
STATUTORY INSTRUMENTS

2013 No. 349

**The National Health Service (Pharmaceutical and
Local Pharmaceutical Services) Regulations 2013**

PART 11

Enforcement, reviews and appeals relating to fitness matters

Extended meaning of “health scheme” in fraud cases

78. The schemes prescribed under section 151(7)(b) of the 2006 Act (disqualification of practitioners) are schemes in the course of which health or medical services are paid for out of public funds and provided—

- (a) other than as part of the health services referred to in section 151(7)(a)—
 - (i) by port health authorities,
 - (ii) by the armed forces of the Crown, or
 - (iii) to persons in accommodation in which they are required in accordance with law to be detained (but not naval, military and air force prisons, which are covered by sub-paragraph (ii)); or
- (b) by or on behalf of the government of a country or territory outside the United Kingdom.

Review of decisions to impose fitness conditions originally imposed on grants of applications

79.—(1) Where the NHSCB has imposed a condition on an NHS chemist (C) under regulation 35 (or thereafter under this regulation), or a Primary Care Trust has imposed a condition on C under regulation 35 or 79 of the 2012 Regulations (which relate to fitness conditions and conditions to combat fraud), the NHSCB may review the decision to impose the condition—

- (a) at its own volition; or
 - (b) where requested to do so by C, but C may not make such a request—
 - (i) in the case of the first such request, until at least 3 months have elapsed since C was included in the relevant pharmaceutical list, or
 - (ii) thereafter, until at least 6 months have elapsed since the NHSCB (or a Primary Care Trust) determined the outcome of the previous review.
- (2) If the NHSCB is undertaking the review of its own volition, it must inform C that it is doing so.
- (3) As part of any review under paragraph (1), the NHSCB must afford C an opportunity to make representations to it in writing.
- (4) As a result of the review, the NHSCB may remove the condition, leave the condition unchanged, vary the condition or impose a different condition, but any varied or different condition must be a condition with a view to—
- (a) preventing any prejudice to the efficiency of the services, or any of the services, which C has undertaken to provide; or

- (b) preventing any act or omission within section 151(3)(a) of the 2006 Act (disqualification of practitioners).
- (5) The NHSCB must notify C of a decision under paragraph (4), and it must include with the notification an explanation of—
 - (a) the reasons for the decision;
 - (b) C's right of appeal against its decision on the review to the First-tier Tribunal (which C has by virtue of this sub-paragraph);
 - (c) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008(1), the application notice must be sent to the Tribunal if an appeal is to be brought; and
 - (d) the continuing application of the condition that applied prior to the review, if there is an appeal, pending the outcome of the appeal.
- (6) If the outcome of the review is that the condition is to be varied or a different decision is to be imposed, that decision is to take effect—
 - (a) if no appeal is brought against the decision, once the period for bringing an appeal has elapsed; or
 - (b) if an appeal is brought against the decision, and the decision of the NHSCB is not changed by the First-tier Tribunal, once the First-tier Tribunal has determined the appeal (if the First-tier Tribunal takes a different decision to the decision taken by the NHSCB, that decision takes effect upon the taking of that decision, unless the First-tier Tribunal directs otherwise).

Removal for breach of fitness conditions imposed under regulation 35 or 79

80. If, in the course of a review under regulation 79 or otherwise, the NHSCB determines that an NHS chemist has failed to comply with a condition imposed under—

- (a) regulation 35 or 79, or as varied under regulation 79; or
- (b) regulation 35 or 79 of the 2012 Regulations (which relate to fitness conditions and conditions to combat fraud), or as varied under regulation 79 of those Regulations,

it may remove that NHS chemist from the relevant pharmaceutical list.

Mandatory removal in suitability cases

81. In unsuitability cases, the NHSCB must remove an NHS chemist (C) from a pharmaceutical list if—

- (a) C (or where C is a body corporate, any director or superintendent of C) has been convicted in the United Kingdom of murder;
- (b) C (or where C is a body corporate, any director or superintendent of C)—
 - (i) has been convicted in the United Kingdom of a criminal offence, other than murder, which was committed after 1st April 2005, and
 - (ii) has been sentenced to a term of imprisonment of over 6 months; or
- (c) C is the subject of a national disqualification.

Fitness cases: procedures for removal or contingent removal from pharmaceutical lists

82.—(1) This paragraph applies where the NHSCB is considering—

(1) [S.I. 2008/2699 \(L 16\)](#); see rule 19 of those Rules.

- (a) removing an NHS chemist (C) from a pharmaceutical list under section 151 or 152(3)(b) of the 2006 Act⁽²⁾ (which relate to disqualification of practitioners and contingent removal);
 - (b) removing C from a pharmaceutical list under regulation 80; or
 - (c) contingently removing C from a pharmaceutical list under section 152(1) of the 2006 Act⁽³⁾.
- (2) Where paragraph (1) applies, before reaching its decision, the NHSCB must—
- (a) notify C of the action the NHSCB is considering taking and its grounds for considering taking that action; and
 - (b) as part of that notification—
 - (i) inform C of any allegation against C, and
 - (ii) advise C that C may make—
 - (aa) written representations to the NHSCB with regard to that action, provided C notifies the NHSCB with those representations within 30 days beginning with the date of the notification by the NHSCB, and
 - (bb) oral representations to the NHSCB with regard to that action, provided C notifies the NHSCB of C's wish to do so within 30 days beginning with the date of the notification by the NHSCB and C (or a representative of C) attends the hearing that the NHSCB arranges for the purpose of hearing those representations, which the NHSCB must give C reasonable notice of; and
 - (c) in an unsuitability case to which regulation 81(a) or (b) applies, if C is a body corporate, advise C that the NHSCB will not remove C from the relevant pharmaceutical list as a consequence of that regulation (without prejudice to any other action it may take), provided that—
 - (i) the director or superintendent ceases to be a director or superintendent of C within the period of 30 days that begins on the date of the notification by the NHSCB, and
 - (ii) within that period, C notifies the NHSCB of the date on which the director or superintendent has ceased or is to cease to be a director or superintendent of C.
- (3) Once the NHSCB has taken its decision, it must notify C of its decision, and it must include with the notification (which may be combined, in appropriate cases, with a notification under regulation 79(5)) an explanation of—
- (a) the reasons for the decision;
 - (b) if the NHSCB has decided to remove or contingently remove C from a pharmaceutical list—
 - (i) C's rights of appeal in relation to that decision under section 158 of the 2006 Act⁽⁴⁾ (appeals), and
 - (ii) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008⁽⁵⁾, the application notice must be sent to the Tribunal if an appeal is to be brought; and
 - (c) if the NHSCB has decided to contingently remove C, the arrangements for review of the conditions under section 157(1) of the 2006 Act⁽⁶⁾ (review of decisions).

(2) Section 151 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 79. Section 152(3) has been amended by the 2012 Act, Schedule 4, paragraph 80.

(3) Section 152(1) has been amended by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 80.

(4) Section 158 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 84, and by S.I. 2010/22.

(5) S.I. 2008/2699 (L 16); see rule 19 of those Rules.

(6) Section 157 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 83, and by S.I. 2010/22.

(4) If the NHSCB has decided to remove or contingently remove C from a pharmaceutical list in accordance with this regulation, that decision is not to take effect—

- (a) if C does not appeal against the decision, until the period for bringing an appeal against the decision has elapsed; or
- (b) if C does appeal against the decision, unless the First-tier Tribunal has determined the appeal and confirmed the decision of the NHSCB (if the First-tier Tribunal takes a different decision to the decision taken by the NHSCB, that decision takes effect upon the taking of that decision, unless the First-tier Tribunal directs otherwise).

Procedure for suspensions in fitness cases

83.—(1) Where the NHSCB is considering suspending an NHS chemist (C) from a pharmaceutical list under section 154(1) or section 155(2) of the 2006 Act⁽⁷⁾ (which relate to suspension and suspension pending appeal), before reaching its decision, it must—

- (a) notify C of the action the NHSCB is considering taking and its grounds for considering taking that action; and
 - (b) as part of that notification—
 - (i) where the NHSCB is considering taking action under section 154(1), inform C of any allegation against C, and
 - (ii) advise C that C may make oral representations to the NHSCB with regard to the possible suspension on a specified day, provided C notifies the NHSCB of C's wish to do so within a specified period (of not less than 24 hours).
- (2) If, within the specified period—
- (a) C does not advise the NHSCB that C wishes to make oral representations to the NHSCB on the specified day, thereafter the NHSCB may suspend C with immediate effect; or
 - (b) C does advise the NHSCB that C wishes to make oral representations to the NHSCB on the specified day, the NHSCB must not suspend C until after the oral hearing, but may then do so with immediate effect.
- (3) Once the NHSCB has taken its decision, it must notify C of its decision as soon as is practicable, and it must include with the notification of its decision an explanation of—
- (a) the reasons for the decision;
 - (b) if the NHSCB has decided to suspend C under section 154(1), the arrangements for review of the suspension under section 157(1) of the 2006 Act⁽⁸⁾ (review of decisions).

Procedure for reviewing some suspensions and contingent removal conditions

84.—(1) This paragraph applies where the NHSCB—

- (a) is required to review a contingent removal or a suspension under section 157(1) of the 2006 Act (review of decisions); or
- (b) decides to review a contingent removal or a suspension that it could be required to review under that section (if section 157(2) were satisfied).

(2) Where paragraph (1) applies, as part of the review, the NHSCB must afford the NHS chemist who has been contingently removed or is suspended (C) the opportunity to make—

⁽⁷⁾ Section 154 has been amended by the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), Schedule 4, paragraph 81, and by [S.I. 2010/22](#). Section 155 has been amended by the 2012 Act, Schedule 4, paragraph 82, and by [S.I. 2010/22](#).

⁽⁸⁾ Section 157 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 83, and by [S.I. 2010/22](#).

- (a) written representations to the NHSCB, provided C notifies the NHSCB with those representations within 30 days beginning with the date of the notification by the NHSCB; and
 - (b) oral representations to the NHSCB with regard to that action, provided—
 - (i) C notifies the NHSCB of C's wish to do so within 30 days beginning with the date of the notification by the NHSCB, and
 - (ii) C (or a representative of C) attends the hearing that the NHSCB arranges for the purpose of hearing those representations, which the NHSCB must give C reasonable notice of.
- (3) Once the NHSCB has taken its decision under section 157(3) of the 2006 Act, it must notify C of its decision, and it must include with the notification of its decision an explanation of—
- (a) the reasons for the decision;
 - (b) if C has a right of appeal in relation to the decision—
 - (i) the right of appeal that C has in relation to that decision under section 158 of the 2006 Act⁽⁹⁾ (appeals), and
 - (ii) the time limit within which, in accordance with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008⁽¹⁰⁾, the application notice must be sent to the Tribunal if an appeal is to be brought; and
 - (c) if C has been or remains suspended or contingently removed, the arrangements for review of the suspension or the conditions under section 157(1) of the 2006 Act.

General power to revoke suspensions in appropriate circumstances

85.—(1) If an NHS chemist is suspended from a pharmaceutical list, in addition to the NHSCB's powers to terminate suspensions under section 157(3)(b) of the 2006 Act⁽¹¹⁾ (review of decisions) on a review, the NHSCB may terminate the suspension at any time, in appropriate circumstances.

(2) If the NHSCB terminates a suspension under paragraph (1), it must notify the NHS chemist that it has done so.

Internal handling of fitness information by the NHSCB or an agent of the NHSCB

86.—(1) The NHSCB must ensure that the records it maintains relating to the fitness of NHS chemists and LPS chemists to be NHS chemists or LPS chemists are only accessible to persons whom the NHSCB employs in circumstances where the NHSCB is satisfied that they—

- (a) should have access to the information on a need-to-know basis; and
- (b) fully understand the confidential nature of the information and the purposes for which they are being permitted access to it.

(2) Where functions of the NHSCB relating to the fitness of NHS chemists or LPS chemists are carried out on behalf of the NHSCB by an agent of the NHSCB—

- (a) the reference in paragraph (1) to persons whom the NHSCB employs includes reference to persons whom the agent employs to perform functions under the agency arrangement (about whom the agent must be satisfied on the NHSCB's behalf as mentioned in subparagraphs (a) and (b) of paragraph (1)); and
- (b) the NHSCB must ensure that the terms of the agency arrangement are such that the information the agent holds relating to the fitness of NHS chemists and LPS chemists to

⁽⁹⁾ Section 158 has been amended by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 84, and by S.I. 2010/22.

⁽¹⁰⁾ See rule 19 of those Rules.

⁽¹¹⁾ Section 157 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 83, and by S.I. 2010/22.

be NHS chemists or LPS chemists as a consequence of the arrangement is not further processed by the agent in a manner which is incompatible with the confidential nature of the information and the purposes for which it has been obtained.

Review periods for national disqualifications

87.—(1) Section 159(8)(a) of the 2006 Act⁽¹²⁾ (national disqualification) is to have effect as if the reference to “two years” were a reference to “five years”, if the First-tier Tribunal determines, when it imposes the national disqualification, that the conduct of the person on whom the national disqualification has been imposed has been such that there is no realistic prospect of a review being successful if held within five years.

(2) Section 159(8)(b) of the 2006 Act is to have effect as if the reference to “one year” were a reference to “three years”, if the First-tier Tribunal determines, on a review, that the conduct of the person on whom the national disqualification has been imposed has been such that there is no realistic prospect of a further review being successful if held within three years.

(3) Section 159(8) of the 2006 Act is to have effect as if the references to “two years” and “one year”—

(a) in a case where—

- (i) a national disqualification has been imposed as a consequence of a criminal conviction, and
- (ii) on appeal, the conviction has been quashed or the penalty imposed by the court has been reduced; or

(b) in a case where—

- (i) a national disqualification has been imposed as a consequence of an adverse decision of a licensing body, and
- (ii) on appeal, the decision of the licensing body has been quashed or the penalty imposed by it has been reduced,

were a reference to a period equal to the period between the date on which that appeal was determined and the date on which the national disqualification was imposed or last reviewed.

Wider notifications of fitness decisions

88.—(1) Where the NHSCB—

- (a) refuses an application from a person (P) by virtue of regulation 33;
- (b) grants an application subject to conditions imposed on P by virtue of regulation 35;
- (c) imposes or varies a condition imposed on P by virtue of regulation 79;
- (d) removes P from a pharmaceutical list by virtue of section 151 or 152(3)(b) of the 2006 Act⁽¹³⁾ (which relate to disqualification of practitioners and contingent removal);
- (e) contingently removes P from a pharmaceutical list by virtue of section 152 of the 2006 Act, or varies or imposes a different condition on P by virtue of that section; or
- (f) suspends P under section 154 or 155 of the 2006 Act⁽¹⁴⁾ (which relate to suspension and suspension pending appeal),

the NHSCB must notify the persons listed in paragraph (2) that it has done so.

⁽¹²⁾ Section 159 has been amended by the Health and Social Care Act 2012, Schedule 4, paragraph 85, and by [S.I. 2010/22](#).

⁽¹³⁾ Section 151 has been amended by the Health and Social Care Act 2012 ([c. 7](#)) (“the 2012 Act”), Schedule 4, paragraph 79. Section 152 has been amended by the 2012 Act, Schedule 4, paragraph 80.

⁽¹⁴⁾ Section 154 has been amended by the Health and Social Care Act 2012 ([c. 7](#)) (“the 2012 Act”), Schedule 4, paragraph 81, and by [S.I. 2010/22](#). Section 155 has been amended by the 2012 Act, Schedule 4, paragraph 82, and by [S.I. 2010/22](#).

- (2) Those persons are—
- (a) the Secretary of State;
 - (b) where known to the NHSCB, any other primary care organisation that—
 - (i) has included P, or a body corporate of which P is a director or superintendent, in a relevant list, or
 - (ii) is considering including P, or a body corporate of which P is a director or superintendent, in a relevant list;
 - (c) the Scottish Ministers;
 - (d) the Welsh Ministers;
 - (e) the Northern Ireland Executive;
 - (f) the General Pharmaceutical Council;
 - (g) any Local Pharmaceutical Committee for the area of the relevant HWB (including any Local Pharmaceutical Committee for part of its area or for its area and that of all or part of the area of one or more other HWBs);
 - (h) in a case that is or may be a fraud case, the NHS BSA; and
 - (i) any person who may and does request to be notified of an adverse fitness decision as regards P.
- (3) A person (Q) comes within paragraph (2)(i) if Q establishes to the satisfaction of the NHSCB (or before the appointed day the relevant Primary Care Trust) that Q—
- (a) has employed or engaged, is employing or engaging or is considering employing or engaging P, or a director or superintendent of P, in a professional capacity; or
 - (b) is a member of a partnership of which P has been or is a member, or which is considering inviting P to be a member.
- (4) A notification under paragraph (1) must include—
- (a) where P is an individual or a partnership—
 - (i) P's, or each member of the partnership's, name, address and date of birth, and
 - (ii) P's, or each member of the partnership's, registration number in the Register of Pharmacists; and
 - (b) where P is a body corporate—
 - (i) P's name, company registration number and the address of P's registered office, and
 - (ii) the registration number in the Register of Pharmacists of P's superintendent and of any director of P who is a registered pharmacist;
 - (c) a copy of the notification of the decision that was sent to P; and
 - (d) the name of and contact details for a person at the NHSCB who is in a position to respond to further enquiries.
- (5) The NHSCB must notify P of whom it has notified under paragraph (1) and include, when it does so, the content of that notification.
- (6) If, in response to an enquiry from a person notified under paragraph (1), the NHSCB notifies that person with further documentation (including documentation in an electronic form) that relates to P, the NHSCB must also notify P with—
- (a) that documentation; and
 - (b) details of the person to whom it has been sent.

(7) If the NHSCB is notified by the First-tier Tribunal of a national disqualification, or the outcome of the review of a national disqualification, it must notify that information to the persons it notified about its own decision in relation to P under paragraph (2)(b) and (g) to (i).

(8) If—

- (a) having notified a person under paragraph (1) of a suspension or a condition (including a condition imposed on contingent removal); or
- (b) after a Primary Care Trust notified a person under regulation 88(1) of the 2012 Regulations (wider notifications of fitness decisions) of a suspension or a condition (including a condition imposed on contingent removal),

the NHSCB terminates the suspension or removes the condition, the NHSCB must notify that person with the notification given to P of the decision to terminate the suspension or remove the condition.