SCHEDULE 1

Regulation 4(1)

Information to be contained in pharmaceutical needs assessments

Necessary services: current provision

1. A statement of the pharmaceutical services that the HWB has identified as services that are provided—

(a) in the area of the HWB and which are necessary to meet the need for pharmaceutical services in its area; and

(b) outside the area of the HWB but which nevertheless contribute towards meeting the need for pharmaceutical services in its area (if the HWB has identified such services).

Necessary services: gaps in provision

2. A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied—

(a) need to be provided (whether or not they are located in the area of the HWB) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;

(b) will, in specified future circumstances, need to be provided (whether or not they are located in the area of the HWB) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Other relevant services: current provision

3. A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are provided—

(a) in the area of the HWB and which, although they are not necessary to meet the need for pharmaceutical services in its area, nevertheless have secured improvements, or better access, to pharmaceutical services in its area;

(b) outside the area of the HWB and which, although they do not contribute towards meeting the need for pharmaceutical services in its area, nevertheless have secured improvements, or better access, to pharmaceutical services in its area;

(c) in or outside the area of the HWB and, whilst not being services of the types described in sub-paragraph (a) or (b), or paragraph 1, they nevertheless affect the assessment by the HWB of the need for pharmaceutical services in its area.

Improvements and better access: gaps in provision

4. A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied—

(a) would, if they were provided (whether or not they were located in the area of the HWB), secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area,

(b) would, if in specified future circumstances they were provided (whether or not they were located in the area of the HWB), secure future improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Other NHS services

5. A statement of any NHS services provided or arranged by a local authority, the NHSCB, a CCG, an NHS trust or an NHS foundation trust to which the HWB has had regard in its assessment, which affect—

(a) the need for pharmaceutical services, or pharmaceutical services of a specified type, in its area; or

(b) whether further provision of pharmaceutical services in its area would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in its area.

How the assessment was carried out

6. An explanation of how the assessment has been carried out, and in particular—

(a) how it has determined what are the localities in its area;

(b) how it has taken into account (where applicable)—

(i) the different needs of different localities in its area, and

(ii) the different needs of people in its area who share a protected characteristic; and

(c) a report on the consultation that it has undertaken.

Map of provision

7. A map that identifies the premises at which pharmaceutical services are provided in the area of the HWB.

SCHEDULE 2 Regulation 10(7)

Applications in respect of pharmaceutical lists and the procedures to be followed

PART 1

Information to be included in routine and excepted applications

Information to be included in all routine and excepted applications

1.—(1) The information mentioned below in this paragraph must be included in all routine and excepted applications.

(2) The name of the relevant HWB.

(3) The type of application being made (for example, the application is for inclusion in a pharmaceutical list and a change of ownership application), including a statement of whether the application is a routine or an excepted application.

(4) The name and address of the applicant (A).

(5) If A is an individual or a partnership carrying on a retail pharmacy business, A or each partner's registration number in the GPhC register.

(6) If A is a body corporate carrying on a retail pharmacy business, the name and registration number in the GPhC register of A's superintendent.

(7) If A is seeking the listing of premises not already listed in relation to A (whether or not A is already listed)—

(a) either—

(i) the address of the premises, or

(ii) if the address is not known and it is a routine application, A's best estimate of where the proposed premises will be;

(b) whether the applicant is currently in possession of the premises;

(c) the proposed core opening hours in respect of the premises; and

(d) the total proposed opening hours for the premises (having regard to both the proposed core opening hours and any supplementary opening hours).

(8) If A is seeking to provide directed services—

(a) details of the directed services to be provided;

(b) confirmation that A is accredited to provide the services, where that accreditation is a prerequisite for the provision of those services;

(c) confirmation that the premises are accredited in respect of the provision of the services, where that accreditation is a prerequisite for the provision of those services; and

(d) a floor plan showing the consultation area where A proposes to offer directed services (where relevant, unless one cannot be provided for reasons that are good cause).

(9) A is not entitled to ask for a routine application to be considered, in the alternative, as an excepted application, or for an excepted application to be considered, in the alternative, as a routine application.

(10) An estimate of the location of premises is only a "best estimate" for the purposes of sub-paragraph (7)(a)(ii) if the NHSCB is satisfied that—

(a) it is the best estimate that A can reasonably make at the time of the application of the location of the premises; and

(b) its reasons for granting or refusing the application would be essentially the same if the applicant located, if the application was granted, at any location within the range of possible locations covered by the estimate.

Information to be included in all routine and excepted applications for inclusion in a pharmaceutical list

2.—(1) The information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

(2) If the applicant (A) is an individual or a partnership—

(a) A's or each partner's full name;

(b) A's or each partner's sex;

(c) A's or each partner's date of birth;

(d) A's or each partner's private address and telephone number;

(e) a declaration that A or each partner is a registered pharmacist, if A is seeking entry in the list mentioned in regulation 10(2)(a);

(f) if A is a partnership, a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act(**1**) (general provisions), if A is seeking entry in the list mentioned in regulation 10(2)(a); and

(g) if A is already included in Part 3 of the GPhC register in respect of any premises, A's registration number in that Part of the GPhC register, if A is seeking entry in the list mentioned in regulation 10(2)(a).

(3) If A is a body corporate—

(a) A's registered name and any other name under which A trades;

(b) A's company registration number;

(c) A's registered office and any fixed line telephone number relating to that office;

(d) the private address and date of birth of A's superintendent (if A is seeking entry in the list mentioned in regulation 10(2)(a));

(e) the name and date of birth of each director of A (who is not A's superintendent), and if any director of A (who is not A's superintendent) is a registered pharmacist, that director's registration number in the GPhC register;

(f) a declaration that A is, or is entitled to be, lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act, if A is seeking entry in the list mentioned in regulation 10(2)(a); and

(g) if A is already included in Part 3 of the GPhC register in respect of any premises, A's registration number in that Part of the GPhC register, if A is seeking entry in the list mentioned in regulation 10(2)(a).

(4) If the services that A undertakes to provide consists of or includes the supply of appliances, the appliances A undertakes to supply.

Fitness information about individuals: routine and excepted applications for inclusion in a pharmaceutical list

3.—(1) Subject to paragraph 5, the information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list, as regards any person (P) who is—

(a) the individual who is making the application;

(b) a partner in the partnership that is making the application; or

(c) a director or (if A is seeking entry in the list mentioned in regulation 10(2)(a)) superintendent of the body corporate that is making the application.

(2) Details of whether P—

(a) has been convicted of any criminal offence in the United Kingdom;

(b) has been bound over following a criminal conviction in the United Kingdom;

(c) has accepted a police caution in the United Kingdom;

(d) has, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging P absolutely (without proceeding to conviction); or

(e) has accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(**2**) (fixed penalty: conditional offer by procurator

(**1**) Section 69 has been amended by the Statute Law (Repeals) Act 1993 (c. 50), Schedule 1, Part 12, and by S.I. 1976/1213, 2007/289 and 3101 and 2010/231.

(**2**) 1995 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).

fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(**3**) (penalty as alternative to prosecution).

(3) Details of whether P has at any time been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England (at the time of the application), could lead to a criminal conviction in England.

(4) Details of any criminal proceedings to which P is currently subject—

(a) in the United Kingdom; or

(b) elsewhere than the United Kingdom if the originating events, if they took place in England, could lead to a criminal conviction in England.

(5) If P is, to P's knowledge, or has been subject to any investigation into, or proceedings relating to, P's fitness to practise by a licensing body—

(a) if the investigation or proceedings have not yet reached their final outcome, details of that investigation or proceedings; or

(b) if the investigation or proceedings have reached a final outcome that was adverse, details of the final outcome of that investigation or proceedings.

(6) If P is, to P's knowledge, or has been subject to any investigation into, or proceedings relating to, P's professional conduct by an employer—

(a) if the investigation or proceedings have not yet reached their final outcome, details of that investigation or proceedings; or

(b) if the investigation or proceedings have reached a final outcome that was adverse, details of the final outcome of that investigation or proceedings.

(7) If P is a pharmacist, details of P's—

(a) pharmaceutical qualifications (including where obtained); and

(b) professional experience (including starting and finishing dates of each appointment), with an explanation of any gaps between appointments and of why P was dismissed from any post (if not already covered by the details provided pursuant to sub-paragraph (6)(b)).

(8) If P is a pharmacist, names and addresses of 2 referees who are willing to provide references in respect of 2 recent posts (which may include any current post) as a pharmacist which lasted at least 3 months without a significant break, or where this is not possible, details of why and the names and addresses of alternative referees who are acceptable to the NHSCB.

(9) If P is, to P's knowledge, or has been subject to any investigation or proceedings that could lead or could have led to P's removal from a relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, details of that investigation or those proceedings, and of any final outcome to that investigation or those proceedings.

(10) If P is, to P's knowledge, or has been where the outcome was adverse, the subject of any investigation by the NHS BSA (or any body that preceded it which had, or outside England which has, primary responsibility for investigating fraud in the health service) in relation to fraud.

(11) If P has been refused inclusion in, or conditionally included in, or contingently removed or suspended from, any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision, details of same.

(12) If P is in the process of applying to be included in another relevant list and proceedings relating to the application have not yet reached their final outcome (including where an application has been deferred), details of that application and the reasons for—

(**3**) 1992 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.

(a) any deferment of that application; or

(b) refusal or conditional inclusion where the refusal or conditional inclusion has not yet reached its final outcome.

(13) If P—

(a) is the person making the application; and

(b) qualified as a pharmacist in Switzerland or an EEA State other than the United Kingdom,

details that demonstrate that P has the level of knowledge of English which, in the interests of P and the persons making use of the services to which the application relates, is necessary for the provision of those services in the area of the relevant HWB.

Fitness information about corporate bodies: routine and excepted applications for inclusion in a pharmaceutical list

4.—(1) Subject to paragraph 5, the information mentioned below in this paragraph must be included in all routine and excepted applications for inclusion in a pharmaceutical list by a body corporate (C1)—

(a) as regards C1; or

(b) as regards any other body corporate (C2) of which a director or superintendent of C1—

(i) is a director or superintendent or has been a director or superintendent in the 6 months prior to the date of the application, or

(ii) has been a director or superintendent for more than 6 months prior to the date of the application, where they were a director or superintendent of C2 at the time of the originating events to which the information relates.

(2) Details of any convictions that C1 or C2 has for offences committed in the United Kingdom that are not spent convictions.

(3) Details of whether C1 or C2 (being corporate bodies registered within the United Kingdom) has at any time been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England (at the time of the application), could lead to a criminal conviction in England.

(4) Details of any criminal proceedings to which C1 or C2 is currently subject—

(a) in the United Kingdom; or

(b) elsewhere than in the United Kingdom if the originating events, if they took place in England, could lead to a criminal conviction in England.

(5) Details of any investigation to which C1 or C2—

(a) is, to its knowledge, subject by the General Pharmaceutical Council in relation to an entry in Part 3 of the GPhC register; or

(b) has been subject by the General Pharmaceutical Council, the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland in relation to an entry in the register required to be kept under section 75 of the 1968 Act(**4**) (registration of premises), the outcome of which was adverse.

(6) If C1 or C2, to its knowledge, is or has been subject to any investigation or proceedings that could lead or could have led to its removal from a relevant list, details of that investigation or those proceedings, and of any final outcome to that investigation or those proceedings.

(**4**) Amended by S.I. 1968/1699 and 2010/231.

(7) If C1 or C2 is, to its knowledge, or has been where the outcome was adverse, the subject of any investigation by the NHS BSA (or any body that preceded it which had, or outside England which has, primary responsibility for investigating fraud in the health service) in relation to fraud.

(8) If C1 or C2 has been refused inclusion in, or conditionally included in (other than by reason of a condition imposed under Part 9), a relevant list, details of that refusal or conditional inclusion.

(9) If C1 or C2 is in the process of applying to be included in another relevant list and proceedings relating to the application have not yet reached their final outcome (including where an application has been deferred), details of that application and the reasons for—

(a) any deferment of that application; or

(b) any refusal or conditional inclusion, where the refusal or conditional inclusion has not yet reached its final outcome.

Fitness information that has already been provided under pharmaceutical or local pharmaceutical services

5.—(1) If information mentioned in paragraph 3 or 4 has already been provided to the NHSCB (or a home Primary Care Trust) on a previous occasion pursuant to regulations under Part 7 of the 2006 Act, an applicant need not provide that information again to the NHSCB in relation to the current application.

(2) An applicant relying on paragraph (1) must, when making its application—

(a) confirm to the NHSCB that the NHSCB already has all the information required under paragraphs 3 and 4; or

(b) if there is any missing information required under those paragraphs—

(i) confirm to the NHSCB what information the NHSCB already has, and

(ii) provide the missing information.

Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises

6. If, as regards a routine or excepted application—

(a) for inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for inclusion also in respect of premises other than those already listed in relation to that person,

the premises which the applicant (A) is seeking to be listed in relation to A are already listed chemist premises or are adjacent to or in close proximity to such premises, A must include with the application details that explain why A believes the application should not be refused pursuant to regulation 31.

Additional information to be included with routine applications

7.—(1) If an applicant (A) is making a routine application and is seeking to satisfy the NHSCB that granting that application would meet a need for pharmaceutical services, or secure improvements to or better access to pharmaceutical services, in circumstances where—

(a) that need, those improvements or that better access has or have been identified in the pharmaceutical needs assessment of the relevant HWB (or Primary Care Trust), A must include in that application details that explain how A intends to meet that need, or secure those improvements or that better access (in whole or in part); or

(b) that need, those improvements or that better access has or have not been identified in the pharmaceutical needs assessment of the relevant HWB (or Primary Care Trust, A must include in that application, details that explain A's belief that regulation 18(1)(b) is satisfied in relation to that application.

(2) Where an applicant includes information in an application pursuant to paragraph (a) but not paragraph (b) of sub-paragraph (1), the NHSCB must not consider whether regulation 18(1)(b) applies in relation to that application when it determines that application.

Additional information to be included with excepted applications

8. If the applicant (A) is making an excepted application, A must include in that application details that explain—

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) of the 2006 Act(**5**) (regulations as to pharmaceutical services) are not to apply in relation to that application; and

(b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

Undertakings

9. An applicant (A) must provide the following undertakings—

(a) an undertaking to notify the NHSCB within 7 days of any material changes to the information provided in the application that occur before—

(i) the application is withdrawn,

(ii) while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or

(iii) if the application is granted, A commences the provision of the services to which the application relates,

whichever is the latest of these events to take place;

(b) an undertaking to notify the NHSCB if A is included, or applies to be included, in any other relevant list of another primary care organisation before—

(i) the application is withdrawn,

(ii) while the application remains the subject of proceedings, the proceedings relating to the application reach their final outcome and any appeal through the courts has been disposed of, or

(iii) if the application is granted, A commences the provision of the services to which the application relates,

whichever is the latest of these events to take place;

(c) if A is seeking inclusion in a pharmaceutical list or (if A is already listed in that list) the listing of premises in relation to A that are not already listed in relation to A, an undertaking—

(i) to comply with all the obligations that are to be their terms of service under regulation 11 if the application is granted, and

(**5**) Section 129(2A) was inserted by the Health Act 2009 (c. 21), section 26(3), and has been amended by the Health and Social Care Act 2012 (c. 7), section 207(4), and Schedule 4, paragraph 66(5).

(ii) in particular, in relation to any proposed pharmacy premises, to provide all the services and perform all the activities at those premises that are required under the terms of service to be provided or performed as or in connection with essential services; and

(d) if A is seeking to provide directed services an undertaking—

(i) that A will provide the directed services mentioned in the application, if the NHSCB does commission the services from A within 3 years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates,

(ii) if the services are commissioned by the NHSCB, that A will provide the services in accordance with an agreed service specification, and

(iii) A's agreement to a service specification will not be unreasonably withheld.

Nature of details to be supplied

10. Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy the NHSCB, with good cause, that no relevant information or documentation is missing, having regard to the uses that the NHSCB may need to make of the information or documentation when carrying out its functions.

PART 2

Preliminary matters

Relevant information or documentation

11.—(1) As regards any routine or excepted application, if the NHSCB considers that relevant information or documentation is missing—

(a) it may request the missing relevant information or documentation from the applicant; and

(b) the applicant must, within the period reasonably specified by the NHSCB in the request under paragraph (a)—

(i) provide any information or documentation reasonably requested,

(ii) notify the NHSCB that there is to be a delay in providing the requested information or documentation, for specified reasons, and specify a date by which the applicant undertakes to provide the information or documentation, or

(iii) if the applicant considers that any information or documentation has been unreasonably requested, notify the NHSCB of that and seek a review by the NHSCB of the reasonableness of the request.

(2) If an applicant refuses to comply with a request under sub-paragraph (1)(a)—

(a) within the period—

(i) reasonably specified by the NHSCB under paragraph (1)(b), or

(ii) ending on the date specified by the applicant in accordance with paragraph (1)(b)(ii), if the NHSCB is satisfied that a delay beyond the period it specified, and the length of the delay, are for good cause,

unless paragraph (b) applies, the application is to be treated as withdrawn;

(b) in circumstances where the applicant has, in accordance with sub-paragraph (1)(b)(iii), sought a review by the NHSCB of the reasonableness of the request, if the review determines that any or all of the information or documentation requested—

(i) must after all, be provided, the application is to be treated as withdrawn unless the information or documentation that must still be provided is provided within a new period reasonably specified by the NHSCB for the provision of that information or documentation,

(ii) need not be provided by the applicant, the request of the NHSCB is to be treated as withdrawn to the extent that it relates to information or documentation that need not be provided.

(3) The NHSCB may request information or documentation under this paragraph at any time after it receives an application and before its determination of that application, but it must consider whether or not it needs to request information or documentation under this paragraph prior to notifying an application (where it is required to do so) under Part 3.

Failure to provide undertakings or fees

12.—(1) If, when an applicant (A) submits an application, A fails to provide with the application—

(a) the undertakings referred to in paragraph 9 that are relevant to the application, the NHSCB must, if the application is notifiable prior to notifying the application under Part 3, request that A provide the relevant undertakings within a specified period; or

(b) any fee payable in respect of that application by virtue of directions under section 131 of the 2006 Act (power to charge), the NHSCB must, if the application is notifiable prior to notifying the application under Part 3, request that A provide the fee (or any missing part of the fee) within a specified period.

(2) If A fails to comply with a request under sub-paragraph (1) within a period reasonably specified by the NHSCB under that sub-paragraph, the application is to be treated as withdrawn.

Functions of the NHSCB in relation to fitness information relevant to applications from bodies corporate

13. Where an applicant (A) is relying on paragraph 5(1), the NHSCB must ensure that the information that it holds about A is aggregated in such a way that it is able to make a reasonable determination as to whether the application should be refused or deferred under regulation 33 or 34.

Deferral of notifiable applications prior to notification

14.—(1) The NHSCB, having received—

(a) a routine application, consideration of which may or must be deferred under regulation 14(1) to (3), 16(1) to (4), 19(1) to (4), 21(1) to (4) or 38(4); or

(b) a notifiable application, consideration of which may be deferred under regulation 32 or 34,

must consider, prior to notifying that application under Part 3 and as soon as is practicable, whether or not to defer consideration of that application under those provisions.

(2) If consideration of the application is deferred prior to notification, once the NHSCB no longer has grounds for deferring the application, it must proceed as soon as is practicable with the notification of the application, unless the application has been withdrawn or the NHSCB is required to treat it as withdrawn.

Refusal of notifiable applications prior to notification because of the language requirement for some NHS pharmacists

15. The NHSCB, having received a notifiable application for inclusion in a pharmaceutical list from a person who is not already included in that list, may without notifying that application under Part 3 (or if no notification is required, as soon as is practicable) decide to refuse that application under regulation 30.

Refusal of notifiable applications on fitness grounds prior to notification

16. The NHSCB, having received a notifiable application for inclusion in a pharmaceutical list from a person who is not already included in that list, may without notifying that application under Part 3 decide to refuse that application under regulation 33(1).

Proposed new pharmacy premises in controlled localities: refusal of routine applications because of preliminary matters prior to notification

17. The NHSCB, having received a routine application where the applicant is seeking the listing of pharmacy premises, must consider, prior to notifying that application under Part 3 and as soon as is practicable, whether or not the application needs to be refused under regulation 40(2).

PART 3

Notification of certain applications

Applications requiring notifications

18. An application is a "notifiable application" for the purposes of this Schedule if—

(a) it is a routine application; or

(b) it is an excepted application pursuant to regulation 24, 25 or 26(2),

and the NHSCB has not decided to dispense with the notification pursuant to paragraphs 15 to 17.

Notification procedure for notifiable applications

19.—(1) As soon as is practicable (having regard to its functions under Part 2), the NHSCB must give notice of a notifiable application to—

(a) any Local Pharmaceutical Committee—

(i) whose area includes the premises or location to which the application relates, or

(ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;

(b) any Local Medical Committee—

(i) whose area includes the premises or location to which the application relates, or

(ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;

(c) any person—

(i) included in a pharmaceutical list for the area of the relevant HWB, or

(ii) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

whose interests might, in the opinion of the NHSCB, be significantly affected if the application were granted;

(d) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected if the application were granted;

(e) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in that area which, in the opinion of the NHSCB, has a significant interest in the outcome of the application;

(f) if the applicant is seeking to locate premises in, or within 1.6 kilometres of, a controlled locality in the area of the relevant HWB—

(i) any provider of primary medical services, or

(ii) any other person on the dispensing doctors list for the area of the relevant HWB if there is one (being a performer but not a provider of primary medical services),

who, in the opinion of the NHSCB, has a significant interest in the outcome of the application;

(g) any Local Health Board any part of whose area is within 2 kilometres of the premises or location to which the application relates; and

(h) the relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the application relates.

(2) The NHSCB may also give notice of the notifiable application to any other person who, in the opinion of the NHSCB, has a significant interest in the outcome of the application.

(3) If any part (PA) of the area of a notified HWB (HWB2) other than the relevant HWB is within 2 kilometres of the premises or location to which the application relates, the NHSCB must also give notice of the application to—

(a) any Local Pharmaceutical Committee—

(i) whose area includes PA, and

(ii) that is not given notice of the application under paragraph (1)(a);

(b) any Local Medical Committee—

(i) whose area includes PA, and

(ii) that is not given notice of the application under paragraph (1)(b);

(c) any person—

(i) included in a pharmaceutical list for the area of HWB2, or

(ii) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

whose interests might, in the opinion of the NHSCB, be significantly affected if the application were granted;

(d) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of HWB2, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected if the application were granted;

(e) any Local Healthwatch organisation for the area of HWB2, and any other patient, consumer or community group in that area which, in the opinion of the NHSCB, has a significant interest in the outcome of the application; and

(f) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in the area of HWB2—

(i) any provider of primary medical services, or

(ii) any other person on the dispensing doctors list for the area of HWB2 if there is one (being a performer but not a provider of primary medical services),

who, in the opinion of the NHSCB, has a significant interest in the outcome of the application.

(4) Those notified under sub-paragraphs (1) to (3) may make representations in writing about the application that is the subject of the notification to the NHSCB, provided they do so within 45 days of the date on which notice of the application was given to them.

Parallel notifications

20.—(1) If the NHSCB is considering, as a consequence of a notifiable application, making (including revising) a determination as to whether or not an area is or is not to be part of a controlled locality, it must give notice under this Part at the same time that it gives notice under regulation 38(1).

(2) If, as a consequence of a notifiable application, the NHSCB is required, by virtue of regulation 41 to determine whether or not an area is a reserved location, the NHSCB must consider giving notice under this Part at the same time that it gives notice under regulation 41(4).

Content of notifications

21.—(1) A person notified under paragraph 19 (P)—

(a) must be informed—

(i) of P's right to make representations under paragraph 19(4);

(ii) of the circumstances in which notified persons would be permitted, pursuant to paragraph 25, to make oral representations at any oral hearing relating to the application, and

(iii) if the NHSCB intends to consider the application together and in relation to any other application, of that intention;

(b) need not be given the same information as other persons notified under paragraph 19 but, subject to sub-paragraphs (2) to (4), P must be provided with sufficient information, from the information supplied by the applicant, to enable P to make informed representations with regard to whether or not the application should be granted, having regard to P's interest in the matter.

(2) P need not be provided with any information that is published as part of the relevant pharmaceutical needs assessment.

(3) P must not be provided with—

(a) information supplied by the applicant (A) under paragraphs 2 to 4, or which A is exempt from supplying by virtue of paragraph 5; and

(b) any private addresses, private telephone numbers or dates of birth supplied by A.

(4) If A advises the NHSCB that—

(a) information supplied by A is considered by A to be confidential to A; and

(b) A does not consent to the information being disclosed as part of the notification,

the NHSCB must withhold that information from P if it considers that the full disclosure principle does not require it to provide that information to P.

(5) The "full disclosure principle" is that information that is relevant to the determination of an application should be available to any individual who has a significant interest in the outcome of the application, unless it is fair and proper for that information to be withheld from that individual.

(6) If information is being withheld from P under paragraph (4), P must be informed of the nature of the information that is being withheld from P.

PART 4

Determination and deferral of applications

Flexibility with regard to determining or deferring applications

22.—(1) Except in so far as these Regulations provide to the contrary, the NHSCB is to determine or defer routine and excepted applications in such manner (including with regard to procedures) as it sees fit.

(2) The NHSCB may determine a routine or excepted application without hearing any oral representations, if it considers that oral representations are unnecessary.

(3) Where appropriate, the NHSCB may if it thinks fit consider 2 or more applications together and in relation to each other, but where it does so, it must give notice to the applicants of its intention to do so (if it has not already done so under Part 3).

Additional matters for consideration in relation to applications for inclusion in a pharmaceutical list

23.—(1) In the case of a routine or excepted application by a person (A) for inclusion in a pharmaceutical list who is not already included in it, the NHSCB must, prior to determining the application—

(a) check with the NHS BSA whether A, and if A is a body corporate whether any director or superintendent of A, has any record of, or is under investigation for, fraud;

(b) check with the Secretary of State whether the Secretary of State holds any information about A, and if A is a body corporate about any director or superintendent of A, that is relevant to its consideration of whether—

(i) the application should be refused or deferred under regulations 33 or 34, or

(ii) conditions should be imposed under regulation 35;

(c) take up references from, and check the references provided by, the referees whose details A is required to provide pursuant to paragraph 3(8).

(2) In such a case, having considered whether—

(a) the application should be refused or deferred under regulations 33 or 34; or

(b) conditions should be imposed under regulation 35,

if it is minded to impose conditions under regulation 35, it must notify A at least 7 days in advance of determining that it is to impose such conditions and consider any representations (which may be at an oral hearing) that A makes prior to the determination with regard to the notification.

Action following deferrals

24.—(1) Where the NHSCB receives a routine or excepted application, consideration or determination of which may be deferred, if it does decide to defer consideration or determination of that application (whether before or after the application is notified, in the case of a notifiable application), it must—

(a) notify the applicant (A) of its decision and the reasons for it; and

(b) where possible, notify A of the period for which the application is being deferred (if necessary by reference to a future event rather than a period of time).

(2) If the application is—

(a) a routine application, consideration of which may be deferred under regulation 14(1)(a), 16(1)(a), 19(2)(a) or 21(1)(a), it must proceed as soon as is practicable to invite other applications under regulation 14(1)(b), 16(1)(b), 19(2)(b) or 21(1)(b), in such manner as it sees fit;

(b) a routine application, consideration of which may be deferred under regulation 14(2), 16(3), 19(3) or 21(3), it must make arrangements that enable it to consider the other applications at the same time as A's application, as soon as is practicable;

(c) a routine application, consideration of which may be deferred under regulation 14(3), 16(4), 19(4) or 21(4), it must, once the appeal relating to the other application has reached its final outcome, notify A of that outcome and that A must within a specified period (of not less than 30 days)—

(i) update A's application, and

(ii) notify the NHSCB as to whether or not A still wishes to proceed with the application;

(d) a routine application, consideration of which may be deferred under regulation 16(2) or 21(2), it must keep under regular review the issue of whether the future circumstances that gave rise to the deferral have arisen;

(e) a routine application, consideration of which may be deferred under regulation 32, it must—

(i) send A a copy of the designation that led to the decision,

(ii) review that decision once the designation that led to the decision has been cancelled or is varied in a manner which means the application may no longer be deferred under regulation 32,

(iii) notify A of the cancellation or variation, and

(iv) require A within a specified period (of not less than 30 days)—

(aa) to update A's application, and

(bb) to notify the NHSCB as to whether or not A still wishes to proceed with the application;

(f) a routine or excepted application, consideration of which may be deferred under regulation 34, once the outcome of the cause for the deferral is known, the NHSCB must notify A that A must within a specified period (of not less than 30 days)—

(i) update A's application, and

(ii) notify the NHSCB as to whether or not A still wishes to proceed with the application; and

(g) a routine application, consideration of which must be deferred under regulation 38(4), it must proceed, as soon as is practicable, with the determination of whether the relevant area is or is not to be part of a controlled locality.

(3) If A informs the NHSCB within the period specified under sub-paragraph (2)(c), (e)(iv) or (f) that A does not wish to proceed with the application, or fails to respond in the required manner to the notification within the specified period, the application is to be treated as withdrawn.

Oral hearings

25.—(1) If the NHSCB does decide to hear oral representations, it must—

(a) give the applicant and any additional presenters not less than 14 days notice of the time and place at which the oral representations are to be heard; and

(b) in the case of the applicant, advise the applicant of who apart from the applicant (including other applicants, where the hearing relates to more than one application), has been invited to make representations at the hearing.

(2) For these purposes, a person (P) is an "additional presenter" if—

(a) the application to which the oral hearing relates is a notifiable application;

(b) P was given notice of the application under Part 3 and made representations about the application in accordance with paragraph 19(4), which—

(i) indicated that, if there were to be an oral hearing in relation to the application, P would wish to make oral representations at that hearing, and

(ii) identified a matter about which the NHSCB considers it would be desirable to hear further evidence from P at the oral hearing; and

(c) the NHSCB is satisfied that P made a reasonable attempt to express P's views on the application adequately in P's written representations.

(3) If the NHSCB decides at or after an oral hearing that an application is to be deferred, it may (but need not) hold a further oral hearing once the period for which the application is deferred expires.

Persons barred from taking part in decision making on routine and excepted applications

26.—(1) No person is to take part in determining or deferring any routine or excepted application 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,

whether or not their involvement would give rise to a reasonable suspicion of bias.

(2) No other person is to take part in determining or deferring a particular routine or excepted application if because of an interest or association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias.

Timetable for determining applications

27. As regards any routine or excepted application—

(a) the NHSCB must endeavour to determine it as soon as is practicable; and

(b) unless consideration of it is deferred in accordance with these Regulations or there is other good cause for delay, in the case of—

(i) a notifiable application, the NHSCB must determine it within 4 months of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it, or

(ii) an application which is not a notifiable application, the NHSCB must determine it within 30 days of the date on which it received from the applicant all the information and documentation the applicant is required to submit in relation to it.

PART 5

Notification, taking effect of decisions and rights of appeal to the Secretary of State

Notification of decisions on routine and excepted applications

28.—(1) As regards any routine application, once it has determined the application, the NHSCB must, as soon as is practicable, give notice of its decision to—

(a) the applicant;

(b) any Local Pharmaceutical Committee—

(i) whose area includes the premises or location to which the application relates, or

(ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;

(c) any Local Medical Committee—

(i) whose area includes the premises or location to which the application relates, or

(ii) any part of whose area is within 2 kilometres of the premises or location to which the application relates;

(d) any person—

(i) included in a pharmaceutical list for the area of the relevant HWB, or

(ii) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;

(e) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;

(f) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision;

(g) if the applicant is seeking to locate premises in or within 1.6 kilometres of a controlled locality in the area of the relevant HWB—

(i) any provider of primary medical services, or

(ii) any other person on the dispensing doctors list for the area of the relevant HWB if there is one (being a performer but not a provider of primary medical services),

who, in the opinion of the NHSCB, has a significant interest in the decision;

(h) any person—

(i) whom the NHSCB notified under paragraph 19(2), and

(ii) who made representations in writing about the application under paragraph 19(4);

(i) any Local Health Board any part of whose area is within 2 kilometres of the premises or location to which the decision relates; and

(j) the relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the decision relates.

(2) If any part (PA) of the area of a notified HWB (HWB2) other than the relevant HWB is within 2 kilometres of the premises or location to which the application relates, the NHSCB must also, as soon as is practicable, give notice of the decision to—

(a) any Local Pharmaceutical Committee—

(i) whose area includes PA, and

(ii) that is not given notice of the application under paragraph (1)(b);

(b) any Local Medical Committee—

(i) whose area includes PA, and

(ii) that is not given notice of the application under paragraph (1)(c);

(c) any person—

(i) included in a pharmaceutical list for the area of HWB2, or

(ii) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;

(d) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of HWB2, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;

(e) any Local Healthwatch organisation for the area of HWB2, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision; and

(f) if the applicant is seeking to locate premises within 1.6 kilometres of a controlled locality in the area of HWB2—

(aa) any provider of primary medical services, or

(bb) any other person on the dispensing doctors list for the area of HWB2 if there is one (being a performer but not a provider of primary medical services),

who, in the opinion of the NHSCB, has a significant interest in the decision.

(3) As regards any excepted application, once it has determined the application, the NHSCB must, as soon as is practicable, give notice of its decision to—

(a) in the case of an application pursuant to regulation 23, the applicant;

(b) in the case of an application pursuant to regulation 24, 25 or 26(2)—

(i) the applicant,

(ii) any Local Pharmaceutical Committee whose area includes the premises or location to which the application relates,

(iii) any Local Medical Committee whose area includes the premises or location to which the application relates,

(iv) the relevant HWB, and if the applicant is relocating to different premises in the area of another HWB, the other HWB, and

(v) any (other) person whom the NHSCB notified under paragraph 19 and who made representations in writing about the application under paragraph 19(4);

(c) in the case of an application pursuant to regulation 26(1) or 27 to 29—

(i) the applicant,

(ii) any Local Pharmaceutical Committee whose area includes the premises or location to which the application relates,

(iii) any Local Medical Committee whose area includes the premises or location to which the application relates,

(iv) any person—

(aa) included in a pharmaceutical list for the area of the relevant HWB, or

(bb) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;

(v) any LPS chemist—

(aa) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB, and

(bb) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision,

(vi) any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision,

(vii) any Local Health Board any part of whose area is within 2 kilometres of the pharmacy premises to which the decision relates, and

(viii) the relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the decision relates.

(4) If, in the case of an application pursuant to regulation 26(1) or 27 to 29, any part (PA) of the area of a HWB (HWB3) notified under sub-paragraph (3)(c) other than the relevant HWB is within 2 kilometres of the premises or location to which the application relates, the NHSCB must also, as soon as is practicable, give notice of the decision to—

(a) any Local Pharmaceutical Committee—

(i) whose area includes PA, and

(ii) that is not given notice of the application under paragraph (3)(c)(ii);

(b) any Local Medical Committee—

(i) whose area includes PA, and

(ii) that is not given notice of the application under paragraph (3)(c)(iii);

(c) any person—

(i) included in a pharmaceutical list for the area of HWB3, or

(ii) who is entitled to be included in that pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;

(d) any LPS chemist—

(i) with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services in the area of HWB3, and

(ii) whose interests might, in the opinion of the NHSCB, be significantly affected by the decision; and

(e) any Local Healthwatch organisation for the area of HWB3, and any other patient, consumer or community group in its area which, in the opinion of the NHSCB, has a significant interest in the decision.

(5) Where the NHSCB has decided to consider 2 or more applications together pursuant to paragraph 22(3), it must give notice to each applicant of the decision taken with regard to each other application considered together with their application.

(6) Each notification of a decision under this paragraph must include a statement by the NHSCB of the reasons for the decision.

Template notice of commencement to be included with a notice of decision

29. The NHSCB must send with a notice of decision under paragraph 28 in respect of the grant of an application a template of a notice of commencement, for the applicant to send to it under paragraph 34, in which the applicant is to provide the following information (some of which the NHSCB may have included in the template that it sends)—

(a) the address of the premises to which the application relates;

(b) the services that are to be provided from those premises;

(c) the date of the grant of the application;

(d) a declaration with regard to when the applicant intends to commence the provision of those services at those premises;

(e) in the case of pharmacy premises, the registration number for those premises with the General Pharmaceutical Council; and

(f) a signature on behalf of the applicant and the date of the notice.

Third party rights of appeal to the Secretary of State where an application is granted

30.—(1) A person with third party rights (as provided for in this paragraph) may appeal to the Secretary of State against a decision of the NHSCB to grant a notifiable application, or an application to which regulation 26(1), 27 or 28 applies, provided that the person notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which that person was notified of the NHSCB's decision under paragraph 28.

(2) For the purposes of this Schedule, a person (P1) is a person with third party rights if—

(a) P1 is a person to whom sub-paragraph (3) applies; or

(b) P1 was entitled to receive notification of the decision to grant the application by virtue of paragraph 28(5).

(3) P1 is a person to whom this sub-paragraph applies if—

(a) P1 was a person whom the NHSCB was required to notify about the decision on the application by virtue of P1 being a person whose interests might, in the opinion of the NHSCB, be significantly affected by the decision, and also being—

(i) included in a pharmaceutical list,

(ii) entitled to be included in a pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

(iii) an LPS chemist, or

(iv) either—

(aa) a provider of primary medical services, or

(bb) another person on the dispensing doctor list for the area of the relevant HWB if there is one (P1 being a performer but not a provider of primary medical services),

but only if the application is in respect of premises in a controlled locality and it was granted partly on the basis that, having regard to regulation 44(3), in the opinion of the NHSCB granting the application would not prejudice the proper provision of relevant NHS services in the area of the relevant HWB or of a neighbouring HWB of the relevant HWB;

(b) in the case of a notifiable application, P1 made representations in writing about the application under paragraph 19(4); and

(c) in the case of a notifiable application but subject to sub-paragraph (6), the NHSCB is satisfied, having regard to those representations in writing and any oral representations made in accordance with paragraph 25, that P1—

(i) made a reasonable attempt to express P1's grounds for opposing the application adequately in P1's representations, and

(ii) has grounds for opposing the application, which—

(aa) do not amount to a challenge to the legality or reasonableness of a pharmaceutical needs assessment, or to the fairness of the process by which a HWB or Primary Care Trust undertook that assessment, and

(bb) are not vexatious or frivolous.

(4) If the NHSCB considers that a person notified under paragraph 28 is a person with third party appeal rights, it must notify that person of that fact when it notifies that person of the determination.

(5) A notice of appeal under sub-paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

(6) A person to whom sub-paragraph (3)(a) and (b) applies (P2) who is not notified by the NHSCB that they are person with third party appeal rights may appeal to the Secretary of State against the determination (D1) by the NHSCB that it is not satisfied as mentioned in sub-paragraph (3)(c), provided that P2—

(a) notifies the Secretary of State within 30 days of the date on which that person was notified of the NHSCB's decision under paragraph 28 (D2) that P2 wishes to appeal against D1 and D2; and

(b) includes within that notification concise and reasoned statements of P2's grounds of appeal against both D1 and D2,

and if the appeal against D1 is successful, P2 is a person with third party appeal rights in relation to D2 for the purposes of this Schedule.

Conditional grant of applications where the address of the premises is unknown

31.—(1) As regards any routine application, sub-paragraph (2) applies where—

(a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and

(b) prior to the determination of the application, A was only able to provide a best estimate of where the proposed listed chemist premises would be (not the address of those premises).

(2) Where this sub-paragraph applies, it is a condition of the grant of that application that A notifies to the NHSCB the address of the premises to be listed within 6 months of—

(a) the date on which A was sent the notice of decision under paragraph 28 (having regard also to paragraph 10(2) of Schedule 3);

(b) if the grant of the application is appealed to the Secretary of State by a person with third party appeal rights, the date on which the appeal is determined by the Secretary of State; or

(c) in a case of an application which is subject to a condition imposed by virtue of paragraph 33(2), the date on which that condition becomes spent,

whichever is the latest.

(3) A notification under sub-paragraph (2) is only valid if the NHSCB is satisfied that the premises are at a location that is within the range of possible locations covered by the estimate referred to in sub-paragraph (1)(b).

(4) If the NHSCB receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—

(a) notify A of whether or not it is satisfied that it is a valid notification;

(b) if it is satisfied that it is a valid notification, notify the address to the persons notified of the decision to grant the application; and

(c) if the NHSCB is not satisfied that it is a valid notification, it must include with that notification—

(i) the reasons for its decision, and

(ii) an explanation of how A's rights of appeal under paragraph 36(1)(b) may be exercised.

(5) The NHSCB may not vary or remove a condition imposed by virtue of this paragraph.

(6) If A breaches a condition imposed by virtue of this paragraph, the grant of the application lapses.

Changes to the premises specified in an application after its grant but before the listing of the premises

32.—(1) As regards any routine application, sub-paragraph (2) applies where—

(a) the applicant (A) is seeking the listing of premises not already listed in relation to A (whether or not A is already included in the pharmaceutical list); and

(b) prior to the determination of the application, A provided the address of where the proposed listed chemist premises would be.

(2) Where this sub-paragraph applies, A may notify to the NHSCB a different address ("new address") as the address to which the application relates within—

(a) 4 months of the date on which A was sent the notice of decision under paragraph 28 (having regard also to paragraph 10(2) of Schedule 3); or

(b) if the grant of the application is appealed to the Secretary of State by a person with third party appeal rights, 4 months of the date on which the appeal is determined by the Secretary of State.

(3) A notification under sub-paragraph (2) is only valid if the NHSCB is satisfied that accepting the notification as valid would neither—

(a) result in a significant change to the arrangements that are in place (having regard to the grant of A's application) for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—

(i) in any part of the area of the relevant HWB, or

(ii) in a controlled locality that is part of the area of a neighbouring HWB of the relevant HWB, where that controlled locality is within 1.6 kilometres of the new address; nor

(b) cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB.

(4) If the NHSCB receives a purported notification under sub-paragraph (2), it must, within 14 days of receiving that purported notification—

(a) notify A of whether or not it is satisfied that it is a valid notification, together with the reasons for its decision;

(b) if the NHSCB is not satisfied that it is a valid notification, it must include with that notification—

(i) the reasons for its decision, and

(ii) an explanation of how A's rights of appeal under paragraph 36(1)(b) may be exercised.

(c) if it is satisfied that it is a valid notification, notify the new address to the persons notified of the decision to grant the application, and must include with that notification—

(i) the reasons for its decision, and

(ii) if the person has a right of appeal under sub-paragraph (5), an explanation of how that right of appeal may be exercised.

(5) A person (X) who—

(a) is notified under sub-paragraph (4)(c); and

(b) was entitled to be notified of the decision to grant the application—

(i) by virtue of paragraph 28(5), or

(ii) as a person whom the NHSCB was required to notify about the application by virtue of X being—

(aa) an LPS chemist,

(bb) included in a pharmaceutical list, or

(cc) entitled to be included in a pharmaceutical list because of the grant of a routine or excepted application but who is not (yet) included,

and a person whose interests might, in the opinion of the NHSCB, be significantly affected by the decision;

may appeal against a decision by the NHSCB to accept the purported notification as a valid notification, provided X notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which X was notified under sub-paragraph (4)(c).

(6) A notice of appeal under sub-paragraph (5) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

Conditional grant in cases relating to future needs or future improvements or better access

33.—(1) Where the NHSCB grants a routine application because doing so—

(a) will meet a future need for pharmaceutical services, or pharmaceutical services of a specified type in its area; or

(b) will secure future improvements or better access to pharmaceutical services, or pharmaceutical services of a specified type, in its area,

sub-paragraph (2) applies.

(2) Where this sub-paragraph applies, the NHSCB may grant the application subject to a condition that pharmaceutical services are not provided at the listed chemist premises to which the application relates (or at any premises to which the business relocates) until—

(a) some or all of the future circumstances, as a consequence of which the application was granted, have arisen; or

(b) a specified date (having regard to when some or all of the future circumstances, as a consequence of which the application was granted, are likely to arise).

(3) The NHSCB may vary or remove a condition imposed by virtue of sub-paragraph (2), but if it varies the condition, the revised condition (which becomes a condition imposed by virtue of sub-paragraph (2)) must be a condition that it also meets the requirements of that paragraph.

(4) The condition imposed by virtue of sub-paragraph (2) becomes spent once—

(a) where a date has been specified, that date passes; or

(b) where the condition relates to future circumstances arising, the NHSCB notifies the successful applicant (P) that the future circumstances have arisen.

(5) P may by a notice request a determination from the NHSCB as to whether the future circumstances have arisen at any time (but only once in any 60 days), and the NHSCB must give notice of that determination within 30 days of that request.

Taking effect of listing decisions: general

34.—(1) As regards any application—

(a) for inclusion in a pharmaceutical list by a person who is not already included in it; or

(b) by a person who is included in a pharmaceutical list and who is seeking—

(i) to open, within the area of the relevant HWB, additional premises from which to provide the same or different pharmaceutical services,

(ii) to relocate to different premises, and at those premises to provide the same or different pharmaceutical services, or

(iii) to provide, from the person's listed chemist premises, services that are in addition to those already listed in relation to that person,

if the application is granted, paragraph (2) applies.

(2) Subject to paragraph 35, the NHSCB may only change a pharmaceutical list to give effect to that decision if the successful applicant (P) gives the NHSCB a valid notice of commencement, in the correct form, informing the NHSCB that P is to commence the provision of the services in respect of which the application was made and at the premises to which the application related in the next 14 days.

(3) A notice of commencement is in the correct form if it—

(a) includes the information required under paragraph 29; and

(b) is in the same format as the version of the notice sent by the NHSCB with the notice of decision under paragraph 28.

(4) A notice of commencement is invalid unless it is sent to the NHSCB within—

(a) if, prior to the NHSCB determining the application—

(i) P undertook to commence the provision of the services in respect of which the application was made within a period of less than 6 months, and

(ii) that undertaking was not withdrawn,

that period;

(b) 6 months of—

(i) unless paragraph (a) applies, the date on which P was sent the notice of the NHSCB's decision under paragraph 28 granting the application,

(ii) if the grant was appealed by a person with third party appeal rights, the date on which that appeal is determined by the Secretary of State,

(iii) if, in the course of granting the application, a decision is taken to impose a condition in accordance with regulation 35 and that condition is appealed by P, the date on which that appeal is determined by the First-tier Tribunal (unless regulation 35(8) applies),

(iv) if the grant of the application was subject to a condition imposed by virtue of paragraph 31, the date on which—

(aa) P validly notifies to the NHSCB under a condition imposed by virtue of paragraph 31 of the address of the premises, or

(bb) if P appeals successfully against a decision of the NHSCB that a notification under a condition imposed by virtue of paragraph 31 is invalid, that appeal is determined by the Secretary of State,

(v) if P, pursuant to paragraph 32—

(aa) notifies the NHSCB of a new address,

(bb) the NHSCB does not accept the validity of the notification, and

(cc) P appeals successfully against that decision,

the date on which that appeal is determined by the Secretary of State, or

(vi) if the grant of the application was subject to a condition imposed by virtue of paragraph 33, the date on which the condition imposed by virtue of that paragraph becomes spent or is removed on appeal, or

whichever is the latest; or

(c) such longer period—

(i) not exceeding a further 3 months as the NHSCB may allow, or

(ii) if—

(aa) the grant is appealed by a person with third party appeal rights,

(bb) a decision to accept a notification pursuant to paragraph 32 is appealed by a third party,

(cc) P appeals successfully against a notice under paragraph 35, or

(dd) if P appeals successfully against a decision not to allow a longer period under sub-paragraph (i),

as the Secretary of State may allow when the appeal is determined,

and so once a valid notice of commencement can no longer be sent in relation to an application (having regard also to paragraph 10(2) of Schedule 3), the grant of that application lapses.

(5) A notice of commencement ceases to have effect if the Secretary of State receives a valid notice of appeal—

(a) from a person with third party appeal rights relating to the grant to which the notice of commencement relates; or

(b) from a third party, in a case to which sub-paragraph (4)(c)(ii)(bb) applies.

Notice requiring the commencement of pharmaceutical services

35.—(1) The NHSCB, having granted a routine application—

(a) for inclusion in a pharmaceutical list by a person (P) not already included; or

(b) if P is already included in a particular pharmaceutical list, for inclusion in that list also in relation to premises not already listed in relation to P,

may, if the grant has not lapsed and is not under appeal to the Secretary of State, give notice to P requiring P to commence the provision of pharmaceutical services by a date specified in the notice.

(2) If the NHSCB gives notice under sub-paragraph (1) but afterwards a valid notice of appeal is given against the grant, the notice under sub-paragraph (1) lapses.

(3) A notice under sub-paragraph (1) may not specify a date that is—

(a) earlier than 30 days from the date of the notice under that paragraph; or

(b) later than 9 months after the date on which the grant of the application was notified to P.

(4) The NHSCB may change its pharmaceutical list to give effect to that notice—

(a) on the specified date, unless the decision to give notice under sub-paragraph (1) is appealed; or

(b) if the notice under paragraph (1) is appealed and the appeal is unsuccessful or discontinued—

(i) if the appeal is discontinued, 30 days after P discontinues the appeal,

(ii) if the appeal is unsuccessful, 30 days after the appeal is determined, or

(iii) on the specified date,

whichever is the latest.

Appeals to the Secretary of State by the applicant

36.—(1) As regards any routine or excepted application, other than an application pursuant to regulation 29, the applicant (A) may appeal to the Secretary of State against a decision by the NHSCB—

(a) to refuse the application on grounds set out in Parts 3 to 5 or 7 of these Regulations;

(b) that a notification pursuant to a condition imposed by virtue of paragraph 31 is invalid;

(c) to refuse to accept that a notification under paragraph 32(2) is a valid notification;

(d) to impose or vary a condition imposed pursuant to paragraph 33;

(e) to refuse to allow A an extension period under paragraph 34(4)(c)(i); or

(f) to give notice under paragraph 35,

provided A notifies the Secretary of State with a valid notice of appeal within 30 days of the date on which A was notified of the decision that is being appealed.

(2) A notice of appeal under paragraph (1) is only valid if it includes a concise and reasoned statement of the grounds of appeal.

SCHEDULE 3 Regs 10(8), 45(3), 63(6), 77(4), 98(9)

Appeals to the Secretary of State

PART 1

Preliminary matters

Determination of third party appeal rights in certain cases

1.—(1) If the Secretary of State has received a notification under paragraph 30(6) of Schedule 2 from a person (P1), the Secretary of State must determine (prior to a notification under Part 2 or a determination under paragraph 2) whether P1 is to have third party appeal rights on the basis that—

(a) P1 is a person to whom paragraph 30(3)(a) and (b) of Schedule 2 applies; and

(b) in relation to P1, the NHSCB should have been satisfied as mentioned in paragraph 30(3)(c) of Schedule 2.

(2) If the Secretary of State has received a notification under regulation 63(5) from a person (P2), the Secretary of State must determine (prior to a notification under Part 2 or a determination under paragraph 2) whether P2 is to have third party appeal rights on the basis that—

(a) P2 is a person to whom regulation 63(3)(a) and (b) applies; and

(b) in relation to P2, the NHSCB should have been satisfied as mentioned in regulation 63(3)(c).

(3) Once the Secretary of State has made a determination under paragraph (1) or (2), the Secretary of State must notify the NHSCB and P1 or P2 of that determination and the reasons for it.

Misconceived appeals

2. If the Secretary of State, after considering a valid notice of appeal under regulation 45, 63 or 77, or paragraph 30, 32(5) or 36 of Schedule 2 against a decision, is of the opinion that the notice—

(a) contains no valid grounds of appeal (for example, because it amounts to a challenge to the legality or reasonableness of a HWB's or Primary Care Trust's pharmaceutical needs assessment, or to the fairness of the process by which the HWB or a Primary Care Trust undertook that assessment); or

(b) contains no reasonable grounds for appeal (for example, where it is vexatious or frivolous),

the Secretary of State may determine the appeal by dismissing it (without proceeding to notify the appeal under Part 2).

PART 2

Notification of appeals

Notification of appeals notices under paragraph 30, 32(5) or 36 of Schedule 2

3.—(1) Unless the Secretary of State determines the appeal under paragraph 2, or the appeal relates to an application pursuant to regulation 23, the Secretary of State must send a copy of a valid notice of appeal sent under paragraph 30, 32(5) or 36 of Schedule 2 to—

(a) the NHSCB;

(b) in the case of an appeal against the grant of an application, any person who was entitled to receive notification of the decision by virtue of paragraph 28(5) of Schedule 2;

(c) in the case of an appeal in relation to a notifiable application, including against decisions as mentioned in paragraphs 32(4) and 36(1)(b) to (f) of Schedule 2—

(i) the applicant (unless they are the person bringing the appeal),

(ii) any person who was notified in relation to that application under paragraph 19 of Schedule 2 who made representations in writing about the application under paragraph 19(4) of that Schedule (unless they are also the person bringing the appeal), and

(d) in the case of an appeal in relation to an application pursuant to regulation 26(1), 27 or 28 (including against decisions as mentioned in paragraph 36(1)(d) to (f) of Schedule 2), any person notified in relation to the decision on that application under paragraph 28(3)(c) or (4).

(2) Any person to whom a notice of appeal is sent under sub-paragraph (1) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they are sent the notice of appeal by the Secretary of State.

Notification of appeals relating to notices under regulation 45

4.—(1) A valid notice of appeal under regulation 45(1)(b) does not need to be notified to others.

(2) The Secretary of State must send a valid notice of appeal—

(a) against a determination under regulation 36(2) to the persons given notice of the proposed determination under regulation 38(1) or (2); or

(b) against a determination under regulation 41(2) or 42(1) to—

(i) the person making the routine application to which the determination relates, and

(ii) any person given notice of the determination who is mentioned in regulation 43(1)(b)(ii),

unless they are the person bringing the appeal.

(3) Any person to whom a notice of appeal was sent under sub-paragraph (2) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they were sent the notice of appeal by the Secretary of State.

Notification of appeals relating to decisions under Part 8 of these Regulations

5.—(1) A valid notice of appeal under regulation 63(1)(a) does not need to be notified to others.

(2) The Secretary of State must send a valid notice of appeal against—

(a) a decision mentioned in regulation 63(1)(b) to the persons, other than the appellant, given notice of the decision under regulation 50(6); or

(b) a decision or determination mentioned in regulation 63(1)(c) to (f) to—

(i) the person who made the original application for outline consent or premises approval,

(ii) any person who was notified in relation to that application under regulation 52(1) to (3) who made representations in writing about the application under regulation 52(4), and

(iii) if the appeal is against a refusal to grant temporary premises approval, the applicant who made the relevant outstanding pharmacy application,

unless they are person bringing the appeal.

(3) Any person to whom a notice of appeal was sent under sub-paragraph (2) may make representations in writing about the appeal, provided they do so within 30 days of the date on which they were sent the notice of appeal by the Secretary of State.

Non notification of appeals relating to notices under regulation 77 or 98

6. A valid notice of appeal under regulation 77 or 98 does not need to be notified to others.

PART 3

Determination of appeals

Flexibility with regard to the manner of determining appeals

7.—(1) Except in so far as these Regulations provide to the contrary, the Secretary of State is to determine the appeal to which a valid notice of appeal under regulation 45, 63 or 77, or under paragraph 30, 32(5) or 36 of Schedule 2, relates in such manner (including with regard to procedures) as the Secretary of State sees fit.

(2) The Secretary of State may determine the appeal without hearing any oral representations, if the Secretary of State considers that oral representations are unnecessary.

(3) Where appropriate, the Secretary of State may, if the Secretary of State thinks fit, consider 2 or more appeals together and in relation to each other, but where the Secretary of State does so, the Secretary of State must give notice of the Secretary of State's intention to do so to—

(a) the NHSCB;

(b) the appellants; and

(c) any other person notified in relation to the appeals under Part 2.

Oral hearings

8.—(1) If the Secretary of State does decide to hear oral representations, the Secretary of State must give not less than 14 days notice of the time and place at which the oral representations are to be heard to—

(a) the NHSCB;

(b) the person who made the original application to which the appeal relates;

(c) if a person other than that applicant is bringing the appeal, the person bringing the appeal;

(d) any Local Pharmaceutical Committee whose area includes all or part of the area, or in whose area is the location or are the premises, to which the decision relates;

(e) any Local Medical Committee whose area includes all or part of the area, or in whose area is the location or are the premises, to which the decision relates; and

(f) any additional presenters,

and they (or their duly authorised representatives) are to be the only persons entitled to make oral representations at the hearing.

(2) For these purposes, a person (P) is an "additional presenter" if—

(a) P was notified of the appeal under Part 2 and has made written representations in accordance with paragraph 3(2), 4(3) or 5(3), which—

(i) indicated that, if there were to be an oral hearing in relation to the appeal, P would wish to make oral representations at that hearing, and

(ii) identified a matter about which the Secretary of State considers it would be desirable to hear further evidence from P at the oral hearing; and

(b) the Secretary of State is satisfied that P made a reasonable attempt to express P's views on the appeal adequately in P's written representations.

Decisions of the Secretary of State

9.—(1) On determining an appeal relating to a valid notice under paragraph 30 or 36, the Secretary of State may—

(a) if the appeal is an appeal to which paragraph 30 or 36(1)(a) of Schedule 2 applies (that is, against a decision to grant or refuse a routine or excepted application)—

(i) confirm the decision of the NHSCB,

(ii) quash the decision and redetermine the application, or

(iii) quash the decision and remit the matter to the NHSCB for it to redetermine the application, where the Secretary of State considers that there should be a (further) notification under paragraph 19 of Schedule 2, subject to such directions as the Secretary of State considers appropriate; or

(b) if the appeal is an appeal to which paragraph 32(5) or 36(1)(b) to (f) applies—

(i) confirm the decision of the NHSCB, or

(ii) substitute for that decision any decision that the NHSCB could have taken when it took that decision.

(2) If the Secretary of State grants or confirms the grant of a routine application, the Secretary of State may direct the NHSCB—

(a) to impose a condition under paragraph 33, in circumstances where the NHSCB could have imposed such a decision if it had granted the application; or

(b) to take such action under regulation 50(4) or (5) as the Secretary of State thinks fit.

(3) On determining an appeal relating to a valid notice under regulation 45, the Secretary of State may—

(a) confirm the decision or determination of the NHSCB;

(b) substitute for that decision or determination any decision or determination that the NHSCB could have taken when it took that decision or made that determination; or

(c) quash the decision or determination of the NHSCB and remit the matter to it for it to redetermine the decision or determination, subject to such directions as the Secretary of State considers appropriate.

(4) On determining an appeal relating to a valid notice under regulation 63, the Secretary of State may—

(a) in the case of decision or determination mentioned in regulation 63(1)(a), (b), (e) or (f)—

(i) confirm the decision or determination of the NHSCB,

(ii) substitute for that decision or determination any decision or determination that the NHSCB could have taken when it took that decision or made that determination, or

(iii) quash the decision or determination of the NHSCB and remit the matter to it for it to redetermine the decision or determination, subject to such directions as the Secretary of State considers appropriate; or

(b) if the appeal is against a decision to grant or refuse an application for outline consent or premises approval—

(i) confirm the decision of the NHSCB,

(ii) quash the decision of the NHSCB and redetermine the application, or

(iii) quash the decision of the NHSCB and remit the matter to it for it to redetermine the application, subject to such directions as the Secretary of State considers appropriate.

(5) On determining an appeal relating to a valid notice under regulation 77, the Secretary of State may—

(a) confirm the decision of the NHSCB; or

(b) substitute for that decision any decision that the NHSCB could have taken when it took that decision.

(6) If the Secretary of State grants or confirms the grant of an application for—

(a) outline consent, the Secretary of State may direct the NHSCB to take such action under regulation 53(3) as the Secretary of State thinks fit; or

(b) premises approval, the Secretary of State may direct the NHSCB to take such action under regulation 57 as the Secretary of State thinks fit.

Notification of decisions and subsequent action by the NHSCB

10.—(1) Once the Secretary of State has determined the appeal, the Secretary of State must notify the following—

(a) the NHSCB;

(b) the person who made the original application to which the appeal relates;

(c) if a person other than that person brought the appeal, the person who brought the appeal; and

(d) any person who made written representations relating to the application pursuant to the notification under Part 2,

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

(2) If the Secretary of State has granted or confirmed the grant of a routine or excepted application—

(a) the NHSCB must send to the applicant a template of the notice of commencement referred to in paragraph 29; and

(b) the time periods in paragraphs 31, 32 and 34 thereafter apply as if the references to the applicant being sent notices of the NHSCB's decision were reference to the applicant being notified by the Secretary of State under paragraph (3).

(3) If the Secretary of State has granted or confirmed the grant of—

(a) a routine application, the NHSCB must proceed as soon as is practicable to take such action under regulation 50(4) or (5) as it thinks fit, subject to any directions of the Secretary of State under paragraph 9(2)(b);

(b) an application for outline consent, the NHSCB must proceed as soon as is practicable to make a determination under regulation 53(3), subject to any directions of the Secretary of State under paragraph 9(6)(a); or

(c) an application for premises approval, the NHSCB must proceed as soon as is practicable take such action under regulation 57 as it thinks fit, subject to any directions of the Secretary of State under paragraph 9(6)(b).

Effect of decisions by the Secretary of State

11. For the purposes of these Regulations, the Secretary of State's decision becomes the NHSCB's decision on the matter (but no further appeal to the Secretary of State on that decision is possible), unless the Secretary of State's decision is overruled by a court.

SCHEDULE 4 Regulation 11(1)(a)(i)

Terms of service of NHS pharmacists

PART 1

General

Responsibilities of NHS pharmacists and pharmacy staff

1.—(1) To the extent that this Schedule imposes a requirement on an NHS pharmacist in respect of an activity which could only, or would normally, be undertaken by a natural person—

(a) if the NHS pharmacist is a registered pharmacist—

(i) that NHS pharmacist must comply with that requirement, or

(ii) if the NHS pharmacist employs or engages natural persons in connection with the provision of pharmaceutical services, the NHS pharmacist must either comply with that requirement or secure compliance with that requirement by—

(aa) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or

(bb) in other cases, by the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services; or

(b) if the NHS pharmacist is not a natural person, that NHS pharmacist must secure compliance with that requirement by—

(i) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or

(ii) in other cases, the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services.

(2) Where in this Schedule reference is made to an NHS pharmacist—

(a) being the subject of any activity, and it is an activity to which a natural person could only, or would normally, be subject; or

(b) forming a view,

that reference is to be construed as a referring, as appropriate, to the NHS pharmacist (if a natural person) or to the NHS pharmacist's staff.

(3) References in this Schedule to an NHS pharmacist are to be construed in accordance with sub-paragraphs (1) and (2).

Breaches by directors and superintendents

2. Where this Schedule imposes a requirement on the director or superintendent of a body corporate that is on a pharmaceutical list, a breach of that requirement is to be deemed to be a breach by the body corporate of its terms of service.

PART 2

Essential services

Essential services

3. For the purposes of these Regulations, "essential services" means—

(a) the services described in this Part; and

(b) the activities described in this Part to be carried out in connection with those services.

Dispensing services

4. An NHS pharmacist must, to the extent that paragraphs 5 to 9 require and in the manner described in those paragraphs, provide proper and sufficient drugs and appliances to persons presenting prescriptions for drugs or appliances ordered by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

Dispensing of drugs and appliances

5.—(1) In this Part, "signed" includes signature with a prescriber's advanced electronic signature.

(2) Subject to the following provisions of this Part, where—

(a) any person presents to an NHS Pharmacist (P) a non-electronic prescription form which contains—

(i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber,

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations(**6**) (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber and including the reference "SLS", or

(iii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS"; or

(**6**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.

(b) subject to sub-paragraph (4), P receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii) and—

(i) any person requests the provision of drugs or appliances in accordance with that prescription, or

(ii) P has previously arranged with the patient that P will dispense that prescription on receipt,

P must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as P supplies in the normal course of business.

(3) Subject to the following provisions of this Part, where—

(a) any person presents to P a non-electronic repeatable prescription which contains—

(i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(**7**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**8**) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber,

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber and including the reference "SLS",

(iii) an order for appliances, not being restricted availability appliances, signed by a prescriber, or

(iv) an order for a restricted availability appliance, signed by a prescriber, and including the reference "SLS",

and also presents an associated batch issue; or

(b) P receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) to (iv) and—

(i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or

(ii) P has previously arranged with the patient that P will dispense that repeatable prescription on receipt,

P must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as P supplies in the normal course of business.

(4) P must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001.

(5) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances shall be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

(a) P has that prescription in P's possession; and

(b) that person presents, or P has in P's possession, an associated batch issue.

(**7**) 1971 c.38; *see* section 2(1)(a) of that Act, which defines "controlled drug" for the purposes of that Act.

(**8**) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

Urgent supply without a prescription

6.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS pharmacist (P) to provide a drug or appliance.

(2) P may provide the drug or appliance requested before receiving a prescription form or repeatable prescription in respect of that drug or appliance, provided that—

(a) in the case of a request for a drug, the drug is neither—

(i) a Scheduled drug, nor

(ii) a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations); and

(b) in the case of a request for a drug or an appliance, the prescriber undertakes to—

(i) give P a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or

(ii) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made.

Preliminary matters before providing ordered drugs or appliances

7.—(1) If a person specified in sub-paragraph (2) asks an NHS pharmacist (P) to do so—

(a) P must give an estimate of the time when the drugs or appliances will be ready; and

(b) if they are not ready by then, P must give a revised estimate of the time when they will be ready (until they are ready).

(2) A person specified in this sub-paragraph is a person—

(a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or

(b) requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription.

(3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, P must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations(**9**) (supply of drugs and appliances by chemists) by virtue of either—

(a) entitlement to exemption under regulation 7(1) of the Charges Regulations(**10**) (exemptions); or

(b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations(**11**) (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations, and at the time of the declaration P already has such evidence available to P.

(**9**) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727, 2011/518 and 2012/470.
(**10**) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.
(**11**) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

(4) If, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (3), is produced to P, P shall endorse the form on which the declaration is made to that effect.

(5) In the case of an electronic prescription, P must transmit to the Electronic Prescription Service—

(a) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—

(i) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case, and

(ii) whether or not satisfactory evidence was produced to P as required by sub-paragraph (3);

(b) in any case where a charge is due, confirmation that the relevant charge was paid; and

(c) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Providing ordered drugs or appliances

8.—(1) Where an NHS pharmacist (P) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, P must only provide the drugs or appliances so ordered—

(a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 5(2) or (3); and

(b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985(**12**) and the following provisions of this Part.

(2) Drugs or appliances so ordered shall be provided either by or under the direct supervision of a registered pharmacist.

(3) Where the registered pharmacist referred to in sub-paragraph (2) is employed or engaged by P, the registered pharmacist must not be someone—

(a) who is disqualified from inclusion in a relevant list; or

(b) who is suspended from the GPhC register.

(4) If the order is for an appliance of a type requiring measuring and fitting (for example a truss), P must make all necessary arrangements for a registered pharmacist—

(a) to measure the person named on the prescription form or repeatable prescription for the appliance; and

(b) to fit the appliance.

(5) If the order is for a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided must comply with any relevant standard or formula specified therein.

(6) If the order—

(a) is an order for a drug; but

(**12**) 1985 c.72.

(b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**13**) (which relate to controlled drugs excepted from certain prohibitions under the Regulations),

and does not prescribe its quantity, strength or dosage, P (in this context, a registered pharmacist) may provide the drug in such strength and dosage as in the exercise of their professional skill, knowledge and care P considers to be appropriate and, subject to sub-paragraph (7), in such quantity as P considers to be appropriate for a course of treatment for a period not exceeding 5 days.

(7) Where an order to which sub-paragraph (6) applies is for—

(a) an oral contraceptive substance;

(b) a drug, which is available for supply as part of pharmaceutical services only together with one or more other drugs; or

(c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, P may provide the minimum size available package.

(8) Where any drug to which this paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by P in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

(a) sterile;

(b) effervescent or hygroscopic;

(c) a liquid preparation for addition to bath water;

(d) a coal tar preparation;

(e) a viscous preparation; or

(f) packed at the time of its manufacture in a special container,

P must provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(9) In this paragraph, "special container" means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(10) Subject to sub-paragraph (11), where a drug is ordered by a prescriber on a prescription form or a repeatable prescription in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a marketing authorisation holder for the drug, P must provide the drug in an original pack (or in original packs) of that size which has been assembled by a manufacturer of the drug for such a marketing authorisation holder, unless—

(a) it is not possible for P to obtain such a pack (or packs) with reasonable promptness in the normal course of business; or

(b) it is not practicable for P to provide such a pack (or packs) in response to the order (for example, because of patient needs or the method of administration of the drug).

(11) In the case of oral liquid methadone, P (in practice, a registered pharmacist) must decide whether it would be most appropriate to provide—

(**13**) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

(a) each dose in a separate container;

(b) an original pack (or original packs); or

(c) the oral liquid methadone in some other way,

and P must then provide it in packaging that accords with that decision.

(12) P must only provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription if—

(a) it is ordered as specified in sub-paragraph (13); or

(b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations(**14**) (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.

(13) A Scheduled drug that is a drug with an appropriate non-proprietary name may be provided in response to an order on a prescription form or repeatable prescription for a drug ("the prescribed drug") that is not a Scheduled drug but which has the same non-proprietary name as the Scheduled drug if—

(a) the prescribed drug is ordered by that non-proprietary name or by its formula;

(b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically); and

(c) the Scheduled drug is not in a pack which consists of a drug in more than one strength, and providing it would involve the supply of part only of the pack.

(14) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (13) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.

(15) P must provide any drug which P is required to provide under paragraph 5 in a suitable container.

Refusal to provide drugs or appliances ordered

9.—(1) An NHS pharmacist (P) may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

(a) P reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because P reasonably believes it has been stolen or forged);

(b) it appears to P that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to P's (in practice, a registered pharmacist's) clinical judgement;

(c) P or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person;

(d) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence; or

(**14**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.

(e) the prescription form or repeatable prescription is incomplete because it does not include the information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—

(i) the remuneration of persons providing pharmaceutical services, and

(ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless P (or the person who employs or engages P) is to receive no pharmaceutical remuneration of any kind in respect of the drug or appliance.

(2) P must refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.

(3) P must refuse to provide drugs or appliances ordered on a repeatable prescription where—

(a) P has no record of that prescription (other than on the first occasion on which the prescription is presented);

(b) P does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to P;

(c) it is not signed by a prescriber;

(d) to do so would not be in accordance with any intervals specified in the prescription;

(e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously;

(f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;

(g) the expiry date on the repeatable prescription has passed; or

(h) P has been informed by the prescriber that the prescription is no longer required.

(4) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), P must only provide the drugs or appliances ordered if P is satisfied—

(a) that the patient to whom the prescription relates—

(i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and

(ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;

(b) that the medication regimen of, or manner of utilisation of the appliance by, the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and

(c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

10.—(1) In connection with the services provided under paragraph 4, an NHS pharmacist (P) must—

(a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—

(i) to enable them to utilise the drugs or appliances appropriately, and

(ii) to meet the patient's reasonable needs for general information about the drugs or appliances;

(b) provide appropriate advice to patients to whom they provide drugs or appliances on—

(i) the safe keeping of the drugs or appliances, and

(ii) returning unwanted drugs or appliances to the pharmacy premises for safe destruction;

(c) when providing drugs to patients in accordance with a repeatable prescription, provide appropriate advice in particular on the importance of only requesting those items which they actually need;

(d) when providing appliances to patients in accordance with a prescription form or repeatable prescription—

(i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and

(ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;

(e) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;

(f) keep and maintain records—

(i) of drugs and appliances provided, in order to facilitate the continued care of the patient;

(ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and

(iii) of notes provided under sub-paragraph (e);

(g) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;

(h) if P takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;

(i) if P provides a drug or appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;

(j) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);

(k) destroy any surplus batch issues relating to drugs or appliances—

(i) which are not required, or

(ii) where a patient is refused the drugs or appliances pursuant to paragraph 9;

(l) ensure that where a person is refused drugs or appliances pursuant to paragraphs 9(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice;

(m) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification;

(n) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 9(4);

(o) when providing appliances, provide a patient with a written note of P's name, address and telephone number; and

(p) when providing specified appliances, comply with the additional requirements set out in paragraph 12.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing services under paragraph 4, P is unable to provide an appliance, or stoma appliance customisation is required and P is unable to provide that, P shall—

(a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

(b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to P.

Additional requirements in relation to electronic prescribing

11.—(1) An NHS pharmacist (P) must, if requested to do so by any person—

(a) explain to that person the Electronic Prescription Service, whether or not it is a service which is available through P's pharmacy premises; and

(b) where the Electronic Prescription Service is not available through P's pharmacy premises, provide that person with contact details of at least 2 NHS pharmacists in the area at whose premises the service is available, if these details are known to P.

(2) Where the Electronic Prescription Service is available through P's pharmacy premises, P must, if requested to do so by any person, enter in that person's PDS patient details—

(a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; or

(b) where the person does have a nominated dispensing contractor—

(i) a replacement dispensing contractor, or

(ii) a further dispensing contractor,

chosen by that person.

(3) Sub-paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors for that person would thereby exceed the maximum number permitted by the Electronic Prescription Service.

(4) Regulation 116(a) to (c) applies to a request under this paragraph as it applies to an application to an NHS chemist for pharmaceutical services.

(5) If P is a nominated dispensing contractor for a person (X) but the nomination was made before P became the person listed in a pharmaceutical list in relation to the pharmacy premises nominated in X's PDS patient details, P must within 6 months of P becoming the person so listed—

(a) explain to X that the ownership of the pharmacy premises has changed; and

(b) ask X whether X wishes to maintain the nomination in respect of those pharmacy premises.

Additional requirements in relation to specified appliances

12.—(1) This paragraph sets out the additional requirements referred to in paragraph 10(1)(p) relating to the provision of specified appliances.

(2) An NHS pharmacist (P) who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

(a) P must offer to deliver the specified appliance to the patient's home;

(b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient;

(c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content; and

(d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), P must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

(a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance; or

(b) if P believes it is appropriate to do so, must—

(i) refer the patient to a prescriber, or

(ii) offer the patient an appliance use review service.

(4) If P is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), P must give the patient the contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to P.

(5) Where P provides a telephone care line in respect of the dispensing of any specified appliance, P must ensure that during out of hours periods—

(a) advice is made available to patients through that telephone care line; or

(b) the telephone number of NHS Direct National Health Service Trust(**15**), or the website address of NHS Direct National Health Service Trust on line, are made available to patients through that telephone care line.

(6) For the purposes of this paragraph—

"expert clinical advice", in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

"out of hours periods", in relation to pharmacy premises, means the periods outside the core opening hours and any supplementary opening hours of the premises.

Disposal service in respect of unwanted drugs

13. An NHS pharmacist must, to the extent paragraph 14 requires and in the manner described in that paragraph, accept and dispose of unwanted drugs presented to the NHS pharmacist for disposal.

Basic procedure in respect of unwanted drugs

14.—(1) Subject to paragraph (2), where a person presents to an NHS pharmacist (P) any drugs provided for a patient in, and which have been kept in—

(a) a private household; or

(b) a children's home; or

(c) a residential care home, that is to say an establishment which exists wholly or mainly for the provision of residential accommodation, together with board and personal care, for persons in need of personal care because of—

(**15**) Established by S.I. 2007/478.

(i) old age,

(ii) mental or physical disability,

(iii) past or present dependence on alcohol or drugs,

(iv) any past illnesses, or

(v) past or present mental disorder,

P must accept the drugs and dispose of them in accordance with sub-paragraph (3).

(2) P is not required to accept any drugs for disposal unless the NHSCB has made arrangements for the collection and disposal of drugs of that description.

(3) On receipt of the drugs, P must—

(a) where required to do so by the NHSCB or by a waste disposal contractor retained by the NHSCB, separate solid drugs or ampoules, liquids and aerosols from each other;

(b) store the drugs in containers provided by the NHSCB, or by a waste disposal contractor retained by the NHSCB, for the purpose of storing drugs of that description; and

(c) comply with any other statutory requirements in respect of storing or the disposal of drugs of that description (meeting those requirements are therefore an essential service for the purposes of these Regulations),

and shall co-operate with any suitable arrangements that the NHSCB has in place for regular collection of the drugs from P's pharmacy premises by or on behalf of the NHSCB.

Further activities to be carried out in connection with the disposal of unwanted drugs

15. In connection with the services provided under paragraph 13, an NHS pharmacist (P) must—

(a) ensure that P (including P's staff) is aware of the risks associated with the handling of waste drugs and the correct procedures to be used to minimise those risks; and

(b) ensure that P (including P's staff) has readily available, and close to any place where waste drugs are stored, appropriate protective equipment, including gloves, overalls and materials to deal with spillages.

Promotion of healthy lifestyles

16. An NHS pharmacist must, to the extent paragraphs 17 and 18 require, and in the manner set out in those paragraphs, promote public health messages to members of the public.

Prescription linked intervention

17.—(1) Where a person using a pharmacy—

(a) presents a non-electronic prescription form or non-electronic repeatable prescription to an NHS pharmacist (P) or requests the provision of drugs or appliances in accordance with an electronic prescription; and

(b) it appears to P that the person—

(i) has diabetes,

(ii) is at risk of coronary heart disease, especially those with high blood pressure, or

(iii) smokes or is overweight,

P must, as appropriate, provide advice to that person with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances.

(2) Advice given under sub-paragraph (1) may be backed up, as appropriate—

(a) by the provision of written material (for example leaflets); and

(b) by referring the person to other sources of information or advice.

(3) P must, in appropriate cases, keep and maintain a record of advice given pursuant to this paragraph, and that record must be in a form that facilitates—

(a) auditing of the provision of pharmaceutical services by P; and

(b) follow-up care for the person who has been given the advice.

Public health campaigns

18. An NHS pharmacist (P) must, at the request of the NHSCB, ensure that—

(a) P (including P's staff) participates, in the manner reasonably requested by the NHSCB, in up to 6 campaigns in each calendar year to promote public health messages to users of P's pharmacy;

(b) where requested to do so by the NHSCB, P records the number of people to whom P (including P's staff) has provided information as part of one of those campaigns.

Signposting

19. An NHS pharmacist must, to the extent paragraph 20 requires and in the manner set out in that paragraph, provide information to users of the NHS pharmacist's pharmacy about other health and social care providers and support organisations.

Service outline in respect of signposting

20.—(1) Where it appears to an NHS pharmacist (P), having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using P's pharmacy—

(a) requires advice, treatment or support that P cannot provide; but

(b) another provider, of which P is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

P must provide contact details of that provider to that person and must, in appropriate cases, refer that person to that provider.

(2) Where, on presentation of a prescription form or repeatable prescription, P is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within P's normal course of business, P must—

(a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

(b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to P.

(3) Where appropriate, a referral under this paragraph may be made by means of a written referral note.

(4) P must, in appropriate cases, keep and maintain a record of any information given or referral made under this paragraph and that record must be in a form that facilitates—

(a) auditing of the provision of pharmaceutical services by P; and

(b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Support for self-care

21. An NHS pharmacist must, to the extent paragraph 22 requires and in the manner set out in that paragraph, provide advice and support to people caring for themselves or their families.

Service outline in respect of support for self-care

22.—(1) Where it appears to an NHS pharmacist (P), having regard to the need to minimise the inappropriate use of health and social care services, that a person (X) using P's pharmacy would benefit from advice from P to help X manage a medical condition (including, in the case of a carer, to help X in assisting in the management of another person's medical condition), P must provide advice to X as regards managing the medical condition, including, as appropriate, advice—

(a) on treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and

(b) on changes to the patient's lifestyle.

(2) P must, in appropriate cases, keep and maintain a record of any advice given under sub-paragraph (1), and of any drugs supplied when the advice was given, and that record shall be in a form that facilitates—

(a) auditing of the provision of pharmaceutical services by P; and

(b) follow-up care for the person to whom or in respect of whom the advice has been given.

PART 3

Hours of opening

Pharmacy opening hours: general

23.—(1) An NHS pharmacist (P) must ensure that pharmaceutical services are provided at P's pharmacy premises—

(a) for 40 hours each week;

(b) for not less than 100 hours each week, in the case of premises in respect of which a 100 hours condition applies;

(c) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 40 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;

(d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided at the premises for more than 40 hours per week, and at set times and on set days, at the times and on the days so set; or

(e) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 40 hours each week, but only on set times and on set days as regards the additional opening hours—

(i) for the total number of hours each week required by virtue of that direction, and

(ii) as regards the additional opening hours for which the person listed in relation to the premises is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which that person is required to provide pharmaceutical services during those additional opening hours, as set out in that direction,

but the NHSCB may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received 3 months notice of the proposed suspension.

(2) The hours during which pharmacy premises must be open by virtue of sub-paragraph (1) are referred to in these Regulations as "core opening hours".

(3) P must notify the NHSCB of other hours during which P's pharmacy premises are to be open, which are hours in addition to P's core opening hours (and which are referred to in these Regulations as "supplementary opening hours").

(4) Unless P is a distance selling chemist, at P's pharmacy premises P must exhibit—

(a) a notice specifying the days on which and times at which the premises are open for the provision of drugs and appliances (including times at which P is providing pharmaceutical services during supplementary opening hours); and

(b) at times when the premises are not open, a notice based on information provided by the NHSCB, where practicable legible from outside the premises, specifying—

(i) the addresses of other NHS pharmacists and the days on which and times at which drugs and appliances may be obtained from those addresses, and

(ii) the addresses of LPS chemists in the area, the type of local pharmaceutical services which those LPS chemists provide, and the days on which and times at which their premises are open.

(5) P must, on request, submit a return to the NHSCB setting out—

(a) the days on which and times at which pharmaceutical services are provided at P's pharmacy premises (including times at which P is providing pharmaceutical services during supplementary opening hours); and

(b) the pharmaceutical services which P ordinarily provides at those premises.

(6) Where P changes—

(a) the supplementary opening hours of P's pharmacy premises; or

(b) the pharmaceutical services which P ordinarily provides at those premises,

P must supply the NHSCB with a return informing it of the change.

(7) Where P has notified to the NHSCB (or, before the appointed day, a Primary Care Trust) the days on which and times at which pharmaceutical services are to be provided at P's pharmacy premises (for example, in a return under sub-paragraph (5) or (6) or in an application for inclusion in a pharmaceutical list)—

(a) P must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the times set out in the notification (unless the notification has been superseded by a return, or a further return, under sub-paragraph (6)); and

(b) P must not change—

(i) the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours which are neither additional opening hours nor in total less than 40 (if those core opening hours are additional opening hours, or are in total less than 40, regulation 65(5) to (7) and paragraphs 25 and 26 apply),

(ii) the total number of any supplementary opening hours (regulation 65(5) to (7) and paragraphs 25 and 26 apply to changes to the total number of core opening hours),

(iii) the days on which or the times at which pharmaceutical services are to be provided at those premises during supplementary opening hours, or

(iv) the pharmaceutical services which P is ordinarily to provide at those premises,

for a period of at least 3 months after that notification was received by the NHSCB (or, before the appointed day, a Primary Care Trust), unless the NHSCB agrees otherwise.

(8) Subject to sub-paragraph (9), where P is prevented by illness or other reasonable cause from complying with P's obligations under sub-paragraph (1), P must, where practicable, make arrangements with one or more NHS pharmacists or LPS chemists whose premises are situated in the same area for the provision of pharmaceutical services or local pharmaceutical services during that time.

(9) P may only make an arrangement with an LPS chemist under sub-paragraph (8) where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which P ordinarily provides.

(10) Where there is a temporary suspension in the provision of pharmaceutical services by P for a reason beyond the control of P, P is not in breach of sub-paragraphs (1) and (7), provided that—

(a) P notifies the NHSCB of that suspension as soon as practical; and

(b) P uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(11) Planned refurbishment of pharmacy premises is neither a "reasonable cause" for the purposes of sub-paragraph (8) nor a "reason beyond the control of P" for the purposes of sub-paragraph (10).

(12) For the purposes of calculating the number of hours that pharmacy premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is to be deemed that the pharmacy premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

(13) For the purposes of this Part, "additional opening hours", where they are required, are hours during which P is required to provide pharmaceutical services pursuant to sub-paragraph (1)(e) which are in addition to the hours during which P would be required to provide pharmaceutical services, if P were subject instead to the condition set out in sub-paragraph (1)(a).

Matters to be considered when issuing directions in respect of pharmacy premises core opening hours

24.—(1) Where the NHSCB issues a direction setting any days or times for the opening hours of pharmacy premises under this Part, it must in doing so seek to ensure that the days and times at which pharmacy premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in its area or other likely users of the pharmacy premises.

(2) In considering the matters mentioned in sub-paragraph (1), the NHSCB—

(a) must treat any local pharmaceutical services being provided in its area as if they were pharmaceutical services being so provided; and

(b) may have regard to any pharmaceutical services that are being provided in its area during supplementary opening hours.

(3) The NHSCB may only direct that an NHS pharmacist (P) may provide pharmaceutical services at premises for less than 40 hours in any week if it is satisfied that the provision of pharmaceutical services in its area is likely to be adequate to meet the need for such services at times when P is not providing pharmaceutical services.

(4) Except in the case of premises that have (at any time) been subject to a direction under regulation 65 or regulation 65 of the 2012 Regulations (core opening hours conditions), the NHSCB may only direct that P must provide pharmaceutical services at premises for more than 40 hours in any week where it is satisfied that P is to receive reasonable remuneration in respect of the additional opening hours for which P is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as mentioned in regulation 91(6) in respect of those hours is "reasonable remuneration" for these purposes).

Determination of pharmacy premises core opening hours instigated by the NHSCB

25.—(1) Where it appears to the NHSCB, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee for the area in which the premises are situated, that the days on which or times at which pharmacy premises are or are to be open for the provision of pharmaceutical services will not, or no longer, meet the needs of—

(a) people in its area; or

(b) other likely users of the pharmacy premises,

for the pharmaceutical services available at or from those premises, it must carry out an assessment as to whether to issue a direction requiring the NHS pharmacist (P) whose premises they are to provide pharmaceutical services at the pharmacy premises at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the NHSCB must—

(a) give notice to P of any proposed changes to the days on which or times at which the pharmacy premises are to be open; and

(b) allow P 30 days within which to make written representations to the NHSCB about the proposed changes.

(3) When it determines the outcome of its assessment, the NHSCB must—

(a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5);

(b) confirm any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5); or

(c) either—

(i) revoke, without replacing it, any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of whichever of paragraph 23(1)(a) or (b) applies, the pharmacy will need to be open for 40 hours each week or for at least 100 hours each week.

(4) Where the NHSCB issues a direction under sub-paragraph (3) in respect of pharmacy premises that are to be required to be open—

(a) for more than 40 hours each week, it must set out in that direction—

(i) the total number of hours each week for which P must provide pharmaceutical services at the pharmacy, and

(ii) as regards the additional opening hours, the days on which and the times at which P is required to provide those services during those hours,

but it must not set out in that direction the days on which or times at which P is to provide pharmaceutical services during hours which are not additional opening hours; or

(b) for less than 40 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at the pharmacy premises.

(5) The NHSCB must not issue a direction under sub-paragraph (3) that has the effect simply of requiring pharmacy premises to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring pharmacy premises to be open for either more or less than 40 hours each week).

(6) The NHSCB must notify P of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which P is to provide pharmaceutical services at pharmacy premises, it must include with the notification a statement of—

(a) the reasons for the change; and

(b) P's right of appeal under paragraph (7).

(7) P may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Secretary of State against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which P is to provide pharmaceutical services.

(8) The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under paragraph (3).

(9) The Secretary of State shall notify P of the determination and shall in every case include with the notification a statement of the reasons for the determination.

(10) If the days on which or times at which P is to provide pharmaceutical services at pharmacy premises have been changed in accordance with this paragraph, P must introduce the changes—

(a) if P has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (6); or

(b) if P has appealed under sub-paragraph (7), not later than 8 weeks after the date on which P receives notification under sub-paragraph (9).

(11) This paragraph does not apply where regulation 65(5) to (7) applies.

Determination of pharmacy premises core opening hours instigated by the NHS pharmacist

26.—(1) An NHS pharmacist (P) may apply to the NHSCB for it to change the days on which or times at which P is obliged to provide pharmaceutical services at P's pharmacy premises in a way that—

(a) reduces the total number of hours for which P is obliged to provide pharmaceutical services at those premises each week (but not those required under any 100 hours condition); or

(b) keeps that total number of hours the same.

(2) Where P makes an application under sub-paragraph (1), as part of that application P must provide the NHSCB with such information as the NHSCB may reasonably request in respect of any changes to the needs of the people in its area, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.

(3) The NHSCB must determine the application within 60 days of receiving it (including any information required of P in accordance with sub-paragraph (2)).

(4) When it determines the application, the NHSCB must—

(a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;

(b) confirm any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises, provided that the existing direction (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (5) and (6); or

(c) either—

(i) revoke, without replacing it, any existing direction in respect of the times at which P must provide pharmaceutical services at the pharmacy premises (whether issued under regulation 65, this Part, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), where this has the effect of granting the application under this paragraph or granting it only in part, or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of whichever of paragraph 23(1)(a) or (b) applies, the pharmacy will need to be open for 40 hours each week or for at least 100 hours each week.

(5) Where the NHSCB issues a direction under sub-paragraph (4) in respect of pharmacy premises that are to be required to be open—

(a) for more than 40 hours each week, it must set out in that direction—

(i) the total number of hours each week for which P must provide pharmaceutical services at the pharmacy premises, and

(ii) as regards any additional opening hours, the days on which and the times at which P is required to provide those services during those hours,

but it must not set out in that direction days on which or times at which P is to provide pharmaceutical services during hours which are not additional opening hours; or

(b) for less than 40 hours each week, it shall set out in that direction the days on which and times at which pharmaceutical services are to be provided at the pharmacy premises.

(6) The NHSCB must not issue a direction under sub-paragraph (4) that has the effect simply of requiring pharmacy premises to be open for 40 hours each week on set days and at set times (that is, the direction must have the effect of requiring pharmacy premises to be open for either more or less than 40 hours each week).

(7) Where the NHSCB is considering taking action under sub-paragraph (4)(a) or (c)(i), it shall consult the Local Pharmaceutical Committee for the area in which the pharmacy premises are situated before determining the application.

(8) The NHSCB must notify P of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send P a statement setting out—

(a) the reasons for the refusal or, as the case may be, for granting the application only in part; and

(b) P's right of appeal under sub-paragraph (9).

(9) P may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under sub-paragraph (4).

(11) The Secretary of State must notify the pharmacist of the determination and must include with the notification a statement of the reasons for the determination.

(12) If the days on which or times at which P is to provide pharmaceutical services at pharmacy premises have been changed in accordance with this paragraph, P must introduce the changes—

(a) if P has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which P receives notification under sub-paragraph (4); or

(b) if P has appealed under sub-paragraph (9), not earlier than 30 days after the date on which P receives notification under sub-paragraph (11).

(13) This paragraph does not apply where regulation 65(5) to (7) applies.

Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services

27.—(1) Notwithstanding the provisions of this Part, during an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may, on application from an NHS pharmacist ("P"), permit P a temporary change to the days on which or times at which P is obliged to provide pharmaceutical services at pharmacy premises, or permit temporary closure of those premises, if—

(a) P gives at least 24 hours notice of the change or closure; and

(b) the reasons given by P for the request are, in the opinion of the NHSCB, adequate reasons.

(2) The NHSCB need not approve the request in advance of the change or closure, but if it does not do so and decides subsequently that P's reasons are not, in its opinion, adequate reasons, then the days on which or times at which P is obliged to provide pharmaceutical services at the premises are to revert to the overridden days or times, from the day after the date on which that decision is given to P.

PART 4

Other terms of service

Clinical governance

28.—(1) An NHS pharmacist (P) must, in connection with the pharmaceutical services provided by P, participate, in the manner reasonably required by the NHSCB, in an acceptable system of clinical governance.

(2) For these purposes a system of clinical governance is "acceptable" if it is considered acceptable by the NHSCB and comprises the following components—

(a) a patient and public involvement programme, which includes—

(i) a requirement that P produces in an approved manner, and makes available in an appropriate manner, a practice leaflet containing approved particulars in respect of P's pharmacy premises,

(ii) a requirement that the pharmacist publicises the essential services and any advanced services that are available at or from the pharmacist's pharmacy,

(iii) a requirement that where a pharmacist publicises the essential services or any directed services that are available at or from the pharmacist's pharmacy (whether the pharmacist is producing their own publicity material or advertising services in material published by another person), the pharmacist does so in a manner which makes clear that the services are funded as part of the health service,

(iv) a requirement that P undertakes an approved patient satisfaction survey annually, in an approved manner,

(v) P's monitoring arrangements for drugs or appliances owed to patients but which are out of stock,

(vi) a requirement that P co-operates appropriately with any reasonable inspection or review that the NHSCB or any relevant statutory authority wishes to undertake, and

(vii) P's monitoring arrangements in respect of P's compliance with the Equality Act 2010(**16**);

(b) a clinical audit programme (normally of 5 days), which includes at least one pharmacy-based audit and one other audit agreed by the NHSCB in each financial year;

(c) a risk management programme, which includes—

(i) arrangements for ensuring that all stock is procured and handled in an appropriate way,

(ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,

(iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,

(iv) arrangements, including record keeping arrangements, for dealing appropriately and timeously with any communications concerning patient safety from the Secretary of State(**17**) and the NHSCB,

(v) appropriate standard operating procedures, including standard operating procedures in respect of dispensing drugs and appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families,

(vi) appropriate waste disposal arrangements (in addition to those required under Part 2) for clinical and confidential waste,

(vii) a clinical governance lead person for each pharmacy, appointed as such by the pharmacist (or who is the pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,

(viii) appropriate safeguarding procedures for service users,

(ix) P's monitoring arrangements in respect of P's compliance with the Health and Safety at Work etc. Act 1974(**18**);

(d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by P—

(i) in respect of the provision of drugs in accordance with a repeatable prescription,

(ii) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or

(iii) to people caring for themselves or their families,

and arrangements for ensuring that P, when giving advice to any patient on a matter mentioned in paragraph (d)(ii), has regard to the details contained in the records maintained under paragraph 10(1)(f) in respect of the provision of appliances and the prescribing pattern relating to the patient in question;

(e) a staffing and staff management programme, which includes—

(i) arrangements for appropriate induction for staff (including locums),

(ii) appropriate training for all staff in respect of any role they are asked to perform,

---

(**16**) 2010 c. 15.

(**17**) The Medicines and Healthcare Products Regulatory Agency, which is an executive agency of the Department of Health, issues safety advice, warnings, alerts and recalls in respect of medical devices on behalf of the Secretary of State, and also safety advice, warnings, alerts and recalls in respect of medicines on behalf of the Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly. The Department of Health also, separately, issues other communications concerning patient safety, on behalf of the Secretary of State.

(**18**) 1974 c. 37.

(iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,

(iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of NHS services, including continuing professional development for registered pharmacists and registered pharmacy technicians, and any necessary accreditation in respect of the provision of directed services,

(v) arrangements for addressing poor performance (in conjunction with the NHSCB as appropriate), and

(vi) arrangements (which must include a written policy) for ensuring that all staff and locums who, arising out of their employment with the pharmacist—

(aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996(**19**) (meaning of protected disclosure) have the rights afforded in respect of such disclosures by that Act, and

(bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to the NHSCB which includes an allegation of a serious nature which they reasonably believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A, have the right not to be subjected to any detriment or to dismissal as a consequence of that act;

(f) an information governance programme, which provides for—

(i) compliance with approved procedures for information management and security, and

(ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the NHSCB to access that assessment; and

(g) a premises standards programme, which includes—

(i) a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of health care acquired infection is minimised, and

(ii) arrangements for compliance, in the areas of the pharmacy in which patients receive NHS services, with any approved particulars that are designed to ensure, in a proportionate manner, that those areas are an appropriate environment in which to receive health care,

and for the purposes of this sub-paragraph, "approved" means approved by the NHSCB.

Professional Standards

29. An NHS pharmacist must provide pharmaceutical services and exercise any professional judgement in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements etc.

30.—(1) An NHS pharmacist (P) (including P's staff) must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of P's business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

(**19**) 1996 c. 18; section 43A was inserted by the Public Interest Disclosure Act 1998 (c. 23), section 1. *See also* section 43K(1)(c) (i) of the Employment Rights Act 1996 (inserted by the Public Interest Disclosure Act 1998, section 1, and amended by: the National Health Service Reform and Health Care Professions Act 2002 (c. 17), Schedule 2, paragraph 63; the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraphs 177 and 178(b); and S.I. 2007/961).

(a) presenting an order for drugs or appliances on a prescription form or repeatable prescription, non-electronic prescription form or non-electronic repeatable prescription;

(b) nominating P as X's dispensing contractor (or one of them) in X's PDS patient details; or

(c) receiving from P any directed services.

(2) Promising, offering or providing an auxiliary aid in relation to the supply of drugs or a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

(3) Nothing in sub-paragraph (1) prohibits P from providing to a patient to whom P is providing any directed services any gift which—

(a) is supplied as part of the provision of any directed service to that patient;

(b) is directly related to that directed service;

(c) is supplied in order to encourage or promote health or well-being or the adoption by the patient or the patient's family of a healthy lifestyle; and

(d) in the case of a gift which—

(i) is not a medicine, has a monetary value not exceeding £10, or

(ii) is a medicine, is supplied as part of the provision of a minor ailments service.

(4) P (including P's staff) must not give, promise or offer to any relevant person any gift or reward (including by way of a share of, or dividend on, the profits of P's business, or by way of a discount or rebate) as an inducement to or in consideration of the relevant person recommending to any person that they—

(a) present to P an order for drugs or appliances on a prescription form or repeatable prescription;

(b) nominate P as their dispensing contractor (or one of them) in their entry in their PDS patient details; or

(c) ask P to provide them with any directed service.

(5) For the purpose of sub-paragraph (4), "relevant person" means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes—

(a) any NHS body or provider of primary medical services; and

(b) any person employed or engaged by any of the persons mentioned in paragraph (a).

(6) In the case of the provision of appliances, P (including P's staff) must not accept or receive any gift or reward in respect of only—

(a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 10(2)(b), 12(4) or 20(2)(b); or

(b) referring a prescription form or repeatable prescription to another NHS pharmacist or NHS appliance contractor pursuant to paragraph 10(2)(a) or 20(2)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness matters as they arise

31.—(1) An NHS pharmacist (P) and, where P is a body corporate, every director and superintendent of P must, within 7 days of its occurrence, inform the NHSCB in writing if they—

(a) are convicted of any criminal offence in the United Kingdom;

(b) are bound over following a criminal conviction in the United Kingdom;

(c) accept a police caution in the United Kingdom;

(d) have, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction);

(e) have accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(**20**) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(**21**) (penalty as alternative to prosecution);

(f) have been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;

(g) are charged in the United Kingdom with a criminal offence, or are charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;

(h) are notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them;

(i) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;

(j) become the subject of any investigation into their professional conduct in respect of any current or previous employment, or are notified of the outcome of any such investigation and any finding against them;

(k) become the subject of any investigation by the NHS BSA in relation to fraud;

(l) become the subject of any investigation by another primary care organisation which might lead to their removal from a relevant list; or

(m) are removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) If a person to whom paragraph (1) applies (X) is, or was at the time of the originating events, a director or superintendent of a body corporate, X must in addition inform the NHSCB within 7 days if any such body corporate—

(a) is convicted of any criminal offence in the United Kingdom;

(b) is convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;

(c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;

(d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;

(e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;

(f) becomes the subject of any investigation by the NHS BSA in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;

(**20**) 1995 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).

(**21**) 1992 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.

(g) becomes the subject of any investigation by another primary care organisation which might lead to its removal from any relevant list; or

(h) is removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) P or X must consent to a request being made by the NHSCB to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Other information to be supplied

32.—(1) An NHS pharmacist (P) must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of—

(a) any occurrence requiring a change in the information recorded about P in the pharmaceutical list which P has not otherwise notified to the NHSCB in accordance with these Regulations;

(b) if P is an individual, any change to P's private address;

(c) if P is a body corporate, any change to the name, registration number, registered office or telephone number relating to that office of the body corporate; and

(d) any occurrence requiring P's addition to or removal from an EPS list or a change in the information recorded about P in that list.

(2) P must give the NHSCB, if it so requests, the name of any pharmacist employed or engaged by P who is responsible for dispensing a particular prescription.

(3) If P is a body corporate, it must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of any changes to—

(a) the names of its directors; and

(b) the name or address of its superintendent.

(4) If P is a body corporate and appoints a superintendent or director who was not listed on P's application for inclusion on a pharmaceutical list, P must, within 30 days of the person's appointment, supply to the NHSCB the information mentioned in paragraph 3 and 4 of Schedule 2 about that person.

(5) If P or a director or superintendent of P (if P is a body corporate) is on, or is a director or superintendent of a body corporate which is on, a relevant list other than a pharmaceutical list held by the NHSCB, they must supply in writing to the NHSCB—

(a) in the case of a director or superintendent of a body corporate, the name and registered office of the body corporate on the other relevant list; and

(b) particulars of the other relevant list.

(6) P or the director or superintendent of P (if P is a body corporate) must inform the NHSCB if they, or a body corporate of which they are a director or superintendent, apply to be included in a relevant list of another primary care organisation, and of the outcome of any such application.

Co-operation with Health Education England

33. An NHS pharmacist must co-operate with Health Education England in the discharge by Health Education England of the duty under section 1F(1) of the 2006 Act(**22**) (duty as to education and training).

Complaints

34.—(1) An NHS pharmacist must have in place arrangements, which comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(**23**), for the handling and consideration of any complaints.

(2) In this paragraph, "complaint" means a complaint about a matter connected with the provision of pharmaceutical services by the NHS pharmacist.

Inspections and access to information

35.—(1) An NHS pharmacist (P) must allow persons authorised in writing by the NHSCB to enter and inspect P's pharmacy premises at any reasonable time, for the purposes of—

(a) ascertaining whether or not P is complying with the requirements of this Schedule;

(b) auditing, monitoring and analysing—

(i) the provision made by P, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and

(ii) the management by P of the pharmaceutical services P provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

(a) reasonable notice of the intended entry has been given;

(b) the Local Pharmaceutical Committee for the area where the pharmacy premises are situated have been invited to be present at the inspection, where this is requested by P;

(c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and

(d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) P must, at the request of the NHSCB or of X, allow it or X access to any information which it or X reasonably requires—

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

(**22**) Section 1F was inserted by the Health and Social Care Act 2012 (c. 7), section 7.
(**23**) S.I. 2009/309; amended by S.I. 2009/1768.

SCHEDULE 5

Regulation 11(2)(a)(i)

Terms of service of NHS appliance contractors

Division of responsibilities between individuals and corporate bodies

1.—(1) To the extent that this Schedule imposes a requirement on an NHS appliance contractor in respect of an activity which could only, or would normally, be undertaken by a natural person—

(a) if the NHS appliance contractor is a natural person—

(i) that person must comply with that requirement, or

(ii) if the NHS appliance contractor employs or engages other natural persons in connection with the provision of pharmaceutical services, the NHS appliance contractor must either comply with that requirement or secure compliance with that requirement by the other natural persons whom the NHS appliance contractor employs or engages; or

(b) if the NHS appliance contractor is not a natural person, that NHS appliance contractor must secure compliance with that requirement by the natural persons whom the NHS appliance contractor employs or engages in connection with the provision of pharmaceutical services.

(2) Where in this Schedule reference is made to an NHS appliance contractor—

(a) being the subject of any activity, and it is an activity to which a natural person could only, or would normally, be subject; or

(b) forming a view,

that reference is to be construed, as referring, as appropriate to the NHS appliance contractor (if a natural person) or to the NHS appliance contractor's staff.

(3) References in this Schedule to an NHS appliance contractor are to be construed in accordance with sub-paragraphs (1) and (2).

Breaches by directors

2. Where this Schedule imposes a requirement on the director of a body corporate that is included in a pharmaceutical list, a breach of that requirement is to be deemed to be a breach by the body corporate of its terms of service.

Dispensing services

3. An NHS appliance contractor must, to the extent that paragraphs 4 to 8 require and in the manner described in those paragraphs, provide proper and sufficient appliances to persons presenting prescriptions for appliances ordered by health care professionals in pursuance of their functions in the health service, the Scottish health service or the Northern Ireland health service.

Dispensing of appliances

4.—(1) In this Part, "signed" includes signature with a prescriber's advanced electronic signature.

(2) Subject to the following provisions of this Schedule, where—

(a) any person presents to an NHS appliance contractor (C) a non-electronic prescription form which contains—

(i) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or

(ii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS"; or

(b) C receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) and (ii) and—

(i) any person requests the provision of an appliance in accordance with that prescription, or

(ii) C has previously arranged with the patient that C will dispense that prescription on receipt,

C must, with reasonable promptness, provide the appliance so ordered if C supplies it in the normal course of business.

(3) Subject to the following provisions of this Schedule, where—

(a) any person presents to C a non-electronic repeatable prescription which contains—

(i) an order for appliances, not being restricted availability appliances, signed by a prescriber, or

(ii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS",

and also presents an associated batch issue; or

(b) C receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in paragraph (a)(i) or (ii) and—

(i) any person requests the provision of appliances in accordance with that prescription, or

(ii) C has previously arranged with the patient that the supplier will dispense that prescription on receipt,

C must, with reasonable promptness, provide such of the appliances so ordered as C supplies in the normal course of business.

(4) For the purposes of this paragraph, a non-electronic repeatable prescription for appliances shall be taken to be presented even if the person who wishes to obtain the appliances does not present that prescription, where—

(a) C has that prescription in the supplier's possession; and

(b) that person presents, or C has in C's possession, an associated batch issue.

Urgent supply without a prescription

5.—(1) This paragraph applies where, in a case of urgency, a prescriber requests an NHS appliance contractor (C) to provide an appliance.

(2) C may provide the appliance requested before receiving a prescription form or repeatable prescription in respect of that appliance, provided that the prescriber undertakes to—

(a) give C a non-electronic prescription form or non-electronic repeatable prescription in respect of the appliance within 72 hours of the request being made; or

(b) transmit an electronic prescription to the Electronic Prescription Service within 72 hours of the request being made.

Preliminary matters before providing appliances

6.—(1) If a person specified in sub-paragraph (2) asks an NHS appliance contractor (C) to do so—

(a) C must give an estimate of the time when the appliance will be ready; and

(b) if it is not ready by then, P must give a revised estimate of the time when it will be ready (until it is ready).

(2) A person specified in this sub-paragraph is a person—

(a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or

(b) requesting the provision of appliances in accordance with an electronic prescription form or an electronic repeatable prescription.

(3) Before providing an appliance in accordance with a prescription form or repeatable prescription—

(a) C must ask any person who makes a declaration that the person named on the prescription form or repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A) of the Charges Regulations(**24**) (supply of drugs and appliances by chemists) by virtue of either—

(i) entitlement to exemption under regulation 7(1) of the Charges Regulations(**25**) (exemptions), or

(ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations(**26**) (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations, and at the time of the declaration C already has such evidence available to C;

(b) if, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by paragraph (a), is produced to C, C must endorse the form on which the declaration is made to that effect; and

(c) in the case of an electronic prescription form or an electronic repeatable prescription, C must transmit to the Electronic Prescription Service—

(i) in a case where exemption from or remission of charges is claimed, a record of—

(aa) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case; and

(bb) whether or not satisfactory evidence was produced to C as required by sub-paragraph (a), and

(ii) in any case where a charge is due, confirmation that the relevant charge was paid.

Providing appliances

7.—(1) Where an NHS appliance contractor (C) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, C must only provide the appliances so ordered—

(a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 4; and

(b) in accordance with the order on the prescription form or repeatable prescription,

(**24**) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727, 2011/518 and 2012/470.
(**25**) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.
(**26**) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

subject to any regulations in force under the Weights and Measures Act 1985(**27**) and the following provisions of this Schedule.

(2) If the order is for an appliance of a type requiring measuring and fitting (for example a truss), C must make all necessary arrangements for—

(a) measuring the person named on the prescription form for the appliance; and

(b) fitting the appliance.

(3) If the order is for an appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the appliance provided must comply with the standard or formula specified therein.

Refusal to provide appliances ordered

8.—(1) An NHS appliance contractor (C) may refuse to provide an appliance ordered on a prescription form or repeatable prescription where—

(a) C reasonably believes that it is not a genuine order for the person named on the prescription form or repeatable prescription (for example because C reasonably believes it has been stolen or forged);

(b) it appears to C that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the appliance would be contrary to C's clinical judgement;

(c) C or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of appliances in accordance with an electronic prescription form or repeatable prescription, or by any person accompanying that person

(d) the person presenting the prescription form or requesting the provision of appliances in accordance with an electronic prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence; or

(e) the prescription form or repeatable prescription is incomplete because it does not include information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—

(i) the remuneration of persons providing pharmaceutical services, and

(ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless C (or the person who employs or engages C) is to receive no pharmaceutical remuneration of any kind in respect of the appliances.

(2) C must refuse to provide appliances ordered on a repeatable prescription where—

(a) C has no record of that prescription (other than on the first occasion on which the prescription is presented);

(b) C does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to the supplier;

(c) it is not signed by a prescriber;

(d) to do so would not be in accordance with any intervals specified in the prescription;

(**27**) 1985 c. 72.

(e) it would be the first time an appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously;

(f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;

(g) the expiry date on the repeatable prescription has passed; or

(h) C has been informed by the prescriber that the prescription is no longer required.

(3) Where a patient requests the supply of appliances ordered on a repeatable prescription (other than on the first occasion that the request is made), C must only provide the appliance ordered if C is satisfied that—

(a) the patient to whom the prescription relates—

(i) is using and is likely to continue to use the appliance appropriately, and

(ii) is not suffering from any side effects of the treatment which indicate the need or desirability of reviewing the patient's treatment;

(b) the manner of utilisation of the appliance by the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and

(c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

9.—(1) In connection with the services provided under paragraph 3, an NHS appliance contractor (C) must—

(a) ensure that appropriate advice is given to patients about any appliances provided to them—

(i) to enable them to utilise the appliances appropriately, and

(ii) to meet the patient's reasonable needs for general information about the appliances;

(b) provide appropriate advice to patients to whom they provide appliances on the safe keeping of the appliances;

(c) when providing appliances to patients in accordance with a prescription form or repeatable prescription—

(i) provide appropriate advice in particular on the importance of only requesting those items which they actually need, and

(ii) for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;

(d) provide a patient with a written note of any appliance which is owed, and inform the patient when it is expected that the appliance will become available;

(e) provide a patient with a written note of C's name, address and telephone number;

(f) keep and maintain records—

(i) of appliances provided, in order to facilitate the continued care of the patient,

(ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescription), and

(iii) of notes provided under paragraph (d);

(g) undertake appropriate training in respect of repeat dispensing having regard to any recommendations in respect of such training set out in the Drug Tariff;

(h) if C takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;

(i) if C provides an appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed;

(j) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);

(k) destroy any surplus batch issues relating to appliances—

(i) which are not required, or

(ii) where a patient is refused an appliance pursuant to paragraph 8;

(l) ensure that where a person is refused appliances pursuant to paragraph 8(1)(b), (2) or (3), the patient is referred back to the prescriber for further advice;

(m) where a patient is provided with appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification;

(n) notify the prescriber of any refusal to provide appliances pursuant to paragraph 8(4); and

(o) when providing specified appliances, comply with the additional requirements set out in paragraph 11.

(2) Where, on presentation of a prescription form or repeatable prescription in connection with the dispensing of appliances under paragraph 4, C is unable to provide an appliance, or stoma appliance customisation is required and C is unable to provide that, C must—

(a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist; or

(b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to C.

Additional requirements in relation to electronic prescribing

10.—(1) An NHS appliance contractor (C) must, if requested to do so by any person—

(a) explain to that person the Electronic Prescription Service, whether or not it is a service which is available through C's appliance contractor premises; and

(b) where the Electronic Prescription Service is not available through C's appliance contractor premises, provide that person with the names of at least 2 NHS appliance contractors through whom the Electronic Prescription Service is available, if these details are known to C.

(2) Where the Electronic Prescription Service is available through C's appliance contractor premises, C must, if requested to do so by any person, enter in that person's PDS patient details—

(a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by that person; or

(b) where the person does have a nominated dispensing contractor—

(i) a replacement dispensing contractor, or

(ii) a further dispensing contractor,

chosen by that person.

(3) Sub-paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors would thereby exceed the maximum number permitted by the Electronic Prescription Service.

(4) Regulation 116(a) to (c) applies to a request under this paragraph as it applies to an application to an NHS chemist for pharmaceutical services.

(5) If C is a nominated dispensing contractor for a person (X) but the nomination was made before C became the person listed in a pharmaceutical list in relation to the appliance contractor premises nominated in X's PDS patient details, C must within 6 months of C becoming the person so listed—

(a) explain to X that the ownership of the appliance contractor premises has changed; and

(b) ask X whether X wishes to maintain the nomination in respect of those appliance contractor premises.

Additional requirements in relation to specified appliances

11.—(1) This paragraph sets out the additional requirements referred to in paragraph 9(1)(o) relating to the provision of specified appliances.

(2) An NHS appliance contractor (C) who dispenses specified appliances in the normal course of business must provide a home delivery service in respect of those appliances and, as part of that service—

(a) C must offer to deliver the specified appliance to the patient's home;

(b) if the patient accepts that offer, the delivery must be made with reasonable promptness and at such time as is agreed with the patient;

(c) the specified appliance must be delivered in a package which displays no writing or other markings which could indicate its content; and

(d) the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered.

(3) In any case where a specified appliance is provided (whether by home delivery or otherwise), C must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and—

(a) must ensure that the patient may, if the patient wishes, consult a person to obtain expert clinical advice regarding the appliance; or

(b) if C believes it is appropriate to do so, must—

(i) refer the patient to a prescriber; or

(ii) offer the patient an appliance use review service.

(4) If C is unable to provide an appliance use review service in accordance with sub-paragraph (3)(b)(ii), C must give the patient the contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to arrange for the service to be provided, if these details are known to C.

(5) Where C provides a telephone care line in respect of the dispensing of any specified appliance, C must ensure that during out of hours periods—

(a) advice is made available to patients through that telephone care line; or

(b) the telephone number of NHS Direct National Health Service Trust(**28**), or website address of NHS Direct National Health Service Trust on line, are made available to patients through the telephone care line.

(6) For the purposes of this paragraph—

"expert clinical advice", in relation to a specified appliance, means advice which is given by a person who is suitably trained and who has relevant experience in respect of the appliance;

"out of hours periods", in relation to the appliance contractor premises, means the periods outside the core opening hours and any supplementary opening hours of the premises.

Signposting

12.—(1) Where, on presentation of a prescription form or repeatable prescription, an NHS appliance contractor (C) is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within C's normal course of business, C must—

(a) if the patient consents, refer the prescription form or repeatable prescription to another NHS appliance contractor or to an NHS pharmacist; and

(b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to C.

(2) C must, in appropriate cases, keep and maintain a record of any information given or referral made under sub-paragraph (1) and that record must be in a form that facilitates—

(a) auditing of the provision of pharmaceutical services by C; and

(b) follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Opening hours: general

13.—(1) An NHS appliance contractor (C) must ensure that pharmaceutical services are provided at C's appliance contractor premises—

(a) for not less than 30 hours each week;

(b) for not less than 100 hours per week, in the case of which a 100 hours condition (originally imposed under the 2005 Regulations) applies;

(c) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for fewer than 30 hours per week, provided that the person listed in relation to them provides those services at set times and on set days, at the times and on the days so set;

(d) if a Primary Care Trust, or on appeal the Secretary of State, has (under previous Regulations) directed that pharmaceutical services are to be provided at the premises for more than 30 hours per week, and at set times and on set days, at the times and on the days so set; or

(e) if the NHSCB or a Primary Care Trust, or on appeal the Secretary of State, has directed that pharmaceutical services are to be provided at the premises for more than 30 hours each week, but only on set times and on set days as regards the additional opening hours—

(i) for the total number of hours each week required by virtue of that direction, and

(**28**) Established by S.I. 2007/478.

(ii) as regards the additional opening hours for which the person listed in relation to the premises is required to provide pharmaceutical services by virtue of that direction, at the days on which and times at which that person is required to provide pharmaceutical services during those additional opening hours, as set out in that direction,

but the NHSCB may, in appropriate circumstances, agree a temporary suspension of services for a set period, where it has received 3 months notice of the proposed suspension.

(2) The hours during which appliance contractor premises must be open by virtue of sub-paragraph (1) are referred to in these Regulations as "core opening hours".

(3) C must exhibit a notice specifying the days on which and times at which the appliance contractor premises are open for the provision of appliances.

(4) C must, on request, submit a return to the NHSCB setting out—

(a) the days on which and times at which pharmaceutical services are provided at C's appliance contractor premises (including times at which C is providing pharmaceutical services when C is not obliged to do so by virtue of sub-paragraph (1), which are referred to in these Regulations as "supplementary opening hours"); and

(b) the pharmaceutical services which C ordinarily provides at those premises.

(5) Where C changes—

(a) the supplementary opening hours of C's appliance contractor premises; or

(b) the pharmaceutical services which C is ordinarily to provide at those premises,

C must supply the NHSCB with a return informing it of the change.

(6) Where C has notified to the NHSCB (or, before the appointed day, a Primary Care Trust) the days on which and the times at which pharmaceutical services are to be provided at C's appliance contractor premises (for example, in a return under sub-paragraph (4) or (5) or in an application for inclusion in a pharmaceutical list)—

(a) C must ensure that pharmaceutical services are provided at the premises to which the notification relates on the days and at the time set out in that notification (unless the notification has been superseded by a return, or further return, under sub-paragraph (5)); and

(b) C must not change—

(i) the days on which or the times at which pharmaceutical services are to be provided at those premises during core opening hours that are neither additional opening hours nor in total less than 30 (but if those core opening hours are additional opening hours, or are in total less than 30, regulation 65(5) to (7) and paragraphs 15 and 16 apply,

(ii) the total number of any supplementary opening hours (regulation 65(5) to (7) and paragraphs 15 and 16 apply to changes to the total number of core opening hours),

(iii) the days on which or the times at which pharmaceutical services are to be provided at those premises during supplementary opening hours, or

(iv) the pharmaceutical services which P is ordinarily to provide at those premises,

for a period of at least 3 months after that notification was received by the NHSCB (or, before the appointed day, a Primary Care Trust), unless the NHSCB agrees otherwise.

(7) Subject to sub-paragraph (8), where C is prevented by illness or other reasonable cause from complying with C's obligations under sub-paragraph (1), C must, where practicable, make arrangements with one or more NHS appliance contractors, NHS pharmacists or LPS chemists whose premises are situated in the same area for the provision of pharmaceutical services or local pharmaceutical services during that time.

(8) C may only make an arrangement with an LPS chemist under sub-paragraph (7) where that LPS chemist provides local pharmaceutical services which are of a similar description as, and a similar extent to, the pharmaceutical services which C ordinarily provides.

(9) Where there is a temporary suspension in the provision of pharmaceutical services by C for a reason beyond the control of C, C is not in breach of sub-paragraphs (1) and (6), provided that—

(a) C notifies the NHSCB of that suspension as soon as practical; and

(b) C uses all reasonable endeavours to resume provision of pharmaceutical services as soon as is practicable.

(10) Planned refurbishment of appliance contractor premises is neither a "reasonable cause" for the purposes of sub-paragraph (7) nor a "reason beyond the control of C" for the purposes of sub-paragraph (9).

(11) For the purposes of calculating the number of hours that premises are open during a week that includes Christmas Day, Good Friday, Easter Sunday or a bank holiday, it is to be deemed that the premises were open on that day at the times at which they would ordinarily have been open on that day of the week.

(12) In this Schedule, the "additional opening hours", when they are required, are those hours during which C would not be providing pharmaceutical services, were C subject to the condition set out in sub-paragraph (1)(a) and not the condition set out in sub-paragraph (1)(e).

Matters to be considered when issuing directions in respect of core opening hours

14.—(1) Where the NHSCB issues a direction setting any days or times under this Schedule, it must in doing so seek to ensure that the hours at which premises are open for the provision of pharmaceutical services are such as to ensure that pharmaceutical services are provided on such days and at such times as are necessary to meet the needs of people in its area, or other likely users of the premises, for pharmaceutical services.

(2) In considering the matters mentioned in sub-paragraph (1), the NHSCB—

(a) must treat any local pharmaceutical services being provided in its area at the days and times in question as if they were pharmaceutical services being so provided; and

(b) may have regard to any pharmaceutical services that are being provided in its area in circumstances where the person providing the services is not obliged to provide those services.

(3) The NHSCB may only direct that an NHS appliance contractor (C) may provide pharmaceutical services at appliance contractor premises for less than 30 hours in any week if it is satisfied that the arrangements for the supply of appliances in its area are likely to be adequate to meet the need for such services at times when C is not providing pharmaceutical services.

(4) Except in the case of premises that have (at any time) been subject to a direction under regulation 65 or regulation 65 of the 2012 Regulations (core opening hours conditions), the NHSCB may only direct that C must provide pharmaceutical services at premises for more than 30 hours in any week if it is satisfied that C is to receive reasonable remuneration in respect of the additional opening hours for which C is required to provide pharmaceutical services (and any additional remuneration payable in accordance with a determination made as mentioned in regulation 91(6) in respect of those hours is "reasonable remuneration" for these purposes).

Determination of core opening hours instigated by the NHSCB

15.—(1) Where it appears to the NHSCB, after consultation with or having considered the matter at the request of the Local Pharmaceutical Committee for the area in which the premises are situated,

that the days on which or times at which appliance contractor premises are or are to be open for the provision of pharmaceutical services will not, or no longer, meet the needs of—

(a) people in its area; or

(b) other likely users of the appliance contractor premises,

for the pharmaceutical services available at or from those premises, it must carry out an assessment as to whether to issue a direction requiring the NHS appliance contractor (C) to provide pharmaceutical services at the premises at set times and on set days (which may include Christmas Day, Good Friday and bank holidays).

(2) Before concluding the assessment under sub-paragraph (1) the NHSCB must—

(a) give notice to C of any proposed changes to the days on which or times at which the appliance contractor premises are to be open; and

(b) allow C 30 days within which to make written representations to the NHSCB about the proposed changes.

(3) After considering any representations made in accordance with sub-paragraph (2)(b), the NHSCB must—

(a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (4) and (5);

(b) confirm any existing direction in respect of the times at which C must provide pharmaceutical services at the appliance contractor premises, provided that the existing direction (whether issued under regulation 65, this Schedule, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (4) and (5);

(c) either—

(i) revoke (without replacing it) any existing direction in respect of the times at which C must provide pharmaceutical services at the premises (whether issued under regulation 65, this Schedule, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of whichever of paragraph 13(1)(a) or (b) applies, the appliance contractor premises will need to be open for not less than 30 hours each week or not less than 100 hours each week.

(4) Where the NHSCB issues a direction under sub-paragraph (3) in respect of appliance contractor premises that are to be required to be open—

(a) for more than 30 hours each week, it must set out in that direction—

(i) the total number of hours each week for which C must provide pharmaceutical services at the premises, and

(ii) as regards the additional opening hours for which C is to provide pharmaceutical services, the days on which and the times at which C is required to provide those services during those additional opening hours,

but it must not set out in that direction the days on which or times at which C is to provide pharmaceutical services during hours which are not additional opening hours; or

(b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(5) The NHSCB must not issue a direction under sub-paragraph (3) that has the effect simply of requiring premises to be open for 30 hours each week on set days and at set times (that is, the

direction must have the effect of requiring premises to be open for either more or less than 30 hours each week).

(6) The NHSCB must notify C in writing of any direction issued or any other action taken under sub-paragraph (3), and where it sets new days on which or times at which the NHS appliance contractor is to provide pharmaceutical services at the premises, it must include with the notification a statement of—

(a) the reasons for the change; and

(b) C's right of appeal under paragraph (7).

(7) C may, within 30 days of receiving notification under sub-paragraph (6), appeal in writing to the Secretary of State against any direction issued or any other action taken under sub-paragraph (3) which sets new days on which or times at which C is to provide pharmaceutical services.

(8) The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under paragraph (3).

(9) The Secretary of State must notify C of the determination and must in every case include with the notification a statement of the reasons for the determination.

(10) If the days on which or times at which C is to provide pharmaceutical services at appliance contractor premises have been changed in accordance with this paragraph, C must introduce the changes—

(a) if C has not appealed under sub-paragraph (7), not later than 8 weeks after the date on which C receives notification under sub-paragraph (6); or

(b) if C has appealed under sub-paragraph (7), not later than 8 weeks after the date on which C receives notification under sub-paragraph (9).

(11) This paragraph does not apply where regulation 65(5) to (7) applies.

Determination of core opening hours instigated by the NHS appliance contractor

16.—(1) An NHS appliance contractor (C) may apply to the NHSCB for it to change the days on which or times at which C is obliged to provide pharmaceutical services at C's premises, in a way that—

(a) reduces the total number of hours for which C is obliged to provide pharmaceutical services each week (but not any of those required under a 100 hours condition); or

(b) keeps that total number of hours the same.

(2) Where C makes an application under sub-paragraph (1), as part of that application C must provide the NHSCB with such information as the NHSCB may reasonably request in respect of any changes to the needs of the people in its area, or other likely users of the premises, for pharmaceutical services that are material to the application.

(3) The NHSCB must determine an application under sub-paragraph (1) within 60 days of receiving it (including any information required of C in accordance with sub-paragraph (2)).

(4) In determining the application, the NHSCB must—

(a) issue a direction (which replaces any existing direction) which meets the requirements of sub-paragraphs (5) and (6) and which has the effect of either granting the application under this paragraph or granting it only in part;

(b) confirm any existing direction in respect of the times at which C must provide pharmaceutical services at the premises, provided that the existing direction (whether issued under regulation 65, this Schedule, the 2005 Regulations or the 1992 Regulations) would meet the requirements of sub-paragraphs (5) and (6); or

(c) either—

(i) revoke (without replacing it) any existing direction in respect of the times at which C must provide pharmaceutical services at the premises (whether issued under regulation 65, this Schedule, the 2012 Regulations, the 2005 Regulations or the 1992 Regulations), where this has the effect of granting the application under this paragraph or granting it only in part, or

(ii) in a case where there is no existing direction, issue no direction,

in which case, by virtue of whichever of paragraph 13(1)(a) or (b) applies, the appliance contractor premises will need to be open for not less than 30 hours each week or not less than 100 hours each week.

(5) Where the NHSCB issues a direction under sub-paragraph (4) in respect of appliance contractor premises that are to be required to be open—

(a) for more than 30 hours each week, it must set out in that direction—

(i) the total number of hours each week for which C must provide pharmaceutical services at the premises, and

(ii) as regards the additional opening hours for which C is to provide pharmaceutical services, the days on which and the times at which C is required to provide those services during those additional opening hours,

but it must not set out in that direction the days on which or times at which C is to provide pharmaceutical services during hours which are not additional opening hours; or

(b) for less than 30 hours each week, it must set out in that direction the days on which and times at which pharmaceutical services are to be provided at those premises.

(6) The NHSCB must not issue a direction under sub-paragraph (4) that has the effect simply of requiring appliance contractor premises to be open for 30 hours each week on set days and at set times (that is, the direction must have the effect of requiring appliance contractor premises to be open for either more or less than 30 hours each week).

(7) Where the NHSCB is considering taking action under sub-paragraph (4)(a) or (c)(i), it must consult the Local Pharmaceutical Committee for the area where the premises are situated before determining the application.

(8) The NHSCB must notify C of any direction issued or any other action taken under sub-paragraph (4), and where this has the effect of refusing an application under this paragraph or granting it in part, it must send C a statement setting out—

(a) the reasons for the refusal or, as the case may be, for granting the application only in part; and

(b) C's right of appeal under sub-paragraph (9).

(9) C may, within 30 days of receiving a notification pursuant to sub-paragraph (8), appeal in writing to the Secretary of State against any action under sub-paragraph (4) which has the effect of refusing an application under this paragraph or granting it only in part.

(10) The Secretary of State may, when determining an appeal, either confirm the action taken by the NHSCB or take any action that the NHSCB could have taken under sub-paragraph (4).

(11) The Secretary of State must notify C of the determination and must in every case include with the notification a statement of the reasons for the determination.

(12) If the days on which or times at which C is to provide pharmaceutical services at appliance contractor premises have been changed in accordance with this paragraph, C must introduce the changes—

(a) if C has not appealed under sub-paragraph (9), not earlier than 30 days after the date on which C receives notification under sub-paragraph (4); or

(b) if C has appealed under sub-paragraph (9), not earlier than 30 days after the date on which C receives notification under sub-paragraph (11).

(13) This paragraph does not apply where regulation 65(5) to (7) applies.

Temporary open hours and closures during an emergency requiring the flexible provision of pharmaceutical services

17.—(1) Notwithstanding the provisions of paragraphs 13 to 16, during an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may, on application from an NHS appliance contractor (C), permit C a temporary change to the days on which or times at which C is obliged to provide pharmaceutical services at appliance contractor premises, or permit temporary closure of those premises, if—

(a) C gives at least 24 hours notice of the change or closure; and

(b) the reasons given by C for the request are, in the opinion of the NHSCB, adequate reasons.

(2) The NHSCB need not approve the request in advance of the change or closure, but if it does not do so and decides subsequently that C's reasons are not, in its opinion, adequate reasons, then the days on which or times at which C is obliged to provide pharmaceutical services at the premises are to revert to the overridden days and times, from the day after the date on which that decision is given to C.

Clinical governance

18.—(1) An NHS appliance contractor (C) must, in connection with the pharmaceutical services provided by C, participate, in the manner reasonably required by the NHSCB, in an acceptable system of clinical governance.

(2) For these purposes a system of clinical governance is "acceptable" if it is considered acceptable by the NHSCB and comprises the following components—

(a) a patient and public involvement programme, which includes—

(i) a requirement that C produces in an approved manner a practice leaflet containing approved particulars in respect of each of the premises from which the supplier provides pharmaceutical services,

(ii) a requirement that C publicises the NHS services that are available at or from C's appliance contractor premises,

(iii) a requirement that C undertakes an approved patient satisfaction survey annually, in an approved manner,

(iv) C's monitoring arrangements in respect of appliances owed to patients but which are out of stock,

(v) an approved complaints system (which meets the requirements of paragraph 24),

(vi) a requirement that C co-operates appropriately with visits by an authorised representative of any relevant Local Healthwatch organisation and takes appropriate action following the outcome of such visits,

(vii) a requirement that C co-operates appropriately with any reasonable inspection or review that the NHSCB or any relevant statutory authority wishes to undertake, and

(viii) C's monitoring arrangements in respect of C's compliance with the Equality Act 2010(**29**);

(b) a clinical audit programme (normally of 5 days) twice in each financial year;

(**29**) 2010 c. 15.

(c) a risk management programme, which includes—

(i) arrangements for ensuring that all stock is procured and handled in an appropriate way,

(ii) arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,

(iii) an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,

(iv) appropriate standard operating procedures, including standard operating procedures in respect of dispensing appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families,

(v) appropriate waste disposal arrangements for clinical and confidential waste,

(vi) identifying a clinical governance lead person in respect of each of C's appliance contractor premises,

(vii) C's monitoring arrangements of C's compliance with the Health and Safety at Work etc. Act 1974(**30**);

(d) a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by C—

(i) in respect of the provision of appliances in accordance with a prescription form or repeatable prescription, or

(ii) to people caring for themselves or their families,

and arrangements for ensuring that C, when giving advice to any patient on a matter mentioned in paragraph (d)(i), has regard to the details contained in the records maintained under paragraph 9(1)(f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;

(e) a staffing and staff management programme, which includes—

(i) arrangements for appropriate induction for staff (including locums),

(ii) appropriate training for all staff in respect of any role they are asked to perform,

(iii) arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,

(iv) arrangements for identifying and supporting the development needs of all staff engaged in the provision of NHS services, including continuing professional development for registered pharmacists, registered nurses and registered pharmacy technicians and any necessary accreditation in respect of the provision of directed services, and

(v) arrangements for addressing poor performance (in conjunction with the NHSCB as appropriate); and

(f) an information governance programme, which provides for—

(i) compliance with approved procedures for information management and security, and

(ii) submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the NHSCB to access that assessment.

(3) For the purposes of sub-paragraph (2), "approved" means approved by the NHSCB.

(**30**) 1974 c. 37.

Professional Standards

19. An NHS appliance contractor must provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements etc.

20.—(1) An NHS appliance contractor (C) (including C's staff) must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of the business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

(a) presenting an order for appliances on a prescription form or repeatable prescription; or

(b) nominating C as X's dispensing contractor (or one of them) in X's PDS patient details.

(2) Promising, offering or providing a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

(3) C (including C's staff) must not accept or receive any gift or reward in respect of only—

(a) providing contact details of alternative NHS pharmacists or NHS appliance contractors pursuant to paragraph 9(2)(b), 11(4) or 12(1)(b); or

(b) referring a prescription form or repeatable prescription to another NHS appliance contractor or NHS pharmacist pursuant to paragraph 9(2)(a) or 12(1)(a) and providing no additional service in connection with the item on that prescription.

Duty to provide information about fitness matters as they arise

21.—(1) An NHS appliance contractor (C) and, where C is a body corporate every director of C must, within 7 days of its occurrence, inform the NHSCB in writing if they—

(a) are convicted of any criminal offence in the United Kingdom;

(b) are bound over following a criminal conviction in the United Kingdom;

(c) accept a police caution in the United Kingdom;

(d) have, in summary proceedings in Scotland in respect of an offence, been the subject of an order discharging them absolutely (without proceeding to conviction);

(e) have accepted and agreed to pay either a procurator fiscal fine under section 302 of the Criminal Procedure (Scotland) Act 1995(**31**) (fixed penalty: conditional offer by procurator fiscal) or a penalty under section 115A of the Social Security Administration Act 1992(**32**) (penalty as alternative to prosecution);

(f) have been convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;

(g) are charged in the United Kingdom with a criminal offence, or are charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;

(**31**) 1995 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).

(**32**) 1992 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.

(h) are notified by any licensing, regulatory or other body of the outcome of any investigation into their professional conduct, and there is a finding against them;

(i) become the subject of any investigation into their professional conduct by any licensing, regulatory or other body;

(j) become subject to an investigation into their professional conduct in respect of any current or previous employment, or are notified of the outcome of any such investigation and any finding against them;

(k) become the subject of any investigation by NHS BSA in relation to fraud;

(l) become the subject of any investigation by another primary care organisation, which might lead to their removal from a relevant list; or

(m) are removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and must give details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(2) If a person to whom paragraph (1) applies (X) is, or was at the time of the originating events, a director of a body corporate, X must in addition inform the NHSCB within 7 days if any such body corporate—

(a) is convicted of any criminal offence in the United Kingdom;

(b) is convicted of an offence elsewhere than in the United Kingdom where the originating events, if they took place in England, could lead to a criminal conviction in England;

(c) is charged in the United Kingdom with a criminal offence, or is charged elsewhere than in the United Kingdom with an offence where the originating events, if they took place in England, could lead to a criminal conviction in England;

(d) is notified by any licensing, regulatory or other body of the outcome of any investigation into its provision of professional services, and there is a finding against the body corporate;

(e) becomes the subject of any investigation into its provision of professional services by any licensing, regulatory or other body;

(f) becomes the subject of any investigation by the NHS BSA in relation to any fraud or is notified of the outcome of such an investigation where it is adverse;

(g) becomes the subject of any investigation by another primary care organisation which might lead to its removal from any relevant list; or

(h) is removed, contingently removed or suspended from, refused inclusion in or conditionally included in any relevant list for a reason relating to unsuitability, fraud or efficiency of service provision,

and X must give the name and registered office of the body corporate and details of any investigation or proceedings which were or are to be brought, including the nature of the investigation or proceedings, where and approximately when that investigation or those proceedings took place or are to take place, and any outcome.

(3) C or X must consent to a request being made by the NHSCB to any employer or former employer or licensing or regulatory body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Other information to be supplied

22.—(1) An NHS appliance contractor (C) must give notice to the NHSCB within 30 days (or if this is impracticable, as soon as practicable thereafter) of—

(a) any occurrence requiring a change in the information recorded about C in the pharmaceutical list which C has not otherwise notified to the NHSCB in accordance with these Regulations;

(b) if C is an individual, any change of C's private address;

(c) if C is a body corporate, any change to the name, registered number, registered office, telephone number relating to that office of the body corporate; and

(d) any occurrence requiring C's addition to or removal from the EPS list or a change in the information recorded about C in that list.

(2) C must give the NHSCB, if it so requests, the name of any pharmacist employed or engaged by C who is responsible for dispensing a particular prescription.

(3) If C is a body corporate, it must give notice to the NHSCB within 30 days (or if this in impracticable, as soon as practicable thereafter) of any changes to the names and addresses of each of its directors.

(4) If C is a body corporate and appoints a director who was not listed on C's application for inclusion on a pharmaceutical list, C must, within 30 days of the person's appointment, supply to the NHSCB the information mentioned in paragraphs 3 and 4 of Schedule 2 about that person.

(5) If C or a director of C (if C is a body corporate) is on, or is a director of a body corporate which is on, a relevant list other than a pharmaceutical list held by the NHSCB, they must supply in writing to the NHSCB—

(a) in the case of a director of a body corporate, the name and registered office of the body corporate on the other relevant list; and

(b) particulars of the other relevant list.

(6) C or a director C (if C is a body corporate) must inform the NHSCB if they, or a body corporate of which they are a director, apply to be included in a relevant list other than a pharmaceutical list held by the NHSCB, and of the outcome of any such application.

Co-operation with Health Education England

23. An NHS appliance contractor must co-operate with Health Education England in the discharge by Health Education England of the duty under section 1F(1) of the 2006 Act(**33**) (duty as to education and training).

Complaints

24.—(1) An NHS appliance contractor must have in place arrangements, which comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(**34**), for the handling and consideration of any complaints.

(2) In this paragraph, "complaint" means a complaint about a matter connected with the provision of pharmaceutical services by the NHS appliance contractor.

(**33**) Section 1F was inserted by the Health and Social Care Act 2012 (c. 7), section 7.
(**34**) S.I. 2009/309; amended by S.I. 2009/1768.

Inspections and access to information

25.—(1) An NHS appliance contractor (C) must allow persons authorised in writing by the NHSCB to enter and inspect any premises C uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

(a) ascertaining whether or not C is complying with the requirements of this Schedule;

(b) auditing, monitoring and analysing—

(i) the provision made by C, in the course of providing pharmaceutical services, for patient care and treatment, including any arrangement made with a person in respect of provision of appliances, and

(ii) the management by C of the pharmaceutical services C provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

(a) reasonable notice of the intended entry has been given;

(b) the Local Pharmaceutical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by C;

(c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and

(d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) C must, at the request of the NHSCB or of X, allow it or X access to any information which it or X reasonably requires—

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

SCHEDULE 6

Regulation 47(1)(a)(i)

Terms of service of dispensing doctors

Persons duly authorised to dispense on behalf of dispensing doctors

1.—(1) Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which the dispensing doctor has duly authorised another person to undertake, if that other person undertakes that activity instead of the dispensing doctor—

(a) that other person must comply with that requirement; and

(b) the dispensing doctor must secure compliance with that requirement by that other person.

(2) Where reference is made in this Schedule to a dispensing doctor—

(a) being the subject of an activity, and in fact a person duly authorised by the dispensing doctor is the subject of that activity; or

(b) forming a view, and in fact a person duly authorised by the dispensing doctor is to form that view,

that reference is to be construed as referring, as appropriate, to that duly authorised person.

(3) References in this Schedule to a dispensing doctor are to be construed in accordance with sub-paragraphs (1) and (2).

Dispensing of drugs and appliances ordered by another prescriber

2.—(1) In this paragraph, "signed" includes signature with a prescriber's advanced electronic signature.

(2) Subject to the following provisions of this Schedule, where—

(a) any person presents to a dispensing doctor (D) a non-electronic prescription form which contains—

(i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber other than D,

(ii) an order for drugs specified in Schedule 2 to the Prescription of Drugs Regulations(**35**) (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber other than D, and including the reference "SLS", or

(iii) an order for restricted availability appliances, signed by a prescriber other than D and including the reference "SLS"; or

(b) subject to sub-paragraph (4), D receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii) and—

(i) any person requests the provision of drugs or appliances in accordance with that prescription, or

(ii) D has previously arranged with the patient that D will dispense that prescription on receipt,

and D is authorised or required by virtue of Part 8 to provide the drugs or appliances so ordered, D must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as D supplies in the normal course of business.

(3) Subject to the following provisions of this Schedule, where—

(a) any person presents to D a non-electronic repeatable prescription which contains—

(i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(**36**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**37**) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber other than D,

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than D and including the reference "SLS",

(iii) an order for appliances, not being restricted availability appliances, signed by a prescriber other than D, or

(iv) an order for a restricted availability appliance, signed by a prescriber other than D, and including the reference "SLS",

and also presents an associated batch issue; or

(**35**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.
(**36**) 1971 c.38; *see* section 2(1)(a) of that Act, which defines "controlled drug" for the purposes of that Act.
(**37**) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

(b) D receives an electronic repeatable prescription from the Electronic Prescription Service which contains an order of a kind specified in paragraph (a)(i) to (iv) and—

(i) any person requests the provision of drugs or appliances in accordance with that repeatable prescription, or

(ii) D has previously arranged with the patient that D will dispense that repeatable prescription on receipt,

and D is authorised or required by virtue of Part 8 to provide the drugs or appliances so ordered, D must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as D supplies in the normal course of business.

(4) D must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001.

(5) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances shall be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

(a) D has that prescription in D's possession; and

(b) that person presents, or D has in D's possession, an associated batch issue.

(6) Drugs and appliances provided under this paragraph must be provided in a suitable container.

Dispensing of drugs and appliances ordered by the dispensing doctor

3. In circumstances where paragraph 2 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor (D) is authorised or required by virtue of Part 8 to provide a drug or appliance to a person—

(a) D must record any order for the provision of any drugs or appliances which are needed for the treatment of the patient, before the drugs or appliances are dispensed (unless it is personally administered)—

(i) on a prescription form completed in accordance with the term of the contract under which primary medical services are provided to the patient which gives effect to paragraph 39 of Schedule 6 to the GMS Regulations(**38**) (other contractual terms – prescribing) or an equivalent provision applying in relation to that contract,

(ii) if paragraph 39A of Schedule 6 to the GMS Regulations(**39**) (other contractual terms – electronic prescriptions) or an equivalent provision applies in relation to the contract under which primary medical services are provided to the patient, on an electronic prescription form, or

(iii) in the case of a personally administered vaccine in respect of which the NHS BSA does not require an individual prescription form in order to process payment, on the form provided by the NHS BSA for the purposes of claiming payments for administering that vaccine (as well, potentially, as claiming other payments), and in the manner required by the NHS BSA (which may be as part of an aggregate total);

(b) D must provide those drugs or appliances in a suitable container (unless it is personally administered);

(c) D must provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations(**40**) (drugs, medicines and other substances that may be ordered only in certain circumstances) only where the conditions in paragraph 42(2) of Schedule 6 to the

(**38**) Paragraph 39 has been amended by S.I. 2005/893, 2007/3491 and 2009/2230.
(**39**) Paragraph 39A was inserted by S.I. 2005/893 and has been amended by S.I. 2007/3491.
(**40**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.

GMS Regulations(**41**) (other contractual terms – a restrictions on prescribing by medical practitioners) are satisfied; and

(d) D must provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

Preliminary matters before providing ordered drugs or appliances

4. Before providing any drugs or appliances in accordance with paragraph 3, or in the circumstances set out in paragraph 5—

(a) a dispensing doctor (D) must ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations(**42**) (supply of drugs and appliances by doctors) by virtue of either—

(i) entitlement to exemption under regulation 7(1) of the Charges Regulations(**43**) (exemptions), or

(ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations(**44**) (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of regulation 7 of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 5 of the Remission of Charges Regulations, and at the time of the declaration D has such evidence available to D;

(b) if, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (a), is produced to D, D must endorse the form on which the declaration is made to that effect; and

(c) in the case of an electronic prescription, D must transmit to the Electronic Prescription Service—

(i) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—

(aa) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which it is claimed applies to the case, and

(bb) whether or not satisfactory evidence was produced to D as required by sub-paragraph (a),

(ii) in any case where a charge is due, confirmation that the relevant charge was paid, and

(iii) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Provision of Scheduled drugs

5.—(1) A dispensing doctor (D) must only provide for a patient any Scheduled drug if—

(a) it is ordered as specified in sub-paragraph (2) or (4); or

(b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations(**45**) (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.

(**41**) Paragraph 42 has been amended by S.I. 2005/893 and 2009/2230.
(**42**) Regulation 4 has been amended by S.I. 2000/2393, 2001/2887, 2002/548 and 2352, 2005/578, 2008/571, 2009/411, 2010/1727 and 2011/518.
(**43**) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.
(**44**) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.
(**45**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.

(2) A Scheduled drug that is a drug with an appropriate non-proprietary name may be provided in response to an order on a prescription form or repeatable prescription for a drug ("the prescribed drug") that is not a Scheduled drug but which has the same non-proprietary name as the Scheduled drug if—

(a) the prescribed drug is ordered by that non-proprietary name or by its formula; and

(b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically).

(3) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (2) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.

(4) Nothing in this Schedule prevents D providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

Refusal to provide drugs or appliances ordered

6.—(1) A dispensing doctor (D) may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

(a) D reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because D reasonably believes it has been stolen or forged);

(b) it appears to D that there is an error on the prescription form or on the repeatable prescription or, in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber) or that, in the circumstances, providing the drugs or appliances would be contrary to D's clinical judgement; or

(c) where the prescription form or repeatable prescription is incomplete because it does not include the information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—

(i) the remuneration of persons providing pharmaceutical services, and

(ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless D (or the person who employs or engages D) is to receive no pharmaceutical remuneration of any kind in respect of the drug or appliance.

(2) D must refuse to provide drugs or appliances ordered on a repeatable prescription where—

(a) D has no record of that prescription;

(b) D does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to D;

(c) it is not signed by a prescriber;

(d) to do so would not be in accordance with any intervals specified in the prescription;

(e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously;

(f) if the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;

(g) the expiry date on the repeatable prescription has passed; or

(h) D has been informed by the prescriber that the prescription is no longer required.

(3) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), D must only provide the drugs or appliances ordered if D is satisfied—

(a) that the patient to whom the prescription relates—

(i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and

(ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;

(b) that the medication regimen of the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and

(c) there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Dispensing doctors issuing prescription forms which may be presented to an NHS chemist

7. Notwithstanding the existence of arrangements under which a dispensing doctor (D) is to provide pharmaceutical services to a patient (P), if D determines that P requires a drug or appliance that is available on prescription from an NHS chemist—

(a) D may with the agreement of P issue; or

(b) if P so requests, D must not unreasonably refrain from issuing,

a prescription form that P may present to any NHS chemist instead of D supplying that drug or appliance to P.

Complaints procedures

8. Where a dispensing doctor is a provider of primary medical services, or is employed or engaged by such a provider, the complaints procedure established by—

(a) the provider or practice; or

(b) the provider or practice that employs or engages the dispensing doctor,

to deal with complaints in relation to the provision of primary medical services is also to apply in relation to a complaint about any matter reasonably connected with the provision of pharmaceutical services by that provider, practice or individual.

Inspections and access to information

9.—(1) A dispensing doctor (D) must allow persons authorised in writing by the NHSCB to enter and inspect any premises D uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

(a) ascertaining whether or not D is complying with the requirements of this Schedule;

(b) auditing, monitoring and analysing—

(i) the provision made by D, in the course of providing pharmaceutical services, for patient care and treatment, and

(ii) the management by D of the pharmaceutical services D provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

(a) reasonable notice of the intended entry has been given;

(b) the Local Medical Committee for the area where the premises are situated have been invited to be present at the inspection, where this is requested by D;

(c) the person authorised in writing (X) carries written evidence of X's authorisation, which X produces on request; and

(d) X does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) D must, at the request of the NHSCB or of X, allow it or X access to any information which it or X reasonably requires—

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the NHSCB, in connection with its functions that relate to pharmaceutical services.

Voluntary closure of premises

10.—(1) Where a dispensing doctor (D) wishes—

(a) to withdraw from a dispensing doctor list, or

(b) except in the circumstances described in paragraph (2), for particular listed dispensing premises no longer to be listed in relation to D,

D must notify the NHSCB of D's wish at least 3 months in advance of the date on which pharmaceutical services are no longer to be provided, unless it is impracticable for D to do so, in which case D must notify the NHSCB as soon as it is practicable for D to do so.

(2) If particular listed dispensing premises no longer need to be listed in relation to D as a consequence of a relocation application under regulation 55, before the date on which D commences the provision of pharmaceutical services at the new premises, D must give notice to the NHSCB of when, before that date, D is to cease to provide pharmaceutical services at the existing premises.

SCHEDULE 7

Regulation 102(3)

Mandatory terms for LPS schemes

General provisions

1.—(1) The LPS contractor must comply with all relevant legislation, including—

(a) the relevant provisions of Part 13 of these Regulations; and

(b) relevant provisions that are—

(i) included in regulations under section 225 of the 2007 Act(**46**) (duties of services-providers to allow entry by Local Healthwatch organisations or contractors), and

(ii) made for the purpose of imposing on a services-provider (within the meaning of that section) a duty to allow authorised representatives (within the meaning of that section) to enter and view, and observe the carrying-on of activities on, premises owned or controlled by the services-provider.

(2) The LPS contractor must comply with the relevant provisions of the Drug Tariff.

(3) The LPS contractor must have regard to all relevant guidance issued by—

(**46**) Section 225 has been amended by the Health and Social Care Act 2012 (c. 7), section 186(6) to (10), Schedule 14, paragraphs 103 and 106, and Schedule 5, paragraphs 148 and 151.

(a) the NHSCB; or

(b) the Secretary of State.

(4) To the extent that the provisions of the terms required by this Schedule impose a requirement on the LPS contractor (C) in respect of an activity which could only, or would normally, be undertaken by a natural person—

(a) if C is a registered pharmacist—

(i) C must comply with the requirement, or

(ii) if C employs or engages a registered pharmacist in connection with the provision of local pharmaceutical services under C's LPS scheme, C must either comply with that requirement or secure compliance with that requirement by the registered pharmacist C employs or engages; or

(b) if C is not a natural person, C must secure compliance with that requirement by the registered pharmacists C employs or engages, and references in this Schedule to an LPS contractor are to be construed accordingly.

Restrictions in an LPS scheme on supply

2.—(1) Where an LPS scheme is limited to the provision of specified drugs or appliances, the LPS contractor must not provide other drugs or appliances at or from the scheme premises.

(2) An LPS scheme must contain the following terms, where applicable—

(a) where the local pharmaceutical services to be provided include the supply of appliances—

(i) the only appliances which may be supplied are appliances listed in Parts IXA, IXB, IXC or X of the Drug Tariff, and

(ii) those appliances must be supplied in accordance with the provisions of the Notes, and the List of Technical Specifications, which appear at the beginning of Part IX of the Drug Tariff, which apply at the time of supply; and

(b) where the local pharmaceutical services to be provided include the supply of chemical reagents, the only chemical reagents which may be supplied are those listed from time to time in Part IXR of the Drug Tariff.

(3) Where an LPS scheme is limited to the provision of services—

(a) to a specified class of persons (for example persons who require the provision of local pharmaceutical services for the treatment of a specified disease or condition); or

(b) to persons residing in a particular place (for example persons in a specified residential home),

the LPS contractor must not provide local pharmaceutical services to persons other than those so specified.

Dispensing

3.—(1) Subject to any provisions of an LPS scheme included pursuant to paragraph 2 and the following provisions of this Schedule, where—

(a) any person presents to the LPS contractor (C) a non-electronic prescription form which contains—

(i) an order for a drug, not being a Scheduled drug, or for an appliance, not being a restricted availability appliance, signed by a prescriber,

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations(**47**) (drugs, medicines and other substances that may be ordered only in certain circumstances), signed by a prescriber and including the reference "SLS", or

(iii) an order for a restricted availability appliance, signed by a prescriber and including the reference "SLS"; or

(b) C receives from the Electronic Prescription Service an electronic prescription form which contains an order of a kind specified in paragraph (a)(i) to (iii), and—

(i) any person requests the provision of a drug in accordance with that prescription, or

(ii) C has previously arranged with the patient that it will dispense that prescription on receipt,

C must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as C supplies in the normal course of business.

(2) Where an LPS scheme includes the provision of repeat dispensing services, subject to any provisions of the LPS scheme included pursuant to paragraph 2 and the following provisions of this Schedule, where—

(a) any person presents to C a non-electronic repeatable prescription which contains—

(i) an order for a drug, not being a Scheduled drug or a controlled drug within the meaning of the Misuse of Drugs Act 1971(**48**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(**49**) (which relate to controlled drugs excepted from certain prohibitions under the Regulations), signed by a prescriber,

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber and including the reference "SLS",

(iii) an order for an appliance, not being a restricted availability appliance, signed by a prescriber, or

(iv) an order for a restricted availability appliance, signed by a prescriber, and including the reference "SLS",

and also presents an associated batch issue; or

(b) C receives from the Electronic Prescription Service an electronic repeatable prescription which contains an order of a kind specified in sub-paragraph (a)(i) to (iv) and—

(i) any person requests the provision of a drug or an appliance in accordance with that repeatable prescription, or

(ii) C has previously arranged with the patient that it will dispense that repeatable prescription on receipt,

C must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as C supplies in the normal course of business.

(3) C must not provide under an electronic prescription form a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001.

(**47**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.
(**48**) 1971 c.38; *see* section 2(1)(a) of that Act, which defines "controlled drug" for the purposes of that Act.
(**49**) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136 and 2012/973, and Schedule 5 has been amended by S.I. 2005/2864.

(4) For the purposes of this paragraph, a non-electronic repeatable prescription for drugs or appliances must be taken to be presented even if the person who wishes to obtain the drug or appliance does not present that prescription, where—

(a) C has that prescription in C's possession; and

(b) that person presents, or C has in C's possession, an associated batch issue.

Urgent supply without a prescription

4. Where, in case of urgency, a prescriber personally known to the LPS contractor (C) requests C to provide a drug, C may provide that drug (where it would otherwise be able to provide that drug in accordance with the LPS scheme) before receiving a prescription form or repeatable prescription, provided that—

(a) the drug is not a Scheduled drug;

(b) the drug is not a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001 (which relate to controlled drugs excepted from certain prohibitions under the Regulations); and

(c) the prescriber undertakes to—

(i) give C a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug within 72 hours of the request being made, or

(ii) transmit to the Electronic Prescription Service within 72 hours of the request being made an electronic prescription.

Preliminary matters before providing ordered drugs or appliances

5.—(1) If a person specified in paragraph (2) asks the LPS contractor (C) to do so—

(a) C must give an estimate of the time when the drugs or appliances will be ready; and

(b) if they are not ready by then, C must give a revised estimate of the time when they will be ready (until they are ready).

(2) A person specified in paragraph (1) is a person—

(a) presenting a non-electronic prescription form or non-electronic repeatable prescription; or

(b) requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription.

(3) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription, C must ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3 (1) or (1A) of the Charges Regulations(**50**) (supply of drugs and appliances by chemists) by virtue of either—

(a) entitlement to exemption under regulation 7(1) of the Charges Regulations(**51**) (exemptions); or

(b) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations(**52**) (entitlement to full remission and payment),

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1)

(**50**) Regulation 3 has been amended by S.I. 2002/2352, 2003/1084, 2004/865, 2005/578, 2008/571, 2009/411, 2010/1727, 2011/518 and 2012/470.
(**51**) Regulation 7 has been amended by S.I. 2000/3189, 2002/2352, 2004/696, 2005/578 and 2009/29.
(**52**) Regulation 5 has been amended by S.I. 2004/663 and 936, 2006/562, 2008/1697 and 2009/411.

of the Charges Regulations or in respect of entitlement to remission by virtue of regulation (5)(1)(e) or (2) of the Remission of Charges Regulations, and at the time of the declaration C already has such evidence available to C.

(4) If, in the case of a non-electronic prescription form or non-electronic repeatable prescription, no satisfactory evidence, as required by sub-paragraph (3), is produced, C must endorse the form on which the declaration is made to that effect.

(5) In the case of an electronic prescription, C must transmit to the Electronic Prescription Service—

(a) in a case where exemption from or remission of charges is claimed for all or some of the items included in the prescription, a record of—

(i) the exemption category specified in regulation 7(1) of the Charges Regulations or the ground for remission under regulation 5 of the Remission of Charges Regulations which is claimed applies to the case, and

(ii) whether or not satisfactory evidence was produced to C as required by sub-paragraph (3);

(b) in any case where a charge is due, confirmation that the relevant charge was paid; and

(c) in a case of a prescription for or including contraceptive substances, confirmation that no charge was payable in respect of those substances.

Providing ordered drugs or appliances

6.—(1) Where the LPS contractor (C) is presented with, or receives from the Electronic Prescription Service, a prescription form or a repeatable prescription, C must only provide the drugs or appliances so ordered—

(a) if the prescription form or repeatable prescription is duly signed and completed as described in paragraph 3(1) or (2); and

(b) in accordance with the order on the prescription form or repeatable prescription,

subject to any regulations in force under the Weights and Measures Act 1985(**53**) and the following provisions of this Schedule.

(2) If the order is for an appliance of a type requiring measuring and fitting by C (for example a truss), C shall make all necessary arrangements for—

(a) measuring the person named on the prescription form or repeatable prescription for the appliance; and

(b) fitting the appliance.

(3) If the order is for a drug or appliance included in the Drug Tariff, the British National Formulary (including any Appendix published as part of that Formulary), the Dental Practitioner's Formulary, the European Pharmacopoeia or the British Pharmaceutical Codex, the drug or appliance provided must comply with the relevant standard or formula specified therein.

(4) If the order—

(a) is an order for a drug; but

(b) is not an order for a controlled drug within the meaning of the Misuse of Drugs Act 1971(**54**), other than a drug which is for the time being specified in Schedule 4 or 5 of the

(**53**) 1985 c. 72.
(**54**) 1971 c.38; *see* section 2(1)(a) of that Act, which defines "controlled drug" for the purposes of that Act.

Misuse of Drugs Regulations 2001(**55**) (which relate to controlled drugs excepted from certain prohibitions under the Regulations),

and does not prescribe its quality, strength or dosage, C (in practice, a registered pharmacist) may provide the drug in such strength and dosage as in the exercise of C's professional skill, knowledge and care C considers to be appropriate and, subject to sub-paragraph (5), in such quantity as C considers to be appropriate for a course of treatment for a period not exceeding 5 days.

(5) Where an order to which sub-paragraph (4) applies is for—

(a) an oral contraceptive substance;

(b) a drug, which is available for supply as part of local pharmaceutical services only together with one or more other drugs; or

(c) an antibiotic in a liquid form for oral administration in respect of which pharmaceutical considerations require its provision in an unopened package,

which is not available for provision as part of local pharmaceutical services except in such packages that the minimum size available contains a quantity appropriate to a course of treatment for a period of more than 5 days, C may provide the minimum size available package.

(6) Where any drug to which this sub-paragraph applies (that is, a drug that is not one to which the Misuse of Drugs Act 1971 applies, unless it is a drug for the time being specified in Schedule 5 to the Misuse of Drugs Regulations 2001), ordered by a prescriber on a prescription form or repeatable prescription, is available for provision by C in a pack in a quantity which is different to the quantity which has been so ordered, and that drug is—

(a) sterile;

(b) effervescent or hygroscopic;

(c) a liquid preparation for addition to bath water;

(d) a coal tar preparation;

(e) a viscous preparation; or

(f) packed at the time of its manufacture in a special container,

C must provide the drug in the pack whose quantity is nearest to the quantity which has been so ordered.

(7) In this paragraph, "special container" means any container with an integral means of application or from which it is not practicable to dispense an exact quantity.

(8) Subject to sub-paragraph (9), where a drug is ordered by a prescriber on a prescription form or repeatable prescription in a quantity that is, or is a multiple of a quantity that is, readily available in a pack size manufactured for a holder of a marketing authorisation for the drug, C must provide the drug in an original pack (or in original packs) of that size which has been assembled by a manufacturer of the drug for such a holder of a marketing authorisation, unless—

(a) it is not possible for C to obtain such a pack (or packs) with reasonable promptness in the normal course of business; or

(b) it is not practicable for C to provide such a pack (or packs) in response to the order (for example, because of patient needs or the method of administration of the drug).

(9) In the case of oral liquid methadone, C (in practice, a registered pharmacist) must decide whether it would be most appropriate to provide—

(a) each dose in a separate container;

(b) an original pack (or original packs); or

(**55**) S.I. 2001/3998. Schedule 4 has been amended by S.I. 2003/1432, 2005/3372, 2007/2154 and 2009/3136, and Schedule 5 has been amended by S.I. 2005/2864.

(c) the oral liquid methadone in some other way,

and C must then provide it in packaging that accords with that decision.

(10) C must only provide a Scheduled drug in response to an order by name, formula or other description on a prescription form or repeatable prescription if—

(a) it is ordered as specified in sub-paragraph (11); or

(b) in the case of a drug specified in Schedule 2 to the Prescription of Drugs Regulations(**56**) (drugs, medicines and other substances that may be ordered only in certain circumstances), it is ordered in the circumstances prescribed in that Schedule.

(11) A Scheduled drug that is a drug with an appropriate non-proprietary name may be provided in response to an order on a prescription form or repeatable prescription for a drug ("the prescribed drug") that is not a Scheduled drug but which has the same non-proprietary name as the Scheduled drug if—

(a) the prescribed drug is ordered by that non-proprietary name or by its formula;

(b) the prescribed drug has the same specification as the Scheduled drug (so the Scheduled drug may be dispensed generically); and

(c) the Scheduled drug is not in a pack which consists of a drug in more than one strength, and providing it would involve the supply of part only of the pack.

(12) If a Scheduled drug is a combination of more than one drug, it can only be ordered as specified in sub-paragraph (11) if the combination has an appropriate non-proprietary name, whether or not the drugs in the combination each have such names.

(13) C must provide any drug which it is required to provide under paragraph 3 in a suitable container.

Refusal to provide drugs or appliances ordered

7.—(1) The LPS contractor (C) may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

(a) C reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example because C reasonably believes it has been stolen or forged);

(b) it appears to C that—

(i) there is an error on the prescription form or on the repeatable prescription, or in the case of a non-electronic repeatable prescription, its associated batch issue (including a clinical error made by the prescriber), or

(ii) in the circumstances, providing the drugs or appliances would be contrary to the C's (in practice, a registered pharmacist's) clinical judgement;

(c) C or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or by any person accompanying that person;

(d) the person presenting the prescription form or repeatable prescription or requesting the provision of drugs or appliances in accordance with an electronic prescription form or a repeatable prescription, or any person accompanying that person, commits or threatens to commit a criminal offence; or

(**56**) Schedule 2 has been amended by S.I. 2004/3215, 2009/2230, 2010/2389 and 2011/680 and 1043.

(e) the prescription form or repeatable prescription is incomplete because it does not include the information relating to the identification of the prescriber that the NHSCB (or a person exercising its functions) requires in order to perform its functions relating to—

(i) the remuneration of persons providing local pharmaceutical services, and

(ii) any apportionment of, or any arrangements for recharging in respect of, that remuneration,

unless C is to receive no pharmaceutical remuneration of any kind in respect of the drug or appliance.

(2) C must refuse to provide a drug ordered on a prescription form or repeatable prescription where the order is for a prescription only medicine which the prescriber was not entitled to prescribe.

(3) C must refuse to provide drugs or appliances ordered on a repeatable prescription where—

(a) C has no record of that prescription;

(b) C does not, in the case of a non-electronic repeatable prescription, have any associated batch issue and it is not presented to C;

(c) it is not signed by a prescriber;

(d) to do so would not be in accordance with any intervals specified in the prescription;

(e) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed (whether electronically or otherwise) more than 6 months previously;

(f) the repeatable prescription was signed (whether electronically or otherwise) more than one year previously;

(g) the expiry date on the repeatable prescription has passed; or

(h) C has been informed by the prescriber that the prescription is no longer required.

(4) Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that he makes such a request), C must only provide the drugs or appliances ordered if C is satisfied—

(a) that the patient to whom the prescription relates—

(i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and

(ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;

(b) that the medication regimen of the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and

(c) that there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Further activities to be carried out in connection with the provision of dispensing services

8. In connection with the services provided under paragraphs 3 to 7, the LPS contractor (C) must—

(a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them—

(i) to enable them to utilise the drugs or appliances appropriately, and

(ii) to meet the patient's reasonable needs for general information about the drugs or appliances;

(b) provide appropriate advice to patients to whom they provide drugs or appliances on—

(i) the safe keeping of the drugs or appliances, and

(ii) returning unwanted drugs or appliances to the scheme premises for safe destruction;

(c) provide a patient with a written note of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;

(d) keep and maintain records—

(i) of drugs and appliances provided, in order to facilitate the continued care of the patient,

(ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and

(iii) of notes provided under sub-paragraph (c);

(e) if C provides a drug or appliance under an electronic prescription, provide the patient, if the patient so requests, with a written record of the drugs or appliances ordered on that prescription and, in the case of an electronic repeatable prescription, of the number of occasions on which it can be dispensed; and

(f) ensure that where a person is refused drugs or appliances pursuant to paragraph 7(1)(b), (2), (3) or (4), the patient is referred back to the prescriber for further advice.

Additional requirements in relation to electronic prescribing

9.—(1) The LPS contractor (C) must, if requested to do so by any person—

(a) explain to that person the Electronic Prescription Service, whether or not it is a service which is available through C's scheme premises; and

(b) where the Electronic Prescription Service is not available through C's scheme premises, provide that person with contact details of at least two pharmacies in the area through which the service is available, if these details are known to C.

(2) Where the Electronic Prescription Service is available through C's scheme premises, C must, if requested to do so by any person, enter in that person's PDS patient details—

(a) where the person does not have a nominated dispensing contractor, the dispensing contractor chosen by the person; or

(b) where the person does have a nominated dispensing contractor—

(i) a replacement dispensing contractor, or

(ii) a further dispensing contractor,

chosen by that person.

(3) Sub-paragraph (2)(b)(ii) does not apply if the number of nominated dispensing contractors for that person would thereby exceed the maximum number permitted by the Electronic Prescription Service.

(4) If C is a nominated dispensing contractor for a person (X) but the nomination was made before C became the person specified in an LPS scheme in relation to the scheme premises nominated in X's PDS patient details, C must within 6 months of C becoming the person so specified—

(a) explain to X that the ownership of the scheme premises has changed; and

(b) ask X whether X wishes to maintain the nomination in respect of those scheme premises.

Further activities in connection with repeat dispensing

10. In connection with the services provided under paragraphs 3 to 7, the LPS contractor (C) must—

(a) provide appropriate advice to patients to whom C provides drugs or appliances in accordance with a repeatable prescription, in particular on the importance of only requesting those items which they actually need;

(b) undertake appropriate training in respect of repeat dispensing, having regard to any recommendations in respect of such training set out in the Drug Tariff;

(c) if C takes possession of a non-electronic repeatable prescription or an associated batch issue, securely store that repeatable prescription or associated batch issue;

(d) maintain records of repeatable prescriptions in such a form as to provide a clear audit trail of supplies under the repeatable prescription (including dates and quantities supplied);

(e) destroy any surplus batch issues relating to drugs or appliances—

(i) which are not required, or

(ii) where a patient is refused the drugs or appliances pursuant to paragraph 7;

(f) where a patient is provided with drugs or appliances under a repeatable prescription, notify the prescriber of any clinically significant issues arising in connection with the prescription and keep a record of that notification; and

(g) notify the prescriber of any refusal to provide drugs or appliances pursuant to paragraph 7(4).

Information to be provided for the NHSCB's lists

11.—(1) The LPS contractor (C) must ensure that C provides to the NHSCB, on request, an up to date record of—

(a) the services that C provides; and

(b) the days on which and times at which those services are provided.

(2) Sub-paragraph (1) is without prejudice to the need for a variation of the LPS scheme if C wishes to change—

(a) the services that C provides; and

(b) the days on which and times at which those services are provided.

Clinical governance

12.—(1) The LPS contractor must participate, in the manner reasonably required by the NHSCB in an acceptable system of clinical governance.

(2) In this paragraph, "system of clinical governance" means a framework through which an LPS contractor endeavours to improve continuously the quality of the LPS contractor's services and safeguards high standards of care by creating an environment in which clinical excellence can flourish.

Professional Standards

13. The LPS contractor must provide local pharmaceutical services and exercise any professional judgement in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.

Inducements etc

14.—(1) The LPS contractor (C) (including C's staff) must not give, promise or offer to any person any gift or reward (whether by way of a share of or dividend on the profits of C's business or by way of discount or rebate or otherwise) as an inducement to or in consideration of a person (X)—

(a) presenting an order for drugs or appliances on a non-electronic prescription form or non-electronic repeatable prescription;

(b) nominating C as X's dispensing contractor (or one of them) in X's PDS patient details; or

(c) being provided with any LP service by C.

(2) Promising, offering or providing an auxiliary aid in relation to the supply of drugs or a home delivery service is not a gift or reward for the purposes of sub-paragraph (1).

(3) C (including C's staff) must not give, promise or offer to any relevant person any gift or reward (including by way of a share of, or dividend on, the profits of C's business, or by way of a discount or rebate) as an inducement to or in consideration of the relevant person recommending to any person that they—

(a) present to C an order for drugs or appliances on a prescription form or repeatable prescription;

(b) nominate C as their dispensing contractor (or one of them) on their PDS patient details; or

(c) are provided with any LP service by C.

(4) For the purpose of sub-paragraph (3), "relevant person" means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes—

(a) any NHS body or provider of primary medical services; and

(b) any person employed or engaged by any of the persons mentioned in paragraph (a).

Duty to provide information about fitness to practise matters as they arise

15.—(1) The LPS contractor (C) must within 7 days of its occurrence supply in writing information to the NHSCB as to whether a person (P) who is a relevant person in relation to C—

(a) has been convicted of any criminal offence in the United Kingdom;

(b) has been convicted elsewhere of an offence which would constitute a criminal offence if committed in England and Wales;

(c) has been charged with an offence and is currently the subject of any proceedings which might lead to a conviction, which have not yet been notified to the NHSCB;

(d) has accepted a police caution in the United Kingdom;

(e) has become subject to an order under section 246(2) or (3) of the Criminal Procedure (Scotland) Act 1995(**57**) (admonition and absolute discharge) discharging R absolutely;

(f) has accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995(**58**) (fixed penalty: conditional offer by procurator fiscal);

(g) has agreed to pay a penalty under section 115A of the Social Security Administration Act 1992(**59**) (penalty as alternative to prosecution);

(**57**) 1995 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.

(**58**) 1995 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).

(**59**) 1992 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.

(h) has, to P's knowledge, become subject to any investigation into P's professional conduct by any licensing body or is notified of the outcome of such an investigation where it is adverse;

(i) has, to P's knowledge, become subject to an investigation into P's professional conduct in respect of any current or previous employment or is notified of the outcome of such an investigation where it is adverse;

(j) has, to P's knowledge, become subject to any investigation by the NHS BSA in relation to fraud or is notified of the outcome of such an investigation where it is adverse;

(k) has, to P's knowledge, become the subject of any investigation by another primary care organisation, which might lead to P's removal from any relevant list; or

(l) either—

(i) has been removed or contingently removed from, refused admission to, or conditionally included in, any relevant list of another primary care organisation,

(ii) has been suspended from such a list, on fitness to practise grounds, and if so, why and the name of that other primary care organisation, or

(iii) has become the subject of a national disqualification,

and if so, C must give details of any investigation or proceedings which are being or were undertaken or brought, including the nature of that investigation or proceedings, where and approximately when that investigation or those proceedings commenced, and any outcome.

(2) P is a "relevant person" in relation to C for these purposes, in the case of a contractor that is—

(a) an individual, if P is C;

(b) a partnership, if P is a partner in C;

(c) a body corporate, if P is a director, the chief executive, the company secretary or the superintendent pharmacist of C.

(3) C or any relevant person must consent to a request being made by the NHSCB to any employer or former employer or licensing body in the United Kingdom or elsewhere, for information relating to a current investigation, or an investigation where the outcome was adverse.

Co-operation with Health Education England

16. The LPS contractor must co-operate with Health Education England in the discharge by Health Education England of the duty under section 1F(1) of the 2006 Act(**60**) (duty as to education and training).

Charges for drugs, appliances and containers, and ownership of containers

17.—(1) Subject to regulations made under Part 9 of the 2006 Act (charging), all drugs, containers and appliances provided under these terms of service must be provided free of charge.

(2) Where the LPS contractor supplies a container in response to an order for drugs signed by a prescriber, other than equipment specified in the Drug Tariff as not returnable to the contractor, the container and equipment must remain the property of the LPS contractor.

Refunds of prescription charges

18.—(1) Where any person who is entitled to a repayment of any charge paid under the Charges Regulations presents the LPS contractor with a valid claim for the repayment within three months of the date on which the charge was paid, the LPS contractor must make the repayment.

(**60**) Section 1F was inserted by the Health and Social Care Act 2012 (c. 7), section 7.

(2) For the purposes of sub-paragraph (1), a claim for repayment is only valid if duly made—

(a) in such form and manner as the Secretary of State has determined for an application for such a repayment under regulation 10(2)(b) of the Charges Regulations(**61**) (repayment of charges); or

(b) on the equivalent form issued in Scotland, Wales or Northern Ireland.

Remuneration, overpayments etc

19.—(1) The NHSCB must ensure that the LPS scheme requires it to remunerate the LPS contractor (C) promptly, in accordance with the remuneration arrangements provided for in the scheme, but subject to the arrangements for reductions of and deductions from payments provided for in the scheme.

(2) The NHSCB must ensure that the LPS scheme requires that payment of any item of remuneration which would, if it were payable to an NHS pharmacist in connection with providing pharmaceutical services, be pharmaceutical reimbursement, is to be paid in accordance with the Drug Tariff.

(3) For these purposes, "pharmaceutical reimbursement" means pharmaceutical remuneration of the type which may be payable to NHS chemists in accordance with determinations by (only) the Secretary of State under section 164 of the 2006 Act(**62**) (remuneration for persons providing pharmaceutical services).

(4) Where an LPS scheme requires a fee, allowance or other item of remuneration to be made in accordance with the Drug Tariff and the Drug Tariff provides that the fee, allowance or other item of remuneration is to be determined by the NHSCB, that fee, allowance or other item of remuneration must be determined by the NHSCB.

(5) The NHSCB must ensure that the LPS scheme—

(a) allows it to recover any payment made to C which should not have been made;

(b) provides that any such recovery of an overpayment is without prejudice to any investigation of any alleged breach of the scheme; and

(c) provides that the remuneration arrangements under the scheme, referred to in sub-paragraphs (1) to (4), are subject to any right the NHSCB may have to set off against any amount payable to C, any amount—

(i) owed by C to it, or

(ii) which it is entitled to withhold under the terms of the scheme (including terms of the Drug Tariff applied by the scheme).

Local resolution of disputes

20. In the case of any dispute arising out of, or in connection with, the LPS scheme, the LPS contractor and the NHSCB must made every reasonable effort to communicate and co-operate with each other with a view to resolving the dispute, before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).

(**61**) Regulation 10 has been amended by S.I. 2000/3189, 2002/2352 and 2004/696.
(**62**) Section 164 has been amended by: the Health and Social Care Act 2008 (c. 14), section 141, and Schedule 15, Part 4; and by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 89.

Dispute resolution: non-NHS contracts

21.—(1) In the case of an LPS scheme which is not an NHS contract, any dispute arising out of or in connection with the scheme, except matters dealt with under the complaints procedure pursuant to paragraph 25, may be referred for consideration and determination to the Secretary of State, if—

(a) the NHSCB so wishes and the contractor has agreed in writing; or

(b) the contractor so wishes (even if the NHSCB does not agree).

(2) In the case of a dispute referred to the Secretary of State under sub-paragraph (1)—

(a) the procedure to be followed is the NHS dispute resolution procedure; and

(b) the parties must agree to be bound by any determination made by the adjudicator.

NHS dispute resolution procedure

22.—(1) The procedure specified in this paragraph and paragraph 23 applies in the case of any dispute arising out of or in connection with an LPS scheme which is referred to the Secretary of State—

(a) in accordance with section 9(6) of the 2006 Act (NHS contracts), where the scheme is an NHS contract; or

(b) in accordance with paragraph 21(1), where the scheme is not an NHS contract.

(2) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send to the Secretary of State a written request for dispute resolution which must include or be accompanied by—

(a) the names and addresses of the parties to the dispute;

(b) a copy of the LPS scheme; and

(c) a brief statement describing the nature and circumstances of the dispute.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send the request under sub-paragraph (2) within a period of 3 years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(4) Where the dispute relates to an LPS scheme which is not an NHS contract, the Secretary of State may determine the matter himself or, if the Secretary of State considers it appropriate, appoint a person or persons to consider and determine it.

(5) Before reaching a decision as to who should determine the dispute, either under sub-paragraph (4) or under section 9(8) of the 2006 Act, the Secretary of State must, within the period of 7 days beginning with the date on which a matter was referred to the Secretary of State, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter.

(6) The Secretary of State must give, with the notice given under sub-paragraph (5) to the party other than the one which referred the matter to dispute resolution a copy of any document by which the matter was referred to dispute resolution.

(7) The Secretary of State must give a copy of any representations received from a party to the other party and must in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.

(8) Following receipt of any representations from the parties or, if earlier, at the end of the period for making such representations specified in the request sent under sub-paragraph (5) or (7), the Secretary of State must, if the Secretary of State decides to appoint a person or persons to hear the dispute—

(a) inform the parties in writing of the name of the person or persons whom the Secretary of State has appointed; and

(b) pass to the person or persons so appointed any documents received from the parties pursuant to sub-paragraph (2), (5) or (7).

(9) For the purpose of assisting them in their consideration of the matter, the adjudicator may—

(a) invite representatives of the parties to appear before the adjudicator to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which the adjudicator wishes them to give special consideration; or

(b) consult other persons whose expertise the adjudicator considers will assist the adjudicator's consideration of the matter.

(10) Where the adjudicator consults another person under sub-paragraph (9)(b), the adjudicator must notify the parties accordingly and, where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, the adjudicator must give to the parties such opportunity as the adjudicator considers reasonable in the circumstances to make observations on those results.

(11) In considering the matter, the adjudicator must consider—

(a) any written representations made in response to a request under sub-paragraph (5), but only if they are made within the specified period;

(b) any written observations made in response to a request under sub-paragraph (7), but only if they are made within a specified period;

(c) any oral representations made in response to an invitation under sub-paragraph (9)(a);

(d) the results of any consultation under sub-paragraph (9)(b); and

(e) any observations made in accordance with an opportunity given under sub-paragraph (10).

(12) In this paragraph, "specified period" means such period as the Secretary of State must specify in the request, being not less than 2, nor more than 4 weeks beginning with the date on which the notice referred to is given, but the Secretary of State may, if the Secretary of State considers that there is good reason for doing so, extend any such period (even after it has expired) and, where the Secretary of State does so, a reference in this paragraph to the specified period is to the period as so extended.

(13) Subject to the other provisions of this paragraph and paragraph 23, the adjudicator is to have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

Determination of dispute

23.—(1) The adjudicator must record the adjudicator's determination, and the reasons for it, in writing and must give notice of the determination (including a record of the reasons) to the parties.

(2) In the case of a scheme referred for determination in accordance with paragraph 21(1), section 9(11) of the 2006 Act must apply as that subsection applies in the case of an LPS scheme referred for determination in accordance with section 9(6) of that Act.

Disputes: supplemental

24.—(1) In this Schedule, where reference is made to any dispute arising out of, or in connection with, an LPS scheme, that includes any dispute arising out of, or in connection with, the termination of the scheme.

(2) Any term of the LPS scheme that makes provision in respect of the requirements in paragraphs 20 to 23 must survive even where the scheme has terminated.

Complaints

25.—(1) The LPS contractor must have in place arrangements which comply with the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(**63**), for the handling and consideration of any complaints.

(2) In this paragraph, "complaint" means a complaint about a matter connected with the provision of local pharmaceutical services by the LPS contractor.

Variation of LPS schemes

26.—(1) Subject to sub-paragraphs (2) to (4), no amendment or variation to the LPS scheme is to have effect unless it is in writing and signed by or on behalf of the NHSCB and the (relevant) LPS contractor (C).

(2) The NHSCB may vary an LPS scheme without C's consent where it—

(a) is reasonably satisfied that it is necessary to vary the scheme so as to comply with the 2006 Act, any regulations made under that Act, or any direction given by the Secretary of State under that Act; and

(b) notifies C in writing of the wording of the proposed variation and the date upon which that variation is to take effect,

and, where it is reasonably practicable to do so, the date that the proposed variation is to take effect must be not less than 14 days after the date on which the notice under paragraph (b) is served on C.

(3) During an emergency requiring the flexible provision of pharmaceutical services, the NHSCB may, on application from C—

(a) permit C a temporary change to the days on which or times at which C is obliged to provide local pharmaceutical services at the scheme premises, or permit temporary closure of those premises, if—

(i) C gives at least 24 hours notice of the change or closure, and

(ii) the reasons given by C for the request are, in the opinion of the NHSCB adequate reasons; or

(b) permit C any other temporary variation to C's LPS scheme that, in the opinion of the NHSCB, will facilitate continuity of the provision of services of a kind that may be provided under section 126, or by virtue of section 127, of the 2006 Act(**64**) (arrangements for pharmaceutical services and additional pharmaceutical services) during the emergency.

(4) The NHSCB need not approve the request referred to in sub-paragraph (3)(a)(ii) in advance of the change or closure, but if it does not do so and decides subsequently that C's reasons are not, in its opinion, adequate reasons, then the days on which or times at which C is obliged to provide local pharmaceutical services at the scheme premises are to revert to the overridden days and times, from the day after the date on which that decision is given to C.

Termination by agreement

27. The NHSCB and the LPS contractor may agree in writing to terminate the LPS scheme (or end the LPS contractor's participation in it, in the case of more than one LPS contractor being party

(**63**) S.I. 2009/309; amended by S.I. 2009/1768.
(**64**) Section 126 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), sections 220(7) and 213(7)(k), and Schedule 4, paragraph 63. Section 127 has been amended by the 2012 Act, Schedule 4, paragraph 64.

to the scheme), and if the parties so agree, they must agree the date upon which that termination should take effect and any further terms upon which the scheme should be terminated.

Termination by serving notice

28.—(1) Either the LPS contractor or the NHSCB may terminate the LPS scheme (or end the LPS contractor's participation in it, in the case of more than one LPS contractor being party to the scheme), at any time by serving notice of not less than 6 months in writing to the other party.

(2) Where a notice is served pursuant to sub-paragraph (1), the LPS scheme must terminate on the expiry of the notice period.

(3) This paragraph is without prejudice to any other rights to terminate the agreement which the LPS contractor and the NHSCB may have.

Termination of arrangements by the NHSCB on grounds of suitability etc

29.—(1) The NHSCB may serve notice in writing on the LPS contractor terminating the LPS scheme (or ending the LPS contractor's participation in it, in the case of more than one LPS contractor being party to the scheme) with immediate effect, or from such date as may be specified in the notice, if, in the case of an LPS scheme (or an agreement that is part of an LPS scheme) entered into—

(a) with an individual as a party, that individual;

(b) with more than one individual (whether or not practising in partnership), any of those individuals; or

(c) with a body corporate—

(i) the body corporate, or

(ii) any director, chief executive, superintendent or company secretary of the body corporate,

falls within sub-paragraph (2) during the existence of the scheme (or the agreement).

(2) A person (X) falls within this sub-paragraph if—

(a) X is the subject of a national disqualification;

(b) subject to sub-paragraph (3), X is disqualified or suspended (other than by an interim suspension order or direction pending an investigation) from practising by any licensing body anywhere in the world;

(c) X is removed from, or refused admission to, a relevant list by 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 X has subsequently been included in such a list;

(d) X has been convicted in the United Kingdom of murder or a criminal offence other than murder—

(i) which was committed on or after 1st April 2006, and

(ii) for which X has been sentenced to a term of imprisonment of over six months;

(e) subject to sub-paragraph (4), X has been convicted outside the United Kingdom of an offence which, if committed in England and Wales—

(i) would constitute murder, or

(ii) would constitute an offence, and—

(aa) which was committed on or after 1st April 2006, and

(bb) for which X has been sentenced to a term of imprisonment of over six months;

(f) X has been convicted of an offence referred to in—

(i) Schedule 1 to the Children and Young Persons Act 1933(**65**) (offences against children and young persons with respect to which special provisions of this Act apply), or

(ii) Schedule 1 to the Criminal Procedure (Scotland) Act 1995(**66**) (offences against children under the age of 17 years to which special provisions apply),

which was committed on or after 1st April 2006;

(g) X—

(i) has been adjudged bankrupt, or sequestration of X's estate has been ordered, unless X has been discharged from the bankruptcy or the order has been annulled,

(ii) has become a person in relation to whom a moratorium period under a debt relief order (under Part 7A of the Insolvency Act 1986(**67**) (debt relief orders)) applies,

(iii) has been made 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(**68**) or Schedule 2A of the Insolvency (Northern Ireland) Order 1989(**69**) (which relate to bankruptcy and debt relief restrictions orders and undertakings), which has not been annulled,

(iv) if X 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, X's creditors and X has not been discharged in respect of it;

(h) in respect of X there is—

(i) an administrator, administrative receiver or receiver appointed, or

(ii) an administration order made under Schedule B1 to the Insolvency Act 1986(**70**) (administration);

(i) X has 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—

(**65**) 1933 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.
(**66**) 1995 c. 46.
(**67**) 1986 c. 45. Part 7A was inserted by the Tribunals, Courts and Enforcement Act 2007 (c. 15), Schedule 17.
(**68**) 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.
(**69**) S.I. 1989/2405 (N.I. 19); Schedule 2A was inserted by S.I. 2005/1455 (N.I. 10).
(**70**) Schedule B1 was inserted by the Enterprise Act 2002 (c. 40), Schedule 16.

(aa) section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990(**71**) (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(**72**) (powers of the Court of Session),

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

(j) X has been subject to—

(i) a disqualification order or disqualification undertaking under the Company Directors Disqualification Act 1986(**73**) or the Company Directors Disqualification (Northern Ireland) Order 2002(**74**), or

(ii) an order made under section 429(2) of the Insolvency Act 1986(**75**) (disabilities on revocation of a county court administration order);

(k) X (in the case of an individual) has refused to comply with a request by the NHSCB for X to be medically examined on the grounds that it is concerned that X is incapable of adequately providing services under the scheme; or

(l) it comes to the attention of the NHSCB that information provided to it pursuant to—

(i) regulation 12 or 17 of the 2006 Regulations,

(ii) a term of the scheme required by paragraph 16 of Schedule 2 to the 2006 Regulations,

(iii) regulation 106, or

(iv) paragraph 15,

was, when given, untrue or inaccurate in a material respect.

(3) The NHSCB is not to terminate the LPS scheme (or end an LPS contractor's participation in it) pursuant to sub-paragraph (2)(b) where it is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make X unsuitable to be—

(a) an LPS contractor; or

(b) in the case of an LPS scheme (or agreement) with a body corporate, a director, chief executive, superintendent or company secretary of a contractor.

(4) The NHSCB is not to terminate the scheme pursuant to sub-paragraph (2)(e) where it is satisfied that the conviction does not make X unsuitable to be—

(a) an LPS contractor; or

(b) in the case of an LPS scheme (or agreement) with a body corporate, a director, chief executive, superintendent or company secretary of an LPS contractor.

Termination by the NHSCB: patient safety and material financial loss

30. The NHSCB may serve notice in writing on the LPS contractor (C) terminating the LPS scheme (or ending the LPS contractor's participation in it, in the case of more than one LPS contractor being party to the scheme) with immediate effect or with effect from such date as may be specified in the notice if—

(**71**) 1990 c.40; section 7 was repealed by the Charities and Trustee Investment (Scotland) Act 2005 (asp 10), Schedule 4, paragraph 7(b).
(**72**) 2005 asp 10; section 34(5) has been amended by the section the Public Services Reform (Scotland) Act 2010 (asp 8), section 122.
(**73**) 1986 c.46.
(**74**) S.I. 2002/3150 (N.I. 4); relevant amendments were made by S.I. 2005/1454 (N.I. 9).
(**75**) Section 429(2) was amended by the Enterprise Act 2002 (c.40), Schedule 23, paragraph 15.

(a) C has breached the scheme and as a result of that breach, the safety of C's patients is at serious risk if the scheme is not terminated (or C's participation in it is not ended, in the case of more than one LPS contractor being party to the scheme); or

(b) C's financial situation is such that the NHSCB considers that the NHSCB is at risk of material financial loss.

Termination and the NHS dispute resolution procedure

31.—(1) Where the NHSCB is entitled to serve written notice on the LPS contractor (C) terminating the LPS scheme (or ending C's participation in it) pursuant to paragraph 29 or 30, it must, in the notice served on C pursuant to those provisions, specify a date on which the scheme terminates (or C's participation in it is to end) that is not less than 28 days after the date on which the NHSCB has served that notice on C, unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the NHSCB is satisfied that a period less than 28 days, or termination with immediate effect, is necessary in order to—

(a) protect the safety of the C's patients; or

(b) protect itself from material financial loss.

(3) In a case falling within sub-paragraph (1), where—

(a) the exceptions in sub-paragraph (2) do not apply;

(b) C invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1); and

(c) C notifies the NHSCB in writing that it has done so,

subject to paragraph (5), the LPS scheme (or C's participation in it) is not to terminate at the end of the notice period but instead is only to terminate in the circumstances specified in sub-paragraph (4).

(4) Subject to paragraph (5), the LPS scheme (or C's participation in it) is only to terminate if and when—

(a) there has been a determination of the dispute pursuant to paragraph 23 and that determination permits the NHSCB to terminate the scheme; or

(b) C ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(5) If the NHSCB is satisfied that it is necessary to terminate the scheme before the NHS dispute resolution procedure is concluded in order to—

(a) protect the safety of the C's patients; or

(b) protect itself from material financial loss,

sub-paragraphs (3) and (4) shall not apply and the NHSCB is entitled to confirm, by written notice to be served on C, that the LPS scheme (or C's participation in it) will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 29(1) or 30.

Third party rights

32. The LPS scheme shall not create any right enforceable by any person not a party to it.

SCHEDULE 8

Regulation 91(1)(a)

Service remuneration determined by the NHSCB

1.—(1) Any fees and allowances payable to NHS pharmacists for professional services provided as part of the provision of pharmaceutical services.

(2) Without prejudice to the generality of sub-paragraph (1), those fees and allowances may include—

(a) fees in connection with the dispensing of drugs and appliances, including any additional fees relating to the dispensing of particular types of drug or appliance;

(b) payments made to NHS pharmacists in respect of their providing particular types of advice or assistance to patients or in respect of their participation in particular activities or schemes; and

(c) payments made to NHS pharmacists that are a contribution to the overall cost of professional services provision (which may be calculated by reference to particular levels of activity).

(3) For the purposes of sub-paragraph (1), "professional services" does not include providing pre-registration training experience for pharmacy graduates or undergraduates.

2.—(1) Any fees and allowances payable to NHS appliance contractors for professional services provided as part of the provision of pharmaceutical services.

(2) Without prejudice to the generality of sub-paragraph (1), those fees and allowances may include—

(a) fees in connection with the dispensing of appliances, including any additional fees relating to the dispensing of particular types of appliance;

(b) payments made to NHS appliance contractors in respect of their providing particular types of advice or assistance to patients or in respect of their participation in particular activities or schemes; and

(c) payments made to NHS appliance contractors that are a contribution to the overall cost of professional services provision (which may be calculated by reference to particular levels of activity).

SCHEDULE 9

Regulation 119

Transitional provisions

The continuity principles

1.—(1) Where by virtue of this Schedule—

(a) a matter is to be dealt with in accordance with the 2006 Regulations or the 2012 Regulations; or

(b) a matter (by virtue of having been dealt with in accordance with Schedule 7 to the 2012 Regulations (transitional provisions)), is to be dealt with in accordance with the 2005 Regulations or the SCAT Regulations,

if that matter under those Regulations would fall to be dealt with by a Primary Care Trust, unless the context requires otherwise, that matter is to be dealt with instead by the NHSCB.

(2) Any matter that is ongoing under the 2006 Regulations or the 2012 Regulations (including, by virtue of Schedule 7 of those Regulations, under the 2005 Regulations or the SCAT Regulations) immediately before the appointed day, unless the context requires otherwise—

(a) is to be treated as ongoing under these Regulations on the appointed day (and where appropriate after that); and

(b) where that matter becomes the responsibility of the NHSCB on the appointed day, anything done in relation to that matter by or with regard to a Primary Care Trust before the appointed day is to be treated as having been done (for the purposes of the ongoing treatment of the matter) by or with regard to the NHSCB.

(3) Where a period of time specified in a provision of the 2006 Regulations or the 2012 Regulations is current on the appointed day, and a period of time is also specified in a corresponding provision of these Regulations, unless the context requires otherwise, these Regulations have effect as if the corresponding provision of these Regulations had been in force when that period began to run.

(4) Where—

(a) consideration of a matter under a provision of these Regulations in respect of a specified period of time requires consideration of a period of time before the appointed day; and

(b) a corresponding provision of the 2006 Regulations or the 2012 Regulations also required consideration of that matter in respect of a specified period of time,

unless the context requires otherwise, the provision of these Regulations has effect as if it had been in force when the period of time specified in it began to run.

(5) Subject to sub-paragraphs (6) and (7), where on or after the appointed day—

(a) a matter is to be dealt with in accordance with the SCAT Regulations, the 2005 Regulations, the 2006 Regulations or the 2012 Regulations; or

(b) a matter that relates to circumstances that arose, or first arose, before the appointed day is to be dealt with in accordance with these Regulations or the Drug Tariff,

in dealing with that matter the NHSCB (or where appropriate, on appeal, the Secretary of State or the First-tier Tribunal) is to apply those Regulations, the Drug Tariff and related provisions of the 2006 Act subject to such modifications as it (or where appropriate, on appeal, the Secretary of State or the First-tier Tribunal) considers necessary or expedient.

(6) Modifications pursuant to paragraph (5) must—

(a) be for a purpose related to—

(i) dealing with the matter justly, or

(ii) effecting an orderly transition from the scheme established by the Regulations mentioned in sub-paragraph (5)(a), read with the 2006 Act as in force before the appointed day, to the scheme established by these Regulations, read with the 2006 Act,

or for purposes related to both; and

(b) take account, as appropriate, of the manner in which—

(i) provisions in the 2005 Regulations were carried forward into the 2012 Regulations,

(ii) provisions in the 2006 Regulations and the 2012 Regulations were carried forward into these Regulations, and

(iii) the 2006 Act was amended by the Health and Social Care Act 2012(**76**).

(7) Modifications pursuant to paragraph (5) may—

(**76**) 2012 c. 7.

(a) be for the purpose of seeking to ensure that a matter is dealt with expeditiously;

(b) be for the purpose of seeking to ensure that a matter is dealt with proportionately, having regard to (as relevant)—

(i) the importance of protecting the safety of persons to whom pharmaceutical and local pharmaceutical services are provided,

(ii) the need for fairness,

(iii) the complexity of the issues,

(iv) the importance of protecting the NHSCB from material financial loss, and

(v) the importance of saving expense; or

(c) (without prejudice to the generality of the power to make modifications) have the effect of—

(i) adding to, modifying or removing functions that would have been performed by a Primary Care Trust under the SCAT Regulations, the 2005 Regulations, the 2006 Regulations, the 2012 Regulations or the 2006 Act as in force before the appointed day, or

(ii) adding to, modifying or removing functions that are to be performed by the NHSCB or a HWB under these Regulations or the 2006 Act.

(8) In this Schedule, "the continuity principles" means the provisions of sub-paragraphs (1) to (7).

Listing applications under the 2005 Regulations: NHS chemists

2.—(1) An application made to a Primary Care Trust under regulation 5(1), 40(1) or 54(2) of the 2005 Regulations (which relate to applications for inclusion in a pharmaceutical list, preliminary consent applications and temporary provision during a period of suspension) which—

(a) has not been determined before the appointed day; and

(b) by virtue of Schedule 7 to the 2012 Regulations (transitional provisions), was to be determined in accordance with the 2005 Regulations and if relevant the 2006 Regulations,

is to be dealt with by the NHSCB in accordance with the 2005 Regulations.

(2) Where an application made under the 2005 Regulations for preliminary consent has been finally granted under those Regulations—

(a) an application under regulation 5(1) of the 2005 Regulations that is in accordance with regulation 41(1) of those Regulations (effect of preliminary consent) may be made in relation to that consent (within the 6 months period referred to in regulation 40(4) of the 2005 Regulations); and

(b) any such application is to be dealt with by the NHSCB in accordance with the 2005 Regulations.

(3) Where on or after the appointed day, by virtue of this paragraph, an application is to be determined by the NHSCB having regard to regulation 13(1)(a) of the 2005 Regulations (exemptions from the necessary or expedient test), for the purposes of that application an area is an approved retail area if on 31st August 2012 it was a retail area that was for the time being approved by the Secretary of State under regulation 15 of those Regulations (approved retail areas).

(4) Where an application under regulation 5(1), 40(1) or 54(2) of the 2005 Regulations has been determined in accordance with the 2005 Regulations, whether before the appointed day or by virtue of this paragraph—

(a) the arrangements for bringing an appeal in relation to that application; and

(b) the determination of any appeal validly brought,

are to be in accordance with the 2005 Regulations.

Listing applications under the 2012 Regulations: NHS chemists

3.—(1) Where a routine application has been made to a Primary Care Trust before the appointed day under the 2012 Regulations, subject to paragraph (2)—

(a) if that application has not been notified under Part 3 of Schedule 2 to the 2012 Regulations (applications in respect of pharmaceutical lists and the procedures to be followed – notification of certain applications) before the appointed day, it is to be dealt with by the NHSCB in accordance with these Regulations; and

(b) if that application has been notified under Part 3 of Schedule 2 to the 2012 Regulations before the appointed day, it is to be dealt by the NHSCB in accordance with the 2012 Regulations and the 2006 Act as in force immediately before the appointed day.

(2) Where—

(a) a routine application has been made to a Primary Care Trust before the appointed day under the 2012 Regulations; and

(b) determination of that application requires determination of whether granting it, or granting it in respect of some only of the services specified in it, would meet a current or future need for pharmaceutical services, or pharmaceutical services of a specified type, which have been included in a pharmaceutical needs assessment,

it is to be dealt with by the NHSCB in accordance with the 2012 Regulations and the 2006 Act as in force immediately before the appointed day, whether or not it has been notified under Part 3 of Schedule 2 to the 2012 Regulations before the appointed day.

(3) Where an excepted application has been made to a Primary Care Trust before the appointed day under the 2012 Regulations—

(a) if that application—

(i) is not a notifiable application, and

(ii) has not been determined by the Primary Care Trust before the appointed day,

it is to be dealt with by the NHSCB in accordance with these Regulations;

(b) if that application—

(i) is a notifiable application, and

(ii) has not been notified under Part 3 of Schedule 2 to the 2012 Regulations before the appointed day,

it is to be dealt with in accordance with these Regulations; and

(c) if that application—

(i) is a notifiable application, and

(ii) has been notified under Part 3 of Schedule 2 to the 2012 Regulations before the appointed day,

it is to be dealt with in accordance with the 2012 Regulations and the 2006 Act as in force immediately before the appointed day.

(4) Where an application under the 2012 Regulations is determined in accordance with the 2012 Regulations, whether before the appointed day or by virtue of this paragraph—

(a) the arrangements for bringing an appeal in relation to that application; and

(b) the determination of any appeal validly brought,

are to be in accordance with the 2012 Regulations.

(5) In applying the continuity principles in relation to decisions which are to be made under the 2012 Regulations by virtue of this paragraph, the NHSCB must ensure that LPS chemists that would, by virtue of paragraph 32(5)(b)(ii) of Schedule 2 to these Regulations, have rights of appeal against particular types of decision under these Regulations, have the same rights of appeal against equivalent decisions under the 2012 Regulations, notwithstanding that those rights of appeal were not provided for in the 2012 Regulations.

Listing applications under the 2005 Regulations: dispensing doctors

4.—(1) An application made to a Primary Care Trust under Part 5 of the 2005 Regulations (provision of pharmaceutical services by doctors) for outline consent or premises approval (including temporary premises approval) which—

(a) has not been determined before the appointed day; and

(b) by virtue of Schedule 7 to the 2012 Regulations (transitional provisions) was to be determined in accordance with the 2005 Regulations,

is to be dealt with by the NHSCB in accordance with the 2005 Regulations.

(2) Where an application under Part 5 of the 2005 Regulations has been determined in accordance with those Regulations, whether before the appointed day or by virtue of sub-paragraph (1)—

(a) the arrangements for bringing an appeal in relation to that application; and

(b) the determination of any appeal validly brought,

are to be in accordance with the 2005 Regulations.

(3) If, before the appointed day—

(a) a Primary Care Trust has required a doctor to provide pharmaceutical services under regulation 60(4)(a) of the 2005 Regulations(**77**) (arrangements for provision of pharmaceutical services by doctors); and

(b) the doctor has appealed against that decision,

the arrangements for bringing that appeal, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

Listing applications under the 2012 Regulations: dispensing doctors

5.—(1) Where an application has been made to a Primary Care Trust before the appointed day under Part 8 of the 2012 Regulations (dispensing doctors) for outline consent or premises approval, other than an application for temporary premises approval to which regulation 58 or 61 of those Regulations (which relate to temporary provision in cases where premises approval has not taken effect or during an emergency requiring the flexible provision of pharmaceutical services) applies—

(a) if that application has not been notified under regulation 52 of the 2012 Regulations (notification of applications for outline consent and premises approval), it is to be dealt with by the NHSCB in accordance with these Regulations; and

(b) if that application has been notified under regulation 52 of the 2012 Regulations, it is to be dealt with by the NHSCB in accordance with the 2012 Regulations.

(2) Where—

(a) an application has been made to a Primary Care Trust before the appointed day under regulation 58 or 61 of the 2012 Regulations for temporary premises approval; and

(b) that application has not been determined before the appointed day,

it is to be dealt with by the NHSCB in accordance with these Regulations.

(**77**) Prior to its revocation, regulation 60(4) was amended by S.I. 2005/1015 and 2006/3373.

(3) Where an application under that Part 8 of the 2012 Regulations has been determined in accordance with the 2012 Regulations, whether before the appointed day or by virtue of this paragraph—

(a) the arrangements for bringing an appeal in relation to that application; and

(b) the determination of any appeal validly brought,

are to be in accordance with the 2012 Regulations.

(4) If, before the appointed day, a Primary Care Trust has required a doctor to provide pharmaceutical services under regulation 48(5)(b) of the 2012 Regulations (arrangements for provision of pharmaceutical services by doctors: applications by patients), and—

(a) the doctor has appealed against that decision before the appointed day; or

(b) the time limit for bringing an appeal against the decision in regulation 63(1) of the 2012 Regulations (appeals against decisions under Part 8) has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations.

Outstanding cases relating to dispensing contractor lists

6.—(1) If, before the appointed day the Primary Care Trust was engaged in a process which could have led to the inclusion or removal of a contractor or premises from a dispensing contractor list, that process and the action to be taken following its outcome (including relating to any appeal) are to be dealt with by the NHSCB in accordance with paragraph 10 of Schedule 7 to the 2012 Regulations (transitional provisions – dispensing contractor lists).

(2) Where—

(a) the NHSCB grants an application for premises approval by virtue of this paragraph; and

(b) the NHSCB is as a consequence required to consider any postponement of the making of arrangements to provide dispensing services, arising out of that grant,

that consideration, the NHSCB's decision on any postponement, the arrangements for bringing an appeal against its decision, and the determination of any appeal validly brought, are to be in accordance with paragraph 10 of Schedule 7 to the 2012 Regulations.

(3) Conditions relating to postponement of the making of arrangements to provide dispensing services which are imposed by virtue of this paragraph, or which continued to have effect by virtue of paragraph 10 of Schedule 7 to the 2012 Regulations, continue to have effect as if imposed under these Regulations in relation to the provision of pharmaceutical services.

Controlled localities

7.—(1) The NHSCB must—

(a) in respect of an area which on the appointed day continues to be, or to be part of, a controlled locality by virtue of regulation 36(1), delineate precisely the boundary of the controlled locality on a map (which may be part of a series of maps which relate to HWB areas);

(b) publish that map; and

(c) make that map available as soon as is practicable to any HWB that has all or part of that controlled locality in its area.

(2) Where—

(a) before the appointed day, a Primary Care Trust was considering whether or not an area is either a controlled locality or part of a controlled locality; or

(b) the NHSCB is required, by virtue of paragraphs 2 to 5, to determine an application and in connection with determining that application, it also needs to determine whether or not an area is or is not a controlled locality, or part of a controlled locality,

paragraph (3) applies.

(3) Where—

(a) consideration by a Primary Care Trust mentioned in sub-paragraph (2)(a) was, or (by virtue of paragraph 2 or 4) an application referred to in sub-paragraph (2)(b) is, to be dealt with under the 2005 Regulations—

(i) the consideration of whether or not a locality is either a controlled locality or part of a controlled locality is to be dealt with by the NHSCB in accordance with the 2005 Regulations, and

(ii) the arrangements for bringing an appeal in relation to the decision of the NHSCB, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations;

(b) consideration by a Primary Care Trust mentioned in sub-paragraph (2)(a) was under the 2012 Regulations (unless it was in connection with an application which by virtue of paragraph 3 or 5 is to be determined in accordance with these Regulations)—

(i) the consideration of whether or not a locality is either a controlled locality or part of a controlled locality is to be dealt with by the NHSCB in accordance with the 2012 Regulations, and

(ii) the arrangements for bringing an appeal in relation to the decision of the NHSCB, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations,

but if that consideration was in connection with an application which by virtue of paragraph 3 or 5 is to be determined in accordance with these Regulations, the consideration of whether or not a locality is either a controlled locality or part of a controlled locality is also to be dealt with by the NHSCB in accordance with these Regulations;

(c) an application referred to in sub-paragraph (2)(b) is to be dealt with under the 2012 Regulations (by virtue of paragraphs 3 or 5)—

(i) the related consideration of whether or not a locality is either a controlled locality or part of a controlled locality is to be dealt with by the NHSCB in accordance with the 2012 Regulations, and

(ii) the arrangements for bringing an appeal in relation to the decision of the NHSCB, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations;

(d) an application referred to in sub-paragraph (2)(b) is to be dealt with under these Regulations, the related consideration of whether or not a locality is either a controlled locality or part of a controlled locality is to be dealt with by the NHSCB in accordance with these Regulations.

(4) Where, by virtue of sub-paragraph (3), it is determined (whether by the NHSCB or on appeal by the Secretary of State) that an area is or is not, or is or is not part of, a controlled locality, the NHSCB must—

(a) delineate precisely the boundary of any resulting controlled locality on a map;

(b) publish that map; and

(c) make that map available as soon as is practicable to any HWB that has all or part of any resulting controlled locality in its area,

and any area that becomes, or becomes part of, a controlled locality as a consequence of that determination is then a controlled locality, or part of a controlled locality, for the purposes of these Regulations (unless or until it is determined under these Regulations that it is no longer, or no longer part of, a controlled locality).

Reserved locations

8.—(1) Where—

(a) an application has been received which is to be determined under the 2005 Regulations—

(i) in accordance with paragraph 2, and

(ii) having regard to regulation 12 or 13 of the 2005 Regulations (which relate to the necessary or expedient test and exemptions from it); and

(b) the premises or relevant location at or from which the applicant wishes to provide pharmaceutical services is or may be a reserved location,

pending the final determination of that application, the classification of any area in relation to those premises or that relevant location as, or as not, a reserved location is to be determined in accordance with the 2005 Regulations (if a further reserved location determination is required after the application is finally determined, it is to be in accordance with these Regulations).

(2) Where a determination of whether or not an area is a reserved location is made under the 2005 Regulations by virtue of—

(a) sub-paragraph (1); or

(b) before the appointed day, paragraph 6 of Schedule 7 to the 2012 Regulations (transitional provisions – reserved locations),

the arrangements for bringing an appeal against the decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(3) Where—

(a) a routine application was received by a Primary Care Trust which the NHSCB is required to determine under the 2012 Regulations in accordance with paragraph 3; and

(b) the premises or relevant location at or from which the applicant wishes to provide pharmaceutical services is or may be a reserved location,

pending the final determination of that application, the classification of any area in relation to those premises or that relevant location as, or as not, a reserved location is to be determined in accordance with the 2012 Regulations (if a further reserved location determination is required after the application is finally determined, it is to be in accordance with these Regulations).

(4) Where before the appointed day—

(a) a Primary Care Trust received a request for a determination under regulation 42 of the 2012 Regulations (second and subsequent determinations of reserved location status), but there is no related routine application which is (still) to be finally determined under the 2012 Regulations in accordance with paragraph 2; and

(b) the request was notified under regulation 42(2)(a) of the 2012 Regulations,

the classification of any area as, or as not, a reserved location pursuant to that request is to be determined in accordance with the 2012 Regulations (if a further reserved location determination is required after that determination, it is to be in accordance with these Regulations).

(5) Where a determination of whether or not an area is a reserved location is made under the 2012 Regulations by virtue of sub-paragraph (3) or (4), the arrangements for bringing an appeal

against the decision, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations.

(6) Where before the appointed day, a request is made to a Primary Care Trust for a reserved location determination, but the determination is not to be made under the 2005 Regulations or the 2012 Regulations by virtue of sub-paragraphs (1) to (5), it is to be made by the NHSCB (or on appeal the Secretary of State) under these Regulations.

(7) Where, by virtue of sub-paragraphs (1) to (5), it is determined (whether by the NHSCB or on appeal by the Secretary of State) that an area is a reserved location, if following the determination a reserved location thereafter takes effect (because the pharmacy premises to which it relates are included in a pharmaceutical list), the NHSCB must—

(a) delineate precisely the boundary of the reserved location on a map;

(b) publish that map; and

(c) make that map available as soon as is practicable to any HWB that has all or part of that reserved location in its area.

Gradual discontinuation of the provision of pharmaceutical services by doctors

9.—(1) Where, when granting an application which by virtue of paragraph 2 is finally determined in accordance with the 2005 Regulations, the NHSCB is required to consider under regulation 20(2) of the 2005 Regulations (imposition of conditions)—

(a) any termination of arrangements with any person on its dispensing doctor list; and

(b) any postponement of any such termination,

arising out of that grant (but not for a reason set out in regulation 50(1)(a) to (c), (e) or (f) of these Regulations), that consideration and its decision are to be in accordance with the 2005 Regulations.

(2) Where before the appointed day a Primary Care Trust was considering under the 2005 Regulations, in any case in which it could postpone the termination of arrangements with a dispensing doctor—

(a) the termination of arrangements with a dispensing doctor; or

(b) the postponement of the termination of arrangements with a dispensing doctor,

that matter is to be dealt with by the NHSCB, in accordance with the 2005 Regulations.

(3) Where, under the 2005 Regulations—

(a) a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor is made by virtue of sub-paragraph (1) or (2); or

(b) before the appointed day, a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor was made by a Primary Care Trust under the 2005 Regulations, and—

(i) that decision has been appealed before the appointed day, or

(ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(4) Where, when granting an application which by virtue of paragraph 3 is finally determined in accordance with the 2012 Regulations, the NHSCB is required to consider under regulation 50(1) or (3) of the 2012 Regulations (discontinuation of arrangements for the provision of pharmaceutical services by doctors)—

(a) any termination of arrangements with any person on its dispensing doctor list; and

(b) any postponement of any such termination,

arising out of that grant, that consideration and its decision are to be in accordance with the 2012 Regulations.

(5) Where before the appointed day a Primary Care Trust was considering under regulation 50(1) to (6) of the 2012 Regulations, in any case in which it could postpone the termination of arrangements with a dispensing doctor—

(a) the termination of arrangements with a dispensing doctor; or

(b) the postponement of the termination of arrangements with a dispensing doctor,

that matter is to be dealt with by the NHSCB, in accordance with the 2012 Regulations.

(6) Where, under the 2012 Regulations—

(a) a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor is made by virtue of sub-paragraph (4) or (5); or

(b) before the appointed day, a decision relating to termination of arrangements, or the postponement of the termination of arrangements, with a dispensing doctor was made by a Primary Care Trust pursuant to the 2012 Regulations, and—

(i) that decision has been appealed before the appointed day, or

(ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations.

(7) Regulation 50(1)(f) applies to a determination under the 2005 Regulations or the 2012 Regulations (either before the appointed day or by virtue of paragraph 8) that a location ceases to be or be part of a reserved location as it does to a determination referred to in regulation 42 as D2.

(8) Conditions imposed by virtue of—

(a) regulation 20(2) or 35(6)(b) (pharmaceutical services in reserved locations) of the 2005 Regulations; or

(b) regulation 50(2), (5) or (6) of the 2012 Regulations,

relating to the postponement of termination of arrangements with a dispensing doctor, whether or not imposed by virtue of this paragraph, continue to have effect as if imposed under these Regulations.

Gradual introduction of the provision of pharmaceutical services by doctors

10.—(1) Where, when granting an application which by virtue of paragraph 4 is finally determined in accordance with the 2005 Regulations, the NHSCB is required to consider under regulation 20(2) of the 2005 Regulations (imposition of conditions) any postponement of the making of arrangements with a dispensing doctor arising out of that grant, that consideration and its decision are to be in accordance with the 2005 Regulations.

(2) Where before the appointed day a Primary Care Trust is considering under regulation 20(2) of the 2005 Regulations the postponement of the making of arrangements with a dispensing doctor, that matter is to be dealt with by the NHSCB, in accordance with the 2005 Regulations.

(3) Where, under the 2005 Regulations—

(a) a decision relating to postponement of the making of arrangements with a dispensing doctor is made by virtue of sub-paragraph (1) or (2); or

(b) before the appointed day, a decision relating to postponement of the making of arrangements with a dispensing doctor was made by a Primary Care Trust under the 2005 Regulations, and—

(i) that decision has been appealed before the appointed day, or

(ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2005 Regulations.

(4) Where, when granting an application which by virtue of paragraph 5 is finally determined in accordance with the 2012 Regulations, the NHSCB is required to consider under regulation 57(1) of the 2012 Regulations (gradual introduction of premises approval)—

(a) any postponement of the making of arrangements with a dispensing doctor arising out of that grant; or

(b) any limitation on the patients to whom a dispensing doctor is able to provide pharmaceutical services,

that consideration and its decision are to be in accordance with the 2012 Regulations.

(5) Where before the appointed day a Primary Care Trust is considering under regulation 57(1) of the 2012 Regulations—

(a) the postponement of the making of arrangements with a dispensing doctor; or

(b) any limitation on the patients to whom a dispensing doctor is able to provide pharmaceutical services,

that matter is to be dealt with by the NHSCB, in accordance with the 2012 Regulations.

(6) Where, under the 2012 Regulations—

(a) a decision relating to—

(i) postponement of the making of arrangements with a dispensing doctor, or

(ii) limiting the patients to whom a dispensing doctor is able to provide pharmaceutical services,

is made by virtue of sub-paragraph (1) or (2); or

(b) before the appointed day, a decision relating to postponement of the making of arrangements with a dispensing doctor, or to limiting the patients the patients to whom a dispensing doctor is able to provide pharmaceutical services, was made by a Primary Care Trust pursuant to the 2012 Regulations, and—

(i) that decision has been appealed before the appointed day, or

(ii) the time limit for bringing an appeal against that decision has not elapsed before the appointed day,

the arrangements for bringing an appeal in relation to that decision, and the determination of any appeal validly brought, are to be in accordance with the 2012 Regulations.

(7) Conditions imposed by virtue of—

(a) regulation 20(2) of the 2005 Regulations relating to postponement of the making of arrangements with a dispensing doctor; or

(b) regulation 57(1) of the 2012 Regulations relating to—

(i) the postponement of the making of arrangements with a dispensing doctor, or

(ii) limiting the patients to whom a dispensing doctor is able to provide pharmaceutical services,

whether or not imposed by virtue of this paragraph, continue to have effect as if imposed under these Regulations.

Giving effect to listing decisions: pharmaceutical lists and dispensing doctor lists

11.—(1) Where, before the appointed day or as a consequence of paragraphs 2 or 4, a person is entitled on the basis of a decision (whether by a Primary Care Trust or the NHSCB, or on appeal)—

(a) to be included in pharmaceutical list but has not been included in that list;

(b) to have listed in relation to their entry in a pharmaceutical list premises that have not been listed in relation to them;

(c) to be included in a dispensing doctor list but has not been included in that list;

(d) to have listed in relation to their entry in a dispensing doctor list premises that have not been listed in relation to them; or

(e) to have listed in relation to their entry in a dispensing doctor list an area that has not been listed in relation to them,

the arrangements for the listing of that person, those premises or that area, and the circumstances in which that decision lapses, are as set out in the 2005 Regulations.

(2) Where, before the appointed day or as a consequence of paragraphs 3 or 5, a person is entitled on the basis of a decision (whether by a Primary Care Trust or the NHSCB, or on appeal)—

(a) to be included in pharmaceutical list but has not been included in that list;

(b) to have listed in relation to their entry in a pharmaceutical list premises that have not been listed in relation to them;

(c) to be included in a dispensing doctor list but has not been included in that list;

(d) to have listed in relation to their entry in a dispensing doctor list premises that have not been listed in relation to them; or

(e) to have listed in relation to their entry in a dispensing doctor list an area that has not been listed in relation to them,

the arrangements for the listing of that person, those premises or that area, and the circumstances in which that decision lapses, are as set out in the 2012 Regulations.

Pharmaceutical lists, EPS lists and dispensing doctor lists: continuity of entries and decisions

12.—(1) Subject to sub-paragraph (2), the entries in pharmaceutical lists, EPS lists or dispensing doctor lists of Primary Care Trusts that are current immediately before the appointed day are to be current entries in the pharmaceutical lists, EPS lists and dispensing doctor lists maintained by the NHSCB on the appointed day under regulations 10 and 46 (albeit that the lists may be maintained by reference to different geographical areas).

(2) Where immediately before the appointed day a Primary Care Trust was required or entitled to give effect to a decision reached before the appointed day to change, remove or include an entry in a pharmaceutical list, EPS list or dispensing doctor list but had not done so, the NHSCB is required or entitled (unless the context requires otherwise) to give effect to that decision on or after the appointed day.

(3) If, as regards a decision to which paragraph (2) applies, before the appointed day—

(a) removal of an entry in a pharmaceutical list, EPS list or dispensing doctor list—

(i) would have resulted in removal of a person from a pharmaceutical list, EPS list or dispensing doctor list but no longer does so, or

(ii) would not have resulted in removal of a person from a pharmaceutical list, EPS list or dispensing doctor list but on or after the appointed day does so; or

(b) inclusion of an entry in a pharmaceutical list, EPS list or dispensing doctor list—

(i) would have required the new inclusion of a person in a pharmaceutical list, EPS list or dispensing doctor list but no longer does so, or

(ii) would not have required the new inclusion of a person in a pharmaceutical list, EPS list or dispensing doctor list but on or after the appointed day does so,

the NHSCB is nevertheless required or entitled (unless the context requires otherwise) to give effect to that decision, and in a manner that reflects the new arrangements for maintaining pharmaceutical lists, EPS lists and dispensing doctor lists, regardless of whether or not a different procedure would have been followed before the appointed day, had the nature of the listing change been as it is on or after the appointed day.

Service provision issues: NHS chemists

13.—(1) Subject to sub-paragraph (3), where by virtue of a transfer scheme or paragraph 12, NHSCB becomes engaged in any matter—

(a) arising under the 2005 Regulations before the appointed day; and

(b) relating to compliance with the terms of service of a chemist (whether compliance by the chemist or a Primary Care Trust),

that matter is to be resolved in accordance with the 2005 Regulations, and where applicable the SCAT Regulations and the Drug Tariff, and the continuity principles are to be applied accordingly.

(2) Subject to sub-paragraph (3), as regards the resolution of any matter—

(a) arising under the 2005 Regulations before the appointed day; and

(b) relating to changing or removing any entry in a pharmaceutical list by virtue the 2005 Regulations other than pursuant to an application under regulation 5(1), 40(1) or 54(2) of those Regulations (which relate to applications for inclusion in a pharmaceutical list, preliminary consent applications and temporary provision during a period of suspension) (paragraph 2 applies in those cases),

that matter is to be resolved in accordance with the 2005 Regulations, and where applicable the SCAT Regulations and the Drug Tariff, and the continuity principles are to be applied accordingly.

(3) Sub-paragraphs (1) and (2) are without prejudice to the ability of the NHSCB to commence proceedings under Chapter 6 of Part 7 of the 2006 Act (pharmaceutical services and local pharmaceutical services – disqualification) on or after the appointed day that relate to matters arising before 1st September 2012 (potentially together with matters arising between 1st September 2012 and the appointed day, or on or after the appointed day), but any decisions in such proceedings are be reached in accordance with the relevant provisions of these Regulations (and that Chapter 6).

(4) Subject to sub-paragraph (6), where by virtue of a transfer scheme or paragraph 12, NHSCB becomes engaged in any matter—

(a) arising under the 2012 Regulations before the appointed day; and

(b) relating to compliance with the terms of service of an NHS chemist (whether compliance by the NHS chemist or a Primary Care Trust),

that matter is to be resolved in accordance with the 2012 Regulations and where applicable the Drug Tariff, and the continuity principles are to be applied accordingly.

(5) Subject to sub-paragraph (6), as regards the resolution of any matter—

(a) arising under the 2012 Regulations before the appointed day; and

(b) relating to changing or removing any entry in a pharmaceutical list by virtue the 2012 Regulations other than pursuant to a routine or excepted application (paragraph 3 applies in those cases),

that matter is to be resolved in accordance with the 2012 Regulations and where applicable the Drug Tariff, and the continuity principles are to be applied accordingly.

(6) Sub-paragraphs (4) and (5) are without prejudice to the ability of the NHSCB—

(a) to commence proceedings under Chapter 6 of Part 7 of the 2006 Act on or after the appointed day that relate to matters arising before the appointed day (potentially together with matters arising on or after the appointed day), but any decisions in such proceedings are be reached in accordance with the relevant provisions of these Regulations (and that Chapter 6);

(b) to issue breach or remedial notices under Part 10 on or after the appointed day that relate to matters arising before the appointed day (potentially together with matters arising on or after the appointed day); or

(c) to take action under regulation 73 based on breach or remedial notices issued by a Primary Care Trust under Part 10 of the 2012 Regulations (performance related sanctions and market exit).

(7) Decisions and reviews of decisions in any proceedings commenced under Chapter 6 of Part 7 of the 2006 Act before the appointed day—

(a) which by virtue of paragraph 10 of Schedule 7 to the 2012 Regulations (transitional provisions – other continuing matters: NHS chemists) were being determined in accordance with the 2005 Regulations and that Chapter 6 are to continue to be so determined; or

(b) were being determined in accordance with Part 11 of the 2012 Regulations (enforcement, reviews and appeals relating to fitness matters) and that Chapter 6 are to continue to be so determined,

except in the case of a review of a decision where the request by the practitioner for a review is made on or after the appointed day (such a review is to be in accordance with the relevant provisions of these Regulations and that Chapter 6).

(8) Where a person was suspended from a pharmaceutical list by virtue of Chapter 6 of Part 7 of the 2006 Act before the appointed day—

(a) decisions on payments in respect of any part of the period of suspension that preceded 1st September 2012, and any appeals relating to those decisions, are to be in accordance with the 2005 Regulations and with the determinations under regulation 58 of the 2005 Regulations(**78**) (payments to suspended chemists) that were in force immediately before 1st September 2012; and

(b) decisions on payments in respect of any part of the period of suspension between 1st September 2012 and 31st March 2013 inclusive, and any appeals relating to those decisions, are to be in accordance with the 2012 Regulations and with the determinations under regulation 98 of the 2012 Regulations (payments to suspended chemists) that were in force immediately before the appointed day.

(9) Any direction or approval under, or that continues in effect under, a provision of Schedule 4 or 5 of the 2012 Regulations (terms of service of NHS pharmacists and terms of service of NHS appliance contractors) is to continue in effect as a direction or approval under the corresponding provision of Schedule 4 or 5 to these Regulations, unless or until it is amended or revoked by virtue of that corresponding provision or as a consequence of a decision under this paragraph.

(**78**) Prior to its revocation, regulation 58 was amended by S.I. 2006/3373.

Service provision issues: dispensing doctors

14.—(1) Where, by virtue of a transfer scheme or paragraph 12, the NHSCB becomes engaged in any matter—

(a) arising under the 2005 Regulations before the appointed day; and

(b) relating to compliance with the terms of service of a dispensing doctor (whether compliance by the dispensing doctor or a Primary Care Trust),

that matter is to be resolved in accordance with the 2005 Regulations, and where applicable the SCAT Regulations and directions under section 87 of the 2006 Act (GMS contracts: payments), and the continuity principles are to be applied accordingly.

(2) Where, by virtue of a transfer scheme or paragraph 12, the NHSCB becomes engaged in any matter arising under the 2012 Regulations before the appointed day and relating to compliance with the terms of service mentioned in regulation 47(2) of the 2012 Regulations (terms of service of dispensing doctors: general), the arrangements mentioned in regulation 47(2)(a) of those Regulations must provide for the matter to be resolved—

(a) justly;

(b) in a manner that effects an orderly transition from the scheme established by the 2012 Regulations to the scheme established by these Regulations; and

(c) if necessary or expedient in a manner that is inconsistent with these Regulations, or with regulations or directions under the 2006 Act that were in force immediately before the appointed day,

and the continuity principles are to be applied, and that matter is to be acted upon, accordingly.

(3) As regards the resolution of any matter—

(a) arising under the 2012 Regulations before the appointed day; and

(b) relating to changing or removing any entry in a dispensing doctor list by virtue the 2012 Regulations other than pursuant to an application under Part 8 of those Regulations (dispensing doctors) for premises approval or outline consent (paragraph 5 applies in those cases),

the matter is to be resolved in accordance with the 2012 Regulations, and the continuity principles are to be applied accordingly.

LPS schemes: replacement of Primary Care Trusts with the NHSCB and service provision issues

15.—(1) For the purposes of this paragraph, "the relevant transitional provisions" means—

(a) in the case of an LPS pilot scheme, paragraph 92(8) of Schedule 4 to the Health and Social Care Act 2012(**79**) (amendments of the National Health Service Act 2006); or

(b) in the case of LPS schemes that are not LPS pilot schemes, paragraph 93(6) of Schedule 4 to the Health and Social Care Act 2012.

(2) The changes to LPS schemes by virtue of the relevant transitional provisions take effect on the appointed day without the need for notices—

(a) in the case of LPS pilot schemes, under any terms of those schemes; or

(b) in the case of LPS schemes that are not LPS pilot schemes, under the terms of the schemes that give effect to paragraph 26 of Schedule 7.

(**79**) 2012 c. 7.

(3) Where, by virtue of a transfer scheme or the relevant transitional provisions, the NHSCB becomes engaged in any matter arising under an LPS scheme before the appointed day and relating to compliance with the terms of the LPS scheme (whether compliance by the LPS chemist or a Primary Care Trust)—

(a) that matter is to be resolved in accordance with the relevant provisions of the LPS scheme, and any applicable provisions of 2006 Regulations and the Drug Tariff; and

(b) the NHSCB may vary those terms, if necessary or expedient in a manner that is inconsistent with—

(i) the 2006 Regulations,

(ii) these Regulations, or

(iii) any directions under Chapter 2 of Part 7 of, and Schedule 11 to, the 2006 Act (which relate to local pharmaceutical services pilot schemes) that were in force immediately before the appointed day,

in order to provide for the matter to be resolved justly and in a manner that effects an orderly transition from the regulatory schemes for local pharmaceutical services established by the 2006 Regulations and directions under the 2006 Act to the regulatory schemes for local pharmaceutical services established by these Regulations and directions under the 2006 Act,

and the continuity principles are to be applied, and the matter is to be acted upon, accordingly.

Notification of LPS designations and completion of reviews

16.—(1) The making, varying or cancellation of a designation by a Primary Care Trust under Part 2 of the 2006 Regulations (designation) before the appointed day that was not, before the appointed day, notified in accordance with that Part is to be notified by the NHSCB as if it were made, varied or notified under Part 13 of these Regulations.

(2) Any review of a designation which was being undertaken by a Primary Care Trust before the appointed day but which was not completed before the appointed day is to be completed by the NHSCB.

The application of Group 12 of Schedule 8 to the Value Added Tax Act 1994

17. Pending amendment of Group 12 of Schedule 8 to the Value Added Tax Act 1994(**80**) (zero rating: drugs, medicines, aids for the handicapped, etc.) to take account of the coming into force of these Regulations, the definition of "relevant provision" in Note (2D) shall apply in relation to supplies on or after the appointed day as if for paragraph (j) there were substituted—

"(j) Part 8 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.".

(**80**) 1994 c.23; relevant amendments have been made to Group 12 by S.I. 2009/2972.

SCHEDULE 10

Regulation 120

Amendments and revocations

Amendment of the National Health Service (Charges for Drugs and Appliances) Regulations 2000

1. In regulation 2(1) of the Charges Regulations(**81**) (interpretation), for the definition of "Drug Tariff" substitute the following definition—

> ""Drug Tariff" has the same meaning as in the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;".

Revocation of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002

2. The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002(**82**) are revoked.

Revocation of the National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002

3. The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002(**83**) are revoked.

Revocation of the National Health Service (Pharmaceutical Services) Amendment Regulations 2005

4. The National Health Service (Pharmaceutical Services) Amendment Regulations 2005(**84**) are revoked.

Revocation of the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 and amendments to those Regulations

5.—(1) The National Health Service (Local Pharmaceutical Services etc.) Regulations(**85**) are revoked.

(2) The following provisions are revoked—

(a) regulation 4 of the National Health Service (Miscellaneous Amendments Relating to Independent Prescribing) Regulations 2006(**86**);

(b) regulation 8 of the National Health Service (Pharmaceutical Services) (Remuneration for Persons Providing Pharmaceutical Services) (Amendment) Regulations 2007(**87**);

(c) Part 2 of the National Health Service (Miscellaneous Amendments Relating to Community Pharmaceutical Services and Optometrist Prescribing) Regulations 2009(**88**);

(**81**) S.I. 2000/620; relevant amendments were made to regulation 2 by S.I. 2003/699, 2004/865, 2006/913, 2007/674 and 2012/1909.
(**82**) S.I. 2002/888.
(**83**) S.I. 2002/2016.
(**84**) S.I. 2005/1015.
(**85**) S.I. 2006/552.
(**86**) S.I. 2006/913.
(**87**) S.I. 2007/674.
(**88**) S.I. 2009/2205.

(d) paragraphs 134 to 136 of Schedule 3 to the Transfer of Tribunal Functions Order 2010(**89**); and

(e) paragraph 53 of Schedule 4 to the Pharmacy Order 2010(**90**).

Revocation of the National Health Service (Pharmaceutical Services) (Amendment) Regulations 2006

6. The National Health Service (Pharmaceutical Services) (Amendment) Regulations 2006(**91**) are revoked.

Amendments to the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009

7. In the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009(**92**)—

(a) in the definition of "relevant complaints procedure" in regulation 2 (interpretation), for paragraphs (i) to (iii) of sub-paragraph (a) substitute the following paragraphs—

"(i) paragraph 34 of Schedule 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;

(ia) paragraph 24 of Schedule 5 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;

(ii) paragraph 8 of Schedule 6 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013; or

(iii) paragraph 25 of Schedule 7 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013; or"; and

(b) paragraph 2 of the Schedule is revoked.

Revocation of the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) Amendment Regulations 2009

8. The National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) Amendment Regulations 2009(**93**) are revoked.

Revocation of the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) (Amendment) Regulations 2010

9. The National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) (Amendment) Regulations 2010(**94**) are revoked.

Revocation of the National Health Service (Local Pharmaceutical Services) Amendment Regulations 2012

10. The National Health Service (Local Pharmaceutical Services) Amendment Regulations 2012(**95**) are revoked.

(**89**) S.I. 2010/22.
(**90**) S.I. 2010/231.
(**91**) S.I. 2006/3373.
(**92**) S.I. 2009/309.
(**93**) S.I. 2009/599.
(**94**) S.I. 2010/914.
(**95**) S.I. 2012/1467.

Revocation of the National Health Service (Pharmaceutical Services) Regulations 2012 and of amendments to those Regulations

11.—(1) The following Regulations are revoked—

(a) the National Health Service (Pharmaceutical Services) Regulations 2012(**96**); and

(b) National Health Service (Pharmaceutical Services) Regulations 2012 (Amendment) Regulations 2012(**97**).

Amendment of the Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch Arrangements etc.) Regulations 2012

12. In regulation 12(3)(d) of the Local Authorities (Partnership Arrangements, Care Trusts, Public Health and Local Healthwatch Arrangements etc.) Regulations 2012(**98**) (National Health Service payments by local authorities to specified NHS bodies in respect of prescribed functions) for "National Health Service (Pharmaceutical Services) Regulations 2012" substitute "National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013".

(**96**) S.I. 2012/1909.
(**97**) S.I. 2012/2371.
(**98**) S.I. 2012/3094.