EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations replace the National Health Service (Pharmaceutical Services) Regulations 2012 ("the 2012 Regulations") and the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 ("the 2006" Regulations") as the Regulations which govern the arrangements, in England, for the provision of pharmaceutical and local pharmaceutical services under Part 7 of the National Health Service Act 2006 ("the 2006 Act").

Part 1 contains introductory provisions. Part 2 sets out the requirements relating to the production of pharmaceutical needs assessments ("PNAs") A PNA is a statement of the assessment that each Health and Wellbeing Board ("HWB") must make, at least every 3 years, of the needs in its area for pharmaceutical services provided as part of the National Health Service. This Part includes the consultation requirements that have to be fulfilled before a PNA is completed and published (regulation 8) and the matters to which a HWB must have regard when producing a PNA (regulation 9) – and Schedule 1 thereafter sets out the information that must be included in PNAs. Pending full revision of a PNA, a HWB may address in a supplementary statement changes to the availability of pharmaceutical services since the PNA was published (regulation 6). Provision is also made for the temporary extension of PNAs of Primary Care Trusts, who were responsible for PNAs prior to their abolition (regulation 7).

Pharmaceutical services provision by virtue of these Regulations is essentially of three types: service provision by virtue of being included in pharmaceutical lists maintained by the National Health Service Commissioning Board ("the NHSCB"); service provision by virtue of being included in a dispensing doctor list maintained by the NHSCB; and service provision by virtue of an agreement to provide local pharmaceutical services with the NHSCB.

The pharmaceutical list system is a system under which retail pharmacy businesses and appliance contractors (together referred to as "chemists") are given permission to provide NHS pharmaceutical services from particular premises, provided both they and the relevant premises are included in a pharmaceutical list maintained by the NHSCB. These lists are kept by reference to the areas of HWBs (regulation 10).

Part 3 includes general matters relating to pharmaceutical lists and applications from chemists join them – and also relating to applications from chemists on the lists to relocate to different premises or open new premises. The presumption is that "routine" applications (defined in regulation 12) will be assessed against the relevant PNA. The detail of the new arrangements, including the matters to which, in addition to the relevant PNA, the NHSCB must have regard when determining applications, is set out in this Part. There is also provision (regulation 18) for granting routine applications that offer improvements or better access to pharmaceutical services that were not foreseen when the relevant PNA was published, in certain circumstances. Subject to this exception, routine applications must be refused unless they offer to meet needs, or secure improvements or better access, that are mentioned in the relevant PNA (regulation 22).

Part 4 sets out a number of types of applications in respect of pharmaceutical lists, known as "excepted" applications, that do not have to be assessed as provided for in Part 3. These include, for example, relocation applications that do not result in significant change to pharmaceutical services provision (regulation 24) and change of ownership applications (regulation 26). Under Chapter 6 of Part 7 of the 2006 Act, there are powers to suspend chemists on pharmaceutical lists during fitness investigations or pending fitness appeals – and an exception is also made in respect of a temporary chemist joining a pharmaceutical list to provide services in place of a suspended chemist (regulation 27). A further exception is made (in regulation 28) to allow chemists who provide local pharmaceutical services a right of return to a pharmaceutical list in appropriate circumstances. A new exception (with effect from 1st April 2013) has been created

to allow for the temporary relocation of chemists to nearby premises where there is a temporary suspension in the provision of pharmaceutical services for a reason beyond the control of the chemist (regulation 29).
Part 5 contains some grounds for refusing different types of applications in respect of pharmaceutical lists, for example because the premises to which the application relates are in an area that has been set aside for tendering arrangements for a contract to provide local pharmaceutical services (regulation 32).
Part 6 provides for refusal and deferral of applications, and for conditional inclusion in pharmaceutical lists, for fitness reasons. There are some mandatory grounds (for example, murder convictions) as a consequence of which a person, partnership or body corporate must be refused entry onto a pharmaceutical list, and some discretionary grounds (regulation 33). If, instead of refusing an application, the NHSCB decides to grant it subject to permissible fitness conditions, and these conditions are not appealed or are upheld on appeal, the applicant has to decide within a set timetable whether or not they wish to withdraw the granted application (regulation 35).
Part 7 covers determinations as to whether or not an area is a controlled locality or a reserved location. Controlled locations are areas that are rural in character where doctors may apply to provide dispensing services (a restricted range of pharmaceutical services), if certain conditions are met. Determinations that an area is a controlled locality may only take place once every 5 years unless there is a substantial change of circumstances in the intervening period (regulation 36). Routine applications from retail pharmacy businesses to locate pharmacy premises in a controlled locality face two additional hurdles to those already set out in Part 3: firstly, applications in defined parts of a controlled locality cannot be made within 5 years of either the refusal of a similar pharmacy application or the grant of a relevant permission to doctors to dispense, unless there is a substantial change of circumstances affecting the locality (regulation 40); and secondly, the applications are subject to the "prejudice test" (regulation 44), under which the NHSCB is required to refuse the application if it would prejudice the proper provision of relevant NHS services. Where an application for a new pharmacy in a controlled locality is granted, the NHSCB may determine that the pharmacy is at the centre of a reserved location – that is, essentially, an area of below a specified population threshold in which patients are to have the option of receiving dispensing services from either a dispensing doctor or a retail pharmacy business.
The procedures, generally, for dealing with pharmaceutical list applications and related appeals are dealt with in Schedules 2 and 3. These procedures provide for the content of applications (Part 1 of Schedule 2), the process for notifying most types of applications to interested parties that might want to make representations in relation to them (Part 3 of Schedule 2), and the decision making processes – including provision for oral hearings (Part 4 of Schedule 2). There are is also provision for the notification of decisions – and arrangements for when, and subject to what notification requirements, chemists may open new premises that are the subject of successful applications (Part 5 of Schedule 2). The procedures with regard to appeals, either by applicants against refusals or by third parties with appeal rights, are for the most part covered in Schedule 3 – and again there is provision for notification of interested parties both of appeals (to allow for third party representations in most cases) and of decisions on appeals.
Part 8 sets out the arrangements under which an NHS general practitioner who has, or whose practice has, a registered patient list may provide dispensing services. Generally to do so, individual general practitioners or their medical practice face three hurdles: firstly, the patients to whom they could provide dispensing services must have applied to them for such services (regulation 48); secondly, they must have been granted premises approval for the medical practice premises from which they wish to dispense; and thirdly, they must have been granted outline consent in relation to the area to whose residents they wish to dispense (or have relevant historic rights to dispense). The taking effect of decisions to grant outline consent and premises approval may be delayed to allow for the processing of outstanding pharmacy applications (regulations 52 and 56) and to mitigate the effects on other providers of pharmaceutical services locally (regulation 57).

Once included on a dispensing doctor list maintained by the NHSCB (under regulation 46) and so permitted to provide dispensing services, dispensing doctors have to comply with the terms of service for dispensing doctors set out in Schedule 6 and which for the most part deal with specific issues relating to dispensing. Dispensing doctors may however be required to discontinue that provision if the conditions that led to the grant of their entitlement to dispense no longer apply (generally, unless the practice premises are in a reserved location, discontinuation will result from the opening of a pharmacy nearby) – subject to arrangements for possible postponement of the discontinuation (regulation 50). There are also circumstances in which outline consent and premises approval may lapse, for example where it has been more than 6 months since any drug or appliance was dispensed under the arrangements with the dispensing doctor (regulation 60) – and there are also procedures for dealing with medical practices either relocating or amalgamating (regulations 54, 55 and 59).

Part 9 sets out some conditions that are to be imposed on chemists as part of their terms of service with the NHSCB, which include requirements relating to co-operation with the NHSCB over local resolution of disputes (regulation 68). These Part 9 conditions are in addition to the principal terms of service for chemists, which are in Schedule 4 for retail pharmacy businesses and Schedule 5 for appliance contractors.

The terms of service in Schedule 4 include obligations to provide what are described as the essential services that must be provided at each pharmacy. These essential services include not only dispensing services but other services, for example disposal services in respect of unwanted drugs and promotion of healthy lifestyles. As well as providing essential services, retail pharmacy businesses are subject to other compulsory requirements by virtue of Schedule 4, for example with regard to having acceptable systems of clinical governance and providing information about fitness matters. The range of necessary services required of appliance contractors in Schedule 5 is more limited, but also includes requirements with regard to dispensing and additional compulsory requirements with regard to clinical governance and providing information about fitness matters. Both of these types of provider of pharmaceutical services are also subject to detailed requirements with regard to their opening hours and changes to them.

Part 10 sets out the arrangements for dealing with breaches of terms of service by chemists (breaches by dispensing doctors are dealt with under their parallel arrangements for providing primary medical services to registered patients, which they must have in order to be providers of pharmaceutical services). Where a dispute between a chemist and the NHSCB cannot be resolved under the local dispute resolution procedures (or where that procedure may be by-passed), the chemist faces the possibility of a breach or remedial notice, as a part of which there may be a payment withholding (regulations 70 to 72). In some cases, repeated failures to comply with terms of service, or failures with particularly serious consequences, may thereafter lead to the removal of a chemist's business premises from the relevant pharmaceutical list. Removal of such premises is also a possibility in other cases, for example (subject to exceptions) where a chemist has not provided NHS pharmaceutical services for more than 6 months, and there are also arrangements for voluntary removal, which may be prevented if the contractor is subject to ongoing fitness proceedings (regulations 73 to 76).

Part 11 contains procedures for dealing with fitness issues with regard to chemists on pharmaceutical lists. These include procedures for reviewing fitness conditions imposed under regulation 35 on chemists as a condition of their inclusion in a pharmaceutical list – but for the most part, the procedures complement the arrangements for imposing fitness sanctions that are set out in Chapter 6 of Part 7 to the 2006 Act. There are also substantive requirements that complement those Chapter 6 arrangements, for example a prescribed list of grounds for which the NHSCB must remove a chemist from a pharmaceutical list in an unsuitability case under section 151(4) of the 2006 Act, a list which includes murder convictions (regulation 81). Where fitness sanctions are imposed, there are notification requirements that provide for dissemination of relevant information to other bodies that may need to consider taking action, for example the devolved administrations and the General Pharmaceutical Council, and to other persons who are entitled to request the information (regulation 88).

Part 12 contains provisions relating to financial matters. Regulation 89 provides for the publication of the Drug Tariff, the main statement of the financial entitlements of chemists that provide pharmaceutical services. The Secretary of State is the determining authority for reimbursement referable to the cost of drugs and appliances, but the NHSCB acts as the determining authority for other remuneration, in particular for some additional services and for the items listed in Schedule 8 (regulation 91). Dispensing doctor remuneration is linked to what their entitlement is or would be under a general medical services contract (regulation 92). There are also provisions for dealing with supplemental matters, for example overpayments and refunds of prescription charges. The Secretary of State is also given powers to make a separate determination of remuneration which will apply to chemists who are suspended from a pharmaceutical list, either during an investigation or pending an appeal, for fitness reasons (regulation 98).

Part 13 and Schedule 7 deal with local pharmaceutical services, which are a set of contractual arrangements, known as LPS schemes, with the NHSCB under which chemists provide pharmaceutical services whilst not on a pharmaceutical list. LPS schemes come in two types: LPS pilot schemes, a set of schemes whose main terms, and any arrangements for entering into them, are set out in a separate set of directions, and the standard form of LPS schemes, the mandatory terms for which are set out in Schedule 7 and cover matters such as dispensing arrangements (all LPS schemes must include provision for the dispensing of drugs – regulation 102), clinical governance, professional standards, inducements, remuneration and charges, complaints, dispute resolution and termination.

Before commissioning services under the standard form of LPS scheme, the NHSCB may decide to designate an area of a HWB, premises or descriptions of premises (regulation 99), the effect of which will be to allow for the deferral of routine applications (regulation 32) for the duration of the designation, facilitating the commissioning of local pharmaceutical services at the location in question. There are also arrangements for the review and cancellation of designations (regulations 100 and 101). Where the NHSCB does enter into the standard form of LPS scheme, there are arrangements for that scheme being (unless the contractor objects) an NHS contract, which affects the arrangements for dispute resolution (regulation 103). Only contractors demonstrating certain fitness requirements may become parties to such schemes (regulation 105), and persons proposing to enter into such schemes must first send the NHSCB information about their fitness to be parties to them (regulation 106). Proposals for the standard form of LPS scheme that may proceed for development also have to be notified to interested parties by the NHSCB (regulation 107). If a contractor, on entering into the standard form of LPS scheme, gives up a right to be on a pharmaceutical list, they may be given a right of return (regulation 108). There are also provisions about whether or not LPS pilot schemes are to be NHS contracts (regulation 109), and about what happens on termination of pilot schemes. In effect, unless the pilot scheme terminates for a reason relating to the fitness of the provider to be a provider of pharmaceutical services, the scheme premises and the contractor are included in a pharmaceutical list (regulation 110). There are also other administrative provisions relating to LPS schemes, including arrangements for dealing with emergencies requiring the flexible provision of pharmaceutical services (regulation 111).

Part 14 deals with some miscellaneous matters, for example a provision that allows for applications for services to be made on behalf of some patients by duly authorised persons (regulation 116) and the delegation of certain functions of the Secretary of State to the National Health Service Litigation Authority (regulation 117).

Regulation 119 introduces Schedule 9, which sets out a number of transitional provisions. These include arrangements to deal with the abolition of Primary Care Trusts. Outstanding listing applications under the 2012 Regulations, and the LPS schemes and listing entries that are already in existence, are preserved. Ongoing matters essentially carry on.

Regulation 120 introduces Schedule 10, which contains a number of consequential amendments and revocations.

These Regulations will be the subject of a published review by 31st August 2017 (regulation 121).

Changes to legislation:
There are currently no known outstanding effects for the The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.