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STATUTORY INSTRUMENTS

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**2012 No. 1909**

**The National Health Service  
(Pharmaceutical Services) Regulations 2012**

**PART 10**

Performance related sanctions and market exit

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

**69.**—(1) Subject to paragraph (3), before issuing a notice under regulation 70 or 71, a Primary Care Trust (PCT1) must make every reasonable effort to communicate and co-operate with an NHS chemist on its pharmaceutical list (C) with a view to resolving any dispute between C and PCT1 relating to C's compliance with C's terms of service.

(2) Where an NHS pharmacist invites the Local Pharmaceutical Committee for its area to participate in the attempts to resolve the dispute, PCT1 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 PCT1 is satisfied—

- (a) the dispute relates to a matter that has already been the subject of dispute resolution between PCT1 and C and there are no new issues of substance that justify delay in issuing a notice under regulation 70 or 71; or
- (b) that it is appropriate to proceed immediately to issuing a notice under regulation 70 or 71—
  - (i) because listed chemist 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 C may provide pharmaceutical services, or
  - (iii) to protect PCT1 from material financial loss.

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

**70.**—(1) Where an NHS chemist (C) breaches a term of service and the breach is capable of remedy, the Primary Care Trust (PCT1) with which C has the arrangements to provide the pharmaceutical services to which the breach relates may by a notice (“a remedial notice”) require C to remedy the breach.

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

- (a) the nature of the breach;
- (b) the steps C must take, to the satisfaction of PCT1, 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 C's rights of appeal under regulation 77(1)(a) may be exercised.

(3) The notice period must be not less than 30 days, unless PCT1 is satisfied that a shorter period is appropriate—

- (a) to protect the safety of any persons to whom C may provide pharmaceutical services; or
  - (b) to protect PCT1 from material financial loss.
- (4) If the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that C 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, PCT1 is to withhold all or part of the remuneration due to C in respect of that period under the Drug Tariff or a determination as mentioned in regulation 91(2);
  - (b) pending C taking the steps that C must take, to the satisfaction of PCT1, in order to remedy the breach, PCT1 is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(2), and in these circumstances—
    - (i) as regards any period for which C remains in breach, any withholding that is attributable to that period is to be permanent, and
    - (ii) once C has taken the steps that C must take, to the satisfaction of PCT1, any withholding that has taken place which is attributable to a period when C is no longer in breach is to be restored to C, provided that C submits a claim, in accordance with the Drug Tariff or a determination as mentioned in regulation 91(2), 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 91(2) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, an enhanced service.
- (6) The period referred to in paragraph (4)(b)(i) may be a longer period than the notice period.
- (7) If PCT1 refuses to restore all or part of any withheld remuneration which is claimed under paragraph (4)(b)(ii), it must notify C 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 C's rights of appeal under regulation 77(1)(b) may be exercised.

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

**71.**—(1) Where an NHS chemist (C) breaches a term of service and the breach is not capable of remedy, the Primary Care Trust (PCT1) with which C has the arrangements to provide the pharmaceutical services to which the breach relates may by a notice (“a breach notice”) require C 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 C's rights of appeal under regulation 77(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 service that C 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, PCT1 is to withhold all or part of the remuneration due to C under the Drug Tariff or a determination as mentioned in regulation 91(2) 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 91(2) where the breach relates to a failure to provide, or a failure to provide to a reasonable standard, an enhanced service.

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

72.—(1) A remedial notice or breach notice may only provide for the withholding of all or any part of the remuneration of an NHS chemist (C) if—

- (a) the Primary Care Trust 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 Primary Care Trust 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 Primary Care Trust 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 C 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 94 and the Drug Tariff.

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

73.—(1) A Primary Care Trust (PCT1) may remove an NHS chemist (C) from its pharmaceutical list, or remove the listing of particular listed chemist premises in relation to C, if C—

- (a) fails to take the steps set out in a remedial notice that C must take, to the satisfaction of the PCT1, in order to remedy the breach, and PCT1 is satisfied that it is necessary to remove C from its pharmaceutical list, or remove the listing of particular listed chemist premises in relation to C—
  - (i) to protect the safety of any persons to whom C may provide pharmaceutical services, or
  - (ii) to protect PCT1 from material financial loss; or
- (b) has breached C's terms of service, and—
  - (i) C has repeatedly been issued with remedial notices or breach notices (or both) in relation to the relevant term of service,
  - (ii) previously been issued with a remedial notice or breach notice in relation to the relevant term of service, and PCT1 is satisfied that C is likely to persist in breaching the term of service without good cause, or
  - (iii) C has repeatedly been issued with remedial notices or breach notices (or both) in relation to different terms of service, and PCT1 is satisfied that C is likely to persist in breaching C's terms of service without good cause.

(2) For the purpose of paragraph (1), PCT1 may only remove—

- (a) particular chemist premises from C's listing if the relevant breaches all relate to those particular chemist premises; or
- (b) C from its pharmaceutical list if the relevant breaches all relate to listed chemist premises which are the only chemist premises listed in its pharmaceutical list in relation to C.

(3) PCT1 may only remove C, or chemist premises listed in relation to C, from its 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) PCT1, when it notifies C of the decision, includes in the notice its duly justified reasons for the decision.
- (4) PCT1 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 C to discover the reasons but has been unable to discover them.
- (5) PCT1 must not remove C, or chemist premises listed in relation to C, from its pharmaceutical list under paragraph (1) because—
  - (a) C has simply ceased to provide pharmaceutical services at particular listed chemist premises (regulation 74 applies in those circumstances); or
  - (b) of failure to provide, or to provide to a reasonable standard, a directed service, unless C is required to provide that service pursuant to a condition imposed by virtue of regulation 66(1) or (3) to (5) (and the removal is justifiable and proportionate etc.).
- (6) Where PCT1 is considering removing C, or remove the listing of particular listed chemist premises in relation to C, from its pharmaceutical list under paragraph (1), it must—
  - (a) give notice to C, at least 30 days in advance of taking the decision, that PCT1 is minded to remove C or the premises from its pharmaceutical list;
  - (b) as part of that notification, advise C that C may make—
    - (i) written representations to PCT1 with regard to that action, provided C notifies PCT1 with those representations within 30 days beginning with the date of the notification by PCT1, and
    - (ii) oral representations to PCT1 with regard to that action, provided—
      - (aa) C notifies PCT1 of C's wish to do so within 30 days beginning with the date of the notification by PCT1, and
      - (bb) C (or a representative of C) attends the hearing that PCT1 arranges for the purpose of hearing those representations, which PCT1 must give C reasonable notice of; and
  - (c) consult any Local Pharmaceutical Committee for its area.
- (7) If PCT1 does decide to remove C, or remove the listing of particular listed chemist premises in relation to C, from its pharmaceutical list under paragraph (1), it must, when it notifies C of that decision, include in that notification—
  - (a) a statement of the reasons for the decision; and
  - (b) an explanation of how C's rights of appeal under regulation 77(1)(d) may be exercised.

**Removal of listings: cases relating to death, incapacity or cessation of service**

- 74.—**(1) Subject to paragraphs (2) and (4), if an NHS chemist (C)—
- (a) dies;
  - (b) in the case of an NHS pharmacist, ceases to carry on a retail pharmacy business; or
  - (c) in the case of an NHS appliance contractor, ceases to carry on a business in the course of which C supplies appliances either by retail sale or in circumstances corresponding to retail sale,

the Primary Care Trust (PCT1) in whose pharmaceutical list C is included must remove C from that list.

- (2) Paragraph (1)(a) or (b) shall not apply in the case of an NHS pharmacist, if—

- (a) a representative of C (as defined in section 72 of the 1968 Act<sup>(1)</sup> (representative of pharmacist in case of death or disability)) is carrying on the retail pharmacy business of C that is included in PCT1's pharmaceutical list ("the business");
  - (b) the conditions specified in section 72(2) of the 1968 Act are fulfilled in relation to the representative and the business;
  - (c) the period applicable in accordance with section 72(3) of the 1968 Act has not expired; and
  - (d) the representative has agreed to be bound by, and continues to agree to be bound by, C's terms of service.
- (3) If PCT1 determines that C has not, during the preceding 6 months, provided pharmaceutical services at particular listed chemist premises ("the particular premises")—
- (a) if there are other chemist premises listed in its pharmaceutical list in relation to C, PCT1 must remove the listing of the particular premises in relation to C; or
  - (b) if there are no other chemist premises listed in its pharmaceutical list in relation to C, PCT1 must remove C from its pharmaceutical list.
- (4) When determining, for the purposes of paragraph (1) or (3), whether C has ceased to carry on a business or ceased to provide pharmaceutical services, no account is to be taken of any time spent by C—
- (a) suspended from PCT1's pharmaceutical list;
  - (b) in whole-time service in the armed forces of the Crown in a national emergency;
  - (c) in compulsory whole-time service in the armed forces of the Crown (including service resulting from reserve liability); or
  - (d) where C is liable for compulsory whole-time service in the armed forces of the Crown, in any equivalent service,
- and in a case of C ceasing to carry on a business, no account is to be taken of the first 6 months after C completes that whole-time service in the armed forces of the Crown or equivalent service.
- (5) Before taking a decision to remove C, or chemist premises listed in relation to C, from its pharmaceutical list under paragraph (1) or (3), PCT1 must—
- (a) give notice to C (or, in appropriate circumstances, a person whom PCT1 reasonably believes is representing C or is an executor of C) of the decision that PCT1 is minded to take;
  - (b) as part of that notification, advise C (or the representative or executor) that they may make—
    - (i) written representations to PCT1 with regard to that action, provided they notify PCT1 with those representations within 30 days beginning with the date of the notification by PCT1, and
    - (ii) oral representations to PCT1 with regard to that action, provided—
      - (aa) they notify PCT1 of their wish to do so within 30 days beginning with the date of the notification by PCT1, and
      - (bb) C (or the representative or executor, or someone representing the representative or executor) attends the hearing that PCT1 arranges for the purpose of hearing those representations, which PCT1 must give C reasonable notice of; and

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(1) Section 72 has been amended by: the Insolvency Act 1985 (c. 65), Schedule 8, paragraph 15; the Insolvency Act 1986 (c. 45), Schedule 14; the Adults with Incapacity (Scotland) Act 2000 (asp 4), Schedule 5, paragraph 12, and Schedule 6; the Mental Incapacity Act 2005 (c. 9), Schedule 6, paragraph 14; the Health Act 2006 (c. 28), section 29; and S.I. 1989/ 2405, 2007/289 and 2010/231

- (c) consult any Local Pharmaceutical Committee for its area.
- (6) If PCT1 does decide to remove C from its pharmaceutical list under paragraph (1) or (3), it must, when it notifies C of that decision, include in that notification—
  - (a) a statement of the reasons for the decision; and
  - (b) an explanation of how C’s rights of appeal under regulation 77(1)(d) may be exercised.

**Voluntary and automatic removal of listings: change of ownership, relocation, temporary provision and voluntary closure**

**75.**—(1) If, as a consequence of a change of ownership application, an NHS chemist (C) is no longer to be the person listed in the pharmaceutical list of a Primary Care Trust (PCT1), in relation to particular pharmacy premises—

- (a) if there are other chemist premises listed in its pharmaceutical list in relation to C, PCT1 must remove the listing of the particular premises in relation to C; or
  - (b) if there are no other chemist premises listed in its pharmaceutical list in relation to C, subject to regulation 76, PCT1 must remove C from its pharmaceutical list.
- (2) If C is relocating from existing chemist premises to new chemist premises—

- (a) if—
  - (i) there are other chemist premises listed by PCT1 in its pharmaceutical list in relation to C, or
  - (ii) the new chemist premises are in the area of PCT1,
 PCT1 must remove the listing of the existing premises in relation to C with effect from the date that C is required to notify to PCT1 under regulation 67(4)(b); or
- (b) if—
  - (i) there are no other premises listed by PCT1 in its pharmaceutical list in relation to C, and
  - (ii) the new chemist premises are in the area of another Primary Care Trust,
 subject to regulation 76, PCT1 must remove C from its pharmaceutical list with effect from the date that C is required to notify to PCT1 under regulation 67(4)(a)(ii).

(3) If C has been providing pharmaceutical services on behalf of a suspended NHS chemist at listed chemist premises (“the temporary provision premises”), once the fixed period referred to in regulation 27(3) expires, if—

- (a) other chemist premises are listed by PCT1 in its pharmaceutical list in relation to C, PCT1 must remove the listing of the temporary provision premises in relation to C; or
- (b) apart from the temporary provision premises, there are no other chemist premises listed by PCT1 in its pharmaceutical list in relation to C, PCT1 must remove C from its pharmaceutical list.

(4) Paragraph (5) applies if C—

- (a) wishes, other than as provided for in paragraphs (1) to (3), to close particular listed chemist premises and so—
  - (i) to withdraw from a pharmaceutical list, or
  - (ii) for particular listed chemist premises no longer to be listed in relation to C; and
- (b) has complied with regulation 67(2).

(5) In the circumstances described in paragraph (4)—

- (a) if there are other chemist premises listed in its pharmaceutical list in relation to C, PCT1 must remove the listing of the particular premises in relation to C; or
  - (b) if there are no other chemist premises listed in its pharmaceutical list in relation to C, subject to regulation 76, PCT1 must remove C from its pharmaceutical list.
- (6) If PCT1 decides not to remove C from its pharmaceutical list under paragraph (5), it must, when it notifies C of that decision, include in that notification—
- (a) a statement of the reasons for the decision; and
  - (b) where appropriate, an explanation of how any rights of appeal that C has under regulation 77(1)(e) may be exercised.

### **Limitation on withdrawal from pharmaceutical lists while fitness investigations or proceedings are ongoing**

**76.**—(1) If a Primary Care Trust (PCT1) would otherwise remove an NHS chemist (C) from its pharmaceutical list under regulation 75, but—

- (a) is investigating an NHS chemist (C) in order to see whether there are grounds for exercising its powers in relation to C under section 151, 152 or 154 of the 2006 Act (2)(which relate to disqualification of practitioners, contingent removal and suspension), or regulation 80;
- (b) has decided to—
  - (i) remove C from its pharmaceutical list under section 151 or 152 of the 2006 Act or regulation 80, or
  - (ii) contingently remove C under section 152 of the 2006 Act, but C has not yet been removed or contingently removed; or
- (c) has suspended C under section 154 of the 2006 Act,

it must not, without the consent of the Secretary of State, remove C from its pharmaceutical list under regulation 75 until the relevant investigation or proceedings have been concluded.

(2) If C's name is kept on PCT1's pharmaceutical list pursuant to paragraph (1)—

- (a) as regards C, PCT1 may exercise its functions under—
  - (i) Part 11 of these Regulations, and
  - (ii) Chapter 6 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – disqualification); but
- (b) for all other purposes, C is to be treated as having been removed from its pharmaceutical list under regulation 75.

### **Appeals against decisions under Part 10**

**77.**—(1) An NHS chemist (C) may appeal against the following decisions by a Primary Care Trust—

- (a) the issuing of a remedial notice under regulation 70, including—
  - (i) the specified steps that C 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

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(2) Section 154 has been amended by [S.I. 2010/22](#).

- (iv) the amount of any withholding;
- (b) a decision not to restore remuneration to C, as provided for in a remedial notice in accordance with regulation 70(4)(b)(ii), or to restore a smaller amount than the amount that C considers should be restored;
- (c) the issuing of a breach notice under regulation 71, 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 C from its pharmaceutical list, or remove the listing of particular listed chemist premises in relation to C, under regulation 73(1) or 74(1) or (3);
- (e) a refusal to remove C from its pharmaceutical list under regulation 75(5), other than a decision to keep C on the pharmaceutical list for limited purposes pursuant to regulation 76,

provided that C notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which C 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 Primary Care Trust must not remove C or the listing of particular listed chemist premises in relation to C (as the case may be) from its pharmaceutical list under regulation 73(1) or 74(1) or (3)—

- (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 Secretary of State.

(4) Schedule 3 has effect in relation to appeals to the Secretary of State against decisions under this Part (as it does in relation to appeals against decisions under Parts 2 to 5, 7, 8 and 12 and Schedule 2).