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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations revoke and replace the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (S.I. 2013/898) (“the 2013 Regulations”) as the Regulations which, in Wales, govern the provision of pharmaceutical services as part of the National Health Service under Part 7 of the National Health Service (Wales) Act 2006.

Part 1 contains introductory provisions, including setting different dates on which provisions come into force. Parts 1 to 4 and Parts 9 to 11 come into force on 1 October 2020. Parts 5 to 8 come into force on 1 October 2021.

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 Local Health Board must make, at least every 5 years, of the needs in its area for pharmaceutical services provided as part of the National Health Service in Wales. This Part includes the consultation requirements that have to be fulfilled before a PNA is completed and published (regulation 7) and the matters to which a Local Health Board must have regard when producing a PNA (regulation 8) – and Schedule 1 thereafter sets out the information that must be included in PNAs. Pending full revision of a PNA, a Local Health Board may address, in a supplementary statement, changes to the availability of pharmaceutical services since the PNA was published (regulation 6). A Local Health Board is required to publish its PNA and any subsequent PNAs on its website (regulation 9).

Part 3 sets out the requirements for each Local Health Board to prepare and maintain for their area—

- (a) pharmaceutical lists of NHS pharmacists and NHS appliance contractors who undertake to provide pharmaceutical services from premises in the area, and
- (b) dispensing doctor lists of doctors who undertake to provide pharmaceutical services from premises in the area.

It also sets out the terms of service, which are the terms on which persons are included in a pharmaceutical or dispensing doctor list and on which they undertake to provide pharmaceutical services as part of the National Health Service.

Part 4 makes provision for a Local Health Board itself, or on application from a Local Medical Committee or Local Pharmaceutical Committee, to determine whether or not a particular area within the area for which the Local Health Board is established is, because it is rural in character, a controlled locality or part of a controlled locality. The significance of a locality being determined to be a controlled locality is that, in certain circumstances, doctors can provide pharmaceutical services to certain of their eligible patients (if those doctors are included in a dispensing doctor list). The procedures that a Local Health Board must follow in determining a question as to whether an area is a controlled locality or part of a controlled locality are set out in Schedule 3. Rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 4.

Part 5 sets out the types of applications in respect of inclusion in or amendment to pharmaceutical lists and the tests which a Local Health Board must apply to determine those applications. Under regulation 15 (applications to be included in or make amendment to a pharmaceutical list) and regulation 18 (applications for preliminary consent and effect of preliminary consent) applications can be granted only if the Local Health Board is satisfied that it would meet a need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant Local Health Board and which have been included in the PNA of that Local Health Board. In addition, the general

position is that if the premises are situated in a controlled locality, the Local Health Board must be satisfied that to grant the application will not prejudice the proper provision of primary medical, dispensing or pharmaceutical services in any locality (the prejudice test). The exception to the general position is where the premises specified in an application are determined by the Local Health Board to be in a reserved location (under regulation 17 (locations in controlled localities that are reserved locations)).

A person already included in a pharmaceutical list can apply to relocate the premises from which they provide pharmaceutical services. Regulation 19 (applications involving relocation within a Local Health Board's area) sets out when a Local Health Board may grant such an application. Applications that fall within regulation 20 (applications involving relocation between neighbouring Local Health Board areas), regulation 21 (applications involving a temporary relocation) and regulation 22 (applications involving a change of ownership) will be assessed in accordance with the specific criteria set out in the provisions of those regulations. The procedures that a Local Health Board must follow in determining applications under Part 5 are set out in Schedule 3, and rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 4.

Part 6 sets out the applications which doctors can make in order to be able to fulfil the conditions on which they can then make arrangements with a Local Health Board to provide pharmaceutical services to their eligible patients in controlled localities. Doctors must apply for outline consent and premises approval under regulation 30 (outline consent and premises approval) and Local Health Boards must consider such applications in accordance with the prejudice test and the proximity of the premises from which the doctor wishes to provide pharmaceutical services to nearby pharmacies. A doctor who has been granted outline consent and premises approval may make arrangements with a Local Health Board to provide pharmaceutical services under regulation 26 (arrangements for the provision of pharmaceutical services by doctors). The procedures that a Local Health Board must follow in determining applications under Part 6 are set out in Schedule 3, and rights of appeal to the Welsh Ministers in respect of decisions made by Local Health Boards are set out in Schedule 4.

Part 7 deals with fitness grounds and inclusion in and removal from pharmaceutical lists. It provides for the deferral and refusal of applications for inclusion in a pharmaceutical list on fitness grounds (regulations 36 and 37) together with an inclusion in a pharmaceutical list being subject to conditions (regulation 38). For certain fitness matters, including where a person has been convicted in the United Kingdom of a criminal offence and has been sentenced to a term of imprisonment of over 6 months, a Local Health Board must remove a person from a pharmaceutical list pursuant to regulation 40 (removal from a pharmaceutical list for other reasons).

Part 8 sets out some conditions that are to be imposed on NHS pharmacists and NHS appliance contractors as part of their terms of service with the Local Health Board, which include requirements relating to co-operation with the Local Health Board over local resolution of disputes (regulation 49). These Part 8 conditions are in addition to the principal terms of service for NHS pharmacists, which are in Schedule 5, and NHS appliance contractors, which are in Schedule 6.

The terms of service in Schedule 5 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, NHS pharmacists are subject to other compulsory requirements by virtue of Schedule 5, for example with regard to having acceptable systems of clinical governance and providing information about fitness matters. The range of necessary services required of NHS appliance contractors in Schedule 6 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. Schedules 5 and 6 also set out the NHS terms of service for NHS pharmacists and NHS appliance contractors in relation to Serious Shortage Protocols (SSPs), where

when a SSP is in place, the NHS pharmacist or NHS appliance contractor must consider whether it is reasonable and appropriate to supply in accordance with the SSP rather than fulfilling the NHS prescription for that product.

Part 9 sets out the arrangements for dealing with breaches of terms of service by NHS pharmacists and NHS appliance contractors (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 an NHS pharmacist, or an NHS appliance contractor, and the Local Health Board cannot be resolved under the local dispute resolution procedures (or where that procedure may be by-passed), the NHS pharmacist or NHS appliance contractor faces the possibility of a breach or remedial notice, as a part of which there may be a payment withholding (regulations 50 to 52). In some cases, repeated failures to comply with terms of service, or failures with particularly serious consequences, may thereafter lead to the removal of an NHS pharmacist's or NHS appliance contractor's business premises from the relevant pharmaceutical list (regulation 53).

Part 10 deals with payments to NHS pharmacists and NHS appliance contractors. Regulation 55 (the Drug Tariff and remuneration of NHS pharmacists and NHS appliances contractors) provides for the publication of the Drug Tariff, the main statement of the financial entitlements of NHS pharmacists and NHS appliances contractors that sets out the determinations on such matters made by the Welsh Ministers as determining authority. Regulation 56 (Local Health Boards as determining authorities) makes provision for the Local Health Boards to be determining authorities where this is set out in the Drug Tariff. There are also provisions for supplemental matters including overpayments and payments to NHS pharmacists and NHS appliance contractors.

Part 11 deals with miscellaneous matters, including transitional provisions for applications and appeals made under the 2013 Regulations before and after these Regulations come into force, as well as setting out the different dates on which provisions within the 2013 Regulations are revoked.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Department for Health and Social Services, Welsh Government, Cathays Park, Cardiff, CF10 3NQ.

**Changes to legislation:**

There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.