Title: The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 changes **IA No:** 9595 **RPC Reference No:** N/A **Lead department or agency:** Department of Health & Social Care **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 21/03/2023 **Stage:** Final Stage **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** CommunityPharmacyTeam@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option (in 2022 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
-£7.4m	-£7.4m	£0.7m	Non Qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

There are two problems under consideration. First contractors are reporting difficulties in fully adhering to their terms of service, including securing enough staff to enable a pharmacy opening for the full contracted hours. As a consequence, we are seeing high numbers of unplanned temporary pharmacy closures. Frequent ad-hoc temporary closures impact on patients and carers, risk damaging the sector's reputation and the professional relationships with GPs and other healthcare providers. They also put pressure on neighbouring pharmacies, leaving them to deal with increased demand from patients without advance notice. Second, there is a specific problem with 100 hours pharmacies which are permanently closing meaning the loss of guaranteed extended hours for patients.

What are the policy objectives of the action or intervention and the intended effects?

The objective is to identify possible regulatory solutions to mitigate against the impact of temporary closures on patients and the wider NHS as well as preventing further closures of 100 hours pharmacies.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1 – Take no action and make no legislative changes (do-nothing)

Other options consider combinations of the following regulatory changes:

a) Make it easier for contractors to close the pharmacy during the day to give staff scheduled rest breaks
b) Allow 100 hours pharmacies to permanently reduce their core opening hours to a minimum of 72 hours, as long as they retain hours 9-5pm Monday to Saturday, total number of Sunday hours and hours between 11am and 4pm on Sundays.
c) Enable coordinated closures in the most affected areas via NHSE temporary local hours plan whilst maintaining access to services in the locality
d) Require all contractors to have business continuity plans in place and use all reasonable endeavours to action these plans in the event of temporary closure for reasons outside of the contractors control.
e) Other minor amendments, agreed by the sector representative body, to simplify and clarify market entry procedures.

Option 2 – regulatory changes b), c) and e)

Option 3 – regulatory changes b), c), e) and a)

Option 4 (Preferred Option) – regulatory changes covering all options a) to e)

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** April/2028

Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro Yes**	**Small Yes**	**Medium Yes**	**Large Yes**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** 0	**Non-traded:** 0	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Neil O'Brien Date: 26/04/2023

Summary: Analysis & Evidence

Policy Option 1

Description: Business As Usual

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0		0	**0**
High	0		0	**0**
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero, by definition.

Other key non-monetised costs by 'main affected groups'

N/A

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0		0	**0**
High	0		0	**0**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero, by definition.

Other key non-monetised benefits by 'main affected groups'

N/A

Key assumptions/sensitivities/risks	Discount rate (%)
N/A	

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	**Benefits:** 0	**Net:** 0	N/A

Summary: Analysis & Evidence

Policy Option 2

Description: Allow 100 hours pharmacies to reduce core hours to a minimum of 72, NHSE temporary local hours plans, other minor amendments to regulations

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** Unquantified

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Unquantified		Unquantified	**Unquantified**
High	Unquantified		Unquantified	**Unquantified**
Best Estimate	Unquantified		Unquantified	**Unquantified**

Description and scale of key monetised costs by 'main affected groups'

Due to uncertainty around the likelihood and magnitude of costs for the secondary legislation, the costs are not included in the cells above.

Other key non-monetised costs by 'main affected groups'

Allowing 100 hours pharmacies to reduce their hours to a minimum of 72 hours could result in a reduction in total community pharmacy hours of 5% and could be an inconvenience to patients of reduced opening hours.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Unquantified		Unquantified	**Unquantified**
High	Unquantified		Unquantified	**Unquantified**
Best Estimate	Unquantified		Unquantified	**Unquantified**

Description and scale of key monetised benefits by 'main affected groups'

Due to uncertainty around the likelihood and magnitude of benefits of the secondary legislation, the benefits are not included in the cells above.

Other key non-monetised benefits by 'main affected groups'

Local hours plans should help improve the patient experience of temporary closures; and help other pharmacies and GP practices manage additional pressures in the locality. Allowing 100 hours pharmacies to reduce their core hours to almost twice the hours other pharmacies are contracted to provide, while protecting key evening and Sunday hours for patients, would reduce pharmacies overall labour costs and should make those pharmacies more sustainable and prevent further permanent closures. This means extended access for patients to pharmaceutical services when other primary care providers are closed will be reduced, but the hours when we anticipate to be in demand, will remain protected. A reduction in the demand for locums from 100 hours pharmacies could help with the availability of locums for all pharmacies.

Key assumptions/sensitivities/risks	**Discount rate (%)**	3.5%

The impacts arising from enabling provisions are uncertain.
There is a risk, like with any regulatory changes that the revised regulations that are brought may not be adhered to.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	**Benefits:** 0	**Net:** 0	N/A

Summary: Analysis & Evidence

Policy Option 3

Description: Allow 100 hours pharmacies to reduce core hours to a minimum of 72, NHSE temporary local hours plans, easier scheduled lunch breaks, and other minor amendments to regulations

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** Unquantified

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Unquantified		Unquantified	**Unquantified**
High	Unquantified		Unquantified	**Unquantified**
Best Estimate	Unquantified		Unquantified	**Unquantified**

Description and scale of key monetised costs by 'main affected groups'

Due to uncertainty around the likelihood and magnitude of costs for the secondary legislation, the costs are not included in the cells above.

Other key non-monetised costs by 'main affected groups'

Making it easier for contractors to close the pharmacy during the day to give staff rest breaks could reduce availability of pharmaceutical service at points during the middle of the day impacting on patient convenience. Allowing 100 hours pharmacies to reduce their hours to a minimum of 72 hours could result in a reduction in total community pharmacy hours of 5%. Reduced opening hours could result in inconvenience for patients who for various reasons may need to access services after 9pm on a weekday or early in the morning as pharmacies will be able to reduce these hours.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Unquantified		Unquantified	**Unquantified**
High	Unquantified		Unquantified	**Unquantified**
Best Estimate	Unquantified		Unquantified	**Unquantified**

Description and scale of key monetised benefits by 'main affected groups'

Due to uncertainty around the likelihood and magnitude of benefits of the secondary legislation, the benefits are not included in the cells above.

Other key non-monetised benefits by 'main affected groups'

Making it easier for contractors to close the pharmacy during the day to give staff rest breaks is likely to help improve the situation surrounding high risks of burnout and poor mental health within the community pharmacy workforce. Local hours plans should help improve the patient experience of temporary closures; and help other pharmacies and GP practices manage additional pressures in the locality. Allowing 100 hours pharmacies to reduce their core hours to almost twice the hours other pharmacies are contracted to provide, while protecting key evening and Sunday hours for patients, would reduce pharmacies overall labour costs and should make those pharmacies more sustainable and prevent further permanent closures. This means maintaining extended access for patients to pharmaceutical services when other primary care providers are closed. A reduction in the demand for locums from 100 hours pharmacies could help with the availability of locums for all pharmacies.

Key assumptions/sensitivities/risks	Discount rate (%)
The impacts arising from enabling provisions are uncertain. There is a risk like with any regulatory changes that the revised regulations that are brought may not be adhered to.	

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	**Benefits:** 0	**Net:** 0	N/A

Summary: Analysis & Evidence

Policy Option 4

Description: Allow 100 hours pharmacies to reduce core hours to a minimum of 72, NHSE temporary local hours plans, easier scheduled lunch breaks, mandatory business continuity plans, and other minor amendments to regulations

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate: -**£7.4m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£0.7m	1	Unquantified	**Unquantified**
High	£1.3m		Unquantified	**Unquantified**
Best Estimate	£1.0m		£0.7m	**£7.4m**

Description and scale of key monetised costs by 'main affected groups'

Costs to pharmacy contractors of producing business continuity plans and implementing the actions in the event of a temporary closure. Due to uncertainty around the likelihood and magnitude of costs for the secondary legislation, the costs of the other regulatory changes are not included in the cells above.

Other key non-monetised costs by 'main affected groups'

Making it easier for contractors to close the pharmacy during the day to give staff rest breaks could reduce pharmacies availability at points during the middle of the day impacting on patient convenience. Allowing 100 hours pharmacies to reduce their hours to a minimum 72 hours could result in a reduction in total community pharmacy hours of 5% an inconvenience to patients of reduced opening hours particularly for people who for various reasons are unable to regularly access NHS pharmaceutical services during normal business hours.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Unquantified		Unquantified	**Unquantified**
High	Unquantified		Unquantified	**Unquantified**
Best Estimate	Unquantified		Unquantified	**Unquantified**

Description and scale of key monetised benefits by 'main affected groups'

Due to uncertainty around the likelihood and magnitude of benefits of the secondary legislation, the benefits are not included in the cells above.

Other key non-monetised benefits by 'main affected groups'

Making it easier for contractors to close the pharmacy during the day to give staff rest breaks is likely to help improve the situation surrounding high risks of burnout and poor mental health within the community pharmacy workforce. Local hours plans and business continuity plans should help improve the patient experience of temporary closures; and reduce the pressures on other pharmacies and GP practices in the locality. Allowing 100 hours pharmacies to reduce their hours and their labour costs should make those pharmacies more sustainable and prevent further permanent closures of these pharmacies thus protecting access for patients to pharmaceutical services when other primary care providers are closed.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5%

The impacts arising from enabling provisions are uncertain.
There is a risk that the revised regulations that are brought may not be adhered to.

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 1.7	**Benefits:** unquantified	**Net:** 1.7	N/A

Evidence Base

Background

1. Community pharmacies are private businesses who provide state-funded NHS pharmaceutical services as set-out in the Community Pharmacy Contractual Framework (CPCF). In July 2019, the CPCF deal for 2019/20 to 2023/24 was jointly agreed between the Department of Health and Social Care (DHSC), NHS England & NHS Improvement (NHSE&I) and the Pharmaceutical Services Negotiating Committee (PSNC). This deal confirmed community pharmacy's future as an integral part of the NHS delivering clinical services. Community pharmacy has the potential to take pressure off other parts of the NHS, including GPs and A&E, allowing them to focus on higher acuity or more complex patients' needs.

2. CPCF funding was cut by over £200 million between 2016 and 2018 and has been held flat since 2019, equivalent to a 25% cut in real terms by the end of 2023/24. The higher-than-expected inflation was not foreseen at the start of the flat-cash five-year deal and has put an additional pressure on community pharmacies over the 5-year period.

3. Contractors report that the flat cash funding for NHS services, coupled with the increase in the cost of running their business, is putting additional pressure on the sector, and threatening the viability of their businesses. The increase in locum costs, baseline staff costs, and utility costs lead to pharmacy contractors seeking to make their business more efficient by for example, reducing opening hours.

4. NHS England is responsible for administering the market entry system including opening hours for pharmacies, which is handled locally by the regional NHS England teams. A pharmacy normally has 40 core hours or 100 for those that have opened under the former exemption from the control of entry test. In addition, all pharmacies can choose to provide supplementary opening hours in addition to their core hours.

5. NHS England does not hold contracts with pharmacy contractors included in its pharmaceutical lists. Such contractors have terms of service set out in schedule 4 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the PLPS Regulations").

6. The scope of this work is narrow and only focuses on the amendments which could be made to the PLPS regulations, and not the full set of options for minimising the risk of pharmacy closures.

Problem under consideration and rationale for intervention

Temporary closures

7. During the COVID-19 pandemic, to enable pharmacy contractors to cope with workforce shortages and other pandemic related pressures, DHSC implemented time limited regulatory easements to allow pharmacy temporary closures and changes to opening hours without the agreement from the commissioner. These regulatory easements began 27 March 2020 and ceased on 31 March 2022.

8. From 1 April 2022, the Government moved away from the allowances made during the COVID-19 pandemic to its next stage pandemic recovery. The normal pharmacy terms of service and requirements around unplanned closures of community pharmacies were resumed. There is no legal mechanism to introduce similar flexibilities in 'normal' times, and the current terms of service are limited in trying to respond to the current situation in the market. Many contractors continue to report difficulties in fully adhering to their terms of

service, due to the inability to secure enough staff to enable a pharmacy opening for the full contracted hours. As a consequence, we have seen an increase in unplanned temporary pharmacy closures. Whilst the majority of these closures are less than 4 hours, they cause disruption to patients and other NHS providers nearby.

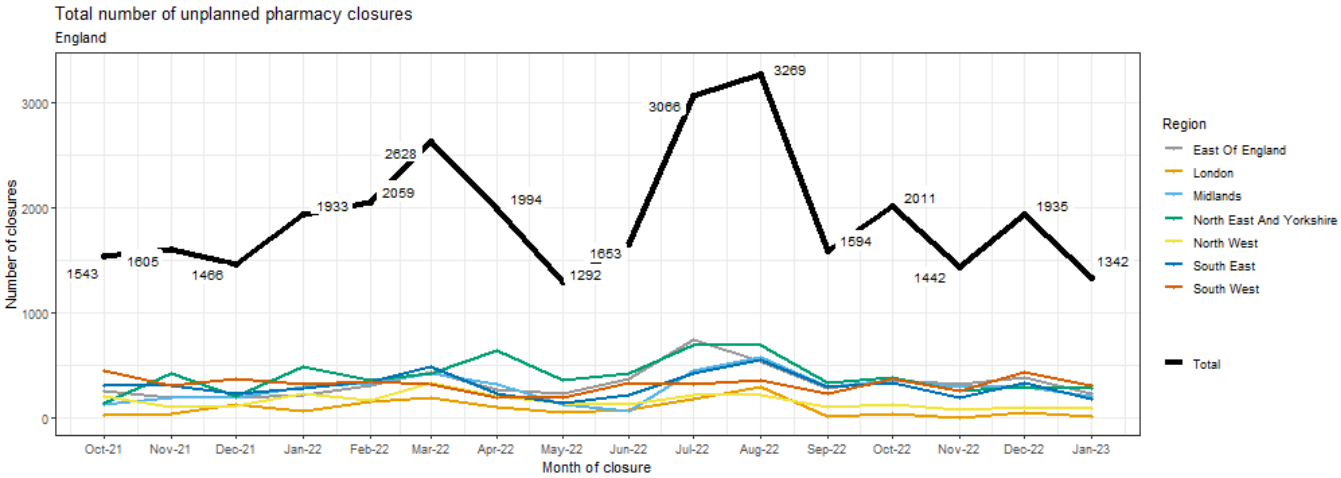
9. According to the regulations, contractors must notify NHS England regional teams of any unplanned closures for staff illness or other reasonable cause beyond a contractor's control. Central monitoring of unplanned closures started in October 2021 when significant concerns were raised, including by patients, about these closures. As the data is based on pharmacy contractors reporting their closures, the true figures could be higher. Both NHSE and DHSC continue to receive significant numbers of inquiries and complaints about temporary pharmacy closures, which could indicate that unplanned closures are under-reported and therefore figures may be an under-estimate.

10. Prior to October 2021 there was no standardised way for NHS regions to collect and report this information. Therefore, there was huge variability in the quality and formatting of any captured data. Given the poor quality of the data it is not considered appropriate to use.

11. The available NHSE data shows that out of the 11,075[1] active pharmacies in England, 4,086 (37%) reported at least one unplanned closure since October 2021. From October 2021 to January 2023, the number of closures per pharmacy has been over 3 times higher for 100 hours pharmacies than for 40 hours pharmacies. In this period, the number of closures per pharmacy in each IMD decile has been variable across regions with no clear trend relating deprivation to the number of unplanned closures. January 2023 saw a 31% decrease in the number of reported unplanned closures compared with January 2022, but it is difficult to know whether this is true reflection given the caveats in the data of potential under-reporting. The most common reason for closure is "locum could not be found". 64% of closures in January were for under 4 hours.

12. Figure 1 below shows a consistent level of unplanned closures with a peak in August 2022 of 3,269 unplanned closures. The peak is likely related to seasonal issues such as requiring holiday cover. The peak month of 3,269 unplanned closures had a duration of around 14,000 hours equivalent to a closure rate of 0.5% of all opening hours.

Figure 1: Total number of unplanned pharmacy closures in England[2]



[1] As of 30 September 2022. The 11,075 includes Distance selling pharmacies (DSP) and pharmacies with Local Pharmaceutical Services (LPS) contracts. It excludes Dispensing Appliance Contractors (DACs). https://opendata.nhsbsa.net/dataset/consolidated-pharmaceutical-list/resource/762437b3-432b-4a0b-bbf4-e6d9d3b6b5df

[2] NHSE Data: Pharmacy contractors notify NHSE regional teams of unplanned closures which then report the data centrally. Any late notification of unplanned closures by contractors will not be seen until the subsequent month

13. The Pharmaceutical Services Negotiating Committee (PSNC – the representative body of all pharmacy contractors in England) have suggested that increasing locum payment rates alongside the uncertainty around the availability of pharmacists has been impacting all pharmacies. Data collected by NHSE from October 2021 until January 2023 corroborates the finding that the availability of pharmacists is impacting pharmacies. The data shows the most common reason for temporary closures outlined by the pharmacy was that a locum could not be found.

14. In addition to dispensing, local pharmacies are delivering a range of clinical services to patients. Therefore, temporary or permanent closures not only disrupt patient access to medicines, but also to support for self-care, health advice and promotion and other specialised services commissioned through CPCF or locally.

15. Frequent ad-hoc temporary closures impact on patients and carers, risk damaging the sector's reputation and the professional relationships with GPs and other healthcare providers. They also put pressure on neighbouring pharmacies, leaving them to deal with increased demand from patients without advance notice. As commissioners are not given any advance notice of closures, this prevents proper planning and puts the overall availability of services in an area at risk.

100 hours pharmacies

16. 100 hours pharmacies must be open for a minimum of 100 hours every week. They came onto the market under an exemption in 2005 that was added to the regulations following a report from the Office of Fair Trading[3]. Pharmacies could get on the NHS list without having to identify a need for pharmaceutical services in an area as long as they committed to being open for at least 100 hours per week. The exemption was removed in 2012. Therefore, it is not possible to open a new pharmacy with 100 core hours, although it is possible to open a 40 hours pharmacy with 60 supplementary hours.

17. There are significant numbers of 100 hours pharmacies permanently closing[4]. Many 100hours pharmacies are in supermarkets and since the start of the 2023, LloydsPharmacy has announced a withdrawal of all its pharmacies in Sainsbury's stores and Tesco and Asda have announced plans to reduce their network. 100 hours pharmacies have told us that this business model is no longer viable unless they can reduce their hours. Permanent closure of these pharmacies is a problem in itself as we are losing the guarantee of extended hours being available to patients.

18. Whilst allowing 100 hours pharmacies to reduce their hours will impact negatively on the availability of hours and therefore access to pharmaceutical services, not doing anything would likely mean many of these pharmacies would close, creating much more serious problems with access.

[3] Pharmacy Report 2003 (publishing.service.gov.uk)

[4] NHSE Pharmacy Openings and Closures January 2023 Open Data Portal

Policy objective

19. The objectives are to identify possible regulatory solutions that:

a) enable 100 hours pharmacies to remain viable and prevent permanent closures and the loss of all extended hours;
b) mitigate against the negative impact of temporary closures;
c) protect the provision of pharmacy opening hours at vulnerable times;
d) support the retention of pharmacy professionals within the community pharmacy sector;
e) support staff availability;
e) support contractors to better protect their staff and patients;
f) reduce the risk of damage to the sector's reputation and the professional; relationships with other NHS providers; and
g) can be implemented without substantial administrative burden on contractors.

Description of options considered

20. Policy interventions other than regulatory change are being considered which could aim to help with staff availability or high locum costs. These include:
    - Developing and extending clinical services delivered in community pharmacies to make the sector an attractive place to work and progress their career for pharmacy professionals, improving recruitment and retention in the sector:
        - In 2023/24, a new, Community pharmacy contraception service will be introduced. Existing services will be expanded: urgent and emergency care setting will be able to refer patients to the pharmacy for minor illness or urgent medicine supply under the Community Pharmacist Contraception service and patients newly prescribed antidepressants will be able to receive support with their medication from a community pharmacist under the New Medicines service.
        - Further services are being developed and piloted with the view of introducing in the later years.
    - At the same time, Health Education England is implementing reforms to the initial education and training of pharmacists and developing cross-sector clinical placements to enable pharmacists to play a greater clinical role across the health system. DHSC has also added pharmacy students to the list of professionals eligible for the Education and Training tariff to fund clinical placements from 1 September 2022. Health Education England has also launched The Pharmacy Technician Workforce Expansion Programme, to help employers access apprenticeships to recruit and develop pharmacy technicians, without destabilising other sectors. The number of pharmacy training places annually is uncapped. In England, each year around 2,500 pharmacists enter training and the net increase in pharmacists practicing has increased by around 1,400 per year since 2016.
    - Several projects are underway to increase capacity of pharmacy teams by enabling better use of skill mix. The Department is reviewing the legislation concerning pharmacist supervision of the dispensing of Prescription Only Medicines (POM) and Pharmacy (P) medicines, and planning to amend legislation to add pharmacy technicians to the list of professions able to supply and/or administer medicines under Patient Group Directions (PGDs). Legislative proposals on both issues will be subject to public consultation later this year.

The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations are generally changed every year following the CPCF negotiations with NHSE and PSNC. The regulations are a flexible tool we have to regularise pharmacy practice and respond to the changing context on the ground. Therefore, the scope of this work is narrow and it is only regulatory changes and not the full set of options for minimising the risk of pharmacy closures that are the focus of this impact assessment. The PSNC has been consulted on the proposed regulatory changes.

Option 1 – Business as usual/no change

21. No regulatory changes are made. As a consequence, we will see continuing disruption to contractors in the form of unplanned and uncoordinated temporary pharmacy closures, causing disruption to patient access to services. In addition, we are likely to see further permanent closures particularly of 100 hours pharmacies, leading to further restrictions of access and a reduction in service for patients.

Make regulatory changes

22. A number of new provisions or amendments could be made to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations. The identified regulatory changes aim to ease pressures, improve continuity of service provision for patients, support staff wellbeing and can be implemented without substantial administrative burden on contractors.

23. The possible proposed amendments are:

    a) Make it easier for contractors to close the pharmacy during the day to give staff **scheduled rest breaks**;
    b) Allow 100 hours pharmacies to permanently **reduce their core opening hours to 72 hours** or above; as long as they retain hours 5-9pm Monday to Saturday, total number of Sunday hours and hours between 11am and 4-pm on Sundays.
    c) Enable coordinated closures in the most affected areas via NHSE **temporary local hours plan**s whilst maintaining access to services in the locality;
    d) Require all contractors to have **business continuity plans** in place and use all reasonable endeavours to action these plans in the event of temporary closure;
    e) **Other minor amendments** agreed by the sector representative body to simplify and clarify market entry procedures.

24. As a minimum DHSC and NHSE would wish to implement the temporary local hours plans and the reduction in core hours to 72 hours or more for 100 hours pharmacies. This is because it would enable at least one regulatory change to target each of the two distinct problems under consideration; temporary closures and 100 hours pharmacies. The local hours plans would enable temporary suspension of the usual terms of service and replace these with terms of service that are manageable for contractors and carry the least risk for the patients. The local plans enable NHSE to find the balance between the need for patient access to pharmaceutical services and the ability of businesses to provide those services. 100 hours pharmacies reduction in hours, also aims to protect certain key hours for patients when other providers may be closed, but also aims for a balance as not all hours are protected. Therefore, both provisions aim to balance the needs of patients and the ability of businesses to meet these needs. DHSC and NHSE would also wish to implement the other minor amendments which are considered of limited impact but have already been agreed with PSNC during year 4 CPCF negotiations. We therefore consider the options set out in Table 1. Option 4 is the preferred option:

Table 1. Breakdown of Options

	Option 2	Option 3	Option 4 (Preferred Option)
a) Make it easier for contractors to close the pharmacy during the day to give staff **scheduled rest breaks**;	X	✓	✓
b) Allow 100 hours pharmacies to permanently **reduce their core opening hours to 72 hours** or above;	✓	✓	✓
c) Enable coordinated closures in the most affected areas whilst maintaining access to services in the locality via NHSE **temporary local hours plan**s;	✓	✓	✓
d) Require all contractors to have **business continuity plans** in place and use all reasonable endeavours to action these plans in the event of temporary closure;	X	X	✓
e) **Other minor amendments** agreed with the PSNC during the CPCF year 4 negotiations.	✓	✓	✓

Evaluation of costs and benefits

25. The remainder of this IA examines the potential costs and benefits of each of the proposed regulatory changes in turn. This impact assessment appraises over a ten-year period from 2023/24. The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations apply to contractors in England. This impact assessment therefore appraises for England only.

Make it easier for contractors to close the pharmacy during the day to give staff scheduled rest breaks

26. It is proposed to amend the regulations to specify that contractors can change their core opening hours and close a pharmacy for one hour during the day if they notify NHSE/ICBs and wait five weeks before making a change to their opening hours. The simplified route through a notification to change when core opening hours are delivered will only be available if such change does not result with the reduction in the pharmacy total opening hours on any given day and week. This will replace the current application route which requires the contractor to provide evidence that patient needs have changed. The current application can

take 60 days to review and may result in rejection even in cases where the total core hours are the same.
Contractors will only be able to schedule and notify a rest break of up to one hour duration if the rest break starts three hours after opening and ends 3 hours before closing., Monday to Saturday.

27. Contractors can still change hours outside these parameters using the provisions already included in the regulations, i.e., by making an application to NHSE or ICB and providing the required evidence (necessity test). We propose changing what evidence is required for the necessity test - replacing the current requirement to evidence there has been a change in such needs with a requirement to evidence that the needs of patients will be met following the change in core hours.

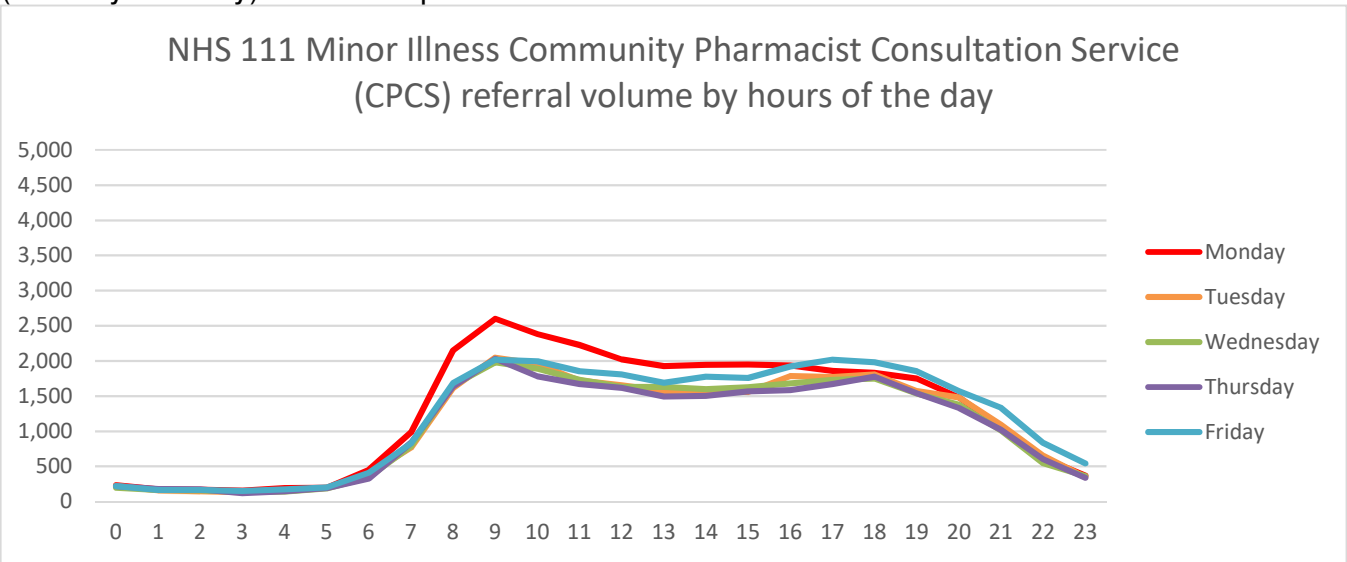
Costs

28. This proposed regulatory change simplifies the ability for pharmacy contractors to change opening hours. It moves from an application process to a notification process for hours during the day. If a pharmacy does decide to introduce scheduled rest breaks into their opening hours, then they may incur administrative costs due to the change in hours such as revising staff rotas or altering advertised opening hours. However, the decision to change opening hours is voluntary and therefore determined by pharmacy contractors, and these administrative costs would occur if the pharmacy changed hours through the current application route as well as the new simplified notification route. Therefore, we do not anticipate any additional costs on pharmacy contractors due to the regulatory change. On the contrary, the costs are reduced for breaks during the day because a simplified notification route does not require collating any evidence to justify the change to NHSE or ICB.

29. This proposed regulation change would make it easier for pharmacies to reduce their availability at points during the day, such as lunch times. However, this will be compensated with either earlier opening times or more likely later closing times as there must not be a reduction in the total opening hours. Therefore, we may see patient accessibility during the middle of the day reduce. We expect that business owners would make decisions about the timing for rest breaks to balance staying open during the busiest times to avoid loss of income and providing rest for staff to avoid burn out and maintain mental wellbeing.

30. There is no data available on the times that patients access all NHS pharmaceutical services. There is some data on the times that referrals through the Community Pharmacist Consultation Service (CPCS) are made to pharmacies. Figure 2 shows that mornings and evenings are the most common referral times, but this does not necessarily mean the pharmacist contacts the patient or undertakes the consultation immediately after the referral.

31. Figure 2 – 111 Minor Illness CPCS referral volume by hours of the day during weekdays (Monday – Friday) between April 2022 and October 2022



32. In terms of the inconvenience for patients, we use data from Department for Transport costs of travel[5], and we have assumed an average distance from a pharmacy of 20 minutes walking time[6]. This leads to an average travel cost to visit a pharmacy of £2.10. This would be the cost to a patient arriving at a pharmacy to find it closed in the middle of the day. However, we do not know how often this would happen and would expect this to be a one-off cost as patients would be become familiar with the revised opening hours. In addition, this is an average so some patients may be impacted to a greater extent than others. For example, in March 2021 80% of the population lived within 20 minutes walking distance of a pharmacy. This suggests that a minimum of 20% may face additional costs of travel, for example if needing to drive, use public transport or living in more isolated areas. Similarly, the average distance to the next closest pharmacy is 0.67 miles, equivalent to around 13.5 minutes walking time valued at a cost of £1.41.

33. We expect that in the 5 weeks before making a change to their opening hours pharmacies will communicate it to their patients and we would expect this to be publicised for example using a notice on the door, social media, or website to say opening hours are changing. There is still a risk that a patient/member of the public will visit a pharmacy to find it closed, but less likely than if pharmacy just has to close with 24 hours or no prior notice to NHSE.

34. Scheduled closures during the day are already permitted in the regulations and the proposed regulatory change simplifies the process for implementing them. This could encourage more pharmacies to make use of scheduled rest breaks. Due to the lack of available data, we have not been able to monetise the inconvenience to patients of reduced access during the day compared to an increase in access at other parts of the day (as reduction in total hours in the day cannot be notified).

Benefits

35. The recent Royal Pharmaceutical Society (RPS) Workforce and Wellbeing Survey 2022[7], which received 1,496 responses, surveyed the UK pharmacy workforce. The survey showed

[5] DfT on valuing walking times can be found in table A1.3.1 of their data book https://www.gov.uk/government/publications/tag-data-book. £6.71 is the perceived cost of non-working time per hour in 2023 prices.

[6] DHSC commissioned analysis in March 2021 on the walking distance between every postcode in England and the closest 5 pharmacies. Which showed a population weighted average of 1 mile. We assume 1 mile is equivalent to 20 minutes walking time.

[7] Workforce and Wellbeing Survey 2022-120123.pdf (rpharms.com)

that higher proportion of respondents (96%) surveyed working within community pharmacy were at high risk of burnout in comparison to the whole of pharmacy workforce at 88% (80% in all other sectors). Burnout was defined as scoring above defined cut offs for exhaustion and disengagement, suggesting that those working within community pharmacy were extremely likely to suffer from burnout. One of the identified contributing factors was a lack of rest breaks alongside others such as long working hours and inadequate staffing. 20% of respondents working in community pharmacy reported not being offered breaks compared to 8% in all other sectors. The survey also found that respondents in community pharmacy were more likely to rate their mental health as poor compared to other sectors. One of the reasons for this was that they were less likely to be offered rest breaks.

36. Making it easier for contractors to close the pharmacy during the day to give staff scheduled rest breaks is likely to help improve the situation surrounding high risks of burnout and poor mental health within the community pharmacy workforce. Rest breaks can contribute to motivated staff, improved efficiency and a reduction in absence and sickness rates[8]. The RPS survey highlighted that 73% of respondents had considered leaving their job or the pharmacy profession in the past year due to the impact of their work on their mental health and wellbeing. Although rest breaks are one of many factors, as shown in the survey, it is a key component and therefore should improve community pharmacy workers wellbeing. However, this will be dependent on the pharmacy owners deciding to use this new provision.

37. Scheduled lunch breaks are not unprecedented and are already allowed in the regulations. For example, analysis of the opening hours of pharmacies shows that around 26% of pharmacies already have at least 1 lunch break in the week. The regulatory change alters the change in hours from an application process to a notification process. Therefore, this will make the process quicker and less onerous for those pharmacies wishing to amend their opening hours for this purpose.

38. While we are making it easier, making use of this enabling provision requires a will of businesses to do so. We have little control over this and cannot dictate that they must give breaks to their staff. Even if a pharmacy was to close for a break, they may still require staff to stay and work.

39. Due to lack of data and the uncertainty of the extent that this regulatory change will encourage more pharmacies to voluntarily introduce scheduled rest breaks we have not monetised the benefits to the pharmacy workers wellbeing. In addition, the benefits to pharmacy contractors of a simplified and smoother process for introducing scheduled rest breaks have not been quantified.

Allow 100 hours pharmacies to permanently reduce their core opening hours to 72 hours or above

40. It is proposed to change the regulations to permit 100 hours contractors to apply to NHSE/ICBs to reduce their core opening hours to 72 or above which is still an average of over 10 hours every day (7 days per week). Overall DHSC and NHSE consider that 72 hours provides the adequate balance between reducing the hours of 100 hours pharmacies to help them remain viable and consistently staying open for their contracted hours and to minimise the impact on patient accessibility.

41. A full-time pharmacist is usually contracted for 40-45 hours a week. Therefore, a 100 hours pharmacy needs to employ a minimum of 2 pharmacists to stay open for 80 to 90 hours, and

[8] Royal Pharmaceutical Society – Reducing workplace pressure through professional empowerment

also rely on locum cover for other hours. A reduction to 80 hours would mean locum costs could be reduced, but the pharmacies would still have to employ two full time pharmacists. A reduction below 80 hours, means one of the employed pharmacists can work part time, meaning the vacancy is attractive to candidates who cannot work full-time and are looking for reduced hours, meaning it is easier to fill the vacancy as the pool of candidates is expanded. Also, a level of 72 hours allows both employed pharmacists to be able to have more flexible working hours, again helping recruitment and retention. The revised requirement of 72 hours is also supported by a confidential report on a specific business's 100 hours pharmacy structure, so is therefore commercially sensitive.

42. Under the proposals contractors will not need to include information addressing the necessity test if they want to reduce hours Monday to Saturday before 5pm and after 9pm in their application. Contractors will not be able to reduce the total number of their hours on a Sunday and remove hours between 11am-4pm but can use the standard application route with the revised necessity test to apply to NHSE and change when they deliver 72 hours provided that numbers of hours on Sundays and Monday to Saturday remain the same and the pharmacy remains open 5-9pm Monday to Saturday and between 11am and 4pm on a Sunday.

Costs

43. We do not know how many 100 hours pharmacies might chose to apply to reduce their core opening hours, or the level of hours they might choose between 72 and 100. In the scenario where all 1,027 100 hours pharmacies reduce their hours to the minimum of 72 hours, this would result in 28,855 hours lost in terms of availability for patients per week. This would be around 5% of weekly hours supplied by community pharmacies. Given the current pressures faced in 100 hours pharmacies we think it is a possible scenario that all 100 hours pharmacies opt to reduce to 72 hours.

44. Around 10% of all pharmacies are open 100 hours per week and these pharmacies help maintain access for people who for various reasons are unable to regularly access NHS pharmaceutical services during normal business hours or who have urgent needs. The number of 100 hours per week pharmacies in an area increases with the levels of deprivation and poor health with over 3 times as many 100 hours pharmacies in the bottom 3 IMD deciles than in the top 3.

45. Although there will be a reduction in total hours, under the regulatory change the hours of Monday to Saturday 5pm to 9pm, total number of Sunday hours and hours between 11am and 4pm on a Sunday will be protected. This is balanced against the risk that under the 'do nothing' option we could continue to see a large number of 100 hours pharmacies permanently close which would result in the loss of all hours which are provided by 100 hours pharmacies including Monday to Saturday 5pm to 9pm and Sunday hours.

46. The main costs will be the potential inconvenience to patients of reduced overall opening hours. For example, if a patient's preferred 100 hours pharmacy chooses to reduce its core hours then it may no longer be open at the time the patient wishes or needs to use the pharmacy. In that circumstance, the patient would either need to alter the time he or she visits that 100 hours pharmacy or use a different pharmacy. Although 5% of weekly hours could be lost, we do not expect this to result in less overall dispensing and consequently associated fees, but that dispensing will be deferred to other pharmacies or other hours of the day.

47. If the patient needed a pharmacy on Monday to Saturday before 5pm, then it is likely that the risk of reduced access will be lessened, and the additional walking time will be small. This is

because around 75% of 100 hours pharmacies are within 10 minutes walking distance of another 40 hours pharmacy. However, if a patient required the pharmacy at a time later than 9pm another pharmacy would need to be open for this to lessen the impact of reduced access.

48. The major health impact of community pharmacies is in enabling patients to receive the medicines they are prescribed. According to the law of demand, an increase in the price of a product will usually lead to a decrease in the consumption of that particular product. The sensitivity of demand with respect to changes in prices can be quantified through a price elasticity of demand (PED). The PED gives the percentage change in demand that can be expected from a one percentage change in price, holding everything else constant.

49. There is a body of research looking at the PED of prescription medicines. Research spans the UK and other countries, and although some evidence is quite old it remains the best available. On average, the PED from the UK studies is approx. -0.32, the PED from meta-analyses is approx. -0.18, and that from papers focusing on other counties is approx. -0.15[9]. The literature indicates variability in the specific size of the PED, but that demand for prescription medicines is price inelastic, i.e. a change in price translates into a less than proportionate change in demand.

50. Although a reduction in pharmacy access hours does not increase the direct cost of the medication, it could be a cost in terms of inconvenience and potential travel and is the best evidence available for potential impacts. Given that demand for prescription medicines is price inelastic, we would infer that demand is also inelastic in relation to inconvenience and travel costs. Some people towards the lower end of the income distribution, including the elderly, may struggle to afford all their travel and therefore be the most likely to not travel again to collect their prescription. Similar we would expect those living in rural areas to be most inconvenienced by potential short-term closures.

51. As shown in the IA the potential increase in journey times will be relatively minor and the evidence from PED suggests that most patients would still collect their prescriptions and would either revisit the pharmacy at a later point or use a different pharmacy, rather than never getting their prescriptions.

52. In addition, particularly where accessibility is an issue, patients will have other means of ensuring they receive the medicines they need. For example, distance-selling pharmacies deliver straight to patients' homes (at no additional cost to the patient), which could be an option if a patient's travel time to their next nearest pharmacy increases beyond a level they are prepared to travel. It is therefore considered that any reduced access hours would not lead to any significant impacts on patient health.

53. We are not able to estimate the number of patients that might be inconvenienced through the reduced overall hours and need to alter when or which pharmacy they use. In addition, we do not know how many of those patients might lose complete access to 100 hours pharmacies through permanent closures if there was no regulatory changes. We therefore have not been able to monetise the inconvenience to the patients of reduced access.

54. If the patients change their behaviour and visit a different pharmacy, this could make the neighbouring pharmacies busier. It could impact positively in that the pharmacy may have increased income and now be able to employ more staff, or negatively if they are trying to manage increased workload within the same resources, and the wellbeing of staff at these pharmacies may therefore be impacted as a result. Due to lack of data we haven't been able

[9] The National Health Service (Amendments Relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicines Shortages) Regulations 2023 (legislation.gov.uk)

to monetise the potential costs on other pharmacies of potentially increased patients' demand and workload.

55. There is also a potential to increase the costs to Integrated Care Boards (ICBs) who from April 2023 assumed responsibility for commissioning pharmaceutical services. For example, in the case where a busy 100 hours pharmacy reduces hours then the ICB might decide that it is necessary to commission extra out of hours provision. Due to the uncertainty around this potential effect, we have not attempted to monetise this cost.

Benefits

56. There are significant numbers of 100 hours pharmacies closing and due to the removal of the exemption in 2012 it is no longer possible for 100 hours pharmacies to enter the market. 100 hours pharmacies have told us that this business model is no longer viable unless they can reduce their hours due to the high staff costs and other overheads, such as energy costs. Many 100 hours pharmacies are in supermarkets. Since the start of 2023, LloydsPharmacy has announced the withdrawal of all their pharmacies in Sainsbury's and both Tesco and Asda have announced plans to reduce their networks.

57. Allowing 100 hours pharmacies to reduce their hours, and consequently their labour costs will make those pharmacies more financially viable. The NHS is reliant on these pharmacies for urgent out of hours provision, so by making them more viable we expect to reduce the risk of further permanent closures of these 100 hours pharmacies thus protecting some access for patients to pharmaceutical services when most other primary care providers are closed (hours 5-9pm Monday to Saturday, total number of Sunday hours and hours 11am-4pm on Sundays). In addition, the reduction of core hours would require the 100 hours pharmacies to require fewer staff or locums to cover the shifts and therefore lessen the risk of temporary closures. It could also potentially free up staff to support other pharmacies in the local area.

58. All pharmacies can notify NHSE of a reduction to their supplementary hours (91% of all 40 hours pharmacies offer supplementary hours and can thus choose to reduce their hours down to 40). Regulations also permit 40 hours pharmacies to apply to NHSE and request a reduction of their core hours to below 40. However, for 100 hours pharmacies there is no ability to reduce their hours below 100. This regulatory change will enable 100 hours pharmacies to make the same decisions as are available to other contractors, while still complying with the requirement to deliver longer hours. In effect, 100 hours contractors might become 72 hours contractors and will have to deliver the full 72 core hours, which is still higher than the majority of 40 hours contractors (95%).

59. At the moment, many 100 hours contractors report that opening for the full 100 contracted core hours is not financially viable, therefore they are considering or already making decisions like Tesco and Asda referenced above to close these pharmacies permanently. There is a benefit that contractors are more likely to be able to stay open if the core hours requirement is reduced to a minimum of 72 hours. A reduction in hours would offer significant cost savings and the opportunity to staff the pharmacy more flexibly. However, as set out previously there is no data available on the days and times that patients access NHS pharmaceutical services. We therefore do not know how much income might be generated at the times the contractors are not permitted to reduce hours i,e. Monday to Saturday 5-9pm, total number of Sunday hours and hours between 11am and 4pm on Sundays. We therefore cannot assess the profitability of these protected hours compared to other hours.

We expect that business owners would make decisions about which hours to reduce outside of these protected extended hours to maximise income.

60. We have highlighted that a maximum of around 28,855 hours a week (from Monday to Saturday before 5pm and after 9pm) could be lost from this regulation change. However, as previously mentioned 100 hours pharmacies are more likely to experience financial difficulties within the current regulations and have been closing at a higher rate than 40 hours pharmacies. Table 3 presents the potential hours lost from 100 hours pharmacies permanently closing.

61. The reduction of hours as a result of the regulation change is not directly comparable with the hours lost as a result of permanent closures. The regulation change protects the key hours of 5pm-9pm Monday to Saturday and 11am-4pm on Sundays when no other pharmacies are likely to be open. The below table would suggest that the maximum reduction in opening hours from regulation changes is similar to the permanent closure of 25% of 100 hours pharmacies. However, permanent closures would reduce key hours whereas regulation change reductions in hours would be times when alternative provision is available. Allowing controlled reduction of hours, protects some evening and weekend hours rather than just accepting that some 100 hours pharmacies may remove all of their hours.

Table 3: 100 hours pharmacies closures and the resulting hours lost per week

Proportion of 100-hrs pharmacies permanently closing	10%	25%	50%	100%
Weekly hours lost	10,280	25,700	51,400	102,799
Proportion of all pharmacy hours	2%	4%	8%	17%

62. We have not been able to monetise the potential benefit to 100 hours pharmacies of being able to reduce their core hours from 100 to 72. Neither has it been possible to monetise the impact on patients in terms of reduced access hours compared to the counterfactual of potential permanent closures.

Enable temporary coordinated closures in the most affected areas through local hours plans

63. The proposal includes a new enabling provision that will allow NHSE or Integrated Care Boards (ICBs) to establish temporary local hours plans. Participation in the plan is voluntary for local pharmacy contractors and plans will exist only where NHSE or the ICB is satisfied that patients in a particular area are experiencing, or are likely to experience, significant difficulty in accessing pharmaceutical services. In practice, this would give NHSE/ICBs a tool to coordinate temporary closures in areas under pressure to mitigate against the impact of unplanned closures. NHSE/ICBs would be able to decide on the duration of the plan and what circumstances satisfy the ‘significant difficulty’ test.

64. Where there is a plan, NHSE/ICBs will agree new opening hours with pharmacy contractors. Contractor participation will be voluntary, giving them an opportunity to have adjusted terms of service such as different core and supplementary hours for the duration of the plan. However, for those participating, failure to comply with the agreement under the plan will be considered a breach of the terms of service. Each contractor participating in the plan will be able to cease participation and return to their usual opening hours, subject to the agreed terms of notice under the plan. New contractors will be able to join the plan.

65. NHSE will produce guidance and supporting documents to ensure consistency in the regions/ICBs approach while enabling local variation in the plans to respond to unique local challenges. This guidance will include how significant difficulty might be established, model plan agreement and other forms to support key processes and procedures.

Costs

66. The proposed regulatory change aims to enable temporary coordinated closures in affected areas through the introduction of local hours plans. NHSE will be producing guidance for ICBs on the local hours plans, and therefore there will be an administrative cost to NHSE of producing the guidance, model plan agreement and other forms.

67. The NHSE guidance will aim to ensure consistency in approach, but it will still enable local variation in the plans to respond to local challenges. Local plans will occur where patients are likely to experience significant difficulty in accessing pharmaceutical services. It is uncertain how that significant difficulty criteria will be determined by regional teams/ICBs and is likely to take a holistic approach. Therefore, it is not possible to test any significant difficulty criteria against the temporary closures that have been seen to date to estimate the potential number of local hours plans that might be introduced.

68. Every time a local plan is produced the ICBs will engage with local pharmacy contractors and Local Pharmaceutical Committees (LPCs) in the affected area. The plan is voluntary so it will be for pharmacy contractors to decide whether to participate in the plan. If pharmacy contractors participate, they will incur the time taken in engaging in discussions with ICBs and processes for producing the plan. In addition, there could be administrative costs of any actions determined within the local hours plans. For example, where new opening hours are agreed for a pharmacy for the duration of the plan, then revised staff rotas may need to be put in place and revised opening hours would need to be communicated to patients.

69. Due to lack of data on the potential number of local hours plans and the voluntary engagement with the plans we have not monetised the costs to pharmacy contractors of this regulatory change. If pharmacy contractors do not comply with the usual terms of service, this also comes at a cost if NHSE begins an investigation of potential non-compliance, which also comes with the risk of sanctions if proven to be the case. Therefore, we assume contractors would only voluntarily engage with the plans where those plans would generate net benefits.

70. There could be disruption to patients due to the temporarily reduced hours of service. For example, if a patient's preferred pharmacy has reduced hours under the local hours plan then it may be closed at the time the patient wishes to use the pharmacy. In that circumstance, the patient would either need to revisit the pharmacy later that day or the next day or go to a different pharmacy.

71. The options available to a patient would depend on the type of service they are seeking from the pharmacy. If it was for self-care then they could either seek an alternative pharmacy for that advice if the need is urgent or visit their usual pharmacy at another time. Community pharmacies can choose to provide advanced services within the CPCF. Therefore, if a patient was seeking an advanced service, the patients could either be referred to an alternative pharmacy or have an appointment at their usual pharmacy at a different time. If the patient needs to pick up medication already prescribed and that prescription was already sent to their usual pharmacy, then another pharmacy is not able to access this prescription. The Electronic Prescription Service (EPS) allows prescribers to send prescriptions electronically to a dispenser of the patient's choice. If the prescription had already been electronically sent to the pharmacy as the nominated dispenser, and the pharmacy is closed

then the prescription could not be fulfilled elsewhere, and the patient would be required to revisit its nominated pharmacy at an alternative time. Alternatively, if the patient was at the prescriber, the medication was required urgently and there was awareness that the usual pharmacy was closed, then the prescriber could arrange for the prescription to go to another pharmacy or provide patient with a paper prescription to take to any pharmacy of their choice.

72. If patients need to visit a different pharmacy or revisit at a different time, then there could be the cost of increased travel time for the patient. The aim is to bring coordination to the reduced capacity in the area that will already be occurring through uncoordinated closures and reduce the impact on patients of short notice, unplanned and uncoordinated closures. Due to the lack of available data, we have not been able to monetise the possible inconvenience to patients of coordinated closures.

Benefits

73. Local hours plans aim to coordinate temporary closures in areas under pressure ensuring the impact to patient accessibility will be minimised. The plans give contractors a time limited opportunity to have opening hours in their terms of service that they can actually comply with. Participating in the local hours plans will enable pharmacies to reduce their core hours to manageable levels without it being a breach of the terms of service. As the contractors agree to their revised hours in the full awareness of their current pressures and what they can deliver, it is less likely that they will have to breach this agreement (than the hours they said they could deliver historically when the pressures were different).

74. Patients will also benefit from local hours plans, for example the local hours plan should help prevent situations where two pharmacies in the same village close on the same day or even for the whole week. Therefore, provision in the area may be reduced but in a controlled way, reducing the impact on patients. Managing capacity in a coordinated way should reduce the impact on patients compared to sudden uncoordinated closures. The local hours plans should also mitigate issues surrounding potential pressure being put on GPs and urgent and emergency care, as the pharmacy services can be rescheduled or potentially delivered by another pharmacy.

75. Due to lack of data and the uncertainty of the extent of this change we have not monetised the benefits to pharmacy contractors or patients of this regulatory change. However, as mentioned above we assume contractors would only voluntarily engage with the plans where those plans would generate net benefits.

Require all contractors to have business continuity plans in place and use all reasonable endeavours to action these plans in the event of temporary closure

76. The current terms of service require contractors to make arrangements for the continuity of patient care with another local pharmacy when there is a temporary closure. This requirement is inadequate as it only requires that pharmacies point to the closest pharmacy rather than making arrangements for their patients. The proposal is to remove this requirement and instead set out in legislation that all contractors must prepare business continuity plans that include additional specific actions they must take in the event of temporary closure to minimise impact on patients and other NHS providers. The proposed arrangements that business continuity plans should cover are:

- Notify the commissioner (NHSE or ICBs) about the closure and if practicable and whenever possible, before the start of the closure;
- Update the pharmacy Directory of Services (DoS) profile after closure and after reopening;
- Notify nearby pharmacies and other local providers of primary medical services about the closure to mitigate against patients being referred to the pharmacy during its closure;
- Display a notice informing the public about the closure, the anticipated duration and alternative options to access pharmaceutical services;
- Make arrangements for ensuring, where appropriate, continuity of care for those patients who are anticipating or are accustomed to receiving pharmaceutical services from the pharmacy, including in respect of any (i) booked appointments, (ii) patients who attend the pharmacy regularly for the supervised administration of medicines.

Costs

77. Business continuity plans will require planning and will increase the burden on pharmacy contractors. The list of requirements has been reduced to only those essential to minimise the burden on contractors. Any costs to contractors will be offset by the removal of the existing requirement to make arrangement with another local pharmacy in the event of temporary closure. In addition, a few of these requirements are already included in the terms of service in the regulations and others are already best practice so the additional burden is unlikely to impact all pharmacies to the full extent of the measures. For example, PSNC have already recommended some of these steps[10] as best practice in the event of temporary closures for reasons outside of contractors' control. In this impact assessment we make no estimate of the extent that these actions are already being implemented under best practice.

Costs of the business continuity plan

78. The regulations will give 2 months' notice to contractors to prepare the business continuity plans. There will be the initial administration costs to contractors of considering the specific actions and procedures to put in place in the event of a closure as well as actually writing the business continuity plan. We estimate that the time taken to do this will be 2-4 hours per plan and likely to be done by the pharmacy owner, assumed here to be a pharmacist.

79. We use the average median hourly wage rate for pharmacists from the Annual Survey of Hours and Earnings[11] of £23.34 and uprate this figure by 30% to account for non-wage costs such as pensions and National Insurance contributions giving a total hourly cost of a pharmacist of £30.34.

80. On the basis of 2-4 hours administrative time, each plan will cost £61-£121 of staff time to produce. This is a regulatory change that would apply to all 11,075 pharmacies. Therefore, we estimate the initial cost of producing the business continuity plans to be £0.67m-£1.34m as a maximum. There may be tweaks required to the business continuity plan in the future, for example, if a new pharmacy or primary care provider were to open in the area. However, major changes to the pharmacy and primary care network are infrequent e.g. in 2022 239 bricks and mortar pharmacies opened (~2% of all pharmacies) and a large proportion of these were changes of ownership that would not necessarily have changed the contact details of the pharmacy. We therefore do not expect updates to the plan to be frequent or significant in magnitude.

[10] PSNC-Briefing-011.22-Temporary-closures-of-community-pharmacies.pdf

[11] ONS, Employee earnings in the UK 2022. https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/annualsurveyofhoursandearnings/2022/relateddata

Costs of the business continuity actions in the event of a temporary closure

81. The specific actions that are built into the business continuity plans and therefore the level of burden will vary from pharmacy to pharmacy. We therefore estimate costs on the basis of an average pharmacy but acknowledge there will be variation in these estimates. Like the production of the business plan, we assume that all of the actions are conducted by the owner of the pharmacy, assumed to be a pharmacist. In practice, while an owner is responsible for the plan, it does not have to be a pharmacist that implements it. Any member of staff could be given the tasks, so the costs reflect the highest estimate, but in practice might be lower.

82. The notification to the commissioner of the temporary closure and the update to the Directory of Services profile are already requirements for pharmacies, albeit not as part of a business continuity plan. Consequently, we assume that there is no additional burden on pharmacies of these two specific actions as a result of the proposed regulatory changes.

83. When there is a temporary closure, pharmacy contractors will need to display a notice informing the public about the closure, the anticipated duration and alternative options to access pharmaceutical services. The content of the notice is likely to remain consistent each time there is a closure apart from dates and durations. We estimate it would take 5 minutes to amend, print, and display the notice so that it is visible from outside the premises or update the webpage for a distance selling pharmacy.

84. Pharmacy contractors will need to notify nearby pharmacies and other local providers of primary medical services about the closure. This will be to avoid patients being referred to the pharmacy during its closure. The number of pharmacy contractors and providers of primary medical services that are nearby will vary by pharmacy. For the purposes of these estimates, we define nearby as within 1 mile. Data[12] on the distances between pharmacies shows that there is an average of 3 other pharmacies within 1 mile of a pharmacy. We do not have similar data on the distances between pharmacies and primary care providers. Pharmacists within DHSC suggest that around 4 GP practices might be attached to an average high street pharmacy. We therefore estimate that an average of 7 contacts might need to be made to other pharmacies or primary care providers to make them aware each time there is a pharmacy closure. We estimate that each contact will take 5 minutes but there will be variation in the number of contacts and ease of making contact between pharmacies. They could also send an email with the blind copy list of all contacts, in which case the time to notify could be reduced.

85. Pharmacies will also need to make arrangements for those with booked appointments. Activity data[13] shows that on average a pharmacy might provide 3 services per day. We use an average but recognise its limitations as activity will vary across contractors as pharmacies choose whether to provide advanced services, and also there will be factors that influence the number of appointments on a specific day e.g. higher in a flu vaccination season. The average of 3 service consultations will not necessarily be booked appointments but we use as a proxy for the number of patients that might need to be contacted. We estimate that each contact will take 5 minutes, with the potential to reduce if a pharmacy utilises a text messaging service. In addition, pharmacies should make arrangements for continuity of care for patients who attend the pharmacy regularly for the supervised administration of medicines. This is a locally commissioned service, so not all pharmacies provide it and the distribution will be lumpy across pharmacies. NHSBSA data on the fees paid for dispensing

[12] The data available is constrained to the distances of the closest 5 pharmacies to each pharmacy. Therefore, this could be an underestimate.

[13] Dispensing contractors' data | NHSBSA

of controlled drugs suggests that on average 1 patient per pharmacy might need to be contacted. This contact is also assumed to take 5 minutes. As 60% of temporary closures are for under 4 hours, this could also reduce the number of people that need to be contacted.

86. The total cost to pharmacy contractors of the actions associated with each temporary closure are estimated at £30.34 per closure. The breakdown of the costs are summarised in Table 2.

Table 2. Average costs to pharmacy contractors of business continuity actions per closure

Action	Tasks	Total Time	Staff Member	Total Cost
Notify the commissioner (NHSE or ICBs) about the closure and if practicable and whenever possible, before the start of the closure;	N/A	N/A	N/A	N/A
Update the pharmacy Directory of Services profile after closure and after;	N/A	N/A	N/A	N/A
Notify nearby pharmacies and other local providers of primary medical services about the closure and ensure that patients requiring urgent care are not referred to the pharmacy during its closure;	A pharmacy will on average need to contact 3 nearby pharmacies and 4 primary medical providers. Each contact takes 5 minutes.	35 mins	Pharmacist	£17.70
Display a notice informing the public about the closure, the anticipated duration and alternative options to access pharmaceutical services;	Pharmacy will need to produce/amend one notice and place on the access point to the pharmacy	5 mins	Pharmacist	£2.53
Make arrangements for ensuring, where appropriate, continuity of care for those patients who are anticipating or are accustomed to receiving pharmaceutical services from the pharmacy, including in respect of any (i) booked appointments, (ii) patients who attend the pharmacy regularly for the supervised administration of medicines.	A pharmacy will on average need to contact 3 patients with booked appointments. A pharmacy will on average need to contact 1 patient with supervised administration of medicines. Each contact takes 5 minutes.	20 mins	Pharmacist	£10.11
Total		**60 mins**		**£30.34**

87. The available NHSE data shows that in the period of a year (Feb-22 to Jan-23), there were 24,285 reported temporary closures. If the actions associated with each closure are estimated at an average of £30.34 per closure, this suggests total costs on pharmacies of £0.74m per year. We do not know what will happen to the number of temporary closures in the future. As the number of temporary closures has been relatively flat over the last 15 months we assume that this trend continues and this cost to pharmacy contractors occurs each year.

Benefits

88. The preparation of the business continuity plans and conducting the actions contained within them should improve the patients experience in situations where pharmacies have to close. For example, patients with booked appointments will be contacted which will prevent them arriving to an appointment that will not happen. For patients that visit the pharmacy the displayed notice should provide enough information to make an informed decision about their options and next steps. In addition, clear communication of the closure with general practices will mean that prescribers can arrange for urgent prescriptions to be sent electronically to another pharmacy to ensure patients can access the medication they need and start treatment sooner.

89. Situations where patients were to arrive for booked appointments, or patients referred to the pharmacy to find the pharmacy closed may damage the sectors reputation if no plans and communication were put in place, especially over a prolonged period. We expect that patients will have a better experience than if no plans were put in place.

90. We think most pharmacies are doing this already, so putting business continuity actions into the regulations will help to ensure that the small number of pharmacies who do not and thus cause damage to patients, are complying. Effectiveness of these plans very much depends on the professional responsibility of contractors to minimise patients' harm. The way the regulatory change is worded, it only requires reasonable and proportionate actions, and what is reasonable and proportionate is the judgement contractors will need to make.

91. Due to lack of data, we have been unable to monetise the improved patient experience through the actions that will be introduced in the event of a temporary closure. In addition, we have not monetised the reputational impact on pharmacies due to the actions it will take when there is such a closure.

Other minor amendments

92. The other minor amendments detailed below are expected to have no monetary impact for pharmacies or the NHS. We anticipate that there will be some unmonetised benefits to the sector in terms of streamlining processes and providing legal certainty of pharmacies' duties in certain circumstances. There may also be benefits around patient accessibility as the pharmacies understand the openings hours likely to suit patients and can now adjust accordingly.

Changes to opening date

93. It is proposed to amend regulations to remove an ambiguity and a potential loophole that currently means a pharmacy can postpone their opening date indefinitely after NHSE approves them joining the pharmaceutical list. The proposal is to amend the regulations to state any number of amendments to the opening date can be made provided the actual opening date specified is no later than 60 days after which the original grant period expired (i.e. one year and 60 days in the normal case). The first notice of commencement will be needed by the end of month 11 from the grant date as the contractor will be required to give 30 days notice of commencement (unless a shorter period has been agreed). This can be changed but the change will still be required within 30 days in advance of revised opening date (unless there is a prior agreement).

94. There is no anticipated cost of this amendment, and this just means that a pharmacy that was allowed to open because there is a need for it, can open quicker and NHSE/ICBs know when.

Notifying NHSE about an increase in supplementary hours

95. The proposal is to amend regulations to state that contractors are required to notify NHSE about their increase in supplementary hours, but notice is to be given before the increase has taken effect. This will make it clear that all notifications about a change in opening hours need to be given before the change is actioned.

96. There is no anticipated cost of this amendment as the regulations already require a notice, the amendment simply means the notice is given before the change in supplementary hours.

Fitness Information

97. As agreed as part of the year 4 negotiations, the regulations will be amended to state a requirement to provide a work history declaration covering the past 7 years and not the whole work history. In addition, fitness information will only be required from new contractors.

98. The requirement to provide fitness information with the new application will be removed if a contractor is already included on the Pharmaceutical List, and has provided this information within the last 7 years. Instead, these applications will be required to declare they complied to the obligation to report any fitness information as it arises.

99. It is anticipated that providing a work declaration for 7 years will take less time than a whole work history and therefore reduce the burden to applicants. It is difficult to measure the potential time savings attributed to this change particularly as it would be dependent on the diversity of the career of an applicant.

100. Similarly, contractors who have been included on the Pharmaceutical List within the last 7 years should experience a time saving from no longer needing to provide fitness information. It is difficult to measure the potential time savings attributed to this change but anticipate it to be minimal.

Change to core hours instigated by NHSE

101. The proposal is to clarify the process already specified in the regulations, specifically that NHSE can initiate a change to 40h pharmacies' core opening hours.

102. There is no anticipated cost of this amendment and the benefit will be that it provides legal certainty of pharmacies' and NHSE duties.

Necessity test for determination of pharmacy premises core opening hours instigated by the NHS pharmacist

103. Many contractors may not have information of what the patient need was when they first opened, so cannot credibly evidence there has been a change. The proposal is to require contractors to provide information sufficient to give NHSE assurance that the change in hours will maintain the adequate provision of pharmaceutical services that continue to meet the needs of patients and other users of pharmacy.

104. There is no anticipated cost of this amendment. While time to collate the evidence would still be required, the evidence required will become more meaningful as it will be related to the current need of patients rather than a historical need.

Summary of all costs and benefits

105. Table 3 summarises the costs and benefits of each of the proposed regulatory changes. The only quantified costs are associated with the additional activity that community pharmacies will need to undertake to prepare business continuity plans and action them in the event of a temporary closures. In accordance with the HMT Green Book the financial costs to community pharmacy contractors are discounted at a rate of 3.5% per year. The present value of these costs over the ten-year period is £7.4 million. As funding to pharmacies is contained within the agreed £2.592bn funding envelope, we do not anticipate any new cost pressures on NHS budgets relating to the regulatory change.

106. As it has not been possible to quantify the expected benefits for any of the regulatory proposals there is a negative Net Present Value but that does not take into account unquantified benefits as set out above. As has been outlined in the relevant sections above and summarised in Table 3 below, the monetised costs of £7.4m are low, with other non-monetised costs expected to be minimal as they are related in most cases to minor administrative changes to the requirements for pharmacy contractors. Allowing 100 hours pharmacies to reduce core opening hours to a minimum of 72 hours could have a cost to patients, but this is thought to be outweighed by the risk of a larger reduction in access if 100 hours pharmacies have to close permanently.

107. It has not been possible to monetise the benefits individually or as a wider package. However, as set out in Table 3 there are lots of unmonetised benefits expected but a smaller number of costs, the majority of which are monetised. The monetised costs of business continuity plans are also expected to be an upper estimate as many of the steps are already recommended as best practice, but we make no estimate of the extent that these actions are already being implemented. It is our assessment that the benefits of improving workforce wellbeing, ensuring level of access of pharmacies and making sure patients are not inconvenienced, will outweigh the minimal costs of the proposals. This is particularly the case with Option 4 where all proposals would be implemented.

108. Overall, the proposals are expected to have significant benefits to patients. They would support continuity of patient access to pharmacies which in turn would support timely access to medication and access other services provided by community pharmacies.

109. The number of community pharmacies has reduced since 2016/17, in particular there are significant numbers of 100 hours pharmacies permanently closing, leading to reduced access to pharmacies. The high number of temporary closures also reduce access to pharmacies and where pharmacies close, patient do not always know where to go instead. The proposals support patient access by supporting extended access to pharmaceutical services, requiring all pharmacies to enact a business continuity plan when they close temporarily for reasons outside of contractors control so that patients know what to do if they

are faced with a closure, and local hours plans can prevent uncoordinated closures which affect negatively on patients.

110. In addition, the proposals support pharmacy business. Local hours plan support businesses as it allows them to close in a more planned way if they choose to participate and businesses are supported by the proposal to make it easier for them to introduce rest breaks if they wish to introduce those.

Table 3: Summary of policy changes with costs and benefits

Group affected	Impact	Present value, £m
Monetised costs		
Contractors	Require all contractors to have **business continuity plans** in place and use all reasonable endeavours to action these plans in the event of temporary closure;	£6.8m
Non-monetised costs		
Contractors	Enable coordinated closures in the most affected areas whilst maintaining access to services in the locality via NHSE **temporary local hours plans**;	Unmonetised but expected to result in minimal costs
	Other minor amendments agreed with the PSNC during the CPCF year 4 & 5 negotiations.	Unmonetised but expected to have no monetary impact
	Make it easier for contractors to close the pharmacy during the day to give staff **scheduled rest breaks**;	Unmonetised but expected to have no increased costs
Patients	Allow 100 hours pharmacies to permanently **reduce their core opening hours to 72 hours** or above;	Unmonetised but potentially leads to some reduction in extended access for patients
Non-monetised benefits		
Contractors	Require all contractors to have **business continuity plans** in place and use all reasonable endeavours to action these plans in the event of temporary closure;	Unmonetised but expected to improve other contractors experience of temporary closures

	Allow 100 hours pharmacies to permanently **reduce their core opening hours to 72 hours** or above;	Unmonetised but potentially reduction in cost base for 100 hours contractors
	Other minor amendments agreed with the PSNC during the CPCF year 4 & 5 negotiations.	Unmonetised but intention to streamline processes and provide legal certainty of pharmacies' duties
Pharmacy staff	Make it easier for contractors to close the pharmacy during the day to give staff **scheduled rest breaks**;	Unmonetised but expected to improve pharmacy workforce wellbeing
Patients	Enable coordinated closures in the most affected areas whilst maintaining access to services in the locality via NHSE **temporary local hours plans**;	Unmonetised but managing capacity should minimise impact on patients of temporary closures
	Require all contractors to have **business continuity plans** in place and use all reasonable endeavours to action these plans in the event of temporary closure;	Unmonetised but expected to improve patients experience of temporary closures
	Allow 100 hours pharmacies to permanently **reduce their core opening hours to 72 hours** or above;	Unmonetised but potentially prevents loss of all extended access for patients

Impacts on small/micro businesses

111. As these Regulations concern the provision of NHS community pharmaceutical services in England on the basis of nationally determined terms of service, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed nation-wide standards and practices in the provision of such services as part of the nationally determined contractual framework. As the pharmacy regulations apply to all businesses equally so must the proposed amendments, and it is not possible to exempt Small and Medium Enterprises (SMEs) from any of the requirements.

112. Participation in the local hours plans is voluntary for local pharmacy contractors so small businesses could choose whether to engage or not. However, plans and therefore the opportunity to participate will exist only in areas where NHSE or the ICB is satisfied that patients are experiencing, or are likely to experience, significant difficulty in accessing pharmaceutical services.

113. Similarly, the regulation changes that simplify the route to changing pharmacy core hours to enable scheduled rest breaks is permissive. It will be up to the contractor to decide whether they wish to change their opening hours. Therefore, we assess that these proposals would be taken up only where it would generate net benefits and so is expected to have a net zero to net benefit impact on SMEs.

114. The requirement that all contractors must prepare business continuity plans that include additional specific actions they must take in the event of temporary closure will apply to all contractors regardless of size. As shown above the cost impact of this requirement is minimal, but will impact SMEs more than larger businesses in terms of the resource available to prepare the plans.

115. The regulations to permit 100 hours contractors to apply to ICBs to reduce their core opening hours to 72 or above will only apply to those 100 hours contractors.

116. Looking at our analysis of the number of companies that the regulatory changes apply to, we have been able to classify them in Table 2. These percentages indicate where a company is potentially impacted by the regulation change. For example, 100% of large multiple businesses could be impacted by allowing 100 hours pharmacies to permanently reduce their core opening hours to 72 hours or above as all large multiple companies own at least one 100 hours pharmacy.

Table 2: Potential impacts by pharmacy type

Pharmacy Type	Number of pharmacies	Total number of businesses [14]	Potential businesses impacted as a proportion of the pharmacy type			
			Introduce NHSE temporary local hours plan	Requirement to have Business continuity plans in place	Easements to close the pharmacy during the day to give staff rest breaks	Allow 100hours pharmacies to permanently reduce their core opening hours to 72 hours or above
Independents	1	2,328	100%	100%	100%	10%
Small chain	2-5	527	100%	100%	100%	16%
Larger chain	6-20	92	100%	100%	100%	30%
Small multiple	21-100	22	100%	100%	100%	45%
Medium multiple	101-500	7	100%	100%	100%	57%
Large multiple	501+	4	100%	100%	100%	100%
Total		2,980				12%

117. If we assume that each pharmacy employs an average of 6 people (based on the HEE workforce survey[15]), this translates into the following number of small and micro businesses:

Table 3: Potential impacts by SME classification

[14] There were 252 pharmacy stores where we were unable to attribute to a company. We have omitted these pharmacies from the above analysis

[15] The Community Pharmacy Workforce in England 2021 The Community Pharmacy Workforce in England 2021 - survey report_0.pdf (hee.nhs.uk)

	Total number of businesses	Potential businesses impacted as a proportion of the pharmacy type			
		Introduce NHSE temporary local hours plan	Requirement to have Business continuity plans in place	Easements to close the pharmacy during the day to give staff rest breaks	Allow 100-hour pharmacies to permanently reduce their core opening hours to 72 hours or above
Micro business (1-9 employees)	2,328	100%	100%	100%	10%
Small (10-49 employees)	575	100%	100%	100%	17%
Remainder (50+ employees)	77	100%	100%	100%	43%
Total	2,980	100%	100%	100%	12%

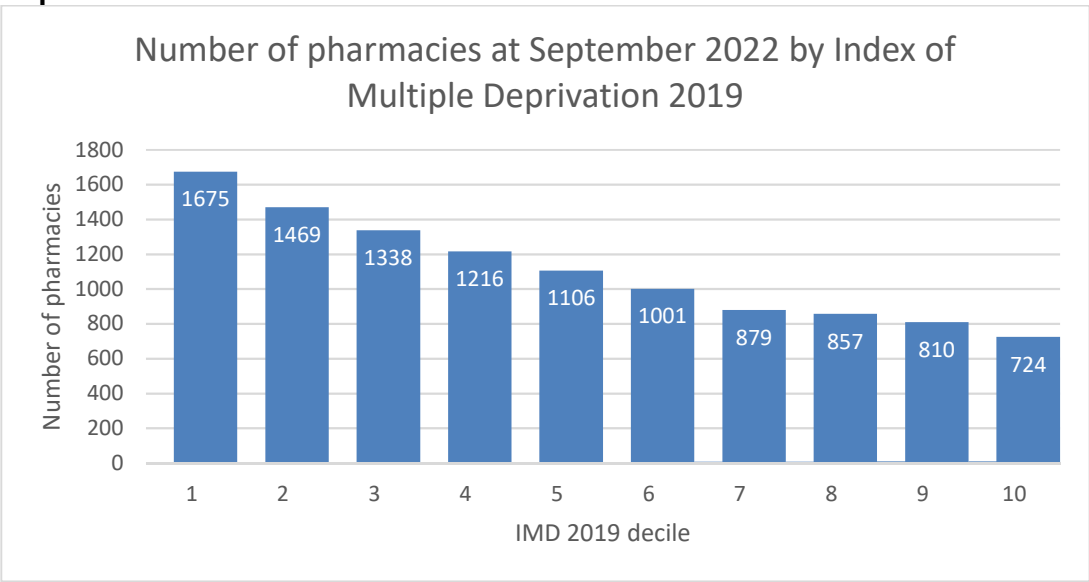
118. As can be seen, the majority of the regulation changes will affect all businesses equally. However, as the allowance of reductions in core hours is only for 100 hours pharmacies this affects a subset of the companies. We see around 10% of micro businesses will benefit from this proposed regulation change. This is slightly lower than for small businesses (at 17%), whereas a much higher proportion (43%) of the remainder businesses will benefit.

Demographic & Distributional Impacts

119. Over 60% of prescription items dispensed in the community are for people aged 60 years of age or older. In addition, around 3 million prescription items per annum are dispensed to women eligible for maternity exemptions. Hence, these groups represent a large proportion of those using essential pharmaceutical services (i.e. especially dispensing of medicines and the related advisory activities) and could therefore be more affected than others in a scenario where temporary closures or a reduction in access hours were to occur.

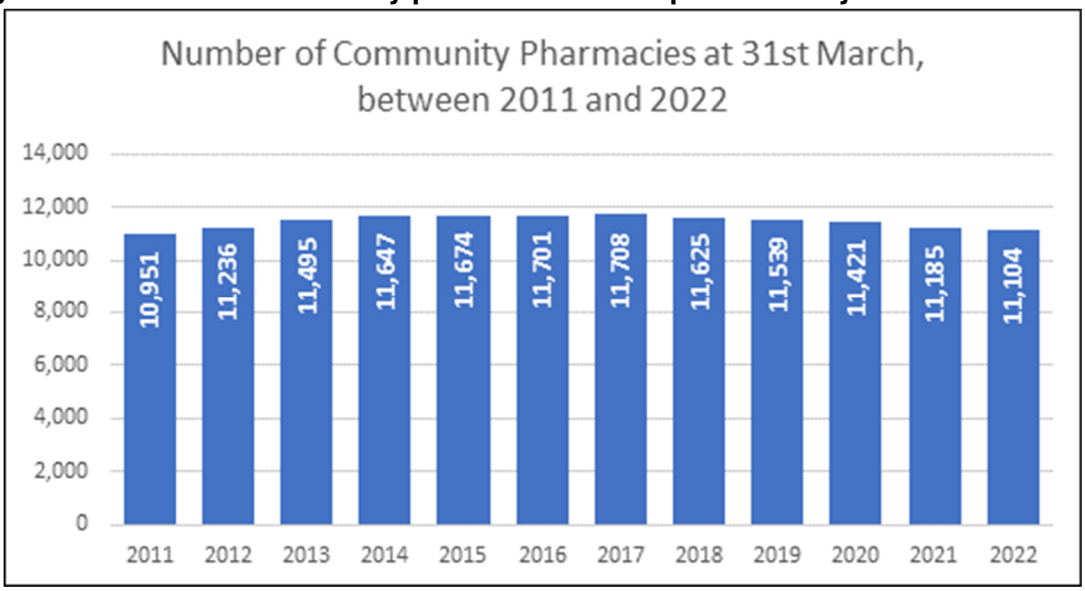
120. Access to pharmaceutical services remains better in the most deprived areas with these communities having twice as many pharmacies as those in the least deprived areas.

Figure 1. Number of community pharmacies at September 2022 by Index of Multiple Deprivation decile 2019



121. There are 11,075 community pharmacies in England dispensing NHS prescriptions (fewer than 10 years ago based on the latest (September 2022) NHS data. The number of community pharmacies has been declining since 2017 as shown in Figure 2.

Figure 2. Number of community pharmacies in the past eleven years[16]



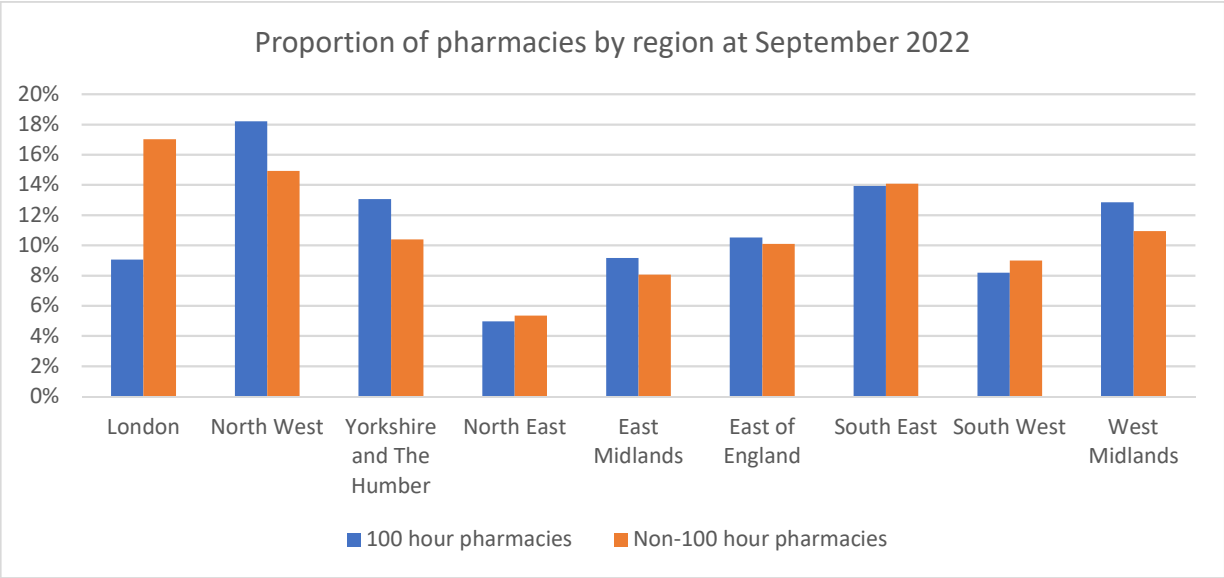
122. Ongoing Departmental monitoring of opening and closures since 2018 indicates that in the 2020/21 financial period, the number of net closures doubled compared to the 2018/19 period and continued to climb in comparison with the 2019/20 period. This accelerated rate of closures appears to have reduced post pandemic and the closures align with announcements made by the large multiples about reducing their network. LloydsPharmacy group recently announced they will be withdrawing all of their pharmacies located in Sainsbury's supermarkets. Tesco has announced plans to close 8 of their 100 hours pharmacies and Asda plans to close 7 pharmacies. If these closures go ahead, the rate of closures next year may increase again.

123. As of 30 September 2022, there were 1,027 100 hours pharmacies on the pharmaceutical list in England, representing 10% of all community pharmacies[17]. As shown in Figure 3, there are proportionally more 100 hours pharmacies in the North West and Yorkshire and Humber regions. These pharmacies help maintain access for people who for various reasons are unable to regularly access NHS pharmaceutical services during normal business hours or have an urgent need for services.

Figure 3. Proportion of pharmacies by region

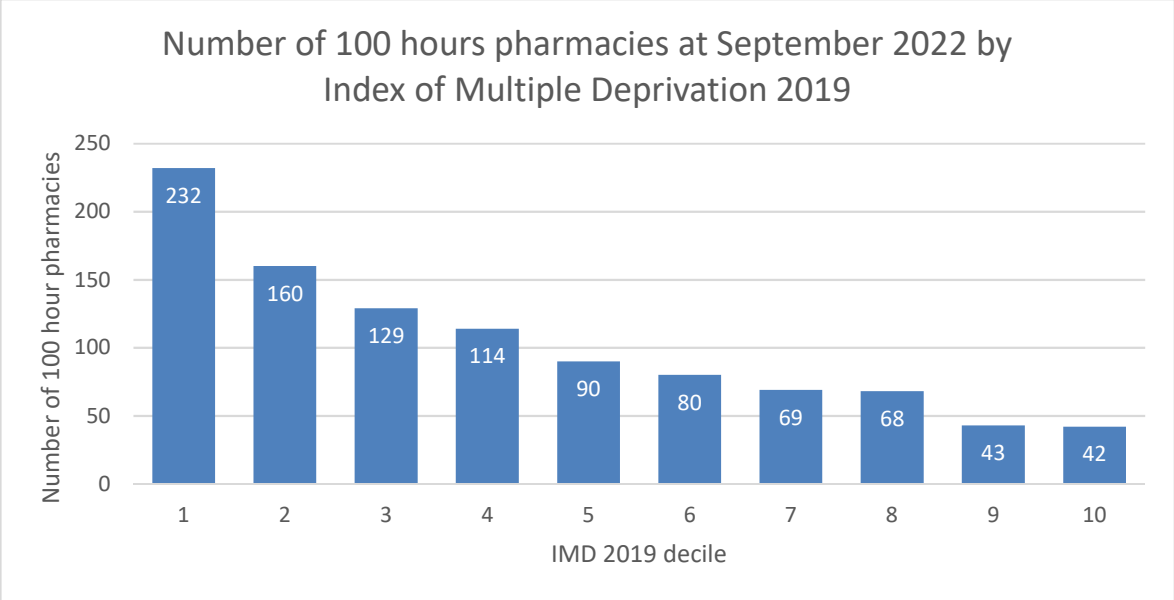
[16] *NHSD General Pharmaceutical Services publication for 2011 to 2015, NHS BSA General Pharmaceutical Services Publication for 2016 to 2022.*

[17] NHSE Pharmacy Openings and Closures January 2023 Open Data Portal



124. The number of 100 hours per week pharmacies in an area increases with the levels of deprivation and poor health. Figure 4 shows that 51% of 100 hours per week pharmacies are situated in areas that are in the bottom three deciles on the Index of Multiple Deprivation and Health Disability.

Figure 4. Number of 100hours pharmacies at September 2022 by Index of Multiple Deprivation 2019



125. It is therefore recognised that closures of 100 hours pharmacies could increase health inequalities. We note however that according to March 2021 distance data, approximately 80% of 100 hours per week pharmacies are within 10 minutes walking distance of another pharmacy. The risk of reduced access for patients using these services during normal business hours is lessened because the additional walking time to access another pharmacy would likely be very small.

Risks

No Engagement with Enabling Regulatory Changes

123. Pharmacies are private businesses and implementation of the new enabling provisions in the regulations, e.g. simplified designation of rest breaks, and participation in local hours plans will be at the discretion of the pharmacy contractors. There is a risk that pharmacy contractors do not engage with the enabling regulatory changes and therefore have a critical impact on the parts of the package that require co-operation with the sector. For example, in local hour plans it would make it more difficult for ICBs to ensure consistency of service across a locality when affected by longer-term temporary closures, and the anticipated benefits would not be realised. We think this is unlikely as the local plans aim to support contractors and they will be able to make a decision that benefits them. This risk could be mitigated to some extent by the provisions being proposed for business continuity plans, which designate the steps contractors who close temporarily would need to take to ensure that the public can access alternative sources of pharmaceutical services in the local area.

124. Currently the NHS regions have limited options to support contractors when they report pressures and closures. The local hours plan will be something ICBs can actually offer to contractors while still fulfilling their duty to secure patient access. We have discounted pilots of local hours plans as they can only be done in some areas and other areas where there may be need to act would have to wait for the outcome and evaluation of the pilots followed by subsequent regulatory changes. The local hours plans will be of a specified duration which could mitigate against any unforeseen challenges and implications and we will be able to remove or modify these provisions following implementation feedback.

Non-adherence with Regulatory Changes

125. There is a risk that despite some of the regulations being brought in that pharmacy contractors may not adhere fully to them. For example, the preparation of the business continuity plans should cover a range of additional specific actions contractors must take in the event of temporary closure. There will be no specific enforcement plan, so there will not be a blanket approach of asking all pharmacy contractors to provide evidence of their business continuity plans or evidence that actions have been carried out in the event of every closure. Therefore, there is a risk that not all contractors will fully implement all of these arrangements and therefore the impact of closures on patients and other NHS providers may not be minimised to the extent anticipated. Not adhering to these regulations would be a breach in the terms of service.

126. Breaching and penalising contractors does not directly help patients and becomes a more effective tool when there is a realistic chance of meeting the terms of the regulations and when it is possible to easily identify and target the pharmacy contractors who cause the most disruption to access to services.

Patient access is not protected

127. Whilst the regulatory amendments would enable 100 hours pharmacies to reduce their operating hours and would therefore reduce the number of hours patients can access services from these pharmacies, the proposals aim to protect the key hours between 5-9pm Monday to Saturday, total number of Sunday hours and hours between 11am and 4pm on Sundays. It is anticipated that this would reduce the current financial pressures being faced by 100 hours pharmacies. This reduction is to support their viability and help to mitigate against the risk of permanent closure, thereby protecting patient access in the longer term. The 72 core hours has been highlighted as a balance between reducing hours and the impact on patient accessibility. However, there is a risk that the revised minimum hours of 72 is still too high, or that the protected extended hours are not the most profitable for pharmacy contractors and there are still some permanent closures of 100-hour pharmacies, meaning

patient access is not protected. In the event of permanent closures and a reduction in access it is expected that patients would switch to an alternative pharmacy. However, it would increase the risk of some patients no longer collecting prescriptions at all and potentially suffering impacts on their health.

128. Where a pharmacy permanent closure creates a gap in patient access, another pharmacy can apply to open in the area. This new pharmacy can have minimum 40 core hours, but may offer higher core hours or additional supplementary hours to meet patients' needs. However, pharmacies have more flexibility with modifying their supplementary hours and do not require NHSE permission to reduce these hours in the future. In contrast, a former 100h pharmacy will be required to deliver the full 72 hours minimum, but can also offer higher number of core hours or extend hours by adding supplementary hours if there is patient need.

Impact of inflation on community pharmacies

129. Funding for community pharmacy was cut by over £200 million between 2016/17 and 2017/18 and has been held flat since. Using GDP Deflator estimates of inflation from the Quarterly National Accounts plus Office for Budget Responsibility (OBR) forecasts for GDP deflator increases as of March 2023, this amounts to a cut in real terms of 25% by the end of 2023/24. The five-year deal is a flat cash deal which we estimate to amount to a cut in real terms of 15% over the five years. Higher inflation has caused some of the problems necessitating these regulatory changes, to help pharmacies be more flexible in dealing with extra cost pressures. We expect the decrease in funding to continue to impact negatively on the ability of pharmacy contractors to attract and retain staff and therefore result in temporary and permanent closures and pressures on the viability of pharmacies as discussed above.

Table 4: Inflationary cost pressures using GDP deflators at March 2023[18]

		(2015/16 baseline)		(2018/19 baseline)	
	Nominal Funding	**Mar-23 GDP Deflator**	**Real Funding**	**Mar-23 GDP Deflator**	**Real Funding**
2015/16	£2.800bn	100.0	£2.800bn		
2016/17	£2.687bn	102.1	£2.633bn		
2017/18	£2.592bn	103.8	£2.498bn		
2018/19	£2.592bn	105.6	£2.454bn	100.0	£2.592bn
2019/20	£2.592bn	108.4	£2.392bn	102.6	£2.526bn
2020/21	£2.592bn	115.1	£2.251bn	109.0	£2.377bn
2021/22	£2.592bn	114.3	£2.267bn	108.3	£2.394bn
2022/23	£2.592bn	120.8	£2.145bn	114.4	£2.265bn
2023/24	£2.592bn	123.9	£2.092bn	117.3	£2.209bn
Change			**-25.3%**		**-14.8%**

130. Table 5 shows the equivalent figures using the inflation forecasts that were available in December 2018 i.e. the point at which the five-year deal was being negotiated. The increase in inflation estimates compared to the forecasts available at the time has resulted in significant unanticipated additional cost pressure falling on the sector. At the time the five-year deal was agreed, it was expected that flat cash would equate to a real terms cut in funding of 9.0% by 2023/24. The most recent inflation estimates in Table 4 suggest that is now 14.8%, equivalent to a further £150m cut in real terms funding.

[18] https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-march-2023-quarterly-national-accounts

Table 5: Inflationary cost pressures using GDP deflators at December 2018[19]

		(2015/16 baseline)		(2018/19 baseline)	
	Nominal Funding	**Dec-18 GDP Deflator**	**Real Funding**	**Dec-18 GDP Deflator**	**Real Funding**
2015/16	£2.800bn	100.0	£2.800bn		
2016/17	£2.687bn	102.3	£2.627bn		
2017/18	£2.592bn	104.3	£2.485bn		
2018/19	£2.592bn	106.2	£2.440bn	100.0	£2.592bn
2019/20	£2.592bn	108.1	£2.398bn	101.8	£2.546bn
2020/21	£2.592bn	110.2	£2.352bn	103.8	£2.498bn
2021/22	£2.592bn	112.3	£2.307bn	105.8	£2.451bn
2022/23	£2.592bn	114.5	£2.263bn	107.8	£2.404bn
2023/24	£2.592bn	116.7	£2.221bn	109.9	£2.359bn
Change			**-20.7%**		**-9.0%**

131. There is a risk that since these estimates were made, inflation has continued to rise, leading to even more unanticipated cost pressures falling on the sector. In addition, these estimates are calculated purely based on changing GDP inflation forecasts since 2018. The GDP deflator may not be representative of the sector's costs, and if we were to start factoring in pharmacy specific cost increases e.g. the sector is reporting large increases in locum rates, then the estimated costs could change. This could mean that the additional reduction in real terms funding amounts to more than the c.£150m outlined above.

132. We do not expect that the proposed regulatory amendments will lead to more pharmacy closures but recognise that the lack of substantial increase in funding given the current inflationary pressures may result with some pharmacy contractors making a decision to sell their business, close or reduce supplementary opening hours despite the additional regulatory easements being introduced.

Monitoring & Evaluation

133. NHSE and DHSC will continue to monitor data on temporary and permanent closures to consider the potential impact of the regulatory changes. In particular, we expect that allowing 100 hours pharmacies to reduce to a minimum of 72 core hours will mitigate against those contractors having temporary and permanent closures. We would therefore expect the monitoring to show a reduction in the temporary and permanent closures for both 40 and 100 hours pharmacy contractors. However, as previously set out, there are limitations to the temporary closures data which will need to be considered as it is based on pharmacy contractors reporting their closures.

134. The new notification process for scheduled rest breaks is an administrative process. Therefore, any revised hours will become evident in a pharmacy contractors reported opening hours. Every quarter the pharmaceutical list is published[20]. This sets out a list of all pharmacy contractors and includes their individual opening hours. This list will be monitored to consider the change in pharmacy contractors scheduling breaks. For example, there will be monitoring of the growth in the number that have at least 1 break per week (currently 26%).

135. The pharmaceutical list will also be monitored to consider the change in total pharmacy access hours. There will be a particular focus on the 100 hours pharmacies where it will be

[19] https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-december-2018-quarterly-national-accounts

[20] https://opendata.nhsbsa.net/dataset/consolidated-pharmaceutical-list

possible to consider the number of pharmacies choosing to reduce their core opening hours and the level chosen between 72 and 100 core hours.

136. We will monitor the establishment of local hours plans. We would expect to see a reduction in patients' complaints and correspondence about temporary closures due to the local hours plans and the business continuity requirements.

137. As per the requirements of section 28 of The Small Business, Enterprise and Employment Act 2015, the 2013 Regulations are reviewed every 5 years. The regulations were reviewed in 2018. A further review of the 2013 Regulations is currently underway.

138. In addition to the legally required reviews, through ongoing discussion with the Pharmaceutical Services Negotiating Committee (PSNC), the Department of Health and Social Care (DHSC) continue to monitor the effectiveness of the 2013 Regulations and make any required legislative amendments to ensure they remain fit for purpose and reflect any changes within the sector. Accordingly, a number of amendments to the 2013 Regulations have been made since their introduction. The impacts of these particular regulatory changes will therefore be reviewed through those ongoing discussions on the regulations with the PSNC.

Conclusion

139. The statutory duty on NHS England to make arrangements for the provision of NHS pharmaceutical services continues and it is important that any proposals are sufficient to ensure that it maintains the core services contractors are expected to deliver as part of providing NHS pharmaceutical services, including the prompt dispensing of prescriptions. The proposed regulatory changes are designed to enable NHS England to fulfil this duty whilst easing some of the pressures the sector is facing at present.

140. Local hours plans will enable ICBs to oversee and manage closures across a locality, ensuring that an appropriate level of access to services continues to be provided. Similarly, the proposals for business continuity plans aim to minimise disruption for patients and other providers by strengthening the responsibility on contractors to ensure continuity of care in the event of temporary closure. The provision for all contractors to be able to take a break is acknowledged as necessary for the wellbeing of the workforce. Whilst the proposals for enabling 100 hours pharmacies to reduce their hours may lead to some reduction in access to services, the proposals protect key hours in the evenings and at weekends.

141. Requirements for business continuity plans have been amended to ensure that, should a pharmacy need to close temporarily, robust plans are in place to ensure that the public continues to be able to access pharmaceutical services elsewhere in the locality.

142. The only quantified costs are associated with the additional activity that community pharmacies will need to undertake to prepare business continuity plans and action them in the event of a temporary closures. The present value of these costs over the ten-year period is £7.4 million. The monetised costs of business continuity plans are expected to be an upper estimate as many of the steps are already recommended as best practice, but we make no estimate of the extent that these actions are already being implemented. Apart from this requirement, we have been unable to quantify the costs of the proposed regulatory changes but expect these to be minimal as they are related in most cases to minor administrative changes to the requirements for pharmacy contractors. Allowing 100 hours

pharmacies to reduce core opening hours to a minimum of 72 hours could have a cost to patients, but this is thought to be outweighed by the risk of a larger reduction in access if 100 hours pharmacies have to close permanently.

143. Non-quantified benefits are expected from the proposals such as the protection of some extended access to pharmaceutical services and a positive impact on patients, other pharmacies, and primary medical providers when temporary closures cannot be avoided. Overall, as there are lots of unmonetised benefits expected but a smaller number of costs, the majority of which are monetised, we feel that costs will be minimal and very likely to be outweighed by the benefits. This is particularly the case with Option 4 where all proposals would be implemented.

144. Other than the business continuity plans and other minor amendments, the regulatory proposals are enabling. Pharmacies are not required to make use of them, with the exception of business continuity plans requirement, and it will be for each pharmacy contractor to decide if they want to make use of these provisions. We assume a pharmacy contractor will only voluntarily engage with the enabling provisions if favourable to them and generate net benefits.

145. We recognise the potential for some groups to be disproportionately impacted, however it is our view that the regulatory amendments are proportionate to the legitimate aim being pursued of maintaining access to the best quality of community pharmacy services within the CPCF funding.

146. Overall, the proposals are expected to have significant benefits to patients. They would support continuity of patients access to pharmacies which in turn would help support timely access to their medication and access to other services provided by community pharmacies.

147. The number of community pharmacies has reduced since 2016/17, in particular there are significant numbers of 100 hours pharmacies permanently closing, leading to reduced access to pharmacies. The high number of temporary closures also reduces access to pharmacies and where pharmacies close, patient do not always know where to go instead. The proposals support patient access by keeping 100-hour pharmacies viable, requiring all pharmacies to enact a business continuity plan when they close temporarily so that patients know what to do if they are faced with a closure and local hours plans can prevent uncoordinated closures which affect negatively on patients.

148. In addition, the proposals support pharmacy business. Local hours plan support businesses as it allows them to close in a more planned way if they choose to participate and businesses are supported by the proposal to make it easier for them to introduce rest breaks if they wish to introduce those.

149. Option 4 of introducing all the regulatory changes is the recommended option.