Pharmaceutical services in rural areas

May 2020

Introduction

This document was originally produced in November 2010. It has been subsequently updated to reflect the current regulations.

Provision for doctors to provide pharmaceutical services in certain circumstances has been made in various NHS Acts and regulations for many decades. These circumstances are in summary:

- A patient satisfies NHS England (referred to in the regulations as the NHS Commissioning Board or NHSCB) or a predecessor that they would have serious difficulty in obtaining any necessary drugs or appliances from pharmacy premises by reason of distance or inadequacy of means of communication (colloquially known as the 'serious difficulty test' which can apply anywhere in England), or
- A patient is resident in an area which is rural in character, known as a controlled locality, at a distance of more than 1.6km (one mile[1]) from any pharmacy's premises (but excluding any distance selling premises). In addition the practice has premises approval and either outline consent or historic rights to dispense to where the patient lives.

The regulations have been amended and expanded over time and this has resulted in the regularised situation summarised above contained in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (the "2013 regulations").

This paper explains the background to the provisions which permit doctors to provide pharmaceutical services to eligible patients.

Background

Dispensing by doctors has been subject to regulations since at least the 1920s and probably since the First World War. In the early 1970s, the representatives of the medical and pharmaceutical professions were both discontented with the 'one-mile rule.' However it had not proved possible for them to agree on an alternative. In October 1975, following an initiative by the then Minister of State (Health), Dr David Owen, the professions agreed between themselves that there should be a voluntary standstill on applications to provide services for patients in rural areas while joint discussions were held with a view to seeking a mutually acceptable resolution. The aim was to secure arrangements acceptable to both professions which would avoid any sudden abrupt changes in arrangements locally on which patients relied.

[1] This distance progressively reduced from two miles to one mile over the years.

A National Joint Committee (NJC) was established chaired by Lt Col Sir Cecil Clothier QC and a report[2] (which became known as the Clothier Report) was published on 9 December 1977 which summarised the history and agreement between the two professions.

Conclusions of the Clothier Report

The report proposed that significant changes to dispensing arrangements in rural areas should be regulated ie that any such changes should require the approval of a body of people representing patients, doctors and pharmacists and whose task it would be to consider all the relevant factors before reaching their decision.

'Significant changes' were defined as:

- Any proposal to start NHS dispensing at a pharmacy for patients in a rural area;
- Any proposal to start NHS dispensing by a medical practice (other than as a result of the serious difficulty test) for patients in a rural area;,
- Any proposal by a dispensing medical practice to provide an NHS dispensing service to a rural area where the practice had not previously dispensed (again, not as a result of the serious difficulty test).

The report concluded that there may be other changes that may or may not be significant:

- The relocation of a pharmacy; and
- The transfer of patients from a prescribing list of a GP to the dispensing list of the same or another practice without a change of the patient's address.

The report concluded some changes were not significant:

- Changes of ownership;
- Dispensing by a successor or a new partner at a GP practice for those patients already on the practice's dispensing list; and
- The addition to the dispensing list of a medical practice of new patients who move into an area where the practice provides a dispensing service.

Other than patients who satisfy the serious difficulty test, the key criterion was that patients must live in areas that are deemed to be rural in character.

Consequently, when an area ceased to be rural in character this may involve a significant change in dispensing arrangements. The report concluded that the question of whether or not an area was rural in character should be considered on its own merits. Due to the potential impact on either doctors or pharmacists, the report recommended that Local

[2] https://www.pcc-cic.org.uk/wp-content/uploads/2020/05/clothier_report_1977.pdf

Medical Committees (LMCs) and Local Pharmaceutical Committees (LPCs) should have the right to appeal against a decision as to whether an area is or is not rural in character.

The report then went on to outline proposals to moderate the impact of any change in dispensing arrangements e.g. to limit the rate at which patients are added to or removed from doctors' dispensing lists. This became known as "gradualisation" and continues to this day.

Rural in character

Prior to 1 April 1983, Family Practitioner Committees (FPCs) or their dispensing sub-committees decided whether an area was rural in character or not. In coming to a decision, they would have taken into account matters such as the extent of building development, the density of population and the extent of services (commercial, public transport etc) available to the residents of the area. They may also have referred to the classifications used as the basis for the Rural Practices Fund.

However, the regulations then in force did not require the FPCs to produce or publish a map or maps that showed those areas that had been defined as rural in character. It is likely though that these areas were defined in a format that helped doctors to know the areas to which they could provide pharmaceutical services. This may have been done by reference to the area of the relevant rural district council.

Introduction of a regularised system

Following the publication of the Clothier Report, amending legislation was introduced to set up a new national body and new regulations came into force on 1 April 1983 (the NHS (General Medical and Pharmaceutical Services) Amendment Regulations 1983, SI 1983/313). These amended the NHS (General Medical and Pharmaceutical Services) Regulations 1974 (SI 1974/160).

Key points from the 1983 amending regulations are:

- Arrangements or requirements made under the 1974 Regulations for a doctor to supply drugs and appliances continued. This is what is known as 'historic rights'.
- Those areas that had previously been determined as rural in character continued and became "controlled localities".
- FPCs were able to determine whether or not an area was rural in character at any time (subject to some restrictions) and these became controlled localities. FPCs were required to delineate the boundaries of any newly determined controlled localities on a map.
- LMCs and LPCs could apply to the FPC for a determination as to whether or not an area was rural in character or not.
- Any doctor wishing to be granted the right to provide pharmaceutical services to patients living in controlled localities to which they had not previously provided such services had, from 1 April 1983, to apply to the FPC for outline consent for that area.

Patients still had to either satisfy the serious difficulty test, or had to live in a controlled locality more than one mile from the premises of a pharmacy, in order to receive

pharmaceutical services from a doctor. However, limitations to this general principle were applied where doctors were providing pharmaceutical services under arrangements existing prior to 1 April 1983. These were:

- The patient had not previously been included in a doctor's list (eg babies); or
- The patient had changed their address from that last notified to the FPC; or
- The patient had not changed their address but immediately before their acceptance as a patient by that doctor they were receiving pharmaceutical services from their previous doctor.

These conditions continue in the 2013 Regulations. Therefore, any doctor with historic rights can only provide pharmaceutical services to patients living in those areas determined as rural in character by an FPC prior to 1 April 1983, if the patient is still at the same address or if the patient meets one of the three criteria listed above. If that doctor has varied their practice area since 1 April 1983 then they should have applied for outline consent to provide pharmaceutical services to any part of that new area (and, since 2005, been granted premises approval). Similarly, if a doctor wished to dispense to patients living in areas that the FPC had made no determination on, then the doctor would have had to apply for outline consent (and premises approval from 1 April 2005). They could not simply decide to offer dispensing services to patients outside previously approved areas unless outline consent was first granted.

Conclusions

As mentioned above, it is possible though unlikely that NHS England will have maps of those areas which the FPCs will have determined as rural in character prior to 1983[3]. Where such maps do not exist, or NHS England has not subsequently published or updated its maps of controlled localities, NHS England should work with its LPCs and LMCs and follow due process to determine whether any such areas are or are not rural in character.

NHS England will also wish to ensure that its procedures for dealing with applications from patients who have requested their doctor provide them with pharmaceutical services reflect the requirements set out in Regulation 48(3) of the 2013 regulations, particularly with regards doctors that have historic rights as identified above. The three conditions for historic rights are set out in Regulation 48(3)(b) of the 2013 regulations.

[3] Not least because of the voluntary standstill on applications between 1975 and 1983