
DIRECTIONS

NATIONAL HEALTH SERVICE ACT 2006

The National Health Service Litigation Authority (Functions Relating to Pharmaceutical Services and Local Pharmaceutical Services) (England) Directions 2012

The Secretary of State for Health gives the following Directions in exercise of the powers conferred by sections 7(1), 8, 272(7) and (8) and 273(1) of the National Health Service Act 2006(a).

Citation, commencement and application

1.—(1) These Directions may be cited as the National Health Service Litigation Authority (Functions Relating to Pharmaceutical Services and Local Pharmaceutical Services) (England) Directions 2012 and come into force on 1st September 2012.

(2) These Directions apply in relation to England.

Interpretation

2.—(1) In these Directions—

“the 2005 Directions” means the National Health Service Litigation Authority (Functions) (England) Directions 2005(b);

“the 2005 Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2005(c), as in force immediately before the appointed day;

“the appointed day” means 1st September 2012;

“the Authority” means the National Health Service Litigation Authority established by the National Health Service Litigation Authority (Establishment and Constitution) Order 1995(d);

“the ESP Directions” means the Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2005(e);

(a) 2006 c. 41.

(b) Signed on 31st March 2005. Relevant amendments were made by the National Health Service (Miscellaneous Amendments Relating to Prescribing, Pharmaceutical Services and Local Pharmaceutical Services etc.) (England) Directions 2006, signed on 8th March 2006.

(c) S.I. 2005/641. These Regulations, and the amendments to them, were revoked by S.I. 2012/1909.

(d) S.I. 1995/2800; amended by S.I. 2002/2621 and 2005/1445.

(e) These Directions were signed on 28th October 2005 and have been amended by: the National Health Service (Miscellaneous Amendments Relating to Prescribing, Pharmaceutical Services and Local Pharmaceutical Services etc.) (England) Directions 2006, signed on 8th March 2006; the Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2007, signed on 22nd February 2007 and revoked with effect from 1st October 2008; the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) Directions 2008, signed on 30th September 2008 and revoked with effect from 1st February 2010; the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) (No. 2) Directions 2008, signed on 14th November 2008 and revoked with effect from 1st February 2010; the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) Directions 2010, signed on 29th January 2010; the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) (No. 2) Directions 2010, signed on 30th September 2010; the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) (No. 3) Directions 2010, signed on 30th November 2010 and revoked with effect from 1st December 2011; the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) Directions 2011, signed on 29th November 2011; and the Local Pharmaceutical Services (Essential Small Pharmacies) (Amendment) Directions 2012, signed on 20th July 2012.

“the LPS Regulations” means the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006(a);

“the PS Regulations” means the National Health Service (Pharmaceutical Services) Regulations 2012(b); and

“the SCAT Regulations means the National Health Service (Service Committees and Tribunal) Regulations 1992(c).

(2) Words and expressions used in directions 4 to 7 and in the PS Regulations bear the meanings they bear in the PS Regulations.

Exercise by the Authority of functions in relation to LPS agreements

3.—(1) The Authority must exercise the following functions of the Secretary of State—

- (a) subject to paragraph (2), the functions of the Secretary of State under the terms of LPS schemes included in accordance with the following provisions of Schedule 2 to the LPS Regulations (contract terms)—
 - (i) paragraph 21 (dispute resolution: non-NHS contracts),
 - (ii) paragraph 22 (NHS dispute resolution procedure), and
 - (iii) paragraph 23 (determination of dispute);
- (b) the functions relating to receiving and determining an appeal by a qualifying pharmacist in accordance with paragraph 26(9) to (11) of Schedule 4 to the PS Regulations (terms of service – determination of pharmacy premises core opening hours instigated by the NHS pharmacist), as that paragraph applies in relation to ESPLPS agreements by virtue of direction 9(3) of the ESP Directions (hours of opening);
- (c) the functions under the terms of ESPLPS agreements included in accordance with direction 20 of the ESP Directions (provisions of LPS Directions which apply) which relate to—
 - (i) appointing an adjudicator for the purposes of dispute resolution, and
 - (ii) receiving requests for dispute resolution.

(2) The Authority must not, pursuant to paragraph (1)(a), exercise the Secretary of State’s functions in relation to dispute resolution or determination where the dispute relates to termination by a Primary Care Trust pursuant to a term of an LPS scheme required by virtue of paragraph 29 of Schedule 2 to the LPS Regulations (termination by a Primary Care Trust on grounds of suitability etc.), but this limitation applies only in so far as the dispute requires a determination as to whether or not a person falls within paragraph 29(2) of that Schedule.

Exercise by the Authority of functions relating to pharmaceutical services

4. The Authority must exercise the following functions of the Secretary of State—

- (a) the functions relating to receiving and determining any appeal under the PS Regulations in relation to which Schedule 3 to the PS Regulations (appeals to the Secretary of State) has effect, including all of the functions of the Secretary of State under that Schedule (which include determining whether certain persons have rights of appeal);
- (b) the functions relating to being contacted about, and providing, information under—
 - (i) regulation 33(2) of the PS Regulations (refusal of applications for inclusion in a pharmaceutical list on fitness grounds),
 - (ii) regulation 86(2) of the PS Regulations (evidence of unsuitability, fraud or inefficiency in service provision: specific matters), and

(a) S.I. 2006/552.

(b) S.I. 2012/1909.

(c) S.I. 1992/664. These Regulations, and the amendments to them, were revoked by S.I. 2012/1909.

- (iii) paragraph 23(1)(b) of Schedule 2 to the PS Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – additional matters for consideration in relation to applications for inclusion in a pharmaceutical list);
- (c) the function of providing consent under regulation 76(1) (limitation on withdrawal from pharmaceutical lists while fitness investigations or proceedings are ongoing);
- (d) the function of receiving notifications under regulation 88(2)(a) of the PS Regulations (wider notifications of fitness decisions); and
- (e) the functions relating to receiving and determining an appeal under—
 - (i) paragraph 25(7) to (9) of Schedule 4 to the PS Regulations (terms of service of NHS pharmacists – determination of pharmacy premises core opening hours instigated by the Primary Care Trust),
 - (ii) paragraph 26(9) to (11) of Schedule 4 to the PS Regulations (terms of service of NHS pharmacists – determination of pharmacy premises core opening hours instigated by the NHS pharmacist),
 - (iii) paragraph 15(7) to (9) of Schedule 5 to the PS Regulations (terms of service of NHS appliance contractors – determination of core opening hours instigated by the Primary Care Trust), and
 - (iv) paragraph 16(9) to (11) of Schedule 5 to the PS Regulations (terms of service of NHS appliance contractors – determination of core opening hours instigated by the NHS appliance contractor).

Dealing with incidental matters etc.

5. The Authority is to exercise the powers of the Secretary of State under section 2 of the National Health Service Act 2006 (Secretary of State's general power) to do anything that is calculated to facilitate, or is conducive or incidental to, the discharge of any duty that the Authority is discharging on the Secretary of State's behalf by virtue of these Directions, but only to the extent that it is necessary for the proper discharge of that duty.

Consideration of pharmaceutical services and local pharmaceutical services issues

6.—(1) The Authority must make arrangements for the following functions under the PS Regulations to be exercised on its behalf by a committee established for the purpose and constituted in accordance with direction 7—

- (a) as regards an appeal against the grant or refusal of an application for inclusion in a pharmaceutical list by a person not already included in it, or for inclusion also in respect of premises other than those already listed in relation to that person—
 - (i) the final deciding of the appeal, and
 - (ii) the hearing, where oral representations are to be made in the course of the appeal, of those oral representations prior to the final deciding of the appeal;
- (b) as regards an appeal against the grant or refusal of an application for outline consent or premises approval—
 - (i) the final deciding of the appeal, and
 - (ii) the hearing, where oral representations are to be made in the course of the appeal, of those oral representations prior to the final deciding of the appeal;
- (c) as regards an appeal against a determination of whether or not an area is, or is part of, a controlled locality—
 - (i) the final deciding of the appeal, and
 - (ii) the hearing, where oral representations are to be made in the course of the appeal, of those oral representations prior to the final deciding of the appeal,
- (d) as regards an appeal to which sub-paragraphs (a) to (c) do not apply but in the course of which it is decided by the Authority that oral representations are to be heard—

- (i) the hearing of those oral representations prior to the final deciding of the appeal, and
- (ii) the final deciding of an appeal.

(2) Any function which—

- (a) the Authority is directed to exercise by virtue of directions 3 to 5; and
- (b) need not be exercised on behalf of the Authority by a committee established under paragraph (1) by virtue of that paragraph,

must be exercised on behalf of the Authority either by an officer or employee of the Authority or by such a committee.

Membership of a committee

7.—(1) A committee established under direction 6(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.

(2) No person is to be a member of a committee established under direction 6(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 a PCTMS practice; or
- (g) is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services.

(3) No other person is to be a member of a committee established under direction 6(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.

(4) In paragraph (1), “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(a) (the Council for Healthcare Regulatory Excellence); or
- (b) a body that preceded B as the statutory regulator of any profession regulated by B.

Amendments and revocations

8.—(1) In the National Health Service Litigation Authority (Functions) (England) Directions 2005—

(a) 2002 c. 17; section 25(3) has been amended by the Health and Social Care Act 2008 (c. 14), Schedule 10, paragraph 17; and by S.I. 2010/231.

- (a) in direction 2(1) (interpretation), omit the definitions of “local pharmaceutical services” and “LPS scheme”;
 - (b) in direction 8 (exercise of miscellaneous functions by the authority)—
 - (i) in paragraph (1)—
 - (aa) omit paragraph (a), and
 - (bb) in paragraph (b) omit “except as provided for in paragraph (a),” and
 - (ii) omit paragraphs (2) to (6);
 - (c) omit direction 8A (functions relating to local pharmaceutical services);
 - (d) in direction 9 (transitional provisions), omit paragraph (4); and
 - (e) in the Schedule, omit the entries under the headings “The Pharmaceutical Regulations” and “The National Health Service (Service Committees and Tribunal) Regulations 1992”;
- (2) Direction 4 of the National Health Service (Miscellaneous Amendments Relating to Prescribing, Pharmaceutical Services and Local Pharmaceutical Services etc.) (England) Directions 2006 is revoked.

Transitional and saving provisions

9.—(1) Where any function of the Secretary of State under the 2005 Regulations or the SCAT Regulations that, immediately before the appointed day, the Authority was directed to exercise is to be exercised on or after the appointed day by virtue of Schedule 7 to the PS Regulations (transitional provisions)—

- (a) that function is to be exercised by the Authority; and
- (b) for these purposes, the 2005 Directions and the SCAT Regulations have effect as they had effect immediately before the appointed day.

(2) A person who—

- (a) before the appointed day was a member of a committee established under direction 8 of the 2005 Directions (exercise of miscellaneous functions by the authority); but
- (b) is prevented from being a member of a committee established under direction 6(1) by virtue of direction 7(2),

may, until the end of 31st August 2013, be a member of a committee established under direction 6(1), notwithstanding direction 7(2), in circumstances where the Authority is satisfied that their involvement in the matter before the committee would not give rise to a reasonable suspicion of bias.

Signed by authority of the Secretary of State for Health



20th July 2012

Jeannette Howe
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