#### STATUTORY INSTRUMENTS

# 2013 No. 349

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

# **PART 13**

#### Local Pharmaceutical Services

# Designation of areas, premises or descriptions of premises

- **99.**—(1) The NHSCB may designate relevant areas, premises or descriptions of premises for the purposes of paragraph 2 of Schedule 12 to the 2006 Act(1) (LPS schemes designation of priority neighbourhoods or premises).
- (2) Any designation made is to be of an area in which, or premises or descriptions of premises at which, local pharmaceutical services are to be provided under a proposed or approved LPS scheme (referred to in this regulation as the "relevant scheme"), but a designation is not necessary in respect of every such scheme.
  - (3) Any designation made must—
    - (a) be made in writing and be dated;
    - (b) include a map showing the location of the area, premises or description of premises designated; and
    - (c) include an outline of the services to be provided under the relevant scheme.
  - (4) The NHSCB must give notice of the designation to—
    - (a) the HWB (HWB1) for the area to which the designation relates, or (as the case may be) for the area in which the premises or descriptions of premises are situated;
    - (b) any Local Pharmaceutical Committee whose area includes the premises, descriptions of premises, or all or part of the area to which the designation relates;
    - (c) any Local Medical Committee whose area includes the premises, descriptions of premises, or all or part of the area to which the designation relates;
    - (d) any NHS chemist whose listed chemist premises—
      - (i) are in the area of HWB1, or
      - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the designation;
    - (e) any person who is entitled because of the grant of a routine or excepted application to be included in a pharmaceutical list—
      - (i) for the area of HWB1, or

<sup>(1)</sup> Paragraph 2 has been amended by: the Health Act 2009 (c. 21), section 29(12); and the Health and Social Care Act 2012 (c. 7), section 207(12), and Schedule 4, paragraph 93(3).

(ii) for the area of a neighbouring HWB, if their interests are likely, in the opinion of the NHSCB, to be affected by the designation,

but who is not (yet) included;

- (f) any LPS chemist whose chemist premises—
  - (i) are in the area of HWB1, or
  - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the designation;
- (g) any dispensing doctor whose listed dispensing premises—
  - (i) are in the area of HWB1, or
  - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the designation; and
- (h) any Local Healthwatch organisation for the area of HWB1.
- (5) A designation under this regulation, and any designation by a Primary Care Trust under regulation 4 of the 2006 Regulations(2) (designation of priority neighbourhoods or premises), may be varied by the NHSCB where—
  - (a) if it relates to an area, the LP services to be provided under the relevant scheme are to be provided in or from part only of that area;
  - (b) if it relates to premises, the LP services to be provided under the relevant scheme are to be provided at or from part only of those premises;
  - (c) if it relates to a description of premises, the LP services to be provided under the relevant scheme are to be provided at or from parts only of the premises described.
  - (6) Where a designation is varied under paragraph (5), that designation must—
    - (a) satisfy the requirements of paragraph (3) (the date of the designation becoming the date on which it is varied); and
    - (b) be notified in accordance with paragraph (4).
  - (7) The NHSCB must—
    - (a) publish—
      - (i) all its (current) designations, including designations it has varied, under this regulation, and
      - (ii) all the (current) designations of Primary Care Trusts, including their varied designations, under regulation 4 of the 2006 Regulations; and
    - (b) ensure that each HWB has access to those designations which is sufficient to enable the HWB to carry out its functions under these Regulations.

## Review of designations

- **100.**—(1) The NHSCB must regularly review—
  - (a) all its designations, including designations it has varied, under regulation 99; and
  - (b) all the designations of Primary Care Trusts, including their varied designations, under regulation 4 of the 2006 Regulations (designation of priority neighbourhoods or premises),

and in any event must review each of those designations before the end of 6 months beginning with either the date of the designation or (if later) the date it concluded its last review of the designation.

- (2) When conducting a review under paragraph (1), the NHSCB must take into account any responses it or a Primary Care Trust received when the designation was last notified.
- (3) In a case where a designation is not varied or cancelled as a result of a review, the NHSCB must give notice of the outcome of the review to the persons who would have been notified under regulation 99(6)(b) if the designation had been varied.

## Cancellation of designations

- **101.**—(1) The NHSCB may at any time cancel—
  - (a) any of its designations, including designations it has varied, under regulation 99; and
  - (b) any of the designations of Primary Care Trusts, including their varied designations, under regulation 4 of the 2006 Regulations (designation of priority neighbourhoods or premises).
- (2) The NHSCB must cancel a designation—
  - (a) if required to do so by a direction given by the Secretary of State under section 168A of the 2006 Act(3) (exercise of functions);
  - (b) within 12 months of the date of the decision to make the designation, disregarding any subsequent decision to vary the designation, if in the case of designation for a proposed LPS scheme, no proposal to enter into an LPS scheme has been received by the NHSCB (or before the appointed day by a Primary Care Trust) for approval;
  - (c) if, in the case of a designation for a proposed LPS scheme, the only (or only remaining) proposal to enter into an LPS scheme that relates to the designation has been refused;
  - (d) if there has been a significant change to the area in which, or to the premises from which, LP services are to be provided, other than a change which leads to a variation of the designation under regulation 99(5); or
  - (e) if or when an LPS contractor commences the provision of LP services at the designated location.
- (3) The NHSCB must give notice of the cancellation to the persons who would have been notified under regulation 99(6)(b) if the designation had instead been varied.
- (4) If a designation has been cancelled under this regulation or regulation 6 of the 2006 Regulations (cancellation of designations by a Primary Care Trust), the NHSCB may only designate the same area, premises or description of premises under regulation 99 within 6 months of that cancellation if the reason for the cancellation was the refusal by the NHSCB or a Primary Care Trust of a proposal to enter into an LPS scheme.

#### Terms of service for LPS schemes: general

- **102.**—(1) Each LPS scheme must specify—
  - (a) the LP services to be provided under the scheme, which must include the dispensing of drugs; and
  - (b) the address of the premises at or from which those services are to be provided ("the scheme premises").
- (2) If the provider of services under an LPS scheme is a health service body, the scheme must state that it is an NHS contract.
- (3) Each LPS scheme must contain the terms, or terms which make provision that has the same effect as the terms, set out in Schedule 7.

#### LPS schemes: health service body status

- **103.**—(1) Subject to paragraph (3), an LPS contractor (C) is to be treated as a health service body for the purposes of section 9 of the 2006 Act(4) (NHS contracts) unless—
  - (a) as regards an LPS scheme established by a Primary Care Trust before the appointed day, either—
    - (i) before the LPS scheme was entered into, the proposed provider (or providers) under the scheme objected to that by a notice in writing to the Primary Care Trust, or
    - (ii) before the appointed day, the LPS scheme was varied under regulation 10(4) of the 2006 Regulations (health service body status), as a consequence of which the scheme ceased to be treated as an NHS contract; or
  - (b) before the LPS scheme is entered into, the proposed provider (or providers) under the scheme object to that by a notice in writing to the NHSCB.
- (2) Where C is to be treated as a health service body for the purposes of section 9 of the 2006 Act, subject to paragraph (3), any variation of the LPS scheme which changes a party to the scheme does not affect the health service body status of the provider (or providers) of goods and services under the scheme.
- (3) C may at any time request a variation of an LPS scheme so as to provide that the scheme is to become, or is to cease to be, an NHS contract, and if C does so—
  - (a) if—
    - (i) C is the only other party to the scheme, the NHSCB must agree to the variation, or
    - (ii) if all the parties to the scheme other than the NHSCB are together making the request, the NHSCB must agree to the variation; and
  - (b) the procedure in paragraph 26 of Schedule 7 is to apply.
- (4) Where, pursuant to paragraph (3), the NHSCB agrees to a variation of an LPS scheme, C is (as the case may be)—
  - (a) to be treated as a health service body; or
- (b) subject to paragraph (6), to cease to be treated as a health service body, for the purposes of section 9 of the 2006 Act from the date on which the variation takes effect.
- (5) Subject to paragraph (6), a person who has been both a provider under an LPS scheme and treated as a health service body for the purposes of that scheme is to cease to be treated as a health service body for the purposes of that scheme where—
  - (a) the scheme is varied so that person is no longer a provider under that scheme; or
  - (b) the scheme, or the agreement that is part of the scheme to which that person is a party, is terminated.
  - (6) Where a person ceases to be treated as a health service body pursuant to—
    - (a) paragraph (4), C is to be bound (as is the NHSCB) by any adjudication which was referred to an adjudicator pursuant to paragraph 22 of Schedule 7 before the variation took effect; or
    - (b) paragraph (5)(b), C is to continue to be treated as a health service body for the purposes of the resolution of any dispute that falls to be resolved in accordance with the terms of the terminated agreement or scheme notwithstanding its termination.

<sup>(4)</sup> Section 9 has been amended by the Health and Social Care Act 2008 (c. 14), Schedule 5, paragraph 82, and by the Health and Social Care Act 2012, Schedule 4, paragraph 6, Schedule 7, paragraph 18, Schedule 14, paragraph 4, Schedule 17, paragraph 10, Schedule 19, paragraph 9, and Schedule 21, paragraph 6.

#### **Development of LPS schemes**

- **104.**—(1) The NHSCB may make payments of financial assistance in respect of the development of LPS schemes.
- (2) If a proposal for an LPS scheme is submitted to the NHSCB, it must consider whether or not to select that proposal for development, unless the proposal is vexatious or frivolous.

# Persons permitted to be parties to LPS schemes: fitness criteria

- **105.**—(1) The NHSCB may only be a party to an LPS scheme with the following—
  - (a) an individual who does not fall within paragraph (2);
  - (b) a partnership (other than a limited liability partnership) where each partner does not fall within paragraph (2);
  - (c) a body corporate where—
    - (i) the body corporate, and
    - (ii) any director, chief executive, superintendent or company secretary of the body corporate,

do not fall within paragraph (2).

- (2) A person (P) falls within this paragraph if—
  - (a) P is the subject of a national disqualification;
  - (b) Subject to paragraph (3), P is disqualified or suspended (other than by an interim suspension order or a direction pending investigation) from practising by a licensing or regulatory body anywhere in the world;
  - (c) P has, within 5 years of the date on which either P would be due to start participating in the LPS scheme, or (if earlier) commits to participating in the scheme, been refused admission to a relevant list for a reason that amounts to inefficiency, fraud or unsuitability (as understood by reference to the conditions in section 151(2) to (4) of the 2006 Act) (disqualification of practitioners), unless P has subsequently been included in a relevant list;
  - (d) P has been convicted in the United Kingdom of murder;
  - (e) P has been convicted in the United Kingdom of a criminal offence other than murder—
    - (i) which was committed on or after 1st April 2006, and
    - (ii) for which P has been sentenced to a term of imprisonment of over 6 months;
  - (f) subject to paragraph (4), P has elsewhere than the United Kingdom been convicted of an offence which, if committed in England or Wales—
    - (i) would constitute murder, or
    - (ii) would constitute a criminal offence, and
      - (aa) which was committed on or after 1st April 2006, and
      - (bb) for which P has been sentenced to a term of imprisonment of over 6 months;
  - (g) P has been convicted of an offence referred to in—
    - (i) Schedule 1 to the Children and Young Persons Act 1933(5) (offences against children and young persons with respect to which special provisions of the Act apply), or

<sup>(5) 1933</sup> c. 12. Schedule 1 has been amended by: the Sexual Offences Act 1956 (c. 69), Schedule 4; the Criminal Justice Act 1988 (c. 33), Schedule 15, paragraph 8, and Schedule 16; the Sexual Offences Act 2003 (c. 42), Schedule 6, paragraph 7; the Domestic Violence, Crime and Victims Act 2004 (c. 28), Schedule 10, paragraph 2; the Coroners and Justice Act 2009 (c. 25), Schedule 21, paragraph 53; and the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 136.

(ii) Schedule 1 to the Criminal Procedure (Scotland) Act 1995(6) (offences against children under the age of 17 years to which special provisions apply),

which was committed on or after 1st April 2006;

- (h) P—
  - (i) has been adjudged bankrupt and has not been discharged from the bankruptcy,
  - (ii) is a person in relation to whom a moratorium period under a debt relief order under Part 7A of the Insolvency Act 1986(7) (debt relief orders) applies,
  - (iii) is the subject of a bankruptcy restrictions order, an interim bankruptcy restrictions order, a debt relief restrictions order or an interim debt relief restrictions order under Schedule 4A or 4ZB to the Insolvency Act 1986(8) or Schedule 2A of the Insolvency (Northern Ireland) Order 1989(9) (which relate to bankruptcy and debt relief restrictions orders and undertakings),
  - (iv) if P is a body corporate, has been wound up under Part 4 of the Insolvency Act 1986;
  - (v) has made a composition or arrangement with, or granted a trust deed for, P's creditors and P has not been discharged in respect of it;
- (i) in respect of P there is—
  - (i) an administrator, administrative receiver or receiver appointed, or
  - (ii) an administration order under Schedule B1 to the Insolvency Act 1986(10) (administration);
- (j) P has, within 5 years of the date on which either P would be due to start participating in the LPS scheme or (if earlier) commits to participating in the scheme, been removed—
  - (i) from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners, the Charity Commission, the Charity Commission for Northern Ireland or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity—
    - (aa) for which the person was responsible or to which the person was privy, or
    - (bb) which the person by their conduct contributed to or facilitated, or
  - (ii) under-
    - (aa) section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990(11) (powers of Court of Session to deal with management of charities), or
    - (bb) section 34(5)(e) or (ea) of the Charities and Trustee Investment (Scotland) Act 2005(12) (powers of the Court of Session),

from being concerned with the management or control of any body;

(k) P has, within 5 years of the date on which either P would be due to start participating in the LPS scheme or (if earlier) commits to participating in the scheme, been subject to—

<sup>(</sup>**6**) 1995 c. 46.

<sup>(7) 1986</sup> c. 45; Part 7A was inserted by the Tribunals, Courts and Enforcement Act 2007 (c. 15), Schedule 17.

<sup>(8)</sup> Schedule 4A was inserted by Schedule 20 to the Enterprise Act 2002 (c.40). Schedule 4ZB was inserted by the Tribunals, Courts and Enforcement Act 2007 (c. 15), Schedule 19.

<sup>(9)</sup> S.I. 1989/2405 (N.I. 19); Schedule 2A was inserted by S.I. 2005/1455 (N.I. 10).

<sup>(10)</sup> Schedule B1 was inserted by the Enterprise Act 2002 (c. 40), Schedule 16.

<sup>(11) 1990</sup> c.40; section 7 was repealed by the Charities and Trustee Investment (Scotland) Act 2005 (asp 10), Schedule 4, paragraph 7(b)

<sup>(12) 2005</sup> asp 10; section 34(5) has been amended by the section the Public Services Reform (Scotland) Act 2010 (asp 8), section 122.

- (i) a disqualification order or disqualification undertaking under the Company Directors Disqualification Act 1986(13) or the Company Directors Disqualification (Northern Ireland) Order 2002(14), or
- (ii) an order made under section 429(2) of the Insolvency Act 1986(15) (disabilities on revocation of a county court administration order); or
- (l) P has, in the case of an individual, refused to comply with a request from the NHSCB for P to be medically examined on the grounds that the NHSCB is concerned that P is incapable of adequately providing services under the scheme.
- (3) A person does not fall within paragraph (2)(b) if the NHSCB is satisfied that the disqualification or suspension imposed by a licensing or regulatory body outside the United Kingdom does not make P unsuitable to be—
  - (a) a party to an LPS scheme; or
  - (b) in the case of an LPS scheme made with a body corporate, a director, chief executive, superintendent or company secretary of a party to an LPS scheme.
- (4) A person does not fall within paragraph (2)(f) where the NHSCB is satisfied that the conviction does not make P unsuitable to be—
  - (a) a party to an LPS scheme; or
  - (b) in the case of an LPS scheme with a body corporate, a director, chief executive, superintendent or company secretary of a party to an LPS scheme.

# LPS proposals: fitness information to be supplied

- **106.**—(1) A person (P) proposing to become a party to an LPS scheme with the NHSCB must supply to the NHSCB, with their proposal, the information listed in paragraph (2) about the following relevant persons—
  - (a) if P is an individual, about P;
  - (b) if P a partnership, about each partner;
  - (c) if P is a body corporate, about—
    - (i) the body corporate, and
    - (ii) any director, chief executive, superintendent or company secretary of the body corporate.
  - (2) That information is whether a relevant person (R)—
    - (a) has any criminal convictions in the United Kingdom;
    - (b) has accepted a police caution in the United Kingdom;
    - (c) has been convicted elsewhere than in the United Kingdom of an offence which would, if committed in England or Wales, constitute a criminal offence;
    - (d) has been subject to an order under section 246(2) or (3) of the Criminal Procedure (Scotland) Act 1995(16) (admonition and absolute discharge) discharging R absolutely;

<sup>(13) 1986</sup> c.46.

<sup>(14)</sup> S.I. 2002/3150 (N.I. 4); relevant amendments were made by S.I. 2005/1454 (N.I. 9).

<sup>(15)</sup> Section 429(2) was amended by the Enterprise Act 2002 (c.40), Schedule 23, paragraph 15.

<sup>(16) 1995</sup> c. 46; section 246(2) and (3) have been amended by the Criminal Justice and Licensing (Scotland) Act 2010 (asp 13), Schedule 2, paragraph 26.

- (e) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995(17) (fixed penalty: conditional offer by procurator fiscal);
- (f) has agreed to pay a penalty under section 115A of the Social Security Administration Act 1992(18) (penalty as alternative to prosecution);
- (g) is the subject of any proceedings which might lead to a conviction and which have not yet been notified to the NHSCB;
- (h) has been subject to any investigation into R's professional conduct by a licensing or regulatory body, the outcome of which was adverse;
- (i) is, to R's knowledge, the subject of an investigation into R's professional conduct by a licensing or regulatory body;
- (j) is, to R's knowledge, or where the outcome was adverse has been, the subject of an investigation into R's professional conduct in respect of any current or previous employment;
- (k) is, to R's knowledge, the subject of an investigation by another primary care organisation, which might lead to removal from a relevant list;
- (l) is, to R's knowledge, or where the outcome was adverse has been, the subject of an investigation by the NHS BSA in relation to fraud;
- (m) on fitness grounds—
  - (i) has had an application for inclusion in a relevant list refused,
  - (ii) has been conditionally included in a relevant list,
  - (iii) has been removed or contingently removed from a relevant list,
  - (iv) is suspended from a relevant list,
  - and if so, the name of the relevant primary care organisation; or
- (n) is or ever has been the subject of a national disqualification,
- and if so, P must give details of the relevant investigation or proceedings, including the nature of the investigation or proceedings, where and when (if known) they took place, and any outcome.
- (3) If information mentioned in paragraph (2) has already been provided to the NHSCB on a previous occasion pursuant to regulations under Part 7 of the 2006 Act, P need not provide that information again to the NHSCB, but if P is relying on this paragraph, P must, when supplying their proposal—
  - (a) confirm to the NHSCB that the NHSCB already has all the information required under paragraph (2); or
  - (b) if there is any missing information required under that paragraph—
    - (i) confirm to the NHSCB what information the NHSCB already has, and
    - (ii) provide the missing information.
- (4) If the NHSCB determines that P may not become a party to the LPS scheme by virtue of regulation 105, the NHSCB must notify P of its determination, the reasons for its determination, and of P's right of appeal under paragraph (5).

<sup>(17) 1995</sup> c. 46. Section 302 has been amended by: the Communications Act 2003 (c. 21), Schedule 17, paragraph 133; the Wireless Telegraphy Act 2006 (c. 36), Schedule 7, paragraph 16; the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6), section 50(1); and the Criminal Justice and Licensing (Scotland) Act 2010 (asp 13), section 70(3).

<sup>(18) 1992</sup> c. 5. Section 115A was inserted by the Social Security Administration (Fraud) Act 1997 (c. 47), section 15, and amended by the Social Security Fraud Act 2001 (c. 11) ("the 2001 Act"), section 14. The amendments made by the 2001 Act are to be repealed by, and other amendments to section 115A are to be made by, the Welfare Reform Act 2012 (c. 5), sections 113 to 115, and Schedule 14, Part 1.

(5) P may appeal against a determination mentioned in paragraph (4) to the First-Tier Tribunal, provided P does so within 30 days of the date on which P was notified of the determination.

# Notification of proposals

- **107.** If the NHSCB decides to select a proposal for an LPS scheme for development, it must give notice of that decision and provide such details of the proposed LPS scheme as it considers appropriate to—
  - (a) the HWB (HWB1) for the area in which are situated the premises at or from which local pharmaceutical services are to be provided under the proposal;
  - (b) any Local Pharmaceutical Committee for the area in which are situated the premises at or from which local pharmaceutical services are to be provided under the proposal;
  - (c) any Local Medical Committee for the area in which are situated the premises at or from which local pharmaceutical services are to be provided under the proposal;
  - (d) any NHS chemist whose listed chemist premises—
    - (i) are in the area of HWB1, or
    - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the proposal;
  - (e) any person who is entitled because of the grant of a routine or excepted application to be included in a pharmaceutical list—
    - (i) for the area of HWB1, or
    - (ii) for the area of a neighbouring HWB, if their interests are likely, in the opinion of the NHSCB, to be affected by the proposal,

but who is not (yet) included;

- (f) any LPS chemist whose scheme premises—
  - (i) are in the area of HWB1, or
  - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the proposal;
- (g) any dispensing doctor whose listed dispensing premises—
  - (i) are in the area of HWB1, or
  - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the proposal; and
- (h) any Local Healthwatch organisation for the area of HWB1.

# Right of return to pharmaceutical lists: LPS contractors

- **108.**—(1) Before the NHSCB becomes a party to an LPS scheme with any person, it must determine whether that person is to be given a right of return to a pharmaceutical list if that person makes an application under regulation 28 and satisfies the conditions for a grant of an application under that regulation.
  - (2) If an LPS scheme is varied so as to—
    - (a) relocate the provision of local pharmaceutical services under the scheme to different scheme premises; or
    - (b) change a party (other than the NHSCB) to the scheme,

the NHSCB must review any right of return granted under this regulation or regulation 15 of the 2006 Regulations (right of return to pharmaceutical lists) arising under that scheme in order to determine whether or not the right of return is to be varied or rescinded.

- (3) If an LPS scheme is varied as mentioned in paragraph (2)(b), the right of return of the person who is no longer a party to the LPS scheme is extinguished (whether or not the right of return is maintained in respect of the new provider under the LPS scheme).
- (4) The NHSCB may review any right of return granted under this regulation or regulation 15 of the 2006 Regulations (right of return to pharmaceutical lists) in order to determine whether or not the right of return is to be varied or rescinded—
  - (a) at any time an LPS scheme is varied other than in order to give effect to an amendment to these Regulations (in addition to those occasions on which it is required to review a right of return under paragraph (2)); or
  - (b) if asked to do so by an LPS contractor.
- (5) The NHSCB must publish the principles by reference to which it makes determinations under this regulation and may amend those principles from time to time.
- (6) Where the NHSCB makes, varies or rescinds a determination under this regulation, it must give notice of that decision to—
  - (a) the HWB (HWB1) for the area in which are situated the scheme premises for the relevant LPS scheme;
  - (b) any Local Pharmaceutical Committee for the area in which are situated the scheme premises for the relevant LPS scheme;
  - (c) any Local Medical Committee for the area in which are situated the scheme premises for the relevant LPS scheme;
  - (d) any NHS chemist whose listed chemist premises—
    - (i) are in the area of HWB1, or
    - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the decision;
  - (e) any person who is entitled because of the grant of a routine or excepted application to be included in a pharmaceutical list—
    - (i) for the area of HWB1, or
    - (ii) for the area of a neighbouring HWB, if their interests are likely, in the opinion of the NHSCB, to be affected by the decision,

but who is not (yet) included;

- (f) any LPS chemist whose scheme premises—
  - (i) are in the area of HWB1, or
  - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the decision;
- (g) any dispensing doctor whose listed dispensing premises—
  - (i) are in the area of HWB1, or
  - (ii) are in the area of a neighbouring HWB and whose interests are likely, in the opinion of the NHSCB, to be affected by the decision; and
- (h) any Local Healthwatch organisation for the area of HWB1.

#### LPS pilot schemes: health service body status

- **109.**—(1) Where a provider (P) of piloted services under an LPS pilot scheme is or has become a health service body for the purposes of section 9 of the 2006 Act (NHS contracts), subject to paragraph (2), any variation of the LPS pilot scheme which changes a party to the scheme does not affect the health service body status of the provider of piloted services under that scheme.
- (2) If P is a health service body for the purposes of an LPS pilot scheme, P may at any time request a variation by the NHSCB of the scheme so as to provide that the scheme is to cease to be an NHS contract, and if P does—
  - (a) the NHSCB must agree to the variation; and
  - (b) subject to paragraph (4), P is to cease to be a health service body for the purposes of section 9 of the 2006 Act from the date on which the variation takes effect.
- (3) Subject to paragraph (4), a person who has been both the provider of piloted services under an LPS pilot scheme and a health service body for the purposes of that scheme is to cease to be a health service body for the purposes of that scheme where the scheme—
  - (a) is varied so that person is no longer the provider of piloted services under that scheme; or
  - (b) is terminated.
- (4) Where a person ceases to be a health service body for the purposes of an LPS pilot scheme agreement pursuant to—
  - (a) paragraph (2), P is to be bound (as is the NHSCB) by any adjudication which was referred to an adjudicator in accordance with the terms of the scheme before the variation took effect; or
  - (b) paragraph (3)(b), C is to continue to be a health service body for the purposes of the resolution of any dispute that falls to be resolved in accordance with the terms of the terminated scheme notwithstanding its termination.
  - (5) Piloted services and pharmaceutical services must not be provided from the same premises.

## LPS pilot schemes: termination

- 110. On the date (D1) on which an LPS pilot scheme terminates because of a term of that scheme provided for in directions under section 138 of, or paragraph 7(1) of Schedule 11 to, the 2006 Act (which relate to terms of LPS pilot schemes) which requires that the scheme is to terminate—
  - (a) for a reason that relates to the fitness of P to be a provider of piloted services, P does not have a right of return to a pharmaceutical list; or
  - (b) either—
    - (i) because listed chemist premises, other than distance selling premises, of an NHS pharmacist have opened less than a kilometre by the nearest practical route available to the public on foot from the premises specified in the LPS pilot scheme,
    - (ii) for a reason relating to the requisite amount of items dispensed at those premises during a financial year,
    - (iii) because the NHSCB (or before it the Primary Care Trust that was party to the scheme) or P has given the other party to the scheme a period of notice of not less than 6 months of their intention to terminate the scheme, or
    - (iv) because all LPS pilot schemes terminate on that date,

the NHSCB must include those premises, and if P is not already so included P, in the pharmaceutical list for the area of the HWB in which the premises are situated with effect from D1.

#### Emergencies requiring the flexible provision of local pharmaceutical services

- 111.—(1) Nothing in these Regulations prevents the NHSCB from making a temporary amendment to an LPS scheme or an LPS pilot scheme which the NHSCB is satisfied is necessary or expedient because of an emergency requiring the flexible provision of pharmaceutical services.
- (2) In the circumstances described in paragraph (1), the NHSCB may make a temporary variation to an LPS scheme or an LPS pilot scheme, but—
  - (a) only for a specified period (which must be no longer than the specified period of the emergency given by the Secretary of State), which the NHSCB may extend or curtail in appropriate circumstances; and
  - (b) the provider under the scheme may revert to their overridden arrangements before the end of the period specified by the NHSCB, on giving the NHSCB at least 24 hours notice.
- (3) There is no right of appeal under these Regulations in respect of a decision to make or not to make, or to extend or curtail the duration of, a temporary amendment under this regulation.

# Sharing of information about LPS chemists and their employees with the General Pharmaceutical Council

112. Where the NHSCB has concerns about the fitness of an LPS chemist, or a pharmacist or pharmacy technician employed by an LPS chemist, to provide local pharmaceutical services, it must where appropriate pass on those concerns and any relevant supporting evidence to the General Pharmaceutical Council.

# Directions to the First-tier Tribunal relating to local pharmaceutical services

- **113.**—(1) The Secretary of State directs the First-tier Tribunal to exercise the functions of the Secretary of State under the terms of an LPS scheme which—
  - (a) give effect to paragraphs 21, 22 and 29 of Schedule 7; and
  - (b) relate to the determination of appeals to the Secretary of State, but only in so far as those functions require a determination by the Secretary of State—
    - (i) as to whether a person falls within paragraph 29(2) of Schedule 7 during the existence of the scheme, or
    - (ii) in respect of a decision by the NHSCB under paragraph 29(3) or (4) of Schedule 7.
- (2) The Secretary of State directs the First-tier Tribunal to exercise the functions of the Secretary of State under the terms of an LPS pilot scheme that relate to the determination of appeals to the Secretary of State, but only in so far as those functions require a determination by the Secretary of State in respect of the fitness of a provider of piloted services to be a provider of piloted services.

# Lists of LPS chemists

- **114.**—(1) In respect of the area of each HWB, the NHSCB must prepare, maintain and publish a list of the LPS chemists (if there are any) who provide local pharmaceutical services at or from premises situated in that area.
  - (2) The lists must include—
    - (a) the addresses of the premises at or from which the local pharmaceutical services are provided;
    - (b) the days on which and times at which, at those premises, the LPS chemist is to provide those services;
    - (c) a description of the services the LPS chemist is to provide.

(3) The NHSCB must ensure that each HWB has access to the lists of LPS chemists that it holds which is sufficient to enable the HWB to carry out its functions under these Regulations.