of their medicines, or
 - (dd) the registered pharmacist or pharmacy technician has, in their professional opinion, reason to consider that the patient would benefit from the service, and
 - (iii) if the NHS pharmacist, or a pharmacy technician employed or engaged by the NHS pharmacist, providing the DMR service has obtained consent to receiving DMR services from the patient to whom the registered pharmacist or pharmacy technician provides those services, which amongst other matters indicates that the patient has either consented or does not consent to particular information, relating to DMR services provided to the patient, being handled in the manner specified by the Welsh Ministers (for example, the purpose of post payment verification).

- (d) the registered pharmacist or pharmacy technician—
 - (i) must maintain a record of any consent obtained under sub-paragraph (c)(iii),
 - (ii) must not provide Part 1 or Part 2 services to a patient unless the patient has consented to receive those services in accordance with sub-paragraph (c)(iii), and
 - (iii) may only process the information, including the patient's personal data, in the manner for which the patient has provided their consent in accordance with sub-paragraph (c)(iii);
- (e) the Part 1 services that are to be provided by the registered pharmacist or pharmacy technician as part of the DMR service must comprise—
 - (i) providing the patient with sufficient information about the DMR service to enable that patient to give their informed consent to receiving the service,
 - (ii) a discussion with the patient about the medicines the patient is taking,
 - (iii) identification by the registered pharmacist or pharmacy technician providing the service of any discrepancies between the medicines the patient is taking and those prescribed at discharge, and
 - (iv) agreement, where possible, between the registered pharmacist or pharmacy technician and the patient of the next steps, that is—
 - (aa) if no discrepancies between the medicines the patient is taking and those prescribed at discharge, agreeing with the patient a time and location for the provision of Part 2 services to the patient,
 - (bb) if any discrepancies or problems are identified under sub-paragraph (e)(iii) and it is the clinical judgment of the registered pharmacist or pharmacy technician that intervention by a general practitioner is required, explaining that to the patient, completing the approved DMR feedback form and referring the matter to the general practitioner with whom the patient is a registered patient,
 - (cc) if any discrepancies or problems are identified under sub-paragraph

- (e)(iii) but it is the clinical judgement of the registered pharmacist or pharmacy technician that intervention by a general practitioner is not required, agreeing with the patient a time and location for the provision of Part 2 services to that patient, and any remedial steps to be taken prior to that intervention;
- (f) the Part 2 services that are to be provided by the registered pharmacist or pharmacy technician as part of the DMR service must comprise—
- (i) a discussion with the patient about the medicines the patient is taking,
 - (ii) an assessment by the registered pharmacist or pharmacy technician performing the Part 2 services of the extent to which any discrepancies between the medicines the patient is taking and those prescribed at discharge have been resolved,
 - (iii) if any problems are identified under sub-paragraph (f)(ii) and it is the clinical judgement of the registered pharmacist or pharmacy technician that intervention by a general practitioner is required, explaining that to the patient, completing the approved DMR feedback form and referring the matter to the general practitioner with whom the patient is a registered patient;
- (g) the registered pharmacist or pharmacy technician ensures that the Choose Pharmacy Record is updated as soon as reasonably practicable after each consultation has been carried out by or on behalf of the NHS pharmacist as part of the DMR service and includes the approved data;
- (h) the NHS pharmacist provides information from the Choose Pharmacy Record to the Local Health Board and Digital Health and Care Wales⁽¹⁾; and
- (i) the NHS pharmacist keeps a copy of the record mentioned in sub-paragraph (g) for at least 2 years, beginning with the date on which the service intervention is completed or discontinued.

(1) Digital Health and Care Wales is a Special Health Authority established under section 22 of the National Health Service (Wales) Act 2006 by the Digital Health and Care Wales (Establishment and Membership) Order 2020 (S.I. No. 1451).

(2) For the purposes of sub-paragraphs (1)(e) and (f), provision to a patient of the DMR service has been completed—

- (a) once a patient has received the Part 1 and, if necessary, Part 2 services, or
- (b) if, as a consequence of an act or omission of the patient, the patient does not receive the Part 2 services at the agreed time and the NHS pharmacist is unable, having made reasonable efforts to do so, to rearrange and provide those Part 2 services on another occasion, once those reasonable efforts have been made.

The Clinical Community Pharmacy Service

6.—(1) Each Local Health Board must make arrangements for the provision of the Clinical Community Pharmacy Service services specified in paragraph (2), for persons within and outside its area, with NHS pharmacists included in its pharmaceutical list who—

- (a) wish to enter into such arrangements and notify the Local Health Board of their intention to provide the Clinical Community Pharmacy Service in accordance with direction 3(2),
- (b) satisfy the conditions set out in direction 3, paragraphs (3) to (7) inclusive, and
- (c) agree to provide the Clinical Community Pharmacy Service in accordance with the relevant specification(1).

(2) An arrangement to provide the Clinical Community Pharmacy Service must include the provision by the NHS pharmacist of—

- (a) a Common Ailment Service, the underlying purpose of which is for the registered pharmacist to provide advice and support to eligible patients complaining of a common ailment, and where appropriate, to supply drugs to them for the treatment of the common ailment;
- (b) an Urgent Contraception Service, the underlying purpose of which is for the registered pharmacist to supply contraception in cases of urgency or emergency, or to supply regular contraception, to a patient under a Patient Group Direction(2);

(1) <https://nwssp.nhs.wales/ourservices/primary-care-services/our-services/pharmacy-services/all-wales-pharmacy-database/>

(2) Patient Group Directions allow health care professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription.

- (c) a Seasonal Influenza Vaccination Service, the underlying purpose of which is for the registered pharmacist to administer an influenza vaccination to a patient under a Patient Group Direction, or a protocol authorised by Welsh Ministers in accordance with regulation 247A of the Human Medicines Regulations (Protocols relating to coronavirus and influenza vaccinations and immunisations);
- (d) an Emergency Medicine Supply Service, the underlying purpose of which is to ensure, at the request of a patient in cases of urgency, prompt access to drugs or appliances—
 - (i) which have previously been prescribed for them in an NHS prescription but for which they do not have an NHS prescription, and
 - (ii) where, in the case of prescription only medicines, the requirements of regulation 225(1) of the Human Medicines Regulations (emergency sale etc. by Pharmacist: at patient’s request) are satisfied.

The Pharmacy Independent Prescribing Service

7.—(1) Each Local Health Board must make arrangements for the provision of the Pharmacy Independent Prescribing Service, for persons within and outside its area, with NHS pharmacists who are independent prescribers, or NHS pharmacists who intend to employ or engage an independent prescriber to deliver the service on their behalf, included in its pharmaceutical list and who—

- (a) are providing the Clinical Community Pharmacy Service under an arrangement with a Local Health Board in accordance with direction 6,
- (b) wish to enter into an arrangement to provide the Pharmacy Independent Prescribing Service and notify the Local Health Board of their intention to do so in accordance with direction 3(2),
- (c) satisfy the conditions set out in direction 3, paragraphs (3) to (7) inclusive, and
- (d) agree to provide the Pharmacy Independent Prescribing Service in accordance with the relevant specification⁽¹⁾.

(1) <https://nwssp.nhs.wales/ourservices/primary-care-services/our-services/pharmacy-services/all-wales-pharmacy-database/>

(2) The underlying purposes of the Pharmacy Independent Prescribing Service are—

- (a) to provide access to prescription only medicines for the treatment of common ailments that require treatment with prescription only medicines that are not available under the Clinical Community Pharmacy Service;
- (b) to provide access to emergency or regular contraception where those needs cannot be met under the Clinical Community Pharmacy Service; and
- (c) for the provision of any other service which the NHS pharmacist agrees with the relevant Local Health Board to provide.

Additional services

8.—(1) Each Local Health Board may make arrangements for the provision of the additional pharmaceutical services specified in paragraph (2), to persons within or outside its area, with NHS pharmacists included in its pharmaceutical list, or in the pharmaceutical list of a neighbouring Local Health Board, who—

- (a) wish to enter into an arrangement to provide an additional service specified in paragraph (2) and notify the Local Health Board of their intention to do so in accordance with direction 3(2),
- (b) satisfy the conditions set out in direction 3, paragraphs (3) to (7) inclusive, and
- (c) agree, where applicable, to provide that additional service in accordance with the relevant specification⁽¹⁾.

(2) The additional pharmaceutical services specified are—

- (a) an Anticoagulant Monitoring Service, the underlying purpose of which is for the NHS pharmacist to test the patient's blood clotting time, review the results and adjust (or recommend an adjustment to) the anticoagulant dose accordingly;
- (b) a Care Home Service, the underlying purpose of which is for the NHS pharmacist to provide advice and support to residents and staff in a care home relating to—

(1) <https://nwssp.nhs.wales/ourservices/primary-care-services/our-services/pharmacy-services/all-wales-pharmacy-database/>

- (i) the proper and effective ordering of drugs and appliances for the benefit of residents in the care home,
 - (ii) the clinical and cost-effective use of drugs,
 - (iii) the proper and effective administration of drugs and appliances in the care home,
 - (iv) the safe and appropriate storage and handling of drugs and appliances, and
 - (v) the recording of drugs and appliances ordered, handled, administered, stored or disposed of;
- (c) a Disease Specific Management Service, the underlying purpose of which is for the NHS pharmacist to advise on, support and monitor the treatment of patients with specified conditions, and where appropriate, to refer the patient to another health care professional;
- (d) an Emergency Pandemic Treatment and Prophylaxis Supply Service—
- (i) the underlying purpose of which is for the NHS pharmacist to supply medicines to a patient under a Patient Group Direction or protocol authorised by Ministers or an NHS body in accordance with regulation 247 of the Human Medicines Regulations (exemption for supply in the event or anticipation of pandemic disease), and
 - (ii) if an NHS pharmacist arranges to provide this service, it must provide it for the duration of the arrangement it has agreed with the Local Health Board;
- (e) an Emergency Pandemic Vaccination Service—
- (i) the underlying purpose of which is for the NHS pharmacist to administer a vaccination to a patient under a Patient Group Direction or protocol authorised by the Welsh Ministers in accordance with regulation 247A of the Human Medicines Regulations (protocols relating to coronavirus and influenza vaccinations and immunisations), and
 - (ii) if an NHS pharmacist arranges to provide this service, it must provide it for the duration of the arrangement it has agreed with the Local Health Board;
- (f) a Gluten Free Food Supply Service, the underlying purpose of which is for the NHS pharmacist to supply gluten free foods to patients;

- (g) a Home Delivery Service, the underlying purpose of which is for the NHS pharmacist to deliver to patients' homes—
 - (i) drugs, and
 - (ii) appliances, other than specified appliances within the meaning of regulation 2(1) of the Pharmaceutical Services Regulations;
- (h) a Language Access Service, the underlying purpose of which is for the NHS pharmacist to provide, either orally or in writing, advice and support to patients in a language understood by them in relation to—
 - (i) drugs which they are using,
 - (ii) their health,
 - (iii) general health matters relevant to them, and
 - (iv) where appropriate, refer the patient to another health care professional;
- (i) a Medication Review Service, the underlying purpose of which is for the NHS pharmacist to—
 - (i) conduct a review of the drugs used by a patient on the basis of information and test results included in the patient's patient care record, with the objective of considering the continued appropriateness and effectiveness of the drugs for the patient,
 - (ii) advise and support a patient regarding the use of their drugs including encouraging the active participation of the patient in decision making relating to their use of drugs, and
 - (iii) where appropriate, refer the patient to another health care professional;
- (j) a Medicines Assessment and Compliance Support Service, the underlying purpose of which is for the NHS pharmacist to—
 - (i) assess the knowledge of, compliance with and use of, drugs by vulnerable patients and patients with additional learning needs, and
 - (ii) offer advice, support and assistance to vulnerable patients and patients with additional learning needs⁽¹⁾ regarding the use of drugs with a view to improving the patient's knowledge of, compliance with and use of, such drugs;

(1) As defined in section 2 of the Additional Learning Needs and Education Tribunal (Wales) Act 2018 (anaw. 2).

- (k) a Needle and Syringe Supply Service, the underlying purpose of which is for the NHS pharmacist to—
 - (i) provide sterile needles, syringes and associated materials to drug misusers,
 - (ii) receive from drug misusers used needles, syringes and associated materials, and
 - (iii) offer advice to drug misusers and where appropriate refer the drug misuser to another health care professional or a specialist drug treatment centre;
- (l) an On Demand Availability of Specialist Drugs Service, the underlying purpose of which is for the NHS pharmacist to ensure that patients or health care professionals have prompt access to specialist drugs;
- (m) an Out of Hours Service, the underlying purpose of which is for the NHS pharmacist to dispense drugs and appliances in the out of hours period (whether or not for the whole of the out of hours period);
- (n) a Patient Group Direction Service, the underlying purpose of which is for the NHS pharmacist to supply or administer prescription only medicines to patients under Patient Group Directions;
- (o) a Prescriber Support Service, the underlying purpose of which is for the NHS pharmacist to support health care professionals who prescribe drugs, and in particular to offer advice on—
 - (i) the clinical and cost-effective use of drugs,
 - (ii) prescribing policies and guidelines, and
 - (iii) repeat prescribing;
- (p) a Schools Service, the underlying purpose of which is for the NHS pharmacist to provide advice and support to children and staff in schools relating to—
 - (i) the clinical and cost-effective use of drugs in a school,
 - (ii) the proper and effective administration and use of drugs and appliances in a school,
 - (iii) the safe and appropriate storage and handling of drugs and appliances, and
 - (iv) the recording of drugs and appliances ordered, handled, administered, stored or disposed of;
- (q) a Screening Service, the underlying purpose of which is for the NHS pharmacist to—

- (i) identify patients at risk of developing a specified disease or condition,
 - (ii) offer advice regarding testing for a specified disease or condition,
 - (iii) carry out such a test with the patient's consent, and
 - (iv) offer advice following a test and refer the patient to another health care professional where appropriate;
- (r) a Stop Smoking Service, the underlying purpose of which is for the NHS pharmacist to—
- (i) advise and support patients wishing to give up smoking, and
 - (ii) where appropriate, to supply appropriate drugs and aids;
- (s) a Supervised Administration Service, the underlying purpose of which is for the NHS pharmacist to supervise the administration of prescribed medicines in the pharmacy;
- (t) a Prescribing Service, the underlying purpose of which is for the NHS pharmacist who is an independent prescriber, or who employs or engages an independent prescriber, to prescribe medicines in circumstances specified by the relevant Local Health Board;
- (u) an Anti-viral Collection Service, the underlying purpose of which is for the NHS pharmacist to supply anti-viral medicines, in accordance with regulation 247 of the Human Medicines Regulations (Exemption for supply in event of or in anticipation of pandemic disease), to patients for treatment or prophylaxis; and
- (v) a Waste Minimisation Service, the underlying purpose of which is to identify prescribed medicines or appliances which are not required by the patient at the point of supply.

(3) The Local Health Board may terminate an arrangement made under paragraph (2) if, in the opinion of the Local Health Board, the NHS pharmacist is not, or no longer, satisfactorily complying with their obligations under Schedule 5 to the Pharmaceutical Services Regulations in connection with the provision of pharmaceutical services.

Payment for provision of clinical services

9. The Local Health Board must make payments to an NHS pharmacist who provides services under an arrangement made pursuant to these Directions in accordance with—

- (a) Part VID of the Drug Tariff, for the provision of the DMR service, the Clinical Community Pharmacy Service or Pharmacy Independent Prescribing Service, and
- (b) Part VIE of the Drug Tariff, for the provision of any other service.

Conditions of payment

10.—(1) A payment under these Directions is only payable if an NHS pharmacist, in respect of each person for which a payment under these Directions is claimed in accordance with the arrangements for claiming payments set out in Parts VID and VIE of the Drug Tariff, has supplied the Local Health Board via Choose Pharmacy, NECAF (where the relevant Choose Pharmacy module is not available), or an alternative mechanism agreed between the NHS pharmacist and Local Health Board, with—

- (a) the name of the person,
- (b) the date of birth of the person,
- (c) the NHS number of the person, where it is known, and
- (d) the date on which the service has been provided to the person.

(2) The Local Health Board may request from an NHS pharmacist any information which the Local Health Board does not have but needs, and the NHS pharmacist either has or could be reasonably expected to obtain, in order for the Local Health Board to form an opinion on whether the NHS pharmacist is entitled to a payment under these Directions.

(3) The Local Health Board may, in appropriate circumstances, withhold payment of any, or any part of, payments due under these Directions if an NHS pharmacist breaches any of these conditions.

Overpayments and withheld amounts

11.—(1) If a Local Health Board makes a payment to an NHS pharmacist pursuant to these Directions and—

- (a) the NHS pharmacist was not entitled to receive all or part thereof, whether because it did not meet the entitlement conditions for the payment or because the payment was calculated incorrectly (including where a payment on account overestimates the amount that is to fall due);
- (b) the Local Health Board was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money has already been paid; or

(c) the Local Health Board is entitled to repayment of all or part of the money paid, regulation 57 of the Pharmaceutical Services Regulations applies and the Local Health Board may recover the money paid by deducting an equivalent amount from any payment payable under these Directions or any other payment payable to an NHS pharmacist in accordance with the Drug Tariff and by virtue of its provision of NHS services, and where no such deduction can be made, it is a condition of the payments made pursuant to these Directions that the NHS pharmacist must pay to the Local Health Board that equivalent amount.

(2) Where a Local Health Board is entitled pursuant to paragraph (1) to withhold all or part of a payment because of a breach of a payment condition, and the Local Health Board does so or recovers the money by deducting an equivalent amount from another payment payable under these Directions or any other payment payable to an NHS pharmacist in accordance with the Drug Tariff and by virtue of its provision of NHS services, it may, where it sees fit to do so, reimburse the NHS pharmacist the amount withheld or recovered, if the breach is remedied.

Underpayments and late payments

12.—(1) If the full amount of a payment that is payable under these Directions has not been paid before the date on which the payment falls due, once it falls due, it must be paid promptly unless—

- (a) this is with the consent of the NHS pharmacist, or
- (b) the amount of, or entitlement to, the payment, or any part thereof, is in dispute.

(2) If the NHS pharmacist's entitlement to the payment is not in dispute but the amount of the payment is in dispute, then once the payment falls due, pending the resolution of the dispute, the Local Health Board must—

- (a) pay to the NHS pharmacist, promptly, an amount representing the amount that the Local Health Board accepts that the NHS pharmacist is at least entitled to, and
- (b) thereafter pay any shortfall promptly, once the dispute is finally resolved.

(3) However, if an NHS pharmacist has—

- (a) not claimed a payment to which it would be entitled under these Directions if it claimed the payment, or
- (b) claimed a payment to which it is entitled under these Directions but a Local Health Board is unable to calculate the payment until after the payment is due to fall due because it

does not have the information it needs in order to calculate that payment (all reasonable efforts to obtain the information having been undertaken),

that payment is (instead) to fall due on the first working day of the month after the month during which the Local Health Board obtains the information it needs in order to calculate the payment.

Payments on account

13. Where a Local Health Board and the NHS pharmacist agree (but the Local Health Board's agreement may be withdrawn where it is reasonable to do so and if it has given the NHS pharmacist reasonable notice thereof), the Local Health Board must pay to an NHS pharmacist on account any amount that is—

- (a) the amount of, or a reasonable approximation of the amount of, a payment that is due to fall due under these Directions, or
- (b) an agreed percentage of the amount of, or a reasonable approximation of the amount of, a payment that is due to fall due under these Directions, and if that payment results in an overpayment in respect of the payment, direction 11 applies.

Post payment verification

14. Post payment verification⁽¹⁾ applies to the provision of services under arrangements made pursuant to these Directions.

Dispute resolution

15.—(1) In the case of a dispute (other than in relation to an overpayment, in which case regulation 57(1)(b) of the Pharmaceutical Services Regulations applies) arising out of, or in connection with, the provision of services under these Directions, the NHS pharmacist and the Local Health Board must make every reasonable effort to communicate and cooperate with each other with a view to resolving the dispute, before referring the dispute for consideration and determination to the Welsh Ministers in accordance with the dispute resolution procedure (or, where applicable, before commencing court proceedings) specified in paragraphs (2) to (15) below.

(1) For more information on post payment verification, please see: <https://nwssp.nhs.wales/ourservices/primary-care-services/general-information/post-payment-verification-ppv/>

(2) The procedure specified in the following paragraphs applies in the case of any dispute arising out of or in connection with the provision of services under these Directions which is referred to the Welsh Ministers.

(3) Any party wishing to refer a dispute as mentioned in paragraph (2) must send to the Welsh Ministers a written request for dispute resolution which must include or be accompanied by—

- (a) the names and addresses of the parties to the dispute,
- (b) a copy of any arrangement made under these Directions, and
- (c) a brief statement describing the nature and circumstances of the dispute.

(4) Any party wishing to refer a dispute as mentioned in paragraph (2) must send the request under paragraph (3) within a period of 3 years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(5) The Welsh Ministers may determine the dispute themselves or, if the Welsh Ministers consider it appropriate, appoint a person or persons to consider and determine it.

(6) Before reaching a decision as to who should determine the dispute, under paragraph (5), the Welsh Ministers must, within 7 days beginning with the date on which a matter under dispute was referred to them, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter under dispute.

(7) The Welsh Ministers must give, with the notice given under paragraph (6), to the party other than the one which referred the matter to dispute resolution a copy of any document by which the matter was referred to dispute resolution.

(8) The Welsh Ministers must give a copy of any representation received from a party to the other party and must in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

(9) Following receipt of any representations from the parties or, if earlier at the end of the period for making such representations specified in the request sent under paragraph (6) or (8), the Welsh Ministers must, if they decide to appoint an adjudicator to hear the dispute—

- (a) inform the parties in writing of the name of the person or persons whom they have appointed, and

- (b) pass to the adjudicator any documents received from the parties under paragraph (3), (6) or (8).

(10) For the purpose of assisting the Welsh Ministers or the adjudicator, as the case may be, in the consideration of the matter, the Welsh Ministers or the adjudicator may—

- (a) invite representatives of the parties to appear before them to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which the Welsh Ministers or the adjudicator wish them to give special consideration, or
- (b) consult other persons whose expertise the Welsh Ministers or the adjudicator consider would assist in the consideration of the matter.

(11) Where the Welsh Ministers or the adjudicator consult another person under paragraph (10)(b), the Welsh Ministers or the adjudicator must notify the parties accordingly in writing and, where the Welsh Ministers or the adjudicator consider that the interests of any party might be substantially affected by the result of the consultation, they must give to the parties such opportunity as they consider reasonable in the circumstances to make observations on those results.

(12) In considering the matter, the Welsh Ministers or the adjudicator must consider—

- (a) any written representations made in response to a request under paragraph (6), but only if they are made within the specified period;
- (b) any written observations made in response to a request under paragraph (8), but only if they are made within the specified period;
- (c) any oral representations made in response to an invitation under paragraph (10)(a);
- (d) the results of any consultation under paragraph (10)(b); and
- (e) any observations made in accordance with an opportunity given under paragraph (11).

(13) Subject to the other provisions within this direction and to any agreement by the parties, the Welsh Ministers or the adjudicator, as the case may be, have wide discretion in determining the procedure for the resolution of the dispute to ensure the just, expeditious, economical and final determination of the dispute.

(14) The determination of the Welsh Ministers or the adjudicator, as the case may be, and the reasons for it, must be recorded in writing and the Welsh Ministers or

the adjudicator must give notice of the determination (including the record of the reasons) to the parties.

(15) In this direction—

“adjudicator” (“*dyfarnwr*”) means the person or persons appointed by the Welsh Ministers under paragraph (5);

“specified period” (“*cyfnod penodedig*”) means such period as the Welsh Ministers specify in a request, being not less than 2, nor more than 4, weeks beginning with the date on which the notice referred to is given, but the Welsh Ministers may, if they consider that there is good reason for doing so, extend any such period (even after it has expired) and, where they do so, a reference in this paragraph to the specified period is to the period as so extended.

Consequential amendments, revocations and savings

16. The Schedule provides for consequential amendments and revocations.

17.—(1) An arrangement entered into by a Local Health Board and NHS pharmacist under direction 4 of the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) Directions 2005 continues to apply as if it were made under direction 8 of these Directions, subject to paragraph (2).

(2) An arrangement for the provision of the Minor Ailment Scheme, the Patient Group Direction Service or the Emergency Supply Service, entered into by a Local Health Board and NHS pharmacist under direction 4 of the Pharmaceutical Services (Advanced and Enhanced Services) (Wales) Directions 2005, continues to apply as if it were made under direction 8 of these Directions until 1 April 2022 when any such arrangement expires.



Signed by Andrew Evans, Chief Pharmaceutical Officer under the authority of the Minister for Health and Social Services, one of the Welsh Ministers

Date: 4 March 2022

Consequential amendments and
revocations

- 1) The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) Directions 2005 are revoked.
- 2) The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2006(1) are revoked.
- 3) The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2008(2) are revoked.
- 4) The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2011(3) are revoked.
- 5) The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2013(4) are revoked.
- 6) The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2014(5) are revoked.
- 7) The Pharmaceutical Services (Advanced and Enhanced Services) (Wales) (Amendment) Directions 2015(6) are revoked.
- 8) In the Pharmaceutical Services (Wales) (Miscellaneous Amendments) Directions 2019(7), omit direction 2.

(1) 2006 No. 88.
(2) 2008 No. 11.
(3) 2011 No. 47.
(4) 2013 No. 7.
(5) 2014 No. 15.
(6) 2015 No. 10.
(7) 2019 No. 40.