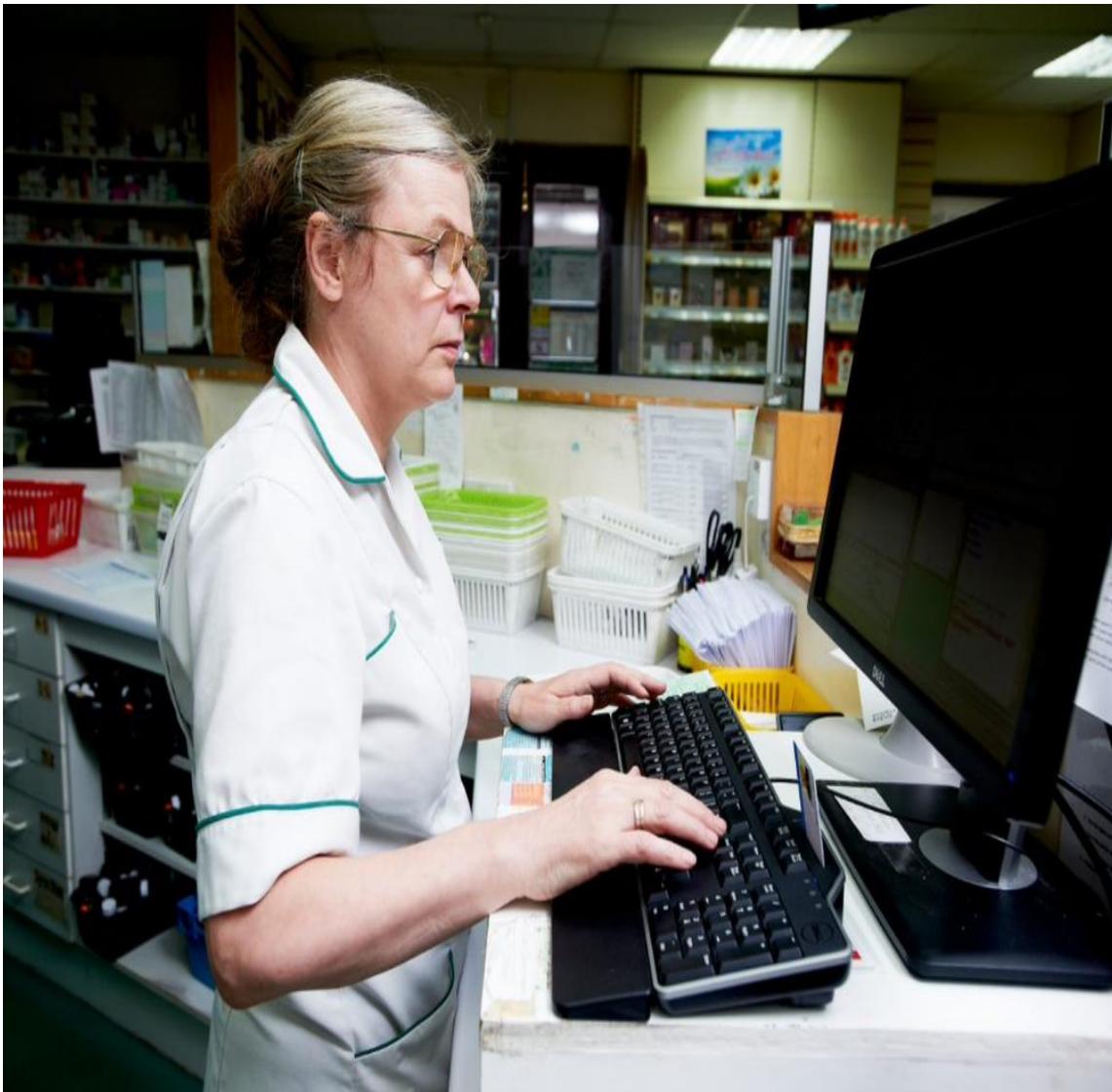


Pharmacy Quality Scheme

Guidance 2019/20



Pharmacy Quality Scheme Guidance 2019/20

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Contents

1. Executive Summary.....	5
2. Background.....	6
3. Gateway Criteria	8
Table 1: Gateway Criteria	8
3.1 Advanced Services.....	8
Aim/Rationale	8
Requirement.....	9
3.2 NHSmail.....	9
Aim/Rationale	9
Requirement.....	10
3.3 The NHS Website: Update opening hours, facilities and services available	12
Aim/Rationale	12
Requirement.....	12
The NHS website profile editor and the assignment of editing rights	14
Distance Selling Pharmacies and the NHS Website	14
3.4 Safeguarding Training.....	16
Aim/Rationale	16
Requirement.....	16
4. Quality Criteria	18
Table 2: Quality Criteria	18
4.1 Domain: Risk Management and Safety	23
4.1.1 CPPE Risk Management training.....	23
Aim/Rationale	23
Reporting.....	23
4.1.2 CPPE sepsis training and assessment.....	23
Aim/ Rationale.....	23
Reporting.....	24
4.1.3 Risk Review update	24
4.1.4 CPPE reducing look-alike, sound alike errors (LASA) training and assessment	25
Aim/Rationale	25
Reporting.....	25
4.1.5 Written Safety Report.....	26
Aim/Rationale	26
Reporting.....	26
Training Requirements	27
4.2 Domain: Medicines safety audits complementing General Practice (GP) Quality and Outcomes Framework (QOF) Quality Improvement (QI) module.....	29
Aim.....	29
Rationale	29
4.2.1 (a) Lithium Audit	29
Aim.....	29
Rationale	30
Reporting.....	31
4.2.1 (b) Methotrexate Audit	33

Aim.....	33
Rationale	33
Reporting.....	35
4.2.1 (c) Amiodarone Audit	36
Aim.....	37
Rationale	37
Reporting.....	38
4.2.1 (d) Phenobarbital Audit	40
Aim.....	40
Rationale	40
Reporting.....	41
4.2.2 Audit process where no lithium, methotrexate, amiodarone or phenobarbital is dispensed	42
4.2.3 Valproate Audit.....	43
Aim.....	43
Rationale	43
Reporting.....	44
4.2.4 Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Audit.....	45
Aim.....	45
Rationale	45
Reporting.....	46
4.3 Domain: Prevention	48
4.3.1 Healthy Living Pharmacy level 1 (self-assessment).....	48
Aim.....	48
Rationale	48
4.3.2 All patient-facing staff are Dementia Friends.....	49
Aim.....	49
Rationale	49
Reporting.....	50
Becoming a Dementia Friend.....	50
4.3.3 Dementia-Friendly Environment Checklist.....	51
Aim.....	51
Rationale	51
Reporting.....	51
4.3.4 Annual foot and eye checks (retinopathy)	51
Aim.....	51
Rationale	51
Eye Check.....	52
Foot Check.....	53
Reporting.....	53
4.3.5 Sugar Sweetened Beverages (SSB)	55
Aim/Rationale	55
Reporting.....	55
4.4 Domain: Primary Care Networks.....	56
Aim.....	56
Rationale	56
Reporting.....	57
4.5 Domain: Asthma.....	59
Aim.....	59

Rationale	59
Reporting	59
4.6 Domain: Digital Enablers	61
4.6.1 NHS 111 DoS Profile update via the DoS updater	61
Aim/Rationale	61
Reporting	61
Access to the DoS Profile Updater	62
Easter Sunday 2020 and public and bank holiday opening	63
Submission Review Timeline	63
Technical Help and Support	63
4.6.2 Accessing NHS Summary Care Records (SCR)	63
5. PQS Declarations and Payments	65
5.1 Manage Your Service (MYS)	65
5.2 Aspiration Payment	67
5.3 Payment Declaration	68
5.4 Datasets for the gateway criteria	69
6. Validation of Claims	71
6.1 Provider Assurance	71

1. Executive Summary

A Community Pharmacy Quality Payments Scheme (QPS), which forms part of the Community Pharmacy Contractual Framework (CPCF), was introduced in December 2016. The QPS was designed to reward community pharmacies for delivering quality criteria in all three of the quality dimensions: Clinical Effectiveness, Patient Safety and Patient Experience.

With the announcement of a five-year (2019/20 to 2023/24) agreement for the Community Pharmacy Contractual Framework, and building upon the success of the previous QPS, NHS England and NHS Improvement have worked with stakeholders to develop the new **Pharmacy Quality Scheme** (PQS) for 2019/20, supporting delivery of the NHS Long Term Plan.

This guide replaces guidance issued regarding all previous schemes.

The aim of this scheme is to continue to move community pharmacy to a more integrated, service focussed function within the wider NHS system, providing even safer, accessible healthcare to patients by incentivising activity in the following quality domains:

- Risk management and patient safety;
- Medicines safety through audits, complementing the Quality and Outcomes Framework Quality Improvement scheme within the GP contract;
- Sickness prevention of ill health and the provision of information and advice to promote healthy living;
- Integration into local Primary Care Networks (PCNs) as part of the multidisciplinary team;
- Asthma reviews and ensuring that appropriate action plans are in place and referrals are made where necessary; and
- Improved updates to pharmacy profiles to support real time referrals and patient access.

The PQS will start on 1 October 2019 and participating contractors will declare their performance against the quality domains during the declaration window between 3 February 2020 and 28 February 2020.

This start is later in the financial year than the previous quality scheme and in recognition that this may lead to pressure on contractor cash flow an aspiration payment has been introduced. The payment will be paid to contractors based on points achieved in the previous QPS scheme in 2018/2019 and what they plan to achieve within the current PQS scheme for 2019/2020.

2. Background

A Community Pharmacy Quality Payments Scheme (QPS), which formed part of the Community Pharmacy Contractual Framework (CPCF), was introduced in December 2016 and was designed to reward community pharmacies for delivering quality criteria in all three of the quality dimensions: **Clinical Effectiveness, Patient Safety and Patient Experience**.

There have since been four review points; in April 2017, November 2017, June 2018 and February 2019. So far, the scheme has driven improvements in the provision of quality services and has laid the foundations for a shift to a service focus for community pharmacy, incentivising:

- NHS mail rollout for the exchange of confidential patient information;
- access to the NHS Summary Care Record (SCR);
- improved community pharmacy profiles for the NHS 111 Directory of Services (DoS) to facilitate referral; and
- improved pharmacy profiles on NHS.UK (previously NHS Choices) with opening times, facilities and service information.

It has also delivered significant wider benefits. For example, over 70,000 patient-facing staff in community pharmacies are now Dementia Friends and over 74,000 are trained in child oral health in support of National Smile Month. Nearly 8,000 additional pharmacies have become Healthy Living Pharmacies (HLPs) taking the total to over 9,500 pharmacies and over 12,500 patients with asthma were identified as being at high risk of harm and referred to their GP practice. Representing a huge effort in community pharmacy, these achievements and others will deliver real benefits to patients.

The CPCF for 2019/20 to 2023/24 was announced in July 2019. It recognised the success of the QPS and outlined that it would continue for the next five years at its current value of £75 million under a new name, the Pharmacy Quality Scheme (PQS).

Details of the PQS for 2019/20 have been provided in [part VIIA of the Drug Tariff](#)¹. This guidance document provides further detail for contractors of how they demonstrate compliance with the scheme requirements, when they make their declaration (see the [gateway criteria - section 3](#) and the [quality criteria - section 4](#)).

The total funding for the PQS in 2019/2020, £75 million, will be divided between qualifying pharmacies based on the number of points they have achieved up to the maximum £128 per point allowed for the scheme. Each point will have a minimum value worth £64 based on all pharmacy contractors achieving maximum points. Payments will be made to eligible contractors depending on how many domains they have met and hence points claimed.

In previous years there have been two declarations in the year and two subsequent payment dates at which contractors could have claimed for QPS. This year there will only be one, therefore in recognition of this, an aspiration payment has been introduced to support cash flow.

The aspiration payment is optional for pharmacy contractors and not claiming it will not impact on the pharmacy contractor's ability to claim payment for the 2019/20 PQS. The payment will be paid to contractors based on the points achieved in the previous QPS in 2018/2019 and what they plan to achieve within the current PQS for 2019/20 (see the [Aspiration Payment - section 5.2](#)).

¹ <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>

NHS England and NHS Improvement has worked with stakeholders to develop both the declaration and the supporting processes that enable contractors to demonstrate that they are meeting the scheme's requirements. It is recommended that contractors thoroughly familiarise themselves with this guidance document if they are considering taking part in the PQS.

Previous Pharmacy QPS guidance has been removed from the NHS England website. Copies of previous guidance can be requested from ENGLAND.CommunityPharmacy@nhs.net. The annexes to this guidance are included in a separate document and can be found on the NHS England website titled [Pharmacy Quality Scheme Guidance 2019/20 Annexes](#)².

² <https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-quality-payments-scheme/pgs/>

3. Gateway Criteria

To qualify for a PQS 2019/20 payment, pharmacy contractors will have to meet the four gateway criteria in [Table 1](#) on the day of their declaration.

Table 1: Gateway Criteria

Gateway Criteria
<p>Advanced Services The contractor must be offering at the pharmacy the New Medicine Service (NMS) and/or the NHS community pharmacy seasonal influenza vaccination service.</p>
<p>NHSmail Pharmacy staff at the pharmacy must be able to send and receive NHSmail from their shared premises specific NHSmail account, which must have at least two live linked accounts.</p>
<p>NHS Website: Opening Hours The contractor must update its NHS website profile in respect of its opening hours (including Easter Sunday 2020 and the following public and bank holidays: Christmas Day 2019, Boxing Day 2019, New Year's Day 2020, Good Friday 2020, Easter Monday 2020, Early May bank holiday 2020 and Spring bank holiday 2020), services and facilities and promptly update this as information changes (including Easter Sunday and public and bank holiday opening hours) to ensure the information is accurate for the public (to be eligible for the PQS 2019/2020 payment, this will have to be done between 00:00 on 1 October 2019 and 23:59 on 30 November 2019); distance selling pharmacies must send an email to the NHS Business Services Authority (NHSBSA) Provider Assurance Team between 00:00 on 1 October 2019 and 23:59 on 30 November 2019 as per the NHS England and NHS Improvement PQS 1019/20 guidance.</p>
<p>Training 80% of all registered pharmacy professionals working at the pharmacy have achieved level 2 safeguarding status for children and vulnerable adults in the last two years prior to the date of their declaration.</p>

To be eligible to take part in the PQS and be eligible for a PQS payment, pharmacy contractors will have to meet the gateway criteria on the day of their declaration. **The declaration must be made between 3 February 2020 and 28 February 2020.**

3.1 Advanced Services

Aim/Rationale

The aim is to ensure that all pharmacies taking part in the scheme meet all of the requirements in their terms of service and in respect of an acceptable system of clinical governance, which they must do before providing any Advanced Services, and are choosing to actively support patients by providing Advanced Services.

Requirement

On the day of the declaration, the contractor must be offering the New Medicine Service (NMS) and/or the NHS Community Pharmacy Seasonal Influenza Vaccination Advanced Service. This could be evidenced by claims for payments made by contractors for these Advanced Services in the period leading up to the day of the declaration.

Community pharmacies must comply with their obligations under Schedule 4 of The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (terms of service of NHS pharmacists) in respect of the provision of Essential Services and in respect of an acceptable system of clinical governance to be able to deliver any Advanced Service.

NHS England and NHS Improvement will use a report produced by the NHS Business Services Authority (NHSBSA) of the claims for payments made by contractors for these Advanced Services in the 18 months period leading up to the review window as evidence of meeting this criterion.

Where such claims have not been received by the NHSBSA, contractors will need to decide how else they will be able to provide evidence of offering these Advanced Services should they be asked to do so by the NHSBSA Provider Assurance Team working on behalf of NHS England and NHS Improvement. Failure to provide such evidence will result in contractors being unable to claim a PQS payment.

Contractors who are claiming they are providing NMS and/or the NHS Community Pharmacy Seasonal Influenza Vaccination Advanced Service must ensure this service is listed on their NHS website profile. If it is not, their NHS website profile will need to be amended before making their PQS declaration so the relevant service information in their profile is included otherwise the contractor will not meet this gateway criterion. Distance selling pharmacies (DSPs) must ensure they include that they are offering either or both services in the email they send to the NHSBSA Provider Assurance Team to meet the NHS website gateway criterion (see the [distance selling pharmacies and the NHS website - section 3.3](#)).

3.2 NHSmail

Aim/Rationale

Pharmacy staff at the pharmacy must be able to send and receive NHSmail from their shared premises NHSmail account to facilitate secure sharing of patient confidential information to support clinical practice.

The PQS promotes the use of NHSmail to support integration amongst community pharmacy and other NHS providers, whilst providing a secure means of communicating sensitive patient data across the NHS, where required.

NHS England and NHS Improvement use NHSmail to communicate important messages to community pharmacy and the wider NHS system, providing information that is essential for the delivery of services in compliance with their contractual requirements.

Inactive NHSmail accounts are removed from the service, it is vital that pharmacies use their NHSmail address regularly if they want to be able to receive NHS referrals in the future.

Requirement

Contractors must have an active premises specific shared NHSmail account, enabling staff at that pharmacy to send and receive NHSmail emails through their linked user accounts.

Note: Premises specific means that there is one account per pharmacy; a contractor cannot use a premises specific NHSmail account to cover multiples premises.

Guidance on setting up, using and maintaining your account can be found in the [Guide for Community Pharmacies using NHSmail](#)³. Further helpful information can also be found on the [PSNC website](#)⁴.

Setting up a shared account includes the creation of up to three user accounts which will be used to access the shared account. Following registration for a shared NHSmail account via the [NHSmail registration portal](#)⁵, log in details will be issued for the user accounts so that they can be activated. Once activated they will allow constant access to the shared account.

To keep an NHSmail user account active it must be accessed at least every 90 days and the password must be changed every 365 days. This will prevent the account from becoming inactive and subsequently deleted, meaning it cannot be accessed.

Note: Contractors are encouraged to ensure that their accounts are active before the day of declaration to avoid finding their account(s) have been suspended / terminated when they come to make their declaration.

Contractors can now use the self-service password reset and unlock function. To use this function for unlocking and / or resetting, a mobile phone number must be included within the user account profile along with the associated security questions. A temporary password will be sent to the mobile number as part of the reset process.

IMPORTANT

Unless a contractor can send and receive emails from their premises specific shared NHSmail account and has two active user accounts, they **will not** meet the gateway criterion. Sending and receiving emails from a user NHSmail account **will not** be considered as having met the gateway criterion.

Each site must have a premises specific shared NHSmail account; this cannot be shared across two or more sites.

Note: Mobile phone numbers are automatically hidden from the [NHSmail directory of users](#). However you [can unhide your number](#) if you would like the phone number to appear in the directory.

Further information is available on [Passwords and Unlocks](#).

³ <https://s3-eu-west-1.amazonaws.com/comms-mat/Comms-Archive/Guide+for+Pharmacies.pdf>

⁴ <https://psnc.org.uk/contract-it/pharmacy-it/nhs-mail/>

⁵ <https://portal.nhs.net/pharmacyregistration#/>

Contractors who meet this gateway criterion will be validated by the NHSBSA against data from NHS Digital showing all shared NHSmail accounts. Contractors **will not** be required to provide the details of their shared NHSmail account in their declaration.

To ensure your premises specific NHSmail account is compliant with the PQS, the naming conventions below must be adhered to:

NHS pharmacy shared premises specific NHSmail account

Shared premises specific NHSmail accounts managed by the National Administration Service (NAS) inside the 'nhspharmacy' container will have the prefix 'nhspharmacy' and will follow the below naming convention: nhspharmacy.location.pharmacynameODScode@nhs.net

Shared premises specific NHSmail accounts that were created prior to the introduction of the NHS pharmacy naming convention typically include the prefix of the organisation that sponsored the creation of the account, i.e. the commissioning organisation that set the account up. These accounts are not supported by the NHS Digital pharmacy administration team; and support for these accounts cannot be guaranteed moving forwards.

As a result, for the PQS, shared legacy accounts will **not** meet the gateway requirement of having a shared premises NHSmail account. Contractors using legacy accounts will be required to register for a new shared premises specific NHSmail account using the [NHSmail Portal](#)⁶ to meet this gateway requirement.

Linked Accounts

Although a minimum of two active user accounts are required to meet this criterion, contractors can request up to ten user accounts to support the operation of the premises specific shared NHSmail account by contacting pharmacyadmin@nhs.net.

Contractors should be advised that the premises specific shared NHSmail account owner is responsible for the governance of the shared premises-specific account and should ensure that only persons that have a legitimate reason for accessing the premises specific shared NHSmail account have access rights (for example, accounts for members of staff and / or regular locum pharmacists).

The following are considered serious information governance breaches and will not meet the gateway criterion:

- **If a pharmacy is using an individual user account as a shared premises specific account.** (In such cases contractors will be required to register for a new shared premises specific NHSmail account using the [NHSmail portal](#)⁷)
- **Inappropriate access by an individual at the premises** – regular housekeeping of the shared premises specific NHSmail account is necessary to ensure the integrity of the account; and
- **If a shared premises specific NHSmail account was linked to the NHSmail account of a member of staff who is no longer working in the pharmacy.** To check the user accounts linked to the shared premises specific NHSmail account, please refer to the guidance available on the [NHSmail portal](#)⁸ where further information regarding pharmacy shared premises specific NHSmail accounts can also be found.

⁶ <https://portal.nhs.net/pharmacyregistration/>

⁷ <https://portal.nhs.net/pharmacyregistration/>

⁸ <https://portal.nhs.net/Help/joiningnhsmail>

A contractor can demonstrate that they have a shared premises NHSmail account by sending an email from the shared account to one or more of the linked user accounts on the day of the declaration. This email should then be saved so that it is accessible to resend to the Provider Assurance Team at the NHSBSA, if required, to demonstrate that the account meets the requirements of this criterion.

Contractors can check the validation report published on the NHSBSA website to ensure that they have met the NHSmail gateway criterion. Any problems or maintenance issues with pharmacy NHSmail accounts can be emailed to the helpdesk: pharmacyadmin@nhs.net. The main NHSmail helpdesk is also available by phone 24 hours a day, seven days a week on 0333 200 1133 or helpdesk@nhs.net.

3.3 The NHS Website: Update opening hours, facilities and services available

Aim/Rationale

To provide up-to-date accessible information to patients, the public and other health care professionals about pharmacy opening hours, facilities and services available.

Increasingly patients and the public are relying on the [NHS website](#)⁹ for accurate information on the opening hours, facilities and services that a pharmacy provides. Other NHS staff and organisations also rely on the NHS website information provided, for example in signposting patients to pharmacies or when planning out of hours service provision for an area.

This gateway criterion was designed to provide greater assurance that the information provided by pharmacies on the NHS website is accurate and so it is essential that any pharmacies declaring that they have met the gateway criteria have done so completely, in accordance with this guidance.

From April 2020, contractors will be required to conduct quarterly checks on their NHS website profile information as part of their Terms of Service. The updates are intended to reduce the burden on contractors, NHS Digital, local NHS England and NHS Improvement teams and Directory of Services (DoS) teams in establishing which contractors are open over the bank holidays for planning purposes, whilst providing accurate information on opening hours to the public.

Requirement

Contractors must update their NHS website profile(s) for services, facilities and opening hours, (including Easter Sunday 2020 and public and bank holiday opening hours for 2019/20, i.e. up to the Spring bank holiday in 2020), to ensure their information is accurate. This update/validation must be completed between 00:00 on 1 October 2019 and 23:59 on 30 November 2019 for the PQS 2019/20. This is to ensure that the information provided to the users of the NHS website is accurate and up-to-date for the Christmas period and the first quarter of 2020/21.

The opening hours published on the NHS website should be the hours that the pharmacy is providing NHS pharmaceutical services, i.e. their core and supplementary hours. The NHS website supports this requirement by allowing contractors to create up to three sets of opening times per day on their profile to allow for closing at lunchtime.

⁹ <https://www.nhs.uk/using-the-nhs/nhs-services/pharmacies/>

Where a pharmacy has scheduled breaks for their pharmacist and so are not providing NHS pharmaceutical services but may be providing other services, e.g. sales of other products, these must not be included in their NHS website opening hours section.

Additional opening hours of non-registered areas of a store, that are not core or supplementary hours, cannot be advertised on the NHS website, however they can be advertised in the pharmacy or locally, provided it is clear to the public that NHS pharmaceutical services are not available at these times. For example, a pharmacy opening between 09:00 to 17:00 with a lunch break for the pharmacist between 13:00 to 14:00 should set two sets of opening times as follows: 09:00-13:00 and 14:00-17:00.

Contractors are required to update or validate each of the following three parts of their NHS website profile:

- **Opening hours**

Including Easter Sunday 2020 and public and bank holiday opening hours for 2019/20, i.e. up to the Spring bank holiday in 2020.

- **Services the pharmacy provides**

Contractors making declarations to the NHSBSA that they are offering either the NMS or the NHS community pharmacy seasonal influenza vaccination service under the Advanced Services gateway criterion must ensure that the service is visible on their NHS website profile on the day of the declaration. The NHS community pharmacy seasonal influenza vaccination service is called seasonal flu vaccination service (at-risk groups) on the NHS website; the seasonal flu vaccination service (not at-risk groups) is used to denote a non-NHS, private flu vaccination service.

- **Facilities available**

This should include all the facilities available to support NHS services e.g. consultation rooms.

Contractors should note that this gateway criterion has been the most problematic for contractors to have demonstrated compliance in past quality schemes. A number of contractors could not be verified as they had not updated all three sections of their profile: opening hours, services provided and facilities available. Contractors are advised to check all three profiles have been updated or validated. Screen shots of the profiles showing the date of updating or validation should be kept for verification purposes.

Contractors should pay particular attention to this section to ensure they meet the validation requirements and do not put their PQS payment at risk; and note that the NHS website profile requirements need to be met ahead of the PQS declaration window i.e. between 00:00 on 1 October 2019 and 23:59 on 30 November 2019.

Contractors will be required to add opening hours for Easter Sunday 2020 and all of the bank holidays listed below to pass this gateway criterion, by creating a 'public holiday and other special dates' entry on their NHS website profile.

Wednesday, 25 December 2019	-	Christmas Day
Thursday, 26 December 2019	-	Boxing Day
Wednesday, 1 January 2020	-	New Year's Day
Friday, 10 April 2020	-	Good Friday
Sunday, 12 April 2020	-	Easter Sunday
Monday, 13 April 2020	-	Easter Monday
Friday, 8 May 2020	-	Early May bank holiday
Monday, 25 May 2020	-	Spring bank holiday

IMPORTANT:

The NHS website entry, including Easter Sunday 2020, and public and bank holiday opening hours, must be up-to-date.

Contractors should not validate their opening hours if they have not entered accurate Easter Sunday 2020 and public and bank holiday opening times. **Doing this will result in failing the NHS website gateway criterion** unless their opening hours for Easter Sunday 2020 and the above public and bank holidays are the same as their normal opening hours for those days.

Please note that a pharmacy must have updated all three sections of its NHS website profile between **1 October 2019 and 30 November 2019**. Therefore, any contractor entering the pharmaceutical list, either as a new pharmacy or as new owners of an existing listed pharmacy, after 30 November 2019 will not be eligible to take part in the PQS 2019/20.

If contractors do not add Easter Sunday and public and bank holiday opening times to their profiles, the NHS website will default to normal opening hours. Therefore, if a contractor has not amended their opening hours by entering them in the 'public holidays and other special dates' section, they may be advertising incorrect opening hours to patients and the public and will, therefore, be non-compliant with the gateway criterion.

The NHS website profile editor and the assignment of editing rights

Each non-DSP contractor can amend or validate their NHS website profile by using the NHS website profile editor. Guidance on how to do this is provided in the [Pharmacy Quality Scheme User guide](#)¹⁰. Amending or validating the NHS website profile will create a record which will act as evidence to NHS England and NHS Improvement that these actions have been undertaken.

To edit the NHS website profile, contractors will need to log into the [NHS website profile editor](#)¹¹ system on the NHS website personalisation page. Further information on managing provider profiles can also be found on the [NHS website provider management page](#)¹². Contractors who do not have editing rights to their profile will need to email the NHS website service desk (nhswebsite.servicedesk@nhs.net). Existing web editors, who have lost their password, can reset their passwords from the [NHS website](#)¹³ using the profile editor log-in.

Distance Selling Pharmacies and the NHS Website

Distance Selling Pharmacies (DSPs) do not, currently, have full NHS website entries, however work is ongoing to enable full profiles from 2020. NHS Digital will populate these profiles with the information that DSPs provide to the NHSBSA Provider Assurance Team. DSPs not taking part in the PQS will need to populate their profiles in 2020 when this becomes a requirement under the terms of service.

¹⁰ <https://assets.nhs.uk/prod/documents/Pharmacy-PQS-user-guide-for-February-2019-declaration.pdf>

¹¹ <https://www.nhs.uk/Personalisation/Login.aspx>

¹² <https://www.nhs.uk/about-us/manage-provider-profiles/>

¹³ <https://www.nhs.uk/Personalisation/ResetPassword.aspx>

The information that DSP will need to provide to meet the PQS NHS Website criterion is:

- a. confirm 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);
- b. confirm the telephone number and website URL on their profile;
- c. confirm the provision of EPS is correctly indicated on their profile;
- d. provide the opening hours for the pharmacy (including Easter Sunday 2020 and public and bank holiday opening hours for 2019/20 (see [requirement - section 3.3](#));
- e. list the services the pharmacy provides. Contractors making declarations to the NHS BSA that they are offering either the NMS or the Influenza Vaccination service under the Advanced Service gateway criterion must ensure that these services are included so that they can be included in the pharmacy profile; and
- f. list the facilities available. This should include all the facilities available to support NHS Services e.g. consultation rooms;

A spread sheet has been produced for the collation of the information a-f above. This is available on the [NHSBSA website](#)¹⁴ and is included in the Annexes as Annex 1. All three sections of Annex 1 (organisation details, opening times and services) need to be completed.

This information must be sent by email to the NHSBSA Provider Assurance Team (nhsbsa.pharmacysupport@nhs.net). The email must include “PQS FEB REVIEW” and the pharmacy ODS code in the subject line. For example, a DSP contractor with an ODS code AAA001 will need to submit an email with the subject line:

PQS FEB REVIEW AAA001

Failure to add the ODS code and “PQS FEB REVIEW” in the subject line will result in the email not being recorded in the summary report of DSP contractors that have achieved this gateway criteria, which will be provided to NHS England. This will mean that the contractor fails the validation process which will be undertaken by the NHS BSA.

DSPs will need to send their email with opening hours spreadsheet to nhsbsa.pharmacysupport@nhs.net between 00:00 on 1 October 2019 and 23:59 on 30 November 2019.

Where DSPs have informed the NHSBSA Provider Assurance Team that the information on the NHS website is correct or have provided the correct information for a previous declaration, they will still be required to email the NHSBSA Provider Assurance Team at nhsbsa.pharmacysupport@nhs.net as detailed above for the February 2020 declaration, as additional information is required (the opening hours, the services provided and the facilities available) for this declarations.

DSP contractors can check that they are listed as a DSP pharmacy in the DSP section of the NHS website by using the [internet pharmacy directory](#)¹⁵. Should any DSP contractor not be listed on the NHS website or find they are listed with a non-DSP community pharmacy profile, and not in the DSP section of the NHS website, they should email the NHS Provider Assurance

¹⁴ <https://www.nhsbsa.nhs.uk/pqs>

¹⁵ <https://www.nhs.uk/Service-Search/pharmacies/internetpharmacies>

Team at nhsbsa.pharmacysupport@nhs.net (including 'UNABLE TO VERIFY PROFILE' in the subject line) with the information in a) to f) above.

Once this information has been received by the NHS BSA Provider Assurance Team this will count as passing the gateway criteria. Contractors should retain a copy of the email sent as evidence of meeting this requirement.

Contractors should note that this gateway criterion has been the most problematic for contractors to have demonstrated in past quality schemes. DSPs have not been verified where they have been unable to provide evidence of an email being sent to nhsbsa.pharmacysupport@nhs.net with confirmation of their profile details.

3.4 Safeguarding Training

Aim/Rationale

Pharmacy professionals should be confident that they would be able to recognise the signs and signals that might indicate potential abuse or risk of harm; and know what action to take if any such abuse or risk of harm was suspected.

NHS England and NHS Improvement are dedicated in ensuring that the principles and duties of safeguarding children, young people, and adults at risk are holistically, consistently and conscientiously applied with the wellbeing of all, at the heart of what we do.

Requirement

80% of all pharmacy professionals (inclusive of pharmacists, pharmacy technicians and locum pharmacists) have completed and passed Level 2 Safeguarding training within two years of the day of the declaration, to ensure maintenance of their knowledge of their role in safeguarding vulnerable adults and children. They should confidently know what to look out for and what actions to take should safeguarding concerns arise.

IMPORTANT:

While the target for achievement of this criterion is set at 80% of registered pharmacy professionals, best practice suggests all staff, including pre-registration graduates, should undergo safeguarding training.

Level 2 safeguarding training is available to all pharmacy professionals registered with the General Pharmaceutical Council (GPhC) via the CPPE website.

Each registered pharmacy professional working in the pharmacy on the day of declaration count as one regardless of how many hours worked. A pharmacy with five registered pharmacy professionals working in the pharmacy will need to ensure that at least four of them have completed a level 2 safeguarding course and have the certification to demonstrate this.

Level 2 safeguarding training may also be available (or have been previously provided) via local training sessions organised by CCGs, NHS England and NHS Improvement, local authorities or other providers, including in-house training. Staff should retain proof that they have completed the training (such as a certificate of completion). Where no suitable evidence is provided, staff should complete the CPPE e-assessment and gain evidence of having acquired the necessary knowledge to meet the level 2 requirements. Contractors should ensure that evidence of this training is kept within the pharmacy.

All those that wish to complete the training via CPPE must be registered on the [CPPE website](#)¹⁶ and logged into their account.

Once the training and associated e-assessment has been completed, a certificate of completion is stored by CPPE in a personal learning record for each learner. Pharmacy professionals can download the certificate to provide evidence of completion. For staff who completed their training with CPPE previously, certificates of completion can also be found in their personal record.

Training must have been completed within two years of the day of declaration to be considered up-to-date and contractors will be required to declare this via the NHSBSA's MYS application.

¹⁶ <https://www.cppe.ac.uk/mycppe/login>

4. Quality Criteria

Pharmacies passing all of the gateway criteria on the day of the declaration will receive a PQS payment if they meet one or more of the domains in [Table 2](#).

Table 2: Quality Criteria

A summary of the quality criteria and point weighting for each domain

IMPORTANT:

Contractors must meet all of the quality criteria in each domain to be eligible for a PQS payment. The PQS payment will depend on how many of the domains the pharmacy meets.

Domain	Quality Criteria	Points
Risk management and safety	<p>On the day of the declaration, 80% of all registered pharmacy professionals working at the pharmacy to have satisfactorily completed the CPPE risk management training and assessment.</p> <p>And</p> <p>On the day of the declaration, 80% of all registered pharmacy professionals working in the pharmacy have satisfactorily completed the CPPE sepsis online training and assessment, can demonstrate that they can apply the learning to respond in a safe and appropriate way when it is suspected that someone has sepsis, and demonstrably ensure all patient-facing staff have understood alert symptoms to ensure referral of suspected sepsis to a pharmacist.</p> <p>And</p> <p>On the day of the declaration, the pharmacy has available, at premises level, an update of the previous risk review undertaken as part of the 2018/19 Quality Payments Scheme (QPS), i.e. updated since the last review date of 15 February 2019, that the pharmacy team at the premises had drawn up for a risk in that pharmacy. This update must include a recorded reflection on the identified risk and the risk minimisation actions that the pharmacy team has been taking and any subsequent actions identified as a result of the reflection. The risk review should include the risk of missing sepsis identification as a new risk as part of the review and record demonstrable risk minimisation actions that have been undertaken to mitigate the risk.</p> <p>Note: Pharmacies that did not claim for the risk management quality criterion previously, who wish to claim for the PQS 2019/20, must have a risk review containing two identified risks, including the risk of missing sepsis as above, as part of completion and claiming for this domain.</p>	30

	<p>And On the day of the declaration, 80% of all registered pharmacy professionals working at the pharmacy to have satisfactorily completed the CPPE reducing look-alike, sound-alike (LASA) errors e-learning and assessment.</p> <p>And On the day of the declaration, pharmacies must have a new written safety report (i.e. new since 15 February 2019 (the last review date) or covering the last year if not previously claimed) at premises level available for inspection from the day of the declaration covering analysis of incidents and incident patterns (taken from an ongoing log), evidence of sharing learning locally and nationally, and actions taken in response to national patient safety alerts.</p> <p>Demonstrable learnings from the CPPE LASA e-learning should also be incorporated into the safety report. This should include a review of, and subsequent actions, where mitigation taken has failed to prevent a LASA incident or LASA near miss from occurring.</p> <p>Demonstrably, the pharmacy contractor actively identifies and manages the risks at premises level associated with the specified LASA medicines identified from the National Reporting and Learning System (NRLS)*.</p> <p>Demonstrably, the pharmacy contractor has put in place actions to prevent these risks, for example, physical separation, staff awareness raising, visual warnings, tags or labels on shelving, fatigue reduction strategies or enhanced checking procedures for these medicines.</p> <p>There must be demonstrable evidence of all actions identified in the patient safety report having been implemented.</p> <p>Demonstrably, the pharmacy contractor uploads any LASA incident reports to the NRLS and keeps a record for confirmation of this activity at the pharmacy premises or within any electronic reporting system used by the contractor. In the description of what happened in the NRLS report, the contractor must include the text 'LASA' as a unique identifier to facilitate future national learning.</p> <p>*NHS Improvement top combinations by likelihood and harm caused - propranolol and prednisolone, amlodipine and amitriptyline, carbamazepine and carbimazole, rivaroxaban and rosuvastatin, atenolol and allopurinol.</p>	
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Domain	Quality Criteria	Points
<p>Medicines safety audits complementing General Practice (GP) Quality and Outcomes Framework (QOF) Quality Improvement (QI) module</p>	<p>On the day of the declaration the pharmacy must have completed a lithium audit, over three consecutive months, aligned with requirements of the National Patient Safety Agency (NPSA) alert on lithium. A link to the NPSA alert is available in the lithium audit section 4.2.1(a) of this NHS England & NHS Improvement Pharmacy Quality Scheme 2019/20 guidance for all patients prescribed lithium. Further details of the required questions to be asked and the details to be recorded can be found in Annex 6 of this NHS England & NHS Improvement Pharmacy Quality Scheme 2019/20 guidance.</p> <p>Before starting the audit, the contractor must check their PMR prior to choosing the consecutive three-month period for the audit to verify whether they have had any ongoing patients to whom they have dispensed lithium in the preceding three months. If the pharmacy has no patients who have had lithium dispensed from the pharmacy in the previous three months, the contractor must complete a safety audit of patients prescribed one of the following medicines instead, in the following order of preference: either methotrexate; amiodarone; or phenobarbital, which are in line with alternatives suggested in the GP QOF QI Prescribing Safety Module (please note that the same process for identifying if the pharmacy has any patients on lithium should be applied for identifying if the pharmacy has any patients on methotrexate, amiodarone or phenobarbital).</p> <p>And</p> <p>On the day of the declaration, contractors should have implemented, into their day-to-day practice, the findings and recommendations from the previous clinical audit on NSAIDs prescribed for those aged 65 years and above without gastroprotection, undertaken as part of the QPS for the February 2019 review point; the link for the report can be found in the NSAIDs section 4.2.4 of this NHS England & NHS Improvement Pharmacy Quality Scheme 2019/20 guidance. The pharmacy must then repeat the updated audit of NSAIDs and gastroprotection for all patients 65 years and over (the link for the updated audit is available in the NSAIDs section 4.2.4 this NHS England & NHS Improvement Pharmacy Quality Scheme 2019/20 guidance including notifying the patient's GP where concerns are identified, sharing their anonymised data with NHS England & NHS Improvement, and incorporating any learning from the re-audit into future practice.</p> <p>Note: Pharmacies that did not claim for the NSAIDs audit quality criterion previously, i.e. at the last review date of 15 February 2019, and wish to claim for this criterion for the PQS 2019/20 as part of claiming for this domain, must complete the NSAIDs audit for the first time and complete the other elements as described above.</p> <p>Submission of information to NHS England & NHS Improvement should be reported on the Manage Your Service (MYS) application for all of the above audits.</p>	25

Domain	Quality Criteria	Points
Prevention	<p>On the day of the declaration, the pharmacy is a Healthy Living Pharmacy level 1 (self-assessment).</p> <p>And</p> <p>On the day of the declaration, all patient-facing staff are Dementia Friends (Alzheimer's Society).</p> <p>And</p> <p>On the day of the declaration, the pharmacy has completed a specified dementia-friendly environment checklist available in Annex 11 of this NHS England & NHS Improvement Pharmacy Quality Scheme 2019/20 guidance in relation to the registered pharmacy premises and created an action plan which includes making some demonstrable recorded changes to the environment in line with the checklist, as appropriate.</p> <p>And</p> <p>On the day of the declaration, the pharmacy must confirm that the pharmacy checked that all patients with diabetes, who presented from 1 October 2019 to 31 January 2020, have had foot and eye checks (retinopathy) in the last 12 months– (please note, eye checks are only for patients with diabetes aged 12 or over). The pharmacy must have recorded the patient's response on the PMR or appropriate form/patient record and signposted/referred patients as appropriate. This record should set out the total number of patients who have had this intervention, the number that have not had one or either check in the last 12 months, and it should be recorded where they have been appropriately signposted/referred and reported as part of this criterion.</p> <p>And</p> <p>On the day of the declaration, pharmacies (the registered pharmacy premises) must have either achieved that the sales by the pharmacy of Sugar Sweetened Beverages (SSB) account for no more than 10% by volume in litres of all beverages sold or must declare that they will be meeting this criterion by 31 March 2020.</p> <p>For the definition of added sugar see Annex B in the following link - https://www.england.nhs.uk/wp-content/uploads/2017/04/sugar-action-doc.pdf.</p>	25

Domain	Quality Criteria	Points
Primary Care Networks (PCNs)	<p>On the day of the declaration, the pharmacy must be able to demonstrate that their pharmacy, and all of the other pharmacies within the Primary Care Network (PCN) footprint who wish to engage with a PCN, have agreed a collaborative approach to engaging with their PCN. This approach must include agreement on a single channel of communication by appointing a named lead representative for all of the community pharmacies who wish to engage with their PCN in the PCN footprint. The Pharmacy PCN Lead must have provided their name to the Local Pharmaceutical Committee (LPC) in which the PCN lies and must have demonstrable evidence that they have started the engagement process with the PCN, i.e. they have made initial contact with the Clinical Director for the PCN either by contacting them through correspondence (post/email) or by arranging a meeting with them or by meeting them.</p> <p>All pharmacies claiming for this domain must submit the name of their appointed Pharmacy PCN Lead and the pharmacy name and ODS code for the Pharmacy PCN Lead as described in PCNs section 4.4 of this NHS England and NHS Improvement Pharmacy Quality Scheme 2019/20 guidance</p> <p>The Pharmacy PCN Lead must declare:</p> <ul style="list-style-type: none"> - that they are the appointed Pharmacy Lead for that PCN; - the name of the PCN; - that they have notified this to the LPC in which the PCN lies; and - that they have evidence of having started the engagement process with the PCN, as outlined above. 	<p>22.5 – PCN lead</p> <p>12.5 – non-PCN lead</p>
Asthma	<p>On the day of the declaration, the pharmacy can show evidence that patients with asthma, for whom more than 6 short-acting bronchodilator inhalers were dispensed without any corticosteroid inhaler within a 6 month period have, since the last QPS review point (i.e. 15 February 2019), been referred to an appropriate healthcare professional for an asthma review; and can evidence that they have ensured that all children aged 5-15 years old prescribed an inhaled corticosteroid for asthma have a spacer device where appropriate in line with NICE TA38 and have a personalised asthma action plan. The pharmacy must be able to show that they have referred patients with asthma to an appropriate healthcare professional where this is not the case.</p>	<p>5</p>
Digital enablers	<p>On the day of the declaration, the pharmacy must have updated its NHS 111 DoS profile via the DoS updater, including its opening hours for Easter Sunday 2020 and public and bank holidays including Christmas Day 2019, Boxing Day 2019, New Year's Day 2020, Good Friday 2020, Easter Monday 2020, Early May bank holiday 2020 and Spring bank holiday 2020, and must promptly update its profile as information changes, to ensure information is accurate for real time referrals, e.g. from NHS 111 providers. The update window for the February 2020 declaration is between 00:00 on 1 October 2019 and 23:59 on 30 November 2019.</p> <p>And</p> <p>On the day of the declaration, the pharmacy can demonstrate access to SCR by having accessed the SCR between 00:00 on 1 October 2019 and the day of the declaration.</p>	<p>2.5</p>

4.1 Domain: Risk Management and Safety

Significant progress has been made to date on developing the safety culture of community pharmacy supported by the Community Pharmacy Patient Safety Group (CPPSG) and incentivised, in part, through the QPS. The QPS has facilitated a more structured approach to development of the safety culture in many pharmacies through the written patient safety report, risk mitigation training and action plan; and through the work to prevent LASA dispensing errors. The Risk Management and Safety domain requires contractors to build on the work undertaken in previous years whilst adding training and assessment on sepsis; and the risk of missing sepsis identification is added as a new risk for 2019/20.

4.1.1 CPPE Risk Management training

Aim/Rationale

The aim of this quality criterion is to ensure that all pharmacy professionals understand the risks associated with their professional practice and how to mitigate the risks in their workplace.

Managing risk is an important part of the General Pharmaceutical Council's (GPhC) standards for pharmacy professionals.

Reporting

The CPPE risk management guide and assessment was included in the 2018/2019 Quality Payments Scheme. If you completed the guide and the assessment in 2018/2019 then you do not need to repeat this.

If pharmacy professionals have completed the previous version of the CPPE learning and e-assessment on risk management then they do not need to complete the new learning programme. However, pharmacy professionals may wish to complete the new learning programme to update their knowledge in areas not covered by the old programme.

Completion of the e-assessment will also allow pharmacy professionals to prove their ongoing competence in this important area of practice and provide them with the self-assurance that their knowledge is up-to-date and in line with current legislation.

On the day of the declaration, 80% of all registered pharmacy professionals working at the pharmacy must have satisfactorily completed the [CPPE risk management training](#)¹⁷. Following the completion of the training, the [CPPE e-assessment](#)¹⁸ must be successfully completed to meet this quality criterion.

This requirement covers the registered pharmacy professionals working at the pharmacy on the day of the declaration. (See [Training Requirements in section 4.1.5](#))

4.1.2 CPPE sepsis training and assessment

Aim/ Rationale

The aim of the CPPE sepsis training is to ensure that pharmacy professionals and their teams are aware of the increasing morbidity and mortality associated with sepsis and can identify red flags and give appropriate safety netting advice where sepsis is a risk.

¹⁷ <https://www.cppe.ac.uk/programmes//riskman-g-02/>

¹⁸ <http://www.cppe.ac.uk/programmes//riskmang-a-02/>

Sepsis training is particularly important given the introduction of the Community Pharmacist Consultation Service.

Both a [UK Parliamentary and Health Service Ombudsman enquiry \(2013\)](#)¹⁹ and a [UK National Confidential Enquiry into Patient Outcome and Death \(NCEPOD, 2015\)](#)²⁰ highlighted sepsis as being a leading cause of avoidable death that kills more people than breast, bowel and prostate cancer combined. Community pharmacy can play a key role in ensuring that patients with sepsis are appropriately referred and help to ensure that patients are provided with treatment in a timely manner.

Reporting

On the day of the declaration, 80% of all registered pharmacy professionals working in the pharmacy have satisfactorily completed the CPPE sepsis online training and assessment; and must be able to demonstrate that they can apply the learning to respond in a safe and appropriate way when it is suspected that someone has sepsis. Pharmacy teams must demonstrably ensure all patient-facing staff have understood alert symptoms to ensure referral of suspected sepsis to a pharmacist.

The CPPE sepsis online training consists of six short case studies on the topic of sepsis. Each case is in a different setting, but all are relevant to pharmacy practice.

Please note, pharmacy professionals are required to complete all of the following six case studies which can be accessed via the [CPPE sepsis gateway page](#)²¹.

- Sepsis 1: Early recognition of Sepsis – Community Setting
- Sepsis 2: Early recognition of Sepsis – Hospital Setting
- Sepsis 3: Early recognition of Sepsis – General Practice Setting
- Sepsis 4: Early recognition of Sepsis – Children
- Sepsis 5: Early recognition of Sepsis – Pregnancy
- Sepsis 6: Early recognition of Sepsis – Care Home Setting

Following the completion of the case studies, the [CPPE e-assessment](#)²² must be successfully completed to meet this quality criterion.

This requirement covers the registered pharmacy professionals working at the pharmacy on the day of the declaration. (See [Training Requirements in section 4.1.5](#))

4.1.3 Risk Review update

Aim/Rationale

The aim of this element of the domain is to help pharmacy teams to identify risks within their pharmacy and to demonstrate how the learning from the risk management training has been applied to reduce potential for harm to patients.

Reporting

On the day of the declaration, the pharmacy must have available, at premises level, an update of the previous risk review undertaken as part of the 2018/19 Quality Payments Scheme, i.e. updated since the last review date of 15 February 2019, that the pharmacy team at the premises

¹⁹ <https://www.ombudsman.org.uk/publications/time-act-severe-sepsis-rapid-diagnosis-and-treatment-saves-lives-0>

²⁰ <https://www.ncepod.org.uk/2015sepsis.html>

²¹ <https://www.cppe.ac.uk/gateway/sepsis>

²² www.cppe.ac.uk/programmes//sepsis-a-01/

had drawn up for a risk in that pharmacy. Contractors may wish to use the 'reflecting on your previous risk review' template in **Annex 2**.

This update must include a recorded reflection on the identified risk and the risk minimisation actions that the pharmacy team has been taking and any subsequent actions identified as a result of the reflection.

The risk review should also include the risk of missing sepsis identification as a new risk as part of the review and contractors must record demonstrable risk minimisation actions that have been undertaken to mitigate the risk. It is recommended that pharmacy professionals complete the CPPE Sepsis training prior to completing the risk review on sepsis. Contractors may wish to use the risk review templates in **Annex 3**.

Note: Pharmacies that did not claim for the risk management quality criterion previously, who wish to claim for the PQS 2019/20, must have a risk review containing two identified risks, including the risk of missing sepsis as above, as part of completion and claiming for this domain.

4.1.4 CPPE reducing look-alike, sound alike errors (LASA) training and assessment

IMPORTANT:

Contractors already have a contractual requirement to report patient safety incidents to the NRLS. When LASA incidents are reported to NRLS directly or via other systems, within the description of the incident, 'LASA' should be included. This will enable NHS Improvement to search for LASA-related reports and information so that learning from such incidents can be maximised.

Aim/Rationale

Look-alike, sound-alike errors are one of the most common causes of medication errors worldwide. [NHS Improvement](#), the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) and the [World Health Organization](#) have all highlighted LASA errors as a key threat to patient safety.

Community pharmacy teams have a key role to play in this area of patient safety and the aim of this element of the composite bundle is to ensure that all pharmacy professionals understand what a LASA error is, where and why LASA errors occur, how LASA errors can be prevented and how to develop a LASA action plan by putting measures in place to minimise risk and improve patient safety.

Reporting

On the day of the declaration, 80% of all registered pharmacy professionals working at the pharmacy to have satisfactorily completed the [CPPE reducing look-alike, sound-alike \(LASA\) errors e-learning](#)²³.

Following completion of the LASA training, the associated [e-assessment](#)²⁴ must be successfully completed to meet this quality criterion.

²³ www.cppe.ac.uk/programmes//safetylasa-e-01/

²⁴ <http://www.cppe.ac.uk/programmes//safetylasa-a-01/>

This requirement covers the registered pharmacy professionals working on the day of the declaration (See [Training Requirements in section 4.1.5](#))

4.1.5 Written Safety Report

Aim/Rationale

The aim of this criterion is to develop a safety culture in community pharmacy, ensuring errors and near misses are recorded and learnt from and actions are taken to prevent future harm.

Reporting

On the day of the declaration, pharmacies must have a new written safety report (i.e. new since 15 February 2019 or the last review date or covering the last year if not previously claimed) at premises level available for inspection from the day of the declaration covering analysis of incidents and incident patterns (taken from an ongoing log), evidence of sharing learning locally and nationally, and actions taken in response to national patient safety alerts.

Contractors who claimed for this criterion in a previous declaration will not be able to use the same patient safety report to make a claim in the February 2020 declaration.

Contractors may wish to use the template in **Annex 4** to collate and review patient safety incidents each month. Contractors can use the output of these forms to complete their annual report. **Annex 5** is a template that can be used to create this report.

The new safety report will need to show how the following details have been updated since the previous patient safety report was completed:

- collated incidents and near misses from an ongoing log;
- analysis of the incidents and near misses and have looked for patterns;
- reflected on learning from these incidents and near misses;
- recorded action taken to minimise future risk from repeated errors;
- shared learning (both nationally and locally); and
- evidenced specific actions taken by the pharmacy in response to local errors and national patient safety alerts issued by the [Central Alerting System](#)²⁵.

Demonstrable learnings from the CPPE LASA e-learning should also be incorporated into the safety report. This should include a review of, and subsequent actions, where mitigation taken has failed to prevent a LASA incident or a LASA near miss from occurring.

The pharmacy contractor must be able to demonstrate having actively identified and managed the risks at premises level associated with the specified LASA medicines identified from the National Reporting and Learning System (NRLS) as shown below:

²⁵ <https://www.cas.mhra.gov.uk/Home.aspx>

Propranolol	+	Prednisolone
Amlodipine	+	Amitriptyline
Carbamazepine	+	Carbimazole
Rivaroxoban	+	Rosuvastatin
Atenolol	+	Allopurinol

These pairs have been identified from Coroners' reports and/or the National Reporting and Learning System (NRLS). Incidents involving these pairings are reported with considerable frequency, have been associated with serious harm and the medications are pharmacologically disparate.

The pharmacy contractor must be able to demonstrate that actions have been put in place to prevent these risks, for example, physical separation, staff awareness raising, visual warnings, tags or labels on shelving, fatigue reduction strategies or enhanced checking procedures for these medicines.

There must also be demonstrable evidence of all actions identified in the patient safety report having been implemented.

The pharmacy contractor should upload any LASA incident reports to the NRLS and keep a record for confirmation of this activity at the pharmacy premises or within any electronic reporting system used by the contractor. In the description of what happened in the NRLS report, the contractor must include the text 'LASA' as a unique identifier to facilitate future national learning. Including in the incident description details of the actions that had been in place in the pharmacy to prevent LASA errors from occurring will help inform learning about the mitigation used in community pharmacy to prevent these errors.

Contractors already have a contractual requirement to report patient safety incidents to the NRLS. This can be done via the e-form following guidance on the [PSNC website](#)²⁶, and some contractors collate reports via corporate systems, which then report centrally to NRLS. Copies of patient safety incident reports made by a pharmacy to NRLS or to corporate or other incident reporting systems should be retained by the contractor.

Training Requirements

The training requirements for the CPPE training criteria: Risk Management, Sepsis and Reducing Look-Alike, Sound Alike errors (LASA) must be completed by 80% of the registered pharmacy professionals (including pharmacists, pharmacy technicians and locums) working in the pharmacy on the day of the declaration. To access the training, visit the [CPPE PQS page](#)²⁷.

It is good practice for pre-registration trainee pharmacists and pre-registration trainee pharmacy technicians to complete the training.

Each registered pharmacy professional working in the pharmacy on the day of the declaration counts as one, regardless of how many hours worked.

²⁶ <https://psnc.org.uk/contract-it/essential-service-clinical-governance/patient-safety-incident-reporting/>

²⁷ <https://www.cppe.ac.uk/services/pharmacy-quality-scheme>

Once the training and associated e-assessments have been completed, a certificate of completion is stored by CPPE in the personal learning record for each learner. Pharmacists and pharmacy technicians can download the certificate to provide evidence of completion.

Contractors should ensure that evidence of this assessment is kept within the pharmacy, including for any locums.

4.2 Domain: Medicines safety audits complementing General Practice (GP) Quality and Outcomes Framework (QOF) Quality Improvement (QI) module

Aim

The aim of these audits is to reduce the risk of harm to patients who are prescribed medicines which provide effective treatment and can have a high risk of causing harm.

Rationale

In 2017, The World Health Organization (WHO) launched a [Global Patient Safety Challenge](#)²⁸ relating to medication safety. The challenge focuses on improving medication safety by strengthening systems to reduce medication errors; its over-arching aim is to reduce the level of severe avoidable harm related to medications by 50% over five years, globally.

Dispensing over one billion prescription items each year, medicines safety is an important quality improvement focus for community pharmacy. By complementing the prescribing safety audits introduced in the new GP contract, there will be opportunity for community pharmacies and general practices across England to work together to reduce the risk of patient harm.

Dispensing over one billion prescription items each year, medicines safety is an important area of focus for Quality Improvement for community pharmacy. By complementing the prescribing safety audits introduced in the new GP contract there will be opportunity for community pharmacies and general practices across England to work together to reduce the risk of patient harm.

[‘Investment and evolution: A five-year framework for GP contract reform to implement The NHS Long Term Plan’](#)²⁹ published in January 2019 introduced the creation of two Quality Improvement modules within a new quality improvement domain. The module on prescribing safety highlighted that it would dovetail with a number of changes including the Quality Payments Scheme, now called the Pharmacy Quality Scheme and work on the nationally backed roll out of the pharmacist-led information technology intervention for medical errors (such as PINCER).

Pharmacies intending on completing the audits in this domain should seek to discuss this with their local GP practices to enable collaborative working for the benefit of patients. This will provide an opportunity for a coordinated approach to reducing patient harm in primary care which may lead to more collaborative working now and in the future.

4.2.1 (a) Lithium Audit

Aim

The aim of this audit is to reduce harm associated with lithium. This will be achieved by improving lithium monitoring and patient understanding through a focus upon auditing patient medication records, engagement of patients and referral to general practice or the prescriber, as appropriate.

²⁸ <https://www.who.int/patientsafety/medication-safety/medication-without-harm-brochure/en/>

²⁹ <https://www.england.nhs.uk/publication/gp-contract-five-year-framework/>

Rationale

In 2009, the National Patient Safety Agency (NPSA) issued the '[Patient Safety Alert NPSA 2009/PSA005 Safer lithium therapy](#)'.³⁰ This described a number of alert actions by all organisations in the NHS and independent sector where lithium therapy is initiated, prescribed, dispensed and monitored. Lithium continues to be a medicine with a high risk of harm to patients.

[NICE guidance Bipolar disorder: assessment and management, NICE \(2014\)](#)³¹ sets out the requirements for patients to be monitored in primary care.

Full details of the NPSA alert and the most recent NICE guidance can be found via the hyperlinks above. It is recommended that both are reviewed and information shared with relevant members of the pharmacy team before commencing the audit.

To ensure that the contractor is able to meet the requirements of this quality criterion as part of this domain, they are required to check their PMR prior to choosing the consecutive three-month period for the audit to verify whether they have had any ongoing patients to whom they have dispensed lithium in the preceding three months. If the pharmacy has no patients who have had lithium dispensed from the pharmacy in the previous three months, the contractor must complete a safety audit of patients prescribed one of the following medicines instead in the following order of preference: methotrexate, amiodarone **or** phenobarbital.

The audit should only include each patient once during the audit period, e.g. during the consecutive three-month audit period if a patient has their lithium dispensed on three occasions the information should only be recorded once as part of the audit.

For all patients that do not attend the pharmacy to collect their lithium, attempts should be made for this discussion to occur via other means, e.g. a phone conversation. Where such attempts have failed this must be recorded on the PMR, or appropriate patient record.

A lithium treatment pack should have been given to patients by the prescriber on initiation of treatment with lithium. The pack consists of a patient information booklet, lithium alert card, and a record book for tracking serum-lithium concentration. All patients should be asked to bring their lithium record book to the pharmacy when they collect their lithium.

Patients should not be refused a supply of their lithium if they do not have their lithium record book with them but the importance of bringing it with them in future should be emphasised. Information on where to purchase lithium treatment packs can be found in the [BNF](#)³².

In line with the above NPSA alert and NICE guidance all patients prescribed lithium should be asked if they have had the relevant blood tests and checks during the specified periods. It is recognised that not all patients may know or remember what all their tests are specifically for, in these cases, it is sufficient that the patient is able to describe that they have/have not had blood tests related to their lithium during the recommended timeframes above. Where a patient is uncertain or does not know whether they have had the relevant tests as described in the NICE guidance, this should be recorded as 'doesn't know' on the data collection table and the patient

³⁰ <https://www.sps.nhs.uk/wp-content/uploads/2018/02/2009-NRLS-0921-Safer-lithium-treatment-2010.01.12-v1.pdf>

³¹ <https://www.nice.org.uk/guidance/cg185/chapter/1-Recommendations#recognising-and-managing-bipolar-disorder-in-adults-in-primary-care-2>

³² <https://bnf.nice.org.uk/drug/lithium-carbonate.html#patientAndCarerAdvice>

should be asked to contact their GP practice or prescriber to find out when their next tests are due. In all cases, the reasons for and importance of tests should be discussed with the patient helping to interpret and personalise for them, the relevant section of the patient information booklet which was provided as part of their lithium treatment pack.

Additionally, if pharmacies do not already have a record of the following information being previously discussed with the patient, they should ask all patients prescribed lithium whether they can describe:

- the signs of lithium toxicity e.g. upset stomach;
- how to prevent toxicity, e.g. adequate fluid intake especially if exercising heavily; and
- what to do if they miss one or more doses.

Discussions should be patient-centred and support the identification of any gaps in understanding or misunderstanding the patient may have. If the patient is unable to describe the above, this information should be discussed with them to improve patient safety and support shared decision making. Whether the patient did/did not know this information should be recorded.

Dehydration and electrolyte imbalance can lead to lithium toxicity. It is essential to provide advice on maintaining adequate fluid intake during exercise, particularly if a patient increases the level of exercise following advice. It is also essential to provide advice relating to safe alcohol consumption for the same reasons. Weight gain is a potential side-effect of lithium and patients should be provided with advice on maintaining a healthy diet.

An assessment of the patient's understanding of the need to seek professional advice before taking non-prescribed medicines, e.g. over the counter (OTC), including herbal remedies or supplements, should take place. The pharmacy team should ensure the patient/carer fully understands the importance of this.

To support this audit a table of questions can be found in **Annex 6**. This table includes an option to record patient initials to support the pharmacy to avoid duplication of patients during the audit period. All audit records should be kept at the pharmacy and be available for at least 2 years for assurance purposes.

Reporting

On the day of the declaration, pharmacies will be required to submit the audit data on the MYS portal based on the total numbers of patients taking lithium and their answers in accordance with the table of questions in **Annex 6**. It is essential that pharmacies accurately record and capture the following audit data for submission and that **no patient identifiable data is submitted**.

- The start and end date of the audit period to enable confirmation of patient numbers against dispensing data, as well as to demonstrate that the audit was completed over a consecutive three-month period.
- Total number of patients dispensed lithium during the audit period, avoiding repetition of patients.
- Total number of patients (or patient representatives if appropriate) that have:
 - o agreed to discuss their lithium with the pharmacist/pharmacy team;
 - o declined to discuss their lithium with the pharmacist/pharmacy team.
- Total number of patients who:

- have a lithium record book;
- do not have a lithium record book.
- Total number of patients who reported that they have
 - had their lithium levels checked in the last 3 or 6 months, as appropriate;
 - not had their lithium levels checked in the last 3 or 6 months, as appropriate;
 - did not know if they have had their lithium levels checked in the last 3 or 6 months, as appropriate.
- Total number of patients who reported that they:
 - have had all the appropriate blood tests in the last 6 months (kidney and thyroid function and calcium levels);
 - have not had all the appropriate blood tests in the last 6 months (kidney and thyroid function and calcium levels);
 - they don't know if they have had all the appropriate blood tests in the last 6 months (kidney and thyroid function and calcium levels).
- Total number of patients who reported they have:
 - had their body mass index (BMI) or weight measured in the last 6 months;
 - have not had their body mass index (BMI) or weight measured in the last 6 months;
 - they don't know if they have had their body mass index (BMI) or weight measured in the last 6 months.
- Total number of patients who:
 - could describe the signs of lithium toxicity (e.g. upset stomach);
 - could not describe the signs of lithium toxicity (e.g. upset stomach).
- Total number of patients who:
 - could describe how to prevent lithium toxicity (e.g. adequate fluid intake especially if exercising heavily);
 - could not describe how to prevent lithium toxicity (e.g. adequate fluid intake especially if exercising heavily).
- Total number of patients who:
 - could describe the appropriate actions to take if they miss one or more doses;
 - could not describe the appropriate actions to take if they miss one or more doses;
- Total number of patients who were provided with general healthy living advice and the topic(s) of this advice:
 - Diet;
 - Exercise;
 - Alcohol;
 - Smoking.
- Total number of patients who:
 - know they should not take non-prescribed medicines, e.g. over the counter (OTC), including herbal remedies or supplements, without first seeking advice from a pharmacist or doctor;
 - who did not know they should not take non-prescribed medicines, e.g. over the counter (OTC), including herbal remedies or supplements, without first seeking advice from a pharmacist or doctor.
- Total number of patients who were referred to their GP or prescriber.
- Total number of patients/patient representatives who were provided with relevant advice when they answered "No" or "Don't know" to any of the above questions (except where they have declined to discuss their medicine).

The following must be recorded on the PMR, or appropriate patient record; the patient reported they:

- have had the relevant tests (as above) during the specified periods, **or**
- have not had the relevant tests (as above) during the specified periods, **or**
- did not know if they have had the relevant tests (as above) during the specified periods, **and**
- if the patient was referred as appropriate

For all patients that do not attend the pharmacy to collect their lithium attempts should be made for this discussion to occur. Where attempts have failed this must be recorded on the PMR, or appropriate patient record.

4.2.1 (b) Methotrexate Audit

IMPORTANT:

The methotrexate audit should only be completed if the pharmacy has:

- not dispensed lithium in the three months before they intend to start the audit; AND
- the pharmacy does not expect to have any prescriptions for lithium during the audit period; AND
- the pharmacy has previously dispensed methotrexate AND expects to dispense methotrexate during the audit period.

Aim

The aim of this audit is to reduce harm associated with oral methotrexate. This will be achieved by improving methotrexate monitoring and patient understanding through a focus upon auditing patient medication records, engagement of patients and referral to general practice or the prescriber, as appropriate.

Rationale

The NPSA alert [Improving compliance with oral methotrexate guidelines](https://www.sps.nhs.uk/articles/npsa-alert-improving-compliance-with-oral-methotrexate-guidelines)³³ highlighted that one of the main reasons for patient harm when taking methotrexate is taking methotrexate daily instead of weekly. To reduce the incidence of harm to patients they made a number of recommendations on initiation of treatment with methotrexate.

The full details of the alert can be read at the above link and it is recommended that this is read in full before starting the audit.

[NICE](https://www.nice.org.uk/guidance/CG146)³⁴ recommend the following monitoring for patients aged 18 years and above:

In view of reports of blood dyscrasias (including fatalities) and liver cirrhosis with low-dose methotrexate, patients should have the following checked:

³³ <https://www.sps.nhs.uk/articles/npsa-alert-improving-compliance-with-oral-methotrexate-guidelines-2006/>

³⁴ <https://cks.nice.org.uk/dmards/#scenario:10>

Test	Frequency
Full Blood Count (FBC)	<ul style="list-style-type: none"> • Every 2 weeks until dose is stable for 6 weeks.
Creatinine/calculated glomerular filtration rate (GFR)	<ul style="list-style-type: none"> • Then monthly for 3 months
Liver Function Tests (LFTs) - alanine aminotransferase (ALT) and/or aspartate transaminase (AST) and albumin	<ul style="list-style-type: none"> • Thereafter, at least every 12 weeks

Methotrexate is usually prescribed as a once a week treatment. Folic acid is routinely co-prescribed with methotrexate in order to reduce adverse effects and toxicity (folic acid is usually taken on a 'non-methotrexate' day).

The audit should only include each patient once during the consecutive three-month audit period, e.g. during the three-month audit period, if a patient has their methotrexate dispensed on three occasions the information should only be recorded once as part of the audit.

For all patients that do not attend the pharmacy to collect their methotrexate attempts should be made for this discussion to occur via other means, e.g. a phone conversation. Where attempts have failed this must be recorded on the PMR, or appropriate patient record.

All patients should have been given a handheld methotrexate information booklet or local equivalent by the prescriber on initiation of treatment. All patients should be asked to bring their methotrexate information booklet to the pharmacy when they collect their methotrexate. Patients should not be refused a supply of their methotrexate if they do not have their information booklet with them, but the importance of bringing it with them in future should be emphasised.

In line with the above NPSA alert and NICE guidance, all patients prescribed methotrexate should be asked if they have had the relevant blood tests in the last 3 months.

It is recognised that not all patients may know or remember what all their tests are specifically for, in these cases it is sufficient that the patient is able to describe that they have/have not had blood tests related to their methotrexate during the recommended timeframes above. Where a patient is uncertain or does not know whether they have had the relevant tests as described above this should be recorded as 'doesn't know' on the data collection table and the patient should be asked to contact their GP practice or prescriber to find out when their next tests are due. In all cases, the reasons for and importance of tests should be discussed with the patient and the pharmacy should check that they understand the information in their methotrexate patient information booklet.

Additionally, if pharmacies do not already have a record of patients understanding of the following information, they should ask all patients prescribed methotrexate whether they:

- know it is essential to take methotrexate once weekly as a single dose
- can describe appropriate action to take if they miss one or more doses

- know to report immediately the onset of any features of blood disorders, liver toxicity and respiratory effects and can give examples of symptoms (blood disorders e.g. sore throat, bruising, and mouth ulcers; liver toxicity; e.g. nausea, vomiting, abdominal discomfort and dark urine; respiratory effects e.g. shortness of breath, stomatitis)

Discussions should be patient-centred and support the identification of any gaps in understanding or misunderstanding the patient may have. If the patient does not know this information and/or is unable to describe symptoms of toxicity, this should be discussed with them to improve patient safety and support shared decision making. Whether the patient did/did not know this information should be recorded.

It is essential to provide advice relating to safe alcohol consumption due to the risks of liver toxicity with methotrexate and other healthy lifestyles advice could be provided and recorded as part of this audit.

An assessment of the patient's understanding of the need to seek professional advice before taking non-prescribed medicines, e.g. OTC medicines, including herbal remedies or supplements, without first seeking advice from a pharmacist or doctor should be checked.

Where a patient was referred to their GP practice or prescriber this should be recorded.

To support this audit a table of questions can be found in **Annex 7**. This table includes an option to record patient initials to support the pharmacy to avoid duplication of patients during the audit period. All audit records should be kept at the pharmacy and be available for at least 2 years for assurance purposes.

Reporting

On the day of the declaration, pharmacies will be required to submit the audit data on the MYS portal based on the total numbers of patients taking methotrexate and their answers in accordance with the table of questions in **Annex 7**. It is essential that pharmacies accurately record and capture audit data for submission and **no patient identifiable data is submitted**.

- The start and end date of the audit period to enable confirmation of patient numbers against dispensing data as well as to demonstrate that the audit was completed over a consecutive three-month period.
- Total number of patients dispensed methotrexate during the audit period, avoiding repetition of patients.
- Total number of patients (or patient representatives if appropriate) that have:
 - o agreed to discuss their methotrexate with the pharmacist/pharmacy team;
 - o declined to discuss their methotrexate with the pharmacist/pharmacy team.
- Total number of patients who:
 - o have a patient handheld methotrexate information booklet;
 - o did not have the patient handheld methotrexate information booklet;
 (if the patient states they have an information booklet at home this is sufficient to answer 'yes' for this question).
- Total number of patients who reported that they:
 - o have had all the appropriate blood tests in the last 3 months (full blood count, kidney and liver function tests);
 - o have not had all the appropriate blood tests in the last 3 months (full blood count, kidney and liver function tests);

- did not know if they have had all the appropriate blood tests in the last 3 months (full blood count, kidney and liver function tests).
- Total number of patients who:
 - know it is essential to take methotrexate once weekly as a single dose;
 - did not know it is essential to take methotrexate once weekly as a single dose.
- Total number of patients who:
 - could describe appropriate action to take if they miss one or more doses;
 - could not describe appropriate action to take if they miss one or more doses.
- Total number of patients who:
 - know to report immediately the onset of any features of blood disorders, liver toxicity and respiratory effects;
 - did not know to report immediately the onset of any features of blood disorders, liver toxicity and respiratory effects.
- Total number of patients who were provided with general healthy living advice and the topic(s) of this advice:
 - Alcohol;
 - Diet;
 - Exercise;
 - Smoking.
- Total number of patients who:
 - know they should not take non-prescribed medicines without first seeking advice from a pharmacist or doctor;
 - did not know they should not take non-prescribed medicines without first seeking advice from a pharmacist or doctor.
- Total number of patients who were referred to their GP or prescriber;
- Total number of patients/patient representatives who were provided with relevant advice when they answered “No” or “Don’t know” to any of the above questions (except where they have declined to discuss their medicine).

The following must be recorded on the PMR, or appropriate patient record. The patient reported they;

- have had the relevant tests (as above) during the specified periods; or
- have not had the relevant tests (as above) during the specified periods; or
- did not know if they have had the relevant tests (as above) during the specified periods; and
- if the patient was referred as appropriate.

4.2.1 (c) Amiodarone Audit

IMPORTANT:

The amiodarone audit should only be completed if the pharmacy has:

- not dispensed lithium or methotrexate in the three months before they intend to start the audit; AND
- the pharmacy does not expect to have any prescriptions for lithium or methotrexate during the audit period; AND
- the pharmacy has previously dispensed amiodarone AND expects to dispense amiodarone during the audit period.

Aim

The aim of this audit is to reduce harm associated with amiodarone. This will be achieved by improving amiodarone monitoring and patient understanding through a focus upon auditing patient medication records, engagement of patients and referral to general practice or the prescriber, as appropriate.

Rationale

Amiodarone is always initiated in secondary care or under specialist supervision. However, primary care practitioners may be expected to continue prescribing amiodarone and to monitor the person for adverse effects (depending on locally agreed shared care guidelines). [The NPSA Rapid Response Report: Preventing fatalities from medication loading doses](#)³⁵ highlighted a number of incidents relating to amiodarone and incorrect loading and maintenance doses, including the continuation of loading doses when a lower maintenance dose should have been prescribed. The maintenance dose of amiodarone is usually 200mg daily or less. The NPSA Rapid Response Report suggested that healthcare professionals in the community know when to query abnormal doses of the identified critical medicines such as amiodarone and any dose over 200mg daily should be immediately checked with the prescriber.

The full details of the alert can be read at the above link and it is recommended that this is read in full before starting the audit.

[NICE](#)³⁶ recommends the following regular monitoring as a requirement for patients prescribed amiodarone:

- Thyroid function tests (TFTs) every 6 months and for 12 months after discontinuation. The prescriber should seek specialist advice if thyroid function tests are abnormal;
- Liver function tests required before treatment and then every 6 months;
- Serum electrolyte and urea measurement every 6 months; and
- Electrocardiography (ECG) every 12 months.

The audit should only include each patient once during the consecutive three-month audit period, e.g. during the three-month audit period if a patient has their amiodarone dispensed on three occasions, the information should only be recorded once as part of the audit.

The total number of patients dispensed amiodarone during the audit period, avoiding repetition of patients, should be recorded and reported. For all patients that do not attend the pharmacy to collect their amiodarone attempts should be made for this discussion to occur via other means, e.g. phone conversation. Where such attempts have failed, this must be recorded on the PMR, or appropriate patient record.

In line with the above NPSA alert and NICE guidance all patients prescribed amiodarone should be asked if they have had the relevant blood tests and an ECG during the specified periods.

It is recognised that not all patients may know or remember what all their tests are specifically for, in these cases it is sufficient that the patient is able to describe that they have/have not had blood tests related to their amiodarone during the recommended timeframes above. Where a patient is uncertain or does not know whether they have had the relevant tests, as described above, this should be recorded as 'doesn't know' on the data collection table and the patient

³⁵ <https://www.sps.nhs.uk/wp-content/uploads/2018/02/NRLS-1288-Preventing-fatamation-2010.11.24-v1.pdf>

³⁶ <https://cks.nice.org.uk/atrial-fibrillation#!prescribingInfoSub:20>

should be asked to contact their GP practice or prescriber to find out when their next tests are due. In all cases, the reasons for and importance of tests should be discussed with the patient and they should be asked to reread the patient information leaflet which is provided with their amiodarone.

If the daily dose of amiodarone is greater than 200mg, this should be queried with the prescriber and must be recorded on the PMR, or appropriate patient record, unless this has been queried and recorded previously, with an appropriate response from the prescriber.

Additionally, if pharmacies do not already have a record of patients' understanding of the following information, they should ask all patients prescribed amiodarone whether they can describe:

- the reason they are taking amiodarone, the dose and frequency;
- appropriate action to take if they miss one or more doses;
- symptoms that may indicate side-effects, i.e. phototoxicity, visual disturbances, cough/new progressive symptoms of breathlessness;
- how to avoid phototoxicity;
- appropriate action to take if they notice any changes in vision (contact their GP for an appointment); and
- appropriate action to take if they develop a cough or new or progressive shortness of breath (e.g. seek advice from their pharmacist, see their GP or go to A&E depending on severity)

Discussions should be patient-centred and support the identification of any gaps in understanding or misunderstanding the patient may have. If the patient does not know this information and/or is unable describe symptoms of toxicity, how to avoid toxicity or action to take should they develop symptoms of toxicity, this should be discussed with them to improve patient safety and support shared decision making. Whether the patient did/did not know this information should be recorded.

It is essential to provide advice relating to safe alcohol consumption due to the risks of liver toxicity with amiodarone and other healthy lifestyles advice should be provided and recorded as part of this audit.

An assessment of the patient's understanding of the need to seek professional advice before taking non-prescribed medicines, e.g. over the counter (OTC), including herbal remedies or supplements without first seeking advice from a pharmacist or doctor should take place.

Where a patient was referred to their GP practice or prescriber this should be recorded.

To support this audit a table of questions can be found in **Annex 8**. This table includes an option to record patient initials to support the pharmacy to avoid duplication of patients during the audit period. All audit records should be kept at the pharmacy and be available for at least 2 years for assurance purposes.

Reporting

On the day of the declaration pharmacies will be required to submit the audit data on the MYS portal based on the total numbers of patients taking amiodarone and their answers in

accordance with the table of questions in **Annex 8** It is essential that pharmacies accurately record and capture audit data for submission and **no patient identifiable data is submitted**.

- The start and end date of the audit period to enable confirmation of patient numbers against dispensing data as well as to demonstrate that the audit was completed over a consecutive three-month period.
- Total number of patients dispensed amiodarone during the audit period, avoiding repetition of patients.
- Total number of patients (or patient representatives if appropriate) that have
 - o agreed to discuss their amiodarone with the pharmacist/pharmacy team;
 - o declined to discuss their amiodarone with the pharmacist/pharmacy team.
- Total number of patients who reported that they:
 - o have had all the appropriate blood tests in the last 6 months (serum electrolytes and thyroid and liver function tests);
 - o have not had all the appropriate blood tests in the last 6 months (serum electrolytes and thyroid and liver function tests);
 - o did not know if they have had all the appropriate blood tests in the last 6 months (serum electrolytes and thyroid and liver function tests).
- Total number of patients who reported that they:
 - o have had an ECG in the last 12 months;
 - o have not had an ECG in the last 12 months;
 - o did not know if they have had an ECG in the last 12 months.
- The total number of patients prescribed a dose of amiodarone:
 - o which was 200mg or less daily;
 - o which was more than 200mg daily and was queried with the prescriber.
- Total number of patients who could:
 - o describe the reason, dose and frequency for taking amiodarone;
 - o not describe the reason, dose and frequency for taking amiodarone.
- Total number of patients who could:
 - o describe the appropriate actions to take if they miss one or more doses;
 - o not describe the appropriate actions to take if they miss one or more doses.
- Total number of patients who could:
 - o describe the symptoms that may indicate side-effects;
 - o not describe the symptoms that may indicate side-effects.
- Total number of patients who could:
 - o describe the appropriate actions to take if they noticed any changes in vision;
 - o not describe the appropriate actions to take if they noticed any changes in vision.
- Total number of patients who could:
 - o describe appropriate actions to reduce the risk of phototoxic reactions;
 - o not describe appropriate actions to reduce the risk of phototoxic reactions.
- Total number of patients who could:
 - o describe the appropriate actions that they would take if they developed a cough or new or progressive shortness of breath;
 - o not describe the appropriate actions that they would take if they developed a cough or new or progressive shortness of breath.
- Total number of patients who were provided with general healthy living advice and the topic(s) of this advice:
 - o Alcohol;
 - o Diet;
 - o Exercise;

- Smoking.
- Total number of patients who:
 - know they should not take non-prescribed medicines without first seeking advice from a pharmacist or doctor
 - did not know they should not take non-prescribed medicines without first seeking advice from a pharmacist or doctor
- Total number of patients who were referred to their GP or prescriber
- Total number of patients/patient representatives who were provided with relevant advice when they answered “No” or “Don’t know” to any of the above questions (except where they have declined to discuss their medicine)

If the daily dose of amiodarone is greater than 200mg, this should be queried with the prescriber and must be recorded on the PMR, or appropriate patient record. For all patients that do not attend the pharmacy to collect their amiodarone attempts should be made for this discussion to occur. Where attempts have failed this must be recorded on the PMR, or appropriate patient record.

4.2.1 (d) Phenobarbital Audit

IMPORTANT:

The phenobarbital audit should only be completed if the pharmacy has:

- not dispensed lithium, methotrexate or amiodarone in the three months before they intend to start the audit; AND
- the pharmacy does not expect to have any prescriptions for lithium, methotrexate or amiodarone during the audit period; AND
- the pharmacy has previously dispensed phenobarbital in the last three months AND expects to dispense phenobarbital during the audit period.

Aim

The aim of this audit is to reduce harm associated with phenobarbital. This will be achieved by improving patient understanding through a focus upon auditing patient medication records, engagement of patients and referral to general practice or the prescriber, as appropriate.

Rationale

[The Commission on Human Medicines \(CHM\)](https://www.gov.uk/drug-safety-update/antiepileptic-drugs-new-advice-on-switching-between-different-manufacturers-products-for-a-particular-drug)³⁷ reviewed spontaneous adverse reactions received by the MHRA and publications that reported potential harm arising from switching of antiepileptic drugs (AEDs) in patients previously stabilised on a branded product to a generic. Phenobarbital was one of the AEDs which they classed as Category 1, where doctors are advised to ensure that their patient is maintained on a specific manufacturer’s product.

The audit should only include each patient once during the consecutive three-month audit period, e.g. during the three-month audit period if a patient has their phenobarbital dispensed on three occasions, the information should only be recorded once as part of the audit.

The total number of patients dispensed phenobarbital during the audit period, avoiding repetition of patients, should be recorded and reported. For all patients that do not attend the pharmacy to

³⁷ <https://www.gov.uk/drug-safety-update/antiepileptic-drugs-new-advice-on-switching-between-different-manufacturers-products-for-a-particular-drug>

collect their phenobarbital attempts should be made for this discussion to occur, via other means, e.g. a phone conversation. Where such attempts have failed this must be recorded on the PMR, or appropriate patient record.

In line with the CHM categorisation of phenobarbital, pharmacies should check the same manufacturer's product of phenobarbital is dispensed to a patient. The details of the manufacturer's product the patient should continue to be dispensed must be recorded on the PMR, or appropriate patient record.

Additionally, pharmacies should ask all patients prescribed phenobarbital whether they:

- have had any changes in seizure frequency; and
- can describe appropriate action to take if they miss one or more doses.

Discussions should be patient-centred and support the identification of any gaps in understanding or misunderstanding the patient may have. If the patient does not know this information, this should be discussed with them to improve patient safety and support shared decision making.

It is essential to provide advice relating to safe alcohol consumption due to combined central nervous system effects of both phenobarbital and alcohol.³⁸ Other healthy lifestyles advice could be provided and recorded as part of this audit.

An assessment of the patient's understanding of seeking professional advice before taking non-prescribed medicines, e.g. OTC medicines, including herbal remedies or supplements, without first seeking advice from a pharmacist or doctor should take place.

Where a patient was referred to their GP practice or prescriber this should be recorded.

To support this audit a table of questions can be found in **Annex 9**. This table includes an option to record patient initials to support the pharmacy to avoid duplication of patients during the audit period. All audit records should be kept at the pharmacy and be available for at least 2 years for assurance purposes.

Reporting

On the day of the declaration pharmacies will be required to submit the audit data on the MYS portal based on the total numbers of patients taking phenobarbital and their answers in accordance with the table of questions in **Annex 9**. It is essential that pharmacies accurately record and capture audit data for submission and **no patient identifiable data is submitted**.

- The start and end date of the audit period to enable confirmation of patient numbers against dispensing data as well as to demonstrate that the audit was completed over a consecutive three-month period.
- Total number of patients dispensed phenobarbital during the audit period, avoiding repetition of patients, should be recorded and reported.
- Total number of patients (or patient representatives if appropriate) that have:
 - o agreed to discuss their phenobarbital with the pharmacist/pharmacy team;
 - o declined to discuss their phenobarbital with the pharmacist/pharmacy team.

³⁸ <https://bnf.nice.org.uk/interaction/phenobarbital-2.html>

- Total number of patients for who there:
 - o was a record on their PMR which manufacturer's product of phenobarbital should be dispensed;
 - o was not a record on their PMR which manufacturer's product of phenobarbital should be dispensed.
- Total number of patients who reported:
 - o a recent change in seizure frequency;
 - o no change in recent seizure frequency.
- Total number of patients who:
 - o can describe the appropriate action to take if they miss one or more doses;
 - o cannot describe the appropriate action to take if they miss one or more doses.
- Total number of patients who:
 - o know the importance of safe alcohol consumption while taking phenobarbital;
 - o did not know the importance of safe alcohol consumption while taking phenobarbital.
- Total number of patients who were provided with general healthy living advice and the topic(s) of this advice:
 - o Diet;
 - o Exercise;
 - o Smoking.
- Total number of patients who:
 - o know they should not take non-prescribed medicines without first seeking advice from a pharmacist or doctor;
 - o did not know that they should not take non-prescribed medicines without first seeking advice from a pharmacist or doctor.
- Total number of patients who were referred to their GP or prescriber.
- Total number of patients/patient representatives who were provided with relevant advice when they answered "No" to any of the above questions (except where they have declined to discuss their medicine).

4.2.2 Audit process where no lithium, methotrexate, amiodarone or phenobarbital is dispensed

In this case the contractor should decide when they will commence the consecutive three-month audit period. During this period, they should conduct the audit on the medicine they first dispense from the above list of four medicines. For example, if they commence their audit period on 1 October 2019 and the first prescription they receive out of lithium, methotrexate, amiodarone and phenobarbital is for amiodarone then they should conduct the amiodarone audit for the rest of their three-month audit period. In this example, if they subsequently receive a prescription for lithium or methotrexate; they should continue to complete the amiodarone audit and not change to lithium or methotrexate. This does not affect the advice any patient should receive in the normal course of dispensing medicines.

If during the pharmacy's selected consecutive three-month audit period, no prescriptions are received for the four medicines, then the pharmacy will be required to declare this on the day of declaration including the start and end date for their three-month audit period.

The NHSBSA has individual dispensing item data for each pharmacy and NHS England and NHS Improvement may review this data as part of a post-payment verification process.

4.2.3 Valproate Audit

Aim

The aim of this audit is to reduce the potential of harm being caused by taking valproate during pregnancy.

Rationale

As part of the [MHRA Drug Safety Update 2018](#)³⁹ all pharmacies were sent a pack of information ([the MHRA guide for healthcare professionals](#)⁴⁰) advising them of the need to identify any girl or woman of childbearing potential currently being prescribed valproate and detailed a series of actions for health professionals, including pharmacists to undertake. A girl or woman of childbearing potential is defined by the MHRA as a pre-menopausal woman who is capable of becoming pregnant.

Valproate use in pregnancy is associated with an increased risk of children being born with congenital abnormalities and developmental delay. Valproate is contraindicated in women of childbearing potential unless the conditions of the valproate pregnancy prevention programme are fulfilled. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant while taking valproate.

It is expected that pharmacy contractors will have undertaken the actions described in the [MHRA Drug Safety Update 2018](#)⁴⁰. To refresh your understanding of this guidance we recommend that you read this in full before starting the audit.

The valproate safety audit is an audit of the provision of advice on pregnancy prevention for girls and women of childbearing potential taking valproate. This audit is to be completed during a consecutive three-month period determined by the pharmacy.

Pharmacists must check the records of girls and women of childbearing potential for whom a prescription is dispensed for valproate, to ensure they have been advised on the risks of taking valproate in line with all the requirements as detailed in the MHRA Drug Safety Update 2018.

Pharmacists should check whether the records include that the patient was advised in line with the MHRA Drug Safety Update 2018, namely:

- whether a [Patient Card](#)⁴¹ has been provided to the patient. This should happen every time valproate is dispensed - the patient card is included with each original pack of sodium valproate;
- that the patient was aware of the risks in pregnancy and the need for use of highly effective contraception;
- that the patient was aware of the need for annual specialist review;
- whether a [Patient Guide](#)⁴² has been provided to the patient; and

³⁹<https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met>

⁴⁰https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708850/123683_Valproate_HCP_Booklet_DR15.pdf

⁴¹https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708848/123683_Valproate_Patient_Card_DR9.pdf

⁴²https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708849/123683_Valproate_Patient_Booklet_DR18.pdf

- if the child or woman of childbearing potential reports that she is not using highly effective contraception, that the patient has been referred to their GP or specialist (including if the pharmacist contacted the GP).

If there is a record of this, this should be logged on the valproate audit data collection table (see **Annex 10**). If there is not a record of this, the above should be discussed with patients for whom a prescription for valproate is received and then be logged on the valproate audit data collection table during the consecutive three-month audit period selected by the pharmacy.

For all patients of childbearing potential that do not attend the pharmacy to collect their valproate, attempts should be made for this discussion to occur (if the records show that this has not previously happened) and a copy of the Patient Guide (if the patient does not have one) and Patient Card be provided to the patient. A Patient Guides should only be provided if the patient has not received one previously or if the patient no longer has a guide in their possession.

The provision of advice to a patient representative should only be made if appropriate; it may be appropriate to follow up directly with the patient. It is important women do not stop taking valproate without first discussing this with their prescriber.

The audit should only include each patient once during the audit period, e.g. during the consecutive three-month audit period if a patient has their valproate dispensed on three occasions, the information should only be recorded once as part of the audit.

The details of the discussion should be recorded on the PMR or appropriate patient record.

Reporting

Contractors are required to report the following data to NHS England and NHS Improvement on the Manage Your Service (MYS) application on the day of declaration for this quality criterion as part of this domain:

- The start and end date for the audit to enable confirmation of patient numbers against dispensing data as well as to demonstrate that the audit was completed over a consecutive three-month period.
- Total number of patients dispensed a prescription for valproate who are of childbearing potential, avoiding repetition of patients.
- Total number of patients (or patient representatives if appropriate) that have:
 - o agreed to discuss their valproate with the pharmacist;
 - o declined to discuss their valproate with the pharmacist.
- Total number of patients who:
 - o have been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child;
 - o have not been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child.
- Total number of patient representatives (only if appropriate) who:
 - o have been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child;
 - o have not been provided with advice and information in line with the MHRA Drug Safety Update 2018, including the potential impact on an unborn child.
- Total number of patients (or patient representative, where appropriate) that:
 - o do have a copy of the Patient Guide;

- do not have a copy of the Patient Guide and have been provided with one.
- Total number of patients (or patient representatives) who:
 - have been provided with a Patient Card;
 - have not been provided with a Patient Card.
- Total number of patients who:
 - have seen their GP or specialist to discuss their use of valproate and the need for appropriate contraception in the past 12 months;
 - have not seen their GP or specialist to discuss their use of valproate and the need for appropriate contraception in the past 12 months;
 - did not know if they have seen their GP or specialist to discuss their use of valproate and the need for appropriate contraception in the past 12 months.
- Total number of patients who have reported that they:
 - are using highly effective contraception in line with the pregnancy prevention programme;
 - are not using highly effective contraception in line with the pregnancy prevention programme.
- Total number of patients referred to their prescriber, as the patient has reported they are not using highly effective contraception in line with the pregnancy prevention programme.
- Total number of patients for whom the detail of the above intervention, the provision of the Patient Guide and Patient Card was recorded on the PMR, or appropriate form/patient record.

To support this audit, a valproate audit data collection table can be found in **Annex 10**. This table includes an option to record patient initials to support the pharmacy to avoid duplication of patients during the audit period, **no patient identifiable data should be submitted** as part of this audit. All audit records should be kept at the pharmacy and be available for at least 2 years for assurance purposes.

4.2.4 Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Audit

Aim

The aim of this quality criterion is to reduce preventable patient harm from the adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs) including cyclooxygenase-2 (COX-2) inhibitors and to embed this initiative into day to day clinical practice.

Rationale

Evidence identifies NSAIDs as a class of medication that is commonly implicated in [medication associated harm](#)⁴³. Adverse effects resulting from NSAID use such as gastro-intestinal (GI) bleeding, stroke and heart attacks are a frequent cause of potentially preventable hospital admissions. The risk of GI bleeding from NSAIDs can be reduced by co-prescribing a protective agent.

The [risk](#)⁴⁴ of suffering from NSAID related adverse effects is increased in patients as they get older. This audit focuses on patients aged 65 and over who are using NSAIDs. The [NICE guidance](#)⁴⁵ for NSAIDs prescribing advises that protection with a proton pump inhibitor (PPI) is prescribed for all patients receiving NSAIDs for the management of osteoarthritis and

⁴³ <http://www.eepru.org.uk/wp-content/uploads/2018/02/eepru-report-medication-error-feb-2018.pdf>

⁴⁴ [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(13\)61128-9.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(13)61128-9.pdf)

⁴⁵ <https://www.nice.org.uk/advice/kt13>

rheumatoid arthritis. The recommendations from the previous national audit that formed part of the February 2019 Pharmacy Quality Scheme will be published on the [SPS website](#)⁴⁶.

Whilst the benefits of appropriate gastro-protection are well documented, pharmacy professionals are reminded of the [potential risks](#)⁴⁷ of proton pump inhibitor (PPI) prescribing, including theoretical risks of infections such as *Clostridium difficile* and community acquired pneumonia, bone fractures and nutritional deficiencies as well as significant costs to the NHS. Current national recommendations are detailed in [NICE guidance CG184](#)⁴⁸, which recommends using the lowest effective dosage with an annual review of this class of drugs. Further information can be found on the NICE website.

This criterion promotes patient-centred care from pharmacy professionals who are in an ideal position to detect NSAIDs prescribed without gastro-protection to patients (aged 65 and above) and to clinically assess whether the patient would benefit from a review with their prescriber. These interventions may already be commonplace in community pharmacies, but this audit seeks to ensure that high risk patients are appropriately referred.

Reporting

On the day of the declaration, contractors should have implemented, into their day-to-day practice, the findings and recommendations from the previous clinical audit on NSAIDs prescribed for those aged 65 years and above without gastroprotection, undertaken as part of the QPS for the February 2019 review point. For further information, you can review the [NSAID safety audit 2018/19](#)⁴⁹.

The pharmacy must then complete the updated audit of NSAIDs and gastroprotection for all patients 65 years and over, including notifying the patient's GP where concerns are identified, sharing their anonymised data with NHS England & NHS Improvement, and incorporating any learning from the re-audit into future practice. Contractors must have submitted data declaring that all patients aged 65 years and over who are regularly taking an oral NSAID or COX-2 inhibitor without gastro-protection have been referred to their GP/appropriate healthcare professional for a review, unless the patient has already seen their prescriber for a review in the previous six months.

Data must be collected for two weeks with a minimum sample size of 10 patients. In cases where there is difficulty in obtaining the minimum sample size, the audit should be extended to four weeks after which contractors will be able to submit the data with the number of patients they have been able to include in the audit even if less than 10. The online portal to record data will be available from 12:00 on 3 October 2019.

The pharmacist should discuss with the patient the risks associated with NSAID use, the benefits of gastro-protection and being referred for a review. Attempts should be made for this discussion to occur with all patients, including patients who have their medication delivered or patients who live in a care home. It may be appropriate to speak to an identified patient representative, family member or member of care staff.

⁴⁶ <https://www.sps.nhs.uk/wp-content/uploads/2018/09/NSAIDS-safety-audit-Jan2019-vs6.pdf>

⁴⁷ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3388523/pdf/10.1177_1756283X12437358.pdf

⁴⁸ <https://www.nice.org.uk/guidance/cg184>

⁴⁹ <https://www.sps.nhs.uk/articles/NSAIDs-safety-audit-2018-19/>

If attempts to contact the patient have failed and there is a potential risk of NSAID related adverse effects to the patient, the prescriber should be contacted to suggest a review is undertaken. This would not constitute a breach of patient confidentiality as the referral is in the best interests of the patient and necessary to ensure patient safety. All identified patients should be referred to their prescriber with a recommendation to review the need for gastroprotection unless this has occurred in the previous six months.

The pharmacy team should support the patient to reduce the risk of adverse effects arising from ongoing NSAID use without gastro-protection through education and advice and adopting principles of shared decision-making.

Pharmacies must be able to evidence ongoing learning from this audit. It is up to the contractor how they choose to implement regular monitoring of patients' use of NSAIDs without gastro-protection into their processes and procedures but at a minimum, all patients and carers requesting oral NSAIDs or COX-2 inhibitors should initially be offered advice about their medicines. The relevant standard operating procedure (SOP) could be amended to include documentation of these interventions in the PMR and/or interventions log, to aid this practice.

Pharmacies that did not previously claim for the NSAIDs audit quality criterion, i.e. at the QPS review date of 15 February 2019, and wish to claim for this criterion for the PQS 2019/20 as part of claiming for the Medicines safety audits complementing GP QOF QI module domain, must complete the NSAIDs audit for the first time and complete all of the other criteria included in this domain as outlined in this guidance.

IMPORTANT:

No patient identifiable data for any of the audits should be submitted via the MYS application.

4.3 Domain: Prevention

4.3.1 Healthy Living Pharmacy level 1 (self-assessment)

Aim

The aim of this quality criterion is to maximise the contribution of pharmacy teams in prevention of ill health, reduction of disease burden, reduction of health inequalities and in support of health and wellbeing.

The Healthy Living Pharmacy (HLP) concept is designed to develop (in respect of health and wellbeing services):

- the community pharmacy workforce;
- community pharmacy engagement with the general public (including “Making Every Contact Count”);
- community pharmacy engagement with local stakeholders such as local authorities, voluntary organisations and other health and social care professionals; and
- the environment in which health and wellbeing services are delivered.

Rationale

To meet this quality criterion, the pharmacy must, on the day of the review, be meeting the requirements of a level 1 HLP as defined by Public Health England (PHE).

The Royal Society for Public Health (RSPH) online register has closed in 2019 so registrations through this route cannot be renewed.

The Community Pharmacy Contractual Framework for 2019/20 to 2023/24 recognised that the majority of community pharmacies are already proactively delivering a wide range of interventions to support people’s health and wellbeing as HLPs. Reflecting the priority that is attached to public health and prevention work, being a Level 1 HLP will become an essential requirement for community pharmacy contractors by April 2020.

The Pharmacy and Public Health Forum has issued a statement – Reassessment of competency:

“The current HLP quality criteria for the profession-led self-assessment state:

The pharmacy owner and Responsible Pharmacist in each HLP pharmacy are responsible for reassessing their pharmacy against the HLP Quality Criteria every two years by re-completing the assessment process/Declaration of Compliance.

HLPs are going to be embedded within the essential services component of the CPCF as of April 2020. The Pharmacy and Public Health Forum has recommended that the re-assessment requirement by pharmacy owners and responsible pharmacists should be automatically extended from two to three years to enable easier transition to the new CPCF arrangements

The Pharmacy and PH Forum also strongly recommends that HLPs that have been accredited locally, also have their accreditation extended to three years and at this time, HLPs progress to the self-assessment process.”

There are then, three ways that contractors can demonstrate meeting this PQS HLP requirement:

- Pharmacies that are accredited locally should have up to date evidence of having satisfied the local accreditation criteria as an HLP locally i.e. in the three years leading up to the date of the declaration locally.
- Pharmacies that have completed the requirements of the profession-led self- assessment process via the RPSH register have evidence of having done so in the three years leading up to the date of the declaration locally.
- Pharmacies that have yet to complete the self-assessment process for level 1 HLPs or where their accreditation/self-assessment has expired, will need to demonstrate they still meet the requirements of an HLP Level 1 as defined by PHE. Once contractors have ensured they meet the requirements, they will need to retain a portfolio of evidence together with the completed assessment of compliance signed by a pharmacy professional, for post payment verification purposes. This compliance with the self-assessment form can be found in the PHE document [Healthy Living Pharmacy Level 1 Quality Criteria Assessment of Compliance Healthy Living Pharmacy \(HLP\) Level 1](#).

Once contractors have ensured they meet the requirements, they will need to retain the evidence for post payment verification purposes. For the profession led self-assessment route a pharmacy professional will need to complete an assessment of compliance and retain this in the pharmacy. This self-assessment can be found in the PHE document [Healthy Living Pharmacy Level 1 Quality Criteria: Assessment of Compliance Healthy Living Pharmacy \(HLP\) Level 1](#).⁵⁰ To support contractors to complete the self-assessment the PSNC have produced a blank “Assessment of Compliance” that can be found under [stage 3 – action once a contractor has met the requirements for HLP Level 1](#)⁵¹ on their website.

4.3.2 All patient-facing staff are Dementia Friends

Aim

The aim of this quality criterion is to help patient-facing pharmacy staff to gain insight into life with dementia and the ways people with dementia and their carers can be better supported by community pharmacy, by committing their learning to action within their day-to-day roles.

Rationale

Over 850,000 people in the UK have dementia and this number is rising⁵². As the majority of people with dementia live in the community, there is an increasing awareness of the need to ensure that communities and professionals are appropriately equipped to support people living with dementia.

For further information, refer to Public Health England’s [A Menu of Interventions for Productive Healthy Ageing – For pharmacy teams working in different settings](#)⁵³ document.

Further resources regarding supporting those living with dementia and their carers can be found on the [Alzheimer’s Society’s website](#)⁵⁴.

⁵⁰ <https://www.gov.uk/government/publications/healthy-living-pharmacy-level-1-quality-criteria>

⁵¹ <https://psnc.org.uk/services-commissioning/locally-commissioned-services/healthy-living-pharmacies/>

⁵² <https://www.alzheimers.org.uk/about-us/news-and-media/facts-media>

⁵³ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/786248/a_menu_of_interventions_for_productive_healthy_ageing.pdf

⁵⁴ <https://www.alzheimers.org.uk/>

Reporting

On the day of the declaration, all patient-facing staff are Dementia Friends (Alzheimer's Society).

Pharmacy staff with a patient-facing role includes all registered pharmacy professionals, all pre-registration graduates, dispensary staff, medicine counter assistants, delivery drivers and locums. Contractors may also have other staff that can be identified as having patient-facing roles.

Many staff will already be Dementia Friends, having attended courses or completed an online registration. For those that are yet to become Dementia Friends, follow the process outlined in the [becoming a dementia friend section below](#). Whilst individuals can make registrations for themselves, it is encouraged that these are completed via the organisational route.

Those contractors who claimed for this criterion in a previous Quality Payments Scheme should review staff turnover to ensure that all patient-facing pharmacy staff are Dementia Friends to confirm that this criterion is met on the day of the declaration.

NHS England and NHS Improvement would advise that any new patient-facing staff should routinely be advised to become a Dementia Friend as part of their induction.

Becoming a Dementia Friend

To become a Dementia Friend, one representative from the pharmacy should complete the following process:

- Register the pharmacy with the [Dementia Friends Initiative](#)⁵⁵;
- Once registration is complete, a unique code will be sent to the email address provided within one week, which will allow the pharmacy team to access a unique dashboard for their pharmacy;
- The dashboard will provide access to the online Dementia Friends videos that demonstrate examples of how staff with patient-facing roles can support a person with dementia; and
- Click 'Watch our videos for organisations' and enter:
 - o The unique code (this code can be shared with team members, which will give them access to the videos for them to complete the training in their own time);
 - o The number of people that are going to watch the videos; and
 - o The postcode of where the videos are being watched (more than likely, the pharmacy location).

Each member of patient-facing staff should watch the introductory videos and at least one of the other videos available.

Contractors can order badges for their patient-facing staff who have become Dementia Friends by emailing programmepartnerships@alzheimersociety.org.uk with the following information:

- The code that the pharmacy was given upon registration;
- The total number of staff in the pharmacy who have become Dementia Friends; and
- The address the badges should be sent to.

⁵⁵ <https://www.dementiafriends.org.uk/register-partner-admin>

Individuals, such as locums, who have not yet become a Dementia Friend can also register via the organisation route by:

- Using the unique code of an already registered pharmacy that they are currently working in and following the process outlined above; or
- Registering as an organisation by following the process outlined above and attaching the title 'Pharmacy Locum' to their name: 'John Smith Pharmacy Locum'.

Alternatively, if face to face information sessions are preferred, patient-facing staff are encouraged to contact their LPC or local [CPPE Regional Tutors](#)⁵⁶ for further information on any sessions they may be holding.

4.3.3 Dementia-Friendly Environment Checklist

Aim

The aim of this criterion is for pharmacies to assess their pharmacy environment to ensure that reasonable steps have been taken to help support the needs of people affected by dementia.

Rationale

Over 90% of people living with dementia have another health condition, one in six people with dementia have six or more health conditions⁵⁷.

Pharmacies that are interested in providing further support to patients with dementia may wish to join their [local dementia friendly community](#)⁵⁸. Becoming part of a dementia-friendly community will inform pharmacy teams about challenges and initiatives locally but also give the pharmacy team the opportunity to inform others.

The Alzheimer's Society recommend that if there is nothing happening in your local area, you may wish to consider [starting a dementia-friendly community](#)⁵⁹.

Reporting

On the day of the declaration, the pharmacy must have completed a specified dementia-friendly environment checklist available in **Annex 11**, in relation to the registered pharmacy premises and created an action plan which includes making some demonstrable recorded changes to the environment in line with the checklist, as appropriate. Some actions identified may need to be considered as part of future development of the pharmacy premises, when this is practicable.

4.3.4 Annual foot and eye checks (retinopathy)

Aim

The aim of checking if a patient with diabetes has had a foot and eye (retinopathy) check is to reduce the risk of harm to patients due to poor control of their diabetes leading to complications.

Rationale

Patients with diabetes should have a number of checks to support the management of their diabetes and they should be monitored for potential complications associated with diabetes. These checks range from HbA1c, generally checked every 3 months when first diagnosed

⁵⁶ www.cppe.ac.uk

⁵⁷ <https://www.dementiastatistics.org/statistics/comorbidities/>

⁵⁸ <https://www.dementiafriends.org.uk/WebArticle?page=dfc-public-listing#.XW5F9mCouUI>

⁵⁹ <https://www.alzheimers.org.uk/get-involved/dementia-friendly-communities/how-to-become-dementia-friendly-community>

(moving to every 6 months once stable)⁶⁰ to annual checks for foot problems⁶¹ and eye (retinopathy)⁶² screening, renal function⁶³, blood pressure and cholesterol.

These checks are to reduce the risk of complications caused by potentially high blood glucose levels which cause peripheral and vascular neuropathy in people with diabetes. With well managed blood glucose levels, these risks are significantly reduced. By supporting patients to understand the reasons and the benefits of attending all their scheduled checks, pharmacies can help to ensure early identification of complications, which significantly reduces the risk of serious complications such as kidney damage, amputations and eyesight loss.

Eye Check

Early detection and management of eye complications, such as diabetic retinopathy, can have a significant impact on prognosis and can prevent people from becoming blind. Diabetic retinopathy can be advanced before changes in eyesight are noticed by patients. Patients who are 12 years and over should have an annual retinopathy eye check; this is different to an eyesight check.

Diabetic eye checks for retinopathy are not carried out at the patient's GP practice. Normally, each GP practice refers all their patients with diabetes who are 12 years and over to a single National Diabetic Eye Screening Programme (NDESP) provider and that provider contacts the patient via letter and/or a phone call with appointment details or contact details to arrange an appointment.

If a patient misses an appointment or does not contact the screening provider to arrange an appointment, the screening provider should send an additional letter or phone the patient to arrange another appointment. Patients are not discharged from the service if they miss one or more appointments. It is likely that patients who have had diabetes for longer than one year will have received one or more letters or phone calls from the NDESP provider. The patient's GP practice should receive all notifications of results and attendance/non-attendance by a patient.

Pharmacies intending to complete this quality criterion as part of the Prevention domain are recommended to discuss this with their local GP practices to enable collaborative working for the benefit of patients. This may include a discussion around the PQS, explaining why the pharmacy is carrying out this activity. It may also include agreement on the patient pathway for patients requiring referral. This discussion may include the pharmacy obtaining the details of the NDESP provider to whom the practice refers their patients for retinopathy checks. This will enable the pharmacy to provide the contact details directly to patients who state they have not had a retinopathy screen in the last 12 months or cannot remember if they have had this. Alternatively, the practice may suggest to the pharmacy that these patients are asked to phone the practice after a certain time of day so someone in the practice team can discuss this with the patient.

⁶⁰ <https://bnf.nice.org.uk/treatment-summary/diabetes.html>

⁶¹ <https://www.nice.org.uk/guidance/ng19/chapter/recommendations#assessing-the-risk-of-developing-a-diabetic-foot-problem-2>

⁶² <https://pathways.nice.org.uk/pathways/type-2-diabetes-in-adults#path=view%3A/pathways/type-2-diabetes-in-adults/identifying-and-managing-complications-in-adults-with-type-2-diabetes.xml&content=view-node%3Anodes-eye-disease>

⁶³ <https://pathways.nice.org.uk/pathways/chronic-kidney-disease#path=view%3A/pathways/chronic-kidney-disease/assessment-and-monitoring-of-chronic-kidney-disease.xml&content=view-node%3Anodes-who-should-be-tested-for-chronic-kidney-disease>

Pregnant women with diabetes require more frequent retinopathy screening and they should be referred to their GP practice if they are uncertain about when they last had screening.

Foot Check

Foot complications are common in people with diabetes. It is estimated that 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives. Diabetic foot ulcers precede more than 80% of amputations in people with diabetes. After a first amputation, people with diabetes are twice as likely to have a subsequent amputation as people without diabetes.

Mortality rates after diabetic foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation and around 50% dying within 5 years of developing a diabetic foot ulcer.⁶⁴

Most of the regular checks for patients with diabetes are performed at the patient's general practice, often by a practice nurse. These checks usually, but not always, include checks for foot problems.

The frequency of assessing the risk of developing a diabetic foot problem is dependent on the age of the patient and should be as follows:

- Children with diabetes who are under 12 years and their family members or carers (as appropriate), should be given basic foot care advice;
- Young people with diabetes who are 12–17 years, the paediatric care team or the transitional care team should assess the young person's feet as part of their annual assessment and provide information about foot care. If a diabetic foot problem is found or suspected, the paediatric care team or the transitional care team should refer the young person to an appropriate specialist; and
- For adults with diabetes, their risk of developing a diabetic foot problem should be assessed at the following times:
 - o When diabetes is diagnosed, and at least annually thereafter (this may be more frequently depending on the person's risk of developing a diabetic foot problem);
 - o If any foot problems arise; and
 - o On any admission to hospital, and if there is any change in their status while they are in hospital.⁶⁵

Based on the above advice, only those who are 12 years old and over should be asked about annual foot checks as part of this quality criterion.

Reporting

Contractors are required to report the following data to NHS England and NHS Improvement on the Manage Your Service (MYS) application on the day of declaration for this quality criterion as part of the Prevention domain:

- The **total number** of patients with diabetes who are 12 years old and over, who presented from 1 October 2019 to 31 January 2020. This must include the total number of patients

⁶⁴ <https://www.nice.org.uk/guidance/ng19/resources/diabetic-foot-problems-prevention-and-management-pdf-1837279828933>

⁶⁵ <https://www.nice.org.uk/guidance/ng19/chapter/recommendations#assessing-the-risk-of-developing-a-diabetic-foot-problem-2>

with diabetes the pharmacy dispenses medicines for during the above period, including patients that do not come into the pharmacy, e.g. delivery patients.

- The total number of patients who:
 - o agreed to discuss their diabetes with a member of pharmacy staff;
 - o declined to discuss their diabetes with a member of pharmacy staff;
 - o could not be contacted.
- The total number of patients that have had:
 - o a retinopathy screen in the last 12 months;
 - o foot check in the last 12 months.
- The total number of patients that:
 - o have not had a retinopathy screen in the last 12 months;
 - o have not had a foot check in the last 12 months;
 - o did not know if they have had a retinopathy screen and/or foot check in the last 12 months;
- Where patients have been appropriately signposted/referred, the total number of patients:
 - o referred for retinopathy screening;
 - o referred for a foot check;
 - o referred as the patient did not know if they have had a retinopathy screen and/or foot check in the last 12 months.

Each patient should only be included once in the totals, even if they have prescriptions dispensed more than once during the period. To support pharmacies to avoid patient duplication there is a box to record patient initials in the 'Diabetes data capture table' in **Annex 12**.

When having a discussion with the patient, the pharmacy team could emphasise the importance of patients attending all of their regular checks. Diabetes UK has a '['15 Healthcare Essentials – getting the care you need'](#)⁶⁶ leaflet that may be useful to support this. Any discussion with the patient should be patient-centred and advice should be provided to the patient to help them recognise the complications that can arise with diabetes and the benefits of identifying any issues as soon as possible.

For all patients with diabetes that do not attend the pharmacy to collect their medicines, e.g. delivery patients or patients who live in a care home, attempts should be made for this discussion to take place either directly with the patient, with their representative or care home staff to confirm these checks have been completed in the last 12 months. Often this cohort of patients are the most vulnerable. Where attempts to have such a conversation with these patients or their representatives have failed, this should be recorded as part of the data collection for submission.

Contractors must make a record on the PMR or on the appropriate patient record for each patient stating whether the patient had had their annual foot and eye checks or if they did not know, and a record should be made to state who the patient was referred to, where appropriate. If attempts to contact the patient have failed, this should also be noted on their record.

⁶⁶ <https://www.diabetes.org.uk/resources-s3/2018-07/15-Healthcare-essentials.pdf>

4.3.5 Sugar Sweetened Beverages (SSB)

Aim/Rationale

The aim of this quality criterion is for community pharmacy to be an environment that promotes healthy living and to align with the rest of the NHS (NHS Standard contract requirements) in helping both their staff and the public avoid sugar sweetened beverages. This requirement builds on the training on Children's oral health in the previous QPS which was introduced to support National Smile Month.

Soft drinks (excluding fruit juice) are one of the largest sources of sugar intake in adults and the largest single source of sugar for children 11 to 18 years of age, providing 29% of their daily sugar intake⁶⁷. Sugar consumption is also one of the main causes of tooth decay in children, with tooth extractions now the leading reason for hospital admissions for children aged five to 14 years of age. In 2013, one-third of five-year olds and almost half of eight-year olds had decay in their milk teeth, with tooth decay also found in 34% and 46% of 12- and 15-year olds respectively. Obesity and its consequences alone cost the NHS £5.1bn per year.⁶⁸

According to the [World Health Organisation](#)⁶⁹, drinks containing high levels of free sugars are a major source of unnecessary calories in people's diets, particularly in children and young adults. Although it is recognised that energy drinks and high sugar drinks can be of benefit to certain patient groups, i.e. people with diabetes (to treat episodes of hypoglycaemia) a reduction in sales and the replacement of SSBs with healthier, low-energy alternatives is recommended.

For the definition of SSBs, refer to the [NHS Standard Contract 2019/20 General Conditions](#)⁷⁰. For the definition of added sugar see **Annex B** in [NHS England and NHS Improvement's Sugar reduction document](#)⁷¹. Further information on which items are liable for the soft drinks industry levy is available in the guidance provided on the [GOV.UK Soft Drinks Industry Levy page](#)⁷².

Reporting

On the day of the declaration, pharmacies (the registered pharmacy premises) must:

- have either achieved that the sales by the pharmacy of Sugar Sweetened Beverages (SSB) account for no more than 10% by volume in litres of all beverages sold or
- declare that they will be meeting this criterion by 31 March 2020.

Contractors will be expected to declare that they have met this criterion via the MYS platform.

⁶⁷ <https://www.england.nhs.uk/wp-content/uploads/2017/04/sugar-action-doc.pdf>

⁶⁸ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/470179/Sugar_reduction_The_evidence_for_action.pdf

⁶⁹ <https://www.who.int/en/news-room/detail/11-10-2016-who-urges-global-action-to-curtail-consumption-and-health-impacts-of-sugary-drinks>

⁷⁰ <https://www.england.nhs.uk/wp-content/uploads/2019/03/4-FL-GCs-1920-sepsis.pdf>

⁷¹ <https://www.england.nhs.uk/wp-content/uploads/2017/04/sugar-action-doc.pdf>

⁷² <https://www.gov.uk/guidance/check-if-your-drink-is-liable-for-the-soft-drinks-industry-levy>

4.4 Domain: Primary Care Networks

Aim

To encourage pharmacies to collaborate and work together to engage effectively with Primary Care Networks.

Rationale

The NHS Long Term Plan (LTP) described the development of local Primary Care Networks (PCNs)⁷³. This was supported by a five-year settlement with GPs⁷⁴. PCNs are the new 'building block' of local healthcare systems and generally cover local populations of 30-50,000.

Ambitions for PCNs over the next five years include systematically delivering new services to implement the Long-Term Plan, including seven new service specifications, and achieving clear, positive and quantified impacts for people, patients and the wider NHS. This will be achieved by dissolving the divide between primary and community care, with PCNs looking out to community partners not just inwards to fellow general practices. Over 1,200 PCNs have been set up across England and each has a boundary that makes sense to:

- its constituent practices;
- community-based providers, who configure their teams accordingly; and
- its local community.

Through the [Network Contract Directed Enhanced Service \(DES\)](#)⁷⁵, general practice is supported to take the leading role in establishing PCNs and each has an appointed Clinical Director. The Clinical Director is accountable to the PCN members and provides strategic and clinical leadership to the PCN, strategic leadership for workforce development, works with commissioners and other networks on local initiatives and service changes, and provides representation at the CCG and Integrated Care System. The Clinical Director will be a practising clinician from within the PCN member practices. The intention of PCNs is to be wider than general practice, incorporating a range of community providers. The Network Contract DES will, from April 2020, require general practice, as part of their PCNs, to collaborate with non-GP providers.

NHS England and NHS Improvement expect to see this collaboration reflected in the Network Agreement, which is agreed by all member general practices, with community pharmacy being a key partner in PCNs. During 2019/20, the expectation is for general practice to be increasingly working with other non-GP providers as part of collaborative PCNs. The details of how this will be demonstrated are still to be agreed.

Further information can be found in [NHS England and NHS Improvement's PCN guide for pharmacy teams](#)⁷⁶.

The Pharmacy PCN Lead will play a critical role in shaping the engagement and providing a single channel of engagement with a PCN. Their suggested key responsibilities are:

- providing leadership as the appointed Pharmacy PCN Lead, collaboratively developing and implementing the approach to engagement with the PCN
- working closely with the key members of staff of the other pharmacies in the PCN to discuss, understand and be able to describe how community pharmacy will support and deliver local improvement programmes aligned to national priorities

⁷³ <https://www.longtermplan.nhs.uk/>

⁷⁴ <https://www.england.nhs.uk/publication/gp-contract-five-year-framework/>

⁷⁵ <https://www.england.nhs.uk/publication/network-contract-directed-enhanced-service-des-specification-2019-20/>

⁷⁶ <https://www.england.nhs.uk/publication/primary-care-networks-a-briefing-for-pharmacy-teams/>

- developing relationships and working closely with other Pharmacy PCN Leads, clinical leaders of other primary care, health and social care providers, local commissioners, Local Medical Committees and LPCs

A communication or meeting with the PCN Clinical Director could include details of the following:

- introducing themselves;
- the number of pharmacies in the PCN the appointed Pharmacy PCN Lead represents;
- short background of community pharmacy and opportunities for integrated working with PCNs (including those described above) and opportunities for maximising electronic repeat dispensing (as outlined in the GP contract);
- the nationally-backed roll-out of the pharmacist-led information technology intervention for medical errors (PINCER or equivalent) by the [AHSNs⁷⁷](#);
- PQS;
 - o Medicines safety audits complementing GP QOF QI prescribing safety module;
 - o Diabetes patients check for retinopathy screening and foot checks.

The Pharmacy PCN Lead must be able to take an objective view and approach to opportunities that they may become aware of or arise as the appointed Pharmacy PCN Lead and share this detail with the rest of the pharmacies who have appointed them as the lead.

The Pharmacy PCN Lead must not abuse or use this information in way that would lead to sole or preferential personal or business gain or gain by their employer. Opportunities should be discussed, and an approach agreed with the rest of the pharmacies that have appointed the Pharmacy PCN Lead. Discussions must take place between all pharmacies in the PCN engaging in this PCN domain to agree the Pharmacy PCN Lead and to provide a single channel of engagement with a PCN. Part of the PQS responsibilities for the lead will be managing any conflicts of interest and managing confidential PCN information.

LPCs may have been preparing or already started to facilitate conversations between local community pharmacies within a PCN. Contractors may want to contact their LPC and/or check their website to identify if they intend to provide any support such as contractor events that provide local information on PCNs, including details of PCN Clinical Directors, introduce contractors to start discussions on collaborating and share information on local health and social care priorities aligned with national goals.

Reporting

Pharmacies must identify which PCN they will align themselves to. They must collaborate with other community pharmacies aligning to the same PCN and nominate between them a Pharmacy PCN Lead.

The Pharmacy PCN Lead must have provided their name to the LPC in which the PCN lies and must have demonstrable evidence that they have started the engagement process with the PCN, i.e. they have made initial contact with the Clinical Director for the PCN either by contacting them through correspondence or by meeting them.

On the day of the declaration, the pharmacy must be able to demonstrate that their pharmacy, and all other pharmacies within the PCN who wish to engage with a PCN, have agreed a collaborative approach to engaging with their PCN. This approach must include agreement on a

⁷⁷ <https://www.ncbi.nlm.nih.gov/pubmed/22357106>

single channel of communication by appointing a named lead representative for all of the community pharmacies who wish to engage with the PCN. This role cannot be shared; the requirement is for a single Pharmacy PCN Lead that had been agreed by all the pharmacies within the PCN who wish to engage with a PCN.

All pharmacies claiming for this domain must submit the following on the MYS application:

- the name of the PCN they have aligned to;
- their appointed Pharmacy PCN Lead; and
- the pharmacy name and ODS code for the Pharmacy PCN lead.

The Pharmacy PCN lead must declare:

- that they are the appointed Pharmacy Lead for that PCN;
- the name of the PCN;
- that they have notified this to the LPC in which the PCN lies; and
- that they have evidence of having started the engagement process with the PCN, as outlined above.

4.5 Domain: Asthma

Aim

The aim of this quality domain is for community pharmacy to contribute to reducing preventable deaths from asthma through clinical surveillance and evidence-based interventions.

Rationale

According to a [new analysis from Asthma UK](#)⁷⁸ - the UK has one of the worst asthma death rates in Europe, with the rate of people dying from an asthma attack increasing by more than 20% in five years.

[The National Review of Asthma Deaths \(NRAD\)](#)⁷⁹ made several recommendations to improve the care of people with asthma. These included:

- People with asthma should have a structured review by a healthcare professional with specialist training in asthma, at least annually; and
- All patients who have been prescribed more than 12 short-acting reliever (bronchodilator) inhalers in the previous 12 months should be invited for an urgent review of their asthma control, with the aim of improving their asthma through education and changes in their treatment if required.

The report made further recommendations identifying that:

- People with asthma should be provided with a personalised asthma action plan (PAAP) which can help to identify worsening asthma, support corrective action and advise patients and carers of how and when to seek help. Patients with a PAAP were four times less likely to die from an asthma attack but 77% of patients included in the NRAD report had no record of having a PAAP.

In addition, [the NICE technological appraisal \(NICE TA38\) guidance](#)⁸⁰ recommends the use of spacer devices in combination with press and breathe pressurised metered-dose inhalers (pMDIs) to achieve optimum asthma management in children between the ages of five to 15 years.

Pharmacy professionals are in an ideal position to detect under and over usage of asthma inhalers through monitoring of patients' ordering of inhalers over a fixed period and to identify children between the ages five and 15 years inclusive, that may benefit from using a spacer device to aid delivery of corticosteroids and check that they have an up-to-date PAAP. This quality domain seeks to ensure this vital information is used to ensure appropriate reviews are taking place as recommended by the NRAD report and to support prevention of further preventable asthma deaths.

Reporting

On the day of the declaration, the pharmacy can show evidence that patients with asthma, for whom more than six short-acting bronchodilator inhalers were dispensed without any corticosteroid inhaler within a six-month period have, since the last review point (i.e. 15 February 2019) been referred to an appropriate healthcare professional for an asthma review.

⁷⁸ <https://www.asthma.org.uk/about/media/news/press-release-uk-asthma-death-rates-among-worst-in-europe/>

⁷⁹ <https://www.rcplondon.ac.uk/projects/outputs/why-asthma-still-kills>

⁸⁰ <https://www.nice.org.uk/guidance/ta38>

For contractors who claimed for this criterion previously as part of QPS 2018-19, a new review since 15 February 2019 will be required. The pharmacy team's knowledge and understanding of the process to identify suitable patients should be reviewed. Methods used to identify 'at risk' patients for referral should be reviewed for effectiveness.

In addition, contractors will be required to meet the requirement and declare that they have identified children aged between five and 15 years who are prescribed press and breathe pMDIs and that they have made recommendations that the patient would benefit from the use of a suitable spacer device and/or a PAAP by referring them to an appropriate health care professional. The contractor will normally be referring the patient to their GP, GP practice based respiratory nurse specialist/asthma nurse or practice-based pharmacist. Contractors should retain evidence that a referral has been made in the pharmacy for this aspect of the domain.

It is up to pharmacy teams how they choose to engage and implement regular monitoring of asthma patients into their processes and procedures. At a minimum, historical dispensing of short acting beta agonist (SABA) and corticosteroid inhalers for patients should be assessed at every point a SABA and/or corticosteroid inhaler is presented for dispensing for the treatment of asthma. In addition, any children aged between five and 15 years, prescribed a press and breathe pMDIs who do not have a spacer device and/or a PAAP to optimise management should be referred to their prescriber. These tasks could be undertaken by any appropriately trained staff within the pharmacy team.

Where no patients are identified for referral, the contractor will still be eligible for payment if they can evidence that they have been working to identify suitable patients and that they have processes in place for referrals should they identify a patient who is suitable for referral. Contractors are advised to record any intervention or referral made in the patient medication record (PMR) and/or interventions log.

4.6 Domain: Digital Enablers

4.6.1 NHS 111 DoS Profile update via the DoS updater

Aim/Rationale

To support digital integration of community pharmacy with other NHS providers to enable communication and referral (importantly to the Community Pharmacist Consultation Service, CPCS) and to support safe and effective clinical care.

The NHS Long Term Plan sets out ambitions for digitally-enabled care to go mainstream across the NHS. Advancement in technology means wider and better access to healthcare and information for patients as well as empowerment and control regarding the healthcare choices they make every day. Technology will play a central role in delivering the Long-Term Plan, reducing bureaucracy and enabling service transformation.

The national roll out of the [NHS App](#)⁸¹ allows patients to access NHS 111 online, their GP record and the ability to book appointments from a computer or smartphone. It is important that contractors maintain their online NHS profile to ensure their information is correct and up to date, as this is made available in the public domain to support patients to access services.

By 2020, every patient with a long-term condition will have access to their health record through the summary care record (SCR) system, which will be accessible via the NHS App.

The use of SCR in community pharmacy supports clinical decision-making, whilst reducing the risk of prescribing errors and delays to urgent care. It reduces burden on general practice and improves patient experience.

Reporting

IMPORTANT:

The DoS profile update window for the February 2020 declaration is between 00:00 on 1 October 2019 and 23:59 on 30 November 2019.

On the day of the declaration, the pharmacy must have updated its NHS 111 DoS profile via the DoS updater:

- including its opening hours for Easter Sunday 2020, public and bank holidays; and
- must promptly update its profile as information changes, to ensure information is accurate for real-time referrals, e.g. from NHS 111 providers for CPCS.

Contractors will be able to search and update their NHS 111 DoS profile using the DoS Profile Updater. All DoS profiles now contain an ODS code (F code).

Contractors should search by ODS code or postcode to ensure all of their service profiles are included on the NHS 111 DoS.

Please note: Pharmacies are profiled on the NHS 111 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

⁸¹ <https://www.nhs.uk/apps-library/nhs-app/>

the guidance on the [NHS Digital website](#)⁸². Contractors will be asked to update their profile information as shown in **Figure 1**.

Figure 1: Example of the information the DoS Profile Updater asks you to review



On the day of declaration, contractors will be required to confirm that the information in the pharmacy's NHS 111 DoS profile is correct on the DoS Profile Updater. This must have been completed between **00:00 on 1 October 2019 and 23:59 on 30 November 2019** to meet the quality criterion.

Any changes, additional information, or confirmation that the profiles are accurate can be input directly into the DoS Profile Updater. Contractors should note that the DoS Profile Updater should be used to correct information on DoS profiles; it is **not** the process for changing existing opening hours. The regulatory processes required to amend either core or supplementary hours described in [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013](#)⁸³ must be followed.

Access to the DoS Profile Updater

[The DoS Profile Updater](#)⁸⁴ requires contractors to have an NHSmail account (see [NHSmail - section 3.2](#)). If they do not have this, they can obtain one via the [NHSmail portal](#)⁸⁵. This allows 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 profiles for more than one pharmacy are reviewed on behalf of a multiple pharmacy group, an email should be received for each pharmacy. This should be instantaneous, however, please allow up to two hours for the emails to be delivered.

If the emails are not received, contractors are advised to check their junk mail folder 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 quality criterion. These confirmation emails will be sent to the NHSmail address that the contractor provided. 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

⁸² <https://dos-profile.service.nhs.uk/guidance>

⁸³ <http://www.legislation.gov.uk/uksi/2013/349/contents/made>

⁸⁴ <https://dos-profile.service.nhs.uk/#/index>

⁸⁵ <https://portal.nhs.net/pharmacyregistration/>

profile. Alternatively, contractors will need to check their junk email folder in case the email has been inappropriately filed.

Easter Sunday 2020 and public and bank holiday opening

Contractors will be asked to enter information about planned opening hours for bank holidays, which will be used to confirm information previously held on NHS 111 DoS. This should be the same as the information provided on the pharmacy's NHS website (previously NHS Choices) profile. Work is ongoing to ensure that the DoS Profile Updater tool feeds into both the NHS website and NHS 111 DoS entries in the future.

To meet this quality criterion, contractors will be required to enter the same bank holiday opening hours as they entered on their NHS website profile:

Wednesday 25 December 2019	-	Christmas Day
Thursday 26 December 2019	-	Boxing Day
Wednesday 1 January 2020	-	New Year's Day
Friday, 10 April 2020	-	Good Friday
Sunday 12 April 2020	-	Easter Sunday
Monday, 13 April 2020	-	Easter Monday
Friday, 8 May 2020	-	Early May bank holiday
Monday, 25 May 2020	-	Spring bank holiday

Submission Review Timeline

Following the contractor's submission, any changes to the DoS will be approved by the NHS England and NHS Improvement Pharmacy Contracts Manager and/or the local DoS Lead.

Where DoS Leads or local NHS England and NHS Improvement teams have queries regarding the information provided, they will contact the contractor to resolve the query. Where the proposed changes can be accepted without reference back to the pharmacy, no follow up contact will be made.

It is intended that the DoS Profile Updater is updated once by each contractor claiming for this criterion. However, if a contractor was to find that the details that have been submitted are incorrect, or have changed, the DoS Profile Updater can be accessed again, and the details updated. Please note that this revised information will need to be reviewed by the DoS Lead and may initiate a query as to why the information has been changed after the original submission.

NHS Digital will prepare a report for NHS England and NHS Improvement of the contractors that have made a submission to the DoS Profile Updater within the above timescales which will be used by the NHSBSA to validate the declarations made by contractors for this quality criterion.

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**.

4.6.2 Accessing NHS Summary Care Records (SCR)

Aim/Rationale

Community pharmacy access to the SCR brings a number of benefits to pharmacy practice, such as improving patient safety and improving operational efficiency and effectiveness. The ability to review the SCR is an essential requirement for the delivery of the CPCS.

The aim of this criterion is to maintain the focus given to accessing the SCR from previous quality schemes and encourage more widespread access of the SCR to support safe, effective provision of services for patients.

A flag is displayed on the SCR screen to highlight when a patient has additional information on their SCR, as well as the core information on medicines, allergies and adverse reactions. This information may include additional details which could help pharmacies to provide more patient centred care such as:

- care preferences;
- long term conditions such as diabetes or dementia; and
- details of their carer.

Reporting

To claim for this quality criterion, the pharmacy must be able to demonstrate access to the SCR between 00:00 on 1 October 2019 and the day of their declaration

Once the pharmacy implements access to SCR, it can view SCR on the spine portal. Please note that a valid smartcard is required for this.

The Summary Care Record in community pharmacy page of the [NHS Digital website](#)⁸⁶ details how the SCR can be accessed in community pharmacy.

Users of web-based systems such as Sonar and PharmOutcomes can now also access SCR via the SCR 1-click functionality these systems provide. The 1-click function allows pharmacy professionals logged in on their smartcard to click straight through to a selected patient's SCR, without having to log in separately and complete a manual search.

To support contractors with their PQS declaration, NHS Digital publishes details of the SCR accesses made by each community pharmacy. This [data](#)⁸⁷ is published each Thursday. Contractors are advised to confirm that any SCR access after the 1 October 2019 has been recorded in the published data, and keep a screen shot of this for validation purposes. If a contractor believes that they have accessed the SCR and it is not included in the published data, they should contact scrpharmacy@nhs.net.

⁸⁶ <https://digital.nhs.uk/services/summary-care-records-scr/summary-care-record-scr-in-community-pharmacy>

⁸⁷ <https://digital.nhs.uk/services/summary-care-records-scr/summary-care-record-scr-in-community-pharmacy/prove-scr-access-for-the-pharmacy-quality-scheme-2019-20>

5. PQS Declarations and Payments

Pharmacies on the pharmaceutical list in England can take part in the PQS and earn a payment for meeting the scheme requirements. This does not include Local Pharmaceutical Services (LPS) contracts. However, NHS England and NHS Improvement may make local payments that are equivalent to the PQS where LPS contracts mirror the contractual arrangements of those of the CPCF. These payments would also need to be claimed via the NHSBSA MYS PQS payment declaration. LPS contractors who wish to take part in an equivalent to the PQS but are unsure if they would be eligible, should contact their local NHS England and NHS Improvement team for advice. Contact details for local teams are available on the [NHS England website](#)⁸⁸.

Contractors who are new to the list, either as new pharmacies or as new owners of existing listed pharmacies must ensure that, when they make their declaration, they are able to demonstrate how the pharmacy meets the terms of the PQS on the day they make their declaration. The contractor must have evidence of how they have met the requirements of the PQS and cannot use the evidence of a previous or different contractor. For example, if the change of ownership of a pharmacy results in a change of ODS code, the new contractor would not be able to use the evidence of the previous contractor, e.g. their patient safety report, or risk log for meeting this part of the Risk Management and Safety domain (see [Domain: Risk Management and Safety - section 4.1](#)). A contractor would need to be able to demonstrate how they had undertaken the work themselves since the change of ownership to meet the PQS requirements.

A pharmacy that has opened or has changed ownership after 30 November 2019 will not be eligible for the PQS as they would not be able to meet the Gateway criterion of updating their NHS website profile before the closure of the update period for this criterion on 30 November 2019.

5.1 Manage Your Service (MYS)

IMPORTANT:

A payment can only be made once the declaration has been submitted to the NHSBSA via the MYS application. Once a contractor has completed and submitted their online declaration (both the aspiration payment and PQS payment declarations) it cannot be altered.

The declarations for the PQS and for the aspiration payment are to be submitted online via the NHSBSA's MYS application. For further information, see [Aspiration Payment - section 5.2](#) and [Payment Declaration - section 5.3](#)

To access MYS, the contractor must complete an [authorisation form](#)⁸⁹ and provide information on which pharmacy and individuals require access via their personal NHSmail addresses. It is advised that the registration form is saved and completed using Microsoft Word before printing and signing. If this is not possible, the document can be printed and completed in full by hand.

⁸⁸ <https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-contract-teams/>

⁸⁹ <https://www.nhsbsa.nhs.uk/sites/default/files/2019-08/MYS%20Access%20Authorisation%20Form.docx>

The completed form can be scanned (NHSBSA will accept a photograph of the authorisation form from a smart phone, which can then be attached to an email) and emailed to the MYS team at nhsbsa.mys@nhs.net or contractors can post their forms to MYS Registrations, 2nd Floor, Bridge House, 152 Pilgrim Street, Newcastle upon Tyne, NE1 6SN. If contractors experience any difficulty with this, they should contact the MYS team (nhsbsa.mys@nhs.net) for assistance.

Once contractors have been enabled for MYS by the NHSBSA, each individual will receive an email to their personal NHSmail address from Microsoft Invitations (invites@microsoft.com) on behalf of MYS Registrations; click 'get started' within the email to start the individual set-up process.

It is possible that this email will go into your junk mail folder, so contractors are advised to check there periodically before calling the NHSBSA to query the non-arrival of the email. The NHSBSA will endeavour to send invitations out within two working days upon receipt of the user access authorisation form; however, this may take longer. Contractors should wait up to five working days before raising any queries with the MYS admin team at nhsbsa.mys@nhs.net.

[The MYS registration guide](#)⁹⁰ is available to help contractors with the MUS sign-up process.

Unless a contractor makes a valid claim by submitting the declaration via the NHSBSA's MYS application during the appropriate declaration period, (for either or both the aspiration payment and the PQS payment) they will not receive the relevant payment.

The contractor will receive an email to their shared NHSmail account from the NHSBSA confirming the successful declaration submission, and the details that have been declared. This email should be retained by the pharmacy as proof that the declaration was submitted, and the claim was made during the declaration period. The email will show the verification status of the gateway criteria and how the contractor responded to each of the quality criteria questions in each domain. Contractors also have the option of providing an additional email address so proof that the declaration was submitted can be sent to another email address in the organisation, such as a pharmacy's head office.

Contractors who do not receive an email as expected, are advised to check their junk mail folder; if they still cannot locate the email they are advised to contact nhsbsa.pharmacysupport@nhs.net to confirm their submission has been received. Please include the pharmacy name and ODS code in the email to avoid processing delays.

Proof of submitting the declaration may be required for verification purposes. It is the contractor's responsibility to ensure that they have this evidence of submission, as well as the evidence to demonstrate how they have met each of the gateway criteria and domains (including each quality criteria in the domain) claimed. These may be required for both pre and post-payment verification and are essential to ensure payment.

Where contractors require support or advice regarding making their declaration or the gateway verification process please contact nhsbsa.pharmacysupport@nhs.net Further support on MYS

⁹⁰ <https://www.nhsbsa.nhs.uk/sites/default/files/2019-08/Manage%20Your%20Service%20Registration%20and%20Log-in%20Guide.docx>

is available in the 'Frequently asked questions on MYS', which can be found on the [PSNC website](#)⁹¹.

Contractors who have not registered with MYS are advised to do so well ahead of the start of the declaration period whether that is for the aspiration payment or the PQS payment. Contractors who already have a registered MYS account can access the platform via the [NHSBSA website](#)⁹².

5.2 Aspiration Payment

IMPORTANT:

The declaration window for aspiration payment claims will open from 09:00 on Monday, 30 September 2019 until 23:59 on Friday, 1 November 2019.

In the previous schemes, contractors were able to claim payments for the completion of quality criteria at two points in the year. For this year's PQS, there will be a single declaration in February 2020 where contractors will declare which domains they have met and are claiming payment for. It was recognised that this may have a cash flow consequence for existing contractors; and so, an aspiration payment has been put in place to enable an earlier payment in the financial year.

Contractors who have previously claimed for QPS in 2018/19 are able to claim an aspiration payment, which is an advance on their PQS payment, which will then be reconciled against their final payment.

A pharmacy must have claimed at one or both QPS review points in 2018/19, to be eligible to claim an aspiration payment, which can only be paid under the same ODS code as the 2018/19 payment(s). The requirement to claim under the existing ODS code applies to both existing contractors and to contractors new to the pharmaceutical list, either through opening a new pharmacy or by purchasing an existing pharmacy.

In addition, if a pharmacy made a declaration for the 2018/19 QPS, but during post-payment verification they were found to have not achieved the gateway criteria or quality criteria they claimed for, and subsequently had money recovered from them, the aspiration payment is then based on the final number of points achieved, not the amount of points declared.

Having reviewed the requirements of the PQS, contractors will need to decide which domains they will be able to meet at the February 2020 declaration period, when they make their aspiration declaration. The maximum number of points a pharmacy can be paid an aspiration payment for, is 70% of their average number of points achieved across the two review points in the 2018/19 QPS. The value of each point for the aspiration payment is set at £64 (i.e. the minimum value of a point for the 2019/20 PQS).

The aspiration payment will be paid to contractors on 30 November 2019. [Part VIIA of the Drug Tariff](#)⁹³ for PQS has worked examples of how the aspiration payment will work in practice.

⁹¹ <https://psnc.org.uk/services-commissioning/nhsbsa-manage-your-service-mys-application/>

⁹² <https://services.nhsbsa.nhs.uk/nhs-prescription-services-submissions/login>.

⁹³ <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>

The aspiration payment will be reconciled with payment for the 2019/20 PQS on 1 April 2020. Contractors who have ceased trading between receiving an aspiration payment and the commencement of the declaration period will have their payment reviewed as part of the post-payment verification process and action will be taken to recover any overpayment.

5.3 Payment Declaration

IMPORTANT:

Pharmacy contractors must claim payments for the 2019/20 PQS during the declaration period which is between **3 February 2020 (opens at 09:00) and 28 February 2020 (closes at 23:59)**.

The MYS PQS section will be open before the declaration period for contractors to see how they are assessed against National Data sets for meeting the Gateway criteria requirements.

Please note that actions to demonstrate compliance with criteria must be completed before the declaration is made. Any submissions made after the declaration period has closed will not be considered and the contractor will not be paid a pharmacy quality payment.

Payment for the February 2020 declaration period will be made as part of the overall payment made by the NHSBSA to contractors on 1 April 2020. Payments will be made to contractors who meet all the Gateway criteria; and all the quality criteria within one or more of the quality domains in [Table 2](#). Pharmacy contractors will need to make a declaration on the NHSBSA MYS application (see [Manage Your Service \(MYS\) - section 5.1](#)).

In the QPS, contractors had to make a declaration that they met the scheme requirements on a specified “review date”. In the PQS there is no specified review date. Contractors can make their PQS declaration at any time during the declaration period and will be required to confirm in their declaration that they:

- meet all the gateway criteria and the domain(s) that they are claiming for; and
- have the evidence that they meet these quality criteria and domains on the day of their declaration.

The only exception to this requirement is if the contractor is planning to meet the Sugar Sweetened Beverages (SSB) criterion in which case they have until 31 March 2020 (see [SSBs - section 4.3.5](#)).

The evidence of meeting the gateway criteria and domains should be retained as it may be required for post payment verification purposes.

Once a contractor has completed and submitted their online declaration via MYS, it cannot be altered.

The funding for the PQS will be divided between qualifying pharmacies based on the number of points they have achieved up to the maximum £128 per point allowed for the scheme. Each point will have a minimum value worth £64, based on all pharmacy contractors achieving maximum points. Payments will be made to eligible contractors depending on how many

domains they have met and hence points claimed. Further information can be found in [part VIIA of the Drug Tariff](#) ⁹⁴.

5.4 Datasets for the gateway criteria

So that contractors can be confident that they have met the gateway criteria before they complete their declaration, the NHSBSA will publish verification reports which will list all contractors who have been assessed as meeting the gateway criteria where there are national datasets available:

- Advanced Services;
- NHSmail;
- NHS Website.

These national datasets will be published on the PQS page of the [NHSBSA website](#)⁹⁵ ahead of the declaration period and will be updated regularly until the date the declaration period closes. The publication schedule for these lists will also be posted on the NHSBSA website. Contractors are advised to review this website to check whether the reports show they meet these gateway criteria; or to access their MYS PQS declaration which will provide confirmation of the pharmacy meeting these gateway criteria

There is no national dataset for the safeguarding gateway criterion as there are different routes for achieving Level 2 safeguarding. Contractors will therefore need to make a declaration that they meet this gateway criterion but may be subject to post payment verification for this gateway criterion so should ensure they keep records and certificates of who has achieved Level 2 safeguarding (see [safeguarding training - section 3.4](#)).

When a contractor accesses their declaration section on the MYS application, an automatic verification assessment of whether a contractor has met the scheme's gateway criteria will be confirmed against the latest national datasets which will be updated twice weekly.

In the first three weeks of the declaration period, if a contractor fails this automatic gateway assessment, they will be unable to make a declaration. This is to enable the contractor to review their gateway data and take the necessary corrective action to meet the criterion/criteria that they have failed. Once this correction is made and included in the relevant national datasets, MYS will be updated to allow the contractor to make their declaration.

Contractors are encouraged to make their declaration early in the declaration period to take advantage of this MYS assessment. Starting the declaration process at the start of the declaration period will enable the contractor to then take corrective action, if necessary, and have their compliance with the gateway criteria confirmed by MYS the following week.

Should a contractor need further information regarding their gateway assessment or wish to query the result they will need to contact the NHSBSA Provider Assurance team at NHSBSA.pharmacysupport@nhs.net ahead of their declaration.

MYS relies on the dataset reports that are provided by other agencies to be able to make the assessment of meeting the gateway criteria. As these reports are provided twice weekly,

⁹⁴ <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>

⁹⁵ <https://www.nhsbsa.nhs.uk/pqs>

contractors who have failed the gateway assessment will need to take corrective action before the next report is collated for it to be included in that data report.

If a contractor takes action following the last report of the declaration period, but before the declaration period closes compliance with the criterion will not be confirmed but in the last week of the declaration period the, MYS will be configured to enable a declaration to be made even when the contractor has been assessed as not meeting the gateway criteria.

Where this happens contractors will be advised that they will be assessed against the final dataset which will be published at midday on Monday 2 March 2020.

Should a pharmacy that has made a PQS declaration be assessed as not meeting the gateway criteria they will not receive a PQS payment unless they are able to demonstrate how they have met the gateway criteria. To do this, a contractor would need to email the NHSBSA Provider Assurance Team (nhsbsa.pharmacysupport@nhs.net) providing evidence of the corrective action taken to demonstrate they meet the gateway criteria. The deadline for this is Friday 6 March 2020.

The NHSBSA Provider Assurance Team will review all corrective activity provided and where it is sufficient to enable verification, contractors will receive a PQS payment. If the evidence is not sufficient to enable verification, contractors will be informed that no PQS payment will be made.

It is the contractor's responsibility to provide evidence of meeting the gateway criteria before this date. Early engagement in this process is therefore encouraged to give contractors sufficient time to demonstrate gateway criteria compliance.

Evidence of meeting gateway criteria from previous QPS declarations will not mean the pharmacy is eligible for a PQS payment. Where a change of ownership has occurred, contractors must have evidence to demonstrate meeting the PQS requirements since the change of ownership. Evidence from the previous contractor is not eligible, even if the same management team and staff are in place in the pharmacy.

6. Validation of Claims

NHS England and NHS Improvement has a duty to be assured that where contractors choose to take part in the PQS that they meet the requirements of the scheme and earn the payments claimed. NHS England and NHS Improvement will continue to work with the NHSBSA Provider Assurance Team to undertake verification checks of all declarations. The verification checks compare the information provided by contractors in their declarations against the datasets available to NHS England and NHS Improvement or evidence provided via the NHSBSA.

When they make their submission, contractors are making a declaration that they meet all of the gateway criteria and all of the quality criteria in each domain they are claiming for. It is the contractor's responsibility to be able provide evidence of meeting the scheme requirements and this may be required if a contractor's PQS declaration cannot be verified.

In cases where NHS England and NHS Improvement consider that a claim has been made for a PQS payment for which the contractor is not eligible, it will be treated as an overpayment. In such cases, contractors will be contacted by the NHSBSA and notified of the overpayment recovery process. Any overpayment recovery would not prejudice any action that NHS England and NHS Improvement may also seek to take under its performance related sanctions and market exit powers under [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013](#)⁹⁶.

6.1 Provider Assurance

The NHSBSA Provider Assurance team has in the past provided support to NHS England for its assurance process of the QPS declarations. They will continue to do so for the PQS this year.

Where possible, assurance is obtained by verifying declarations against national datasets (see [datasets for the gateway criteria - section 5.4](#)). The datasets produced will provide the NHSBSA Provider Assurance team with the records that the NHS holds for individual pharmacies for a particular activity. These datasets have enabled the NHSBSA Provider Assurance team to verify a pharmacy as meeting the requirements of the previous quality schemes and will be used again for the PQS.

However, it is recognised that there may be rare instances where the NHS does not hold a full record of activity; or may hold information incorrectly. In such instances the NHSBSA Provider Assurance team will support contractors where a contractor has made a claim that has not been verified against a national dataset by helping to identify evidence that could be used to demonstrate compliance with the PQS requirements,

As well as providing assurance to NHS England and NHS Improvement the Provider Assurance team can assist contractors if they are having problems with any of the systems or processes involved in the PQS. It is expected that this guidance will provide contractors with the information required to successfully meet the scheme requirements and so should be read thoroughly before seeking alternative assistance. However, if the answer to a problem cannot be found within the guidance, the NHSBSA Provider Assurance team can be contacted at nhsbsa.pharmacysupport@nhs.net.

⁹⁶ <https://www.legislation.gov.uk/uksi/2013/349/contents/made>

The PSNC have supported the production of this guidance. They have also developed a [website](#)⁹⁷ that provides further information, additional resources and FAQs on the PQS. The CPPE have also produced a [website](#)⁹⁸ dedicated to supporting contractors to meet the requirements of the PQS.

⁹⁷ <https://psnc.org.uk/services-commissioning/pharmacy-quality-scheme/>

⁹⁸ <https://www.cppe.ac.uk/services/pqs>