

When CoE gives way to PNA

Richard Hough, a practitioner in pharmacy law, explains how pharmaceutical needs assessments will replace the control of entry regulations and warns contractors to be on their guard



The Health Bill 2009 ("the Bill"), which proposes measures to improve the quality of NHS care, public health and the performance of NHS services, is edging its way to becoming law. Among its provisions, which will be of interest to aspiring and existing pharmacy contractors, are measures which aim to reform the current arrangements for pharmacists applying to provide NHS pharmaceutical services (control of entry requirements).

Assuming it receives Royal Assent, section 25 of the Bill will insert the following wording into section 128A of the National Health Service Act 2006:

"Each Primary Care Trust (PCT) must in accordance with the regulations: (a) assess needs for pharmaceutical services in its area, and (b) publish a statement of its first assessment and of any revised assessment."

Obligation

A primary obligation will, therefore, be placed on each PCT to assess its area's pharmaceutical needs, such needs forming the basis of the Pharmaceutical Needs Assessment (PNA). Once drafted, the PNA must then be published and updated in accordance with the secondary legislation made further to the Bill ("the regulations"). The regulations, which have not yet been finalised, are expected to be ready by April, 2010, which would then give PCTs time to develop their PNAs over the following year. It is, therefore, envisaged that control of entry regulations will change to a PNA-based system around April, 2011. The regulations, when drafted, "must make provision: (a) as to information which must be contained in a statement; (b) as to the extent to which an assessment must take account of likely future needs (c) specifying the date by which a PCT must publish the statement of its first assessment; and (d) as to the circumstances in which a PCT must make a new assessment."

The regulations will, therefore, stipulate the factors a PCT must take into consideration when drafting its first and subsequent PNAs. In particular, the PCT will be obligated to

assess both present and future needs, which will not only be vitally important to existing contractors, who may wish to approach the PCT to commission those services it has identified as not currently being provided, but also to aspiring contractors who are looking to enter the market.

The regulations "may make provision: (a) as to the pharmaceutical services to which an assessment must relate; (b) requiring a PCT to consult specified persons about specified matters when making an assessment; (c) as to the manner in which an assessment is to be made; and (d) as to matters to which a PCT have regard when making an assessment."

There remains uncertainty as to whether a PCT will be required to consult with specified persons, take into account specified matters or include specified pharmaceutical services when drafting its PNA. It is, however, envisaged that the regulations will require PCTs to consult with existing pharmacy contractors, local pharmaceutical committees and patient groups when preparing their PNAs.

PNAs are a relatively new concept and herald a radical departure from the current control of entry system, which came into force in 1987. The law currently states that, further to regulation 12 of the National Health Service (Pharmaceutical Services) Regulations 2005 ("the 2005 Regulations"), an application for entry into the pharmaceutical list shall be granted by a PCT "only if it is satisfied that it is necessary or expedient¹ to grant the application in order to secure, in the neighbourhood in which the premises from which the applicant intends to provide the services are located, the adequate provision, by persons included in the pharmaceutical list, of the services, or some of the services, specified in the application" ("the necessary or expedient test").

The current system is not without its faults, not least the fact that it is perceived by many to be anti-competitive. Attempting to address these concerns, the Office of Fair Trading (OFT) investigated and subsequently published its report in January, 2003, on retail pharmacy

services in the UK. The conclusion to the OFT's report was that the control of entry regulations were unduly impeding the way the market worked to the ultimate detriment to the public. It, therefore, recommended that the control of entry regulations should be lifted as they inhibited price competition, stifled efficiency improvements and innovation and limited the availability of pharmaceutical services.

The OFT's recommendations were not adopted and the control of entry test was maintained but subject to four new exemptions, which are set out at regulation 13 of the 2005 Regulations. This states that regulation 12 (the necessary or expedient test) "shall not apply to an application in respect of premises:

- (a) which are in an approved retail area;
- (b) where the applicant is willing to keep open for at least 100 hours per week for the provision of pharmaceutical services;
- (c) which are in a new one-stop primary care centre; or
- (d) at which essential services are to be provided but the means of providing those services are such that all persons receiving them do so otherwise than at those premises ('distance selling premises')."

Dissatisfaction

The 2005 Regulations have only partially achieved the OFT's aims of increasing competition and increasing the availability of pharmaceutical services. Dissatisfaction with the legislation led to the publication of the Galbraith Report, the conclusions of which stated that the 2005 Regulations were complex for PCTs to administer and contractors were concerned about the consistency of PCT decision making. It also acknowledged that the exemptions in the 2005 Regulations were at odds with the commissioning framework because they eschewed the necessary forward planning of local provision of pharmaceutical services, casting PCTs in a passive or reactive role. This made it difficult for PCTs to plan strategically and match local pharmaceutical services provision to areas of need. This is highlighted no more so than when witnessing the clusters of applications for 100 hour pharmacies being granted close to busy GP surgeries because each application meets the 100 hour exemption criterion, irrespective of pharmaceutical need or desirability. The report concluded that the control of entry system should be linked to PNAs.

It is evident that, should a PCT be inconsistent in its commissioning of pharmaceutical services, control of entry could effectively disappear. If, for example, a PNA identifies a pharmaceutical need which has not previously been met by existing contractors

solely because the PCT has not previously commissioned a particular service, the barrier to entry for aspiring contractors is effectively removed because an applicant who is prepared to meet this unmet need could make an application for entry on to the pharmaceutical list and the PCT would be obliged to grant it.

It will be vital for existing pharmacy contractors to ensure they are familiar with their PCT's current PNA. PNAs will be subject to change and contractors should ensure that they make themselves aware of subsequent revisions. Otherwise, opportunities may present themselves for aspiring contractors to enter the market at their expense.

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Reference

1. Regulation 5 of Part 1 of the the National Health Service (Miscellaneous Amendments relating to Community Pharmaceutical Services and Optometrist Prescribing) Regulations 2009, SI 2009 No 2205, September 17, 2009.

This regulation substitutes the word "desirable" with the word "expedient".