THE NATIONAL HEALTH SERVICE (CORONAVIRUS) (CHARGES AND FURTHER AMENDMENTS RELATING TO THE PROVISION OF PRIMARY CARE SERVICES DURING A PANDEMIC ETC.) REGULATIONS 2020

OUTLINE IMPACT ASSESSMENT

1. The regulations will enable a number of easements of normal processes in order to better support patients, pharmacies and the NHS Business Services Authority (NHS BSA) during the COVID-19 pandemic.
2. We have conducted proportionate analysis in line with the expected level of economic impacts and the urgency of the need for this legislation. In summary, our assessment is that the net impacts of these easements are small and likely to provide a net benefit to UK society in terms of:
    - helping manage the UK response to the COVID-19 pandemic;
    - having due regard for patient access to medicines, dentistry, ophthalmology services and to wider pharmaceutical services; and
    - ensuring businesses are not unfairly prevented from opening as a result of the pandemic

a. The suspension of the need for a patient to sign prescription, dental and ophthalmic forms for a fixed period.

3. The effect of this change is that patients will not have to sign forms to claim their exemptions from prescription and dental charges nor to certify they have paid a charge. They will also not be expected to sign treatment plans.

Benefits

4. This change is likely to offer pharmacists, dentists and ophthalmologists and their patients a degree of protection from the spread of the virus through limiting the need to touch the paper forms, pass them back and forth across the counter and from sharing pens in the pharmacy. It is supported by the British Medical Association (BMA) and the Pharmaceutical Services Negotiating Committee.
5. Any direct economic impacts on health professionals and their patients in terms of time savings will be small. However, it will offer their staff some comfort as part of the overall steps being taken to protect them from viral transmission.

Risks

6. Pharmacy, dental and ophthalmology staff will still ask to see evidence that someone is entitled to a free prescription and can still check that on the Real Time Exemption Checking system where they are part of that. Despite this, there is a potentially small risk of increased fraud by contractors and/or patients where patient signatures are not collected to confirm payment or entitlement to exemption from charges. Some patients may revert to fraud they had formerly abandoned as a result of increased checks by NHSBSA in the period before the pandemic.

7. As context, the NHS Counter Fraud Authority (NHSCFA) estimates that Help with Health Costs (patient fraud & error) accounts for a loss of around £250m per annum[1]. It is not possible to estimate an increase in this loss due to additional fraud and error, but a 1% increase due to patients no longer being required to sign would equate to a loss of around £2.5m per annum (less over a shorter period).

COMMUNITY PHARMACY PROPOSALS

8. The Pharmaceutical Services Regulations 2013 govern the arrangements in England for the provision of pharmaceutical and local pharmaceutical services. The Regulations include a pharmaceutical list system of approved contractors who are entitled to dispense NHS prescriptions. Routine applications to join these lists are mostly assessed against a local plan known as a pharmaceutical needs assessment (PNA). Successful applicants have limited time after the grant of their application to open.

b. Suspending the publication of Pharmaceutical Needs Assessments (PNAs)

9. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (PLPS), would shortly require Health and Wellbeing Boards of local authorities (HWBs) to initiate reviews of their PNAs for publication in April 2021. Health and Wellbeing Boards of local authorities are required to publish PNAs every three years or sooner. PNAs were last published in 2018.

10. We are proposing to suspend this requirement until 1 April 2022. This will reduce the immediate burden on local authority HWBs and the other public authorities to consult in the development of their assessment. The new provision provides HWBs with the option of suspending the publication of a revised – or a first – PNA for a time limited period in order to prioritise the provision of other services and/or activities that may have arisen as a result of the COVID-19 pandemic.

Benefits

11. Suspending the publication of revised PNAs until April 2022 will help reduce the immediate burden on 152 HWBs who are currently prioritising delivery to other urgent services during the COVID-19 pandemic. The PNA development goes through an extensive engagement and formal consultation process. A PNA is likely to take in excess of 6 months to prepare, and the process can take up to a year or even more. A PNA review process at this time would be unnecessarily burdensome given the current low level of market change in community pharmacy, and a delay in publication would also postpone the costs of the Consultation.

12. The proposals should not have any detrimental impact on the ability of NHS England and NHS Improvement (NHSE-I) to determine applications from existing or potential pharmacy contractors as we have retained the ability for an HWB to issue updates (known as 'supplementary statements') to existing PNAs, where changes occur in the provision of pharmaceutical services in an area that would

[1] https://cfa.nhs.uk/fraud-prevention/reference-guide/nhscfa-thematic-fraud-areas/help-with-health-costs

affect the granting of an application to join the pharmaceutical list or alter services provided.

Risks

13. NHSE-I use PNAs as the basis for determining market entry. A contractor who wishes to provide NHS pharmaceutical services applies by proving they are able to meet a pharmaceutical need as set out in the relevant PNA. In 2019-20 there were 790 applications to the pharmaceutical list including applications for change of ownership and location. For all these applications any relevant information in the PNA was included in the decision process, but only 5 of the applications related to either current need, future needs and improvements or better access and were therefore assessed directly against the PNA..
14. By suspending the publication of revised PNAs for a year there is the risk that applications (both successful and unsuccessful) might be based on outdated needs, improvements, or better access identified in 2018.
15. However, contractors can apply to join the pharmaceutical list on the basis of an 'unforeseen benefit', to secure improvements or better access to pharmaceutical services that have not been identified in the PNA. This application route ensures there is flexibility within the system in circumstances whereby a PNA has not identified an opportunity to provide improvements or better access to pharmaceutical services. This means that if there was an outdated PNA nor any supplementary statements from the HWB, a contractor could still apply based on needs not contained in the PNA.

c. Opening a community pharmacy premises

16. The new provision will extend the statutory time frame for opening a new community pharmacy premises to better support contractors. The current arrangements allow for up to 9 months, which consists of a standard 6 months and a further discretionary 3 months with NHSE-I's agreement. The new proposals will allow all eligible contractors between 15 and 18 months to open depending on the stage they are at in the application process.
17. We are aware that a small number of contractors, who are due to open new community pharmacy premises, and have already been granted an extension by NHSE-I under the current PLPS timeframes for that purpose, may not be able to open even within the extended period. This is largely due to circumstances beyond the contractor's control – for example, building supplies being held up, because of the wider impact of the COVID-19 pandemic.
18. As of early May 2020, seven contractors had already been given a discretionary 3 month extensions which were due to expire by the end of May and a further 16 applications had been awarded discretional extensions due to expire before the end of September 2020. It is not clear how many further contractors will be affected, as this will depend on the number of new applicants granted in the future, and how long these regulations remain in place for. As a reference, approximately 50 pharmacies open per year.

Benefits

19. The extended time period would enable existing applicants time to open and prevent the need for those pharmacies to reapply to the pharmaceutical list, potentially incurring repeat application fees and wait times associated with the approval process. Application fees range from £150 for a minor relocation to £750 for a new application, and NHSE must determine notifiable applications within 4 months unless there is good cause for delay.

20. There may also be benefits to NHSE-I in terms of avoiding re-work for lapsed applications. Furthermore, there may be benefits to patients in terms of more timely access to local pharmaceutical services from an extension rather than a repeat application process.

Risks

21. We assess that the impact of any delays to opening pharmacies on the provision of pharmaceutical services is likely to be low as the numbers of applications affected are few.

22. Where an application has been received and determined by NHSE-I, no further applications can be made. This may be detrimental to other potential contractors wishing to enter the market during the extended period given for the first applicant to open. In the unlikely event that those contractors would have been able to enter the market more quickly, this could cause a delay in patients being able to access the pharmaceutical services they need. However, we have no evidence that other contractors would necessarily be in a position to avoid such barriers to opening (especially as the current delays faced by contractors are due to COVID-19 and so would likely affect all businesses). Given the few opportunities and small number of applications to enter the market we assess these risks to be low.

23. We will regularly review and, if necessary, change the regulations to ensure that there are minimal limitations on contractors making their premises ready for opening. There is the risk that further regulatory change is not accomplished and the that the intended temporary extension goes beyond the duration of the COVID-19 pandemic. However, we consider, on balance, the detriment to be small given the extra extension that is provided for by this change is relatively short – an extra 6 – 9 months, the current market is not conducive to new applications and we intend to revert to the original regulations once the COVID-19 pandemic's impact on contractor's ability to fit out and prepare their businesses for opening has diminished.

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