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WELSH STATUTORY INSTRUMENTS

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**2020 No. 1073**

**The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020**

**PART 9**

**Performance related sanctions and Market Exit**

**Local dispute resolution before serving remedial notices or breach notices**

**49.**—(1) Subject to paragraph (3), before issuing a notice under regulation 50 or 51, the Local Health Board must make every reasonable effort to communicate and co-operate with an NHS pharmacist or NHS appliance contractor with a view to resolving any dispute between the NHS pharmacist or NHS appliance contractor and the Local Health Board relating to compliance by the NHS pharmacist or NHS appliance contractor with the terms of service.

(2) Where an NHS pharmacist or NHS appliance contractor invites a Local Pharmaceutical Committee to participate in the attempts to resolve the dispute, the Local Health Board must make every reasonable effort to communicate and co-operate with the Committee in its attempts to assist in resolving the dispute.

(3) Paragraphs (1) and (2) do not apply where the Local Health Board is satisfied—

- (a) the dispute relates to a matter that has already been the subject of dispute resolution between the Local Health Board and the NHS pharmacist or NHS appliance contractor and there are no new issues of substance that justify delay in issuing a notice under regulation 50 or 51, or
- (b) that it is appropriate to proceed immediately to issuing a notice under regulation 50 or 51—
  - (i) because listed premises are not, or have not been, open during core opening hours or supplementary opening hours without good cause,
  - (ii) to protect the safety of any persons to whom an NHS pharmacist or NHS appliance contractor may provide pharmaceutical services, or
  - (iii) to protect the Local Health Board from material financial loss.

**Breaches of terms of service: remedial notices**

**50.**—(1) Where an NHS pharmacist or NHS appliance contractor breaches a term of service and the breach is capable of remedy, the Local Health Board may by a notice (“a remedial notice”) require the NHS pharmacist or NHS appliance contractor to remedy the breach.

(2) To be valid, the remedial notice must include—

- (a) the nature of the breach,
- (b) the steps the NHS pharmacist or NHS appliance contractor must take, to the satisfaction of the Local Health Board, in order to remedy the breach,
- (c) the period (“the notice period”) during which the steps must be taken, and

- (d) an explanation of how the NHS pharmacist or NHS appliance contractor's rights of appeal under regulation 54(1)(a) may be exercised.
- (3) The notice period must be not less than 30 days, unless the Local Health Board is satisfied that a shorter period is appropriate—
- (a) to protect the safety of any persons to whom the NHS pharmacist or NHS appliance contractor may provide pharmaceutical services, or
  - (b) to protect the Local Health Board from material financial loss.
- (4) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service that an NHS pharmacist or NHS appliance contractor is required to provide, the remedial notice may provide that—
- (a) as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, the Local Health Board is to withhold all or part of the remuneration due to the NHS pharmacist or NHS appliance contractor in respect of that period under the Drug Tariff or a determination as mentioned in regulation 56(2)(b);
  - (b) pending the NHS pharmacist or NHS appliance contractor taking the steps that either must take, to the satisfaction of the Local Health Board, in order to remedy the breach, the Local Health Board is to withhold all or part of the remuneration due to the NHS pharmacist or NHS appliance contractor under the Drug Tariff or a determination as mentioned in regulation 56(2)(b), and in these circumstances—
    - (i) as regards any period for which the NHS pharmacist or NHS appliance contractor remains in breach, any withholding that is attributable to that period is to be permanent, and
    - (ii) once the NHS pharmacist or NHS appliance contractor has taken the steps required, to the satisfaction of the Local Health Board, any withholding that has taken place which is attributable to a period when the NHS pharmacist or NHS appliance contractor is no longer in breach is to be restored, provided that the NHS pharmacist or NHS appliance contractor submits a claim, in accordance with the Drug Tariff or a determination as mentioned in regulation 56(2)(b), for restoration of the withheld remuneration attributable to that period.
- (5) The remedial notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 56(2)(b) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service.
- (6) The period referred to in paragraph (4)(b)(i) may be a longer period than the notice period.
- (7) If the Local Health Board refuses to restore all or part of any withheld remuneration which is claimed under paragraph (4)(b)(ii), it must notify the NHS pharmacist or NHS appliance contractor of that decision as soon as is practicable, and that notification must include—
- (a) a statement of the reasons for the decision, and
  - (b) an explanation of how the NHS pharmacist or NHS appliance contractor's rights of appeal under regulation 54(1)(b) may be exercised.
- (8) A Local Health Board may vary or revoke a remedial notice issued in accordance with this regulation at any time after it has been issued.

### **Breaches of terms of service: breach notices**

**51.**—(1) Where an NHS pharmacist or NHS appliance contractor breaches a term of service and the breach is not capable of remedy, the Local Health Board may by a notice (“a breach notice”) require the NHS pharmacist or NHS appliance contractor not to repeat the breach.

- (2) To be valid, the breach notice must include—

- (a) the nature of the breach, and
- (b) an explanation of how the NHS pharmacist or NHS appliance contractor's rights of appeal under regulation 54(1)(c) may be exercised.

(3) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service that an NHS pharmacist or NHS appliance contractor is required to provide, the breach notice may provide that, as regards the period during which there was a failure to provide, or a failure to provide to a reasonable standard, that service, the Local Health Board is to withhold all or part of the remuneration due to the NHS pharmacist or NHS appliance contractor under the Drug Tariff or a determination as mentioned in regulation 56(2)(b) in respect of that period.

(4) The breach notice may only provide for the withholding of all or part of the remuneration payable under a determination as mentioned in regulation 56(2)(b) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a pharmaceutical service.

(5) A Local Health Board may vary or revoke a breach notice issued in accordance with this regulation at any time after it has been issued.

#### **Payment withholdings: supplementary matters**

**52.**—(1) A remedial notice or breach notice may only provide for the withholding of all or any part of the remuneration of an NHS pharmacist or NHS appliance contractor if—

- (a) the Local Health Board is satisfied that the breach to which the withholding relates is, or was, without good cause;
- (b) the amount withheld is justifiable and proportionate, having regard to the nature and seriousness of the breach and the reasons for it;
- (c) the Local Health Board includes in the notice its duly justified reasons for both the decision to withhold remuneration and the amounts that are, and (where applicable) are to be, withheld.

(2) The Local Health Board need not take into account the reasons for the breach, pursuant to paragraph (1)(b), if it has made every reasonable effort to communicate with the NHS pharmacist or NHS appliance contractor to discover the reasons but it has been unable to discover them.

(3) Withholdings of payments provided for in remedial notices and breach notices are without prejudice to the arrangements in place for recovering overpayments under regulation 57 and the Drug Tariff.

(4) For the purposes of regulations 50(4) and 51(3), remuneration determined by the Welsh Ministers, or by the Local Health Board acting as determining authority pursuant to regulation 56(2)(b), is remuneration due to the NHS pharmacist or NHS appliance contractor under the Drug Tariff.

#### **Removal of listings: cases relating to remedial notices and breach notices**

**53.**—(1) The Local Health Board may remove an NHS pharmacist or NHS appliance contractor from a pharmaceutical list, or remove the listing of a particular listed premises in relation to the NHS pharmacist or NHS appliance contractor, if the NHS pharmacist or NHS appliance contractor—

- (a) fails to take the steps set out in a remedial notice, to the satisfaction of the Local Health Board, in order to remedy the breach, and the Local Health Board is satisfied that it is necessary to remove the NHS pharmacist or NHS appliance contractor from the pharmaceutical list, or remove the listing of a particular listed premises in relation to the NHS pharmacist or NHS appliance contractor—
  - (i) to protect the safety of any persons to whom the NHS pharmacist or NHS appliance contractor may provide pharmaceutical services, or
  - (ii) to protect the Local Health Board from material financial loss, or

- (b) has breached terms of service for NHS pharmacists and NHS appliance contractors, and—
  - (i) has repeatedly been issued with remedial notices or breach notices (or both) in relation to the relevant term of service,
  - (ii) been previously issued with a remedial notice or breach notice in relation to the relevant term of service, and the Local Health Board is satisfied that the NHS pharmacist or NHS appliance contractor is likely to persist in breaching the term of service without good cause, or
  - (iii) has repeatedly been issued with remedial notices or breach notices (or both) in relation to different terms of service, and the Local Health Board is satisfied that the NHS pharmacist or NHS appliance contractor is likely to persist in breaching their terms of service without good cause.
- (2) For the purpose of paragraph (1), the Local Health Board may only remove—
  - (a) particular premises from a NHS pharmacist or NHS appliance contractor’s listing in a pharmaceutical list if the relevant breaches all relate to those particular premises, or
  - (b) an NHS pharmacist or NHS appliance contractor from a particular pharmaceutical list if the relevant breaches all relate to listed premises which are the only premises listed in that pharmaceutical list in relation to the NHS pharmacist or NHS appliance contractor.
- (3) The Local Health Board may only remove an NHS pharmacist or NHS appliance contractor, or a premises listed in relation to an NHS pharmacist or NHS appliance contractor, from a pharmaceutical list under paragraph (1) if—
  - (a) the removal is justifiable and proportionate, having regard to the nature and seriousness of the breaches (or likely breaches) and the reasons for them, and
  - (b) the Local Health Board, when it notifies the NHS pharmacist or NHS appliance contractor of the decision, includes in the notice its duly justified reasons for the decision.
- (4) The Local Health Board need not take into account the reasons for the breaches (or likely breaches), pursuant to paragraph (3)(a), if it has made every reasonable effort to communicate with the NHS pharmacist or NHS appliance contractor to discover the reasons but has been unable to discover them.
- (5) Where the Local Health Board is considering removing an NHS pharmacist or NHS appliance contractor, or removing the listing of particular premises listed in relation to an NHS pharmacist or NHS appliance contractor, from a pharmaceutical list under paragraph (1), it must—
  - (a) give notice to the NHS pharmacist or NHS appliance contractor, at least 30 days in advance of taking the decision, that the Local Health Board is minded to remove the NHS pharmacist, NHS appliance contractor or the premises from a pharmaceutical list,
  - (b) as part of that notification, advise the NHS pharmacist or NHS appliance contractor that they may make—
    - (i) written representations to the Local Health Board with regard to that action, provided the NHS pharmacist or NHS appliance contractor notifies the Local Health Board with those representations within 30 days beginning with the date of the notification by the Local Health Board, and
    - (ii) oral representations to the Local Health Board with regard to that action, provided—
      - (aa) the NHS pharmacist or NHS appliance contractor notifies the Local Health Board of the NHS pharmacist or NHS appliance contractor’s wish to do so within 30 days beginning with the date of the notification by the Local Health Board, and
      - (bb) the NHS pharmacist or NHS appliance contractor (or a representative) attends the hearing that the Local Health Board arranges for the purpose of

hearing those representations, which the Local Health Board must give the NHS pharmacist or NHS appliance contractor reasonable notice of, and

- (c) consult any Local Pharmaceutical Committee whose area includes the particular listed premises or the only premises of the NHS pharmacist or NHS appliance contractor on that pharmaceutical list.

(6) If the Local Health Board does decide to remove a NHS pharmacist or NHS appliance contractor, or to remove the listing of particular premises listed in relation to the NHS pharmacist or NHS appliance contractor, from a pharmaceutical list under paragraph (1), it must, when it notifies the NHS pharmacist or NHS appliance contractor of that decision, include in that notification—

- (a) a statement of the reasons for the decision, and
- (b) an explanation of how the NHS pharmacist or NHS appliance contractor's rights of appeal under regulation 54(1)(d) may be exercised.

### **Appeals against decisions under Part 9**

**54.**—(1) An NHS pharmacist or NHS appliance contractor may appeal against the following decisions by the Local Health Board—

- (a) the issuing of a remedial notice under regulation 50, including—
  - (i) the specified steps that an NHS pharmacist or NHS appliance contractor must take that are in the notice,
  - (ii) the duration of the notice period in the notice,
  - (iii) any decision to provide for a withholding of remuneration that is included in the notice, and
  - (iv) the amount of any withholding;
- (b) a decision not to restore remuneration to the NHS pharmacist or NHS appliance contractor, as provided for in a remedial notice in accordance with regulation 50(4)(b)(ii), or to restore a smaller amount than the amount that the NHS pharmacist or NHS appliance contractor considers should be restored;
- (c) the issuing of a breach notice under regulation 51, including—
  - (i) any decision to provide for a withholding of remuneration that is included in the notice, and
  - (ii) the amount of any withholding;
- (d) a decision to remove an NHS pharmacist or NHS appliance contractor from a pharmaceutical list, or remove the listing of particular listed premises in relation to the NHS pharmacist or NHS appliance contractor, under regulation 53(1);

provided that an NHS pharmacist or NHS appliance contractor notifies the Welsh Ministers with a valid notice of appeal within 30 days of the date on which the NHS pharmacist or NHS appliance contractor was notified of the decision that is being appealed.

(2) A notice under paragraph (1) is valid only if it includes a concise and reasoned statement of the grounds of appeal.

(3) The Local Health Board must not remove an NHS pharmacist, NHS appliance contractor or the listing of particular listed premises in relation to an NHS pharmacist or NHS appliance contractor (as the case may be) from a pharmaceutical list under regulation 53(1)—

- (a) if no appeal is brought against the decision to remove, until the period for bringing the appeal has elapsed, or
- (b) if an appeal is brought against the decision to remove but it is unsuccessful, before the appeal is determined by the Welsh Ministers.

(4) Schedule 4 has effect in relation to appeals to the Welsh Ministers against decisions under this Part.