Department of Health

Market entry by means of pharmaceutical needs assessments - Annexes

November 2013

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Chairman	Paul Burns
NHS Employers	Taryn Harding
	Kelvin Rowland-Jones
	David Thorne
Patients' Association	
	Katherine Murphy
Pharmaceutical Services Negotiating Committee	
	Sue Sharpe
	Steve Lutener
	Gary Warner
Local Government Association/Health and Wellbeing Boards	
	Alyson Morley
	Sarah Billington
	Graham Jones
General Practitioners' Committee of the British Medical Association (BMA)	
	Dr Russell Walshaw
British Healthcare Trades Association	
	Ray Hodgkinson

NHS Commissioning Board Authority

Sam Illingworth

Primary Care Contracting

Charlotte Goodson

Organisations receiving papers

Which? – Helen McCallum

Observer Matthew Isom (until July 2012)

Catharina Öhman-Smith (from August 2012)

Secretariat to the Advisory Group

Peter Dunlevy

Gillian Farnfield

Catriona Patterson

Charlotte Bone

Department of Health

Susan Grieve

Hamid Butt

Theresa Prendergast

Department of Health Lead Sponsor

Jeannette Howe

Departmental lawyer

Michael Adam

Annex B – Glossary of defined terms and phrases

Term or phrase	Definition as per Regulation 2	Explanation
Best estimate	In the context of the location of proposed appliance contractor premises or pharmacy premises mentioned in a routine application, is to be construed in accordance with paragraph 1(10) of Schedule 2.	Where the applicant is not able to identify the address for the proposed premises, they are required to describe the proposed location, for example 10-20 High Street. NHS England must be satisfied that it is the best description the applicant can give at the time the application is submitted and that if the actual premises fall within any of the potential locations within the range given, that NHS England would have to the same conclusion on the application. An example is given in chapters 5 to 9.

Breach notice	Is to be construed in accordance with regulation 71(1).	Where a pharmacy contractor or DAC is in breach of their terms of service and the breach is not capable of remedy, NHS England may issue a notice requiring them not to repeat the breach. More information on this can be found in the performance sanctions guidance.
Change of ownership application	Means an application under regulation 26.	See chapter 12 for more information.
Controlled localities/controlled locality	Means an area that is a controlled locality by virtue of regulation 36(1) or is determined to be so in accordance with regulation 36(2).	See chapter 14 for more information.
Core opening hours	Is to be construed, as the context requires, in accordance with paragraph 23(2) of Schedule 4 or paragraph 13(2) of Schedule 5, or both.	Pharmacies are required to be open for 40 hours per week, unless they were approved under Regulation 13(1)(b) of the 2005 Regulations in which case they are required to open for 100 hours per week. DACs are required to be open for not less than 30 hours per week.
Directed services	Means additional pharmaceutical services provided in accordance with directions under section 127 of the 2006 Act.	These are advanced and enhanced services as set out in Directions.

Dispensing doctor(s)	Is to be construed in accordance with regulation 46(1).	These are providers of primary medical services who provide pharmaceutical services from medical practice premises in the area of the relevant local authority Health and Wellbeing Board (HWB); and general practitioners who are not providers of primary medical services but who provide pharmaceutical services from medical practice premises in the area of the relevant HWB.
Distance selling premises	Listed chemist premises, or potential pharmacy premises, at which essential services are or are to be provided but the means of providing those services are such that all persons receiving those services do so otherwise than at those premises.	These premises could have been approved under the 2005 Regulations in which case they could be pharmacies or DACs. Under the 2012 and 2013 Regulations only pharmacy contractors may apply to provide services from distance selling premises. See chapter 11 for more information.
Emergencies requiring the flexible provision of pharmaceutical services	Has the meaning given in regulation 29(4).	It may be necessary for the Secretary of State for Health to declare an emergency as a result of which NHS England has additional flexibilities within the 2013 Regulations to ensure the provision of pharmaceutical services.

Enhanced services	Means the additional pharmaceutical services that are referred to in direction 4 of the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013.	
Essential services	Except in the context of the definition of "distance selling premises", is to be construed in accordance with paragraph 3 of Schedule 4.	
Excepted application(s)	Means an application to which section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) do not apply by virtue of any provision of Part 4.	See chapters 10 to 13 for further information.
Final outcome	Where reference is made in these Regulations to proceedings (but not investigations) reaching their final outcome- (a) in relation to any proceedings where there are rights of appeal under these Regulations either to the Secretary of State or the First Tier Tribunal (FTT), means the outcome of the proceedings- (i) once the period for bringing an appeal has expired without an appeal being brought; or (ii) if an appeal is brought in accordance with those rights, once the Secretary of State or the FTT has determined the appeal,	In the case of NHSCB decisions, the final outcome date is the date the appeal rights elapse (assuming no appeal). In the case of FHSAU and FTT decisions, it is the date of the actual decision, not the date the decision is communicated.

	whether or not the matter is thereafter appealed through the courts; (b) in relation to any other proceedings where there are rights of appeal (but not including appeals through the courts against decisions referred to in sub-paragraph (a)(ii)), means the outcome of the proceedings- (i) once the period for bringing an appeal has expired without an appeal being brought; or (ii) if an appeal is brought in accordance with those rights, once those rights have been exhausted.	
Listed chemist premises	Is to be construed in accordance with regulation 10(3)(a).	The address of the premises in the area of NHS England at which the person has undertaken to provide services.
Listed dispensing premises	Is to be construed in accordance with regulation 46(2)(a)(i).	Any premises in the area of the relevant HWB for which a listed dispensing doctor has premises approval.

Medical practice premises	(a) in relation to a provider of primary medical services, premises which are identified in the provider's arrangements with NHS England as the practice premises from which primary medical services are to be provided during core hours to patients on the provider's patient list; or (b) in relation to a person on a dispensing doctor list who is not a provider of primary medical services— (i) in the case of a general practitioner who performs services on behalf of a provider of primary medical services, the practice premises from which primary medical services are to be provided during core hours to patients on the provider's patient list, or (ii) in the case of a general practitioner who performs services on behalf of a PCTMS [**DN: ?]** practice, the practice premises that NHS England has nominated as the practice premises for that practice.	
NHS chemist	Means an NHS appliance contractor or an NHS pharmacist	
NHS pharmacist	Means a person included in a pharmaceutical list of the type referred to in regulation 10(2)(a).	Pharmacy contractors

Notice	Except in the context of a period of notice, means a notice or notification in writing, which may (except in the context of a notice to be exhibited) be in an electronic form, and "notify" is to be construed accordingly.	
Notice of commencement	Means a notice given, or to be given, under paragraph 34(2) of Schedule 2.	At least 14 days before a pharmacy contractor or DAC begins to provide pharmaceutical services from new premises they must notify NHS England of their intentions. This is the notice of commencement and must contain certain information. Further information can be found in the chapters.
Notifiable application	Is to be construed in accordance with paragraph 18 of Schedule 2.	Notifiable applications are those that NHS England must send to certain persons before coming to a decision on them: • all routine applications are to be notified (chapters 5 to 9), • relocations that do not result in result in significant change (chapter 10), • distance selling premises (chapter 11), • joint change of ownership and relocation (chapter 13).

Notification	Except in the context of a period of notice, means a notice or notification in writing, which may (except in the context of a notice to be exhibited) be in an electronic form, and "notify" is to be construed accordingly.	
Notify	Except in the context of a period of notice, means a notice or notification in writing, which may (except in the context of a notice to be exhibited) be in an electronic form, and "notify" is to be construed accordingly.	
Outline consent	In the context of— (c) an application for outline consent, is to be construed in accordance with regulation 51(1)(a); or (d) of a subsisting outline consent, means outline consent granted under these Regulations or the 2005 Regulations.	If a doctor wishes to be able to provide pharmaceutical services to patients living in an area to which they currently do not provide such services, they are required to apply to NHS England for approval to do so. As apart of the application they must describe the area. If granted they are given outline consent to provide pharmaceutical services to that area.

Outstanding pharmacy application	Has the meaning given in regulation 53(7): (a) an application which has not yet reached its final outcome— (i) for inclusion in a pharmaceutical list (not necessarily that of the relevant HWB), or (ii) from a person included in a pharmaceutical list— (aa) to relocate to different premises in the area of the relevant HWB, or (bb) to open, within the area of that HWB, additional premises from which to provide pharmaceutical services, where the applicant is seeking the listing of pharmacy premises other than distance selling premises; or (b) circumstances where an application of the type mentioned in paragraph (a) has been granted, and—	Further information and an example are given in chapter 15. In summary they are applications for pharmacy premises: • which NHS England has not yet determined, or • which have been granted but the premises have yet to be included in the pharmaceutical list.

	(i) the provision of pharmaceutical services from the premises for which listing was sought has not yet commenced, and (ii) the grant has not yet lapsed.	
Pharmaceutical services	In the context of— (a) Part 2 and Schedule 1, means the pharmaceutical services to which a pharmaceutical needs assessment must relate by virtue of regulation 3(2); and (b) arrangements made or to be made for the provision of pharmaceutical services by medical practitioner, means the dispensing of drugs and appliances but not pharmaceutical services as mentioned in section 132(7)(a) or (b) of the 2006 Act (persons authorised to provide pharmaceutical services).	There are two definitions of pharmaceutical services used within the 2013 Regulations. One definition is used for Part 2 and Schedule 1 (regulations relating to the PNA) and includes the services provided by pharmacy contractors, DACs and dispensing doctors that are described in Schedules 4, 5 and 6 respectively. It also includes those described in Directions. The second definition is used for all other Parts and Schedules and is narrower as it relates to only those services described in Schedules 4 to 6.

Pharmacy premises	Means listed chemist premises (or in the context of an applicant seeking the listing of premises, proposed listed chemist premises) of an NHS pharmacist.	
Pharmacy procedures	Are the procedures required by section 72A(3) of the 1968 Act (the responsible pharmacist).	
Premises approval	In the context of— (a) an application for premises approval, is to be construed in accordance with regulation 51(1)(b); or (b) a subsisting premises approval, means premises approval granted under these Regulations, the 2012 Regulations or the 2005 Regulations.	Where a doctor wishes to provide pharmaceutical services they must have outline consent and premises approval. See chapter 15 for further information.
Relevant list	Means— (a) a pharmaceutical list or an equivalent list maintained by another primary care organisation; or (b) a list maintained by NHS England or another primary care organisation of approved performers or providers of primary medical, dental or ophthalmic services.	

Relevant NHS services	Means pharmaceutical services, local pharmaceutical services, dispensing services and primary medical services.	
Remedial notice	Is to be construed in accordance with regulation 70(1).	Where a pharmacy contractor or DAC is in breach of their terms of service NHS England and the breach is capable of remedy, NHS England may issue a notice requiring them not to put right the breach. More information on this can be found in the performance sanctions guidance.
Reserved location(s)	Means, except in the context of making a determination that an area is a reserved location under these Regulations, an area determined as such under— (c) regulation 41(2) or 42(1) of the 2013 and 2012 Regulations; or (d) regulation 35 of the 2005 Regulations (pharmaceutical services in reserved locations);	If within a 1.6 kilometre radius of the proposed pharmacy premises: (a) the number of individuals residing in that area who are on a patient list (which may be an aggregate number of patients on more than one patient list) is less than 2,750; and (b) NHS England is satisfied that if pharmaceutical services were provided at the reserved location, the use of those services would neither be similar

		to, nor be greater than, the use that might be expected if the number of individuals residing in that area who are on a patient list were 2,750 or more; NHS England may define it to be a reserved location. See chapter 14 for more information.
Routine application(s)	Is to be construed in accordance with regulation 12.	Routine applications are those which offer to meet an identified need within the PNA, or offer to provide improvements or better access that are identified within the PNA. They may also offer unforeseen benefits. See chapters 5 to 9 for further information.
Supplementary opening hours	Is to be construed, as the context requires, in accordance with paragraph 23(3) of Schedule 4 or paragraph 13(4)(a) of Schedule 5, or both.	These are opening hours which are over and above the core opening hours.

Annex C – Section 129 of the National Health Service Act 2006

(1) Regulations must provide for securing that arrangements made by the Board under section 126 will –

(a) enable persons for whom drugs, medicines or appliances mentioned in that section are ordered as there mentioned to receive them from persons with whom such arrangements have been made, and

(b) ensure the provision of services prescribed under subsection (3)(e) of that section by persons with whom such arrangements have been made.

(2) The regulations must include provision—

(a) for the preparation and publication by the Board of lists of persons, other than medical practitioners and dental practitioners, who undertake to provide pharmaceutical services from premises in England,

(b) that an application to the Board for inclusion in a pharmaceutical list must be made in the prescribed manner and must state—

(i) the services which the applicant will undertake to provide and, if they consist of or include the supply of appliances, which appliances he will undertake to supply, and

(ii) the premises from which he will undertake to provide those services,

(c) that, except in prescribed cases (which may, in particular, include

cases of applications for the provision only of services falling within subsection (7))—

(i) an application for inclusion in a pharmaceutical list by a person not already included, and

(ii) an application by a person already included in a pharmaceutical list for inclusion also in respect of services or premises other than those already listed in relation to him,

may be granted only if the Board is satisfied as mentioned in subsection (2A).

(d) for the removal of an entry in respect of premises from a pharmaceutical list if it has been determined in the prescribed manner that the person to whom the entry relates—

(i) has never provided from those premises, or

(ii) has ceased to provide from them,

the services, or any of the services, which he is listed as undertaking to provide from them.

(2A) The Board is satisfied as mentioned in this subsection if, having regard to the needs statement for the relevant area and to any matters prescribed by the Secretary of State in the regulations, it is satisfied that to grant the application would-

(a) meet a need in that area for the services or some of the services specified in the application, or

(b) secure improvements, or better access, to pharmaceutical services in that area.

(2B) In subsection (2A), “relevant area”, in relation to a needs statement, is the area of the Health and Well-being Board which includes the premises from which the application states that the applicant will undertake to provide services.

(2C) In relation to cases where the Board is satisfied as mentioned in subsection (2A), the regulations may make provision as to-

(a) the manner in which the Board is to determine whether to grant the application,

(b) matters which the Board must or must not take into account for the purpose of determining whether to grant the application.

(2ZA) The Board may not include the Secretary of State, or such other persons as the regulations may prescribe, in a list prepared for the purposes of provision under subsection (2)(a).

(2ZB) Regulations under subsection (2)(a) may, in particular, require a list of persons to be prepared by reference to the area in which the premises from which the services are provided are situated (and regulations imposing that requirement must prescribe the description of area by reference to which the list is to be prepared).

(3) The regulations may prescribe the extent to which the provision of LP services (within the meaning given by paragraph 1 of Schedule 12) must be taken into account in determining whether to grant an application for inclusion in a pharmaceutical list.

(3A) The regulations may prescribe circumstances in which two or more applications referred to in subsection (2)(c)(i) or (ii) may be considered together by the Board.

(4) The regulations may make the provision for the Board to take into account prescribed matters in the case where—

(a) [intentionally blank]

(b) two or more applications referred to in subsection (2)(c)(i) or (ii**)** are considered together by the Board, and

(c) the Board would be satisfied as mentioned in subsection (2A) in relation to each application taken on its own, but is not so satisfied in relation to all of them taken together.

(4A) Regulations under subsection (4) may in particular make the provision mentioned in subsection (5), with or without modifications.

(5) The provision mentioned in this subsection is provision for the Board, in determining which application (or applications) to grant, to take into account any proposals specified in the applications in relation to the sale or supply at the premises in question, otherwise than by way of pharmaceutical services or in accordance with a private prescription, of—

(a) drugs and medicines, and

(b) other products for, or advice in relation to, the prevention, diagnosis, monitoring or treatment of illness or handicap, or the promotion or protection of health.

(6) The regulations may include provision—

(za) for the circumstances and manner in which the Board may invite applications for inclusion in a pharmaceutical list

(a) that an application to the Board may be granted in respect of some only of the services specified in it,

(b) that an application to the Board relating to services of a prescribed description may be granted only if it appears to the Board that the applicant has satisfied such conditions with regard to the provision of those services as may be prescribed,

(c) that an application to the Board by a person who qualified to have his name registered in the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007 by virtue of a qualification in pharmacy awarded in an EEA state other than the United Kingdom, or in Switzerland, may not be granted unless the applicant satisfies the Board that he has the knowledge of English which, in the interest of himself and persons making use of the services to which the application relates, is necessary for the provision of pharmaceutical services,

(d) that the inclusion of a person in a pharmaceutical list in pursuance of an application to the Board may be for a fixed period,

(e) that, where the premises from which an application states that the applicant will undertake to provide services are in an area of a prescribed description, the applicant may not be included in the pharmaceutical list unless his inclusion is approved by reference to prescribed criteria by the Board in whose area those premises are situated,

(f) that the Board may give its approval subject to conditions,

(g) as to other grounds on which the Board-

(i) may, or must, refuse to grant an application (including grounds corresponding to the conditions referred to in section 151(2), (3) or (4) as read with section 153), and

(ii) may, or must remove a person or an entry in respect of premises from a pharmaceutical list.

(h) as to information which must be supplied to the Board by a person included, or seeking inclusion, in a pharmaceutical list (or by arrangement with him),

(i) for the supply to the Board by an individual—

(i) who is included, or seeking inclusion, in a pharmaceutical list, or

(ii) who is a member of the body of persons controlling a body corporate included, or seeking inclusion, in a pharmaceutical list,

of a criminal conviction certificate under section 112 of the Police Act 1997 (c. 50), a criminal record certificate under section 113 of that Act or an enhanced criminal record certificate under section 115 of that Act,

(j) for grounds on which the Board may defer a decision whether or not to grant an application,

(k) for the disclosure by the Board, to prescribed persons or persons of prescribed descriptions, of information of a prescribed description about applicants for inclusion in a pharmaceutical list, and refusals by the Board to grant such applications,

(l) as to criteria to be applied in making decisions under the regulations (other than decisions required by virtue of paragraph (e)),

(m) as to the making of declarations about—

(i) financial interests,

(ii) gifts above a prescribed value, and

(iii) other benefits received.

(7) A service falls within this subsection if the means of providing it is such that the person receiving it does so otherwise than at the premises from which it is provided.

(8) The regulations may, in respect of services falling within subsection (7), include provision—

(a) requiring persons to be approved for the purposes of providing such services, or

(b) requiring the Board to make the grant of an application subject to prescribed conditions.

(9) The approval mentioned in subsection (8)(a) is approval by the Secretary of State or such other person as may be specified in the regulations, in accordance with criteria to be specified in or determined under the regulations (whether by the Secretary of State or by another person so specified).

(10) Before making regulations by virtue of subsection (6)(m), the Secretary of State must consult such organisations as he considers appropriate appearing to him to represent persons providing pharmaceutical services.

(10A) The Board must give reasons for decisions made by virtue of this section.

(10B) In this section a needs statement means the statement required by section 128A(1)(b) as most recently published by the relevant Health and Well-being Board.

(11) In this Act a “pharmaceutical list” means a list published in accordance with regulations made under subsection (2)(a).

Annex D – What is meant by a Change of Ownership

See Chapter 12 of the market entry guidance.

This is likely to be clear-cut when a small independent contractor sells his business to someone of similar status. However, there are circumstances where the transfer of ownership may be far less clear-cut. Each case must be considered on its circumstances and the facts applying at the time.

What should be borne in mind is that the object of requiring a change of ownership application when ownership of a pharmacy is transferred is to ensure that the provision of pharmaceutical services does not fall into the hands of unregistered practitioners or persons who are not lawfully conducting a retail pharmacy business.

In effect, a change of ownership application may not be required where a retail pharmaceutical business (i.e. a limited liability company) takes over another which retains its identity (i.e. name, board of management etc.) as the subsidiary of the parent company and retains separate legal personality. This should usually be the case where all that happens is that ownership of the issued share capital in a limited company transfers to the new company. However, where a company has been taken over and it loses its identity by becoming a division of the company taking it over, a change of ownership application is required whether or not the company which takes it over is a retail pharmaceutical company. If there are doubts in a particular case, it may be advisable to seek legal advice.

Annex E – Prejudice

As noted in Chapter 14, the Board has the power to refuse a *routine application* where the proposed premises are in a *controlled locality* to the extent that granting it would prejudice the proper provision of *relevant NHS services* in the relevant HWB area or in the area of a neighbouring HWB.

The Regulations do not provide any further definition of the concept of prejudice. In general, prejudice means that nothing must be done which would compromise the ability of people in any *controlled locality* to access primary medical, pharmaceutical services and LPS, at the level of service which they are right to expect.

In the 1996 case R –v- North Yorkshire FHSA ex parte Dr. Wilson and Partners Justice Carnwath said "It is not part of the scheme of those regulations or indeed of the statute that pharmaceutical services should be relied upon to provide financial underpinning for medical services which are intended to be financed in other ways".

A mere reduction in the total level of service provided by a particular pharmacist or a doctor is not of itself prejudice; prejudice arises where the service that people can rightly expect to be provided by the NHS has in some respect to cease or otherwise be curtailed or withdrawn without proper substitution in the area.

In practice, the existence of prejudice involves, to a greater or lesser extent, making a judgment about events that will occur in the future. Inevitably, therefore, it can often be extremely difficult to judge whether or not there will be prejudice.

The burden of proof is on the party alleging that prejudice will occur.

Each case will, therefore, turn very much on its own particular facts. In considering questions of prejudice, it is important that decision-takers focus only on those services which have to be provided within the terms of service of NHS primary medical and pharmaceutical services provision. The fact that non-NHS services or NHS services provided above the standard level set by the terms of service may be curtailed should not be regarded as relevant.

Example

A *routine application* is submitted to open a pharmacy within a village which is situated in a *controlled locality*. There is a GP practice within the same village that provides pharmaceutical services to its patients living within the *controlled locality* more than 1.6 km from a pharmacy.

The Board does a GP registered patient count on the day it receives the application and after checking that all the relevant information and documentation has been received it *notifies* the application to interested parties.

The GP practice responds to the *notification* saying that if the application was approved then the practice would have to close as the loss of income for those dispensing patients living within 1.6 km of the proposed premises. No further information is provided to substantiate this statement.

When it comes to determine the application, the Board notes the practice's statement but in the absence of any evidence from either the practice or any other interested party it concludes that there would be no prejudice to the proper provision of *pharmaceutical services*.

Annex F – Charging for applications

Background

1. The NHS Act 2006 enables the Secretary of State to give Directions to NHS England requiring it to charge a fee for pharmaceutical applications (section 131). The National Health Services Pharmaceutical Services (Fees for Applications) Directions 2013, specify the types of application for which a fee will be payable and the levels of such fees.

2. **Paragraph 12 of Schedule 2 to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013** specifies that where NHS England charges a fee under the Directions in relation to a routine or excepted application, that application is not valid unless the appropriate fee has been paid. An applicant must send that fee with the application before NHS England begins to process the application. NHS England should only begin formal consideration of the application once it is satisfied that payment has been received and cleared. In this respect, a missing fee is like missing information or documentation that NHS England has to chase up in accordance with paragraph 11 of Schedule 2. If an applicant pays by cheque, NHS England will in practice need to allow adequate time for the cheque to be cleared through their finance offices and bank before they can start formal consideration of the application.

3. **Direction 3(1)(b)** states that fees are not payable in the case of the following excepted applications:

    - regulation 27 applications - temporary listings arising out of suspensions
    - regulation 28 applications - persons exercising a right of return to a pharmaceutical list
    - regulation 29 applications - emergencies requiring the flexible provision of pharmaceutical services.

4. Direction 3 further provides that where NHS England invites routine or excepted applications, it can decide whether to accept a fee for the application or waive that fee (**Direction 3(1)(a)**).

5. The Department will consult as appropriate on any further revisions to fees before they are implemented.

What fees are payable

6. The range of fees that are payable from 1 April 2013 are set out in Table 1 below and in **Direction 3(2)**. These fees are payable irrespective of the location to which the application relates (i.e. there is no differential fee payable because an area is particularly well off or socially deprived). The fees are set at levels, which represent a contribution towards NHS costs and do not represent full recovery of NHS costs. The fee is not refundable whether the application is successful or not, having regard to the fact that NHS England will incur costs in all cases in determining an application whatever its outcome. Nor, because of the same considerations, is the fee refundable if an applicant subsequently decides to withdraw an application before NHS England has reached a decision on it.

The meaning of duplicate and subsequent applications

7. A duplicate application is where an applicant submits a second application that is of the same type as an earlier application and contains information relating to:

- the premises and opening hours, and
- the provision of *pharmaceutical services* or *directed services*

which is the same or similar to the information contained in the first application, within 180 days of the first application being finally determined (be that by NHS England or, on appeal, by the NHS Litigation Authority's Family Health Services Appeal Unit).

This applies to all *routine* and *distance-selling* applications **made under the 2012 or 2013 Regulations**.

8. A higher fee is charged for duplicate applications. This is to deter the very few applicants who repeatedly waste NHS time and resources where there is no prospect of an application being granted. Where a third subsequent application which repeats the same or similar information is received within 180 days of the duplicate application being finally determined , the fee is set at a higher level **(Direction 3(3) and (4))**. The application must be for premises located in the same locality [**DN: locality within the HWB area or whole HWB area?]** (having regard to how the HWB has identified different localities in its area in its PNA) (**Direction 3(5)**).

9. However, these increased fees do not apply where applicants who, having had a previous application rejected, submit a revised application which addresses NHS England's reasons for rejecting the original application. This is to avoid the original applicant being disadvantaged by a competitor applicant seeking to gain a commercial advantage over the original applicant. NHS England will, therefore, need to distinguish carefully where such circumstances apply. Nor do the higher fees apply where a contractor submits a further application on expiry of the period of grant of a previous successful application.

10. The higher level of fees also do not apply where NHS England requests the provision of missing information, documentation or undertakings under paragraph 11 or 12 of Schedule 1 of the NHS (Pharmaceutical Services) Regulations 2013.

Table 1: Fee levels (as set out in the National Health Services Pharmaceutical Services (Fees for Applications) Directions 2013)

Type of application (including where the applicant applies for preliminary consent)	Fee level (£)
Routine application by a contractor who wishes to be included on the pharmaceutical list for the relevant Health and Wellbeing Board (HWB) area for the provision of services in England (current/future needs; improvements or better access; unforeseen benefits; relocation of premises that do result in significant change; applications from those already on the list in respect of additional premises)	**750**
Excepted application for distance-selling premises	**750**
Excepted application from applicant already on the a pharmaceutical list that relates to enhanced services only	**100**
Relocation of premises that do not result in a significant change to pharmaceutical services provision	**250**
Change of ownership (where the applicant is already on a pharmaceutical list)	**150**
Change of ownership (where the applicant is not already on a pharmaceutical list)	**250**
Change of ownership and relocation of premises that do not result in a significant change to pharmaceutical services provision (where the applicant is already on a pharmaceutical list)	**250**
Change of ownership and relocation of premises that do not result in a significant change to pharmaceutical services provision (where the applicant is not already on a pharmaceutical list)	**350**
Duplicate application within 180 days of an original application failing (routine or distance-selling exception applications)	**1,500**
Subsequent application within 180 days of a duplicate application failing (routine or distance-selling exception applications)	**3,000**

11. No fees or additional fees are payable in respect of the following types of applications and procedures:

- potentially, where NHS England invites applications (for example by advertising or circulating contractors). NHS England has a discretion not to charge a fee in these circumstances;

- where a pharmaceutical contractor, previously suspended from a pharmaceutical list, seeks a review of a suspension decision (Section 157 of the 2006 Act read with **regulations 84 and 85**) (no application, within the terms of the Regulations, needs to be submitted);

- where a temporary chemist applies to provide services during a period of a contractor's suspension from a pharmaceutical list (**Regulation 27**);

- where a local pharmaceutical contractor exercises a right to return to a pharmaceutical list (**Regulation 28**) as the contractor is exercising an existing right;

- applications relating to emergencies requiring the flexible provision of pharmaceutical services (**Regulation 29**);

- where the Board is asked by a Local Pharmaceutical or Medical Committee, or decides of its own volition, to determine or to review its decision whether or not an area is rural in character (**Regulation 36**) since determination of rurality is a secondary matter to determination of an application;

- where NHS England determines whether a particular part of a rural area should be designated a "reserved location" or not (**Regulation 41**) as this may or may not be a direct consequence of an application being received for which a fee has already been paid;

- where NHS England considers whether or not an application will prejudice the provision of primary medical, pharmaceutical or local pharmaceutical services in a given area (**Regulation 44**) since this will be included as part of NHS England's overall deliberations and not a separate application;

- where a dispensing doctor applies for outline consent to provide dispensing services to patients in controlled "rural" areas (**Regulation 51**) as the "market entry" test and exceptions etc do not apply to such applications which are made at the request of the patient;

- where a dispensing doctor applies for approval of premises, to amalgamate with another practice or to relocate their premises (Part 8 of the 2013 Regulations) as no fee is payable for contractors applying to provide primary medical services;

- notifications of premises where a best estimate was given in the original application (**Paragraph 31, Schedule 2**); and

- notifications of changes to premises specified in an application after it is granted but before the premises are included in a pharmaceutical list (**Paragraph 32, Schedule 2**)

(**Direction 3(1)(b)**)

Banking and clearing of fees for applications

12. NHS England is strongly advised to publicise how fees are to be paid. This could be done via their website and should include the following information:

- the preferred payment method e.g. cheque or bank transfers (BACs payments);
- to whom cheques should be made payable;
- to whom cheques should be sent; and
- if payment is made by bank transfer, the payment reference that should be given.

13. When submitting an application that attracts a fee, applicants must ensure that they either include a cheque or make a bank transfer at the same time. They must also ensure they have sufficient funds for the payment to clear.

14. Before beginning the process of formal consideration of an application that attracts a fee, NHS England must be satisfied that payment has been received. If not only the fee, but also information, documentation or undertakings are missing, NHS England can raise the question of the missing fee with the applicant at the same time as raising the question of the missing information, documentation or undertakings with them.

15. Applications should not be delayed unnecessarily because of delays at the Board in processing cheques.

Examples

Example 1

Applicant A wants to open a NHS pharmacy in the Chumley HWB area. They read the HWB's PNA which outlines a future need for a pharmacy near a health centre which is planned to be built on brown belt land just outside Chumley. It is not thought that the centre will open for at least 18 months – the disused factory has not even been demolished. They make a routine application and send a fee of **£750**. NHS England grants the application on 31st July.

When the grant period ends on 30th January (assuming it was not a conditional grant, having regard to paragraph 33 of Schedule 2), Applicant A sends in a further, duplicate, application on the same day for the same site which has now been cleared but with little further progress. Applicant A needs to send NHS England **£750** (whilst this is a duplicate application, NHS England approved the previous application and therefore the higher fee for duplicate applications is not applicable). Again, NHS England grants the second application on 25th May. Again, the consent period ends without them opening on 24th November.

The applicant sends in a third application on the same day, as the health centre is now due to open in six month's time. They need to send **£750** (see above).

Applicant B also applies at the same time as Applicant A to open on the brown belt site. They send in the correct fee of **£750.** Applicant B is, however, unsuccessful because of insufficient evidence regarding the fitness to practise declarations and references provided by the directors and superintendent pharmacist of the company. NHS England refuses Applicant B on 31st July. They do not appeal.

Knowing that Applicant A's original grant is expiring the following January, Applicant B submits a duplicate application on 20th January just before Applicant A submits their second application for the same locality. The correct fee payable by Applicant B in this instance is **£1,500** (the applicant's first application was refused, it is "the same as or similar" to the first application and has been made within 180 days of that first application being refused), unless the Applicant B has included sufficient evidence regarding the fitness to practise declarations and references provided by the directors and superintendent pharmacist of the company. However, Applicant B has not, and NHS England remains concerned as before and rejects this second application on 25th May. Applicant B again does not appeal but makes a third application on 23rd November just before Applicant A, but still with the same problems with the application. The fee payable by Applicant B is now **£3,000** (reasons as above).

Example 2

Applicant K is a sole trader and sees from Chumley HWB's PNA that there is a need for pharmacy in a run-down housing estate in one of their market towns. The pharmaceutical needs assessment has specified that applicants must agree to provide a minor ailment service and for the pharmacist to be a supplementary prescriber to support this service. The applicant applies to NHS England and sends a fee of **£750**.

On the application form, they say they are about to enrol on a course to become a supplementary prescriber and the next course is due to run in three months' time. NHS England rejects the application. Later that year, Applicant K is accredited as a supplementary prescriber and sends in a further application together with their certificate. They pay a fee of **£750** (the applicant has taken the necessary steps to meet NHS England's reasons for the original refusal and NHS England has received new information directly relevant to the application and decision-making). Whilst directly comparable, this second application is not to be treated as "the same as or similar" to the first application. NHS England approves this application.

After the pharmacy has been open for a year, applicant K applies to NHS England to relocate a few doors away from their existing premises to better premises which would result in no significant change. They send the appropriate fee of **£250**. NHS England checks the application and notices that the applicant has not indicated whether the new premises are constructed or in their possession. NHS England requests this missing information which the applicant duly provides but he does not pay a further fee as this was an administrative or minor technical error.