Guidance on the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020

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Summary

The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2020 (the 2020 regulations) introduced regulatory changes effective from 9 November 2020, 1 January 2021, 15 February 2021 and 1 April 2021.

The regulatory changes effective from 9 November 2020 are:

- **Entering administration.** Chapter 4 details new requirements when this occurs.

- **Pandemic treatment protocols (PTPs).** Chapter 5 and Chapter 16 outline the supply and provision of drugs arrangements in accordance with a PTP during a pandemic for pharmacies and dispensing doctors respectively. Changes to enable contractors to limit the provision of pharmaceutical services to ‘relevant immunisation services’ during a pandemic are detailed in Chapter 9.

- **Dispensing services.** Chapter 6 details changes to activities to be carried out in connection with the provision of dispensing services relating to the Electronic Prescription Service (EPS).

- **Referrals, communication, information and remote access.** Chapter 12 details new requirements for contractors to ensure:
  1. their staff have access to the premises-specific NHSmail account, patient’s summary care record and the EPS;
  2. Directory of Services and NHS website profiles are comprehensive and accurate for their pharmacy;
  3. they are registered with the Medicines and Healthcare products Regulatory Agency to receive Central Alerting System notifications.

  Chapter 14 explains how contractors must allow access to any information reasonably requested by NHS England and NHS Improvement via electronic communications. Chapter 13 provides full details of the requirement for contractors to facilitate remote access to services provided at or from their pharmacy premises. Chapter 15 explains how these changes affect Local Pharmaceutical Services (LPS) contracts.

- **Health campaigns.** Chapter 7 includes changes to the type and timing of health campaigns and informing NHS England and NHS Improvement on their delivery.
• **Notices of commencement.** [Chapter 17](#) provides details of the submission of notices of commencement for new entrants to the pharmaceutical list.

The regulatory changes on 1 January 2021 are:

• **Promotion of healthy living.** [Chapter 10](#) describes the regulatory changes and requirements that support a new focus on the provision of healthy living advice and interventions by pharmacies.

• [Chapter 11](#) details the contractual requirements for pharmacies to have an area for confidential consultations, with certain exceptions until 1 April 2023.

The regulatory changes on 15 February 2021 are:

• **NHS Discharge Medicines Service.** [Chapter 8](#) describes this new essential service. Community pharmacy will receive referrals from NHS trusts to support patients post discharge, along with information about medication changes made in hospital to improve outcomes, prevent harm and reduce readmissions.

The regulatory changes on 1 April 2021 are:

• [Chapter 12](#) details the requirement for distance selling contractors to have a website with an interactive page that promotes healthy lifestyles.
1. Background

The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the 2013 regulations) set out:

- the requirements for the publication of pharmaceutical needs assessments by health and wellbeing boards
- the maintenance of lists of contractors who provide pharmaceutical services or Local Pharmaceutical Services (LPS), namely pharmacies, dispensing appliance contractors and dispensing doctors
- how applications for inclusion in a pharmaceutical list maintained by NHS England are made and determined
- specific matters relating to the provision of services in rural areas
- the terms of service for those contractors who provide pharmaceutical services, including pharmacies and general practices that provide dispensing services
- other miscellaneous provisions.

Pharmacies included in a pharmaceutical list are required to provide essential services and participate in an acceptable system of clinical governance and healthy living. They may choose to provide one or more of the advanced services and NHS England may choose to commission enhanced services from them against identified patient need. Collectively these three tiers of service are known as the Community Pharmacy Contractual Framework (CPCF).


As a result of these changes to the CPCF, and as part of the response to the COVID-19 pandemic, amendments to the 2013 regulations were required.

This guidance sets out the changes, and the implications for contractors and their staff, and staff working in NHS England and NHS Improvement regional teams and the

Primary Care Support England (PCSE) market entry team. A glossary of the terms used which contractors and staff may find useful can be found in Chapter 18.

References to regulations and paragraphs in this document are to the 2013 regulations unless otherwise specified. This guidance is intended to complement the 2013 Regulations and should be read alongside them (and not in place of them).
2. Introduction

The terms of service for the provision of essential services and clinical governance are set out in Schedule 4 of the 2013 regulations and these have been amended to incorporate the nationally agreed changes to the CPCF. The amendments are set out in the NHS (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (the 2020 regulations) and this document provides information for pharmacy and dispensing appliance contractors. See Chapters 4 to 17.

The 2020 regulations also include measures that are part of the response to the COVID-19 pandemic and the related expansion of the national programme of immunisation against flu (see Chapter 9).

Pharmacies providing services under an LPS contract are included in the LPS lists maintained by NHS England and NHS Improvement, as opposed to one of the pharmaceutical lists. Their terms of service are set out in Schedule 7 of the 2013 regulations but may be expanded with the agreement of both the contractor and NHS England and NHS Improvement. Some of the changes agreed on for the CPCF also apply to contractors providing services under an LPS contract and further information on those can be found in Chapter 15. LPS contractors may wish to read Chapter 15 to familiarise themselves with the other changes in case:

- they wish to ask NHS England and NHS Improvement to include them in their LPS contract or
- NHS England and NHS Improvement wish to vary their LPS contract to include changes such as the provision of the Discharge Medicines Service (DMS) (see Chapter 8).

Changes have also been made to the terms of service for general practices that provide a dispensing service, to reflect the measures that are part of the response to the COVID-19 pandemic. Information on these can be found in Chapter 9.

Where a pharmacy or dispensing appliance contractor wishes to open new premises, relocate additional premises or buy existing premises, they are required to submit an application to NHS England and NHS Improvement. The process by which applications are submitted, processed and determined is known as ‘market entry’. Where an
application is granted, the applicant is required to notify NHS England and NHS Improvement of the date on which service provision will commence. The 2020 regulations set out a change to the timescale for submission of the ‘notice of commencement’ (see Chapter 17).

All contractors included in a pharmaceutical list are required to notify NHS England and NHS Improvement if they enter administration, and further information on when and how to do this can be found in Chapter 4.
3. Dates the regulatory changes come into force

The NHS (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 (the 2020 regulations) were laid before Parliament on 19 October 2020 with four coming into force dates – that is, the dates on which the amendments take effect and contractors are required to be compliant with them.

With effect from 1 January 2021 pharmacy contractors:

- will be required to be compliant with the changes to the system of clinical governance including the promotion of healthy living requirements
- are required to have a consultation room (with some exceptions).

With effect from 15 February 2021 pharmacy contractors are required to provide the NHS DMS.

With effect from 1 April 2021 pharmacy contractors operating distance selling premises are required to have a website on which there is an interactive page that promotes healthy lifestyles.

Pharmacy contractors, LPS contractors, dispensing appliance contractors and dispensing doctors are required to comply with all the other changes with effect from 9 November 2020.
4. Companies entering administration

4.1. Background

There may be instances where a company that is included in a pharmaceutical list or pharmaceutical lists held by NHS England and NHS Improvement enters administration. The company could be operating as a pharmacy or a dispensing appliance contractor.

Going into administration means that the company has entered a legal process set out in the Insolvency Act 1986 (the 1986 Act). An administrator, a licensed insolvency practitioner, is appointed by the directors of the company, a creditor or the court, and their purpose is to fulfil the administration process as described in the 1986 Act.

4.2. Telling NHS England and NHS Improvement

From 9 November 2020, if a company that is included in a pharmaceutical list or pharmaceutical lists held by NHS England and NHS Improvement enters administration, it must notify NHS England and NHS Improvement of that fact (regulation 67A).²

For the avoidance of doubt ‘enters administration’ is the date on which the appointment of an administrator takes effect.

A form has been developed for this purpose and can be found on the NHS England and NHS Improvement website.³ It is to be completed and submitted, as detailed on the form, on the date on which the appointment of the administrator takes effect.

Companies are required to submit separate forms for each of their premises that are included in a pharmaceutical list. It is not possible to include more than one set of premises on the form.

² Inserted by regulation 3, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
5. Pandemic treatment protocols

5.1. Introduction

This chapter is for pharmacy contractors only.

A pandemic treatment protocol (PTP) is defined in regulation 2\(^4\) as a protocol:

- relating to the supply of a prescription-only medicine to be used for the prevention of or as a treatment for a disease that is, or in anticipation of it being imminently, pandemic
- approved in accordance with regulation 247 of the Human Medicines Regulations 2012 (exemption for supply in the event or in anticipation of pandemic disease).

Similar to a patient group direction, a PTP provides a legal framework within which pharmacies and dispensing doctors may supply specified prescription-only medicines (as defined in the Human Medicines Regulations 2012) to a pre-defined group of patients in specified circumstances, without the patient first having to see a prescriber or a prescription being issued.

The protocol must:

- be approved by Ministers or NHS England and NHS Improvement
- specify how the medicinal product is to be used for the prevention or treatment of the disease
- contain requirements as to the recording of:
  - the name of the person who supplies the product to the person to be treated (the patient) or to a person acting on the patient’s behalf
  - evidence that the product was supplied to the patient or to a person acting on the patient’s behalf.

\(^4\) Inserted by regulation 2, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
Until such time as a PTP is issued contractors are not required to comply with those parts of their terms of service which solely apply to supply under a PTP. It is however recommended that they and their staff familiarise themselves with the provisions.

5.2. Supply in accordance with a pandemic treatment protocol

With effect from 9 November 2020:

- where a contractor receives via a secure service approved by NHS England and NHS Improvement an electronic message that amounts to an order for the supply of a drug in accordance with a PTP
- a person who is entitled to be supplied with that drug, or their representative, requests the provision of the drug

the contractor must, with reasonable promptness, provide the drug in line with the order (paragraph 5B(1), Schedule 4). NHS England and NHS Improvement will determine how orders are to be sent; examples of ‘a secure service’ include an email to the contractor’s premises-specific NHSmail account.

If the person or their representative asks when the drug will be dispensed and ready for collection, the contractor must provide them with an estimate of the time when the drug will be ready. If the drug is not ready by the appointed time, the contractor must give the person a revised estimate of the time, and continue to do so until the drug is ready for collection (paragraph 5B(2), Schedule 4).

5.3. Providing a drug under a pandemic treatment protocol

Paragraph 8, Schedule 4 sets out the requirements on contractors in relation to providing drugs or appliances ordered via a prescription, electronic prescription or a repeatable prescription. Paragraph 8(15), Schedule 4 requires contractors to provide drugs in a suitable container. It was previously amended to also include items supplied

5 Inserted by regulation 6, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
6 Inserted by regulation 6, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
under a serious shortage protocol\textsuperscript{7} and from 9 November 2020 further amended to include drugs supplied under a PTP.

Paragraph 8, Schedule 4 (providing ordered drugs or appliances) is amended so that the requirements set out in paragraphs 8(5) to (10), Schedule 4 apply to the provision of drugs under a PTP in the same way as they apply to the provision of a drug under a prescription or repeatable prescription or an associated batch issue (paragraph 8(17), Schedule 4).\textsuperscript{8} These requirements relate to pack size and:

- If the PTP is for a drug that is included in the Drug Tariff, the British National Formulary (including any appendix published as part of the formulary), the European Pharmacopoeia or the British Pharmaceutical Codex, the drug provided must comply with any relevant standard or formula specified therein.
- If the PTP does not prescribe the quality, strength or dosage, the responsible pharmacist may provide the drug in such strength and dosage that, in their professional skill, knowledge and care, they consider to be appropriate, and in such quantity as they consider to be appropriate for a course of treatment for a period not exceeding five days.

Where a contractor provides a drug under a PTP, they must include a dispensing label on the product's packaging. In addition to the information required or permitted by Part 2, Schedule 26 of the Human Medicines Regulations 2012, the label must include information to the effect that the product is being supplied in accordance with a PTP and identify the specific PTP (paragraph 8(18), Schedule 4).\textsuperscript{9}

\section*{5.4. Refusal to provide drugs in accordance with a pandemic treatment protocol}

With effect from 9 November 2020, contractors may refuse to provide a drug that is, or is purportedly, in accordance with a PTP where:

- it appears not to be a genuine order for the person requesting it or someone requesting it on their behalf

\textsuperscript{7} Amended by regulation 4(4)(d), the National Health Service (Amendments Relating to Serious Shortage Protocols) Regulations 2019/990
\textsuperscript{8} Inserted by regulation 7, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\textsuperscript{9} Inserted by regulation 7, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
• providing it would be contrary to the responsible pharmacist’s clinical judgement
• the contractor, their staff or other persons present at the pharmacy are subjected to, or threatened with, violence by the person who requests the provision of the drug or by a person accompanying them, or
• the person requesting the provision or any person accompanying them commits or threatens to commit a criminal offence (paragraph 9(5), Schedule 4).\textsuperscript{10}

In addition, a contractor must refuse to provide a drug that is, or is purportedly, in accordance with a PTP where they are not satisfied that it is in accordance with that PTP (paragraph 9(6), Schedule 4).\textsuperscript{11}

\textsuperscript{10} Inserted by regulation 8, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126

\textsuperscript{11} Inserted by regulation 8, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
6. Activities to be carried out in connection with the provision of dispensing services by pharmacy contractors

6.1. Refusal to provide drugs or appliances ordered via a prescription

Paragraph 9, Schedule 4 sets out specific instances where a contractor may refuse to provide drugs or appliances ordered via a prescription. These include:

- an error on the prescription
- the prescription is believed to have been forged
- the contractor, their staff or other people in the pharmacy are subjected to, or threatened with, violence by the person presenting the prescription or by any person accompanying them.

Paragraph 9(2A) was inserted with effect from 26 November 2018 and allows a contractor to refuse to provide a drug or appliance ordered on an electronic prescription where access to the Electronic Prescription Service (EPS) is such that the item cannot be dispensed promptly or at all.

It is further amended with effect from 9 November 2020 so that where a contractor is unable to access the EPS to dispense an item (either promptly or at all), they must take all reasonable steps to ensure that the item is supplied within a reasonable timescale. These steps may include:

12 Inserted by regulation 7(4), The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018/1114
• providing details of other pharmacies (including those providing services under an LPS contract) in the area that may be able to provide the prescribed item or items;
• urgent supply without a prescription in accordance with paragraph 6, Schedule 4, or
• contacting the prescriber and asking them for the urgent provision of a non-electronic prescription form (paragraph 9(2A), Schedule 4).

This provision applies only to electronic prescriptions. Contractors are advised to update their standard operating procedures (SOPs) accordingly and to ensure all staff are aware of this change.

Details of other pharmacies that may be able to provide the prescribed item or items can, if necessary, be sourced from the NHS website.

Contractors will also wish to note the new requirement to ensure that access to the EPS at their pharmacy premises must be constant and reliable throughout core and supplementary opening hours, as far as that is within their control.

6.2. Further activities to be carried out in connection with the dispensing of prescriptions

Paragraph 10, Schedule 4 lists further activities to be carried out when dispensing prescriptions and includes:

• providing appropriate advice to patients on the safe keeping of drugs or appliances and returning unwanted drugs to the pharmacy premises for safe destruction
• providing appropriate advice on the importance of only requesting those items listed on a repeatable prescription that are needed
• providing appropriate advice to enable the person to use the drugs or appliances appropriately and to meet their reasonable needs for general information about the dispensed drugs or appliances.

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13 Inserted by regulation 8, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
14 https://www.nhs.uk/service-search/find-a-pharmacy
A further required activity is the provision of a written note of any drug or appliance which is owed and advising when the owed item or items will be available. With effect from 9 November 2020, this written note may be in an electronic form (paragraph 10(1)(e), Schedule 4),\textsuperscript{15} eg via a text, email or an app used by the pharmacy.

Contractors are advised to update their SOPs accordingly and to ensure all staff are aware of this change.

Previously, contractors have been required to undertake appropriate training in respect of repeat dispensing, with further information on that training in the Drug Tariff. With effect from 9 November 2020, although paragraph 10(1), Schedule 4 has been amended to remove this requirement,\textsuperscript{16} contractors are still required to ensure their staff have undertaken appropriate training to dispense repeatable prescriptions by virtue of a change to the clinical governance requirements (see Chapter 10 for further information).

6.3. Additional requirements in relation to electronic prescribing

Additional requirements in relation to the EPS are set out in paragraph 11, Schedule 4. With effect from 9 November 2020, these requirements have been amended to reflect the fact that all contractors are required to ensure that access to the EPS is available at their pharmacy premises throughout the core and supplementary opening hours.

Where access to the EPS is temporarily unavailable at a contractor’s pharmacy premises, persons requesting the dispensing of an electronic prescription must be provided with the contact details of at least two other pharmacies in the area that can access the EPS, where this information is known to the pharmacy staff (paragraph 11(1), Schedule 4).\textsuperscript{17}

Where the issue only relates to the contractor’s pharmacy premises, and as all LPS pharmacies and pharmacies included in a pharmaceutical list are required to ensure the EPS can be accessed throughout their pharmacy premises’ opening hours, the

\textsuperscript{15} Amended by regulation 9, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126

\textsuperscript{16} Amended by regulation 9, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126

\textsuperscript{17} Amended by regulation 10, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
contractor will be able to identify other pharmacies in the area by searching the NHS website.\footnote{18}

Where there is a national issue with the EPS such that no pharmacies are able to access it, then the contractor would not be able to provide details of other pharmacies.

As access to the EPS is required throughout core and supplementary opening hours, paragraph 11(2), Schedule 4 has been amended\footnote{19} so that from 9 November 2020 all pharmacies included in a pharmaceutical list are required to set or amend patient’s nominations in that person’s Patient Demographics Service patient details.

Contractors are advised to update their SOPs accordingly and to ensure all staff are aware of this change.

\footnote{18}{https://www.nhs.uk/service-search/find-a-pharmacy}
\footnote{19}{Amended by regulation 10, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126}
7. Health campaigns

7.1. Introduction

One of the essential services that all pharmacies are required to provide is to participate, at NHS England and NHS Improvement’s request, in six campaigns to promote health messages to users of the pharmacy (paragraph 18, Schedule 4). The topics for these campaigns are chosen by NHS England and NHS Improvement.

In addition, where requested to do so by NHS England and NHS Improvement, each pharmacy must record the number of people to whom information is provided as part of one of these campaigns.

Two changes have been made to the requirements for this service.

7.2. Timing of health campaigns

Now referred to as ‘health campaigns’ rather than ‘public health campaigns’, from 9 November 2020 pharmacies will be required to participate in six campaigns per financial year (defined in regulation 2 as 1 April to 31 March) rather than per calendar year (paragraph 18(a), Schedule 4).

As the change occurs part way through 2020, and it had previously been agreed that the campaigns would be suspended in 2020/21 due to the COVID-19 pandemic, NHS England and NHS Improvement and PSNC have agreed that pharmacies will be required to participate in two campaigns between 9 November 2020 and 31 March 2021.

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20 Inserted by regulation 2, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
21 Amended by regulation 11, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
7.3. Provision of information to NHS England and NHS Improvement

In relation to health campaigns which take place on or after 9 November 2020 and in future years, pharmacies may be required to:

1. record the number of people to whom they have provided information as part of one of the health campaigns
2. provide NHS England and NHS Improvement with the number of people to whom information has been provided under a campaign in a specified electronic format
3. if NHS England and NHS Improvement have reasonably requested other information to be recorded, provide that additional information to NHS England and NHS Improvement (paragraph 18(c), Schedule 4) electronically.

The information recorded under (3) is to be provided in an anonymised form if to do otherwise would identify any person to whom information has been provided.

Both the format in which the information is to be provided and what, if any, additional information is to be provided and how it is to be provided will be confirmed by NHS England and NHS Improvement in advance of the campaign.

22 Amended by regulation 11, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
8. NHS Discharge Medicines Service

8.1. Introduction

Pharmacy contractors are required from 15 February 2021 to provide the NHS Discharge Medicines Service (DMS) as an essential service through the community pharmacy contractual framework. The requirements for the service can be found in paragraphs 22B and 22C, Schedule 4.23

This guidance supports pharmacy contractors in understanding and adhering to the 2013 regulations. It contains information on the context and aims of the NHS DMS, defines a referral, details the prerequisites and action required by pharmacy contractors at each stage of the service, and provides detail on the data collection required and payment processes.

For more detailed information and examples to support pharmacy contractors, as well as more information on the roles of NHS trusts and primary care networks (PCNs) in delivering an integrated and safer approach to medicines optimisation, please see the cross-sector NHS Discharge Medicines Service toolkit.

8.2. Context

Discharge from hospital is associated with an increased risk of avoidable medication related harm.24 NICE guideline NG0525 included the following recommendations:

a) medicines-related communication systems should be in place when patients move from one care setting to another

b) medicines reconciliation processes should be in place for all persons discharged from a hospital or another care setting back into primary care, and the act of

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23 Inserted by regulation 12, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
25 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes. Available at https://www.nice.org.uk/guidance/ng5
reconciling the medicines should happen within a week of the patient being discharged.

Implementation of these recommendations requires pharmacy professionals and their teams across NHS trusts, PCNs and community pharmacies to work together much more effectively.

Academic health science networks have been supporting NHS trusts to put in place communication and referral systems with the patient’s community pharmacy team at home, through their work on Transfers of Care Around Medicines (TCAM).\textsuperscript{26} This involves patients who have been identified as at risk from adverse effects or needing support with their medicines on discharge being referred via secure electronic message for advice and support to their usual community pharmacy. As the roll out of TCAM across England continues and more hospitals start to upgrade their IT systems or introduce electronic prescribing and medicines administration systems, it is expected more referrals to community pharmacies will be made.

NHS England and NHS Improvement have introduced the NHS DMS into community pharmacy to set out clearly the expectations of pharmacy contractors when receiving a discharge referral, including when they should involve PCN pharmacy teams and NHS trusts. This will form part of a suite of measures aimed at delivering a more integrated and safer approach to medicines through our Medicines Safety Improvement Programme.\textsuperscript{27}

\textbf{8.3. Aims}

The NHS DMS has been established to ensure better communication of changes to a patient’s medicines in hospital. Its aims are to:

- optimise the use of medicines, while facilitating shared decision-making
- reduce harm from medicines at transfers of care
- improve patients’ understanding of their medicines and how to take them following discharge from hospital
- reduce hospital readmissions

\textsuperscript{27} https://www.england.nhs.uk/patient-safety/national-medicines-safety-programme/
• support the development of effective team working across hospital, community and PCN pharmacy teams and general practice teams, and provide clarity about respective roles.

8.4. Prerequisites for service provision

The NHS DMS is an essential service and pharmacy contractors must therefore comply with the three following prerequisites detailed in this section.

8.4.1. Staff competency

Pharmacy contractors are already required to have appropriate training and staff development programmes to ensure all staff can undertake any role they are asked to perform (paragraph 28(2)(e)(ii), Schedule 4). Therefore, contractors must ensure that staff are competent to provide the NHS DMS through reading paragraphs 22B and C, Schedule 4, this guidance and the accompanying cross-system NHS Discharge Medicines Service toolkit. It is strongly recommended that all pharmacists and pharmacy technicians delivering this service complete the CPPE NHS Discharge Medicines Service training to reinforce their knowledge. Where there is any doubt that staff are competent to provide the NHS DMS, pharmacy contractors should arrange further staff training in readiness for service commencement on 15 February 2021.

Pharmacists and pharmacy technicians involved in providing the service must also demonstrate to the pharmacy contractor that they have the necessary knowledge and skills by completing the NHS DMS Declaration of Competence (paragraph 28(2)(e)(iv), Schedule 4).28

8.4.2. Premises requirements

Paragraph 28A, Schedule 429 details the premises’ requirements in respect of consultation rooms for pharmacy contractors. As a prerequisite to the provision of the NHS DMS, all pharmacy contractors must ensure that they are compliant with these premises’ requirements, in particular ensuring that the duty of confidentiality is met (paragraph 22C(5)(a), Schedule 4). Further information is provided in Chapter 11 on premises’ requirements in respect of consultation rooms.

28 Amended by regulation 14, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
29 Inserted by regulation 15, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
8.4.3. Standard operating procedure

As part of their risk management programme, pharmacy contractors must have appropriate SOPs in place (paragraph 28(2)(c)(v), Schedule 4). From 15 February 2021, pharmacy contractors are also required to have a SOP for provision of the NHS DMS. All members of the pharmacy team involved in the provision of this service must ensure they are familiar with and adhere to the SOP. As part of this service SOP, the contractor must have procedures in place to check for new referrals via the premises-specific NHS mail account at appropriate intervals throughout each day the pharmacy is open (paragraph 22C(1), Schedule 4). The SOP must also include details of how issues and discrepancies in information about medicines will be communicated to the relevant general practice or NHS trust, where appropriate (paragraphs 22C(2)(d) and 22C(4)(b), Schedule 4).

8.5. Referrals to the NHS Discharge Medicines Service

NHS trusts will determine, using the cross-system NHS Discharge Medicines Service Toolkit as a guide (and engaging with community pharmacy and primary care networks), when a patient needs the NHS DMS and will then instigate a referral. This may be when a patient is discharged from hospital or when they are being transferred to another provider of NHS services (paragraphs 22B(a) and (b), Schedule 4). The NHS trust will also seek the patient’s consent for provision of the NHS DMS.

Paragraph 22C(1), Schedule 4 states that an NHS referral must be in the form and manner approved for the purpose of the NHS DMS. To fulfil their requirements under the NHS DMS, pharmacy contractors must consider any communication in the following form and manner as constituting a referral: “Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient’s discharge to usual primary care services and their medicines regimen”.

It is a contractual requirement that referrals received in this way are acted on as described below. Action may be taken against a contractor for not taking the required action when a referral is received.

Amended by regulation 14, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
The essential minimum dataset which should be transferred to community pharmacy by an NHS trust with a referral at discharge is detailed in Box 8.1.

**Box 8.1: Minimum dataset to be transferred with a referral to community pharmacy**

- Demographic and contact details of the person and their registered general practice (including their NHS number and their hospital medical record number).
- The medicines being used by the patient at discharge (including prescribed, over-the-counter and specialist medicines, as there may be medicines interactions), including the name, strength, form, dose, timing, frequency and planned duration of treatment for all, and the reason for prescribing.
- How the medicines are taken and what they are being taken for.
- Changes to medicines, including medicines started or stopped, or dosage, and reason for the change.
- Contact details for the referring clinician or hospital department, to use where the pharmacy has a query.
- Ideally, the referral should also contain the hospital’s Organisation Data Service (ODS) code.

On receipt of a referral, the contractor must then provide the NHS DMS to the patient who has been referred for advice, assistance and support with their medication regimen (paragraphs 22B(a) and (b), Schedule 4).

### 8.6. Providing the NHS Discharge Medicines Service

It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the accompanying NHS Discharge Medicines Service toolkit) could happen at any stage in the process.

In accordance with paragraph 22C, Schedule 4, pharmacy contractors must, in a timely manner, record on the patient’s medication record or other appropriate record, all relevant information relating to their provision of the service. This information can then be shared with other healthcare professions where appropriate for clinical care.
The following sections set out the requirements of the three stages of the service. They detail the actions required of pharmacy contractors to complete each stage and ensure compliance with the terms of service.

8.7. Stage 1

Pharmacy contractors must provide stage 1 of the NHS DMS (as detailed in paragraph 22C(2), Schedule 4) within 72 hours of receipt of a referral (excluding hours of days on which the pharmacy premises are not open for business). Box 8.2 provides some examples of how the timescales for providing stage 1 of the service are to be calculated.

**Box 8.2: Calculating the 72-hour period**

1. The opening hours for pharmacy A are:
   - Monday to Friday – 09:00-13:00 and 14:00-18:00
   - Saturday – closed
   - Sunday – closed.

   An NHS DMS referral is received at 17:00 on Friday 30 October. As the pharmacy is not open on Saturdays and Sundays, the contractor must complete stage 1 of the service as soon as possible and no later than 17:00 on Wednesday 4 November.

2. The opening hours for pharmacy B are:
   - Monday to Friday – 08:30-12:00 and 15:00-18:30
   - Saturday – 09:00-13:00
   - Sunday – closed.

   An NHS DMS referral is received at 17:00 on Friday 30 October. As the pharmacy is not open on Sundays, the contractor must complete stage 1 of the service as soon as possible and no later than 17:00 on Tuesday 3 November.

3. The opening hours for pharmacy C are:
   - Monday – 08:00-23:00
   - Tuesday to Friday – 07:00-23:00
Guidance on the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020

• Saturday – 07:00-22:00
• Sunday – 10:00-16:00.

An NHS DMS referral is received at 17:00 on Friday 30 October. As the contractor is open every day of the week, they must complete stage 1 of the service as soon as possible and no later than 17:00 on Monday 2 November.

As pharmacies are not required to open on Christmas Day, Good Friday, Easter Sunday and bank holidays, those days are not included when calculating the 72-hour period, unless the pharmacy is directed or chooses to open. Box 8.3 shows how the 72-hour period is to be calculated in these situations.

Box 8.3: Calculating the 72 hour period on public and bank holidays and Easter Sunday

1. The opening hours for pharmacy A are:
   • Monday to Friday – 09:00-13:00 and 14:00-18:00
   • Saturday – closed
   • Sunday – closed.

Monday 28 December is a bank holiday in lieu of Saturday 26 December and the pharmacy has chosen not to open on that day.

An NHS DMS referral is received at 09:00 on Thursday 24 December. As the pharmacy is closed on Friday (Christmas Day), Saturday and Sunday (as usual) and Monday (bank holiday), the contractor must complete stage 1 of the service as soon as possible and no later than 09:00 on Thursday 31 December.

2. The opening hours for pharmacy B are:
   • Monday to Friday - 08:30-12:00 and 15:00-18:30
   • Saturday – 09:00-13:00
   • Sunday – closed.

Monday 28 December is a bank holiday in lieu of Saturday 26 December and the pharmacy has chosen to open between 09:00 and 13:00 on that day.
An NHS DMS referral is received at 09:00 on Thursday 24 December. As the pharmacy is closed on Friday (Christmas Day) and Sunday (as usual), the contractor must complete stage 1 of the service as soon as possible and no later than 09:00 on Tuesday 29 December.

3. The opening hours for pharmacy C are:

- Monday to Friday – 09:00-17:00
- Saturday – 09:00-13:00
- Sunday – closed.

Monday 28 December is a bank holiday in lieu of Saturday 26 December and the pharmacy has chosen not to open on that day. NHS England and NHS Improvement have directed the pharmacy to open for two hours on Friday 25 December.

An NHS DMS referral is received at 09:00 on Thursday 24 December. As the pharmacy is closed on Sunday (as usual) and Monday (bank holiday), the contractor must complete stage 1 of the service as soon as possible and no later than 09:00 on Tuesday 29 December.

Where a pharmacy is closed for the day due to a temporary suspension in the provision of pharmaceutical services at those premises for reasons that are beyond the contractor’s control (in line with paragraph 23(10), Schedule 4), then that day is not included within the 72-hour period.

However, if the reason for the closure is within the control of the contractor, then the 72-hour period would include the day that the pharmacy closed in breach of the terms of service.

If a contractor closed their premises without good cause and failed to complete stage 1 of the service within 72 hours, then it is not possible to issue a breach notice in respect of a failure to comply with both terms of service. A breach notice could only be issued, having first undertaken local dispute resolution, in relation to a breach of one of the terms of service.

Table 8.1 sets out the actions required of pharmacy contractors when providing stage 1 of the NHS DMS (paragraph 22C(2), Schedule 4).
Table 8.1: Actions required of pharmacy contractors when providing Stage 1 of the NHS Discharge Medicines Service

<table>
<thead>
<tr>
<th>Actions</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>The electronic referral is received by the pharmacy and the following actions are undertaken:</td>
<td></td>
</tr>
<tr>
<td>a) Check for clinical information and actions contained in the referral which need to be undertaken. Details of what to look for are outlined in the toolkit which accompanies this service guidance.</td>
<td>Pharmacist</td>
</tr>
<tr>
<td>b) Compare the medicines the patient has been discharged on with those they were taking at admission. This should include all medicines and not just those that are taken orally. This will include reference to the patient’s medication record and may include reference to the patient’s summary care record (SCR).</td>
<td>Pharmacist/ pharmacy technician</td>
</tr>
<tr>
<td>c) Where necessary, discuss any changes that may be appropriate or raise any issues of concern identified with the NHS trust or the patient’s general practice, as appropriate.</td>
<td>Pharmacist/ pharmacy technician</td>
</tr>
<tr>
<td>d) Ensure an appropriate record is kept which alerts pharmacy staff to conduct stages 2 and 3 of the service when the first prescription is received or at first contact with the patient/carer.</td>
<td>Pharmacist/ pharmacy technician</td>
</tr>
<tr>
<td>e) Check any previously ordered prescriptions for the patient in the dispensing process or awaiting collection to see if they are still appropriate. Particular attention should be paid to electronic repeatable prescriptions as these could be pulled down from the system sometime after the patient has been discharged from hospital.</td>
<td>All relevant members of the pharmacy team</td>
</tr>
</tbody>
</table>

8.8. Stage 2

Once the first prescription is received by the contractor following the patient’s discharge (which may or may not be a repeatable prescription), they must provide stage 2 of the NHS DMS as detailed within paragraph 22C(4), Schedule 4.

Table 8.2 sets out the actions required of pharmacy contractors when providing stage 2 of the NHS DMS.
Table 8.2: Actions required of pharmacy contractors when providing stage 2 of the NHS Discharge Medicines Service

<table>
<thead>
<tr>
<th>Actions</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) The pharmacist/pharmacy technician ensures medicines prescribed post discharge take account of the appropriate changes made during the hospital admission.</td>
<td>Pharmacist/pharmacy technician</td>
</tr>
<tr>
<td>b) If there are discrepancies or other issues of concern, these are to be raised with the general practice, using existing communication channels. Complex issues may need to be resolved by the general practice undertaking a Structured Medication Review.</td>
<td></td>
</tr>
<tr>
<td>c) Ensure an appropriate record is kept which alerts pharmacy staff to conduct stage 3 of the service.</td>
<td></td>
</tr>
</tbody>
</table>

8.9. Stage 3

Completing stage 3 of the DMS requires the pharmacist or pharmacy technician to undertake a discussion (taking a shared decision-making approach) with the patient to ensure they understand their medicines regimen, including any changes made while being treated by the NHS trust (paragraph 22C(5), Schedule 4). Normally this would occur when the first post-discharge prescription is received – this is usually one week to one month post discharge, dependent on the quantity of medicines supplied by the hospital at discharge.

Note that when providing the NHS DMS and engaging with a patient (or their carer), pharmacy contractors must ensure that appropriate safeguarding procedures are in place for service users (paragraph 28(2)(c)(viii), Schedule 4).

Table 8.3 sets out the actions required of pharmacy contractors when providing stage 3 of the NHS DMS.
**Table 8.3: Actions required of pharmacy contractors when providing stage 3 of the NHS Discharge Medicines Service**

<table>
<thead>
<tr>
<th>Actions</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) This will involve a confidential discussion, adopting a shared decision-making approach, with the patient and/or their carer to check their understanding of what medicines they should now be taking/using, when they should be taken/used and any other relevant advice to support medicines taking/use.</td>
<td>Pharmacist/pharmacy technician</td>
</tr>
<tr>
<td>b) Where the patient and/or their carer cannot attend the pharmacy for this discussion, eg if they are housebound or convalescing following surgery, this support and advice can be provided in a manner which meets the patient's/carer's needs, eg by telephone or video consultation (see Chapter 13 for further information on the requirement for facilitating remote access to pharmaceutical services).</td>
<td></td>
</tr>
<tr>
<td>c) Information that would be of value to the general practice/PCN clinical pharmacist to support the ongoing care of the patient should be communicated appropriately.</td>
<td></td>
</tr>
<tr>
<td>d) For those patients in a private household or residential care home, there should also be an offer to dispose of any medicines that are no longer required, to avoid potential confusion and prevent an adverse event (paragraphs 13 and 14, Schedule 4).</td>
<td></td>
</tr>
<tr>
<td>e) Where appropriate, other services which form part of the CPCF can also be provided. The New Medicine Service could be offered if clinically appropriate and if the patient would get additional benefit from provision of the service.</td>
<td></td>
</tr>
</tbody>
</table>

**8.10. Situations where not all stages of the NHS Discharge Medicines Service can be provided**

The process described in the above three sections represents the normal flow of patients through the service. However, on occasions this will not be the case and there are circumstances where the contractor is not to or to cease to provide the service (paragraph 22C(6), Schedule 4). Box 8.4 details some of these circumstances.
Box 8.4: Instances where normal flow of patients through the service may not be appropriate

1. A referral is received for a new patient: Where a referral is received for a patient who is new or unknown to the pharmacy, the pharmacy contractor may then need to contact the NHS trust and/or the patient for more information and also to check that the patient wishes to continue to use this pharmacy for the service.

2. Patient uncontactable or withdraws consent following completion of stage 1: Where stage 1 of the service has been delivered but the patient withdraws consent to receive the service, or the first prescription post discharge is not received by the pharmacy contractor to complete stage 2 of the service and no contact is made by the patient, the pharmacy contractor must make reasonable attempts to contact the patient using the contact details set out in the referral. In this scenario, it is possible that the patient has been readmitted to hospital, admitted to a care home or has died. Where the pharmacy contractor is unable to reach the patient (or the patient has been readmitted to hospital or admitted to a care home), they should share any findings of concern from stage 1 of the service with the patient’s general practice.

3. Patient uncontactable or withdraws consent following completion of stage 1 and stage 2: Where stage 1 and stage 2 of the service is provided by the pharmacy contractor but they are unable to contact the patient to complete stage 3 of the service, reasonable attempts must be made by the pharmacy contractor to contact the patient using the contact details set out in the referral. In this scenario, it is possible that the prescription may have been collected by the patient or a representative and: the patient either was unable to discuss their medicines at the point of collection; or the patient/carer does not attend an agreed consultation; or the patient/carer refuses to take calls from the pharmacy contractor; or that the patient/carer states that they do not wish to engage with a consultation about their medicines. Where the community pharmacy is unable reach the patient or the patient withdraws consent to receive the service at this point, the pharmacy contractor should share any findings of concern from stage 1 and stage 2 of the service with the patient’s general practice.

4. Patient moves community pharmacy after stage 1 of the service has been provided: The situation may occur where stage 1 of the service has been delivered by a pharmacy contractor and that pharmacy contractor subsequently finds out that the patient wishes to use a different pharmacy contractor for the provision of the service. The first pharmacy contractor should contact the second pharmacy contractor and offer to send them, via a secure electronic message (eg to the pharmacy contractor’s premises-specific NHSmail account) and with the patient’s consent, the referral information received from the NHS trust and any relevant
information and/or findings identified during stage 1 of the service. The same approach could be taken if another pharmacy contractor contacts the first pharmacy contractor to inform them that the patient has asked them to dispense the first prescription post discharge.

5. Temporary community pharmacy closure means that the complete service cannot be provided: Where a temporary community pharmacy closure of one week or more means that a pharmacy contractor cannot provide the service, reasonable attempts must be made by the pharmacy contractor to contact the patient using the contact details set out in the referral. The pharmacy contractor should inform the patient of the situation and identify another pharmacy contractor to refer the patient to for completion of the service. In these circumstances, the pharmacy contractor should contact the identified pharmacy contractor and offer to share, via secure electronic message (e.g., to the pharmacy contractor’s premises-specific NHSmail account) and with the patient’s consent, the referral information received from the NHS trust and any relevant information and/or findings identified during stage 1 or stage 2 of the service if already provided.

8.11. Record keeping, reporting and monitoring

For each NHS DMS provision, pharmacy contractors will be required to report a standard dataset through the NHS Business Services Authority (NHSBSA) ‘Manage your Service’ (MYS) portal. Pharmacy contractors will be required to submit this data monthly for payment, service evaluation and monitoring purposes.

Information on the content of this essential dataset is in the Discharge Medicines Service data specification.

NHS England and NHS Improvement will conduct an evaluation to ensure service effectiveness. If additional information is required from contractors to support this evaluation, the data and evaluation periods will be agreed nationally with PSNC and communicated to contractors when any submission is required.

8.12. Payment

Information regarding payment for providing the NHS DMS can be found in Part VIA of the Drug Tariff (Payment for Essential Services (Pharmacy Contractors)).

9. Flexible provision of relevant immunisation services during a pandemic by pharmacy contractors

9.1. Introduction

Contractors are required to open for 40 core opening hours per week and the days and times of these hours are initially chosen by the contractor as part of their application for inclusion in the relevant pharmaceutical list. There are three exceptions to the requirement to be open for 40 core hours:

- 100 hour pharmacies are required to be open for 100 core opening hours per week
- pharmacies may have fewer than 40 core opening hours where NHS England and NHS Improvement (or a preceding organisation) have issued a direction to this affect
- where a contractor undertook to open for more than 40 core opening hours per week as part of their application for inclusion in a pharmaceutical list and the application was partly granted on the basis of that undertaking.

Contractors may choose to open for longer and these opening hours are referred to as supplementary opening hours. Throughout their core and supplementary opening hours, contractors must provide all essential services, any advanced services that they have chosen to provide and any enhanced services commissioned from them by NHS England and NHS Improvement.

Where a contractor wishes to change their core opening hours, they must first apply to NHS England and NHS Improvement (paragraph 26, Schedule 4) and cannot implement the change unless and until that application is granted and may take effect. Where they wish to change their supplementary opening hours, they must notify NHS
England and NHS Improvement of the change, giving at least three months’ notice (paragraph 23(7), Schedule 4).

9.2. Flexible provision of relevant immunisation services only

As contractors are required to, as a minimum, provide all essential services throughout their core and supplementary opening hours, it would not be possible for a pharmacy to remain open and just provide one specific service or a limited range of services. However, with effect from 9 November 2020, a new provision has been inserted into the 2013 regulations which allows a contractor, in specified circumstances, to limit the range of pharmaceutical services provided to ‘relevant immunisation services’ for a specified period of time only (paragraph 27B, Schedule 4).32

‘Relevant immunisation services’ are defined within paragraph 27B(3), Schedule 4 as either advanced or enhanced services33 (referred to in the paragraph as ‘directed services’) that provide for the administration of a medicinal product for vaccination or immunisation against coronavirus (as defined in section 1(1) of the Coronavirus Act 2020) or influenza virus. Administration of such a product is to be in accordance with:

- a patient group direction that meets the conditions of regulation 233 of the Human Medicines Regulations 2012 (exemption for supply, etc under a patient group direction by a person conducting a retail pharmacy business) or
- a protocol that meets the conditions of regulation 247A of the Human Medicines Regulations 2012 (protocols relating to coronavirus and influenza vaccinations and immunisations (paragraph 27B(3), Schedule 4).

Where a pharmacy is only open to provide relevant immunisation services, no other pharmaceutical services should be provided, although the pharmacy can continue to provide any private services such as the sale of OTC medicines.

9.3. Process

After the Secretary of State identifies that a serious, or potentially serious, risk to human health arises as a consequence of a disease being, or in anticipation of a disease being

32 Inserted by regulation 13, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
33 Enhanced services may only be commissioned by NHS England and NHS Improvement. This provision therefore does not relate to any immunisation services commissioned by local authorities or CCGs.
imminently, pandemic there are two processes by which a contractor may limit the pharmaceutical services they provide to relevant immunisation services only.

Contractor initiated:

1. Where a contractor wishes to limit the pharmaceutical services provided at their pharmacy premises to relevant immunisation services only, they complete the notification form on the NHS England and NHS Improvement website and submit it in line with the advice on the form.

2. NHS England and NHS Improvement consider the contractor’s notification and either agree to it or do not. They advise the contractor accordingly.

3. The contractor may limit the pharmaceutical services provided in line with the notification from the point it is approved by NHS England and NHS Improvement.

NHS England and NHS Improvement initiated:

1. NHS England and NHS Improvement make an announcement that there are particular arrangements relating to the flexible provision of relevant immunisation services that they are prepared to agree to.

2. Where a contractor wishes to limit the pharmaceutical services provided at their pharmacy premises to relevant immunisation services only, in accordance with the particular arrangements detailed in the NHS England and NHS Improvement announcement, they complete the notification form on the NHS England and NHS Improvement website and submit it in line with the advice on the form.

3. NHS England and NHS Improvement consider the contractor’s notification and either agree to it or do not. They advise the contractor accordingly.

4. The contractor may limit the pharmaceutical services provided in line with the notification from the point it is submitted to NHS England and NHS Improvement.


5. Where NHS England and NHS Improvement do not agree, the contractor must resume the full provision of pharmaceutical services with effect from the date on which NHS England and NHS Improvement notify them of their decision.

There are no rights of appeal against a decision by NHS England and NHS Improvement not to agree to a contractor limiting service provision to relevant immunisation services.

A separate notification form must be completed for each set of pharmacy premises at which the contractor wishes to flexibly provide relevant immunisation services.

Part 2 of the notification form makes provision for a change of supplementary opening hours where a contractor wishes, eg to stay open for longer to solely provide relevant immunisation services. While changes to supplementary opening hours usually require at least three months’ notice, paragraph 23(7), Schedule 4 does allow NHS England and NHS Improvement to agree to a shorter notice period. Where a contractor notifies a change of supplementary opening hours to stay open for longer and provide relevant immunisation services, NHS England and NHS Improvement will agree to a shorter notice period and this will be confirmed to the contractor.

9.4. Effect of only providing relevant immunisation services and updating profiles

From 9 November 2020, contractors are required to keep their NHS website and NHS 111 Directory of Services (DoS) profiles up to date. Further information on this requirement can be found in Chapter 12.

Where a contractor will be staying open for longer to solely provide relevant immunisation services, these supplementary opening hours are not to be added to the pharmacy’s profile on the NHS website. This is to avoid patients or their representatives visiting the pharmacy to have a prescription dispensed, to collect an item that has already been dispensed or to access another service. Similarly these supplementary opening hours are not to be added to the pharmacy’s DoS profile so as to avoid referrals under the Community Pharmacist Consultation Service (CPCS).

Where a contractor will only be providing relevant immunisation services during part of their usual core or supplementary opening hours, they must update their opening hours on both their NHS website and DoS profiles so that they show as closed at those times.
While the pharmacy can still be nominated for EPS purposes, showing the pharmacy as closed will reduce the number of people attending the pharmacy having first viewed its profile on the NHS website to have a prescription dispensed, for example. It will also ensure that no referrals are made to the pharmacy under the CPCS during the period the pharmacy is only providing relevant immunisation services.

9.5. Coronavirus and influenza vaccinations and immunisations

The NHS (Charges for Drugs and Appliances) Regulations 2015 set out the charges that are payable for the supply of drugs and appliances on behalf of the NHS in England.

With effect from 9 November 2020, they were amended to ensure that all coronavirus and influenza vaccinations or immunisations supplied and administered by contractors (and other NHS providers) to patients in a nationally identified at-risk group are to be supplied free of charge (regulation 13B of the NHS (Charges for Drugs and Appliances) Regulations 2015). This means that patients in at-risk groups eligible for NHS vaccination will not need to pay a prescription charge for either influenza or coronavirus vaccinations.

36 https://www.legislation.gov.uk/uksi/2015/570/contents
37 Inserted by regulation 29, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
10. Clinical governance and the promotion of healthy living

10.1. Introduction

As part of the Community Pharmacy Contractual Framework 2019-2024 it was agreed that the attainment of:

- Safeguarding Level 2 for all pharmacy professional in the last two years; and
- Healthy Living Pharmacy (HLP) Level 1 status

would be an essential requirement for all pharmacies in England. In order to demonstrate this, pharmacy contractors must be compliant with the amended 2013 regulations, in which the system of clinical governance has been expanded to include the promotion of healthy living (paragraph 28, Schedule 4\footnote{38}).

Pharmacy contractors must ensure they are compliant with the requirements relating to paragraph 28, Schedule 4 from 1 January 2021\footnote{39}. For Safeguarding this would mean having the evidence available to demonstrate that all pharmacy professionals have attained level 2 Safeguarding in the last two years.

The requirements detailed below should be read by all pharmacy contractors and staff, whether they are just embarking on implementing the new requirements or are refreshing their offer in light of the essential requirement.

The process of self-assessment used to demonstrate contractor compliance will remain in place. Contractors, particularly those that have not previously met the Public Health England (PHE) HLP level 1 criteria, may wish to use the assessment of compliance for the promotion of healthy living template to ensure they are fully compliant with the

\footnote{38} Amended by regulation 14, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\footnote{39} To note, distance selling premises have until 1 April 2021 to comply with new website requirements.
requirements set out in this document and have evidence of meeting these requirements if this is requested by NHS England and NHS Improvement.

10.2. Context

The emergence of HLPs marked a significant development for community pharmacy and its contribution to health promoting interventions. The HLP framework aims to improve people’s health and help reduce health inequalities, and ensures community pharmacy can continue to contribute to the government’s ambition of putting prevention at the heart of the NHS, as required by the NHS Long Term Plan. It provides a mechanism for community pharmacy teams to utilise their local insight and experience in the delivery of high-quality health promoting initiatives. By requiring contractors to have trained health champions on site who proactively engage in local community outreach within and outside the pharmacy, HLPs have cemented the idea that every interaction in the pharmacy and the community is an opportunity for a health promoting intervention.

The HLP framework is primarily about adopting a change in culture and ethos within the whole pharmacy team. The HLP framework means community pharmacies can supplement their medicines optimisation role with an enhanced commitment to health promoting interventions in the pharmacy setting and engagement in community outreach activities.

The HLP framework is underpinned by three enablers:

1. **Workforce development**: A skilled team to proactively support and promote behaviour change and improve health and wellbeing, including a qualified health champion who has undertaken the Royal Society for Public Health (RSPH) level 2 award ‘Understanding Health Improvement’, and a pharmacist or manager who has undertaken leadership training.

2. **Engagement**: Local stakeholder engagement with other health and care professionals, community services, local authorities and members of the public.

3. **Environment (premises requirements)**: Premises that facilitate health promoting interventions with a dedicated health promotion zone.
10.3. HLP development: 2009 to 2019

The HLP framework was first developed in 2009. PHE has provided strategic leadership for the development, acceleration and implementation of the HLP programme. In 2016, PHE moved from a commissioner-led to a profession-led, self-assessment process for the attainment of HLP level 1 status, which included the development of the PHE quality criteria. The PHE quality criteria underpinned the HLP enablers and set out the criteria that community pharmacies needed to meet to attain HLP level 1 status.

Following this, NHS England introduced the achievement of HLP level 1 status, as set out in the PHE quality criteria, as a criterion for payment under the Pharmacy Quality Scheme (previously known as the Quality Payments Scheme) for 2017/18.

Collectively, these initiatives introduced greater consistency in the delivery of public health interventions and saw the number of HLPs rise to over 9,500 in 2019. PHE research published in 2016 showed the impact of HLPs in communities, which is summarised in Figure 10.1.

Figure 10.1: Impact of HLPs infographic

42 PHE (2016) Healthy Living Pharmacy Infographic Slides. Available at: https://app.box.com/s/ocbzg4ky8y6457ry1xhxwdq7g1ecqf1
10.4. Requirements for the promotion of healthy living and how to meet them

Amendments to paragraph 28, Schedule 4 introduce requirements for the promotion of healthy living, which pharmacy contractors must be compliant with from 1 January 2021.\(^{43}\) Pharmacies will no longer be required to comply with the PHE quality. This has been superseded by the amendments to the terms of service.\(^{44}\) It is important to note however that the PHE quality criteria have informed the development of the updated requirements.

The requirements for the promotion of healthy living in the terms of service are detailed in the following sections. After reading these requirements, contractors should work with members of their team to develop an action plan for how they will achieve each of the requirements and demonstrate compliance to NHS England and NHS Improvement.

\(^{43}\) Amended by regulation 14, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\(^{44}\) PHE will continue to use the PHE HLP Quality Criteria as the basis for commissioning public health service delivery through community pharmacy.
PSNC resources\(^{45}\) are also available to support staff to comply with the legislative changes.

### 10.5. Achieving the essential requirements

The below guidance is split into three sections on workforce development, engagement and premises requirements.

The requirements apply to all pharmacies, including distance selling premises (DSPs), except where specifically noted that different requirements apply to DSPs.\(^ {46}\)

#### 10.5.1. Workforce development

Paragraph 28(2)(e)(ii), Schedule 4 states that pharmacy contractors must have appropriate training and staff development programmes to ensure all staff can undertake any role they are asked to perform. With regards to the promotion of healthy living, this section outlines the requirements for contractors to support the development of staff so they are well equipped to understand public health needs, spread a health and wellbeing ethos, demonstrate team leadership and can communicate appropriate health and wellbeing information to patients and the public.

##### 10.5.1.1. Public health needs

All patient-facing pharmacy staff should have an **awareness of the public health and pharmaceutical needs of the population they serve**. Pharmacy contractors must therefore:

- Consider the ways in which they engage with their local community, so they can seek to meet the needs of the local area and help address health inequalities, including by targeting deprived communities. This may include the use of virtual and digital communication, as well as provision of face-to-face public health promoting interventions.
- **DSPs** will provide services to patients in a wider geographical area than that of most other pharmacies, so they will need to reflect on the broad health needs of their patients wherever they may live, rather than those living in a specific local

\(^{45}\) [https://psnc.org.uk/services-commissioning/essential-services/healthy-living-pharmacies/](https://psnc.org.uk/services-commissioning/essential-services/healthy-living-pharmacies/)

\(^{46}\) To note, content in the section of the document has been informed by, and in some cases taken directly from, the PHE ‘Healthy Living Pharmacy Level 1 Quality Criteria’ (2016).
area, eg by seeking information on the health profile of their patients when undertaking patient experience surveys or similar.

**Box 10.1: Suggested evidence for public health needs**

- List of the website links to the Joint Strategic Needs Assessment (JSNA), Pharmaceutical Needs Assessment (PNA) and/or health profiles for their area or correspondence about them or evidence of attendance at seminars or meetings on them.
- Copies of the relevant extracts of the JSNA, PNA and/or health profiles for their area as digital files or printed files (as these may be very bulky documents, printing the front page or web page is acceptable).
- List of pharmacy events in the local area or local/national campaigns showing direct links to the local public health and pharmaceutical needs.
- Questions linked to health and wellbeing services have been included in the contractor’s activities to assess patients’ and the public’s experience of their services.

**10.5.1.2. Health and wellbeing ethos**

All patient-facing pharmacy staff should **understand the basic principles of health and wellbeing**, and that every interaction is an opportunity for a health promoting intervention.

Pharmacy contractors must ensure that:

- They have at least one member of the patient-facing pharmacy staff (one full time equivalent) who has completed the training and assessment of the RSPH level 2 award ‘Understanding Health Improvement’ and is therefore a qualified health champion. Health champion training and assessment may be undertaken through face-to-face or virtual (online) methods.
- Where a pharmacy has less than one full time equivalent patient-facing staff member, excluding the responsible pharmacist, at least one staff member should complete the training and assessment.
- Where a health champion leaves the employment of the contractor and this means no trained health champion is in post, the contractor must put in place an action plan to recruit or train a staff member as a health champion as soon
as possible and within six months at the latest of the previous staff member leaving.

**Box 10.2: Suggested evidence for health and wellbeing ethos**

- Certificate(s) for the RSPH level 2 award 'Understanding Health Improvement' by any pharmacy team members either displayed in the pharmacy or in the evidence portfolio.
- Certificate(s) of any health and wellbeing training completed by any pharmacy team members either displayed in the pharmacy or in the evidence portfolio.
- Minutes of pharmacy team meetings that show shared learning from the health champion(s) to the rest of the pharmacy team.
- 'Making Every Contact Count’ training records for all staff who provide health advice to patients and the public.

### 10.5.1.3. Team leadership

Contractors should have an appointed **health and wellbeing leader** from the pharmacy team who has undergone leadership training, internally or through an organisation, that maps to/encompasses the following domains:

- inspiring a shared purpose
- sharing the vision
- engaging the team
- developing capability
- influencing for results.

Leadership training and assessment may be undertaken through face-to-face or virtual (online) methods.

Where a health and wellbeing leader leaves the employment of the contractor and this means no trained health and wellbeing leader is in post, the contractor must put in place an action plan to recruit or train a staff member as a health and wellbeing leader as soon as possible and within six months at the latest of the previous staff member leaving.
Box 10.3: Suggested evidence for team leadership

- Certificate(s) or registration for any leadership training or equivalent completed by a pharmacist or the pharmacy manager either displayed in the pharmacy or in the evidence portfolio.
- An HLP action plan developed by either the pharmacy team leader, the pharmacy team or health champion in the evidence portfolio.
- Written feedback from pharmacy team members on their team leader in the evidence portfolio.

10.5.1.5. Communication

Since April 2005, contractors have been required to provide health advice to users of their pharmacy in a number of circumstances:

- Where a person requests the dispensing of a prescription and they appear to have diabetes, be at risk of coronary heart disease, smokes or is overweight, the contractor must provide advice to increase the person’s knowledge and understanding of the health issues that are relevant to them (paragraph 17, Schedule 4).
- Under paragraph 18, Schedule 4 contractors are required to participate in six health campaigns per year (see Chapter 7 for details of changes to this term of service) to promote health messages to users of the pharmacy.
- Paragraph 22, Schedule 4 requires contractors to provide advice on lifestyle changes to help with the management of a person’s medical condition.
- As part of the provision of some advanced services, contractors are required to provide advice on self-care, self-management of long-term conditions and appropriate lifestyle changes.

With regards to the promotion of healthy living, pharmacy contractors should therefore ensure that:

- All patient-facing pharmacy staff can use the NHS website and other appropriate public health information sources, eg PHE Resource Centre, when providing advice on health issues and where appropriate.
• The patient-facing pharmacy staff are friendly, welcoming and sensitive to the need for privacy for different individuals seeking advice, including by respecting people’s values and beliefs.

• The patient-facing pharmacy staff routinely explain who they are, wear a name badge and inform people about the information and/or services on offer.

• All patient-facing pharmacy staff receive training on how to approach people to discuss difficult or sensitive public health issues (paragraph 28(2)(e)(ii), Schedule 4).

• All patient-facing pharmacy staff are able to provide brief health and wellbeing advice (2-3 minutes) and have an awareness that the person may need additional support for behavioural change (paragraph 17, Schedule 4).

• When communicating with patients and the public and offering advice on difficult or sensitive issues, contractors and staff need to consider how they offer and maintain patient privacy. The approach taken may differ between contractors depending on the physical structure of the pharmacy, whether they provide services via remote means (e.g. phone and video consultation), the local population they serve and other factors. Paragraph 28B, Schedule 4 outlines the updated requirements for premises. Further information is provided in Chapter 11.
Box 10.4: Suggested evidence for communication

- ‘Making Every Contact Count’ training records for all staff who provide health advice to patients and the public.
- ‘Very Brief Advice’ training records for staff to support stop smoking services.
- Health Education England E-learning modules, eg All Our Health.
- Briefing notes for health promotion events that include top tips to engage people. Notes should include a briefing record to capture the names, signatures and dates of participating staff.

10.5.2. Engagement

Paragraph 20(1), Schedule 4 requires contractors to signpost or refer patients to other health and care providers if it is clear they require advice, treatment and/or support that the contractor is unable to provide.

Paragraph 17, Schedule 4 requires contractors to, where a person requests the dispensing of a prescription and they appear to have diabetes, be at risk of coronary heart disease, smokes or is overweight, provide advice to increase the person’s knowledge and understanding of the health issues that are relevant to them. As per paragraph 17(2)(b), Schedule 4, the contractor can back up any advice given by referring the person to other sources of information or advice.

With regards to the promotion of healthy living, contractors should:

- proactively engage with patients and the public using the pharmacy, to offer them advice, support and signposting to other providers of services in the community
- encourage charities and other providers to work with the pharmacy to deliver key health messages
- direct patients and the public to health and wellbeing providers and resources appropriate to their needs, where this is necessary (eg specialist clinics, Smoking Cessation, drug and alcohol services, Health Trainer Service, weight management services, mental health services, community exercise groups).
Paragraph 28(2)(a)(viii), Schedule 4\(^{47}\) introduces a new requirement with regards to community engagement exercises. This part of the terms of service requires contractors to undertake an approved community engagement exercise at least once per financial year (1 April to 31 March) for the promotion of healthy living. In relation to this part of the terms of service, ‘approved’ means approved by NHS England and NHS Improvement.

To undertake an approved community engagement exercise, the contractor must:

- actively work in collaboration with other organisations to deliver pharmacy outreach and any locally commissioned services
- take prevention and health promotion services beyond the pharmacy premises. Pharmacy outreach may be face-to-face or virtual and take services to people where they live or spend time.

When contractors and staff work in collaboration with other community organisations to undertake pharmacy outreach and any commissioned services, the contractor and the other organisation must undertake a risk assessment prior to the outreach activity to ensure that any activities are undertaken in a safe and culturally competent way.

**Box 10.5: Suggested evidence for engagement**

- SOP for health promoting interventions and staff training log.
- Photographs annotated with dates of the pharmacy team engaging with the public (with appropriate consent).
- Case studies and photographs (with appropriate consent) of outreach work (eg roadshows attended).
- List of community health and wellbeing resources readily available in the pharmacy.
- A local health and wellbeing notice board prominently displayed in the pharmacy.
- A signposting folder including a signposting log.
- A list of appropriate health and social care providers (eg specialist clinics, Smoking Cessation, drug and alcohol services, weight management services, mental health services and sexual health clinics).

\(^{47}\) Inserted by regulation 14, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
DSPs could collate a list of both local and national health and social care providers to direct patients to, where they have enquiries or need healthy living support, including Smoking Cessation, drug and alcohol services, weight management services, mental health services, sexual health clinics and Health Trainer Services.

10.5.3. Premises requirements

This section outlines the new premises requirements in respect of consultation rooms for pharmacy contractors (paragraph 28A, Schedule 4), including for DSPs (paragraph 28B, Schedule 4). Pharmacy contractors must also ensure they are compliant with NHS England and NHS Improvement’s approved particulars for premises.

Contractors should aim to create a health promoting environment that is reflected by the premises, as well as in the actions and attitudes of the pharmacy staff. It should be clear to the public that free confidential advice on their health and wellbeing can be accessed.

Contractors must therefore ensure:

- Pharmacies that are visited by patients and the public have a dedicated health promotion zone, of sufficient prominence and containing up-to-date professional health and wellbeing information that meets the needs of the population they serve (paragraph 28(2)(g)(ii), Schedule 4 and the premises approved particulars).
- DSPs have a website for patients and the public accessing their services to use, which must have an interactive page that is clearly promoted when they first access the website. This page must provide public access to a reasonable range of up-to-date materials that promote healthy lifestyles, by addressing a reasonable range of health issues (paragraph 28C, Schedule 4). DSPs should note that with effect from 1 April 2021 they are required to have a website.

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48 Inserted by regulation 15, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
49 Inserted by regulation 15, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
50 https://www.england.nhs.uk/publication/approved-particulars/
51 Inserted by regulation 15, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
Contractors must also comply with new requirements with regards to consultation rooms. Further information on these can be found in Chapter 11.

**Box 10.6: Suggested evidence for premises requirements**

- Photographs of pharmacy and consultation area.
- List of leaflets or promotional material used in the health promotion zone. Consider barriers to access, eg material in different languages to reflect the local population, easy read material, etc.
- Other formats for the health and wellbeing information may include: a touchscreen, plasma screen, books, DVDs, leaflets, promotional displays, demonstration models, etc.
- Data from the contractor’s assessment of patient experience.
- Record of health promotion zone being checked by a member of the pharmacy staff at least once a month and updated and restocked appropriately.
- A prominently displayed local health and wellbeing notice board.
- DSPs – screenshots of online content on their website’s health and wellbeing promotion section, and records of the content being checked on a monthly basis and the dates when updates are made. If health and wellbeing advice is also included in any apps the pharmacy makes available to patients, screenshots of this could also be retained as evidence. Additionally, where healthy living advice is provided in emails sent to patients, copies of these could also be retained as evidence of meeting the requirements.

**10.5.3.1. Sustainability**

Contractors should consider environmental sustainability in the way they operate their business. This may include reducing the use of paper materials and providing more information online, where appropriate for patient care, eg some patients may not be able to access online materials. Contractors could also consider highlighting to patients the environmental benefit of returning used inhalers to the pharmacy for safe disposal via the disposal of unwanted medicines service.
For more information, contractors may wish to refer to the NHS England and NHS Improvement ‘Delivering a ‘Net Zero’ National Health Service report’, which details the approach for increasing the environmental sustainability of the health service in England.

Box 10.7: Suggested evidence for sustainability

- Photographs of recycling bins, paper disposal system, etc.
- Screenshots of websites and online materials.
- Waste transfer notes.
- Examples of how messages on safe inhaler disposal are communicated to patients.

10.6. Evidencing initial and ongoing compliance

To ensure contractors meet their terms of service, it is recommended that they review their compliance against the requirements at least every three years.

Contractors should complete a self-assessment of their compliance and retain this in the pharmacy. It is recommended that contractors complete a template such as the assessment of compliance for the promotion of healthy living template for this self-assessment. Additional resources for compliance are available from the PSNC website.

Evidence of health promotion events, outputs and learning for the future should be captured and used to update an evidence portfolio to demonstrate the requirements have been met. The contractor may need to use this evidence during NHS England and NHS Improvement contract monitoring activities or during discussions with other organisations, such as the General Pharmaceutical Council or the local authority.

53 [https://psnc.org.uk/services-commissioning/essential-services/healthy-living-pharmacies/](https://psnc.org.uk/services-commissioning/essential-services/healthy-living-pharmacies/)
11. Premises requirements in respect of consultation rooms

11.1. Introduction

Under the Medicines Act 1968, a business or organisation must register a physical premises as a pharmacy if it intends to carry out one or more of the following activities from those premises:

- sale of pharmacy medicines (P medicines)
- supply of P medicines or prescription-only medicines (POMs) against prescriptions, which require the product to be labelled for a specific patient as a dispensed medicinal product
- supply of P medicines or POMs against prescriptions written by veterinary practitioners for the treatment of animals under the ‘cascade’.

Registration of pharmacy premises is the responsibility of the General Pharmaceutical Council which maintains a searchable register on its website.\(^5^4\)

Since April 2005, where a contractor wishes to provide one or more of the advanced services, they have been required to have an area for confidential consultations, and the requirements for these areas were specified in the Pharmaceutical (Advanced and Enhanced) Services (England) Directions 2005 and subsequent versions.

With effect from 1 October 2011, amendments were made to the NHS (Pharmaceutical Services) Regulations 2005. These amendments introduced a premises standards programme for pharmacy premises which included:

1. A system for maintaining cleanliness at the pharmacy, which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of healthcare acquired infection is minimised.

2. Arrangements for compliance, in the areas of the pharmacy in which patients receive NHS services, with any approved particulars that are designed to

\(^5^4\) [https://www.pharmacyregulation.org/registers/pharmacy](https://www.pharmacyregulation.org/registers/pharmacy)
ensure, in a proportionate manner, that those areas are an appropriate environment in which to receive healthcare (paragraph 26(2)(g), Schedule 1 of the NHS (Pharmaceutical Services) Regulations 2005).

This programme was carried forward and continues to be part of the system of clinical governance and promotion of healthy living that all pharmacies included in a pharmaceutical list are required to participate in (paragraph 28, Schedule 4).

Approved particulars for the premises standards programme have been published by NHS England and NHS Improvement.55

With effect from 1 January 2021, the premises requirements relating to the area for confidential consultations are part of the terms of service set out in Schedule 4 and must be complied with by all pharmacies included in a pharmaceutical list, with three exceptions (paragraph 28A, Schedule 4)56 – see Sections 11.3, 11.4 and 11.5 for the exceptions.

**11.2. Premises requirements in respect of consultation rooms**

With effect from 1 January 2021, pharmacies included in a pharmaceutical list must have a consultation room that is:

- clearly designated as a room for confidential conversations, eg a sign is attached to the door to the room saying ‘Consultation room’
- distinct from the general public areas of the pharmacy premises
- a room where both the person receiving the service and the person providing it are able to sit down together and communicate confidentially, eg without the details of that conversation being overhead by other people outside the consultation room who are in the pharmacy (paragraph 28A(1), Schedule 4).

Contractors will therefore need to review their area for confidential consultations and ensure it meets the above requirements.

55 [https://www.england.nhs.uk/publication/approved-particulars/](https://www.england.nhs.uk/publication/approved-particulars/)

56 Inserted by regulation 15, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
Contractors who have not previously had an area for confidential consultations will need to develop and implement a plan to incorporate a consultation room into their pharmacy premises.

Contractors who open new pharmacy premises on or after 1 January 2021 will be required to ensure that there is a consultation room that meets these requirements with effect from day one.

The consultation room must be located within the pharmacy premises that are included in the relevant pharmaceutical list. It is not possible for the room to be located in other premises because paragraph 28A(1), Schedule 4 states that the consultation room must be at the ‘pharmacy premises’, and the term ‘pharmacy premises’ is defined within regulation 2 as the premises that are included in the relevant pharmaceutical list.

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**Box 11.1: Location of consultation room**

1. A pharmacy is located in a large store at 2 High Street, Anytown, the address that is included in the pharmaceutical list for the area of Anytown Health and Wellbeing Board. The pharmacy is located in part of the overall space occupied by the store.

   Provided the consultation room is located in the part of the store registered as the pharmacy then this is acceptable. However, where proposed the consultation room is located elsewhere in the store, this is not be acceptable.

2. A pharmacy is located at 36A Church Street, Anytown, the address that is included in the pharmaceutical list for the area of Anytown Health and Wellbeing Board. The pharmacy occupies the whole of the ground floor but does not have a consultation room.

   The contractor has access to the flat above the pharmacy, the address for which is 36B Church Street, Anytown, and is considering creating a consultation room in the flat as it can be accessed by a lift as well as stairs. However, as 36B Church Street, Anytown is not included in the pharmaceutical list for the area of Anytown Health and Wellbeing Board the consultation room cannot be located in the flat.

3. A pharmacy is co-located with a general practice and the address included in the relevant pharmaceutical list is Anytown Health Centre. The pharmacy has permission to use one of the practice’s consultation rooms to provide pharmaceutical services. However, as the practice’s
consultation room is not within the registered premises of the pharmacy despite being within Anytown Health Centre, the consultation room cannot be located outside the registered premises.

11.3. Exception – pharmacies that are too small

Where a contractor believes that their pharmacy is too small for a consultation room, they will need to complete and submit a request\(^\text{57}\) to the NHS England and NHS Improvement regional team in whose area the pharmacy is located.

The relevant Pharmaceutical Services Regulations Committee will consider the information provided by the contractor and where it is of the opinion that the pharmacy is too small for a consultation room it will confirm this with the contractor. The contractor must then ensure that they put arrangements in place at the pharmacy which enable the person providing a pharmaceutical service, eg the pharmacist, to communicate confidentially with the person receiving the service by:

- telephone or another live audio link
- a live video link.

For example, a pharmacy may not have sufficient space to create a consultation room that would allow two people to sit down together. However, it would be possible to create an office space to accommodate one person with a phone and IT facilities where the pharmacist, for example, could sit and hold a virtual consultation with a patient or member of the public.

The arrangements must ensure both the person providing the service and the person receiving it can see and hear each other. If the arrangements only provide for a telephone conversation they will not comply with the terms of service.

While the terms of service require the arrangements to ensure that both parties can see and hear each other, it may be that a patient declines to turn the camera on for the live video link. That is acceptable and, in such circumstances, if the person providing the service is advised to record that fact in the clinical record if they consider this to be clinically relevant.

\(^{57}\) https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-manual/pharmacy-application-forms/
Where the Pharmaceutical Services Regulations Committee is not of the opinion that the pharmacy is too small for a consultation room, the contractor will be advised accordingly of the decision and its reasoning. There is no right of appeal against the committee’s opinion and the contractor must therefore ensure the required arrangements are put in place.

It is unlikely that reasons such as a loss of retail space will be sufficient to satisfy a Pharmaceutical Services Regulations Committee that a pharmacy is too small. The five-year deal for community pharmacy signals the beginning of a fundamental shift towards clinical service delivery, focused initially on minor illness and the prevention and detection of ill health. Contractors will therefore need to ensure their pharmacy premises are sufficient to meet this agreed commitment.

11.4. Exception – pharmacies that have not previously provided advanced services

Where a pharmacy is included in a pharmaceutical list as at 1 January 2021 but no advanced services were provided at or from the pharmacy during the 12 months ending on 31 December 2020, the contractor will have until 1 April 2023 to create a consultation room within their pharmacy (paragraph 28A(3), Schedule 4).

Where a contractor believes that their pharmacy is too small for a consultation room, they will need to complete and submit a request to the NHS England and NHS Improvement regional team in whose area the pharmacy is located. This will then be treated in the same way as applications from pharmacies that are too small – see Section 11.3 above.

11.5. Exception – distance selling premises

Contractors who operate DSPs must ensure that arrangements are in place at the pharmacy which enable the person providing a pharmaceutical service, eg the pharmacist, to communicate confidentially with the person receiving the service:

- telephone or another live audio link
- a live video link

without any other person (including pharmacy staff) overhearing the conversation (paragraph 28B, Schedule 4).

The arrangements must ensure both the person providing the service and the person receiving it can see and hear each other. If the arrangements only provide for a telephone conversation, they will not comply with the terms of service.

While the terms of service require the arrangements to ensure that both parties can see and hear each other, it may be that a patient declines to turn the camera on for the live video link. That is acceptable and in such circumstances the person providing the service is advised to record that fact in the clinical record if relevant.

Such contractors may choose to have a consultation room that meets the regulatory requirements so that they can provide advanced and enhanced services at their DSPs. However, where they choose to provide such services at their pharmacy premises, they must ensure they remain compliant with the requirements of regulation 64, in particular:

- they must not offer to provide pharmaceutical services other than advanced and enhanced services (ie they must not offer essential services to persons who are present at, or in the vicinity of, the DSP)
- the way in which essential services are provided must be such that any person receiving one or more of the essential services does so other than at the DSP and without face-to-face contact (this does not include electronic communications) between any person receiving the services, whether on their own or on someone else’s behalf, and pharmacy staff.

Care must be taken to ensure that no element of essential services are offered or provided to a person attending the DSP for an advanced or enhanced service.
12. Electronic communications and having an online presence

12.1. Introduction

The Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan\(^{59}\) stated that, to ensure the move to service provision is successful and to facilitate successful integration into primary care networks, the requirements around the following will become part of essential services for contractors:

- usage of NHSmail
- accessing the NHS summary care record (SCR)
- maintenance of an up-to-date profile on DoS
- maintenance of an up-to-date profile on the NHS website.

These have been requirements of the Quality Payment Scheme (QPS) and its successor, the Pharmacy Quality Scheme (PQS), for a number of years.

Originally planned to become essential service requirements from April 2020, this was delayed by the COVID-19 pandemic and instead became part of the terms of service with effect from 9 November 2020.

12.2. NHSmail

‘NHSmail’ is defined as the secure email service of that name that is to be used for the sharing of patient identifiable and patient sensitive information, for which the Health and Social Care Information Centre (referred to as NHS Digital) is responsible (regulation 2).\(^{60}\)


\(^{60}\) Inserted by regulation 2, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
Premises-specific NHSmail accounts began to be rolled out to contractors from late 2016. Each pharmacy premises included in a pharmaceutical list maintained by NHS England and NHS Improvement was given the ability to have one NHSmail account that is specific to the premises and, to access that account, up to two linked individual NHSmail accounts.

Except in exceptional circumstances, up to 10 new personal NHSmail accounts can now be created per pharmacy. These personal accounts can then be linked to the premises-specific account so that staff are able to send and receive NHSmail from the premises-specific account.

The naming convention for the premises-specific NHSmail accounts was initially established as nhspharmacy.location.pharmacynameODScode@nhs.net. However, from mid-September 2020 this changed to pharmacy.ODScode@nhs.net following feedback that the original naming convention was too long and a shorter version would be preferred by contractors.

From 9 November 2020, paragraph 29C(1), Schedule 4\(^6\) requires contractors to ensure their staff (which includes locums and other persons engaged on contracts for services who act as staff) have access to, and are able to send and receive NHSmail from, the premises-specific NHSmail account.

To meet this requirement contractors must ensure that at least two members of the staff at their pharmacy premises have live personal NHSmail accounts that are linked to the premises-specific NHSmail account. The only exception to this requirement is in the unlikely situation where fewer than two members of pharmacy staff are engaged in the provision of NHS services at the pharmacy premises (paragraph 29C(2), Schedule 4).\(^6\) ‘NHS services’ includes all services provided under the NHS whether that is part of pharmaceutical services for NHS England and NHS Improvement or under a contract with a clinical commissioning group (CCG) or the public health team at a local authority.

Contractors will therefore need to ensure that:

- they have a premises-specific NHSmail account for each of their pharmacy premises which meets the naming convention requirements

\(^6\) Inserted by regulation 17, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\(^6\) Inserted by regulation 17, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
• those staff who will need to send and receive NHSmail have live personal NHSmail accounts
• the personal NHSmail accounts are linked to the premises-specific NHSmail account
• staff are reminded of the need to regularly check the premises-specific NHSmail account and respond accordingly to emails that have been received
• the linked personal NHSmail accounts are regularly reviewed so that as staff leave, their personal NHSmail account is unlinked from the premises-specific NHSmail account to avoid any data breaches.

While the regulations require at least two members of staff to be able to access the premises-specific NHSmail account via their personal NHSmail account, contractors will need to ensure that it can be accessed throughout their core and supplementary opening hours. Pharmacies with extended opening hours are likely to require more than two members of staff who can access the premises-specific NHSmail account, as are those that have a high proportion of part-time staff.

Where a new pharmacy opens, or a pharmacy changes ownership and a new ODS code is allocated, the contractor must ensure they register for a premises-specific NHSmail account as soon as possible via the community pharmacy NHSmail registration portal.63 For contract monitoring purposes, it is recommended that the contractor retains evidence that such an account has been registered.

NHS Digital has produced guidance64 on:

• how to register for NHSmail
• how to get started using NHSmail
• what to do about any issues with NHSmail.

NHSmail is now routinely used by NHS England and NHS Improvement, NHSBSA and PCSE for communicating with contractors. It will also be used for referrals under the DMS and the CPCS, and by the Medicines and Healthcare products Regulatory Agency (MHRA) in relation to CAS alerts (see Section 12.6). It is therefore imperative that contractors ensure their staff are able to access and use the premises-specific NHSmail account routinely throughout the pharmacy’s opening hours.

63 https://portal.nhs.net/pharmacyregistration#/  
64 NHSmail guide for organisations managed by the national administration service, NHS Digital
12.3. Summary care records

Since 1 April 2016, it has been a term of service (paragraph 29A, Schedule 4)\(^{65}\) for contractors to ensure their staff access patients’ SCRs where such access is possible and where:

- in the responsible pharmacist’s clinical judgement it is in the best interests of the patient to do so
- in doing so the contractor is acting in accordance with ‘The NHS Care Record Guarantee’ published in ‘The Care Record Guarantee – Our Guarantee for NHS Care Records in England’.\(^{66}\)

Examples of use of the SCR in practice include resolving prescription queries, advising patients on suitable medication, providing emergency supplies and when carrying out medication reviews.

12.3.1. New requirement

From 9 November 2020, paragraph 29A(1), Schedule 4\(^{67}\) requires contractors to ensure that:

- appropriate staff working in their pharmacy or pharmacies, ie pharmacists and pharmacy technicians, can access SCR at the premises
- such access is consistent and reliable during the core and supplementary opening hours, in so far as that is within the control of the contractor
- Appropriate staff access the summary information in a patient’s SCR whenever providing pharmaceutical services to a patient, to the extent that the person providing the service considers, in their clinical judgement, that it is appropriate to do so (paragraph 29A(2), Schedule 4).

Examples of situations where consistent and reliable access to SCRs are likely to be considered outside the control of the contractor include:

- the system is down nationally

\(^{65}\) Inserted by regulation 4, The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2016, SI 2016/296

\(^{66}\) [https://digital.nhs.uk/binaries/content/assets/legacy/pdf/1/8/care_record_guarantee.pdf](https://digital.nhs.uk/binaries/content/assets/legacy/pdf/1/8/care_record_guarantee.pdf)

\(^{67}\) Amended by regulation 16, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
• a network outage due to damage to the contractor’s internet provider’s equipment
• a failure by the contractor’s internet provider to resolve an issue reported by the contractor
• any period of time where the contractor’s internet provider is investigating or resolving a reported issue
• a power failure affecting the contractor’s pharmacy premises that the contractor has reported.

Circumstances that are considered to be within the control of the contractor include:

• a failure to report to their provider that their internet access is not working
• failing to arrange or ensure a new member of staff, including locums, has a working smartcard
• failing to ensure that smartcards for staff, including locums, are updated as required
• the internet connection being stopped due to non-payment of bills
• the power supply being cut off due to non-payment of bills.

Contractors must ensure they have updated their SOPs to ensure all staff are able to access SCRs as required, including any new or temporary staff who will require such access. They must also review and update the business continuity plan for the pharmacy, which is required as part of the Data Security and Protection toolkit, to ensure it includes both the electrical supply to the pharmacy and access to the internet.

Staff having problems accessing the SCR can email scrpharmacy@nhs.net for support.

12.4. NHS 111 Directory of Services

The DoS is a central directory of information, maintained by NHS Digital, which provides NHS 111 call handlers and others with real-time information about services available to support a patient. A pharmacy’s services and opening hours are included in the DoS and it is important to the efficient working of NHS 111 and some other urgent care providers that information on pharmacy services is accurate to allow patients to be appropriately referred to a pharmacy.
Contractors have been required under the PQS and its predecessor the QPS to ensure that the profile for their pharmacy is, or pharmacies are, up-to-date.

12.4.1. Requirement to keep DoS profiles up–to-date

With effect from 9 November 2020, contractors must ensure that there is a comprehensive and accurate profile in the DoS for their pharmacy (paragraph 29C(3), Schedule 4).68

In addition, contractors must verify and, where necessary, update the information contained in that profile at least once each quarter of the financial year (paragraph 29C(3), Schedule 4). For the avoidance of doubt, financial quarters are:

- 1 April to 30 June
- 1 July to 30 September
- 1 October to 31 December
- 1 January to 31 March.

The first verification and update must therefore be undertaken by 31 December 2020. Any changes, additional information or confirmation that the profiles are accurate can be input directly into the DoS profile updater.69

Contractors are able to search and update their DoS profile(s) using the DoS profile updater. As all DoS profiles should contain the ODS code (F code), contractors should search by ODS code or postcode to ensure all their service profiles are included on the DoS. Guidance is available to support contractors with this requirement.70

Please note: Pharmacies are profiled on the DoS using a series of different profiles. The number of these profiles varies, depending on where in the country the pharmacy is located. To understand the number of profiles contractors should expect to see, please refer to the guidance71 on the NHS Digital website.

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68 Inserted by regulation 17, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
69 https://dos-profile.service.nhs.uk/
70 https://dos-profile.service.nhs.uk/guidance
71 https://dos-profile.service.nhs.uk/guidance
Contractors will be asked to update the profile information that will appear as shown in Figure 12.1.

Figure 12.1: Example of the information the DoS profile updater asks you to review

NHS Digital will prepare a report for NHS England and NHS Improvement of the contractors who have made a submission to the DoS profile updater each quarter, which will be used for contract management purposes.

12.4.2. Requirements relating to opening hours

Contractors are reminded that the opening hours included in their DoS profile must be those agreed with NHS England and NHS Improvement. Where a contractor wishes to change:

- their supplementary opening hours, they must notify NHS England and NHS Improvement at least three months in advance, preferably using the relevant form
- their core opening hours, they must first apply to NHS England and NHS Improvement using the relevant form.72

Contractors must ensure they update their DoS profile where the pharmacy’s opening hours change, either temporarily or permanently. The only exception to that is where a contractor will be staying open for longer to solely provide relevant immunisation services (see Chapter 9 for further information). In that instance, the supplementary opening hours are not to be added to the pharmacy’s DoS profile so as to avoid referrals under the CPCS.

Where a contractor will only be providing relevant immunisation services during part of their usual core or supplementary opening hours (see Chapter 9), they must update

their opening hours on their DoS profile so that the pharmacy premises show as closed at those times. This will also ensure no referrals are made to the pharmacy under the CPCS during the period it is only providing relevant immunisation services.

Contractors are required to include their opening hours on bank holidays, Christmas Day, Good Friday and Easter Sunday, which will be used to confirm information previously held on DoS. This must be the same as the information provided on the pharmacy’s NHS website profile.

12.4.3. Access to the DoS profile updater

The DoS profile updater requires contractors to have an NHSmail account (either the premises-specific NHSmail account or a personal NHSmail account), to allow user validation to support security of the DoS profile updater website.

Once the details on the DoS profile updater have been submitted, the contractor will receive an email confirming submission. If a reviewer is reviewing the profiles for more than one pharmacy on behalf of a multiple, they should receive an email for each pharmacy reviewed. This should be instantaneous; however, please allow up to two hours for the emails to be delivered. If the emails are not received, please check junk mail first before emailing exeter.helpdesk@nhs.net with ‘Profile Updater Email Access’ in the subject line of the email to confirm that the submission has been received.

Contractors are advised to retain these confirmation emails as evidence of meeting this term of service.

To help ensure contractors receive their confirmation emails, contractors are advised to add noreply@dos-profile.service.nhs.uk to their safe senders list before they update their profile. Alternatively, contractors will need to check their junk email folder in case the email has been inappropriately filed.

12.4.4. Changes

The information provided by contractors on the DoS profile updater will be automatically reflected on the DoS approximately 10 minutes after the change has been submitted. Please note that the changes will not be reflected back on the profile updater until the following day because the profile updater has a nightly data feed from DoS. Where DoS leads or NHS England and NHS Improvement have queries regarding the information
provided, they will contact the contractor to resolve these. Where the proposed changes can be accepted without reference back to the pharmacy, no follow-up contact will be made.

For temporary closures, pharmacies should ensure their DoS RAG status is amended to ‘RED’, meaning that the delivery of clinical services has been temporarily suspended and will not present as an option on the DoS. This can be done using the DoS capacity status tool, which can be accessed from the login page on the DoS Profile Updater. The capacity status will need to be changed to RED for each service that is affected. Any changes to the capacity status can be made for a period of up to five calendar days. After this time, the status will automatically revert to GREEN unless changes are re-applied. For more information, see Appendix A of the Guidance and standard operating procedures: Community pharmacy in the context of coronavirus (COVID-19).

12.4.5. Technical help and support

If contractors have any technical difficulties accessing the DoS profile updater, they can email the NHS Digital helpdesk (exeter.helpdesk@nhs.net) or call them on 0300 303 4034.

12.5. NHS website

12.5.1. Introduction

The NHS website73 was launched in 2007 and is the official website of the NHS in England. It is designed to meet the requirements of those with health or care needs, either directly (eg patient or service user) or indirectly (eg carer).

With over 48 million visits per month, it has become the UK’s biggest health website, accounting for a quarter of all health-related web traffic. It strives to be a world leading, multi-channel service for everyone engaging with the NHS and social care.

Information, advice or data about health and care providers is made accessible via the NHS website for the benefits of patients and other users of NHS services. This includes details of how to access health and care services, to make interactions with health and

73 www.nhs.uk
care services as easy as possible. It also contains information for patients about medicines.\textsuperscript{74}

Most pharmacies in England have their own profile on the NHS website. However, the profiles are only useful to users if the information they contain is correct and up to date. Generally, the pharmacy profile allows users to view opening times, and information on services, facilities and staff. It also provides users with a comprehensive directory in one place, searchable by postcode, name or address. The profiles for DSPs have a limited range of information compared to ‘bricks and mortar’ pharmacies.

Up-to-date service and opening times information are important to support service signposting from other pages of the NHS network where patients and carers can access information about medical conditions and symptoms. This supports the NHS website’s aim of providing patients with the right information about self-care and where services can be accessed, to reduce avoidable contacts in general practice and urgent care services. Contractors have been required under the PQS and its predecessor the QPS to ensure that the profile for their pharmacy is, or pharmacies are, up to date.

Each contractor can verify or amend their profile through the NHS website Provider Information Management System (PIMS). Guidance on how to do this is available on the NHS website.\textsuperscript{75} Amending or verifying an NHS website profile creates a record which will act as evidence to NHS England and NHS Improvement that these actions have been undertaken.

\textbf{12.5.2. Requirement to keep NHS website profiles up-to-date}

From 9 November 2020, contractors must ensure that the profile for their pharmacy is comprehensive and accurate (paragraph 29C(4), Schedule 4).\textsuperscript{76} In addition, contractors must verify and, where necessary, update the information contained at least once each quarter of the financial year. For the avoidance of doubt financial quarters are:

\begin{itemize}
  \item 1 April to 30 June
  \item 1 July to 30 September
  \item 1 October to 31 December
\end{itemize}

\textsuperscript{74} https://www.nhs.uk/medicines/
\textsuperscript{75} https://www.nhs.uk/about-us/manage-provider-profiles/
\textsuperscript{76} Inserted by regulation 17, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
• 1 January to 31 March.

The first verification and update must therefore be undertaken by 31 December 2020 and must include any changes to the pharmacy’s opening hours over the holiday period.

NHS Digital will provide information to NHS England and NHS Improvement on a quarterly basis to show which contractors have verified or updated their profile. This will be used by NHS England and NHS Improvement for contract monitoring purposes.

The following information forms part of a pharmacy’s profile:

• organisational name
• address
• opening hours (this includes the usual opening hours plus those on any of the bank holidays, Christmas Day, Good Friday and Easter Sunday)
• facilities the pharmacy provides, eg consulting room and car parking
• services the pharmacy provides
• telephone number
• website URL.

Contractors are required to verify and update, where required, all elements of their profile to meet this term of service. It should be noted that as of October 2020, there is no ‘validate’ button for the telephone number or website URL. However, contractors must still check those details, add them if they are missing and amend as and when they change. A ‘validate’ button for these two elements of the profile will be developed.

Any inaccuracies between a contractor’s NHS website profile and their contractual opening hours, facilities and the services provided are the responsibility of the contractor.

A user guide for managing NHS website profiles is available on the NHS website.77

All contractors must ensure that they are registered to edit the profile of their pharmacy or each of their pharmacies. It should be noted that it may take up to a week for editing rights to be received. Contractors who are unable to edit their profile must apply in sufficient time to undertake their first verification deadline; the first of these deadlines after the changes to the terms of service comes into effect on 31 December 2020. It is

77 https://www.nhs.uk/about-us/manage-provider-profiles/
recommended that evidence of a request for editing rights is retained for contract monitoring purposes.

Contractors are encouraged to use their premises-specific NHSmail accounts when requesting editing rights as it has been agreed with the NHS website team that these addresses will be used to validate the request. Use of other email accounts may lead to a delay in editing rights being granted as these will require manual validation. To apply for editing rights, contractors must supply the below information, ideally by copying and pasting the table below into an email to nhswebsite.servicedesk@nhs.net and completing all the required information.

‘Profile Editor Access Request’ must be added to the subject line of the email; failure to add the code to the subject line may result in a processing delay.

Table 12.1: Information required when applying for editing rights

<table>
<thead>
<tr>
<th>Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Email address (preferably the pharmacy premises-specific NHSmail account):</td>
<td>(This will be used as your username on the website.)</td>
</tr>
<tr>
<td>Telephone number:</td>
<td></td>
</tr>
<tr>
<td>Job title:</td>
<td></td>
</tr>
<tr>
<td>Organisation:</td>
<td></td>
</tr>
<tr>
<td>ODS code:</td>
<td></td>
</tr>
</tbody>
</table>

Contractors who own more than one pharmacy premises may apply for editing rights by sending the additional pharmacy names and ODS codes with their email.

Contractors are reminded that their editing rights are password protected. If a password has been forgotten, it can be reset. Once completed an email containing a new password should be received almost immediately. However, please allow up to two hours before emailing the NHS website service helpdesk on nhswebsite.servicedesk@nhs.net for assistance.

78 https://www.nhs.uk/Personalisation/ResetPassword.aspx
12.5.3. Requirements relating to opening hours

The opening hours on NHS website profiles must be the hours that the pharmacy is providing pharmaceutical services, i.e., its core and supplementary hours. Where a pharmacy has scheduled breaks for its pharmacist and so are not providing pharmaceutical services, but may be providing other non-NHS services, e.g., sales of other products, then these must not be included in the opening hours section of their NHS website profile.

Contractors are required to update their NHS website profile to show their opening hours, if any, on bank holidays, Christmas Day, Good Friday, and Easter Sunday. To do this, contractors will need to create a ‘public holiday and other special day’ entry on their NHS website profile.79

If contractors do not add their opening times on these days, their profile will default to their normal opening hours. Therefore, if contractors have not amended their opening hours by entering them in the ‘public holidays and other dates’ section, they may be advertising incorrect opening hours, and NHS England and NHS Improvement may deem them to be in breach of this term of service.

NHS England and NHS Improvement will use the ‘public holidays and other dates’ opening hours entered in each pharmacy’s profile to plan provision of services on those dates. If the pharmacy’s planned opening hours for these days change after the editing and/or validation of its NHS website profile, the contractor must update their opening hours within their NHS website profile and notify the NHS England and NHS Improvement team in whose area the pharmacy is located.

Additional opening hours that are not core or supplementary hours can be advertised in the pharmacy or locally, but not on the NHS website, provided it is clear to the public that pharmaceutical services are not available at these times.

The NHS website profile allows contractors to create up to three sets of opening times per day on their profile. For example, a pharmacy opening between 9:00 am and 5:00 pm that does not provide pharmaceutical services between 1:00 pm and 2:00 pm should set two sets of opening times as follows: 9:00 am to 1:00 pm and 2:00 pm to 5:00 pm.

79 https://www.nhs.uk/about-us/manage-provider-profiles/
Where a contractor will be staying open for longer to solely provide relevant immunisation services, the supplementary opening hours are not to be added to the pharmacy’s profile on the NHS website. This is to avoid patients or their representatives visiting the pharmacy to have a prescription dispensed, to collect an item that has already been dispensed or to access another service.

Where a contractor will only be providing relevant immunisation services during part of their usual core or supplementary opening hours, they must update their opening hours on their NHS website profile so that it shows as closed at those times. While the pharmacy can still be nominated for EPS purposes, showing the pharmacy as closed will reduce the number of people attending the pharmacy having first viewed its profile on the NHS website to have a prescription dispensed, for example.

Contractors are reminded that the opening hours included in their profile on the NHS website must be those agreed with NHS England and NHS Improvement. Where a contractor wishes to change:

- their supplementary opening hours, they must notify NHS England and NHS Improvement at least three months in advance, preferably using the relevant form
- their core supplementary opening hours, they must first apply to NHS England and NHS Improvement using the relevant form.

Information on how to manage temporary changes to opening hours can be found on the NHS website.

12.5.4. Contractors with multiple branches

Contractors with multiple branches will need to decide whether to complete the review of NHS website profiles at head office or branch level. Each profile is specific to that branch and when a profile is edited or validated, staff will need to ensure that the branch details submitted are accurate for that particular branch at the time of completion. Any inaccuracies that result from editing by head offices or local pharmacy teams will be the responsibility of the contractor.

81 https://www.nhs.uk/about-us/manage-provider-profiles/
12.5.5. Automating the NHS website profile update process

An application programming interface (API) is available to automate the process of updating profile information on the NHS website. This will be useful for contractors with multiple profiles to manage. Rather than using the NHS website PIMS to enter the information, pharmacies can use the API to connect their IT systems to the NHS website to create an automated way of updating their profile information, saving time and ensuring that their information on the NHS website is always up to date. Pharmacies can make changes to the editable fields using the API.

For further information on using the API, please email the NHS website service helpdesk (nhswebsite.servicedesk@nhs.net) requesting a call back from the Syndication team. Please add ‘Pharmacy Organisation API’ in the subject field of the email and include one contact per organisation.

12.5.6. Opening of new pharmacy premises

Where a new pharmacy opens, the contractor’s name and address are provided to NHS Digital so that an initial profile may be created. For DSPs, the website URL is also provided and added to the initial profile.

Contractors opening new pharmacy premises will need to register for editing rights as soon as possible, check their initial profile and add to it so that it contains all the required information. They are advised to retain evidence of requesting editing rights for contract management purposes.

12.5.7. Distance selling premises

As of 1 April 2021, all DSPs will be required to have a website and must therefore ensure that the website URL is included in the NHS website profile (paragraph 28C, Schedule 4).^2

At the time of publication, the information contained with the profiles for DSPs is not as extensive as for ‘bricks and mortar’ pharmacies. However, work is being undertaken to

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[^2]: Amended by regulation 10, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
create profiles for DSPs so that they mirror those for other pharmacies, and is expected to be completed in 2021.

Until that time profiles for the DSPs are located separately from those for ‘bricks and mortar’ pharmacies. If a contractor with a DSP finds they are listed within the main pharmacy section of the NHS website, they must email the NHSBSA Provider Assurance Team (nhsbsa.pharmacysupport@nhs.net) following the steps below and inform them that they are listed in the incorrect section of the website.

Under the terms of service, DSPs will be required to:

- check the name of their pharmacy on the NHS website – it must be the trading name rather than the registered company name (unless the registered company name is the same as the trading name)
- check the telephone number and website URL on their profile
- email the NHSBSA Provider Assurance Team (nhsbsa.pharmacysupport@nhs.net), including ‘DSPNHS.UKQuarterlyValidation’ and the pharmacy ODS code in the subject line, and confirming in the body of the email that the current information is correct or providing the correct information. For example, a DSP contractor with an ODS code AAA001 will need to submit an email with the subject line of ‘DSPNHS.UKQuarterlyValidation AAA001’.

Failure to add the ODS code and ‘DSPNHS.UKQuarterlyValidation’ in the subject line will result in the email not being recorded in the NHS website summary report of DSP contractors who have complied with this term of service, which will be provided to NHS England and NHS Improvement.

The above steps must be completed each financial quarter. For the avoidance of doubt financial quarters are:

- 1 April to 30 June
- 1 July to 30 September
- 1 October to 31 December
- 1 January to 31 March.

[83] https://www.nhs.uk/service-search/other-services/pharmacies/internetpharmacies
The first verification and update must therefore be undertaken by 31 December 2020.

Contractors with DSPs that are not listed on the NHS website must email the NHSBSA Provider Assurance Team (nhsbsa.pharmacysupport@nhs.net), including ‘UNABLETOVERIFYPROFILE’ in the subject line with the following information:

- pharmacy name (trading name)
- ODS code
- address
- telephone number
- website URL.

It is suggested that contractors retain evidence of this email in case asked for it by NHS England and NHS Improvement.

12.6. Central Alerting System

The Central Alerting System (CAS) is a web-based cascading system operated by the MHRA for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care.

Alerts available on the CAS website include National Patient Safety Alerts, NHS England and NHS Improvement Patient Safety Alerts (PSA) and Estates Alerts, MHRA Dear Doctor letters, Medical Device Alerts (MDA) and Drug Alerts, Chief Medical Officer (CMO) Alerts and DHSC Supply Disruption Alerts.

Specific requirements regarding premises-specific NHSmail accounts and CAS alerts have been introduced to the terms of service (paragraph 29C(5), Schedule 4).\(^{84}\)

With effect from 9 November 2020, contractors must register the premises-specific NHSmail account for each of their pharmacy premises with the MHRA as the address to which CAS notifications are to be sent, unless they have already done so. A bulk upload of the premises-specific NHSmail accounts set up by NHS Digital was organised to meet this requirement, and contractors set up in this way would have received an email from MHRA on 10 November to confirm their registration. Contractors who have not

\(^{84}\) Inserted by regulation 17, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
created the premises-specific NHSmail account ahead of 9 November 2020 will need to do this and register it with MHRA to meet this term of service.

If the contractor changes their premises-specific NHSmail account, they must immediately notify MHRA (safetyalerts@mhra.gov.uk) of the new address.

Contractors must also ensure their premises-specific NHSmail address or addresses are monitored with sufficient frequency throughout core and supplementary opening hours so as to ensure the safe and effective supply of medicinal products at or from their pharmacy premises. They must also act on CAS alerts as appropriate.

Where a contractor opens a new pharmacy or sells a pharmacy on a non-debts and liabilities basis, they must:

- register for a premises-specific NHSmail account (see Section 12.2) as soon as possible
- ask the national administration service for at least two personal NHSmail accounts to be linked to it
- register the premises-specific NHSmail account with the MHRA.

Where a pharmacy is sold on a debts and liabilities basis, the ODS code will remain the same. As a result the new owner will be able to continue to use the existing premises-specific NHSmail account. However, they must ensure that at least two of its staff have personal NHSmail accounts linked to the premises-specific NHSmail account and if not, arrange for that to happen as soon as possible. This will therefore allow the new owner to continue to be able to access the premises-specific NHSmail account to check for and respond to CAS alerts.

The NHSBSA will advise MHRA on a quarterly basis of any pharmacy closures in that quarter so that the premises-specific NHSmail account can be removed from its distribution list.

12.7. Electronic Prescription Service

The EPS allows prescribers to send prescriptions electronically to a dispenser (such as a pharmacy) of the patient’s choice. This makes the prescribing and dispensing process more efficient and convenient for patients and staff. While initially used by general
practices, its use by other prescribers has increased and now, for example, includes urgent care settings.

As of July 2020:

- 96.7% of general practices
- 99.8% of pharmacies
- 96.5% of dispensing appliance contractors

were live with the EPS. 88.8% of items dispensed in that month were from an electronic prescription. Use of the EPS increased considerably during the COVID-19 pandemic.

While pharmacies have been required to dispense electronic prescriptions for some time, from 9 November 2020 contractors are required to ensure that their staff have access to the EPS at their pharmacy premises, and must ensure that such access is constant and reliable throughout core and supplementary opening hours in so far as that is within their control (paragraph 29B, Schedule 4).85

Examples of situations where consistent and reliable access to the EPS is likely to be considered outside or within the control of the contractor are similar for those for accessing the SCR record, see Section 12.3.1.

Contractors must ensure they have updated their SOPs to ensure all staff are able to access the EPS as required, including any new or temporary staff who will require such access. They must also review and update the business continuity plan for the pharmacy, which is required as part of the Data Security and Protection Toolkit to ensure it includes both the electrical supply to the pharmacy and access to the internet.

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85 Inserted by regulation 17, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
13. Facilitating remote access to pharmaceutical services

13.1. Introduction

‘The Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan’ signalled a shift towards clinical service delivery. To underpin the delivery of more clinical services by pharmacies, the requirements for consultation rooms, including how they can be used to deliver services remotely, have become terms of service.

The COVID-19 pandemic has substantially changed the way that services are delivered across the NHS, with a rapid move towards virtual consultations. To support this, all contractors who provide services remotely to patients are required to ensure they have the infrastructure to support remote access to the full range of NHS pharmacy services provided by the pharmacy where that is appropriate and feasible.

13.2. Remote access requirements

With effect from 9 November 2020, contractors must, to the extent reasonable:

- facilitate remote access to the pharmaceutical services provided at or from their pharmacy premises where users of the services wish to access such services under arrangements that make the services available remotely
- establish, maintain and keep under review their procedures to facilitate remote access to those pharmaceutical services (paragraph 32A, Schedule 4).

This requirement only applies to those services commissioned by NHS England and NHS Improvement, ie essential, advanced and enhanced services. It does not apply to

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87 Inserted by regulation 18, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
services commissioned by CCGs or local authorities. Requirements for any remote
access to those services would be contained in the contract issued to the contractor.

The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions
2013 were amended from 1 November 2020\textsuperscript{88} to allow medicine use reviews, the New
Medicines Service (NMS) and appliance use reviews to be provided by telephone or
video link, with the prior agreement of the patient and in circumstances where the
telephone or video link conversation cannot be overheard (except by someone who the
patient wants to hear the conversation, eg a carer).

While remote access will not be possible for all services, eg flu vaccination and hepatitis
C antibody testing, contractors will wish to review the services they provide for NHS
England and NHS Improvement and consider how they could be delivered remotely
using telephone or video links.

While contractors’ DSPs have always been required to ensure patients access the
essential services remotely, they will wish to review their procedures for the provision of
essential services to ensure they meet this requirement.

\textsuperscript{88} Amendments made by The Pharmaceutical Services (Advanced and Enhanced Services and
Emergency Declaration) (England) (Amendment) (No. 2) Directions 2020
14. Access to information held by pharmacy contractors

14.1. Introduction

Contractors are required to allow someone who is authorised in writing by NHS England and NHS Improvement to enter and inspect their pharmacy premises at any reasonable time for the following purposes:

- ascertaining whether or not the contractor is complying with the terms of service set out in Schedule 4
- auditing, monitoring and analysing the contractor’s provision for patient care and treatment, including any arrangement made in respect of the provision of appliances
- auditing, monitoring and analysing the management of the pharmaceutical services that the contractor is providing (paragraph 35(1), Schedule 4).

However, there are specific conditions that must first be met. These are:

- reasonable notice of the inspection has been given
- the relevant local pharmaceutical committee (LPC) has been invited to be present at the inspection where the contractor requests this
- the person undertaking the visit carries written evidence of their authorisation and produces it if asked to do so by the contractor
- the person undertaking the visit does not enter any part of the premises which are used solely as residential accommodation without the consent of the resident (paragraph 35(2), Schedule 4).

Contractors must, at the request of NHS England and NHS Improvement or the person undertaking the visit, allow access to any information which they reasonably require for the purposes set out in the first paragraph above (paragraph 35(3), Schedule 4).
These requirements have been expanded with effect from 9 November 2020.

Contractors remain under a separate duty to submit specified data on a quarterly basis in relation to the provision of the New Medicines Service and the medicine use reviews, the latter until such time as it comes to an end with effect from 1 April 2021.

14.2. Provision of information via electronic communications – requests from NHS England and NHS Improvement pharmacy teams

Paragraph 35(4), Schedule 4\(^{89}\) requires contractors, where asked to do so by NHS England and NHS Improvement, to submit any information to which a person authorised in writing by NHS England and NHS Improvement would have access to during a visit carried out under paragraph 35(1), Schedule 4. The information is to be provided in the electronic format specified in NHS England and NHS Improvement’s request.

The requested information is to be provided where the contractor has it in a form that can be sent electronically, or where it is reasonable for NHS England and NHS Improvement to ask the contractor to convert the information into a form which can then be sent electronically (and NHS England and NHS Improvement make such a request).

Examples of information that may be requested include copies of:

- the responsible pharmacist log
- the practice leaflet
- material to publicise the essential and advanced services provided at or from the pharmacy premises
- the pharmacy’s arrangements for owings
- the procedure by which the contractor checks the qualifications and references of all staff engaged in the provision of NHS services
- SOPs
- evidence of training.

Requests will be made using the premises-specific NHSmail account.

\(^{89}\) Inserted by regulation 19, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
14.3. Provision of information via electronic communications – national requests

NHS England and NHS Improvement (or a person authorised in writing by NHS England and NHS Improvement) may ask contractors to submit a completed questionnaire the purpose of which is to enable them to determine whether or not it is necessary or expedient to undertake a visit for the purposes of:

- ascertaining whether or not the contractor is complying with the terms of service set out in Schedule 4
- auditing, monitoring and analysing the contractor’s provision for patient care and treatment, including any arrangement made in respect of the provision of appliances
- auditing, monitoring and analysing the management of the pharmaceutical services that the contractor is providing.

The questionnaire is to be provided via an electronic communication and will be in a format approved by NHS England and NHS Improvement (paragraph 35(5), Schedule 4). Before requesting the information, NHS England and NHS Improvement must consult with PSNC on the terms of the request (paragraph 35(6), Schedule 4).

A screening questionnaire was introduced by NHS England and NHS Improvement for the purposes of monitoring compliance with the terms of service set out in Schedule 4. All contractors are asked to complete it and, from the responses, NHS England and NHS Improvement then identify which contractors are to be asked to complete the full Community Pharmacy Assurance Framework (CPAF).

Completion of both the screening questionnaire and CPAF has been encouraged by PSNC as a way for contractors to demonstrate that they are meeting the terms of service.

From 9 November 2020, completion of the screening questionnaire will be mandatory for all contractors in relation to each of their pharmacy premises. Where contractors are

90 Inserted by regulation 19, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
91 Inserted by regulation 29, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
asked to complete the CPAF, this will also be mandatory (paragraph 35(5), Schedule 4). Any replacement for, or future versions of, either document will be discussed and agreed with PSNC in advance of being rolled out nationally and therefore will fall within the provisions of paragraph 35(5), Schedule 4.

Contractors must therefore ensure they comply with any request to complete either the screening questionnaire or the CPAF (or their replacements) to comply with the terms of service. Requests will be made using the premises-specific NHSmail account.
15. Local Pharmaceutical Services contracts

15.1. Introduction

Contractors who hold an LPS contract are not included in a pharmaceutical list maintained by NHS England and NHS Improvement; instead they are included in one of the LPS lists. The mandatory terms of service for LPS contracts are set out in Schedule 7 and not all the changes described in the previous chapters will automatically apply to LPS contracts.

NHS England and NHS Improvement are required to vary their LPS contracts in line with the amendments that have been made to the LPS terms of service. However, it is for NHS England and NHS Improvement and LPS contractors to discuss any of the other changes to the terms of service set out in the preceding chapters that they wish to incorporate into the LPS contracts.

This chapter sets out the mandatory changes to the LPS terms of service. LPS contractors may wish to read the earlier chapters in this document with a view to seeing what other changes they may wish to negotiate into their contract. Similarly, NHS England and NHS Improvement will wish to consider which, if any, changes they wish to negotiate into their LPS contracts to meet the needs of the population who use, or may use, those pharmacies providing services under an LPS contract.

15.2. Refusal to provide drugs or appliances ordered via a prescription

Paragraph 7, Schedule 7 sets out specific instances where an LPS contractor may refuse to provide drugs or appliances ordered via a prescription. These include:

- an error on the prescription
- the prescription is believed to have been forged
- the LPS contractor, their staff or other people in the pharmacy are subjected to, or threatened with, violence by the person presenting the prescription or by any person accompanying them.
Paragraph 7(2A) was inserted with effect from 26 November 2018\(^{93}\) and allows an LPS contractor to refuse to provide a drug or appliance ordered on an electronic prescription where access to the EPS is such that the item cannot be dispensed promptly or at all.

It is further amended with effect from 9 November 2020 so that where an LPS contractor is unable to access the EPS to dispense an item (either promptly or at all), they must take all reasonable steps to ensure that the item is supplied within a reasonable timescale.

These steps may include:

- providing details or other pharmacies in the area that may be able to provide the prescribed item or items
- urgent supply without a prescription in accordance with paragraph 4, Schedule 7
- contacting the prescriber and asking them for the urgent provision of a non-electronic prescription form (paragraph 7(2A), Schedule 7).\(^{94}\)

This provision applies only to electronic prescriptions. LPS contractors are advised to update their SOPs accordingly and to ensure all staff are aware of this change.

Details of other pharmacies that may be able to provide the prescribed item or items can, if necessary, be sourced from the NHS website.\(^{95}\)

LPS contractors will also wish to note the new requirement to ensure that access to the EPS at their pharmacy premises must be constant and reliable throughout core and supplementary opening hours, as far as that is within their control. Further information on this can be found in Section 12.7.

\(^{93}\) Inserted by regulation 10(4), The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018/1114

\(^{94}\) Inserted by regulation 24, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126

\(^{95}\) https://www.nhs.uk/service-search/find-a-pharmacy
15.4. Further activities to be carried out in connection with the dispensing of prescriptions

Paragraph 8, Schedule 7 lists further activities to be carried out when dispensing prescriptions and includes:

- providing appropriate advice to patients on the safe keeping of drugs or appliances, and returning unwanted drugs to the pharmacy for safe destruction
- providing appropriate advice to enable the person to use the drugs or appliances appropriately and to meet their reasonable needs for general information about the dispensed drugs or appliances.

A further required activity is the provision of a written note of any drug or appliance which is owed and advising when the owed item or items will be available. With effect from 9 November 2020, this written note may be in an electronic form (paragraph 8(c), Schedule 7), eg via a text, email or any app used by the pharmacy.

LPS contractors are advised to update their SOPs accordingly and to ensure all staff are aware of this change.

15.5. Electronic Prescription Service

The EPS allows prescribers to send prescriptions electronically to a dispenser (such as a pharmacy) of the patient's choice. This makes the prescribing and dispensing process more efficient and convenient for patients and staff. While initially used by general practices, its use by other prescribers has increased and now, for example, includes urgent care settings.

As of July 2020:

- 96.7% of general practices
- 99.8% of pharmacies
- 96.5% of dispensing appliance contractors

96 Amended by regulation 25, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
were live with the EPS. 88.8% of items dispensed in that month were from an electronic prescription. Use of the EPS increased considerably during the COVID-19 pandemic.

While LPS contractors have been required to dispense electronic prescriptions for some time, from 9 November 2020 they are required to ensure that their staff have access to the EPS at their pharmacy premises, and must ensure that such access is constant and reliable throughout their opening hours in so far as that is within the control of the contractor (paragraph 13B, Schedule 7).97

Examples of situations where consistent and reliable access to EPS is likely to be considered outside or within the control of the contractor are similar for those for accessing the SCR; see Section 12.3.1.

LPS contractors must ensure they have updated their SOPs to ensure all staff are able to access the EPS as required, including any new or temporary staff who will require such access. They must also review and update the business continuity plan for the pharmacy required as part of the Data Security and Protection Toolkit, to ensure it includes both the electrical supply to the pharmacy and access to the internet.

15.6. Additional requirements in relation to electronic prescribing

Additional requirements in relation to the EPS are set out in paragraph 9, Schedule 7. With effect from 9 November 2020, these requirements have been amended to reflect the fact that all LPS contractors are required to ensure that access to the EPS is available at their pharmacy premises throughout their opening hours.

Where access to the EPS is temporarily unavailable at an LPS contractor’s pharmacy premises, persons requesting the dispensing of an electronic prescription must be provided with the contact details of at least two other pharmacies in the area that can access the EPS, where this information is known to the pharmacy staff (paragraph 9(1), Schedule 7).98

Where the issue only relates to the contractor’s pharmacy premises, and as LPS pharmacies and all pharmacies included in a pharmaceutical list are required to ensure

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97 Inserted by regulation 28, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
98 Amended by regulation 26, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
the EPS can be accessed throughout their pharmacy premises’ opening hours, the contractor will be able to identify other pharmacies in the area by searching the NHS website.99

Where there is a national issue with the EPS such that no pharmacies are able to access it, then the contractor would not be able to provide details of other pharmacies.

As access to the EPS is required throughout the opening hours, paragraph 9(2), Schedule 7 has been amended100 so that from 9 November 2020 all LPS pharmacies are required to set or amend patient’s nominations in their Patient Demographics Service (PDS) patient details.

LPS contractors are advised to update their SOPs accordingly and to ensure all staff are aware of this change.

15.6. Summary care records

Since 1 April 2016, it has been a term of service (paragraph 13A, Schedule 7)101 for LPS contractors to ensure their staff access patients’ SCRs where such access is possible and where:

- in the responsible pharmacist’s clinical judgement, it is in the best interests of the patient to do so
- in doing so the contractor is acting in accordance with ‘The NHS Care Record Guarantee’ published in ‘The Care Record Guarantee – Our Guarantee for NHS Care Records in England’.102

Examples of use of the SCR in practice include resolving prescription queries, advising patients on suitable medication, providing emergency supplies and when carrying out medication reviews.

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99 https://www.nhs.uk/service-search/find-a-pharmacy
100 Amended by regulation 26, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
101 Inserted by regulation 4, the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2016. SI 2016/296
102 https://digital.nhs.uk/binaries/content/assets/legacy/pdf/1/8/care_record_guarantee.pdf
15.6.1. New requirement

From 9 November 2020 paragraph 13A(1), Schedule 7\textsuperscript{103} requires LPS contractors to ensure that:

- staff working in their pharmacy or pharmacies are able to access SCRs at the pharmacy premises
- such access is consistent and reliable during the pharmacy’s opening hours, in so far as that is within the control of the contractor.

In addition, LPS contractors must ensure that their staff access the summary information in a patient’s SCR whenever providing LPS to a patient to the extent that the person providing the service considers, in their clinical judgement, that it is appropriate to do so (paragraph 13A(2), Schedule 7).\textsuperscript{104}

Examples of situations where consistent and reliable access to SCRs is likely to be considered outside or within the control of the contractor can be found in Section 12.3.1.

LPS contractors must ensure they have updated their SOPs to ensure all staff are able to access SCRs as required, including any new or temporary staff who will require such access. They must also review and update the business continuity plan for the pharmacy, required as part of the Data Security and Protection Toolkit, to ensure it includes both the electrical supply to the pharmacy and access to the internet.

Staff having problems accessing the SCR can email scrpharmacy@nhs.net for support.

15.7. NHSmail

‘NHSmail’ is defined as the secure email service of that name that is to be used for the sharing of patient identifiable and patient sensitive information, for which the Health and Social Care Information Centre (referred to as NHS Digital) is responsible (regulation 2).\textsuperscript{105}

\textsuperscript{103} Inserted by regulation 27, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\textsuperscript{104} Inserted by regulation 28, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\textsuperscript{105} Inserted by regulation 2, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
Premises-specific NHSmail accounts began to be rolled out to contractors from late 2016. Each pharmacy included in an LPS list maintained by NHS England and NHS Improvement was given the ability to have one NHSmail account that is specific to the pharmacy premises and, to access that account, at least two linked individual NHSmail accounts.

Except in exceptional circumstances, up to 10 new personal NHSmail accounts can now be created per pharmacy. These personal accounts can then be linked to the premises-specific account so that staff are able to send and receive NHSmail from the premises-specific account.

The naming convention for the premises-specific NHSmail accounts was initially established as nhspharmacy.location.pharmacynameODScode@nhs.net. However, from mid-September 2020 this changed to pharmacy.ODScode@nhs.net following feedback that the original naming convention was too long and a shorter version would be preferred by contractors.

From 9 November 2020, paragraph 13C(1), Schedule 7 requires LPS contractors to ensure their staff (which includes locums and other persons engaged on contracts for services who act as staff) have access to, and are able to send and receive NHSmail from, the premises-specific NHSmail account.

To meet this requirement LPS contractors must ensure that at least two members of the staff at their pharmacy premises have live personal NHSmail accounts that are linked to the premises-specific NHSmail account. The only exception to this requirement is in the unlikely situation where fewer than two members of pharmacy staff are engaged in the provision of NHS services at the pharmacy premises (paragraph 13C(2), Schedule 7). ‘NHS services’ includes all services provided under the NHS whether that is part of pharmaceutical services for NHS England and NHS Improvement or under a contract with a CCG or the public health team at a local authority.

LPS contractors will therefore need to ensure that:

- they have a premises-specific NHSmail account for their pharmacy which meets the naming convention requirements

106 Inserted by regulation 28, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
107 Inserted by regulation 28, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
• those staff that will need to send and receive NHSmail have personal NHSmail accounts
• the personal NHSmail accounts are linked to the premises-specific NHSmail account
• staff are reminded of the need to regularly check the premises-specific NHSmail account and respond accordingly to emails that have been received
• the linked personal NHSmail accounts are regularly reviewed so that as staff leave their personal NHSmail account is unlinked from the premises-specific NHSmail account to avoid any data breaches.

While the regulations require that at least two members of staff are able to access the premises-specific NHSmail account via their personal NHSmail account, LPS contractors will need to ensure that it can be accessed throughout their opening hours. Pharmacies with extended opening hours are likely to require more than two members of staff who can access the premises-specific NHSmail account, as are those that have a high proportion of part-time staff.

NHS Digital has produced guidance\textsuperscript{108} on:

• how to register for NHSmail
• how to get started using NHSmail
• what to do about any issues with NHSmail.

NHSmail is now routinely used by NHS England and NHS Improvement, NHSBSA and PCSE for communicating with LPS contractors, and by the MHRA in relation to CAS alerts (see below). It is therefore imperative that LPS contractors ensure their staff are able to access and use it routinely during each day of opening.

\textbf{15.8. Central Alerting System}

The Central Alerting System (CAS) is a web-based cascading system operated by the MHRA for issuing patient safety alerts, important public health messages, and other safety critical information and guidance to the NHS and others, including independent providers of health and social care.

\textsuperscript{108} \textbf{NHSmail guide for organisations managed by the national administration service}, NHS Digital
Alerts available on the CAS website include National Patient Safety Alerts, NHS England and NHS Improvement Patient Safety Alerts (PSA) and Estates Alerts, MHRA Dear Doctor letters, Medical Device Alerts (MDA) and Drug Alerts, Chief Medical Officer (CMO) Alerts and DHSC Supply Disruption Alerts.

Specific requirements regarding premises-specific NHSmail accounts and CAS alerts have been introduced to the LPS terms of service (paragraph 13C(3), Schedule 7).\textsuperscript{109}

With effect from 9 November 2020, LPS contractors must register the premises-specific NHSmail account for their pharmacy premises with the MHRA as the address to which CAS notifications are to be sent, unless they have already done so. A bulk upload of the premises-specific NHSmail accounts set up by NHS Digital was organised to meet this requirement. However, contractors must still check that their premises-specific NHSmail account has, or addresses have, been uploaded. Contractors who have not created the premises-specific NHSmail account ahead of 9 November 2020 will need to do this and register it with MHRA to meet this term of service.

If the LPS contractor changes their premises-specific NHSmail account, they must immediately notify MHRA (safetyalerts@mhra.gov.uk) of the new address.

Contractors must also ensure their premises-specific NHSmail account is monitored with sufficient frequency throughout the pharmacy’s opening hours so as to ensure the safe and effective supply of medicinal products at or from their pharmacy premises. They must also act on CAS alerts as appropriate.

Where a pharmacy operating under an LPS contract closes, the relevant NHS England and NHS Improvement regional team will need to advise MHRA that the premises-specific NHSmail account is to be closed.

\textsuperscript{109} Inserted by regulation 28, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
16. Changes affecting the provision of pharmaceutical services by dispensing doctors

16.1. Introduction

The terms of service for the provision of pharmaceutical services by some GPs are included in Schedule 6. By virtue of regulation 47(2), these terms of service must be included in the general practice Primary Medical Services contract.

NHS England and NHS Improvement are required to vary the Primary Medical Services contract held with dispensing practices in line with the amendments that have been made to the dispensing doctor terms of service.

This chapter sets out the changes to the dispensing doctor terms of service in relation to PTPs.

16.2. Pandemic treatment protocols

A PTP is defined within regulation 2\textsuperscript{110} as a protocol:

- relating to the supply of a prescription-only medicine to be used for the prevention of or as a treatment for a disease that is, or in anticipation of it being imminently, pandemic
- approved in accordance with regulation 247 of the Human Medicines Regulations 2012 (exemption for supply in the event or in anticipation of pandemic disease).

Similar to a patient group direction, a PTP provides a legal framework within which pharmacies and dispensing doctors may supply specified prescription-only medicines

\textsuperscript{110} Inserted by regulation 2, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
The protocol must:

- be approved by Ministers or NHS England and NHS Improvement
- specify how the medicinal product is to be used for the prevention or treatment of the disease
- contain requirements as to the recording of:
  - the name of the person who supplies the product to the person to be treated (the patient) or to a person acting on the patient’s behalf
  - evidence that the product was supplied to the patient or to a person acting on the patient’s behalf.

Until such time as a PTP is issued, contractors are not required to comply with those parts of their terms of service which solely apply to supply under a PTP. It is however recommended that they and their staff familiarise themselves with the provisions.

**16.3. Supply in accordance with a PTP**

With effect from 9 November 2020, where a dispensing doctor:

- receives via a secure service approved by NHS England and NHS Improvement an electronic message that amounts to an order for the supply of a drug in accordance with a PTP
- a person who is entitled to be supplied with that drug, or their representative, requests the provision of the drug

they must, with reasonable promptness, provide the drug in line with the order (paragraph 3B(1), Schedule 6). NHS England and NHS Improvement will determine how orders are to be sent; examples of ‘a secure service’ include an via NHSmail.

If the person or their representative asks when the drug will be dispensed and ready for collection, the contractor must provide them with an estimate of the time when the drug will be ready. If the drug is not ready by the appointed time, the contractor must give the

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93 | Guidance on the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020
person a revised estimate of the time, and continue to do so until the drug is ready for collection (paragraph 3B(2), Schedule 6).\textsuperscript{112}

16.4. Providing a drug under a PTP

Where a dispensing doctor provides a drug under a PTP, they must include a dispensing label on the product packaging. In addition to the information required or permitted by Part 2, Schedule 26 of the Human Medicines Regulations 2012, the label must include information to the effect that the product is being supplied in accordance with a PTP, and identify the specific PTP (paragraph 3B(3), Schedule 6).\textsuperscript{113}

16.5. Refusal to provide drugs in accordance with a PTP

With effect from 9 November 2020, dispensing doctors may refuse to provide a drug that is, or is purportedly, in accordance with a PTP where:

- it appears not to be a genuine order for the person requesting it or on whose behalf it is requested
- providing it would be contrary to the doctor’s clinical judgement
- the dispensing doctor, their staff or other persons are subjected to, or threatened with, violence by the person who requests the provision of the drug or by a person accompanying them, or
- the person requesting the provision or any person accompanying them commits or threatens to commit a criminal offence (paragraph 6(5), Schedule 6).\textsuperscript{114}

In addition, a dispensing doctor must refuse to provide a drug that is, or is purportedly, in accordance with a PTP where they are not satisfied that it is in accordance with that PTP (paragraph 6(6), Schedule 6).\textsuperscript{115}

\textsuperscript{112} Inserted by regulation 21, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\textsuperscript{113} Inserted by regulation 21, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\textsuperscript{114} Inserted by regulation 22, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
\textsuperscript{115} Inserted by regulation 22, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
17. Notices of commencement

17.1. Introduction

Where a person wishes to:

• open a pharmacy or dispensing appliance contractor premises and provide pharmaceutical services
• apply to relocate existing premises or
• buy an existing business

they must first apply to NHS England and NHS Improvement to be included in the relevant pharmaceutical list.

Where such an application is granted, the applicant will then have a specified period of time within which to submit a ‘notice of commencement’. The notice of commencement advises NHS England and NHS Improvement of the date on which the applicant intends to start to provide services, and it is on this date that the applicant and their premises are included in the relevant pharmaceutical list and the contractual relationship between the two parties commences.

The regulatory requirements relating to the submission and content of notices of commencement are set out in paragraph 34, Schedule 2, and a number of changes have been made to this paragraph.

17.2. Period of time within which to submit a notice of commencement

With effect from 14 September 2020, applicants will have 12 months within which to submit a valid notice of commencement (paragraph 34(4)(b), Schedule 2). Previously it was six months.

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116 Amended by regulation 4(3)(a), The National Health Service (Coronavirus) (Charges and Further Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020. SI 2020/885
Table 17.1 sets out when the 12-month period starts for the most common scenarios. Paragraph 34(4), Schedule 2 should be referred to for all other types of scenario.

### Table 17.1: Submission of notices of commencement

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Date the 12 month period starts</th>
</tr>
</thead>
<tbody>
<tr>
<td>The applicant identified the premises at which they wish to provide pharmaceutical services. The application was granted and no appeal against that decision was received by NHS Resolution.</td>
<td>The date on which the applicant was sent the decision letter by PCSE on behalf of NHS England and NHS Improvement.</td>
</tr>
<tr>
<td>The applicant identified the premises at which they wish to provide pharmaceutical services. The application was granted, and an appeal against that decision was received by NHS Resolution. NHS Resolution upheld the decision to grant the application.</td>
<td>The date on which the appeal is determined by NHS Resolution.</td>
</tr>
<tr>
<td>The applicant identified the premises at which they wish to provide pharmaceutical services. The application was refused, and an appeal against that decision was received by NHS Resolution. NHS Resolution granted the application.</td>
<td>The date on which the appeal is determined by NHS Resolution.</td>
</tr>
<tr>
<td>The applicant gave a best estimate of the address at which they wish to provide pharmaceutical services. The application was granted and no appeal against that decision was received by NHS Resolution. The applicant notifies NHS England and NHS Improvement of the address of the premises at which they wish to provide pharmaceutical services. This notification is accepted as valid.</td>
<td>The date on which NHS England and NHS Improvement confirm the notification is valid.</td>
</tr>
<tr>
<td>The applicant gave a best estimate of the address at which they wish to provide pharmaceutical services. The application was granted and no appeal against that decision was received by NHS Resolution. The applicant notifies NHS England and NHS Improvement of the address of the premises at which they wish to provide pharmaceutical services. This notification is not accepted as valid. The applicant appeals this decision and NHS Resolution accepts it as a valid notification.</td>
<td>The date on which the appeal is determined by NHS Resolution.</td>
</tr>
</tbody>
</table>
17.3. Date on which services are to commence

The second change to the submission of notices of commencement relates to how far in advance they may be submitted to PCSE (acting on behalf of NHS England and NHS Improvement).

With effect from 9 November 2020, notices of commencement must be submitted no fewer than 30 days prior to the date on which the applicant intends to commence service provision (paragraph 34(3A), Schedule 2).\textsuperscript{117} It was previously up to 14 days in advance.

There is one exception to this rule and that is where NHS England and NHS Improvement agree to a shorter notice period. The form to be used for this purpose can be found on PCSE’s website.\textsuperscript{118}

\begin{center}
\begin{tabular}{|l|
\hline
\textbf{Box 17.1: Examples} \\
\hline
1. An application to open a new dispensing appliance contractor premises has been granted, and the applicant has until 30 November to submit a valid notice of commencement. The applicant wishes to commence service provision on 30 November. They must therefore submit a valid notice of commencement no later than 31 October.

2. A change of ownership application for a pharmacy has been granted and the applicant has until 28 February 2021 to submit a valid notice of commencement. The sale of the business is due to complete on 1 February and the applicant intends to commence service provision on 2 February. The latest date for submission of a valid notice of commencement is therefore 3 January.

On 7 December 2020 the buyer and seller agree that the sale of the business can complete earlier, and the buyer will commence service provision on 4 January. As that is less than 30 days away, the applicant will need to ask NHS England and NHS Improvement to agree to a
\hline
\end{tabular}
\end{center}

\textsuperscript{117} As inserted by regulation 4, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020, SI 2020/1126
\textsuperscript{118} https://pcse.england.nhs.uk/services/market-entry/market-entry-application-forms/
shorter notice period. Only if that is agreed to can the notice of commencement be submitted giving 4 January as the date on which service provision is to commence.

3. An application to open a new pharmacy has been granted and the applicant has until 1 November to submit a valid notice of commencement. The applicant submits their notice on 19 October stating that they intend to commence service provision on 9 November. The notice of commencement is invalid as it has been submitted fewer than 30 days before service provision is to commence. The applicant would need to either:

- submit a new notice of commencement ensuring that the new date for service provision to commence is no fewer than 30 days from the date the notice is submitted or
- ask NHS England and NHS Improvement to agree to a shorter notice period.

4. An application to relocate an existing pharmacy into new premises has been granted and the applicant has until 16 November to submit a valid notice of commencement. They submit such a notice on 16 October, but it did not include all the required information and so is not in the correct form as required by paragraph 34(3), Schedule 2. The applicant was advised of this on 19 October.

The applicant would be required to submit a new notice of commencement and either change the date that service provision is to commence to meet the requirements of paragraph 34(2) and (3A), Schedule 2 or ask NHS England and NHS Improvement to agree to a shorter notice period.

### 17.4. Changing the date on which service provision is to commence

Where a valid notice of commencement is received, NHS England and NHS Improvement are required to amend the relevant pharmaceutical list to include the applicant and their premises. This is done on the date given in the notice of commencement (paragraph 34(2), Schedule 2).

From 9 November 2020, where the applicant has submitted a notice of commencement, they may change the date on which service provision is to commence (paragraph
34(3B), Schedule 2). The applicant must notify NHS England and NHS Improvement via PCSE as soon as practicable of any change to the date on which service provision is to commence. The form to use for this purpose can be found on PCSE’s website.

However, where an applicant has submitted a notice of commencement specifying the date on which service provision will commence and subsequently wishes to change that date, they may only do so in advance of the original date on the notice of commencement (paragraph 34(3B), Schedule 2).

**Box 17.2: Examples**

1. A change of ownership application was granted, and the applicant submitted a notice of commencement to NHS England and NHS Improvement advising that service provision will commence on 16 November.

   The sale of the business is delayed at the last minute and the applicant completes the relevant form and submits it to NHS England and NHS Improvement on 15 November, advising that they will commence service provision on 26 November.

   As the applicant has notified NHS England and NHS Improvement in advance of 16 November (the original date on the notice of commencement), the relevant pharmaceutical list will now be amended on 26 November.

2. An unforeseen benefits application was granted, and the applicant submitted a notice of commencement to NHS England and NHS Improvement, advising that service provision will commence on 30 November.

   For reasons outside their control the applicant is unable to open on 30 November and contacts NHS England and NHS Improvement later that week to advise that they will now open on 7 December 2020.

   However, as the pharmaceutical list was amended with effect from 30 November, the applicant is required to provide services from that date. They may now be seen to be

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119 Inserted by regulation 4, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
120 [https://pcse.england.nhs.uk/services/market-entry/market-entry-application-forms/](https://pcse.england.nhs.uk/services/market-entry/market-entry-application-forms/)
121 As inserted by regulation 4, the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulation 2020. SI 2020/1126
breaching the requirement to provide pharmaceutical services during their core and supplementary opening hours.

The applicant is advised that if there is likely to be any change to the date on which services are to commence, they must discuss this with NHS England and NHS Improvement at the earliest opportunity.

It should be noted that this change does not apply to the submission of notices of consolidation. Once a valid notice of consolidation has been submitted the date on which the consolidation will be affected cannot be unilaterally changed by the applicant.
18. Glossary

2013 regulations – The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and amending legislation. These regulations govern the provision of pharmaceutical services in England by pharmacy contractors, dispensing appliance contractors and dispensing doctors. They include provisions for how applications for inclusion in a pharmaceutical list may be made and determined, and contain the terms of service for pharmacy contractors, dispensing appliance contractors and dispensing doctors.

Contractor – a term used within this document to describe persons included in a pharmaceutical list who provide pharmaceutical services.

Dispensing doctor – a GP who provides a dispensing service to eligible patients.

Local Pharmaceutical Services (LPS) – an alternative to the national framework for the provision of services by pharmacy contractors. It allows NHS England and NHS Improvement to commission services that meet the specific needs of a population and contracts may include services not traditionally provided by pharmacies. A contract sets out the services that are provided, at what times and from which premises. At the time of publication there are 27 LPS contracts in England. Persons providing LPS are included in the LPS list rather than the pharmaceutical list.

LPS list – NHS England and NHS Improvement are required to maintain and publish a list of the persons providing LPS in the area of a health and wellbeing board. The list contains the name of the contractor, the address or addresses of their premises and the opening hours. Contractors included in such a list are required to comply with the terms of service set out Schedule 7 of the 2013 regulations. These terms of service are set out in an LPS contract and may, with the agreement of both parties, include additional requirements.

Pharmaceutical list – NHS England and NHS Improvement are required to maintain and publish a list of all the pharmacy contractors providing pharmaceutical services in the area of a health and wellbeing board. The list contains the name of the contractor, the address or addresses of their premises and the opening hours. Contractors included
in such a list are required to comply with the terms of service set out Schedule 4 of the 2013 regulations.

**Pharmaceutical services** – pharmacy contractors included in a pharmaceutical list are required to provide the essential services and participate in an approved system of clinical governance and promotion of healthy living. They may choose to provide advanced services and may be required by NHS England and NHS Improvement to provide enhanced services. Collectively these three types of service are referred to as pharmaceutical services in this document.

**Pharmaceutical Services Regulations Committee** – NHS England and NHS Improvement have established local committees, to be known as Pharmaceutical Services Regulations Committees, as the committees which make decisions required by the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended. These include:

- applications for new pharmacy premises, relocations of existing premises or changes of ownership
- the issuing of breach or remedial notices
- changes to core opening hours.

**Pharmacy premises** – in this document this is the term for premises that are included in a pharmaceutical list or a LPS list.

**Pharmacy staff** – in this document this term includes staff employed or engaged by a contractor to assist in the provision of pharmaceutical services. It includes locums and other persons engaged on contracts for services who act as staff.

**Terms of service** – the requirements for the services to be provided by those included in a pharmaceutical list, local pharmaceutical list or dispensing doctor list. For dispensing doctors and LPS contractors, the terms of service are incorporated into their Primary Medical Services contract and LPS contract respectively.