

Pharmacy changes (including consolidations and mergers)

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Introduction

Under current regulations¹, Health and Wellbeing Boards (HWBBs) are required to produce an assessment of needs for pharmaceutical services in their area at least every three years.

The Cheshire East Pharmaceutical Needs Assessment (PNA) looks at the current

¹ The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013: <http://www.legislation.gov.uk/uksi/2013/349/contents/made>

provision of pharmaceutical services across the borough and how well needs for pharmaceutical services are being met. Once the PNA has been finalised, NHS England (NHSE) is required to use it to consider applications to open a new pharmacy, move an existing pharmacy or to commission additional services from a pharmacy. In order to open a community pharmacy, a contract must be granted by NHSE.

If a PNA identifies a 'gap' in pharmaceutical service provision then an application for a new pharmacy contract could be made by a pharmacy contractor and could be granted by NHSE. NHSE also receive applications from existing pharmacy contractors for changes including change in ownership, location or opening hours. NHSE notify the HWBB of these changes and if they affect the need for pharmaceutical services as outlined in the current PNA, the HWBB are required to refresh the PNA or where this would be disproportionate, to produce a supplementary statement.

In December 2015 the Department of Health announced that it considered that there were too many pharmacies. It introduced changes to legislation which would allow pharmacies in an area to consolidate or merge without it creating a 'gap'. This change in legislation (regulation 26A) in the amended NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations² puts an obligation on HWBBs to express an opinion when such an application is submitted. The opinion of the HWBB on whether proposed consolidations or mergers within their area will create a 'gap' in pharmaceutical services is to assist NHSE in making its decision. The amended regulations also require the HWBB to produce a supplementary statement if NHSE grant the merger application.

This policy sets the principles, process and timescale for responding to all notifications of pharmacy changes from NHS England. It therefore supports the Health and Wellbeing Board in fulfilling its legal responsibilities.

Policy scope

This policy outlines the background and statutory requirements for Health and Wellbeing Boards (HWBBs) who are required to respond to requests from NHS England (NHSE) on proposed consolidation (merger) applications from community pharmacy contractors.

It also incorporates a process to handle other pharmacy change notifications received, to ensure that the HWBB are aware of significant changes and can make informed decisions on whether there is a need for a PNA supplementary statement or a complete refresh of the PNA.

² NHS England, the National Health Service (Pharmaceutical services, charges and prescribing) (Amendment) Regulations 2016
http://www.legislation.gov.uk/ukxi/2016/1077/pdfs/ukxi_20161077_en.pdf

This policy does not cover producing supplementary statements or refreshing the PNA as a result of population changes that affect the need for pharmacies (such as occupation of new housing estates or changes to local traffic such as local employers relocating or significant shopping developments). The process for notifying Public Health when developments will impact on population levels (e.g. people moving into new housing estates) needs to be developed to enable an assessment of any impacts on pharmacy provision.

It also does not cover the impact on pharmaceutical provision of CCG, Public Health or Social Care commissioning decisions made during the life of the PNA; NHSE are not required to consider local commissioning arrangements when making decisions about pharmacy applications.

Principles

- Use the current PNA and in particular the first four regulatory statements to assess whether consolidation/merger or change will impact on provision or need
- Ensure that all decisions and recommendations are based on the interpretation of the pharmaceutical regulations rather than any other influence
- Give consideration to variations in need associated with localities and with protected characteristics as defined in 2010 Equality Act (i.e. age, gender, race, disability, marital status, religion, sexual orientation)
- Be evidence-based
- Discard any responses where there is a conflict of interest
- Be transparent and communicate clearly to residents via an updated pharmacy provision map, supplementary statement or revised PNA
- Deciding whether to produce a supplementary statement or full PNA refresh will be proportionate to the impact of the pharmacy changes granted by NHSE
- Communicate to NHSE in accordance with the regulations within the 45 day timescale

Policy in practice: processes

There are two situations when a HWBB is required to issue a supplementary statement regarding pharmaceutical provision within their area.

The first is a statutory requirement when NHSE grant a consolidation or merger.

The second is if other pharmacy change notifications from NHSE (for example changes to opening hours or change of pharmacy location) are deemed to change the conclusion of the current PNA but a full refresh of the PNA is judged to be disproportionate. For example, pharmacy changes that affect how well the needs for pharmaceutical services are met in one town could be covered by a supplementary statement whereas changes affecting how well needs are met across a wider geographical area may require a full PNA refresh. Current pharmacy provision in

Cheshire East means that changes to opening hours are unlikely to significantly affect the market and so a supplementary statement would not be required.

This process is designed to give governance around the handling of these notifications to ensure that decisions are based on evidence, are transparent and communicated clearly.

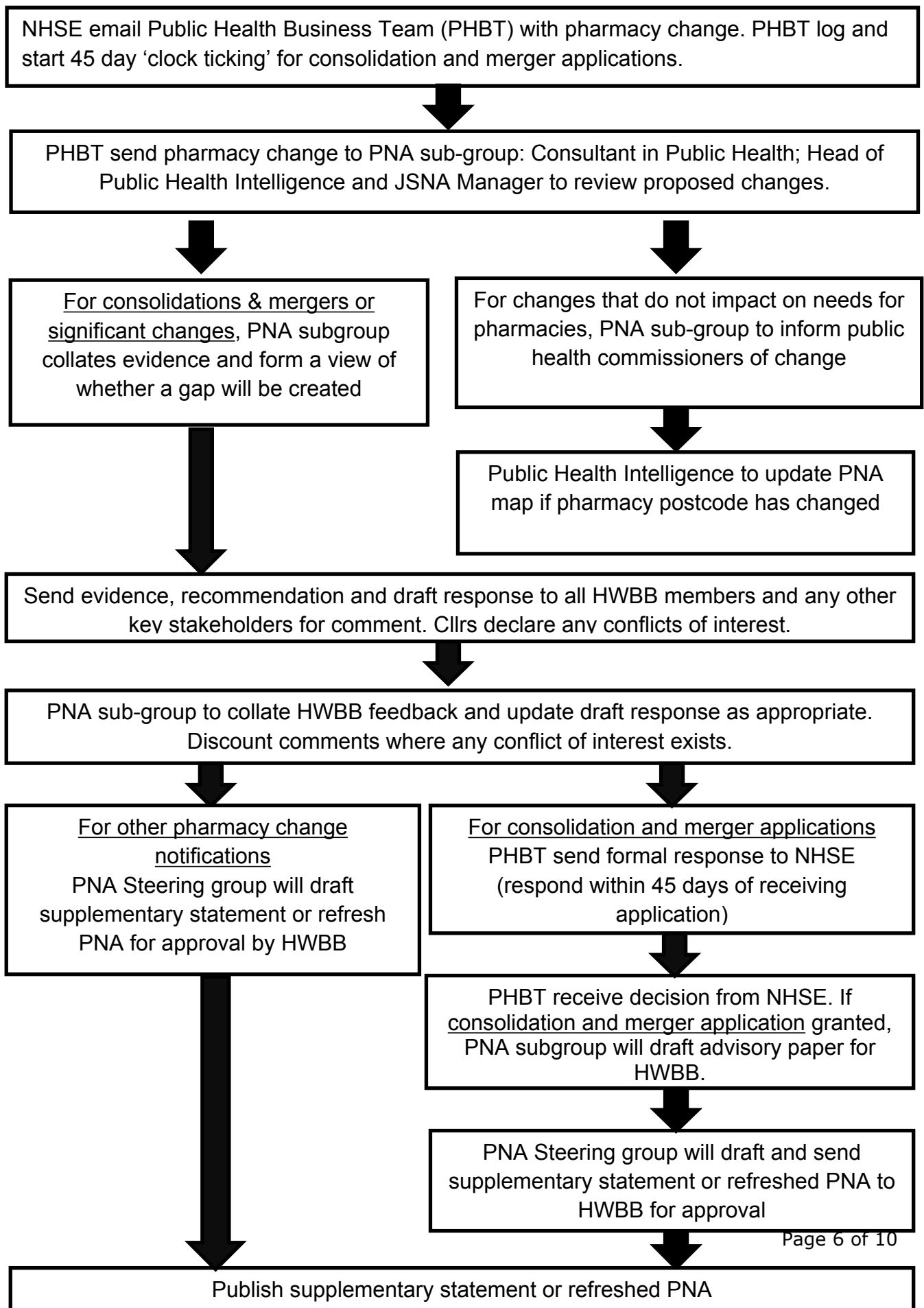
This process enables the HWBB to meet the regulatory timescale for consolidation or merger applications by responding to NHSE within 45 days and thus enabling NHSE to incorporate the HWBB opinion into its application timescales requirement of 4 months.

Process for responding to notifications of pharmacy changes

1. NHSE will formally request an opinion from the HWBB on any consolidation or merger application and will e-mail all other pharmacy change notifications to the Public Health Business Team. Receipt of the request or notification will be logged, paperwork saved on Share-point and for consolidations and mergers the 45 day response time will start.
2. The request or notification of change is passed to a sub-group of the PNA steering group; the Consultant in Public health, Head of Public Health Intelligence and JSNA Manager, for consideration.
3. This sub-group identifies the pharmacy or pharmacies in question and identifies them on the PNA's pharmacy map.
4. The sub-group makes an initial assessment of whether a potential merger or other changes in provision will create a gap in pharmaceutical services meeting the needs of the local population living in the immediate vicinity of the pharmacy. With reference to the existing PNA, the sub-group will consider changes in location, opening hours, physical access and the essential services provided. (See Appendix B considerations checklist)
5. If the notification does not involve a consolidation or merger and the impact of the change is deemed insignificant, no action is required by the HWBB. Public health commissioners will be informed and if any relocation involves a change of postcode the pharmacy provision map will be updated by Public Health Intelligence. Head of Public Health Intelligence will record the action taken and the date closed on the notification/request log.
6. If the notification is of a consolidation or merger or the impact of the change is deemed significant the recommendation of the sub-group is passed, together with the findings and a draft response for NHSE to all HWBB members and any other key stakeholders for comment.
 - a. All data and findings should be considered against the 4 regulatory statements (see Appendix A). These are the current PNA assessment criteria and will aid the HWBB to assess whether the closure or change will affect pharmaceutical need in the area and thus create a 'gap' in provision.
 - b. If a proposed merger results in a large discrepancy in opening hours between the closing and remaining pharmacy (e.g. if a 100hr pharmacy were to merge with a 40hr one), the HWBB should be aware that the remaining pharmacy can withdraw any supplementary hours in the future

- by giving 3 months' notice, without any restriction. This could be flagged with NHSE as a potential issue for their consideration.
- c. It is also important to realise that any public health commissioned services don't necessarily have to be provided at the remaining pharmacy as these are not essential services.
 - d. It is recommended that a mapping exercise is undertaken of pharmacies in the immediate vicinity of the changing pharmacy and travel times of the surrounding populations considered. This will allow a visual representation of the impact on the local population of removing or changing the affected pharmacy.
 - e. Where there are conflicts of interest such as the Chair of the HWBB being a councillor for the ward where the 2 pharmacies are located these must be explicit and openly declared.
 - f. All decisions must be based on an interpretation of the pharmaceutical regulations rather than any other influence.
 - g. Additional support when making these assessments can be obtained from both the Champs Collaborative and also the Local Pharmaceutical Committee (LPC).
7. Feedback is collated. Further clarification and discussion may be necessary. Once a consensus on the recommendation is reached:-
- a. For consolidations and mergers a formal response will be issued to NHSE by the Public Health Business Team on behalf of the HWBB.
 - b. For other significant changes the PNA steering group will draft a supplementary statement or commence the process of refreshing the PNA
8. If NHSE confirm that a consolidation or merger has been approved, the PNA subgroup will draft a paper for the HWBB to decide whether a supplementary statement or full revision of the PNA is required and to delegate responsibility for this to the PNA steering group that drafted the 2018 PNA.
9. The HWBB will approve draft supplementary statements and PNA refreshes before they are published

Process flowchart for responding to notifications of pharmacy changes



Responsibilities

It is a statutory responsibility of the HWBB to respond to requests from NHSE for an opinion as to whether they consider that a proposed consolidation or merger will create a 'gap' in pharmaceutical provision. However, this decision cannot be made in isolation and requires intelligence on pharmaceutical provision and needs. The decision also needs to be based on evidence, be transparent, communicated clearly and undertaken in responsible timescales. To achieve this, clear areas of responsibility have been established along the process.

Public Health Business Team

- Log all requests from NHSE regarding consolidations and mergers and pharmacy change notifications
- Ensure that all paperwork is forwarded to the members of the PNA sub-group.
- Ensure that for Consolidations and mergers that the 45 day timescales are met for sending a response to NHSE.
- Send HWBB approved formal response to NHSE.

PNA sub-group

- Undertake initial analysis to grade change notifications as significant or insignificant
- Inform public health commissioners of pharmacy changes
- Adhere to process laid out in this policy to meet 45 days response deadline
- Engage Champs Collaborative and LPC for additional support if necessary
- Collate evidence, make clear recommendations to enable HWB members to make informed decisions and draft response for NHSE
- Ensure that all recommendations are based on the interpretation of the pharmaceutical regulations rather than any other influence.
- Escalate any issues or barriers they cannot solve to the Director of Public Health and HWBB Chair.
- Respond to further requests for clarification from the HWBB in a timely manner.
- Collate HWBB members' feedback and decide whether their recommendations have been upheld and that all draft paperwork reflects this.
- Discard any responses where there is a conflict of interest.
- Finalise the response to NHSE

Head of Public Health Intelligence

- Ensure the pharmacy map is updated where there are changes to pharmacy postcodes
- Record the action taken and the date closed on the pharmacy change notification/request log.

PNA steering group

- Draft supplementary statements and revisions to the PNA as required

HWBB members

- Undertake the statutory responsibility of advising NHSE formally of their opinion on whether or not any application for a consolidation or merger would create a gap in pharmaceutical services provision.
- Read and respond to documentation from PNA sub-group to ensure adherence to deadlines
- Represent the Health and Wellbeing Board, rather than their individual organisation
- Make any conflicts of interest known e.g. if elected member for the area where a proposed change is occurring.
- Ensure that all decisions are based on the interpretation of the pharmaceutical regulations rather than any other influence.

Evaluation and review

The policy will be reviewed in the light of operating experience and/or changes in legislation. Any significant changes will be approved by the Health and Wellbeing Board.

Glossary

Essential services	These are services which every community pharmacy providing NHS pharmaceutical services must provide and is set out in their terms of service – these include the dispensing of medicines, promotion of healthy lifestyles and support for self-care. Distance-selling pharmacy contractors cannot provide essential services face to face at their premises.
Supplementary hours	Pharmacies are required to be open for 40 hours per week, unless they were approved under Regulation 13(1)(b) of the 2005 Regulations in which case they are required to open for 100 hours per week. These are known as the Core opening hours. Pharmacies may choose to open extended hours beyond these contracted core hours, these are referred to as 'supplementary hours'.

APPENDIX A: PNA Regulatory Statements

Statement one: Necessary services: Current provision

A statement of the pharmaceutical services that the Health and Wellbeing Board (HWB) has identified as services that are provided:

- A - In the area of the HWB and which are necessary to meet the need for pharmaceutical services in its area; and
- B - Outside the area of the HWB but which nevertheless contribute towards meeting the need for pharmaceutical services in its area (if the HWB has identified such services).

Statement two: Necessary services: Gaps in provision

A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied-

A - Need to be provided (whether or not they are located in the area of the HWB) in order to meet a current need for pharmaceutical services, or pharmaceutical services of a specified type, in its area;

B - Will, in specified future circumstances, need to be provided (whether or not they are located in the area of the HWB) in order to meet a future need for pharmaceutical services, or pharmaceutical services of a specified type, in its area.

Statement three: Other relevant services: Current provision

A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are provided-

A - In the area of the HWB and which, although they are not necessary to meet the need for pharmaceutical services in its area, nevertheless have secured improvements, or better access to pharmaceutical services in its area;

B - Outside the area of the HWB and which, although they do not contribute towards meeting the need for pharmaceutical services in its area, nevertheless have secured improvements, or better access, to pharmaceutical services in its area;

C - In or outside the area of the HWB and, whilst not being services of the types described in sub-paragraph (A) or (B), or paragraph one, they nevertheless affect the assessment by the HWB of the need for pharmaceutical services in its area.

Statement four: Improvements and better access: Gaps in provision

A statement of the pharmaceutical services that the HWB has identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied-

A - Would, if they were provided (whether or not they were located in the area of the HWB), secure improvements, or better access to pharmaceutical services, or pharmaceutical services of a specific type, in its area

B - would, if in specified future circumstances they were provided (whether or not they were located in the area of the HWB), secure future improvements, or better access, to pharmaceutical services, or pharmaceutical services or a specified type, in its area.

APPENDIX B: Matters to consider when assessing the impact of pharmacy changes

- Will the change/closure still provide sufficient choice of providers in the locality?
- Will the change/closure impact on the time and distance patients may be required to travel to access services at the remaining or relocated pharmacy?
- Will the proposed merger results in a large discrepancy in opening hours between the closing and remaining pharmacy? Supplementary hours can be withdrawn by giving 3 months' notice, without any restriction.
- Will current service provision in the locality be adequate? Only access to NHS commissioned service is considered under regulations. Local authority public health services and CCG are not a consideration.
- Will the change/closure have an impact on groups with protected characteristics as defined in 2010 Equality Act (i.e. age, gender, race, disability, marital status, religion, sexual orientation)?
- Will specialist services or equipment, which currently improve the provision of, or access to, services for specific populations or vulnerable groups be affected?
- Could the merger/change lead to improvement e.g. new premises may have better access or parking?

Potential future needs, are there:-

- plans for the development/expansion of new centres of population in the vicinity of the change/closure i.e. housing estates, or changes in the pattern of population i.e. urban regeneration, local employers closing or relocating?
- plans in and arising from local joint strategic needs assessments or joint health and wellbeing strategies?
- plans for changes in the number and/or sources of prescriptions i.e. changes in providers of primary medical services, or the appointment of additional providers of primary medical services in the area?
- plans for developments which would change the pattern of local social traffic and therefore access to services, i.e. shopping centres or significant shopping developments whether these are in town, on the edge of town or out of town developments?
- plans for the development of NHS services?
- plans for changing the commissioning of public health services by community pharmacists, for example, weight management clinics, health checks?
- introduction of special services commissioned by clinical commissioning groups?
- new strategy by social care/occupational health to provide aids/equipment through pharmacies or dispensing appliance contractors?