# Sub-contracting your dispensing service, pharmacy closures and PNAs - opportunities or threats?

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# Pharmaceutical needs assessments

# England (1)

- Health and wellbeing boards are required to produce a pharmaceutical needs assessment (PNA) every three years
- For most this means the next one is to be published by 1 October 2025
- A PNA describes the demographics and health needs of a health and wellbeing board’s population now and how they are expected to change in the three-year lifetime of the document
- Identifies the current provision of pharmaceutical services
- Identifies any current gaps in the provision of pharmaceutical services by pharmacies and dispensing appliance contractors

# England (2)

- Also identifies any gaps that may arise in provision of pharmaceutical services by pharmacies and dispensing appliance contractors during the lifetime of the document
- Articulates these gaps as needs for, or improvements or better access to, one or more pharmaceutical services
- Applications may then be submitted by pharmacy contractors or dispensing appliance contractors to meet those needs or secure those improvements or better access
- Pharmacy closures and loss of opening hours (particularly evenings and weekends) are of concern

# Wales

- The health boards are required to produce a PNA every five years
- This means the next ones are to be published by 1 October 2026
- Similar to the English PNAs, however they identify current or future needs in the provision of pharmaceutical services by:
    - pharmacy contractors,
    - dispensing appliance contractors, or
    - dispensing doctors

# Engagement

- A steering group will be established and the LMC invited to attend – some do, some don’t
- Questionnaires will be developed and circulated to capture the views of contractors and information that is not available from other sources – important that they are completed, but it is recognised that contractors are busy
- Practices and LMCs will be consulted on a draft of the document – 60 days to respond

 

# Potential threat? (1)

- The PNA identifies the need for certain pharmaceutical services to be provided by a pharmacy in an area that you dispense to – how likely is this?
- Just because a PNA identifies the need for (or improvements or better access to) certain pharmaceutical services doesn't mean that anyone will apply to meet that need
- Of the 829 applications submitted in England between 1 January and 29 August 2024, only 162 were for new premises. The rest related to existing premises – change of ownerships and relocations, for example

 

# Potential threat? (2)

- Of these 162, 58 were for distance selling premises (aka internet pharmacies) so if granted and the pharmacy opens any dispensing patient living within 1.6km of them can continue to be dispensed to
- Dispensing practices generally dispense to people living in less populated areas which have been determined to be a “controlled locality”
- “Controlled localities” – areas that the ICB, NHS England or a preceding organisation has determined as ‘rural in character’
- If an application to open a pharmacy is received in a “controlled locality” the ICB must consider whether the proposed premises are in a “reserved location”

# Potential threat? (3)

- If the ICB determines that the proposed pharmacy is in a reserved location then if it opens, those dispensing patients who live in the reserved location remain registered as dispensing patients
- Reserved locations determined where the number of people living within 1.6km of the proposed pharmacy, who are registered with a GP is less than 2,750
- In general, if a reserved location is determined in connection with a proposed pharmacy, it is unlikely to open as it is unlikely to be financially viable
- Therefore, how much of a threat is this?

 

# Potential threat? (4)

- In Wales, the PNA is also used to determine applications from dispensing doctors
- An application to dispense to a new area, or to start to dispense, must be refused unless it would meet a need for one or more pharmaceutical services that is included in the health board's PNA
- This will have implications in connection with the award of a new GMS contract
- Same threat as in England where a PNA identifies the need for pharmaceutical services to be provided by a pharmacy in an area that you dispense to

# Potential opportunity?

- Yes, if you are thinking of opening a pharmacy
- Have a look at the PNA for your area – are there needs identified (England and Wales) or improvements or better access identified (England only)?
- If there aren't then this isn't the end of the process in England as you could still submit an "unforeseen benefits" application
- Unfortunately, there is no equivalent in Wales so if there are no needs identified in your health board's PNA you couldn't apply to open a pharmacy

 

# Pharmacy closures

 

# Closures – context (1)

- The annual amount of money paid to pharmacies for the provision of essential and advanced services is set by Department of Health and Social Care
- It is paid via a number of different fees which are adjusted to ensure the full amount is paid in-year
- Fees and drug prices may be reduced in-year to ensure no over-delivery
- The amount has been fixed for six years

 

# Closures – context (2)

- However, the costs of providing those services has increased:
  - The agreed five-year funding deal meant no uplifts to the funding envelope paid to pharmacies for the provision of essential and advanced services despite increasing numbers of items being prescribed and more clinical services being rolled out
  - Cost of living crisis
  - Medicines shortages – more time spent trying to source medicines
  - Shortage of pharmacists (enticed away to primary care networks and practices) and increased reliance on locums, who may have increased their rates as a result

 

# Consequences

- Unprecedented numbers of closures, particularly 100 hour pharmacies
- Opening a new pharmacy is not financially attractive – but buying an existing pharmacy still seems to be
- Between 1 January and 30 June 2024, 135 applications were submitted to open a new pharmacy – not all are guaranteed to open
- Over the same period the number of pharmacies fell by 174

 

# Opportunity? (1)

- Closures mean that you may be able to dispense to more patients
- But it all depends on whether you have outline consent or historic rights to dispense
- If you have outline consent to dispense to specified areas it will not cover the area that is within 1.6km of the pharmacy that has closed
    - You therefore cannot dispense to patients living in that area
    - You would first need to apply for outline consent for that area and premises approval for the premises from which you will dispense to that area
    - But if there is a pharmacy within 1.6km of the premises for which you are seeking premises approval the application must be refused

 

# Opportunity? (2)

- If you have historic rights to dispense to eligible patients (ie you were dispensing before 1 April 1983) you will need to ensure that the patients who live within the area that is within 1.6km of the pharmacy that has closed meet one or more of the conditions set out in regulation 48 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
- If they don’t you cannot dispense to them

 

# Historic rights

- The patient lives:
  - in a controlled locality,
  - more than 1.6km from a pharmacy, and

  the practice has historic rights and premises approval for the area in which the patient lives, and
- The patient:
  - has not previously been registered with a practice whilst living in the health and wellbeing board's area, or
  - has been so registered but has moved within the health and wellbeing board's area, or
  - has been so registered, hasn't moved, but their previous doctor dispensed to them

 

# Sub-contracting your dispensing service

 

# Background to a recent case

- A partnership had established a company and successfully applied to open a pharmacy
- The pharmacy was subsequently sold to a pharmacy contractor and at some point the partnership sub-contracted provision of the dispensing service to the pharmacy contractor
- The ICB became aware of this and sought legal advice as to whether the dispensing service can be sub-contracted and any other matters that it needed to be aware of

 

# Sub-contracting of clinical matters (1)

- The GMS contract regulations allow a practice to sub-contract its obligations to provide clinical matters in certain circumstances
    - The practice must take reasonable steps to satisfy itself that it is reasonable to sub-contract the service,
    - It must satisfy itself that the sub-contractor is qualified and competent to provide the service,
    - The practice gives notice in writing to the ICB of its intention to sub-contract as soon as reasonably practicable before the date on which the proposed sub-contract is intended to come into effect
    - The notice must contain certain information
- Same provision in the PMS agreement regulations

# Sub-contracting of clinical matters (2)

- The ICB may request information on the proposed sub-contract and the practice must supply it
- The ICB may give notice in writing that it objects to the proposed sub-contract on patient safety grounds or if it would put NHS England at risk of material financial loss – this would stop the sub-contract from taking effect

 

# Authorising persons to carry out dispensing activities

- Under paragraph 1, Schedule 6 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations, duly authorised persons may carry out dispensing activities on behalf of a dispensing doctor provided:
  - That person complies with any statutory requirements, and
  - The dispensing doctor must secure compliance with those requirements
- Where a sub-contract is in place, the dispensing doctor must maintain an element of oversight and control over the sub-contractor as they remain primarily responsible for ensuring compliance

# Premises approval

- The legal advice confirmed that the practice must have “premises approval” for the “medical practice premises” at which the dispensing service is to be provided
- This would require the practice to first apply for premises approval for those premises or apply to relocate the premises approval for its current premises to the sub-contractor’s premises – not guaranteed to be granted and may have to be refused
- In addition, the sub-contractor premises must be included in the practice’s GMS contract – this will require a request for a contract variation to be agreed by the ICB

# Hub and spoke dispensing (1)

- Government consulted on hub and spoke dispensing and issued its response to the consultation in May 2024
- This set out proposed amendments to the Medicines Act 1968 and the Human Medicines Regulations 2012
- The response confirmed that dispensing doctors will be able to be a spoke under the new regulations should they wish, but not a hub
- Response silent on what, if any, amendments will be made to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 which govern the dispensing service provided by some practices

# Hub and spoke dispensing (2)

- Potential issues
  - You require premises approval for the hub you are using and will need to apply for this
  - If those premises are a pharmacy that is included in a pharmaceutical list the application has to be refused by the ICB
  - You still require premises approval for your premises
  - The ICB may not agree to vary your contract to include the hub's premises
  - The ICB may not agree to the sub-contract
- Watch this space!

 

# Final questions?