

June 2017

PSNC Briefing 036/17: Regulation 26A Consolidations

A Regulation 26A consolidation is a merger of two pharmacy businesses that does not create a gap in the provision of pharmaceutical services. It will involve the closure of one of the pharmacies and may involve an associated change of ownership. The first such consolidation applications are currently under consideration by NHS England, following which it is likely to provide guidance on the process through an update to [the NHS England Pharmacy Manual](#).

Regulation 26A consolidations were introduced on 5th December 2016 through the National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016 (Consolidation Amendment Regulations) (www.legislation.gov.uk/uksi/2016/1077/contents/made), which amended the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (2013 Regulations) (psnc.org.uk/contract-it/pharmacy-regulation).

While the merger and closure of two pharmacies could be done before this provision was introduced, the special feature of this type of consolidation is the statutory protection it gives against a new pharmacy simply replacing the closing pharmacy.

This PSNC Briefing aims to give the background to the Consolidation Amendment Regulations, details of the three main consolidation options, key requirements of a consolidation, the procedural steps for an application and the statutory protection from subsequent applications seeking to replace the closing pharmacy.

The key points in the Regulations

The 10 key points of a Regulation 26A consolidation are:

1. The consolidation is of two pharmacies on the pharmaceutical list (which may be owned by the same contractor/legal entity) located at two separate sites in the same Health and Wellbeing Board (HWB) area – contractor **P1** at site **S1** and contractor **P2** at site **S2**.
2. NHS England will approve the consolidation only if it does **not** create a gap in the provision of pharmaceutical services.
3. **S1** is always the **site** of the remaining pharmacy.
4. **S2** is always the **site** of the closing pharmacy.
5. If **P1** and **P2** are different contractors, when the pharmacy at **S2** closes, the pharmacy at **S1** will be owned by either contractor **P1** or **P2**.
6. The contractor who will own the remaining pharmacy, **P1** or **P2**, makes the consolidation application.
7. As appropriate, contractors **P1** or **P2** give notice of taking effect of the consolidation and no longer providing pharmaceutical services at the closing pharmacy.
8. The core opening hours of the pharmacy at **S1** remain after the consolidation, even where contractor **P2** moves from **S2** to **S1**.
9. The contractor at the remaining pharmacy, at **S1**, may wish to offer additional supplementary hours to seek to ensure the consolidation does not create a gap in the provision of pharmaceutical services.
10. The statutory protection against a new pharmacy opening up in response to the closure of the pharmacy at **S2** is limited and, also, only lasts until the next Pharmaceutical Needs Assessment (PNA) is issued.

Background to the Regulations

In 2015, PSNC proposed the principle of ‘protected’ consolidations, to enable contractors to consolidate pharmacies without another contractor simply seeking to establish a new pharmacy in place of the closing pharmacy. In 2016, the proposal was progressed as part of the ongoing consultation process and draft Consolidation Amendment Regulations were agreed between the Department of Health (DH) and PSNC (separate to the rest of the consultation process from 17th December 2015 to 20th October 2016).

In the decision imposed by DH on 20th October 2016 (www.gov.uk/government/publications/community-pharmacy-reforms), the Secretary of State for Health confirmed the introduction of the Consolidation Amendment Regulations, stating:

As part of the consultation on community pharmacy 2016/17 and beyond, the PSNC proposed changes to pharmaceutical services regulations to prevent a new pharmacy stepping in straight away if a chain closes a branch or two pharmacy businesses merge and one closes.

We propose to make regulations which provide some protection for two pharmacies that choose to consolidate on a single existing site, where this does not create a gap in provision. Subject to the usual Ministerial and Parliamentary approvals our aim is for the changes to come into force in December.

The three main consolidation options

There are three main Regulation 26A consolidation options:

1. regulation 26A(3)(a);
2. regulation 26(3)(b); and
3. regulation 26A(4).

The regulations, as a whole, are drafted on the basis that:

- **S1** is always the site of the remaining pharmacy - at the **start, contractor P1 has a pharmacy at site S1**;
- **S2** is always the site of the closing pharmacy – at the **start, contractor P2 has a pharmacy at site 2**;
- The remaining contractor may be **P1** at site **S1**, or **P2** who will move to from site **S2** to **S1**; and,
- The application is always made by the contractor who will have the remaining consolidated pharmacy at **S1**.

Regulation 26A (3) (a) and (b) consolidations – two options

This application is made by contractor P1 with the pharmacy at site S1, whose pharmacy will **not** move its location or site.

P1 must provide at S1 any Enhanced services that P2 was formerly providing at S2 (not already provided by P1 at S1), if NHS England wishes to commission these.

If P1 is the same contractor/legal entity as P2, the application will not involve a change in ownership of the closing pharmacy at site S2. This is a **Regulation 26A (3)(a) consolidation**.

If P1 is a different contractor to P2, the application must include an application by P1 for a change of ownership of the pharmacy at S2 (with the consent of P2); and that both contractors consent to S2 ceasing to be a listed chemist premises. This is a **Regulation 26A (3)(b) consolidation**.

Regulation 26A (4) consolidation

This application is made by P2, the owner of the remaining pharmacy that is originally located at S2, but which consolidates with the business carried on at S1.

P2 must provide the pharmaceutical services that were formerly provided by P1 at that site.

P2 must also provide at S1 any Enhanced services that it was formerly providing at S2 (not already provided by P1 at S1), if NHS England wishes to continue to commission those.

The application must include an application by P2 for a change of ownership of the pharmacy at S1 (with the consent of P1); and that both contractors consent to S2 ceasing to be a listed chemist premises.

Key requirements of a consolidation

Health and Wellbeing Board (HWB)

The two consolidating pharmacies must be located in the same Health and Wellbeing Board (HWB) area.

Distance Selling Premises (DSPs), appliance contractor premises and Local Pharmaceutical Services (LPS) pharmacies

Neither pharmacy may be a Distance Selling Premises (DSP) or appliance contractor premises; and, as the pharmacy must be on the pharmaceutical list, such applications may not include Local Pharmaceutical Services (LPS) pharmacies.

Change of ownership

If a consolidation is occurring between pharmacies owned by two different contractors (legal entities) it must include:

- A change of ownership application by the remaining contractor; and
- The consent of that other contractor.

No gap in the provision of pharmaceutical services

NHS England will refuse an application, if granting it would create a gap in the provision of pharmaceutical services that could be met by a routine application:

- To meet a current need (regulation 13 of the 2013 Regulations);
- To meet a future need (regulation 15 of the 2013 regulations); or
- To secure improvements, or better access (regulation 17 of the 2013 Regulations)

Enhanced services

NHS England will refuse an application:

- If the contractor who will own the consolidated pharmacy at S1 (and must carry on its business) will not also provide any additional Enhanced services carried out at S2, that NHS England wants to commission at S1.

An appropriate undertaking is required from the applicant and NHS England may, for good cause, allow any interruption in the Enhanced services moving from S2 to S1.

Opening hours

The core opening hours at S1 remain after the consolidation, regardless of who owns the consolidated business.

Therefore:

- If P1 continues with the consolidated business at S1, the core hours at S1 remain.
- If P2 has consolidated the business from S2 with that at S1, the former core hours of the pharmacy at S1 continue. **(The former S2 core hours are no longer relevant).**

A consolidation will always result in a reduction of total core hours: two 40-hour pharmacies consolidating (total core hours $2 \times 40 = 80$) will reduce to one pharmacy's core hours (1×40 hours).

Where a 40-hour and 100-hour pharmacy combine, the remaining core hours will depend on whether the 100 hours contract was at S1 or S2 - the core hours of S1 continue (but bear in mind that a reduction in the availability of a 100-hour pharmacy may create a gap in the provision of pharmaceutical services, which would trigger a refusal of the application).

The remaining pharmacy business may wish to offer supplementary hours to seek to ensure the consolidation does **not** create a gap in the provision of pharmaceutical services.

An ordinary (non-Regulation 26A) merger/closure may be more appropriate if a 100-hour pharmacy purchases a 40-hour pharmacy and wishes to use the 40-hour contract instead of the 100-hour contract (the 40-hour contract is at S1). In this case, there would need to be a series of linked applications: a change of ownership and a relocation of the 40-hour contract that does not result in significant change to pharmaceutical provision; overcoming regulation 31 (the same or adjacent premises test), at the same time as a closure of the 100-hour pharmacy. Such a series of linked applications will not be granted if they would cause significant detriment to NHS England's proper planning of pharmaceutical services in the area.

Procedural steps for an application

The Regulation 26A consolidation is an excepted application and, therefore, Section 129(2A) of the NHS Act 2006 does not apply – i.e. the PNA based test (the need to meet a current or future need, improvement or better access) does not apply.

In due course information on applications for a Regulation 26A consolidation will be available from:

The NHS England Pharmacy Manual (Currently being updated)

www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/04/pharmacy-manual-apr16.pdf

Pharmacy application forms (currently only available on request from NHS England)

www.england.nhs.uk/commissioning/primary-care-comm/pharmacy/app-forms

Broadly, the process is as follows:

- The remaining contractor makes the application on the form providing the information in the 'template notice of consolidation' set out in the 2013 Regulations (Paragraph 29A of Schedule 2);
- NHS England should make a decision within 4 months of receipt of the application. (Some consideration should be given to the requirement to obtain the views of the HWB, the timing of which will not be within NHS England's control);
- Relevant undertakings may be sought on Enhanced services (Paragraph 9(2) of Schedule 2);
- The notification and appeal procedure is similar to other applications (Paragraph 18 of Schedule 2);
- Regulation 31 (the same or adjacent premises test) does not apply;
- The voluntary notice of closure applies with the leaving contractor giving notice of ceasing to provide pharmaceutical services (Regulation 67(5) and (6));
- The taking effect of the decision is subject to specific provisions, for example, the consolidation notice in the correct form (informing NHS England that the consolidation will take effect in the next 14 days) is valid if sent to NHS England within 6 months of the date on which the applicant was sent notice granting the application; or for such longer period not exceeding 3 months, as NHS England may allow, or as determined following an appeal (Paragraph 34A of Schedule 2); and

More than one Regulation 26A consolidation application may be made at the same time (by the same or different contractors) and if more than one application is considered at the same time, NHS England may refuse each application based on the cumulative effect of the applications.

Statutory protection such applications offer from subsequent applications that seek to replace the closing pharmacy

There are four main statutory protections for a consolidated pharmacy – a quadruple lock – to discourage or prevent subsequent applications for a pharmacy seeking to replace a closing pharmacy. These statutory protections are not absolute because the mechanisms within the 2013 Regulations are designed to respond to changing local circumstances to ensure the appropriate provision of pharmaceutical services.

1. The HWB considers that the application, if granted, would create a gap in pharmaceutical services

An HWB notified of a Regulation 26A consolidation application must make representations in writing to NHS England indicating whether, if the application were granted, the proposed closure of the pharmacy (P2) and its removal from the pharmaceutical list would or would not create a gap in pharmaceutical services that could be met by a routine application to meet a current or future need or to secure improvements, or better access, to pharmaceutical services (paragraph 19(5) of schedule 2 of the 2013 Regulations).

This ensures that an application granted by NHS England should not subsequently be deemed by the HWB to create a gap in the provision of pharmaceutical services.

2. NHS England must refuse an application if it would create a gap in pharmaceutical services

NHS England must refuse a Regulation 26A consolidation application if it would create a gap in pharmaceutical services (regulation 26A(5)(a)). In reaching its decision, NHS England will have to take into account the opinion of the HWB.

This means that NHS England may grant a Regulation 26A consolidation only where it does not create a gap in the provision of pharmaceutical services.

3. The HWB must publish a supplementary statement if the closure does not create a gap in pharmaceutical services

The HWB must publish a supplementary statement explaining that the removal of a pharmacy from the pharmaceutical list, following the Regulation 26A consolidation, ‘does not create a gap in pharmaceutical services provision’ that could be met by a routine application to meet a current or future need or to secure improvements, or better access, to pharmaceutical services...’ (regulation 6(4) of the 2013 Regulations). It is likely that the HWB will be confirming its earlier opinion.

This makes public that no gap has been created by the consolidation and should avoid future unsuccessful applications to replace the closing pharmacy.

4. Unforeseen benefits applications will be refused if based on an alleged gap in pharmaceutical services created by a Regulation 26A consolidation

NHS England must refuse an application for unforeseen benefits if it is satisfied that the application ‘presupposes that a gap in pharmaceutical services provision has been or is to be created by’ the closing pharmacy (its removal from the pharmaceutical list) as a result of a Regulation 26A consolidation. Crucially, this statutory protection only applies until the PNA is revised. (Regulation 18(2)(g) and Regulation 19(5)).

This ensures that any future unforeseen benefits application during the relevant PNA will fail, if it is based on the argument that a Regulation 26A consolidation created a gap in the provision of pharmaceutical services.

The Pharmaceutical Needs Assessment (PNA)

A new (revised) PNA must be issued within 3 years of the last one; and for many, the 3-year period comes to an end in April 2018.

The PNA must include the information set out in Schedule 1 of the 2013 Regulations and this includes the available pharmaceutical services and any gaps in provision of pharmaceutical services. The PNA is not required to indicate **areas** where a Regulation 26A consolidation might be accepted, but it is not prohibited from doing so. Caution should be exercised in seeking to identify such **areas**, partly because there may be an incomplete picture of the pharmaceutical services provided by each contractor or how they are provided, and partly because this is not the function of the HWB and it might have unintended commercial repercussions on individual contractors.

Any new (revised) PNA might usefully record where consolidations have taken place and no gap was created, to ensure this knowledge is not lost. This should avoid future unsuccessful applications based on the closing pharmacy where there remains no gap in the provision of services.

If you have queries on this PSNC Briefing, or you require more information, please contact [Gordon Hockey, Director of Operations and Support](#).