
WELSH STATUTORY INSTRUMENTS

2009 No. 1491

The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2009

Substitution of Part 6 of Schedule 2 to the principal Regulations

19.—(1) For Part 6 of Schedule 2 to the principal Regulations (terms of service for doctors who provide pharmaceutical services) substitute the following Part—

“PART 6

Terms of service for doctors who provide pharmaceutical services

Persons duly authorised to dispense on behalf of dispensing doctors

34. Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which he or she has duly authorised another person to undertake, if that other person undertakes that activity instead of the dispensing doctor—

- (a) that other person must comply with that requirement; and
- (b) that dispensing doctor must secure compliance with that requirement by that other person,

and references in this Schedule to a dispensing doctor are to be construed accordingly.

Dispensing of drugs and appliances ordered by another prescriber

35.—(1) Subject to the following provisions of this Schedule, where—

- (a) any person presents to a dispensing doctor a prescription form which contains—
 - (i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor,
 - (ii) an order for drugs specified in Schedule 2 to the Prescription of Drugs Regulations, signed by a prescriber other than the dispensing doctor, and including the reference “SLS”, or
 - (iii) an order for restricted availability appliances, signed by a prescriber other than the dispensing doctor and including the reference “SLS”,

and the dispensing doctor is authorised or required by virtue of regulation 20 of these Regulations to provide the drugs or appliances so ordered, he or she will, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he or she supplies in the normal course of his or her practice or business.

(2) Subject to the following provisions of this Part, where any person presents to a dispensing doctor a repeatable prescription which contains—

- (a) an order for drugs, not being Scheduled drugs or controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drugs which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber,
- (b) an order for a drugs specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber and including the reference “SLS”,
- (c) an order for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, and including the reference “SLS”,

and also presents an associated batch issue and the dispensing doctor is authorised or required by regulation 20 to provide the drugs or appliances so ordered, the dispensing doctor must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he or she supplies in the normal course of his or her practice or business.

(3) For the purposes of this paragraph, a repeatable prescription for drugs or appliances will be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

- (a) the dispensing doctor has that prescription in his or her possession; and
- (b) that person presents, or the dispensing doctor has in his or her possession, an associated batch issue.

(4) Drugs and listed appliances provided under this paragraph must be provided in a suitable container.

Dispensing of drugs and appliances ordered by the dispensing doctor

36. In circumstances where paragraph 34 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor is authorised or required by virtue of regulation 20 of these Regulations to provide drugs or appliances to a person, the dispensing doctor must—

- (a) record an order for the provision of any drugs or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with the term of a contract which gives effect to paragraph 39(3) of Schedule 6 to the GMS Regulations or an equivalent provision applying in relation to that contract;
- (b) provide those drugs or appliances in a suitable container;
- (c) provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied; and
- (d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

Preliminary matters before providing ordered drugs or appliances

37. Before providing drugs or listed appliances recorded on a prescription form in accordance with paragraph 35, or in the circumstances set out in paragraph 36—

- (a) the dispensing doctor must ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations by virtue of either—
 - (i) entitlement to an exemption under regulation 8(1) of the Charges Regulations, or
 - (ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations,to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of remission by virtue of regulation 5(1)(e) or 5(2)(e) or (f) of the Remission of Charges Regulations, and at the time of the declaration the dispensing doctor already has such evidence available to him or her; and
- (b) if no satisfactory evidence, as required by sub-paragraph (a) is produced to the dispensing doctor, the dispensing doctor must endorse the form on which the declaration is made to that effect.

Provision of Scheduled drugs

38.—(1) Subject to sub-paragraph (2), a dispensing doctor must not provide for a patient any Scheduled drug, except that, where the dispensing doctor or an independent prescriber has ordered a drug which has an appropriate non-proprietary name either by the name or by its formula, he or she may provide a drug which has the same specification notwithstanding that it is a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(2) Nothing in this Part prevents a dispensing doctor providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

Refusal to provide drugs or appliances ordered

39.—(1) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

- (a) the dispensing doctor reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example, because the dispensing doctor reasonably believes that it has been stolen or forged); or
- (b) it appears to the dispensing doctor that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber), or that, in the circumstances, providing the drugs or appliances would be contrary to the dispensing doctor's clinical judgement.

(2) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription, or which he or she is otherwise authorised or required to provide by virtue of regulation 20 of these Regulations, where—

- (a) the dispensing doctor or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription or repeatable prescription, or by any person accompanying that person; or
- (b) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(3) A dispensing doctor must refuse to provide drugs or appliances ordered on a repeatable prescription where—

- (a) the dispensing doctor has no record of that prescription;
- (b) it is not signed by a repeatable prescriber;
- (c) to do so would not be in accordance with any intervals specified in the prescription;
- (d) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than six months previously;
- (e) if the repeatable prescription was signed more than one year previously;
- (f) the expiry date on the repeatable prescription has passed; or
- (g) where the dispensing doctor has been informed by the repeatable prescriber that the prescription is no longer required.

(4) Where the patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), a dispensing doctor may only provide the drugs or appliances ordered if he or she is satisfied—

- (a) that the patient to whom the prescription relates—
 - (i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and
 - (ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;
- (b) that the medication regimen of the patient to whom the prescription relates has not altered in a way that indicates the need or desirability of reviewing the patient's treatment; and
- (c) that there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Fees and charges

40.—(1) The terms of a GMS contract giving effect to regulation 24 of, and Schedule 5 to, the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a dispensing doctor as they apply in relation to prescriptions for drugs and appliances.

(2) Where a dispensing doctor provides a drug or appliance under pharmaceutical services or provides any additional service associated with the dispensing of such drugs and appliances in accordance with an agreement with the Local Health Board—

- (a) in accordance with this Part or an agreement with the Local Health Board; and
- (b) had the drug, appliance or additional service been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled by, by virtue of directions given by the Welsh Ministers under section 45 of the 2006 Act, to a payment—
 - (i) in respect of the drug or appliance; or
 - (ii) in respect of the additional service provision,the Local Health Board will credit him or her with the payment.

Complaints procedures

41.—(1) Where a dispensing doctor—

- (a) is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which give effect to paragraph 90 of Schedule 6 to the GMS Regulations;
- (b) is an APMS contractor, or is engaged or employed by an APMS contractor, the complaints procedure established by the relevant APMS contract to deal with complaints in relation to the provision of primary medical services;
- (c) is employed or engaged by a Local Health Board for the purposes of providing services within an LHBMS practice, the complaints procedure established by that LHBMS practice to deal with complaints in relation to the provision of primary medical services,

applies in relation to any matter reasonably connected with the provision of pharmaceutical services as it applies as respects to services provided under that contract or agreement, or within that practice.

(2) Accordingly, the term of any GMS contract which gives effect to paragraph 95 of Schedule 6 to the GMS Regulations also applies in relation to complaints about such matters.

Inspections and access to information

42.—(1) A dispensing doctor must allow persons authorised by the Local Health Board to enter and inspect any premises that he or she uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

- (a) ascertaining whether or not the dispensing doctor is complying with the requirements of this Part;
- (b) auditing, monitoring and analysing—
 - (i) the provision made by the dispensing doctor, in the course of providing pharmaceutical services, for patient care and treatment, and
 - (ii) the management by the dispensing doctor of the pharmaceutical services he or she provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

- (a) reasonable notice of the intended entry has been given;
- (b) the Local Medical Committee for the area in which the premises are situated has been invited to be present at the inspection, where this is requested by the dispensing doctor;
- (c) the person authorised in writing carries written evidence of his or her authorisation, which must be produced on request; and
- (d) he or she does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A dispensing doctor must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow it or that person access to any information which it or that person reasonably requires—

- (a) for the purposes mentioned in sub-paragraph (1); or
- (b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.”.