WG23-27

THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

The Primary Care (E-Prescribing Pilot Scheme) Directions 2023

Made	*31 May 2023*
Coming into force	*1 June 2023*

The Welsh Ministers, in exercise of the powers conferred on them by sections 12(3) and 203(9) and (10) of the National Health Service (Wales) Act 2006(**a**), make the following Directions.

Title, application and commencement

1.—(1) The title of these Directions is the Primary Care (E-Prescribing Pilot Scheme) Directions 2021.

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

(3) These Directions come into force on 1 June 2023 and expire on 1 October 2023.

Interpretation

2. In these Directions—

"the Act" means the National Health Service (Wales) Act 2006;

"advanced electronic signature" means an electronic signature which meets the following requirements—

(a) it is uniquely linked to the signatory,

(b) it is capable of identifying the signatory,

(c) it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under the signatory's sole control, and

(d) it is linked to the data signed in such a way that any subsequent change in the data is detectable;

"batch issue" means a form in the format required by a Local Health Board and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable an NHS pharmacist or NHS appliance contractor to receive payment for the provision of repeat dispensing services which is in the required format, and which—

(a) is generated by a computer and not signed by a repeatable prescriber,

(b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription,

(**a**) 2006 c. 42.

(c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided, and

(d) specifies a number denoting its place in the sequence referred to in paragraph (c);

"dentist" means a dental practitioner;

"dispenser" means an NHS pharmacist, NHS appliance contractor, medical practitioner or GMS contractor whom a patient wishes to dispense the patient's electronic prescriptions;

"DHCW" means Digital Health and Care Wales, established by The Digital Health and Care Wales (Establishment and Membership) Order 2020(**a**);

"dispensing services" means the provision of drugs, medicines or appliances that may be provided as pharmaceutical services by a medical practitioner in accordance with arrangements under section 80 (arrangement for pharmaceutical services) and section 86 (persons authorised to provide pharmaceutical services) of the Act;

"doctor" means a registered medical practitioner;

"E-Prescribing Pilot Scheme Specification" means the Specification at the Schedule to these Directions:

"electronic communication" has the meaning given by section 15(1) of the Electronic Communications Act 2000(**b**)(general interpretation);

"electronic prescription" means an electronic prescription form or an electronic repeatable prescription;

"electronic prescription form" means data created in an electronic form for the purpose of ordering a drug or appliance which—

(a) is signed, or is to be signed, with a prescriber's advanced electronic signature;

(b) is transmitted, or is to be transmitted, as an electronic communication to a nominated dispenser by the ETP service, or via an information hub by the Electronic Prescription Service; and

(c) does not indicate that the drug or appliance ordered may be provided more than once;

"Electronic Prescription Service" means the service of that name which is managed by NHS England;

"electronic repeatable prescription" means a prescription which falls within paragraph (a)(ii) of the definition of "repeatable prescription";

"electronic signature" means data in electronic form which is attached to or logically associated with other data in electronic form and which is used by the signatory to sign;

"electronic signature creation data" means unique data which is used by the signatory to create an electronic signature;

"engaged GMS contractor" means a GMS contractor that agrees with a Local Health Board to provide the Scheme pursuant to an agreement made in accordance with paragraph 4(1);

"EPS token" means a form (which may be an electronic form), that complies with the specification issued by NHS England, which—

(a) may be issued by a prescriber at the same time as an electronic prescription is created, and

(b) has a barcode or unique identifier that enables the prescription to be dispensed by a provider of pharmaceutical services that is able to use the Electronic Prescription Service for the purposes of dispensing prescriptions, in circumstances where the provider is not dispensing the prescription as a nominated dispenser;

(**a**) S.I. 2020/1451 (W. 313).

(**b**) 2000 c. 7. The definition of "*electronic communication*" was amended by the Communications Act 2003 (c. 21), Schedule 17, paragraph 158.

"ETP service" means the 2-dimensional barcoded prescription service which forms part of the information technology systems in prescribing and dispensing systems in Wales and used by the health service in Wales to transfer and hold prescription information relating to patients;

"GMS contract" means a general medical services contract under section 42 of the Act (general medical services contracts: introductory);

"GMS contractor" means a party to a GMS contract, other than the Local Health Board;

"independent nurse prescriber" means a person—

(a) who is registered in the Nursing and Midwifery Register, and

(b) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs and appliances as a community practitioner nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber;

"Local Health Board" means a Local Health Board established in accordance with section 11(2) of the Act;

"medical practitioner" has the meaning given by section 206(1) of the Act;

"NHS appliance contractor" means a person who is included in a pharmaceutical list under regulation 10 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020(**a**) (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services only by the provision of appliances;

"NHS pharmacist" means a—

(a) registered pharmacist, or

(b) person lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(**b**),

whose name is included in a pharmaceutical list under regulation 10 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (preparation and maintenance of pharmaceutical lists) for the provision of pharmaceutical services in particular by the provision of drugs;

"nominated dispenser" means a dispenser who has been nominated in respect of a patient where the details of that nomination are held in respect of that patient in the Patient Demographics Service which is managed by NHS England;

"non-electronic prescription form" means a prescription form which falls within paragraph (a) of the definition of "prescription form";

"non-electronic repeatable prescription" means a prescription which falls within paragraph (a)(i) of the definition of "repeatable prescription";

"nurse independent prescriber" means a person—

(a) whose name is registered in the Nursing and Midwifery Register,

(b) against whose name in that register is recorded an annotation or entry signifying that they are qualified to order drugs, medicines and appliances as—

(i) a nurse independent prescriber, or

(ii) a nurse independent/supplementary prescriber, and

who, in respect of a person practising in Wales on or after 19 July 2010, has passed an accredited course to practise as a nurse independent prescriber;

"optometrist independent prescriber" means a person—

(a) who is an optometrist registered in the register of optometrists maintained under section 7 of the Opticians Act 1989(**c**) (which relates to the register of optometrists and the register

(**a**) S.I. 2020/1073 (W. 241).
(**b**) 1968 c. 67.
(**c**) Amended by S.I. 2005/848.

of dispensing opticians) or the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act, and

(b) against whose name is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

"paramedic independent prescriber" means a person—

(a) who is registered as a paramedic in Part 8 of the Health and Care Professions Council register, and

(b) against whose name is recorded in Part 8 of that register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a paramedic independent prescriber;

"pharmacist independent prescriber" means a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**a**) (which relates to registers and the registrar) is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"physiotherapist independent prescriber" means a person—

(a) who is a physiotherapist, and

(b) against whose name in Part 9 of the register maintained under article 5 of the Health and Social Work Professions Order 2002(**b**) is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

"podiatrist or chiropodist independent prescriber" means a person—

(a) who is a podiatrist or a chiropodist, and

(b) against whose name in Part 2 of the register maintained under article 5 of the Health and Social Work Professions Order 2002 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a podiatrist or chiropodist independent prescriber;

"prescriber" means a doctor, dentist, independent nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist or chiropodist independent prescriber, therapeutic radiographer independent prescriber, paramedic independent prescriber or a supplementary prescriber, who is either engaged or employed by the GMS contractor, or is a party to a GMS contract;

"prescription form" means—

(a) a form provided by a Local Health Board, an NHS Trust, an NHS Foundation Trust or an equivalent body and issued by a prescriber, or

(b) an electronic prescription form,

that enables a person to obtain pharmaceutical services and does not include a repeatable prescription;

"repeatable prescriber" means a person who—

(a) is a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 5 (repeatable prescribing services) of the E-Prescribing Pilot Scheme Specification, or

(b) is employed or engaged by—

(i) a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 5 of the E-Prescribing Pilot Scheme Specification, or

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(**a**) S.I. 1976.1213 (N.I. 22).
(**b**) Amended by S.I. 2009/1182.

(ii) a Local Health Board for the purposes of providing primary medical services within a LHBMS practice which provides repeatable prescribing services in accordance with a provision in directions made by the Welsh Ministers under section 12(3) of the Act in relation to LHBMS which is the equivalent provision to paragraph 5 of the E-Prescribing Pilot Scheme Specification;

"repeatable prescription" means a prescription contained in a form provided by a Local Health Board for the purpose of ordering a drug, medicine or appliance which is in the format required by the NHS Business Services Authority and which—

(a) is either—

(i) generated by computer but signed by a repeatable prescriber, or

(ii) a form created in an electronic format, identified using a repeatable prescriber's code, transmitted as an electronic communication to a nominated NHS pharmacist, NHS appliance contractor or dispensing doctor by the ETP service and is signed with a repeatable prescriber's advanced electronic signature,

(b) is issued or created to enable a person to obtain pharmaceutical services, and

(c) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;

"Scheme" means the Primary Care E-Prescribing Pilot Scheme established by a Local Health Board in accordance with paragraph 3;

"signatory" means a natural person who creates an electronic signature;

"supplementary prescriber" means means—

(a) a registered pharmacist against whose name in Part 1 of the General Pharmaceutical Council Register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber,

(b) a person whose name is registered in the Nursing and Midwifery Register and against whose name in that Register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a nurse independent/supplementary prescriber,

(c) a person—

(i) who is registered in a part of the register maintained under article 5 of the Health Professions Order 2001 (establishment and maintenance of register) which relates to chiropodists and podiatrists, dieticians, paramedics, physiotherapists or radiographers, and

(ii) against whose name in that register is recorded an annotation signifying that they are qualified to order drugs, medicines and appliances as a supplementary prescriber, or

(d) an optometrist against whose name in the register of optometrists maintained under section 7 or 8B(1)(a) of the Opticians Act 1989 is recorded an annotation signifying that the optometrist is qualified to order drugs, medicines and appliances as a supplementary prescriber;

"therapeutic radiographer independent prescriber" means a person—

(a) who is a registered radiographer, and

(b) against whose name is recorded in Part 11 of the Health and Care Professions Council register—

(i) an entitlement to use the title "therapeutic radiographer", and

(ii) an annotation signifying that they are qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber .

Establishment of a Primary Care E-Prescribing Pilot Scheme

3.—(1) Each Local Health Board is required under section 41 of the Act (primary medical services) to exercise its functions so as to provide, or secure the provision of, primary medical services in its area.

(2) As part of the discharge of those functions each Local Health Board must establish, operate and, as appropriate, revise a Primary Care E-Prescribing Pilot Scheme for its area.

(3) The underlying purpose of the Scheme is to enable medicines to be prescribed and administered through the application of digital services by GMS contractors via a piloted implementation of the Electronic Prescription Service as part of the health service in Wales.

Primary Care E-Prescribing Pilot Scheme

4.—(1) As part of its Scheme, each Local Health Board may enter into arrangements for the provision of services in accordance with the E-Prescribing Pilot Scheme Specification with a GMS contractor in relation to the registered patients of that GMS contractor.

(2) Where arrangements are made between a Local Health Board and a GMS contractor pursuant to sub-paragraph (1), those arrangements must include—

(a) a requirement that the engaged GMS contractor—

(i) reads and takes account of these Directions alongside complying with the E-Prescribing Pilot Scheme Specification, which in combination provide the detailed requirements of the Scheme;

(ii) has access to a software system approved by the Welsh Ministers which enables the engaged GMS contractor, or a prescriber, to issue electronic prescription forms to the registered patients of that GMS contractor;

(iii) maintains and keeps up to date a record of all persons who are prescribed medication electronically under the Scheme;

(iv) provides the services required by the Specification and, as appropriate, in line with the plan specified in sub-paragraph (3) or sub-paragraph (iv);

(v) ensures consistent coding for capture of data and compliance with relevant information governance legislation;

(vi) supplies its Local Health Board with such information as the Local Health Board may reasonably request for the purposes of monitoring the engaged GMS contractor's performance of its obligations under the Scheme;

(vii) provides such other detail or assurances that the Local Health Board may reasonably request from the engaged GMS contractor;

(b) a requirement that the engaged GMS contractor—

(i) ensures that each prescriber who takes part in the Scheme has the necessary skills, training competence and experience in order to provide the services, and

(ii) ensures that each prescriber who takes part in the Scheme is adequately indemnified/insured for any liability arising from the work performed.

(3) The Local Health Board must, where necessary, vary the engaged GMS contractor's GMS contract so that arrangements made pursuant to sub-paragraph (1) comprise part of the GMS contractor's GMS contract and the requirements of the arrangements are conditions of the contract.

Dispute resolution

5.—(1) In the case of any dispute arising out of, or in connection with, the Scheme, the engaged provider 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 Scheme dispute

resolution procedure (or, where applicable, before commencing court proceedings) specified in sub-paragraphs (2) to (15) below.

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

(3) Any party wishing to refer a dispute as mentioned in sub-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 the Scheme, and

(c) a brief statement describing the nature and circumstances of the dispute.

(4) Any party wishing to refer a dispute as mentioned in sub-paragraph (2) must send the request under sub-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 matter 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 sub-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 sub-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 sub-paragraph (6) or (8), the Welsh Ministers must, if they decide to appoint a person or persons to hear the dispute—

(a) inform the parties in writing of the name of the person or persons whom it has appointed, and

(b) pass to the person or persons so appointed any documents received from the parties under sub-paragraph (3), (6) or (8).

(10) For the purpose of assisting the adjudicator in the consideration of the matter, the adjudicator may—

(a) invite representatives of the parties to appear before the adjudicator 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 adjudicator wishes them to give special consideration, or

(b) consult other persons whose expertise the adjudicator considers will assist in the consideration of the matter.

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

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

(a) any written representations made in response to a request under sub-paragraph (6), but only if they are made within the specified period;

(b) any written observations made in response to a request under sub-paragraph (8), but only if they are made within the specified period;

(c) any oral representations made in response to an invitation under sub-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 sub-paragraph (11).

(13) Subject to the other provisions within this direction and to any agreement by the parties, the adjudicator has wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

(14) The determination of the adjudicator and the reasons for it, must be recorded in writing and the adjudicator must give notice of the determination (including the record of the reasons) to the parties.

(15) In this direction—

"specified period" 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.

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

Dated: 31 May 2023

SCHEDULE

Direction 4

E-Prescribing Pilot Scheme Specification

Prescribing and Dispensing

Introduction

The introduction of the Primary Care Electronic Prescription Service (EPS) will make the entire process of prescribing and dispensing medicines electronic resulting in the prescribing and dispensing of medicines everywhere in Wales, easier, safer, more efficient and effective through digital. It will focus on the electronic signing and transfer of prescriptions from GPs and non-medical prescribers to the community pharmacy or dispenser of a patient's choice. A key enabler of this is the legislative change to enable a prescription to be signed electronically rather than wet-signed as they are currently.

In order to ensure that EPS is safe, fit for purpose and able to be rolled out across Wales, it will first be implemented in a small number of sites and tested. The location of these sites will be dependent on the prescribing system in use, the flow of prescriptions to community pharmacies and also the ability of the community pharmacy systems to be able to manage electronic prescriptions. The EPS programme team has undertaken data analysis and identified a number of potential GP sites at which EPS could be tested. These sites will require the ability to sign prescriptions electronically to be able to take part prior to the implementation of the GMS contract in October 2023. It is worth noting, that there are several

independent factors that need to be taken into account for a site to be suitable, all of which will be considered in site selection.

Prescribing: general

1.—(1) The engaged GMS contractor must ensure that any prescription form or repeatable prescription for drugs, medicines or appliances issued by a prescriber, complies, as appropriate, with the requirements in paragraphs 2, and 5 to 10.

(2) In paragraphs 2, and 5 to 10, a reference to "drugs" includes contraceptive substances and a reference to "appliance" includes contraceptive appliances.

Orders for drugs, medicines and appliances

2.—(1) Subject to sub-paragraph (2) and to the restrictions on prescribing in paragraphs 8 and 9, a prescriber must order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under a GMS contract by—

(a) issuing to the patient a non-electronic prescription form or a non-electronic repeatable prescription completed in accordance with sub-paragraph (5); or

(b) creating and transmitting an electronic prescription in circumstances to which paragraph 3(1) applies,

and a non-electronic prescription form, non-electronic repeatable prescription or electronic prescription that is for health service use must not be used in any other circumstances.

(2) If, on a particular occasion when a drug, medicine or appliance is needed as mentioned in sub-paragraph (1)—

(a) the prescriber is able, without delay, to order the drug, medicine or appliance by means of an electronic prescription,

(b) the Electronic Prescription Service software that the prescriber would use for that purpose provides for the creation and transmission of electronic prescriptions without the need for a nominated dispenser, and

(c) none of the reasons for issuing a non-electronic prescription form or a non-electronic repeatable prescription given in sub-paragraph (3) apply,

the prescriber must create and transmit an electronic prescription for that drug, medicine or appliance.

(3) The reasons given in this sub-paragraph are—

(a) although the prescriber is able to use the Electronic Prescription Service, the prescriber is not satisfied that—

(i) the access that the prescriber has to the Electronic Prescription Service is reliable, or

(ii) the Electronic Prescription Service is functioning reliably;

(b) the patient, or where appropriate the patient's authorised person, informs the prescriber that the patient wants the option of having the prescription dispensed elsewhere than in Wales; or

(c) the patient, or where appropriate the patient's authorised person, insists on the patient being issued with a non-electronic prescription form or a non-electronic repeatable prescription for a particular prescription and in the professional judgment of the prescriber the welfare of the patient is likely to be in jeopardy unless a non-electronic prescription form or a non-electronic repeatable prescription is issued.

(4) A prescriber may order drugs, medicines or appliances on a repeatable prescription only where the drugs, medicines or appliances are to be provided more than once.

(5) In issuing a non-electronic prescription form or a non-electronic repeatable prescription, the prescriber must—

(a) sign the prescription form or repeatable prescription in ink in the prescriber's own handwriting, and not by means of a stamp, with the prescriber's initials, or forenames, and surname; and

(b) only sign the prescription or repeatable prescription after particulars of the order have been inserted in the prescription form or repeatable prescription.

(6) A prescription form or repeatable prescription must not refer to any previous prescription form or repeatable prescription form.

(7) A separate prescription form or repeatable prescription must be used for each patient, except where a bulk prescription is issued for a school or institution under paragraph 10.

(8) Where a prescriber orders the drug buprenorphine or diazepam or a drug specified in Part 1 of Schedule 2 to the Misuse of Drugs Regulations 2001(**a**) (controlled drugs to which regulations 14 to 16, 18 to 21, 23, 26 and 27 of those Regulations apply) for supply by instalments for treating addiction to any drug specified in that Schedule, the prescriber must—

(a) use only the prescription form provided specially for the purposes of supply by instalments,

(b) specify the number of instalments to be dispensed and the interval between each instalment, and

(c) order only such quantity of the drug as will provide treatment for a period not exceeding 14 days.

(9) The prescription form provided specially for the purpose of supply by instalments must not be used for any purpose other than ordering drugs in accordance with sub-paragraph (8).

(10) In an urgent case, a prescriber may request an NHS pharmacist to dispense a drug or medicine before a prescription form or repeatable prescription is issued or created, only if—

(a) that drug or medicine is not a Scheduled drug;

(b) the drug is not a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Part 1 of Schedule 4 (controlled drugs subject to the requirements of regulations 22, 23, 26 and 27) or Schedule 5 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) to the Misuse of Drugs Regulations 2001; and

(c) the prescriber undertakes to—

(i) furnish the NHS pharmacist, within 72 hours beginning with the time of the request, with a non-electronic prescription form or a non-electronic repeatable prescription completed in accordance with sub-paragraph (6), or

(ii) transmit an electronic prescription by the Electronic Prescription Service within 72 hours, beginning with the time of the request.

(11) In an urgent case, a prescriber may request an NHS pharmacist to dispense an appliance before a prescription form or repeatable prescription is issued or created, only if—

(a) the appliance does not contain a Scheduled drug, or a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26);

(b) where the appliance is a restricted availability appliance, the patient is a person, or the appliance is for a purpose, specified in the Drug Tariff; and

(c) the prescriber undertakes to—

(**a**) Schedule 2 was amended by S.I. 2003/1432, S.I. 2009/3136, S.I. 2011/448, S.I. 2014/1275 and 3277, S.I. 2015/891, S.I. 2018/1055 and S.I. 2018/1383.

(i) provide the NHS pharmacist, within 72 hours beginning with the time of the request, with a non-electronic prescription form or non-electronic repeatable prescription completed in accordance with sub-paragraph (5), or

(ii) transmit an electronic prescription by the Electronic Prescription Service within 72 hours, beginning with the time of the request.

Electronic prescriptions

3.—(1) A prescriber may only order drugs, medicines or appliances by means of an electronic prescription if the prescription is not—

(a) for a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Schedules 2 to 5 to the Misuse of Drugs Regulations 2001, or

(b) a bulk prescription issued for a school or institution under paragraph 10.

(2) If a prescriber orders a drug, medicine or appliance by means of an electronic prescription, the prescriber must issue the patient with—

(a) subject to sub-paragraph (4), an EPS token, and

(b) if the patient, or where appropriate the patient's authorised person, so requests, a written record of the prescription that has been created.

(3) On and after the GMS contractor's EPS go live date, if the order is eligible for Electronic Prescription Service use, the prescriber must ascertain if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.

(4) The prescriber must not issue the patient with an EPS token if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.

Nomination of dispensers for the purposes of electronic prescriptions

4.—(1) A GMS contractor authorised to use the Electronic Prescription Service for its patients must, if a patient, or where appropriate the patient's authorised person, so requests, enter into the particulars relating to the patient which are held in the Welsh Demographic Service managed by DHCW or the Person Demographic Service managed by NHS England—

(a) where the patient does not have a nominated dispenser, the dispenser chosen by the patient, or where appropriate the patient's authorised person, and

(b) where the patient does have a nominated dispenser—

(i) a replacement dispenser, or

(ii) a further dispenser,

chosen by the patient.

(2) Sub-paragraph (1)(b)(ii) does not apply if the number of the nominated dispensers would thereby exceed the maximum number permitted by the Electronic Prescription Service.

(3) A GMS contractor must—

(a) not seek to persuade a patient or a patient's authorised person to nominate a dispenser recommended by the prescriber or the GMS contractor, and

(b) if asked by a patient or a patient's authorised person to recommend a NHS pharmacist whom the patient or the patient's authorised person might nominate as the patient's dispenser, provide the patient or, as the case may be, the patient's authorised person with the list given to the GMS contractor by the Local Health Board containing all NHS pharmacists in the area who provide an Electronic Prescription Service.

Repeatable prescribing services

5.—(1) A GMS contractor may only provide repeatable prescribing services to a person on its list of patients if the GMS contractor—

(a) satisfies the conditions in sub-paragraph (2), and

(b) has notified the relevant Local Health Board of its intention to provide repeatable prescribing services in accordance with sub-paragraphs (3) and (4).

(2) The conditions referred to in sub-paragraph (1)(a) are—

(a) the GMS contractor has access to computer systems and software which enable it to issue non-electronic repeatable prescriptions and batch issues, and

(b) the practice premises at which the repeatable prescribing services are to be provided are located in an area of the Local Health Board in which there is also located the premises of at least one NHS pharmacist who has undertaken to provide, or has entered into an arrangement to provide, repeat dispensing services.

(3) The notification referred to in sub-paragraph (1)(b) is a notification, in writing, by the GMS contractor to the relevant Local Health Board that it—

(a) wishes to provide repeatable prescribing services,

(b) intends to begin to provide those services from a date specified in the notification, and

(c) satisfies the conditions in sub-paragraph (2).

(4) The date specified by the GMS contractor under sub-paragraph (3)(b) must be at least 10 days after the date on which the notification specified in sub-paragraph (1) is given.

(5) Nothing in this paragraph requires a GMS contractor or prescriber to provide repeatable prescribing services to any person.

(6) A prescriber may only provide repeatable prescribing services to a person on a particular occasion if—

(a) that person has agreed to receive such services on that occasion, and

(b) the prescriber considers that it is clinically appropriate to provide such services to that person on that occasion.

(7) The GMS contractor may not provide repeatable prescribing services to any person on its list of patients to whom any person specified in sub-paragraph (8) is authorised or required by the Local Health Board to provide pharmaceutical services in accordance with arrangements under section 80 (arrangements for pharmaceutical services) and section 86 (persons authorised to provide pharmaceutical services) of the Act.

(8) The persons referred to in sub-paragraph (7) are—

(a) in the case of a contract with an individual medical practitioner, that medical practitioner;

(b) in the case of a contract with two or more individuals practising in partnership, any medical practitioner who is a partner;

(c) in the case of a contract with a company limited by shares, any medical practitioner who is both a legal and beneficial shareholder in that company; or

(d) any medical practitioner employed by the GMS contractor.

Repeatable prescriptions

6.—(1) — A prescriber who issues a non-electronic repeatable prescription must at the same time issue the appropriate number of batch issues.

(2) Where a prescriber wants to make a change to the type, quantity, strength or dosage of drugs, medicines or appliances ordered on a person's repeatable prescription, the prescriber must—

(a) in the case of a non-electronic repeatable prescription—

(i) give notice to the person, and

(ii) make reasonable efforts to give notice to the NHS pharmacist providing repeat dispensing services to that person,

that the original repeatable prescription is no longer to be used to obtain or provide repeat dispensing services and make arrangements for a replacement repeatable prescription to be issued to the person; or

(b) in the case of an electronic repeatable prescription—

(i) arrange with the Electronic Prescription Service for the cancellation of the original repeatable prescription, and

(ii) create a replacement repeatable prescription relating to the person and give notice to the person that this has been done.

(3) Where a prescriber has created an electronic repeatable prescription for a person, the prescriber must, as soon as practicable, arrange with the Electronic Prescription Service for its cancellation if, before the expiry of that prescription—

(a) the prescriber considers that it is no longer safe or appropriate for the person to—

(i) receive the drugs, medicines or appliances ordered on the person's electronic repeatable prescription, or

(ii) continue to receive repeatable prescribing services;

(b) the prescriber has issued the person with a non-electronic repeatable prescription in place of the electronic repeatable prescription; or

(c) it comes to the prescriber's notice that the person on whose behalf the prescription was issued has been removed from the list of patients of the GMS contractor.

(4) Where a prescriber has cancelled an electronic repeatable prescription relating to a person in accordance with sub-paragraph (3), the prescriber must give notice of the cancellation to the person as soon as possible.

(5) A prescriber who has issued a non-electronic repeatable prescription in relation to a person must, as soon as possible, make reasonable efforts to give notice to the NHS pharmacist that that repeatable prescription should no longer be used to provide repeat dispensing services to that person, if, before the expiry of that repeatable prescription—

(a) the prescriber considers that it is no longer safe or appropriate for the person to—

(i) receive the drugs, medicines or appliances ordered on the person's repeatable prescription, or

(ii) to continue to receive repeatable prescribing services;

(b) the prescriber issues or creates a further repeatable prescription in respect of the person to replace the original repeatable prescription other than in the circumstances referred to in sub-paragraph (2)(a) (for example, because the person wants to obtain the drugs, medicines or appliances from a different NHS pharmacist); or

(c) it comes to the prescriber's notice that the person on whose behalf the prescription was issued has been removed from the list of patients of the GMS contractor.

(6) Where the circumstances in sub-paragraph (5)(a) to (c) apply in respect of a person, the prescriber must as soon as possible give notice to that person that their repeatable prescription must no longer be used to obtain repeat dispensing services.

Prescribing for electronic repeat dispensing

7.—(1) Subject to paragraphs 2, 3, 5 and 6(2)(b) to (4), where a prescriber orders a drug, medicine or appliance by means of an electronic repeatable prescription, the prescriber must issue the prescription in a format appropriate for electronic repeat dispensing where it is clinically appropriate to do so for that patient on that occasion.

(2) In this paragraph, "electronic repeat dispensing" means dispensing as part of pharmaceutical services or local pharmaceutical services which involves the provision of drugs, medicines or appliances in accordance with an electronic repeatable prescription.

Restrictions on prescribing by medical practitioners

8.—(1) A medical practitioner, in the course of treating a patient to whom the practitioner is providing treatment under the contract, must comply with the following sub-paragraphs.

(2) The medical practitioner must not order on a listed medicines voucher, prescription form or a repeatable prescription, a drug, medicine or other substance specified in any directions given by the Welsh Ministers in regulations made under section 46 of the Act (GMS contracts: prescription of drugs etc) as being drugs, medicines or other substances which may not be ordered for patients in the provision of medical services under the contract.

(3) The medical practitioner must not order on a listed medicines voucher, a prescription form or repeatable prescription a drug, medicine or other substance specified in any directions given by the Welsh Ministers under section 46 of the Act (GMS contracts: prescription of drugs etc) as being a drug, medicine or other substance which can only be ordered for specified patients and for specified purposes unless—

(a) the patient is a person of the specified description,

(b) the drug, medicine or other substance is prescribed for that patient only for the specified purpose, and

(c) if the order is on a prescription form, the practitioner includes on the form the reference "SLS".

(4) The medical practitioner must not order on a prescription form or repeatable prescription a restricted availability appliance unless—

(a) the patient is a person, or the restricted availability appliance is for a purpose, specified in the Drug Tariff, and

(b) the practitioner includes on the prescription form the reference "SLS".

(5) The medical practitioner must not order on a repeatable prescription a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), other than a drug which is for the time being specified in Schedule 4 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) or Schedule 5 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26) to the Misuse of Drugs Regulations 2001.

(6) Subject to regulation 24(2)(b) of the National Health Service (General Medical Services Contracts) (Wales) 2004 and to sub-paragraph (7), nothing in the preceding sub-paragraphs prevents a medical practitioner, in the course of treating a patient to whom this sub-paragraph refers, from prescribing a drug, medicine or other substance or, as the case may be, a restricted availability appliance or a controlled drug within the meaning of section 2 of the Misuse of Drugs Act 1971 (which relates to controlled drugs and their classification for the purposes of that Act), for the treatment of that patient under a private arrangement.

(7) Where, under sub-paragraph (6), a drug, medicine or other substance is prescribed under a private arrangement, if the order is to be transmitted as an electronic communication to a NHS pharmacist for the drug, medicine or appliance to be dispensed—

(a) if the order is not for a drug for the time being specified in Schedule 2 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27) or 3 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 22, 23, 24, 26 and 27) to the Misuse of Drugs Regulations 2001, it may be transmitted by the Electronic Prescription Service, but

(b) if the order is for a drug for the time being specified in Schedule 2 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27) or 3 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 22, 23, 24, 26 and 27) to the Misuse of Drugs Regulations 2001, it must be transmitted by the Electronic Prescription Service.

Restrictions on prescribing by supplementary prescribers

9.—(1) The contractor must have arrangements in place to secure that an individual who is a supplementary prescriber may—

(a) issue or create a prescription for a prescription only medicine;

(b) administer a prescription only medicine for parenteral administration; or

(c) give directions for the administration of a prescription only medicine for parenteral administration,

as a supplementary prescriber only under the conditions set out in sub-paragraph (2).

(2) The conditions referred to in sub-paragraph (1) are that—

(a) the individual satisfies the applicable conditions set out in regulation 215 of the Human Medicines Regulations 2012 (prescribing and administration by supplementary prescribers), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of those Regulations;

(b) the drug, medicine or other substance is not specified in any directions given by the Welsh Ministers under section 46 of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;

(c) the drug, medicine or other substance is not specified in any directions given by the Welsh Ministers under section 46 of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless—

(i) the patient is a person of the specified description,

(ii) the medicine is prescribed for that patient only for the specified purposes, and

(iii) if the supplementary prescriber is giving a prescription, he or she endorses the face of the form with the reference "SLS".

(3) Where the functions of a supplementary prescriber include prescribing, the contractor must have arrangements in place to secure that that person may only give a prescription for—

(a) an appliance, or

(b) a medicine which is not a prescription only medicine,

(c) as a supplementary prescriber under the conditions set out in sub-paragraph (4).

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

(a) the supplementary prescriber acts in accordance with a clinical management plan which is in effect at the time the supplementary prescriber acts and which contains the following particulars—

(i) the name of the patient to whom the plan relates,

(ii) the illness or conditions which may be treated by the supplementary prescriber,

(iii) the date on which the plan is to take effect, and when it is to be reviewed by the medical practitioner or dentist who is a party to the plan,

(iv) reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan,

(v) any restrictions or limitations as to the strength or dose of any medicine which may be prescribed or administered under the plan, and any period of administration or use of any medicine or appliance which may be prescribed or administered under the plan,

(vi) relevant warnings about known sensitivities of the patient to, or known difficulties of the patient with, particular medicines or appliances,

(vii) the arrangements for notification of—

(aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse

reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan,

(bb) incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of health of the patient, and

(viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the medical practitioner or dentist who is a party to the plan;

(b) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any medical practitioner or dentist who is a party to the plan;

(c) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Welsh Minister under section 46 of the Act as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract;

(d) if it is a prescription for a drug, medicine or other substance, that drug, medicine or other substance is not specified in any directions given by the Welsh Ministers under section 46 of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes unless—

(i) the patient is a person of the specified description,

(ii) the medicine is prescribed for that patient only for the specified purposes, and

(iii) when giving the prescription, the supplementary prescriber endorses the face of the form with the reference "SLS";

(e) if it is a prescription for an appliance, the appliance is listed in Part IX of the Drug Tariff; and

(f) if it is a prescription for a restricted availability appliance—

(i) the patient is a person of a description mentioned in the entry in Part IX of the Drug Tariff in respect of that appliance,

(ii) the appliance is prescribed only for the purposes specified in respect of that person in that entry, and

(iii) when giving the prescription, the supplementary prescriber endorses the face of the form with the reference SLS.

(5) In sub-paragraph (4)(a), "clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

(a) the patient to whom the plan relates,

(b) the medical practitioner 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.

Bulk prescribing

10.—(1) A prescriber may use a single non-electronic prescription form where—

(a) a GMS contractor is responsible under the contract for the treatment of ten or more persons in a school or other institution in which at least 20 persons normally reside, and

(b) the prescriber orders, for any two or more of those persons for whose treatment the GMS contractor is responsible, drugs, medicines or appliances to which this sub-paragraph applies.

(2) Where a prescriber uses a single non-electronic prescription form for the purpose mentioned in sub-paragraph (1)(b), the prescriber must (instead of entering on the form the names of the persons for whom the drugs, medicines or appliances are ordered) enter on the form—

(a) the name of the school or other institution in which those persons reside, and

(b) the number of persons residing there for whose treatment the GMS contractor is responsible.

(3) This sub-paragraph applies to any drug, medicine or appliance which can be supplied as part of pharmaceutical services or local pharmaceutical services and which in the case of—

(a) a drug or medicine, is not a prescription only medicine, or

(b) an appliance, does not contain such a product.