EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations insert into the National Health Service (Pharmaceutical Services) Regulations 2005 ("the 2005 Regulations") new requirements relating to pharmaceutical needs assessments ("PNAs"). A PNA is a statement of the assessment each Primary Care Trust ("PCT") must make, under section 128A(1) of the National Health Service Act 2006, of the needs in its area for pharmaceutical services provided as part of the National Health Service ("NHS"). In due course, PNAs will form the basis for decisions to grant applications for inclusion in a pharmaceutical list (listing is a prerequisite for a pharmacy business being allowed to provide services under the 2005 Regulations), and applications to change the pharmaceutical services that a listed pharmacy business provides or to change the premises from which a listed pharmacy business is allowed to provide them.

These Regulations also make some unrelated, minor amendments to the 2005 Regulations – and to the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 ("the 2006 Regulations").

Regulation 3(b) and (c) inserts definitions into the 2005 Regulations that relate to the new PNA provisions, and regulation 4 inserts a new Part 1A into the 2005 Regulations. The new regulations in Part 1A include: a clarification of the services that are to be covered by PNAs (new regulation 3A); an obligation upon current PCTs to publish their first PNAs on or before 1st February 2011, and for new PCTs to publish their first PNAs within 10 months of establishment (new regulation 3C); and obligations relating to subsequent assessments, including provision for supplementary statements, in limited circumstances, pending full revision of a PNA (new regulation 3D). Because, in due course, every locality will need to be covered by a PNA in order for certain decisions relating to pharmaceutical list entries to be made, where a PCT is dissolved or its boundaries are changed and this means that a locality is no longer covered by a PNA produced by its PCT, provision is made so that the PNA produced by the previous PCT for the locality continues to have effect pending the production of a new or revised PNA by the locality's new PCT (new regulation 3E). There are also consultation requirements that have to be fulfilled before each PNA is published (new regulation 3F) and provisions relating to a number of matters to which PCTs must have regard when producing their PNAs (new regulation 3G).

Regulation 9 inserts a new Schedule 3A into the 2005 Regulations, which sets out the information that must be included in PNAs. This includes statements of current provision and statements identifying both unmet needs in the PCT's area for pharmaceutical services and gaps in current provision which, if filled, would secure improvements to, or better access to, pharmaceutical services. The PNA must also include an explanation of how the assessment was carried out – and a map identifying the premises at which pharmaceutical services and dispensing services (services similar to pharmaceutical services that are provided under contractual arrangements with GP practices) are provided in the area of the PCT. There is also provision for that map to be kept up to date (the new regulation 3B, which also introduces the new Schedule 3A).

The unrelated minor amendments are as follows. Regulations 3(a) and (b), 6 and 11(a) make modifications to the 2005 and 2006 Regulations which are consequential upon the abolition, on 18th January 2010, of the Family Health Service Appeals Authority. Regulation 5 amends the 2005 Regulations so that, as regards applications from doctors for outline consent or premises approval, the grounds for refusal given in regulation 18(2) of those Regulations apply in relation to all applications relating to controlled localities. Regulations 7(a), 8(b) and 10 amend the requirements

relating to application forms and notification of information so that when details identifying directors and superintendents of bodies corporate need to be supplied, the information to be provided includes dates of birth and any professional registration numbers. Regulations 7(b) and 11(c) remove references from the 2005 and 2006 Regulations to two forms which are no longer in use but which were for claims for repayment of NHS charges. Regulation 8(a) corrects a numbering error in Schedule 1 to the 2005 Regulations. Regulation 11(b) amends regulation 4 of the 2006 Regulations, which is about the designation of priority neighbourhoods and premises, to make it clear that the scheme for designations under that regulation does not require a designation to be in place in respect of all pharmacy premises from which local pharmaceutical services are, or are to be, provided.

An Impact Assessment has been prepared and can be obtained from www.dh.gov.uk. Copies are also available from the Department of Health, Skipton House, 80 London Road, London SE1 8LH.