



## The draft NHS pharmaceutical services regulations 2012 – market entry

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PCTs have a statutory duty to ensure that arrangements are in place to ensure that prescriptions can be dispensed to their populations. One way of fulfilling that duty is by considering applications to open new pharmacy or dispensing appliance contractor premises submitted under the NHS (Pharmaceutical Services) Regulations 2005 as amended (the 2005 regulations). This process is complex and PCT decisions are frequently appealed against with appeals heard by the NHS Litigation Authority.

### Background

If a pharmacy or dispensing appliance contractor (DAC) wishes to provide NHS pharmaceutical services they must first apply to the PCT in whose area they wish to open premises. If a GP wishes to provide NHS pharmaceutical services they must also first apply to their PCT. PCTs are required to consider such applications under the 2005 regulations. The law on the subject is complex and contained in acts of parliament, regulations and reported decisions of the courts – case law – as well as directions to primary care trusts. Decisions taken by PCTs can be appealed to either the NHS Litigation Authority or the courts.

In 2009 the NHS Act 2006 was amended to:

- Require each PCT to develop and publish a pharmaceutical needs assessment (PNA)
- Use the PNA as the basis for determining market entry to NHS pharmaceutical services provision.

Regulations for the first clause came into force on 24 May 2010 and all PCTs were required to publish a PNA which met the requirements of these regulations by 1 February 2011.

Regulations to underpin the second clause have been drafted and are currently out to [consultation](#) (Gateway reference 16176). This briefing highlights the main changes between the current and draft NHS (Pharmaceutical Services) Regulations 2012 (the draft regulations) as they relate to pharmacies and DACs. No changes have been made to the provisions for GPs.

It should be noted that changes may be made to the draft regulations as a result of the Department of Health's consultation.

## Main changes

At present, pharmacies and DACs are required to satisfy the PCT that their application to open new or additional premises is either necessary or expedient. Once the draft regulations come into force applications will be submitted based on:

- Current or future needs identified in the PNA
- Current or future improvements, or better access, to pharmaceutical services identified in the PNA
- Improvements, or better access, to pharmaceutical services that were not identified in the PNA (“unforeseen benefits”).

The latter is likely to generate most applications to open new pharmacies as few PNAs have identified needs, improvements or better access to pharmaceutical services as provided by pharmacies. It is also anticipated that most applications from DACs will be submitted as unforeseen benefits.

Not all types of applications will have to meet an identified need, improvement or better access. These are changes of ownership, relocations that do not result in significant change and distance selling premises (internet pharmacies). However such applications will need to meet the requirements of the draft regulations in order to be approved.

Three of the current “exempt” types of application will cease to exist: 100 hour pharmacies, out of town retail areas and one-stop primary care centres. However as noted above distance selling premises will continue although the requirements for such applications have been strengthened.

The draft regulations confirm that 100 hour pharmacies which were approved under the 2005 regulations must continue to provide pharmaceutical services for 100 hours per week.

Some changes have been made to the way applications are processed. For example the PCT receives an application offering to meet an identified current need but has already approved an application offering to meet the same need which is currently subject to an appeal. The PCT could defer the second application while it awaits the outcome of the appeal.

PCTs will also be able to conditionally approve applications which offer to provide enhanced services to meet an identified need, improvement or better access. This will ensure that applicants do indeed provide such services, something which PCTs can currently only do in relation to three of the current exempt categories.

## Next steps

As well as the draft regulations and usual consultation documents, DH has also issued comprehensive draft guidance and it is recommended that PCTs read all the published documents. PCC is developing a comprehensive support package for subscribing organisations to help them understand the requirements of the draft regulations.

PCTs are advised to ensure that their PNA is up to date and to ensure that any needs, improvements or better access to pharmaceutical services have been clearly identified. A separate [briefing](#) has been produced to assist PCTs in keeping their PNA up to date.