



**A Guide to
English NHS Pharmacy
Market Entry Applications**

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Introduction

Obtaining a pharmacy contract or opposing an application that would impact on an existing pharmacy business is not a straightforward process. The regulations and the law are complicated. What is more, rights can easily be lost if specific requirements are not met, such as the right to appeal.

I act for both applicants and interested parties and have been involved in key developments and changes in the law for almost 20 years and continue to lead the way with up-to-the-minute expertise and my active participation in the Users Group of NHS Resolution.

As a law firm regulated by the Solicitors Regulation Authority, we provide our clients with:

- The highest professional standards
- Unrivalled experience
- Unique legal expertise
- Clear advice without legalese or jargon
- The confidence that we will act in our client's best interests
- Representation and advocacy at hearings
- Fee estimates (and we are also happy to discuss fixed fee arrangements)

This guide is intended as an overview of market entry applications. It deals with the most common questions that my clients ask me when they are considering making an application or have received notification of an application in their local area.



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Market Entry and Pharmaceutical Needs Assessments

What is market entry and what is an NHS pharmacy contract?

NHS England is required to maintain lists for every Health and Wellbeing Board (HWB) area. Health and Wellbeing Boards cover local authority areas. These lists contain the names and addresses of companies and pharmacists who provide NHS pharmaceutical services.

Only someone who is in a pharmaceutical list can provide pharmaceutical services under the NHS (such as dispensing an NHS GP prescription) and be paid for doing so. Being included in a pharmaceutical list is often referred to as having an NHS contract.

The term “market entry” refers to being entered in a pharmaceutical list. The term “control of entry” is sometimes used to mean the same thing.

Pharmaceutical Needs Assessments

Every HWB must publish a pharmaceutical needs assessment (PNA) for its area and these should be regularly reviewed, with new PNAs published every three years. Where a change has occurred which may impact on the provision of pharmaceutical services but where it would be disproportionate to issue a whole new PNA, the HWB may issue a supplementary statement.

The PNA will list the services available throughout the area and refer to any need that has been identified for additional services that are required now or in the future (typically when a future event has occurred).

PNAs tend to take an overview of local authority wards or significant towns. They usually do not look at particular needs in smaller localities.

The PNA should be the starting point for anyone who is thinking of making an application for a new pharmacy contract or anyone who wants to object to an application being granted.

I can review the relevant PNA and advise you on the best type of application to make.

Getting it right from the start

I have listed, below, the main types of application that can be made:

Current need	•identified in the PNA
Improvements or better access	•Identified in the PNA
Future need	•Identified in the PNA
improvements or better access	•not identified in the PNA (often referred to as an unforeseen benefits application)
Distance selling	•Sometimes called "mail order" or "internet" pharmacy
Relocation	•Also referred to as a "no significant change relocation"
Change of ownership	•To change an existing pharmacy to a new owner, for example after a sale
Consolidation	•To consolidate two pharmacies onto a single site

There are standard application forms that must be used for each type of application. It is important to use the right application form from the beginning because the type of application being made cannot be changed once the form has been sent to NHS England. I can provide you with the relevant application form. Applications can also be made electronically using an online portal.

Applicants do not have to own premises when they make an application. If they cannot put a specific address in their application form, they must give their best estimate of where their premises would be (except for distance selling applications or relocation applications where a specific address must be given). Applications should not be made for premises which are already listed save in specific circumstances.

There is an application fee payable to NHS England ranging from £150 to £3,000. I can advise on the appropriate fee.

There are additional rules for applications made in "controlled localities" (areas which have been defined as essentially rural in character and where there may be dispensing doctors).

New contracts

Current and future needs applications

If the PNA identifies any current or future need for a pharmacy, then an application can be made to meet this need. An application that meets a need identified in the PNA will usually be granted, but can be refused if certain conditions apply. It is rare for a PNA to identify a need for a new pharmacy. When a need is identified, it typically relates to:

- A need for out-of-hours or weekend services
- An area where there is no existing pharmacy
- A significant new housing development
- A significant change in the provision of GP services

Unforeseen benefits applications

If a PNA does not identify a current or future need for a new pharmacy, an application can still be made to secure improvements or better access to services that were not foreseen in the relevant PNA. This is often called an “unforeseen benefits” application.

The applicant will need to show that granting the application would confer significant benefits on people in the HWB area. Three matters must be taken into account when deciding whether an application would confer significant benefits:

- The desirability of having a reasonable choice regarding obtaining services in the area
- Whether people with a protected characteristic (like age or infirmity) who require access to a specific pharmaceutical service have difficulty accessing that service
- Innovative approaches to providing services

Choice is the most important of these factors, in my experience.

What other information will be relevant to the decision-maker?

Apart from the contents of the local PNA, other relevant information may include:

- The local population size, and whether it is growing
- Local demographics
- The locations of existing GP surgeries (and any recent or future changes)
- The location and accessibility of existing pharmacies
- The appointment times of GPs and the opening times of existing pharmacies
- The provision of services by existing pharmacies
- Any recent pharmacy closures
- Any expressed views from local residents or representatives

Why might an unforeseen benefits application be turned down?

If an applicant does not demonstrate that improvements or better access would be secured and that significant benefits would be conferred on local people, the application will be turned down.

An application will also be refused if granting it would cause significant detriment to:

- proper planning of pharmaceutical service provision
- the current arrangements in place for the provision of services

These factors may involve consideration of any plans NHS England has in relation to health services and whether an existing pharmacy would lose so many prescriptions that it could close, leaving a gap in services that the new pharmacy would not fill.

Distance selling applications

There are several restrictions for a distance selling application. These include:

- Distance selling contracts cannot be located at the site of a GP practice
- Essential pharmacy services cannot be provided (or offered) to patients who are present on (or in the vicinity of) premises that have a distance selling contract
- Applicants must satisfy NHS England that there would be safe and effective provision of essential services without face-to-face contact with patients or carers
- Services cannot be limited to a locality and must be available on a nationwide basis
- Service provision must be uninterrupted during the opening hours of the pharmacy

In order to demonstrate that services would be provided safely and effectively, applicants often send details of their procedures (for example in the form of SOPs) with their application forms. These will be scrutinised rigorously, for example to see if they might involve patients receiving services at the premises, and to make sure that there will be satisfactory arrangements for dealing with controlled drugs and fridge lines.

Where SOPs are provided, these should be tailored to the proposed distance-selling pharmacy.

I have a lot of experience of reviewing SOPs when acting for both applicants and objectors. I can provide detailed guidance on the contents of SOPs and can review draft SOPs and advise on changes that will help to secure a grant. For objectors, I can review the SOPs provided by the applicant and spot areas of weakness to help secure a refusal.

Changes to existing pharmacies

As well as including new pharmacies in the pharmaceutical list, NHS England can make changes to pharmacies which are already listed.

Relocations

Applicants who want to relocate an existing pharmacy contract must show that the new premises will not be significantly less accessible for the patient groups who use the existing pharmacy. They must also show that granting an application would not result in a significant change in arrangements for the provision of services in the local area and would not cause significant detriment to proper planning for services in the area. Relocation applications are often highly contentious, and the question of defining a patient group has proved to be complicated and has involved arguments in the High Court

There are different rules for relocating a distance selling pharmacy, akin to those which apply to opening a new distance selling pharmacy.

Change of ownership

Change of ownership applications are needed when pharmacies are sold (from a sole trader/partnership or an asset sale of a limited company). Applications are generally straightforward and should be dealt with by NHS England within 30 days, although it usually takes longer, particularly if the buyer does not already operate a pharmacy and has to undergo “fitness to practise” checks.

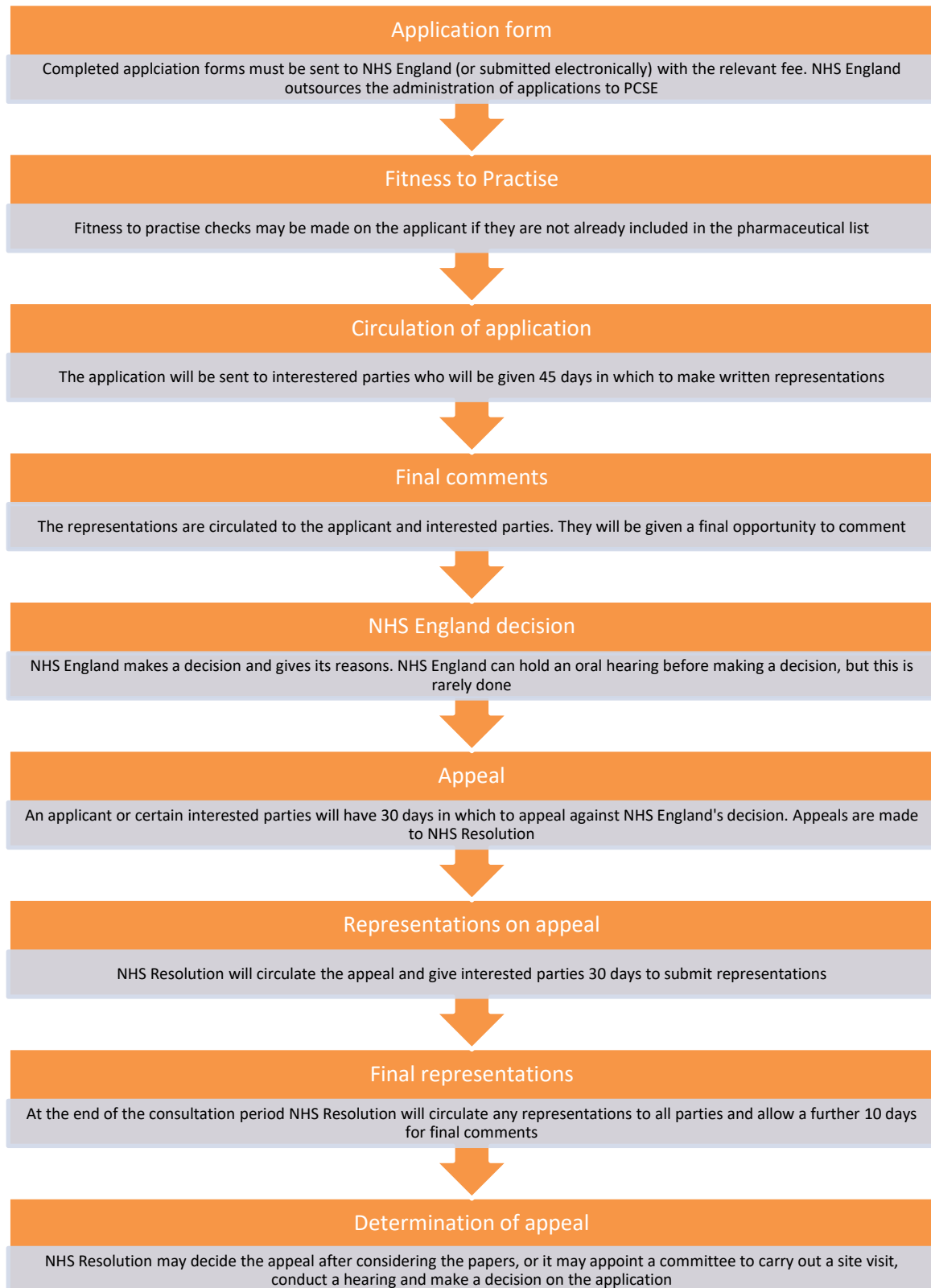
Consolidation

Where two pharmacies operate close to each other (whether they are owned by the same legal entity or not), they can apply to consolidate onto a single site. The hours and services of the pharmacy that is to remain open following consolidation must remain the same.

NHS must grant a consolidation if it is satisfied that doing so would not result in a gap in service provision that could be met by the granting of a new contract application.

Where a consolidation application is approved, the HWB for the area in which the pharmacies are located may update its PNA to state that the consolidation has not created a gap in service provision. This would prevent another person from applying for a new contract based on the closure.

What is the procedure for applications?



How long does it take?

NHS England should make its decision within 4 months of receiving the completed application although it often does not meet this time limit.

If there is an appeal, it typically takes up to 15 weeks to receive a decision from NHS Resolution, or up to 25 weeks if there is an oral hearing.

What happens after an application has been granted?

Within 12 months of an application being granted, the applicant must send a form to NHS England giving notice of the date on which services will commence. At least 30 days' notice must be given unless NHS England agrees a shorter notice period.

If the applicant has submitted a "best estimate" location for a new contract application, within 6 months of the grant it must notify NHS England of the actual address of the new pharmacy (which must be within the previously defined best estimate location) and then has 12 months to give notice of commencement.

If there was an appeal, the 12 months will run from the date of the appeal decision.

It may be possible to obtain an extension of up to 3 months before services commence if the Applicant can show "good cause".

What if you are unhappy with an appeal decision?

There is no right of appeal against a decision of NHS Resolution.

If NHS Resolution has got the law wrong or was unfair in some way, it may be possible to apply to the High Court to overturn the decision (a process known as "judicial review"). It is essential to act quickly or you may lose your rights.

How can I help?

Since 2005 I have dealt with hundreds of cases and have many satisfied clients – applicants for whom I have secured valuable contracts, and objectors who credit me with having saved their businesses.

I will tailor our services to meet your needs and resources. These services can include:

- Site visits
- Assessing and advising you on your chances of success
- Completing application forms
- Reviewing application forms before submission to NHS England
- Drafting objections to applications
- Drafting responses to objections
- Drafting appeals against NHS England decisions
- Making written representations to NHS Resolution
- Advocacy at NHS England and appeal hearings
- Advice on whether appeal decisions can be overturned
- Bringing or defending judicial review cases

I provide a cost-effective service by adapting my approach to meet your individual needs. I recognise the importance of achieving a successful outcome and can tailor the cost to suit your resources, depending on which of the listed services you want.

I understand that every client is different. I am happy to work with you, providing as much or as little support as you need. I can offer a full service from start to finish, but some clients choose to instruct me later in the application process. This means that I can provide a service that meets your individual needs.

I am happy to visit the local area if you would like, although my experience means that I am able to carry out a significant amount of research using online resources. This helps keep costs down for clients.

Most of my clients choose a fee structure that means I only charge for the work that I do. I will always provide you with a fee estimate before starting work to help you budget.

Other clients prefer the certainty of a fixed fee structure, and I am happy to discuss these.



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