

**South West**  
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Dear Colleague

**Applications by Ruby Country Medical Group for outline consent to dispense medicines, and for dispensing premises approval for premises in Hatherleigh, under Part 8 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013**


Please find enclosed a copy of the above applications which have been made to NHS England. I can confirm that no information that has been received in relation to this application is being withheld under regulation 52(9) of the Regulations. Please also find attached some explanatory notes and background information.

You have an opportunity to make written representations to us, at the postal or email address above, regarding these applications within 45 days of the date of this letter, ie by 1 September 2018.

Any representations received will be copied to the applicant and other interested parties, who will have an opportunity to make observations on them.

If the application is granted, in whole or in part, we would then need to consider whether there would be any adverse effects on other providers of pharmaceutical services. If there would be any adverse effects, regulation 57 allows conditions to be imposed to postpone the coming into effect of outline consent for such period as we think fit or to limit the patients that can be dispensed to. Please include comments regarding this issue in your representations if you wish.

Yours faithfully



**David Ward**  
**Asst Contract Manager, Pharmacy Team**

## **BACKGROUND AND EXPLANATORY NOTES (by NHS England)**

### **Background**

At the end of June 2018 Dr Francis Fernandez and Ms. Maria Guerra-Jimenez resigned from their contract as the operators of the GP surgeries at Hatherleigh Medical Centre, Sanctuary Lane, Hatherleigh and Beech House Surgery, Shebbear.

In rural areas where there are no community pharmacies nearby, surgeries may be authorised to dispense prescription-only medication directly. Both Hatherleigh Medical Centre and Beech House Surgery had approval to dispense medicines to patients and did so from dispensaries within those premises.

Following a procurement process undertaken by NHS England, Ruby Country Medical Group was appointed as the provider of medical services in Hatherleigh and Shebbear, and it was agreed that they would take over the running of the surgeries from Monday 2 July to ensure patients had continued access to primary care.

It had been planned that Ruby Country Medical Group would provide services from the existing surgery premises in Hatherleigh and Shebbear as branches of Holsworthy Medical Centre, however that unexpectedly proved to not be possible. Dr Fernandez owns the current GP premises, and since the contract was awarded to Ruby Country Medical Group at the beginning of June they worked hard to secure the continued use of the buildings when they took over. However, despite best efforts it was not possible to secure agreement to use the premises.

NHS England and Ruby Country Medical Group are working to bring services back to Hatherleigh and Shebbear as soon as possible, for example by exploring the option of using a mobile surgery as temporary premises. Ruby Country Medical Group is also doing everything they can to secure new permanent premises to provide patient care. They have already identified potential alternative premises and have been holding detailed discussions with the owner, and hope to be ready to open new premises in early autumn.

### **Interim dispensing arrangements**

Because Ruby Country Medical Group is unable to use the existing practice premises it cannot use the existing dispensaries in Hatherleigh and Shebbear.

At present prescriptions are being dispensed by community pharmacies in Holsworthy, Okehampton, North Tawton and Torrington, however this does involve many patients needing to travel much further to collect their medicines than they have had to before.

### **What are these applications about?**

These applications seek approval for new, permanent arrangements for dispensing from the planned new surgery in Hatherleigh.

In these applications, Ruby Country Medical Group are applying for:

- Outline consent to dispense: updated permission for patients of Holsworthy Medical Centre who live in the area outlined on maps 1 and 2, attached, to receive dispensing services.

This will cover almost all of the patients who have been collecting their medicines from Hatherleigh Medical Centre and Beech House Surgery until recently. It will also include patients of Holsworthy Medical Centre itself who live in the defined area and who may wish to use the new surgery in Hatherleigh in future. It will not include a small number of patients located a long way from Hatherleigh / Shebbear.

Note: a doctors' dispensary can only dispense medicines to patients registered with that practice, in this case Holsworthy Medical Centre, which now includes patients formerly registered with Hatherleigh Medical Centre/Beech House Surgery. A dispensary cannot dispense medicines to patients of other practices, even if they live within the defined area.

- Dispensing premises approval for a permanent dispensary to be established at the new surgery in Hatherleigh when it is ready.

It is not intended to establish a dispensary at any new surgery in Shebbear, and instead arrangements will be made for medicines for Shebbear patients to be dispensed at the new Hatherleigh dispensary and then taken to the new Shebbear surgery for patients to collect.

### **Who does NHS England consult about the applications?**

Before NHS England decides the applications, the Regulations require us to consult:

- nearby pharmacies
- nearby doctors' surgeries
- the local representative bodies for pharmacies and surgeries
- the Health & Wellbeing Board at Devon County Council
- Devon Healthwatch, which exists to represent local patients in general.

We consult them by sending them a copy of the application and inviting them to make comments within 45 days. Comments can be made by letter or email.

In addition, the law requires us to involve patients in our decision-making. We are doing this by sending copies of the application to:

- Hatherleigh Town Council
- Shebbear Parish Council
- the appropriate West Devon Borough and Torridge District councillors.

Copies will also be made available:

- at locations in Hatherleigh and Shebbear
- on the Holsworthy Medical Centre website.

Anyone wishing to make comments can do so within the 45 days.

Applications are not confidential. If you want, you may share details with anyone else who might be interested. They can also make comments within the same 45-day period.

Any comments we receive will be sent to the applicant. They will have a chance to respond to us about those comments.

A report will then be prepared setting out details of the applications, the comments received, the applicable legislation and policies, and other relevant information. This will be considered by the South West Pharmaceutical Services Regulations Committee.

**What issues will the Committee consider?**

The Regulations (attached for reference) set out a number of things the Committee must consider as part of its decision. These include:

If the Committee concludes that any part of the area for which outline consent is sought is:

- not in a 'controlled locality' (that is, an area which has been officially designated as rural) – attached is a map showing which parts of this area of Devon are controlled localities, or
- within 1.6 kilometres (1 mile) of a community pharmacy

then that part must be excluded from the outline consent area (regulation 51(6)).

If the Committee is of the opinion that granting the applications would prejudice pharmaceutical services provided by pharmacies or other doctors' surgeries, or medical services provided by other doctor's surgeries, then it must refuse the application (unless the prejudice can be removed by reducing the area for which consent is granted) (regulation 51(8)-(9)).

If the Committee does not think that there would be prejudice, but still thinks that nearby pharmacies would be adversely affected, it can impose conditions to postpone the coming into effect of the outline consent or to limit the patients that can be dispensed to (regulation 57).

**Is the Committee's decision final?**

If the applications are refused, Ruby Country Medical Group would be able to appeal.

If the applications are granted, a nearby surgery or pharmacy which opposed the application would be able to appeal.

If there is an appeal it would be handled by the Primary Care Appeals Service, which is part of NHS Resolution, a separate organisation from NHS England.

Extracts<sup>1</sup> from Part 8 (Dispensing Doctors) of:

**The National Health Service (Pharmaceutical and  
Local Pharmaceutical Services) Regulations 2013 (SI 2013/349)**

Outline consent and premises approval: applications by doctors

51.—(1) A person or partnership with a patient list, or a person who performs services on behalf of a provider of primary medical services, who wishes to be granted the right to provide pharmaceutical services to patients on their own list or the provider's list (if the patients apply under regulation 48(1) on the basis of Condition 2 or 3) may apply in writing to the NHSCB<sup>2</sup> for—

(a) consent (“outline consent”) to the provision of pharmaceutical services to patients who request those services and who reside in the area specified in the application;

(b) approval of any medical practice premises from which D<sup>3</sup> wishes to dispense (“premises approval”).

(2) Where D has outline consent that has taken effect and wishes to apply for premises approval in relation to—

(a) additional medical practice premises from which to provide pharmaceutical services to patients who reside in the area for which D has an outline consent; or

(b) medical practice premises from which D wishes to relocate to provide pharmaceutical services to patients who reside in the area for which D has an outline consent, but the move to new medical practice premises is not a relocation of the type provided for in regulation 55(2),

the premises approval application need not have a related outline consent application, but in all other cases a premises approval application under paragraph (1)(b) must have a related outline consent application.

(3) An application for premises approval must include details of the address of the premises and whether those premises are already listed in relation to a different area.

(4) Except in so far as these Regulations provide to the contrary, the NHSCB is to determine applications for outline consent and premises approval in such manner (including with regard to procedures) as it sees fit.

(5) The NHSCB must refuse an application under paragraph (1) (but not regulation 54, 55 or 58) for premises approval if the premises in respect of which approval is sought are within 1.6 kilometres of pharmacy premises that are not distance selling premises.

(6) The NHSCB must refuse an application for outline consent to the extent that any part of the area specified in the application—

(a) is not, or is not part of, a controlled locality; or

(b) is within 1.6 kilometres of pharmacy premises that are not distance selling premises.<sup>4</sup>

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1. The full text of the Regulations can be found at [www.legislation.gov.uk/uksi/2013/349/contents](http://www.legislation.gov.uk/uksi/2013/349/contents)

2. ‘NHSCB’ means NHS England

3. ‘D’ means the dispensing doctor

(7) Where the NHSCB is minded to refuse an application for outline consent pursuant to paragraph (6)(a), it may defer that decision in order to make a determination under regulation 36(2).

(8) Subject to paragraph (9), the NHSCB must refuse an application under paragraph (1) (but not regulation 54, 55 or 58) if granting it would, in its opinion, prejudice the proper provision of relevant NHS services in the area of—

- (a) the relevant HWB;<sup>5</sup> or
- (b) a neighbouring HWB of the relevant HWB.

(9) If the NHSCB determines that an application for outline consent would, if it had been made for a smaller area within the area specified in the application, not prejudice the proper provision of relevant NHS services in the area of—

- (a) the relevant HWB; or
- (b) a neighbouring HWB of the relevant HWB,

it may grant the application in respect of that smaller area.

(10) The NHSCB must refuse an application (A1) under paragraph (1)—

- (a) for outline consent to the extent that any part of the area specified in A1 is the same as the area or any part of the area specified in an application for outline consent which was refused within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made; or
- (b) for premises approval (but not under regulation 54, 55 or 58) if the premises specified in A1 were specified in an application for premises approval, or relate to an application for outline consent where any part of the area specified in that application is the same as the area or any part of the area specified in an earlier application for outline consent, which was refused—
  - (i) under this regulation,
  - (ii) under regulation 51 of the 2012 Regulations (outline consent and premises approval: applications by doctors), or
  - (iii) by virtue of regulation 18(2) of the 2005 Regulations (refusal: outline consent and premises approval where patients are in a controlled locality),

within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made, unless the NHSCB is satisfied that there has been a substantial and relevant change of circumstances affecting the controlled locality to which the application relates since those proceedings reached their final outcome.

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4. 'Distance selling premises' means a pharmacy which may only dispense medicines by post/courier; there are no such pharmacies in this part of Devon

5. 'HWB' means Health and Wellbeing Board; in this case the relevant HWB is Devon Health and Wellbeing Board

Gradual introduction of premises approval

57.—(1) Where a dispensing doctor (D) has outline consent but the NHSCB considers that the provision of pharmaceutical services by any NHS pharmacist, or of LP services by any LPS chemist, is likely to be adversely affected if D provides pharmaceutical services from medical practice premises which have been subject to a related application for premises approval (whether under regulation 51, 54 or 55), the NHSCB may by conditions—

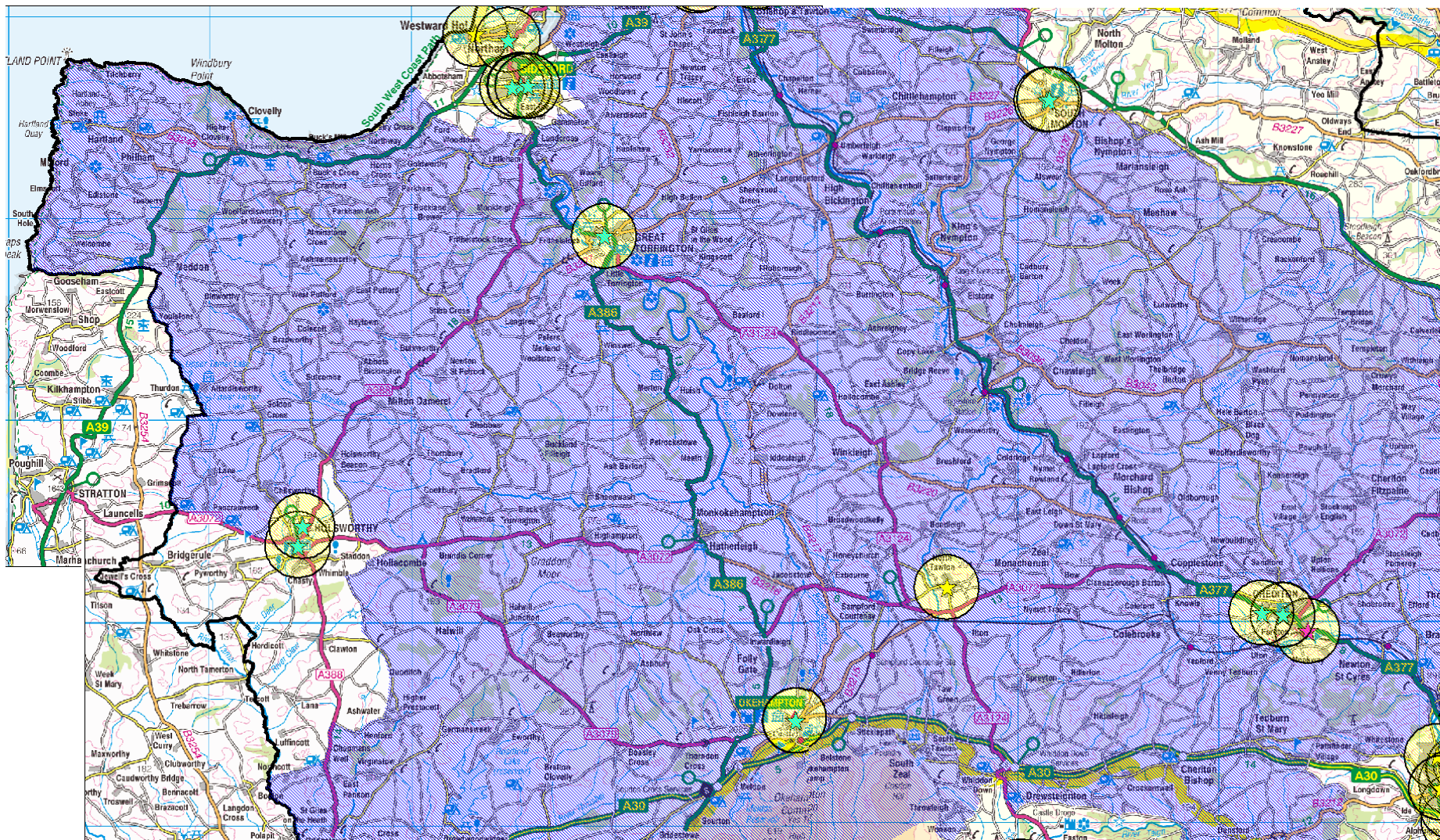
(a) postpone the taking effect of the related premises approval for such period as it thinks fit; or

(b) limit the patients to whom D (or any successor to D) is able to provide pharmaceutical services from the medical practice premises in such manner, and for such periods, as it thinks fit.

(2) The NHSCB must decide whether or not to impose conditions under paragraph (1)—

(a) if there was a delay in the related outline consent taking effect because of an outstanding pharmacy application, when it determines that the outline consent is to come into effect; or

(b) in any other case, when it determines the application for premises approval.



### Extract from Devon Controlled Localities map

Purple shaded = Controlled locality

Non-shaded = Non-controlled locality

Circles with yellow shading = 1.6km area around a pharmacy

Blue stars = 100hrs pharmacies

Yellow stars = all other pharmacies