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D I R E C T I O N S

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**NATIONAL HEALTH SERVICE ACT 2006**

The National Health Service Litigation Authority  
(Pharmaceutical Remuneration – Overpayments) (England)  
Directions 2018

The Secretary of State for Health and Social Care gives the following Directions in exercise of the powers conferred by sections 7(1), 8 and 272(7) and (8) of the National Health Service Act 2006(a).

**Citation, commencement, application and interpretation**

1.—(1) These Directions may be cited as the National Health Service Litigation Authority (Pharmaceutical Remuneration – Overpayments) (England) Directions 2018 and come into force on 1st August 2018.

(2) These Directions apply in relation to England.

(3) In these Directions—

“the 2013 Regulations” means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(b);

“appellant” means a person bringing an appeal of the nature described in direction 2(1);

“the Authority” means the National Health Service Litigation Authority established by the National Health Service Litigation Authority (Establishment and Constitution) Order 1995(c) (or, where the context so requires, persons or a committee exercising functions on its behalf in accordance with direction 2(4) and 3(1)); and

“the decision” is to be construed in accordance with direction 2(1).

(4) In these Directions, words and expressions used in these Directions and in the 2013 Regulations bear the meanings they bear in the 2013 Regulations.

**Disputes relating to the recovery of overpayments of pharmaceutical remuneration: delegation of functions to the Authority and to its committees and staff**

2.—(1) The Authority is directed to exercise the functions of the Secretary of State relating to receiving and determining any dispute referred to the Secretary of State under section 9(6) of the 2006 Act(d) (NHS contracts) in respect of the recovery of an overpayment from an NHS pharmacist under regulation 94(1) of the 2013 Regulations (recovery of overpayments) which is in the nature of an appeal against a decision of the NHSCB that there has been an overpayment (“the decision”).

(2) The Authority must determine the appeal itself and not appoint a person to consider and determine the appeal pursuant to section 9(8) of the 2006 Act.

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(a) 2006 c. 41. Section 7 has been amended by the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), section 21. Section 8 has been amended by the 2012 Act, Schedule 4, paragraph 5, and Schedule 14, paragraph 3.

(b) S.I. 2013/349.

(c) S.I. 1995/2800; amended by S.I. 2002/2621, 2005/1445 and 2012/1641.

(d) Section 9 has been amended by: the Health and Social Care Act 2008 (c. 14), Schedule 5, paragraph 82; the Health and Social Care Act 2012, Schedule 7, paragraphs 6 and 18, Schedule 17, paragraph 10, Schedule 19, paragraph 9, and Schedule 21, paragraph 6; the Care Act 2014 (c. 23), Schedule 5, paragraph 16; and S.I. 2008/2250.

(3) The Authority is directed to exercise the powers of the Secretary of State under section 2 of the 2006 Act<sup>(a)</sup> (general power) to do anything that is calculated to facilitate, or is conducive or incidental to, the discharge of the functions of the Secretary of State that the Authority is exercising by virtue of paragraph (1), but only to the extent that it is necessary for the proper exercise of that function.

(4) The functions that the Authority is directed to exercise by virtue of paragraphs (1) and (3) may be exercised on behalf of the Authority either by an officer or employee of the Authority or by a committee established in accordance with direction 3(1).

### **Membership of a committee**

**3.—**(1) The Authority may (and where direction 6(3)(a) applies must) make arrangements for any of the functions that it is directed to exercise by virtue of direction 2(1) and (3) to be exercised on its behalf by a committee established for the purpose and constituted in accordance with this direction.

(2) A committee established under paragraph (1)—

- (a) may, but need not, be composed wholly or partly of officers of the Authority; and
- (b) is to consist of no more than 5 members, of whom—
  - (i) in the case of a committee consisting of 2 members, both members must be lay persons, or
  - (ii) in the case of a committee consisting of more than 2 members, a majority or all of the members must be lay persons.

(3) No person is to be a member of a committee established under paragraph (1) (whether or not their involvement would give rise to a reasonable suspicion of bias) who—

- (a) is a person who is included in a pharmaceutical list or is an employee of such a person;
- (b) assists in the provision of pharmaceutical services under Chapter 1 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – provision of pharmaceutical services);
- (c) is an LPS chemist, or provides or assists in the provision of local pharmaceutical services;
- (d) is a provider of primary medical services;
- (e) is a member of a provider of primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
- (f) is employed or engaged by a primary medical services provider; or
- (g) is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services.

(4) No person is to be a member of a committee established under paragraph (1) which is considering any matter if, because of an interest or association they have, or because of a pressure to which they may be subject, their involvement in that consideration would give rise to a reasonable suspicion of bias.

(5) In paragraph (2), “lay person” means a person who is not and never has been registered by—

- (a) a body (B) mentioned in section 25(3)(a) to (ga) of the National Health Service Reform and Health Care Professions Act 2002<sup>(b)</sup> (the Professional Standards Authority for and Social Care); or
- (b) a body that preceded B as the statutory regulator of any profession regulated by B.

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(a) Section 2 was substituted by the Health and Social Care Act 2012, Schedule 4, paragraph 1(1).

(b) 2002 c. 17; section 25(3) has been amended by: the Health and Social Care Act 2008 (c. 14), Schedule 10, paragraph 17; S.I. 2010/231; the Health and Social Care Act 2012 (c. 7), Schedule 15, paragraph 56(b); and the Children and Social Work Act 2017 (c. 16), Schedule 4, paragraph 2.

#### **Dismissing appeals: preliminary matters**

4. The Authority must determine an appeal against the decision by dismissing it—
- (a) if—
    - (i) the NHSCB has advised the appellant that the appeal to the Authority must be brought within 30 days of the date on which the appellant was notified of the decision by the NHSCB, and
    - (ii) the appellant does not bring it within 30 days of that date; or
  - (b) if it is of the opinion that the notification of the appeal from the appellant to the Authority contains no valid grounds of appeal (for example, because it amounts to a challenge to the legality or reasonableness of these Directions, the 2013 Regulations or the Drug Tariff).

#### **Flexibility with regard to the manner of determining appeals**

5.—(1) Except in so far as these Directions provide to the contrary, the Authority is to determine the appeal against the decision in such manner (including with regard to procedures) as the Authority sees fit.

(2) Where appropriate, the Authority may, if the Authority thinks fit, consider two or more appeals together and in relation to each other, but where the Authority does so, the Authority must give notice to the appellants and the NHSCB of the Authority's intention to do so.

#### **Oral hearings**

6.—(1) Subject to paragraph (2), the Authority may determine the appeal without hearing any oral representations.

(2) Before the appeal is finally decided, the appellant may ask to make oral representations, and if such a request is made, a hearing must be arranged, unless the Authority is satisfied that—

- (a) a hearing is unnecessary; or
  - (b) it must dismiss the appeal by virtue of direction 4.
- (3) If a hearing is arranged—
- (a) the hearing must be before a committee established under direction 3(1); and
  - (b) the Authority must give not less than 14 days notice of the time and place at which the oral representations are to be heard to—
    - (i) the NHSCB, and
    - (ii) the appellant,and they (or their duly authorised representatives) are to be the only persons entitled to make oral representations at the hearing.

#### **Decisions of the Authority**

7.—(1) On deciding an appeal against a decision, the Authority may—

- (a) dismiss the appeal and confirm the decision;
- (b) substitute for the decision any decision that the NHSCB could have taken when it took the decision; or
- (c) quash the decision, with or without remitting the matter to the NHSCB for it to take the decision again subject to such directions as the Authority considers appropriate.

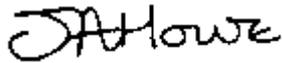
(2) Once the Authority has determined the appeal, the Authority must notify the following of its decision—

- (a) the NHSCB; and
- (b) the appellant,

and must include with that notification a statement of the reasons for the Authority's decision and the Authority's findings of fact.

(3) For the purposes of the 2013 Regulations and the Drug Tariff, the Authority's decision becomes the NHSCB's decision on the matter (but no further appeal to the Authority on that decision is possible), unless the Authority's decision is overruled by a court.

Signed by authority of the Secretary of State for Health and Social Care

A handwritten signature in black ink that reads "J. Howe". The signature is written in a cursive, slightly stylized font.

16 July 2018

*Jeannette Howe*  
Head of Pharmacy  
Department of Health and Social Care