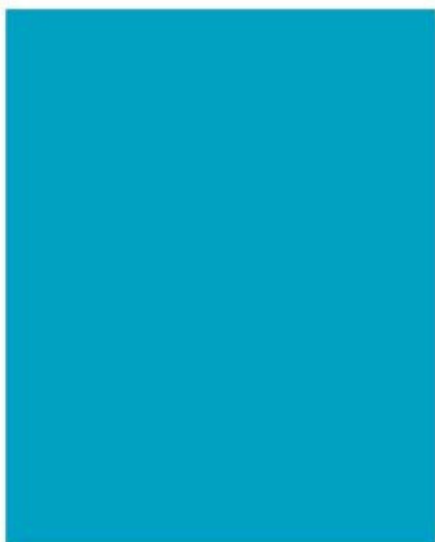


Rurality and related  
determinations policy



# Rurality and related determinations policy

## *Standard operating policies and procedures for primary care*

Issue Date: Draft v6

Document Number: OPS\_1009

Prepared by: Primary Care Commissioning (PCC)

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## Information Reader Box

Directorate	Purpose
Medical	Tools
Nursing	Guidance
Patients & Information	Resources
Finance	Consultations
Operations	
Commissioning Development	
Policy	
Human Resources	

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### **Document Status**

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## Purpose of policy

- 1 NHS England is responsible for direct commissioning of services beyond the remit of clinical commissioning groups, namely primary care, offender health, military health and specialised services.
- 2 This document forms part of a suite of policies and procedures to support commissioning of primary care. They have been produced by Primary Care Commissioning (PCC) for use by NHS England's area teams (ATs).
- 3 The policies and procedures underpin NHS England's commitment to a single operating model for primary care – a “do once” approach intended to ensure consistency and eliminate duplication of effort in the management of the four primary care contractor groups from 1 April 2013.
- 4 All policies and procedures have been designed to support the principle of proportionality. By applying these policies and procedures, Area Teams are responding to local issues within a national framework, and our way of working across NHS England is to be proportionate in our actions.
- 5 The development process for the document reflects the principles set out in *Securing excellence in commissioning primary care*<sup>1</sup>, including the intention to build on the established good practice of predecessor organisations.
- 6 Primary care professional bodies, representatives of patients and the public and other stakeholders were involved in the production of these documents. NHS England is grateful to all those who gave up their time to read and comment on the drafts.
- 7 The authors and reviewers of these documents were asked to keep the following principles in mind:
  - Wherever possible to enable improvement of primary care
  - To balance consistency and local flexibility
  - Alignment with policy and compliance with legislation
  - Compliance with the Equality Act 2010
  - A realistic balance between attention to detail and practical application
  - A reasonable, proportionate and consistent approach across the

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<sup>1</sup> Securing excellence in commissioning primary care <http://bit.ly/MJwrfA>

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four primary care contractor groups.

8 This suite of documents will be refined in light of feedback from users.

9 This document should be read in conjunction with:

- The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and accompanying DH guidance
- The policy for determining applications received for new or additional premises under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
- The procedure for the determination of controlled localities (Rurality01)
- The procedure for determining serious difficulty applications.

### **Policy aims and objectives**

10 The aim of this policy is to ensure that the NHS England makes:

- determinations regarding controlled localities in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the 2013 Regulations);
- decisions on gradualisation consistently; and
- decisions on serious difficulty applications in a consistent manner that is fair to patients.

### **Background**

11 Pharmacies may not always be viable in every part of the country, especially in more rural areas. That is where the services of dispensing doctors can, and do, play an important role; ensuring patients receive their medicines promptly, efficiently, conveniently and to high quality.

12 Whether a patient is eligible to receive NHS dispensing services from a GP or not depends on certain conditions being met. The first condition is whether or not they live in a designated controlled locality.

13 A controlled locality is an area that has been determined by NHS England, a predecessor organisation or on appeal by the NHS Litigation Authority's Family Health Services Appeal Unit (FHSAU), to be 'rural in character'. For the rest of this document, reference is only made to NHS England as a

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formal determining body but ATs should bear in mind the other bodies that could have reached such determinations.

- 14 Areas that have not been determined as rural in character are not controlled localities unless and until NHS England formally determines them to be so. NHS England will need to consider a range of characteristics and features about a locality before reaching such a determination. Certain features (e.g. population density, concentration of communities, the extent of amenities and services, the availability of public transport) may be important factors in reaching a determination. However, this does not mean they are conclusive in their own right. NHS England will have to consider all the evidence and form a reasoned opinion as to whether or not an area is controlled.
- 15 Similarly, any area that is determined not to be rural in character cannot be a controlled locality, even if it has some features of a rural area, for example low population density. Where NHS England determines that an area that was once determined to be rural in character, is no longer rural, that area shall cease to be a controlled locality. This can happen, for example, where there has been substantial economic or social development, or communities have joined up over time and boundaries have become blurred.
- 16 Equally, areas that previously were industrialised or had characteristics associated with more urban areas (e.g. high density housing), can become more rural in nature for various reasons. For example, where there have been significant industry closures, the population has reduced or dispersed, or environmental initiatives have altered the character of the locality. Again, where such changes occur, such areas are not controlled localities unless and until NHS England determines them to be so.

**To whom can doctors dispense?**

- 17 Dispensing doctors may generally only provide pharmaceutical services to patients who live in a designated controlled locality, more than 1.6km (as the crow flies) from a pharmacy. If a new pharmacy opens and a dispensing patient now lives within 1.6km of that pharmacy, the patient must have their prescriptions dispensed at a pharmacy, which may be the new pharmacy or any other one. The patient is no longer eligible to be treated as a dispensing patient. The only exceptions to this are where the pharmacy is a distance selling pharmacy or a reserved location has been determined in connection with the pharmacy, or NHS England has granted a serious difficulty application to the patient. Doctors may continue to dispense to their patients who live further than 1.6km from the new pharmacy.

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- 18 ATs should bear in mind that this can result in complaints to NHS England that patients are being forced to use a particular service or they are not being given choice. The position here is that such patients are able to choose to use any pharmacy they wish to have their medicines dispensed – it is simply that they are no longer eligible to receive dispensing services from their doctor. This feature has been in place for many years and was most recently confirmed in a 2001 agreement between doctors’ and pharmacists’ representatives.

### **Gradualisation**

- 19 When NHS England considers that an area is not, or is no longer, a controlled locality it must decide whether the provision of pharmaceutical services by a dispensing practice will be adversely affected. If NHS England considers it will be, then NHS England has to inform those patients who are no longer eligible that they can no longer receive dispensing services. NHS England may delay terminating these dispensing arrangements so that the effects are introduced over a period of time. This procedure is commonly known as gradualisation.
- 20 The same considerations apply if a new pharmacy opens (other than distance selling premises) and patients in designated controlled localities now live within 1.6km of that new pharmacy. In other words, if patients are no longer eligible to receive dispensing services because they are too close to a new pharmacy or the area in which they live is no longer a designated controlled locality NHS England can phase in the switch to the new arrangements.
- 21 Gradualisation can help mitigate any untoward financial impacts on the dispensing surgery (e.g. winding down stock) from the loss of some or many of its dispensing patients and allows patients a period of time within which to adjust to the change. Typically, this period can last one to three months but may be longer if NHS England is satisfied this is justified.
- 22 The one exception to this is where a new pharmacy opens in a controlled locality but NHS England designates the immediate area surrounding the pharmacy as a ‘reserved location’.

### **Reserved locations**

- 23 Reserved locations in controlled localities are where the patient population (on the patient lists of primary medical service providers, excluding temporary residents) within 1.6km of the premises or the best estimate of the proposed location is 2,750 or less.

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- 24 If the pharmaceutical services regulations committee decides that an area is a reserved location, then the pharmacy will not have the usual 1.6km protection that it would normally have in a controlled locality. Patients in the reserved location can continue to exercise a choice as to whether to receive dispensing services from their doctor or use a pharmacy.

### **Serious difficulty**

- 25 Provision has been in place for many decades to enable a patient who has serious difficulty in accessing a pharmacy to receive NHS dispensing services from a doctor instead. This applies across the whole country, in rural and non-rural areas. There is no minimum distance limit as to a patient's eligibility as applies for dispensing patients in controlled localities.
- 26 The criteria in the 2013 Regulations are that serious difficulty arises by virtue of distance or inadequacy of means of communication. For example, a patient may live within a short distance of a pharmacy as the crow flies but the layout or geographical features of the area means that the most practicable route to access a pharmacy presents considerable difficulties. Such patients may apply to NHS England and, if they can demonstrate that they would have serious difficulty in accessing a pharmacy, they can be determined as eligible to be treated as a dispensing patient.
- 27 Such instances are likely to be much rarer now than previously. Total pharmacy numbers have increased over the last few years, internet-based services are more common and accepted by patients, communities and populations may have grown to enable pharmacies to be viable in more remote areas, and many pharmacies now offer home delivery services. Nonetheless, it is possible that the pharmaceutical services regulations committee will have to deal with such applications.

### **Scope of the policy**

- 28 This policy applies to determinations made by NHS England relating to controlled localities in England. It also applies to decisions regarding periods of gradualisation, which may be given to a provider of primary medical services that holds a contract for such with NHS England. Such decisions may be related to controlled locality determinations or to the determination of a routine application<sup>2</sup> made under Regulation 12 of the 2013 Regulations.

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<sup>2</sup> Routine applications are those offering to meet a current or future need or to secure current or future improvement or better access identified in a pharmaceutical needs assessment, and those offering unforeseen benefits.

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- 29 Finally, the policy applies to the determination of serious difficulty applications received from people registered with a provider of primary medical services that holds a contract for such with NHS England.

### **Governance arrangements**

- 30 An essential element of good governance arrangements for making determinations and decisions under this policy is the establishment of a clear decision-making process for handling concerns when they arise. The pharmaceutical services regulations committee will make determinations and decisions under this policy and the accompanying procedures. The terms of reference for this committee can be found in the policy for determining applications received for new or additional premises under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
- 31 The following are appealable to the FHSAU:
- Refusal to make a controlled locality determination by virtue of the 'five year bar' set out in regulation 37 of the 2013 Regulations.
  - Determinations that an area is or is not , or is or is not part of, a controlled locality
  - Decisions to give or not to give gradualisation.
- 32 Decisions on serious difficulty applications are not appealable to the FHSAU and may only be overturned by the courts.
- 33 Robust audit trails will be maintained and all determinations and decisions will be fully reasoned.

### **Controlled localities**

- 34 Decisions relating to the determination of controlled localities will be made by the pharmaceutical services regulations committee in line with the procedure that accompanies this policy.
- 35 Before 1 April 1983, the term 'controlled locality' did not exist in legislation; it was introduced by the NHS (General Medical and Pharmaceutical Services) Amendment Regulations 1983. Before that date family practitioner committees (FPCs) had to form an opinion by virtue of the extant regulations as to whether an area was rural in character.

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- 36 From 1 April 1983, such determinations became known as controlled localities and FPCs and successor organisations were required to delineate the boundaries of any controlled localities that they subsequently determined on a map. Later regulations required these maps to be published.
- 37 Any areas that had been determined as rural in character before 1 April 1983 automatically became termed controlled localities from that date. However, there was no requirement to delineate such areas on a map, although some FPCs may have chosen to do so. ATs may therefore find themselves in the position where they have:
- maps of controlled localities that were determined from 1 April 1983;
  - lists of villages that were determined to be rural in character before 1 April 1983;
  - descriptions of areas that were determined to be rural in character before 1 April 1983;
  - a mixture of the above; or
  - none of the above.
- 38 Changes to the nature and characteristics of a controlled locality may have occurred since an area was determined as rural and therefore the pharmaceutical services regulations committee may need to consider afresh whether an area is or is not a controlled locality either alongside a routine application, at the request of a local pharmaceutical committee or local medical committee or of its own accord. Whenever a controlled locality determination is to be made, a site visit will be undertaken.
- 39 There is no prescribed way to define what is rural in character. Each case must be judged on individual circumstances and will depend on various factors.
- 40 A rural area is normally characterised by a limited range of local services. The pharmaceutical services regulations committee may consider factors (relevant at the time of the determination) when determining whether an area is rural. These have been clarified over the years and include:
- environmental – the balance between different types of land use;
  - employment patterns (bearing in mind that those who live in rural areas may not work there);
  - community size and distance between settlements;

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- the overall population density;
- transportation – the availability or otherwise of public transport and the frequency of such provision including access to services such as shopping facilities; and
- the provision of other facilities, such as recreational and entertainment facilities.

41 Pharmaceutical services regulations committees may find the Department for Environment, Food and Rural Affairs Rural Strategy's definition of rurality<sup>3</sup> useful.

### **Gradualisation**

42 The pharmaceutical services regulations committee will make decisions relating to the determination of controlled localities. Gradualisation is to be considered alongside controlled locality determinations and determinations of routine applications where these have an impact on existing dispensing doctor services.

43 The aim of gradualisation is two-fold. First it allows patients a period of time within which to adjust to being given a prescription to take to a pharmacy rather than having their drugs and/or appliances dispensed at the surgery. Second, it allows the affected dispensing practice time to make whatever alterations to its working practices as may be necessary, such as reducing stock holdings and altering staff duties.

44 There is no separate procedure for making decisions on gradualisation. However, consideration of the matter has been incorporated into the relevant market entry procedures. As well as considering any representations received, the following factors are to be taken into account when the pharmaceutical services regulations committee considers whether a period of gradualisation is to be given:

- The number of patients affected.
- The proportion of the GP practice's dispensing patient list that this represents.
- Where a new pharmacy opens serving previous dispensing patients, the opening date of the pharmacy and its ability to absorb former dispensing patients alongside others who choose to access its services.

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<sup>3</sup><http://tinyurl.com/cgnetva>

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- 45 Periods of gradualisation should generally be no shorter than one month from the opening of the pharmacy and, other than in exceptional circumstances, should last no longer than three months. Exceptional circumstances may include:
- the loss by a dispensing practice of all their dispensing patients;
  - where the reduction in number of dispensing patients would lead to staff changes or redundancy; or
  - where there is only one pharmacy within a 1.6km radius of the practice premises and that is the pharmacy that is opening and its ability to absorb former dispensing patients effectively needs to be staged over time.
- 46 In such cases the pharmaceutical services regulations committee may give up to six months' gradualisation.
- 47 When considering whether to grant a period of gradualisation the committee will bear in mind the 1996 case R –v- North Yorkshire FHSA ex parte Dr Wilson and Partners in which Justice Carnwath said: "It is not part of the scheme of those regulations or indeed of the statute that pharmaceutical services should be relied upon to provide financial underpinning for medical services which are intended to be financed in other ways".
- 48 Decisions on gradualisation are appealable to the FHSAU and therefore must be fully minuted and documented

### **Serious difficulty applications**

- 49 The pharmaceutical services regulations committee will make decisions relating to the determination of serious difficulty applications. Such applications will only be approved where the individual demonstrates they would have serious difficulty in accessing a pharmacy on one of the following grounds:
- by reason of distance; or
  - by reason of inadequacy of communication.

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- 50 The following are not considered to be acceptable grounds in their own right:
- Lack of a car.
  - Delays in dispensing at a pharmacy since it may offer home delivery services.
  - Working away from home regularly since a patient may be able access pharmacies near where they work.
  - Claims that a pharmacy is inaccessible but the patient is able to access their GP surgery and/or other healthcare services without apparent difficulty.
  - No internet access.
  - Patient convenience.
- 51 Each case is to be considered on its merits.
- 52 For the reasons set out earlier, it is expected that pharmaceutical services regulations committees will grant few serious difficulty applications.

### **Monitoring and review of policy**

- 53 This policy will be reviewed regularly, with frequency determined by NHS England. There are robust arrangements for the maintenance and storage of all records, minutes, and reports associated with the procedure to ensure a clear audit route through the procedures related to this policy. NHS England may instigate an internal audit, or be required to submit information to an external body for scrutiny.

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## Annex 1: abbreviations and acronyms

A&E	accident and emergency
APHO	Association of Public Health Observatories (now known as the Network of Public Health Observatories)
APMS	Alternative Provider Medical Services
AT	area team (of NHS England)
AUR	appliance use reviews
BDA	British Dental Association
BMA	British Medical Association
CCG	clinical commissioning group
CD	controlled drug
CDAO	controlled drug accountable officer
CGST	NHS Clinical Governance Support Team
CIC	community interest company
CMO	chief medical officer
COT	course of treatment
CPAF	community pharmacy assurance framework
CQC	Care Quality Commission
CQRS	Calculating Quality Reporting Service (replacement for QMAS)
DAC	dispensing appliance contractor
Days	calendar days unless working days is specifically stated
DBS	Disclosure and Barring Service
DDA	Disability Discrimination Act
DES	directed enhanced service
DH	Department of Health
EEA	European Economic Area
ePACT	electronic prescribing analysis and costs
ESPLPS	essential small pharmacy local pharmaceutical services
EU	European Union
FHS	family health services
FHS AU	family health services appeals unit
FHSS	family health shared services
FPC	family practitioner committee
FTA	failed to attend
FTT	first-tier tribunal
GDP	general dental practitioner
GDS	General Dental Services
GMC	General Medical Council

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GMS	General Medical Services
GP	general practitioner
GPES	GP Extraction Service
GPhC	General Pharmaceutical Council
GSMP	global sum monthly payment
HR	human resources
HSE	Health and Safety Executive
HWB	health and wellbeing board
IC	NHS Information Centre
IELTS	International English Language Testing System
KPIs	key performance indicators
LA	local authority
LDC	local dental committee
LETB	local education and training board
LIN	local intelligence network
LLP	limited liability partnership
LMC	local medical committee
LOC	local optical committee
LPC	local pharmaceutical committee
LPN	local professional network
LPS	local pharmaceutical services
LRC	local representative committee
MDO	medical defence organisation
MHRA	Medicines and Healthcare Products Regulatory Agency
MIS	management information system
MPIG	minimum practice income guarantee
MUR	medicines use review and prescription intervention services
NACV	negotiated annual contract value
NCAS	National Clinical Assessment Service
NDRI	National Duplicate Registration Initiative
NHAIS	National Health Authority Information System (also known as Exeter)
NHS Act	National Health Service Act 2006
NHS BSA	NHS Business Services Authority
NHS CB	NHS Commissioning Board (NHS England)
NHS CfH	NHS Connecting for Health
NHS DS	NHS Dental Services
NHS LA	NHS Litigation Authority
NMS	new medicine service
NPE	net pensionable earnings
NPSA	National Patient Safety Agency

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OJEU	Official Journal of the European Union
OMP	ophthalmic medical practitioner
ONS	Office of National Statistics
OOH	out of hours
PAF	postcode address file
PALS	patient advice and liaison service
PAM	professions allied to medicine
PCC	Primary Care Commissioning
PCT	primary care trust
PDS	personal dental services
PDS NBO	Personal Demographic Service National Back Office
PGD	patient group direction
PHE	Public Health England
PLDP	performers' list decision panel
PMC	primary medical contract
PMS	Personal Medical Services
PNA	pharmaceutical needs assessment
POL	payments online
PPD	prescription pricing division (part of NHS BSA)
PSG	performance screening group
PSNC	Pharmaceutical Services Negotiating Committee
QOF	quality and outcomes framework
RCGP	Royal College of General Practitioners
RO	responsible officer
SEO	social enterprise organisation
SFE	statement of financial entitlements
SI	statutory instrument
SMART	specific, measurable, achievable, realistic, timely
SOA	super output area
SOP	standard operating procedure
SPMS	Specialist Personal Medical Services
SUI	serious untoward incident
UDA	unit of dental activity
UOA	unit of orthodontic activity

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**Version control tracker**

Version Number	Date	Author Title	Status	Comment/Reason for Issue/Approving Body
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