Contract and IT

December 2021

PSNC Briefing 050/21: Regulatory amendments in late 2021/early 2022

Regulatory changes introduce a range of new measures, including a new type of pharmaceutical service, the National Enhanced Service, various pandemic related changes and previously indicated changes related to Pharmaceutical Needs Assessments (PNAs); as well as a change to the market entry regulations.

This briefing gives a summary of each regulatory change. These are set out in the **NHS (Charges, Primary Medicinal Services and Pharmaceutical and Local Pharmaceutical Services (Coronavirus)(Further Amendments) Regulations 2021 (SI 2021 No. 1346)** and make amendments to the **NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the Regulations).**

Unless stated as coming into force on 1 January 2022, the regulatory changes come into force on 21 December 2021.

National Enhanced Service

A new type of Enhanced service, the national Enhanced Service (NES) is introduced: where NHS England and NHS Improvement (NHSE&I) commissions an Enhanced service with a service specification that sets *standard conditions nationally*. PSNC becomes the body consulted on the service and its funding, rather than one or more Local Pharmaceutical Committees (LPCs).

In many ways a NES equivalent is already in place with the coronavirus vaccination Local Enhanced Services, which is provided nationally. So the regulatory changes provide a better structure for what is already happening.

LPCs will continue to be consulted on Local Enhanced Services (LESs).

Enhanced Services are agreed between NHSE&I and individual contractors/pharmacies. This means both that contractors can choose whether to deliver the service and NHSE&I can choose whether it wants a specific contractor/pharmacy to deliver the service.

In agreeing the introduction of this new type of service, PSNC will be able to influence NHSE&I's:

- decision whether to commission a new service as a National Enhanced Service, available to some contractors, or as an Advanced Service, available to all contractors; and
- the national process for selecting pharmacies to provide any new Enhanced service, to seek to ensure the process is fair and transparent.

Normally, funding for Enhanced services is from outside the global sum and this has remained so for Enhanced services introduced during the pandemic that are in effect national. PSNC has indicated this should continue to be the case for NESs introduced in the future that are not pandemic related.

The Department of Health and Social Care (DHSC) has committed to building in a process for Secretary of State consultation or approval for any NES that NHSE&I may seek to introduce, as a further measure to ensure that the introduction of a NES is appropriate.

Pandemic response programme

Contractors' Terms of Service have been revised to allow NHSE&I to introduce a pandemic response programme, which includes:

- conducting an infection control risk assessment, in the approved manner;
- appropriate infection control measures at the pharmacy premises, designed to support the safety of service users and pharmacy staff, particularly where they have or may have COVID-19;
- arrangements, which may be approved, for communicating with potential service users about service availability and service provision at or from the pharmacy premises during the pandemic,
- arrangements for appropriate updating of the pharmacy's standard operating procedures or business continuity plan, and
- arrangements for appropriate updating of the premises standards programme including any new approved particulars in response to the pandemic.

NHSE&I must consult PSNC before introducing a pandemic response programme.

The additional regulations are included in the *clinical governance and the promotion of healthy living* part of the Terms of Service, in schedule 4 of the Regulations

This change was **agreed** between PSNC, DHSC and NHSE&I following Year 3 negotiations and comes into force on 1 January 2022.

Listed Prescription Item Voucher schemes (LPIV)

A Listed Prescription Item Voucher (LPIV) scheme is introduced, a further option for the community pharmacy supply of treatments or medicines during or in anticipation of pandemic disease. This may be used for the supply of medicines without charge to the patient.

There are two other options, the Pandemic Treatment Protocol (PTP) and the Pandemic Treatment Patient Group Direction (PTPGD) and a reminder of these is set out below. The LPIV is slightly wider in scope (e.g. any medicines not only POMs; and any emergency that threatens or has caused serious damage or risk to public health in any part of England rather than limited to a pandemic).

With the LPIV:

- NHSE&I provide an electronic voucher through a secure system to a community pharmacy. If the item is a POM, the voucher will be a prescription from an authorised prescriber but will not be an ordinary FP10 prescription.
- Following receipt of the voucher, the community pharmacy, must supply the medicine with reasonable promptness to a person entitled to receive the medicine.

An LPIV scheme is part of the Essential services that contractors must provide, unless introduced as an Enhanced service (including a NES) or an Advanced service.

Aspects of the Essential service dispensing service apply including giving a time estimate of when the item will be ready, and supply may be refused if for example, the pharmacist does not consider this is an LPIV for the person requesting the medicine or the person's representative, or supply would be contrary to the pharmacist's clinical judgement. Professionally, it may be appropriate to add a dispensing label for the individual patient.

Certain record keeping requirements will apply as this information is likely to be necessary for contractors to claim a fee and any reimbursement for a supply.

Pandemic Treatment Protocols and Pandemic Treatment Patient Group Direction (PTP and PTPGD)

These were introduced in regulatory changes in **2020** and **2021** for supply of a prescription only medicine (POM) for the prevention or treatment of a disease that is, or is anticipated to be imminently, pandemic,

Contractors may supply a POM to a person in accordance with a Pandemic Treatment Protocol (PTP) or Pandemic Treatment Patient Group Direction (PTPGD), if and when one is issued by NHSE&I.

With a PTP or PTPGD:

- where the contractor receives, via a secure service approved by NHSE&I, an electronic message that amounts to an order for the supply of a POM in accordance with a PTP or PTPGD (for a PGD supply the requirements for PGDs must also be met); and,
- having made appropriate checks; and
- having regard to what is reasonable and appropriate …

…. the person who is entitled to be supplied with that medicine in accordance with that order or request, the medicine must be supplied with reasonable promptness.

Again, a PTP or PTPGD is part of the Essential services that contractors must provide, unless introduced as an Enhanced service (including a NES) or an Advanced service.

Aspects of the Essential service dispensing service also apply as above, including times when a supply may be refused; and **certain record keeping requirements will apply.** In addition, medicines must be supplied with a dispensing label.

As these are issued in accordance with section 247 of the Human Medicines Regulations 2012 (HMRs), they may not be used for a supply of a Schedule 2, 3, or part 4(1) Controlled Drugs.

Pharmaceutical Needs Assessments

In March this year, after being informed by DHSC, **PSNC announced** that the next date for the publication of the revised Pharmaceutical Needs Assessment (PNA) would be put back by a further 6 months to October 2022. This is now included in the Regulations.

In addition, there are changes to the Regulations to allow:

- Health and Wellbeing Boards (HWBs) created after 1 January 2022 must publish their first PNA no later than 12 months after being established; and
- Such new HWBs may issue supplementary statements, as appropriate, in relation to the former HWB's PNA for the area they inherit.

So, the date by which most HWBs will need to publish their PNA is now officially 6 months later to 1 October 2022.

PNA based market entry applications offering additional or different hours

A new regulation 21A is introduced and provides that NHSE&I must refuse certain routine applications for premises not already listed if it is satisfied that granting the application would result in an undesirable increase in the availability of essential services in the HWB. This extends the scope of existing provisions in the Regulations for the basis on which NHSE&I may refuse new applications.

The routine applications subject to this new Regulation 21A are those:

- to meet a need, or secure improvements or better access, identified in the PNA (whether current or future gaps in provision); and
- where this is in respect of the days or times when Essential services are provided in the HWB.

Regulation 21A should give NHSE&I greater scope to refuse applications for new pharmacies seeking to provide a small number of additional opening hours - which seek to fulfil a need, or improvement or better access, identified in the PNA - and may be a relevant matter for contractors and LPCs to bring to NHSE&I's attention when responding to routine notifications of relevant applications. These are new applications to fulfil a current or future need, or secure current or future improvements or better access.

This change was **agreed** between PSNC, DHSC and NHSE&I following Year 3 negotiations.

If you have queries on this PSNC Briefing or you require more information please contact **Gordon Hockey, Director, Legal.**