

Pharmacy Integration Fund

# **NHS Community Pharmacy New Medicine Service (NMS) Expansion Pilot: Inclusion of Depression as a Therapeutic Area and Revised Service Delivery Model**

## **Service Level Agreement**

Pharmacy Local Enhanced Service

NHS England



## 1 Document history

### Approvals

This document requires the following approvals:

Name	Title	Status
Anne Joshua	Head of Pharmacy Integration, NHS England	Approved
Lisa Simpson	Deputy Director of Community Pharmacy Strategy and Contracts, NHS England	Approved
Bruce Warner	Deputy Chief Pharmaceutical Officer, NHS England	Approved

### Change history

Version and Date	Change details
Version 1.0 10 August 2022	n/a

## 2 Parties to the agreement

### 2.1 This agreement is between

**NHS England** (the commissioner)

[NHS England <insert area team name>

**and the Provider** (the pharmacy)

Trading name and address of pharmacy

.....

.....

.....

Contractor ODS code: F.....

2.2 For the provision of services to test the inclusion of depression as a new therapeutic area in the New Medicine Service (NMS) and to test a revised NMS service model. The pilot service is a Local Enhanced Service as defined by Part 4 paragraph 14(1)(c) of the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 (as amended).

2.3 By signing up to this Service Level Agreement (SLA) you are agreeing that you fully comply with the Terms of Service as outlined in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and agree to comply with the full terms and conditions as outlined in this SLA and the service specification. NHS England reserves the right to remove you from this pilot if you become unable to meet your Terms of Service during the pilot period.

2.4 Failure to comply with the full terms and conditions as outlined in this SLA and the service specification may result in suspension from the pilot. Before any suspension, the pharmacy and commissioner will discuss the reason for the suspension to identify a possible resolution.

2.5 Sign up to the service is via the NHS Business Services Authority (NHS BSA) website: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/nhs-community-pharmacy-new-medicine-service-nms-expansion-pilot>

2.6 By registering to sign up to the service you are agreeing to the terms outlined in this SLA for the Service.

### 3 Purpose and scope

- 3.1 The community pharmacy NMS has a strong evidence base that demonstrates an increased patient medicine adherence compared with normal practice, which translates into increased health gain at reduced overall cost<sup>1</sup>. Expansion of the therapeutic areas included within the NMS is part of the Community Pharmacy Contractual Framework (CPCF) 2019-2024 commitment for developing clinical services. Additional therapeutic areas were included in Year 3 with the intention to pilot other areas as part of a fully integrated model<sup>2</sup>.
- 3.2 The proposed expansion to include depression into the NMS therapeutic areas supports the vision of the NHS Long Term Plan (LTP) to '*make greater use of community pharmacists' skills and opportunities to engage patients*'<sup>3</sup>. It also aligns with the vision of mental health care set out in the Five Year Forward View for Mental Health<sup>4</sup> and the LTP, which state respectively that '*most [mental health] care should be provided in community and primary care settings*' and that '*new and integrated models of primary and community mental health care*' will be developed to support adults with mental health conditions.
- 3.3 Building upon these policy positions, the Royal Pharmaceutical Society (RPS) considered in a report how pharmacy can support people with mental health problems, proposing a next step of inclusion of antidepressants in the NMS<sup>5</sup>. Wider support for expansion of the NMS to include depression as a therapeutic area also exists within the pharmacy sector and representative bodies.
- 3.4 The guidance on [Structured Medication Reviews](#) (SMRs) for the 2021/22 GP Network Contract Directed Enhanced Service (DES) includes a requirement to work with community pharmacies to connect patients appropriately to the NMS, and [NHS Discharge Medicines Service \(DMS\) Toolkit](#) suggests the pharmacist or pharmacy technician should consider whether the patient should also be provided with the NMS where clinically appropriate. The proposed revision of the NMS service model for depression will build upon this, supporting further opportunities for integration of the NMS into local primary care provision/pathway. Sharing patient information via secure electronic means where appropriate to ensure aligned and patient-centric support is essential for the proposed therapeutic area of depression.
- 3.5 The aim of the pilot is to test the inclusion of depression as a therapeutic area in the NMS and to test a revised NMS service model that would align more closely with the treatment of depression in primary care as part of an integrated clinical pathway.

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<sup>1</sup> Elliott, R.A., Tanajewski, L., Gkountouras, G. et al. Cost Effectiveness of Support for People Starting a New Medication for a Long-Term Condition Through Community Pharmacies: An Economic Evaluation of the New Medicine Service (NMS) Compared with Normal Practice. *PharmacoEconomics* 35, 1237–1255 (2017). <https://doi.org/10.1007/s40273-017-0554-9>

<sup>2</sup> <https://www.gov.uk/government/publications/community-pharmacy-contractual-framework-2019-to-2024/community-pharmacy-contractual-framework-5-year-deal-year-3-2021-to-2022>

<sup>3</sup> Para 4.21 NHS Long Term Plan 2 August 2019 [NHS Long Term Plan v1.2 August 2019](#)

<sup>4</sup> Pg47, Independent Mental Health Taskforce to NHS in England 2018, '[The Five Year Forward View for Mental Health](#)'.

<sup>5</sup> 7. Next Steps, [RPS Report](#) 2018, '[No health without mental health: How can pharmacy support people with mental health problems](#)'.

- 3.6 An evaluation of the service will be undertaken encompassing quantitative and qualitative measures, including service user experience and the experience of pharmacy staff and primary care health professionals.
- 3.7 Subject to the results of the pilot evaluation, this pilot will inform the potential inclusion of depression as a NMS therapeutic area and/or a more flexible, patient-centric service model that aims to be better integrated into local care pathways, enabled by enhanced local signposting and data sharing.

## **4 Timescale**

- 4.1 This agreement and pilot service delivery covers the start date of the pilot (due to commence August 2022) until 31 March 2024, or before, if sufficient data has been collected to evaluate the service and commission nationally. Contractors will be notified of the end of the pilot with one months' notice of final consultation dates and claims submissions deadline.

## **5 Termination and notice period**

- 5.1 One month's notice of termination must be given in writing to the commissioner if the pharmacy contractor wishes to terminate the agreement before the given end date.
- 5.2 The commissioner may suspend or terminate this agreement forthwith if there are reasonable grounds for concern including, but not limited to, malpractice, negligence, or fraud on the part of the pharmacy contractor.

## **6 Obligations**

- 6.1 The pharmacy contractor will provide the service in accordance with the service specification and ensure that all pharmacists and pharmacy staff, including locum staff engaged by the contractor, are aware of it.
- 6.2 The service must be provided by a pharmacist who is competent based on the training and development detailed in the service specification.
- 6.3 Pharmacists will need to consider their competency in order to provide the service. Commissioners may request evidence of the training and development completed.
- 6.4 The pharmacy contractor and staff will participate fully in the pilot evaluation and provide the data set out in the service specification within the timescales specified.
- 6.5 The commissioner will monitor and assure the service in accordance with the service specification.

## 7 Standards

7.1 The service will be provided in accordance with the standards detailed in the service specification.

## 8 Eligibility criteria

8.1 Service providers will need to satisfy the following criteria to demonstrate ability to participate in this pilot.

- Compliant with the Essential Services elements of the CPCF.
- Already be registered to deliver the NMS as an advanced service within the CPCF for a minimum of six months and claimed payment for at least 20 completed NMS interventions in 2021/22.
- In good standing with NHS England.
- Must be invited to participate by the NHS England regional and/or national teams via email.
- Located within the agreed pilot footprint. The details of this can be found on the NHS BSA website: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/nhs-community-pharmacy-new-medicine-service-nms-expansion-pilot>
- Registered to provide the pilot service.
- Can comply with all the elements described in the service specification.
- The pharmacy must be able to offer face to face appointments inside a confidential consultation room that complies with relevant standards and regulations. The consultation area must be clearly signed as a private consultation room and must be an area where service users and the pharmacy team member are able to sit and speak normally, without being overheard. Distance selling pharmacies who are invited to provide the service at their registered pharmacy premises must also meet these consultation room requirements.
- Remote consultations via telephone, another live audio link or live video link are also permitted for all community pharmacies participating in the pilot. When delivering remote consultations, the contractor must ensure that there are arrangements in place at the pharmacy which enable staff and service users to communicate securely and confidentially where the conversation cannot be overheard, except by someone whom the patient wants to hear the conversation, for example a carer. Any contractor providing remote consultations must comply with the principles defined in the General Pharmaceutical Council Guidance (GPhC) Guidance<sup>6</sup> for registered pharmacies providing pharmacy services at a distance, including on the internet.

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<sup>6</sup> [Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet](#), March 2022, GPhC

- Contractors can provide the NMS in patients' homes, but they must ensure appropriate safe-guarding arrangements are in place, including ensuring pharmacists have a valid enhanced DBS certificate, and there are appropriate procedures and indemnity arrangements in place. Any costs associated with establishing these arrangements will be borne by the contractor. Evidence of safeguarding checks, procedures and indemnity must be made available to NHS England upon request.

## 9 Confidentiality

- 9.1 Both parties shall adhere to applicable data protection legislation including the General Data Protection Regulation 2018 and to the Freedom of Information Act 2000.
- 9.2 Registered pharmacy professionals are expected to follow the most recent GPhC Guidance on Confidentiality<sup>7</sup>.
- 9.3 The service provider must have in place a whistleblowing policy. The aim of which is to allow an employee to raise at the earliest opportunity, any general concern that they might have about a risk, malpractice or wrongdoing at work, which might affect patients, the public, other staff, or the organisation itself.
- 9.4 Any approaches by the media for comments or interviews relating to this service must be referred to the regional and/or national NHS England team.

## 10 Indemnity

- 10.1 The pharmacy contractor and/or pharmacist shall maintain adequate insurance for public liability and professional indemnity against any claims which may arise out of the terms and conditions of this agreement. Any litigation resulting from an accident or negligence on the part of the pharmacy is the responsibility of the pharmacy contractor and/or pharmacist who will meet the costs and any claims for compensation, at no cost to the commissioner.

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<sup>7</sup> [In practice: Guidance on confidentiality](#), June 2018, GPhC

# **NHS Community Pharmacy New Medicine Service (NMS) Expansion Pilot: Inclusion of Depression as a Therapeutic Area and Revised Service Delivery Model**

## **Service Specification**

Pharmacy Local Enhanced Service

NHS England





## Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between an individual / patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities."

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## 1 Service background

- 1.1 The New Medicine Service (NMS) is an advanced service included within the Community Pharmacy Contractual Framework (CPCF) and commenced in October 2011. Through the NMS, community pharmacists provide support to patients and carers, helping them manage newly prescribed medicines for a long-term condition, and supporting patients to make shared decisions about their care. This service also provides an opportunity to promote lifestyle changes or other non-pharmacological interventions to enhance well-being in people with long term conditions.
- 1.2 The NMS is an evidence-based intervention, with research<sup>8</sup> showing that pharmacists can successfully intervene when a medicine is newly prescribed, with repeated follow up in the short term, to increase effective medicine taking for the treatment of a long-term condition. The NMS demonstrates an increase in patient medicine adherence compared with normal practice, which translates into increased health gain at reduced overall cost<sup>9</sup>. Given this evidence base, the Department of Health and Social Care (DHSC) and NHS England (NHSE) are keen to further expand the therapeutic areas included in the NMS where appropriate.
- 1.3 Depression is not currently an eligible condition in the NMS. A proposed expansion to include depression as a therapeutic area aims to provide patients with better support in managing their medicines and adherence. This includes supporting patients to manage expected side effects, to understand the side effect profile of that medicine, and to understand that their medicines will take time to have an effect.
- 1.4 The proposed expansion to include depression into the NMS therapeutic areas supports the vision of the NHS Long Term Plan (LTP) to '*make greater use of community pharmacists' skills and opportunities to engage patients*'<sup>10</sup>. It also aligns with the vision of mental health care set out in the Five Year Forward View for Mental Health<sup>11</sup> and the LTP, which state respectively that '*most [mental health] care should be provided in community and primary care settings*' and that '*new and integrated models of primary and community mental health care*' will be developed to support adults with mental health conditions.
- 1.5 To support the inclusion of depression, a revised NMS service model is proposed to ensure flexibility and a patient-centric approach with patients able to decide when, how

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<sup>8</sup> Elliott R, Boyd M, Salema Nde, et al (2011) Supporting adherence for people starting a new medication for a long-term condition through community pharmacies: a pragmatic randomised controlled trial of the New Medicine Service (<https://www.nottingham.ac.uk/~pazmjb/nms/>)

<sup>9</sup> Elliott, R.A., Tanajewski, L., Gkountouras, G. et al. Cost Effectiveness of Support for People Starting a New Medication for a Long-Term Condition Through Community Pharmacies: An Economic Evaluation of the New Medicine Service (NMS) Compared with Normal Practice. *PharmacoEconomics* 35, 1237–1255 (2017). <https://doi.org/10.1007/s40273-017-0554-9>

<sup>10</sup> Para 4.21 NHS Long Term Plan 2 August 2019 [NHS Long Term Plan v1.2 August 2019](#)

<sup>11</sup> Pg47, Independent Mental Health Taskforce to NHS in England 2018, '[The Five Year Forward View for Mental Health](#)'.

and where they receive the service, and introduces an additional follow-up as part of a shared decision making process.

- 1.6 The inclusion of depression and a revised NMS service model to include longer-term support for patients aims to incorporate a shared decision making approach that is fully integrated in local pathways and can better utilise the clinical skills of community pharmacists in supporting patients with mental health conditions in the community.

## 2 Aims and objectives

- 2.1 The aim of the pilot is to test the inclusion of depression as a therapeutic area in the NMS and to test a revised NMS service model to inform future development of the national service model for the NMS.

### **Objectives:**

1. To test the expansion of the NMS to include people newly prescribed eligible antidepressants for depression.
2. To test a more patient-centric service model, with an emphasis on greater flexibility and shared decision making around how and when service stages are initiated, scheduled and subsequently delivered.
3. To test the extension of the NMS support through an optional additional follow-up stage. This additional follow-up could occur up to maximum of 5 months following the last NMS appointment.
4. To understand the training and support requirements for community pharmacists to be able to support patients with mental health needs.
5. To understand and support opportunities for greater integration of the NMS into local primary care provision/pathways.
6. To identify the comprehensive data set that should be shared with the registered GP practice, and/or referrer/prescriber where appropriate for this service expansion and integrated model.

## 3 Service sign up and self-declaration

- 3.1 Community pharmacy registration for the pilot will be via the NHS Business Services Authority (NHS BSA) website: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/nhs-community-pharmacy-new-medicine-service-nms-expansion-pilot>
- 3.2 Prior to provision of the service, the pharmacy contractor must:
  - Be satisfactorily complying with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in

respect of the provision of Essential services and an acceptable system of clinical governance.

- Notify the NHSE regional and national team that they intend to provide the service by completion of an electronic registration declaration through the NHS BSA website: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/nhs-community-pharmacy-new-medicine-service-nms-expansion-pilot>
- Be satisfied that all pharmacy staff (engaged or employed) involved in the provision of the service are competent to do so based on the training requirements outlined in section 7.9.
- Already be registered to deliver the NMS as an advanced service within the CPCF for a minimum of six months and claimed payment for at least 20 completed NMS interventions in 2021/22.
- Notify general practices within their locality of their intention to deliver services as part of this pilot. This is to encourage effective partnership working between general practices and the community pharmacy to ensure the service delivers good outcomes for patients.
- Ensure that pharmacy staff providing the service have access to the NHS Summary Care Record (SCR) and the pharmacy's shared NHSmail mailbox (the email address of which must be in the following format: pharmacy.ODScode@nhs.net).
- Have a standard operating procedure (SOP) in place covering the provision of the service, including eligibility criteria, roles that pharmacy staff may be required to perform and key contact details for the service. The SOP must include escalation, signposting details and staff training, with a designated pharmacy team member responsible for implementing the SOP. This should be reviewed regularly and following any significant incident or change to the service.
- Further guidance and pilot resources will be hosted on the FutureNHS webpage for this pilot; <https://future.nhs.uk/PharmacyIntegration/view?objectId=36277872>

## 4 Service description

The service is split into four stages, which are outlined below:

1. Patient engagement
2. Intervention (*up to 14 days after patient engagement*)
3. Follow up (*up to 28 days after intervention*)
4. Optional Additional follow-up (*where appropriate up to 140 days after follow up*)

Please refer to Appendix B for a flow diagram describing the service.

## Patient engagement stage

- 4.1 Following the prescribing of a new medicine<sup>12</sup> for the management of depression, patients can be recruited to the service via multiple entry routes into the NMS from different care settings. These may include, but is not limited to, the following referral and identification routes:
- recruited by pharmacy staff;
  - Self-referral;
  - Community, general practice and wider primary care practitioners, e.g. a referral made as part of a Structured Medicine Review;
  - Specialist or secondary care practitioners, e.g. referred as part of NHS Discharge Medicines Service;
  - an Electronic Prescription Service (EPS) note from the prescriber;
  - signposted by a third sector organisation.
- 4.2 To be eligible for the service, the patient is not required to have visited the pharmacy on a previous occasion or nominated the pharmacy for the EPS.
- 4.3 It is not generally appropriate for the service to be provided where there has been a formulation change. The rationale for this is that a change from one solid dosage form to another is unlikely to lead to clinical issues for a patient and hence provision of the NMS in such circumstances would not provide value to the NHS. However, there may be circumstances, where in the professional opinion of the pharmacist, they believe the patient would benefit from the provision of the NMS where they are moving from one formulation of a medicine to another. In this case the NMS can be provided, and the pharmacist should document the rationale for their professional decision.
- 4.4 If the patient has been identified by the contractor or referred following prescribing of an eligible new medicine, the new medicine will be dispensed in accordance with the Terms of Service. For the pilot service, patients may be identified at the point of their first or second prescription for a new medicine if they have not previously been offered the service. In circumstances where the patient has been referred by a healthcare professional that has already dispensed the new medicine, it is not a requirement that the contractor has dispensed the first prescription.
- 4.5 Initial advice will be given to the patient about the medicine and its use in accordance with the Terms of Service. At this stage the contractor should also, if appropriate, offer the patient opportunistic advice on healthy living/public health topics as part of the promotion of healthy lifestyles essential service and signpost to appropriate guidance and relevant supporting organisations.

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<sup>12</sup> If more than one medicine covered by the service is prescribed at the same time, that instance of the service will cover all those medicines.

- 4.6 The patient will be given information on the service. For example, this could be verbally, via a leaflet or directing the patient to a web link where the patient can access information online.
- 4.7 Prior to provision of the service, informed verbal consent<sup>13</sup> must be sought from the patient and recorded in the pharmacy's clinical record for the service and supplied pilot web-based reporting tool. This consent covers the provision of the service and engagement with pilot evaluation activities. See section 10 for further details.
- 4.8 The pharmacy staff and patient will agree a method and time for the intervention (up to a maximum of 14 days after patient engagement). This agreement should place an emphasis on greater flexibility and shared decision making around how and when services are initiated, scheduled and subsequently delivered.
- 4.9 The service can be provided to patients who are not registered with a GP practice. In this instance the pharmacy staff should recommend that the patient registers with a GP practice and support them to do so. The pharmacist must be satisfied that the prescriber of the new medicine is identified and contactable to ensure that any clinically relevant information following the consultation can be fed back to them. This should be recorded in the patient's clinical record and the pilot web-based reporting tool.

#### **Intervention stage (up to 14 days after patient engagement)**

- 4.10 The pharmacist and patient will have a discussion in the pharmacy's consultation room, remotely (via telephone, another live audio link or live video link) or in the patient's home. If the discussion does not happen at the agreed time, the pharmacy staff will make at least one attempt to follow up with the patient. If contact with the patient cannot be made, the service is ended as incomplete and payment cannot be claimed. This must still be recorded using the pilot web-based reporting tool.
- 4.11 At the start of the discussion, the pharmacist will reconfirm that the patient understands the information they were given during patient engagement, as described in section 10, and that they are happy to continue with the service.
- 4.12 The pharmacist will assess the patient's adherence to the medicine(s), identify problems and determine the patient's need for further information and support. The pilot web-based reporting tool and/or [NMS interview worksheet](#) may be used to guide this consultation.
- 4.13 The pharmacist will provide advice and further support and will agree one of the following next steps with the patient:
  - a. the patient is adhering to the medicine(s) and no problems have been identified - agree method and time for the follow up stage (up to a maximum of 28 days after the initial intervention stage). This agreement should place an emphasis on greater

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<sup>13</sup> Where that consent cannot be given by the patient themselves, e.g. younger children and for people who are unable to give consent but may benefit from the service, consent can be sought from the carer or parent/guardian, with them being involved in the subsequent discussions which make up the service.

flexibility and shared decision making around how and when services are initiated, scheduled and subsequently delivered.

- b. problems are identified and it is the clinical judgement of the pharmacist that intervention by the patient's prescriber or primary care network clinical pharmacist is not required – pharmacist and patient agree any appropriate remedial steps to be taken and agree a method and time for the follow up stage (up to a maximum of 28 days after the initial intervention stage). This agreement should place an emphasis on greater flexibility and shared decision making around how and when services are initiated, scheduled and subsequently delivered.
  - c. problems are identified and it is the clinical judgement of the pharmacist that intervention by the prescriber is required – explain this to the patient, complete the NMS pilot feedback form and refer the matter to the patient's prescriber using secure electronic messaging<sup>14</sup>. At this point the service will have been completed, the patient will exit the service and a claim can be submitted (claim point 1 only) except in the circumstance described in the footnote<sup>15</sup>.
- 4.14 At this stage the pharmacy staff should also, if appropriate, offer the patient opportunistic advice on healthy living/public health topics in line with the promotion of healthy lifestyles essential service and signpost them as appropriate to any further mental health support and/or resources available locally or nationally.

### **Follow-up stage (up to 28 days after intervention)**

- 4.15 The pharmacist and patient will have a discussion at the agreed time in the pharmacy's consultation room, remotely (via telephone, another live audio link or live video link) or in the patient's home. If the discussion does not happen at the agreed time, the pharmacy staff will make at least one additional attempt to follow up with the patient. If the pharmacy staff are then unable to contact the patient, the service will have been completed, the patient will exit the service and a claim can be submitted (claim point 1 only). This must be recorded using the pilot web-based reporting tool.
- 4.16 The pharmacist will assess the patient's adherence to the medicine(s), identify problems and determine the patient's need for further information and support. The pilot web-based reporting tool and/or [NMS interview worksheet](#) may be used to guide this consultation.
- 4.17 The pharmacist will provide advice and further support and will agree one of the following next steps with the patient:
- a. the patient is adhering to the medicine(s) and no problems have been identified – the patient can exit from the service (at which point the service will have been completed – claim point 1) or continue with an additional follow-up stage where it

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<sup>14</sup> The Minimum Viable Product (MVP) for secure electronic messaging is NHSmail.

<sup>15</sup> If the NMS episode covers multiple medicines and not all medicines prompt the need for referral to the GP practice, steps a. and b. will be undertaken for the medicines that do not require referral to the GP practice.

is clinically appropriate and required (claim point 1 should still be submitted). If the optional additional follow-up stage is required, the pharmacy staff and patient should agree a method and time for the additional follow-up (up to a maximum of 140 days after the initial follow-up stage). This agreement should place an emphasis on greater flexibility and shared decision making around how and when services are initiated, scheduled and subsequently delivered.

- b. problem identified – pharmacist and patient agree any appropriate remedial steps to be taken. The patient can exit from the service (at which point the service will have been completed – claim point 1) or continue with an additional follow-up stage where it is clinically appropriate and required (claim point 1 should still be submitted). If an optional additional follow-up stage is required, the pharmacy staff and patient should agree a method and time for the additional follow-up (up to a maximum of 140 days after the initial follow-up stage). This agreement should place an emphasis on greater flexibility and shared decision making around how and when services are initiated, scheduled and subsequently delivered.
- c. problems are identified and it is the clinical judgement of the pharmacist that intervention by the prescriber is required – explain this to the patient, complete the NMS pilot feedback form and refer the matter to the patient’s prescriber using secure electronic messaging<sup>16</sup>. At this point the service will have been completed, the patient will exit the service and a claim can be submitted (claim point 1 only) except in the circumstance described in the footnote<sup>17</sup>

4.18 At this stage the pharmacy staff should also, if appropriate, offer the patient opportunistic advice on healthy living/public health topics in line with the promotion of healthy lifestyles essential service and signpost them as appropriate to any further mental health support and/or resources available locally or nationally.

4.19 On completion of this stage of the service, the pharmacy may send the appropriate post event message (PEM) using the pilot PEM template, containing relevant information related to the eligible NMS medicine and therapeutic area, to the patient’s prescriber via secure electronic messaging<sup>19</sup>.

### **Optional Additional Follow-up stage (where appropriate up to 140 days after follow up)**

4.20 The pharmacist and patient will have a discussion at the agreed time in the pharmacy’s consultation room, remotely (via telephone, another live audio link or live video link) or in the patient’s home. If the discussion does not happen at the agreed time, the pharmacy staff will make at least one additional attempt to follow up with the patient. If the pharmacy staff are then unable to contact the patient, the service will have been

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<sup>16</sup> The Minimum Viable Product (MVP) for secure electronic messaging is NHSmail.

<sup>17</sup> If the NMS episode covers multiple medicines and not all medicines prompt the need for referral to the GP practice, steps a or b will be undertaken for the medicines that do not require referral to the GP practice.



completed and no further claim may be submitted. This must be recorded using the pilot web-based reporting tool.

- 4.21 The pharmacist will assess the patient's adherence to the medicine(s), identify problems and determine the patient's need for further information and support. The pilot web-based reporting tool and/or [NMS interview worksheet](#) may be used to guide this consultation.
- 4.22 The pharmacist will provide advice and further support and will agree one of the following next steps with the patient:
- a. the patient is adhering to the medicine(s) and no problems have been identified – exit from service. At this point the service will have been completed (claim point 2).
  - b. problem identified – pharmacist and patient agree any appropriate remedial steps to be taken. At this point the service will have been completed (claim point 2).
  - c. problem identified which needs escalation – explain this to the patient, complete the NMS pilot feedback form and refer the matter to the patient's prescriber for review using secure electronic messaging<sup>18</sup>. At this point the service will have been completed (claim point 2).
- 4.23 At this stage the pharmacy staff should also, if appropriate, offer the patient opportunistic advice on healthy living/public health topics in line with the promotion of healthy lifestyles essential service and signpost them as appropriate to any further mental health support and/or resources available locally or nationally.
- 4.24 On completion of this optional stage of the service, pharmacy staff may send the appropriate post event message (PEM) using the pilot PEM template, containing relevant information related to the eligible NMS medicine and therapeutic area, to the patient's GP practice via secure electronic messaging.

## 5 Managing appointments and patient initiation

- 5.1 The revised service delivery model aims to ensure flexibility and a patient-centric approach with patients able to decide when, how and where they receive the service. The pharmacy staff and patient should work in collaboration to make a shared decision on when and how the patient will receive their consultation as part of the pilot.
- 5.2 The pharmacy staff must ensure that local copies of completed consultation records submitted via the pilot web-based reporting tool are retained and accessible to pharmacists delivering the service.
- 5.3 The pharmacy staff may wish to manage appointments and requests from patients using any existing booking systems available to them.
- 5.4 The revised service delivery model also introduces an optional additional follow-up stage in circumstances where it is clinically appropriate and required. Patients can engage

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<sup>18</sup> The Minimum Viable Product (MVP) for secure electronic messaging is NHSmail.

with the additional follow-up element of the service at any point up to a maximum of 140 days after the initial follow-up stage.

## 6 Equipment

- 6.1 There is no specific equipment required to deliver the service, however with the consent of the patient the pharmacist may offer to undertake clinical observation(s) or examination(s) depending on clinical need or refer the patient into an existing commissioned service, for example, the [NHS Community Pharmacy Blood Pressure Check Service](#) if the pharmacy provides this service. Where equipment is used it should be maintained and used in accordance with the manufacturer's instruction.

## 7 Community pharmacy requirements and responsibilities

- 7.1 Prior to commencing provision of the service, pharmacy contractors must comply with any service eligibility criteria in the Service Level Agreement.
- 7.2 The pharmacy contractor must ensure that the service is available to be offered to eligible patients during the contracted core opening hours with subsequent interactions to be arranged at mutually agreed times. All pharmacy staff involved in the delivery of the service must be appropriately trained and competent to do so, including any required training outlined in section 7.9 – 7.11.
- 7.3 The pharmacy contractor should maintain appropriate records to ensure effective ongoing service delivery and audit.
- 7.4 The pharmacy contractor must have a consultation room at the pharmacy, which complies with the requirements detailed in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended), part 4 schedule 4, paragraphs 28A – 28C. If NHSE have agreed that the pharmacy premises are too small for a consultation room<sup>19</sup>, then the contractor can instead provide the service remotely or in the patient's home.
- 7.5 Remote consultations via telephone, another live audio link or live video link are also permitted for all community pharmacies participating in the pilot. When delivering remote consultations, the contractor must ensure that there are arrangements in place at the pharmacy which enable staff and service users to communicate securely and confidentially where the conversation cannot be overheard, except by someone whom the patient wants to hear the conversation, for example a carer. Any contractor providing remote consultations must comply with the principles defined in the General

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<sup>19</sup> Where a contractor believes that their pharmacy is too small for a consultation room to meet the Terms of Service requirements, they must complete and submit a request to their NHS England regional team using the published form ([NHS England » Pharmacy regulations guidance forms](#)). Where the NHS England regional team agree that the pharmacy is too small for a consultation room, the contractor must then ensure that they put arrangements in place at the pharmacy which enable staff and patients to communicate confidentially by telephone or another live audio link and a live video link.

Pharmaceutical Council Guidance (GPhC) Guidance<sup>20</sup> for registered pharmacies providing pharmacy services at a distance, including on the internet.

- 7.6 Contractors can provide the NMS in patients' homes, but they must ensure appropriate safe-guarding arrangements are in place, including ensuring pharmacists have a valid enhanced DBS certificate, and there are appropriate procedures and indemnity arrangements in place. Any costs associated with establishing these arrangements will be borne by the contractor. Evidence of safeguarding checks, procedures and indemnity must be made available to NHS England upon request.
- 7.7 Following a change of ownership of a pharmacy, the new contractor must ensure the above requirements continue to be met. This review should be documented, and this documentation must be made available to NHSE upon request.

## Training Aims

- 7.8 The package of training outlined in section 7.9 is designed to:
- Help pharmacists to consider what is different about consulting with people with mental health problems, and how they can prepare for and approach these consultations so that people get the most benefit from them.
  - Refresh knowledge of common antidepressants; how they work, why they are prescribed, their effects and side-effects, and alternative treatments.
  - Enhance skills and confidence to help someone who may be considering suicide and focusses on breaking stigma and encouraging open conversations.

Pharmacists delivering the service will also be confident and competent to:

- Ensure a patient centred approach is maintained when providing the service
- Identify and use current reference sources and maintain up to date knowledge
- Confidently deal with common issues encountered when providing effective advice and services to patients with depression.
- Use evidence-based judgement to decide when to refer a patient and identify patients who require onward signposting to appropriate guidance and supporting organisations.

## Training Requirements

- 7.9 To support the delivery of this service, completion of the following training resources within the last two years is required: <https://www.cppe.ac.uk/services/anms-pilot>

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<sup>20</sup> [Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet](#), March 2022, GPhC

- a. Centre for Pharmacy and Postgraduate Education (CPPE): Consulting with people with mental health problems (*up to 120min*)
- b. Royal College of Psychiatrists: Antidepressants (*up to 90min*)
- c. Royal College of Psychiatrists: Anxiety, panic and phobias (*up to 60min*)
- d. Zero Suicide Alliance (ZSA) Suicide Awareness Training (*up to 20min*)
- e. Scenario-based educational videos (*up to 30min*)
  - *Disorganised thinking*
  - *Someone expressing loneliness*
  - *Uncertainty around antidepressants*
  - *Someone expressing anhedonia*
  - *When someone returns feeling worse*

7.10 A self-assessment ('test yourself' quiz) will support to gauge the understanding of the required learning and direct further learning and readiness to deliver this service with confidence. Optional further learning resources and resources for patients are available on the CPPE website: <https://www.cppe.ac.uk/services/anms-pilot>

7.11 Pharmacists wishing to provide the service must submit an electronic declaration via the shared enrolment form to confirm that the above training materials have been completed, and that they have read and understood the operational processes to provide the service as described in the service specification, standard operating procedures, and pilot briefing materials. Pharmacists may register to deliver the service at more than one registered pharmacy participating in the pilot.

## Training Evidence

7.12 Evidence of competencies must be retained within each pharmacy for all pharmacists and staff delivering this service including the requirements of the Advanced Service Specification for NMS<sup>21</sup>.

7.13 Evidence of competencies must be dated within the last two years and may be requested at any time by the commissioner.

## 8 Indemnity

8.1 Pharmacy Contractors should ensure that this service, and all clinical professionals and other staff working within it are covered by appropriate indemnity.

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<sup>21</sup> <https://www.england.nhs.uk/wp-content/uploads/2021/10/B0936-service-specification-nhs-nms-advanced-service.pdf>

- 8.2 Pharmacy Contractors must ensure they have adequate commercial insurance in place to cover all liabilities (e.g. public and employers).

## 9 Data and information management

- 9.1 All parties shall adhere to applicable data protection legislation including the General Data Protection Regulation 2018 and to the Freedom of Information Act 2000. The requirement for confidentiality will be balanced with the needs of the person accessing the service.

## 10 Consent

The pharmacist will be required to obtain consent from the person for the following purposes:

- 10.1 Participate in the pilot service and agree to a consultation in line with this service specification.
- Pharmacy staff will be required to obtain verbal consent from the person to proceed with a consultation. This consent is captured at the start of the patient engagement stage and recorded in the pilot web-based reporting tool. This consent is to allow pseudonymised data to be shared with commissioners and evaluation teams for service monitoring, evaluation and processing payments to the pharmacy contractor. **This consent is required to proceed any further.**
- 10.2 To share referral advice and shared decisions with the person's registered practice.
- This consent informs the person that their information will be shared with their registered general practice to enable the provision of appropriate care and stored by the pharmacy in line with ['Records Management Code of Practice for Health and Social Care.'](#) **This consent is required to proceed any further.**
- 10.3 To share demographic data.
- People accessing the service will be asked in the pharmacy if they consent to being contacted by an evaluation team to complete a service user survey and/or interview. This is likely to be accessed via SMS messaging. **If a person does not consent to participate in the evaluation, they can still access the service.**
- 10.4 Evidence of consent should be retained for an appropriate period of time. As pharmacy contractors are the data controller, it is for each contractor to determine what the appropriate length of time is. Decisions on this matter must be documented and should be in line with ['Records Management Code of Practice for Health and Social Care.'](#)

## 11 Safety and incident reporting

11.1 The pharmacy is required to report any patient safety incidents in line with the 2012 NHS guidance on Clinical Governance Approved Particulars for Pharmacies<sup>22</sup> and also using the shared NMS pilot incident reporting form.

## 12 Review and evaluation

12.1 The commissioner reserves the right to audit or conduct post payment verification (PPV) on the information and data held at the pharmacy in respect of this service

12.2 As a pilot service, independent evaluation of the service and its outcomes is key to ongoing service development and review of the effectiveness of the pilot. The pharmacy contractor is required to participate in evaluation by ensuring submission of all relevant data and taking part in a questionnaire or survey, and telephone interview if requested.

12.3 Pharmacists delivering the pilot service will be required to participate in a questionnaire or survey and may also be invited to take part in a 45 – 60 min telephone interview.

12.4 Payments for participation in evaluation activities is outlined in Appendix A.

12.5 Aspects of the service to be examined will include, but are not limited to:

- The experience and satisfaction of the person accessing the service.
- Patient self-reported adherence to newly prescribed medicine.
- Pharmacy staff and primary care health professionals experience.
- Acceptability, practicability and usefulness of training resources.
- Operational efficiency including numbers of potential people approached and rates of participation throughout the service stages.
- Operational issues with the running of the service, which may prompt changes to its design or future development.
- Scope opportunity to get feedback on communications work / support via the programme evaluation
- Impact on health inequalities (linking to post codes of those accessing the pilot service).
- Any variation between pilot areas and pilot sites.
- The cost of implementation including time and resources required.
- Learning from incidents.

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<sup>22</sup> NHS <https://www.gov.uk/government/publications/clinical-governance-approved-particulars>

## 13 Data collection and payments

- 13.1 The pharmacy contractor shall provide information, reports, and other data as and when required by NHSE and authorised agents.
- 13.2 The pharmacy contractor will be responsible for ensuring that accurate and complete records of consultations, advice and referrals provided to each person is recorded at each stage of the NMS using the pilot web-based reporting tool within 48 hours of the activity. This web-based reporting tool shall also be used for the purposes of audit and processing payment. See Appendix A for a description of fees for service delivery.
- 13.3 Activity under the pilot service will be limited to 40 completed NMS claims per contractor in the first instance. This cap and its application to contractors may be amended at the discretion of NHSE.
- 13.4 Any claims for payments (claim point 1 and claim point 2) will be processed monthly based on submissions provided via the pilot web-based reporting tool. Contractors are required to register with the NHS BSA to deliver this service and are advised to do this as soon as possible to ensure registration is complete when they wish to make a claim for payment.
- 13.5 Any delivery of NMS in the therapeutic area of depression undertaken as part of this pilot service will be separate from any activity as part of the [NHS New Medicines Service](#) commissioned as an Advanced Service. Payment of all fees and completed claims as part of this pilot will be funded from the Pharmacy Integration Fund, and will not count towards the 1% of prescription volume cap that is associated with the Advanced Service. Pharmacy contractors must ensure that any activity undertaken as part of this pilot is not included in any Advanced Service claims submitted to the NHSBSA, and vice versa.

## Appendix A – Fees for service delivery

- If the contractor is commissioned to deliver any related services, the contractor may not claim twice for the same activity.
- The commissioner reserves the right to revise fees during the pilot period.
- There are two claim points in relation to provision of services in the pilot
  - Claim point 1: Initial NMS delivery, i.e. patient engagement, intervention and follow-up stages
  - Claim point 2: New optional additional follow-up stage for depression therapeutic area where appropriate
- Payment will be based on the completed consultation records submitted via the pilot web-based reporting tool.



**Table 1 Payment for pilot NMS expansion and revised service delivery model**

Reimbursement will be paid on the condition that the pharmacy has provided the service in accordance with the service specification

Payments and deductions	
Pharmacy set up costs	One-off payment of <b>£400</b> per pharmacy premises. This will be paid automatically on signing up to deliver the service via the NHSBSA website
Participation in evaluation and engagement	One-off payment of <b>£125</b> per pharmacy premises for pharmacists who participate in the evaluation interview(s). This will be paid automatically on completion of the interview with the pharmacist. Pharmacy contractors do not need to claim for this.
<p>Evaluation and Data costs, which include but not limited to:</p> <ul style="list-style-type: none"> <li>• Collection of data to support evaluation via pilot web-based reporting tool</li> <li>• Support for service user exit survey</li> <li>• Engaging with the service and promoting activity</li> <li>• Developing a working relationship with the local PCN and other stakeholders to engage them in the service</li> <li>• Participation in questionnaire(s) or survey(s)</li> </ul>	<p>One-off payment of <b>£225</b> per pharmacy premises.</p> <p>This will be paid at the end of the pilot and is dependent on the pharmacy contractor's declaration that they have participated in the evaluation and data submission and will keep records to evidence the declaration.</p>
Service Fee: Claim point 1	<p><b>£28 per NMS</b></p> <p><b>(up to 40 completed NMS per contractor)</b></p>
Service Fee: Claim point 2	<p><b>£14 per NMS</b></p> <p><b>(up to 40 completed NMS per contractor)</b></p>

## Appendix B – Service pathway

