

April 2023

PSNC Briefing 012/23: DHSC's changes to the Pharmaceutical Regulations

Today, on 27th April 2023, the Department of Health and Social Care (DHSC) introduced regulatory changes in response to increased temporary closures (temporary suspensions in the provision of pharmaceutical services) of pharmacies in England and related pressures. The changes are contained within [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) \(Amendment\) Regulations 2023](#) and add to and amend the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (PLPS regulations).

The regulatory changes take effect on 25th May 2023, except for a new requirement for a business continuity plan dealing with temporary closures (suspensions), which takes effect on 31st July 2023.

Outline of the regulatory changes

The following new Terms of Service are introduced:

- a notification procedure for introducing or changing **rest breaks**, by changing core opening hours;
- a requirement to have a **business continuity plan dealing with temporary closures** and to action it in the event of a temporary closure (suspension);
- provision for **local hours plans** to be agreed by the local Integrated Care Board (ICB) with temporarily reduced opening hours for participating pharmacies within the area of the plan;
- a 'notification' procedure for **100-hour pharmacies** to reduce their total weekly hours to no less than 72 hours, subject to various requirements; and
- other regulatory amendments, including changes to **fitness information** and the procedures for **applying to change core opening hours** and **notifying changes of supplementary opening hours**.

PSNC's view on the changes

The regulatory changes are divisive. While the allowance to change core hours may bring some small relief to contractors of 100-hour pharmacies, PSNC was clear that any such change needed to be matched with provisions for all other contractors who are facing the same pressures. We believe that it is unwise for the NHS to interfere with the level playing field for contractors in such a difficult economic climate.

The package of regulatory changes was opposed by PSNC on the basis that:

- Taken together, the changes do not adequately address the crippling pressures that contractors are facing.
- The 100-hour changes do not provide equivalent support to other pharmacy contract types (for example, 40-hour pharmacies) which constitute the majority (approximately 90%) of the sector, and who are facing the same workforce and cost pressures.
- On the 100-hour changes, contractors should be able to expect stable and objective economic regulation of the sector to give them the certainty to make long-term business decisions. This change is contrary to the

policy of DHSC to fund activity, rather than the establishment of pharmacies or the network; and there has been no consultation of the change open to all contractors.

- DHSC policy was to conduct a review of 100-hour pharmacies before considering any changes to their terms of service (recommendation 8 of the [2018 post-implementation report on the NHS \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013](#)). We have no knowledge that this has been done.
- The proposal is contrary to the DHSC's stated intention to reduce pharmacy clusters (paragraph 33 of the [Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan](#)) as 100-hour pharmacies have significant representation in clusters.

We put forward more than 30 proposals for wider regulatory easements to help relieve the pressure on the whole sector. We argued that more could be done to ease the current pressures for **all** contractors and sought for example:

- wider regulatory easements, that would give **all** contractors greater control and flexibility over their opening hours, in the face of current workforce issues;
- easements that would give greater scope for **all** contractors to seek to reduce the impact of rising business costs; and
- additional funding for **all** contractors to address the current severe underfunding of the sector.

DHSC is introducing the 100-hours changes to help to relieve the current pressures on these pharmacies and to seek to ensure patient access to NHS pharmacy services (pharmaceutical services) over their extended opening hours. DHSC and NHS England (NHSE) said that these changes were necessary, due to the higher rate of unplanned temporary suspensions seen amongst 100-hour pharmacies compared to the sector as a whole.

NHS England advice on the regulatory changes

NHSE will be issuing guidance on the regulatory changes and template application and notification forms in due course.

PSNC's advice on the regulatory changes

Rest Breaks

We sought the introduction of rest breaks deducted from core opening hours.

Instead, DHSC has introduced an option for contractors to notify ICBs of new or revised rest breaks, but the core opening hours for each day must be maintained.

Contractors may notify their ICB of rest breaks, or a change in the length or timing of an existing lunch or other break in core opening hours, and at least 5-weeks later implement those changes. No permission is required provided that the changes are in accordance with the regulations on rest breaks, the key aspects of which are set out in the table below. If contractors want to make changes to core opening hours that are not in accordance with the regulations for rest breaks, they must make an application in the usual way and wait for a decision by the ICB (see later in the briefing for new information on such applications).

Rest Breaks	
Length of rest break	No more than 1 hour (but more than one rest break is permitted).
When in the day on Mondays to Saturdays	At least 3 hours after the start and 3 hours before the end of the pharmacy's opening hours for the day.
When in the day on Sundays	Anytime.
Core hours in any day	No change is allowed to the total number of core opening hours for any particular day.

Supplementary hours	Supplementary opening hours may not be reduced if the result is a rest break that starts or ends less than 3 hours from the start or end of the pharmacy's opening hours. (Monday to Saturday) A reduction in supplementary hours and the change of the time in the day of a rest break may be notified at the same time but are effective only if they comply with the requirements for rest breaks.
Notice period before rest breaks may be introduced or revised	Contractors must wait at least 5 weeks' after notifying the ICB. The 5-week period starts from the day on which the notification is received by the ICB (email notification is usually received on the day sent, so if sent on a Wednesday, five weeks later on the relevant Wednesday, the rest break(s) may be introduced).
ICB confirmation	No confirmation or receipt is required from the ICB, but it is advisable for contractors to retain a copy of the notification email and delivery receipt as evidence in case of any dispute at a later date.
Is a specific form required for notification	No.
Is a form available for contractors	NHSE will provide a template form in due course.
When can I apply	Notifications can be made in advance of 25th May, but the earliest the 5-week notice period can start is 25th May 2023.
Start date for the notification of a new or changed rest break	25th May 2023

Key benefit - a key benefit of the notification procedure for rest breaks is that contractors have a straightforward and fast way of changing their core opening hours to introduce, or revise existing, rest breaks for staff (this is not the usual, longer, procedure for changing core opening hours, for which see the new information on such applications later in this briefing).

Key disadvantage - a key disadvantage of the proposal is that the total number of core opening hours remains the same and the length of the working day for pharmacy owners and staff becomes longer.

Contractors should note that if they change core opening hours, the NHS website and Directory of Services entries must be updated via NHS Profile Manager on the date the change takes effect. <https://psnc.org.uk/digital-and-technology/databases-of-pharmacies-and-services/nhs-profile-manager/>

Local Hours Plans

We sought an application procedure for planned temporary closures (planned suspensions in the provision of pharmaceutical services) by contractors and, separately, coordinated temporary closures between contractors, while the workforce pressures continue - to ensure NHS pharmacy services could be maintained locally without sudden temporary closures.

Instead, DHSC has introduced local hours plans that are largely at the discretion of the ICB. They may introduce **local hours plans** if satisfied that people in a particular area are experiencing, or are likely to experience, significant difficulty in accessing NHS pharmacy services.

Local hours plans replace a pharmacy's core and supplementary opening hours with temporary opening hours. They are voluntary and contractors agree with the ICB new temporary opening hours that will be specified in the plan. ICBs may seek to introduce local hours plans where there are high rates of temporary closures, with the aim of

agreeing with contractors opening hours for their pharmacies that are more realistic for them to achieve with the current workforce pressures. Key details of local hours plans are set out in the table below.

Local Hours Plans	
When can ICBs introduce local hours plans	If the ICB is satisfied that people in a particular area are experiencing, or likely to experience, significant difficulty in accessing NHS pharmacy services (pharmaceutical services).
More than one ICB	Two or more ICBs may collaborate to introduce a local hours plans, but each ICB must have its own plan.
LPC consultation	The ICB must consult any LPC for the area unless this is impracticable.
LPC notification	The ICB must notify any LPC in the area of a local hours plan of its contents.
Key details in local hours plan	
Area of the plan	The areas can be of any size, so it could be for the whole of the ICB's area or a smaller area. If more than one ICB is involved, they can collaborate to produce separate but collaborative local hours plans.
Duration of the plan	As determined by the ICB.
Opening hours	The pharmacy's core and supplementary hours are temporarily suspended, and NHS pharmacy services must be provided during the agreed temporary opening hours contained in the local hours plan.
Contractor participation	Contractors agree with the ICB the temporary opening hours they will adopt if they want to take part in the plan (taking part in the plan is voluntary)
Contractor notice to leave	Each contractor agrees a notice period with the ICB.
Revising the plans	
Revising a plan	The ICB may revise a local hours plan, which could include new pharmacies and extend the duration of the plan.
Contractor participation	Any revisions to a pharmacy's temporary opening hours or notice period must be agreed with the contractor.
LPC notification	The ICB must notify the LPCs in the area of the plan of a revision to a local hours plan, including the details of the pharmacies joining and leaving a plan.
Contractor notice to leave	If the ICB is revising the plan, contractors may give shorter notice to leave if it is not reasonably practicable to give the agreed notice period before the plan is revised.
End of plan	The local hours plan ends on its expiry date (which may have been revised).
Start date for the introduction of local hours plans	
Start date	25th May 2023

Contractors may notify changes to supplementary opening hours and apply to change core opening hours in the usual way while providing NHS pharmacy services during temporary opening hours under a local hours plan. When the local hours plan ceases to have effect, or the contractor has left the plan, the pharmacy returns to their core and supplementary hours, with any amendment, if relevant.

Key benefit - Local hours plans have the potential to reduce and coordinate the opening hours of pharmacies in an area, in a way that maintains continuity of NHS pharmacy services for the benefit of patients, the public and other healthcare professionals.

Key disadvantage – Local hours plans do not enable contractors to respond quickly to changing circumstances, pressures and demands and their introduction is largely at the discretion of ICBs.

Business continuity plans for dealing with temporary suspensions (closures)

We believe this proposal is a disappointing response to our request, on behalf of contractors, for help in the face of workforce pressures. This regulatory change places additional burdens on contractors and suggests a desire to resort to regulatory force rather than the NHS working with the sector to arrive at a reasonable solution.

DHSC has introduced business continuity plans to deal with temporary closures (temporary suspensions of pharmaceutical services), to ensure a standard response from pharmacies that temporarily close. The plans require contractors to record preparations for any unplanned temporary closures, and include identifying a series of actions they will carry out if a temporary closure (suspension) is likely to happen, or happens. Contractors must have business continuity plans dealing with temporary closures (suspensions) from 31st July 2023.

The regulatory provisions, which are set out in the table below, build on existing provisions for unplanned temporary suspensions and existing PSNC advice (see unplanned temporary suspensions of pharmaceutical services at: <https://psnc.org.uk/quality-and-regulations/pharmacy-regulation/opening-hours/>)

Business continuity plans for dealing with temporary closures	
What is required	<p>Contractors must have a business continuity plan for their premises to deal with temporary suspensions of pharmaceutical services because of illness or another reason beyond the control of the contractor and the plan must be available at the pharmacy premises.</p> <p>Note:</p> <ol style="list-style-type: none"> 1. Staff absence, including the inability of a contractor to find a locum pharmacist may be beyond the control of a contractor. 2. Contractors should be prepared to demonstrate to the ICB that the temporary suspension was for a reason beyond their control. 3. The ICB must make reasonable efforts to liaise with a contractor to ask whether a temporary suspension was for a reason beyond their control before deciding whether to issue a breach notice alleging that a pharmacy was not open for good cause (PLPS regulation 69(3)(b)(i)). 4. The ICB should consider on a case-by-case basis whether an unplanned temporary suspension is beyond the control of the contractor (paragraph 66 of Chapter 36, opening hours, of the Pharmacy Manual). Policies that specify breach notices will be issued automatically after a pharmacy has been closed for a particular number of hours are not appropriate.
Detail required	The business continuity plan must be proportionate to the needs of the people who anticipate using the pharmacy or who are accustomed to doing so.
What must be included in the plan?	
Plan requirements - notification	<p>How the contractor will notify the ICB in an <i>'approved manner'</i>:</p> <ul style="list-style-type: none"> - when a temporary suspension is likely; and - about a temporary suspension and its anticipated duration (wherever possible before the start of the start of the suspension). <p>(The <i>'approved manner'</i> of notification will be decided and published by NHSE, after consultation with PSNC).</p>
Plan requirements - DoS	The need for the contractor to update the pharmacy's Directory of Services (DoS) entries about the suspension and, later, the re-commencement of services.

	Keeping the pharmacy’s DoS and NHS website profiles up to date (and verifying this quarterly) are already requirements of the PLPS regulations.
Plan requirements – reducing referrals for urgent care services	Where the contractor provides urgent care services (for example the community pharmacist consultation service (CPCS)), arrangements for ensuring, to the extent practicable, that people are not referred to the pharmacy during the period of suspension. For example, updating the pharmacy’s profile on DoS will reduce the likelihood of NHS 111 referring patients under the CPCS.
Plan requirements – notifying GPs and other contractors	How the contractor will notify GPs and other pharmacy and dispensing appliance contractors about the temporary suspension and its anticipated duration. This requirement is ‘as practicable’ and ‘to the extent reasonable’, having regard to the needs of the people who may or usually use the pharmacy. Arguably, this is likely to be interpreted as the main GPs who prescribe prescriptions dispensed at the pharmacy and contractors of pharmacies local to the pharmacy. How to notify is not specified in the regulations.
Plan requirements – displaying information	How the contractor will display information regarding the suspension and anticipated duration: For physical (bricks and mortar) pharmacies - by notice visible from the outside of the premises, the notice to provide information in an <i>approved manner</i> . (This requirement is ‘as practicable’ and ‘to the extent reasonable’, having regard to the needs of the people who may or usually use the pharmacy) (The ‘ <i>approved manner</i> ’ for the notice/information will be decided and published by NHSE, after consultation with PSNC). For virtual pharmacies (Distance Selling Pharmacies (DSPs)) - by clearly promoting the information to any user of the pharmacy’s website when they first visit it. Note: DSPs must already have a website for use by patients and the public accessing their services, which has an interactive page clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up-to-date materials that promote healthy lifestyles, by addressing a reasonable range of health issues.
Plan requirements – continuity of patient care	Arrangements, where practicable, for: <ul style="list-style-type: none"> - the continuity of care of patients with booked appointments; and - those who attend the pharmacy regularly for supervised administration of medicines.
Actioning business continuity plans	
When to use the business continuity plan	When there is a temporary suspension or when a temporary suspension is likely.
How to implement	Contractors must use reasonable endeavours to implement the plan. If a temporary suspension is likely, implementation must be proportionate to the likelihood of the suspension.
Terms of Service	
When is there no breach of the terms of service	There is no breach for temporary suspensions for illness or another reason beyond the control of the contractor, if the contractor:

for temporary suspension?	<ul style="list-style-type: none"> - notifies the ICB as soon as practicable in the <i>approved manner</i> (wherever possible before the start of the temporary suspension); - uses all reasonable endeavours to implement the business continuity plan for dealing with temporary suspensions; and - uses all reasonable endeavours to resume the provision of NHS pharmacy services as soon as practicable.
Start date	
Start date	From 31st July 2023, contractors must have a business continuity plan dealing with temporary suspensions and action it as appropriate.

Key benefit - there should be a standard response from pharmacies when temporary suspensions are likely or when they occur, which should be of benefit to patients and the public, as well as local GPs and other local contractors.

Key disadvantage - there are more hurdles for contractors to navigate in the event of an unplanned temporary suspension when they are least able to manage additional burdens. There is greater emphasis on the technical rules, rather than recognition that contractors do their best in difficult circumstances.

100-hours pharmacy changes

PSNC opposed these changes in the strongest possible terms (see the information on the first page of this briefing). DHSC introduced these changes to help to relieve current pressures on 100-hour pharmacies and seek to ensure patient access to NHS pharmacy services over their extended opening hours.

This regulatory exemption applies only to 100-hour pharmacies and provides a ‘notification’ procedure for reducing core hours to no less than 72 per week. Contractors may only reduce their core opening hours if the notification complies with the regulatory requirements, which are listed in the table below.

100-hour pharmacy changes	
What is the maximum allowed reduction of core opening hours?	A reduction to not less than 72 core opening hours each week.
What times of the day may core opening hours not be changed?	<p>Any existing core opening hours must remain that are:</p> <ul style="list-style-type: none"> - Monday to Saturday between 5pm and 9pm (it is understood that no rest breaks are permitted during this time); - Sunday between 11am and 4pm (a rest break is permitted during the time, subject to the requirements for rest breaks); and - Sunday's total opening hours (i.e. the existing, total core opening hours on Sundays must remain). <p>i.e. the reduction of total core opening hours per week to not less than 72 is conditional on maintaining the above core opening hours.</p>
Rest breaks	Any rest breaks must start at least 3 hours after the pharmacy's opening time and end at least 3 hours before the pharmacy's closing time and last for no longer than one hour.

Route to change	By application to the ICB, followed by a direction by the ICB. The application is a technicality and is effectively a notification – the ICB must grant the application if made in accordance with the PLPS regulations (the changes are permitted by the new amendments to the regulations).
Waiting period before changing core opening hours	If... <ul style="list-style-type: none"> - A valid application is made in accordance with the PLPS regulations (the above requirements); - The date on which the contractor wishes to change their core opening hours is five weeks or more after the day on which the application is received by the ICB, and - the ICB has not made a decision by that date, the applicant contractor may change the core opening hours for the 100-hour pharmacy in accordance with the application, while the ICB decision and direction are pending.
Invalid application	If an application is invalid, core opening hours may not be changed.
Application form	NHSE will publish an application form. Contractors are advised to wait for the form to be published, to use the form, and wait for the ICB decision to be received, to ensure the application is valid and core opening hours are only changed following a valid application.
Can other changes be made to core opening hours?	Yes, but not to Monday to Saturday 5-9pm and on Sundays, 11am-4pm or total core opening hours.
Future owners	Future owners of the pharmacy must retain the directed core opening hours of no less than 72.
When may contractors make an application?	Applications can be made in advance of 25th May, but the earliest the 5-week period can start is 25th May 2023.
Date from which ICBs will be able to make decisions	25th May 2023.

Broadly, the other terms of service in relation to 100-hour pharmacies remain applicable. For example, any pharmacy that has had a 100-hours condition is still required to give six months' notice if they wish to withdraw from the relevant pharmaceutical list, even if they have reduced their total core opening hours.

Other Regulatory Changes

Directed opening	
ICB directions in relation to opening hours	From 25th May 2023, directions continue to have effect after a change of ownership or relocation. This means, for example, that if a pharmacy is directed to open on a bank holiday and there is a change of ownership, the new owners are still bound by the direction and must open the pharmacy on the bank holiday.
Fitness information - general	

<p>Fitness information required for applications</p>	<p>From 25th May 2023, the requirement for pharmacist owners or partners, directors who are pharmacists, and superintendent pharmacists to provide all their <i>professional experience</i>, changes to a requirement to provide their <i>personal work history</i> for the last 7 years, together with a declaration that:</p> <ul style="list-style-type: none"> - this is complete and accurate; - they have not been dismissed from any role (if they have, the reasons for this must be provided in the personal work history); and - they have not had a break from work of more than 6 months (if they have, the reasons for this must be provided in the personal work history). <p>In addition, a declaration is required that if they are included in a pharmaceutical list (either as the applicant, or where they are a partner of another partnership, or a director and/or superintendent of another body corporate) they have complied with the requirements to provide fitness information as it arises.</p>
<p>Fitness information from existing contractors</p>	
<p>Fitness information required from applicants who have previously provided fitness information</p>	<p>From 25th May 2023, if...</p> <ul style="list-style-type: none"> - fitness information has been provided in the last 7 years and - the contractor/individual has notified the relevant ICB of any relevant changes (e.g. to the contractor, directors, partners, superintendent pharmacist, including information on fitness, changes of ownership and changes of directors) <p>... the ICB should not ask for any further fitness information unless there is a particular need (a declaration may be required, for example, to update <i>personal work history</i>)</p> <p>In practice, this should mean that most of the time, existing contractors should not need to provide additional fitness information as part of, for example, change of ownership applications, where the previously provided fitness information meets the requirements and the required declarations have been made.</p>
<p>Notice of Commencement (NoC)</p>	
<p>Notice of Commencement (NoC)</p>	<p>In general, NoCs must be submitted to Primary Care Support England (PCSE) within the 12-month grant period. This can be extended up to 3 months, to 15 months, by the ICB.</p> <p>Within the NoC, the applicant is required, amongst other information, to confirm the date on which service provision will commence, and this date must be no fewer than 30 days after the date on which the NoC is given to PCSE (unless the ICB agrees otherwise). The date on which service provision will commence can be changed later.</p> <ul style="list-style-type: none"> - From 25th May 2023, the date on which service provision will commence (even if changed) must be within the 12-month grant period, or within 60 days of the end of that period. If the ICB extends the 12 months up to 3 months, to 15 months, the date on which service provision will commence must be within that period or within 60 days of its end.
<p>Applications to change core opening hours</p>	
<p>Contractor applications to reduce core opening hours or changes to the days or times of core opening hours</p> <p>or</p>	<p>From 25th May 2023, the ICB may issue directions, or grant a change to core opening hours following an application by a contractor, either:</p> <ul style="list-style-type: none"> - to maintain the existing level of NHS pharmacy provision; or - to maintain a sustainable level of adequate NHS pharmacy provision where maintaining the existing level of provision is either unnecessary or not realistically achievable. <p>Note1: The previous requirement for there to be a change in the needs of patients before a change in core opening hours could be made has been removed.</p> <p>Note 2: The new lower threshold for ICBs to direct core opening hours, or grant a change to a pharmacy's core opening hours means that ICBs have the ability to grant</p>

ICB directions in relation to core opening hours	applications by contractors either to amend the times at which they provide core opening hours, or to reduce their core opening hours, to what may be realistically achievable for the contractor.
Notifications to change to supplementary opening hours	
Contractor notifications to change supplementary opening hours	<p>The notice period to reduce or amend supplementary opening hours remains at 5 weeks. If a contractor notifies the ICB of a reduction in supplementary opening hours, or a change in the days or times they are provided, at least 5 weeks later the contractor can make those changes. Contractors can ask the ICB to agree to a shorter notice.</p> <p>There is no notice period for increasing supplementary opening hours, but from 25th May 2023, contractors must notify the ICB of any increase in the number of supplementary opening hours before they implement the increase.</p>

If having read this PSNC Briefing you have further queries about the changes to the Pharmaceutical Regulations, or you require more information please contact the [PSNC Regulations Team](#).