COVID-19 Guidance - Prescription Management Process in Clinical Homecare Services during COVID-19

Version 1: 7th September 2020

Scope

This guidance has been developed by NCHA in conjunction with NHS colleagues in response to COVID-19. The pandemic clause of Human Medicine Regulations (HMR) 2012 Section 226 gives significant flexibility for the homecare pharmacy to make appropriate supplies of prescription only medicines. Robust governance processes in clinical and medicines homecare services require a co-ordinated approach across organisational boundaries. The overall aim of this guidance is to enable a consistent approach to homecare medicines supplies made under the pandemic clause of Human Medicine Regulations 2012 Section 226 whilst maintaining good clinical governance and maintaining patient safety.

The authority to supply homecare medicines should be provided at the highest level that is reasonably practical. Current processes include provision of a valid prescription or emergency supply at the request of a prescriber. This guidance includes process deviations that may be applied to make appropriate supplies of medicines and ancillaries to homecare patients during a pandemic when risk assessments show it is not appropriate to follow current prescription management processes. The process deviation(s) described in this guidance are only to be used in cases where following current prescription management processes would delay patient access to their medicines and therefore would introduce risk to continuity of care or would adversely impact wider COVID-19 response activities within the NHS e.g. redeployment of pharmacy staff to the front line or remote working patterns of pharmacy staff.

This guidance describes deviations from the current practice where original ink-signed prescriptions are produced and physically presented to the homecare pharmacy. The regulations allow for digital transmission of copies of original prescriptions to be presented to the homecare pharmacy for dispensing as an emergency supply at the request of a prescriber. In these cases the original prescription is expected to be presented to the homecare provider within 72 hours. Where the original prescription is presented to the homecare provider after dispensing but later than 72 hours, this should be treated as a deviation from emergency supply process rather than dispensing under pandemic exemption. When dispensing under the pandemic exemption clause 226, the homecare pharmacy never receives a valid original prescription. This is an important distinction as provision of an original prescription to the homecare pharmacy after dispensing under the pandemic clause 226 increases the risk of duplicate dispensing.

Individual agreements between homecare organisations where copies of original prescriptions are digitally presented to the homecare pharmacy and the original documents are kept and archived by the prescribing organisation on behalf of the homecare pharmacy as routine practice are not common-place and are not considered in this guidance.

This guidance outlines the information and assurance that homecare pharmacies[1] should seek from NHS Clinical Referring Centres to enable the homecare pharmacy to make appropriate supplies of homecare medicines to individual homecare patients using the pandemic exemption clause 226 of the Human Medicine Regulations.

Whilst there may be circumstances where it is appropriate to use Patient Group Directives[2] to enable homecare pharmacies to make supplies of medicines to specific groups of homecare patients, this is not within the scope of this guidance. Reference is made in this guidance to using details within any financial authorisation as evidence of appropriate supply, however, for the avoidance of doubt, provisions for financial authorisation of the supply of homecare medicines are not within the scope of this guidance.

Supply of Schedule 2 and Schedule 3 controlled drugs are extremely rare in homecare services, and should be risk assessed and provisions for appropriate supply agreed on a case-by-case basis.

Aims

The aims of proposed process deviations are:-

- to ensure homecare patients continue to receive appropriate supplies of homecare medicines and ancillaries
- to reduce patient safety risk during the COVID-19 pandemic
- to remove a significant part of the administrative burden of homecare prescription management
- to ensure good clinical governance standards are maintained
- to simplify processes for staff working from home (e.g. self-isolation)
- to enable focus of NHS resources on front line patient care

Background

The General Pharmaceutical Council published a statement on 18th March 2020 acknowledging that even during highly challenging circumstances professionals quite rightly want to meet the legal requirements that apply, however, professional activities may need to deviate from the norm to maintain patient safety even though this may not be in strict accordance with the regulations as normally understood.

The patient specific medicine supply authorisation from the clinical referring centre would, under the current prescription management process, be via a valid prescription for medicines, often accompanied by a purchase order or similar financial authorisation specifying product and service items to be supplied, for example ancillaries, nurse home visit.

[1] see appendix 1 for list of homecare pharmacies
[2] https://www.sps.nhs.uk/articles/what-is-a-patient-group-direction-pgd/

The normal provisions for emergency supply of medicines at the request of patients in community pharmacy settings are not appropriate for NHS Medicines Homecare Services. It is not appropriate to ask NHS patients to self-pay for an emergency supply of high cost homecare medicines and associated ancillaries and services. The current process for Prescription Management Process in Clinical Homecare Services includes governance guidance for emergency supply at the request of a prescriber. Whilst the prevailing regulations allow any form of communication for the emergency supply request, existing guidance for prescription management in homecare services requires the provision of a copy of a valid prescription. Acceptance of alternative forms of communication is at the sole discretion of the Homecare Provider's Responsible Pharmacist on duty at the time of supply.

The overarching principles within this guidance are

- that a suitable patient specific supply order and financial authorisation are provided by the relevant clinical referring centre
- the homecare pharmacy is reasonably assured of the validity of the information received and therefore the appropriateness of the medicine supply to be made

COVID-19 Prescription Management Process Deviation Overview

There are two types of process deviation depending on whether the NHS clinical referring centre prescribers are or are not able to use an approved electronic prescription and medicines administration (ePMA) system for homecare prescribing. The deviations for prescribing processes for ePMA and non-ePMA are outlined in Figures 1 and 2 respectively.

Within NHS clinical referring centres, the operational impact of the deviation should be "business as usual" using existing e-prescribing processes with additional intervention from the NHS clinical referring centre's pharmacy team limited to validating their organisation's prescriber, performing appropriate clinical checks and securely transmitting the patient specific supply order to the appropriate homecare provider.

Details of the process and legal basis of deviation from existing homecare prescription management process are in Appendix 2. An overall risk assessment of the COVID-19 prescription management process has been prepared by NCHA and NHMC.

Further background information can also be found in Appendix 3.

Figure 1 COVID-19 Homecare Prescription Management High Level Process Flow for EPMA prescribing

Important Note: It is important that good governance practices are followed as detailed in this deviation guidance to maintain regulatory compliance and patient safety. This deviation should only be used where the Trust internal EPMA does not capture the prescriber's advanced electronic signature or is not able to securely transmit a valid e-prescription to the homecare provider and therefore the authorised prescription form generated by the EPMA system is not a legally valid homecare prescription.

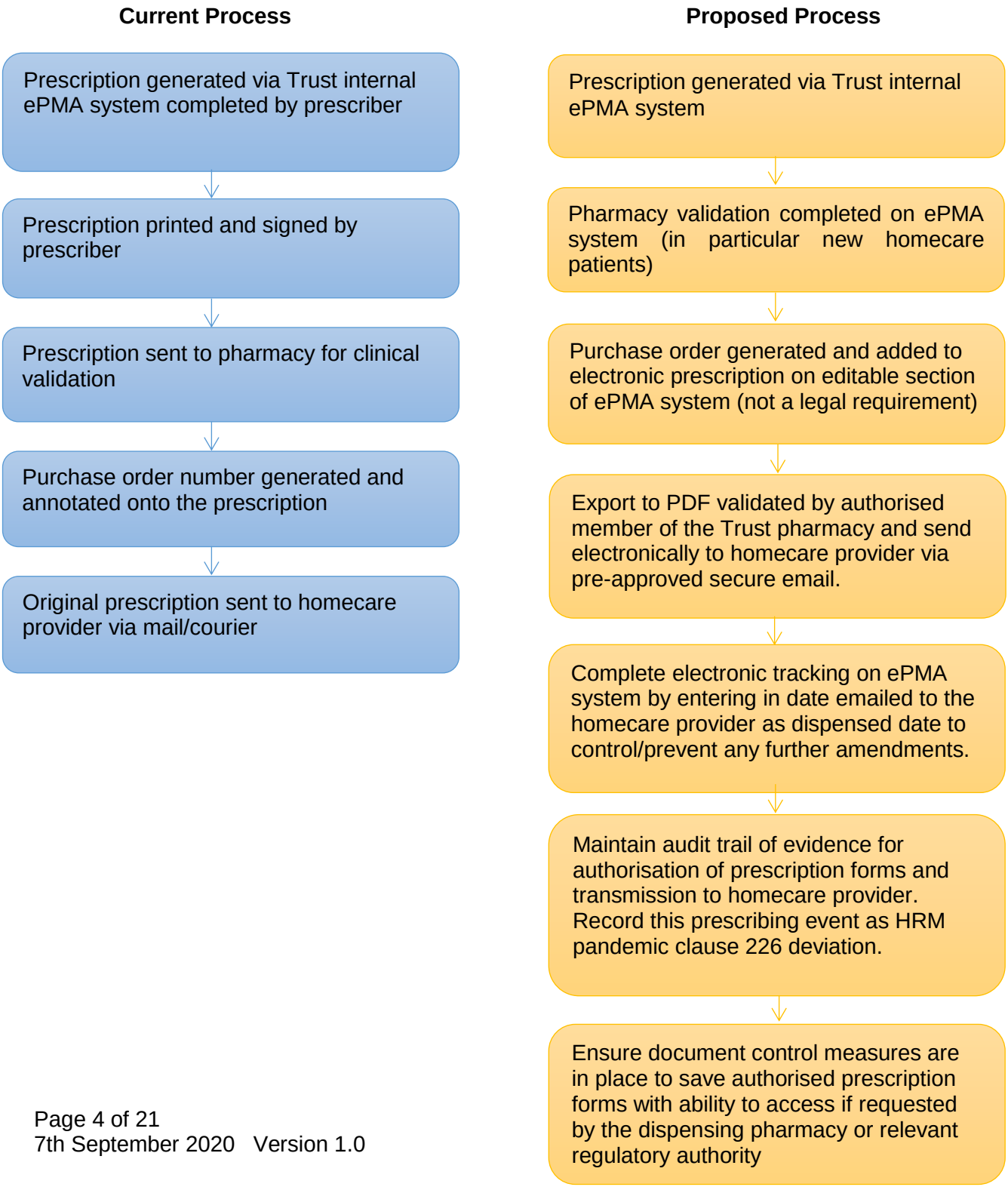
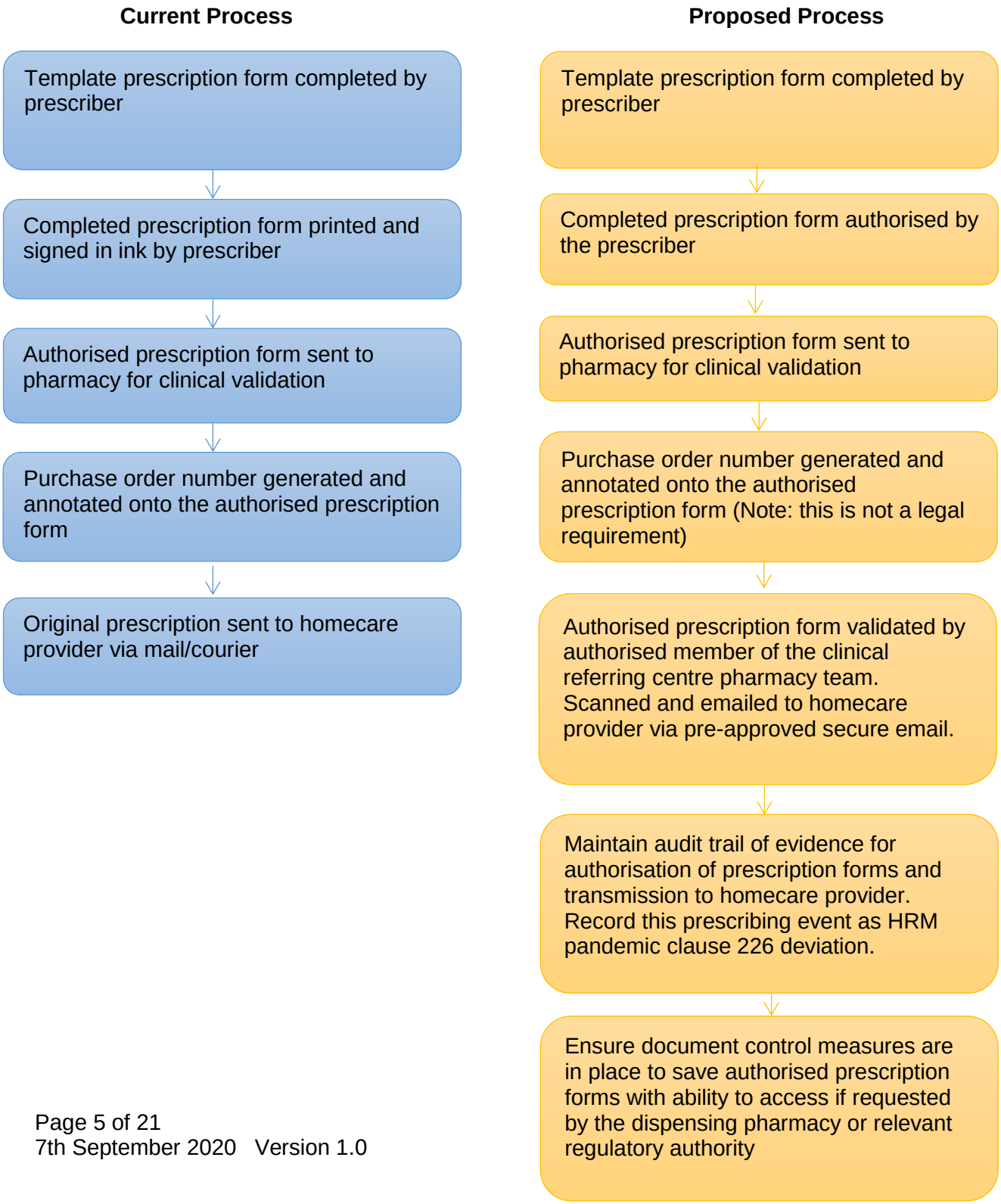


Figure 2 COVID-19 Homecare Prescription Management High Level Process Flow for non-EPMA prescribing

Important Note: It is important that good governance practices are followed as detailed in this deviation guidance to maintain regulatory compliance and patient safety. If the prescriber authorisation of the completed prescription form is via ink signature the authorised prescription form is a legally valid prescription and the current prescription management process for emergency supply at the request of a prescriber should be followed.



Governance of COVID-19 Prescription Management Process

Good clinical governance processes must be maintained in all organisations implementing this guidance in order to mitigate any risks to patient safety. Whilst each organisation must perform their own risk assessment, an overarching risk assessment relating to the implementation of this deviation is available from NCHA and NHMC.

Where homecare provider pharmacies provide NHS services, the Joint letter from the Department for Health and Social Care, NHS Resolution, and NHS England and NHS Improvement: clinical negligence indemnity in response to Coronavirus[3] confirms that the additional indemnity provided by the Coronavirus Act 2020 covers NHS services commissioned from non-NHS providers.

Governance Principles

This guidance includes process deviations that may be applied to make appropriate supplies of medicines and ancillaries to homecare patients during a pandemic when risk assessments show it is not appropriate to follow current prescription management processes. The process deviation(s) described in this guidance are only to be used in cases where following current prescription management processes would delay patient access to their medicines and therefore would introduce risk to continuity of care or would adversely impact wider COVID-19 response activities within the NHS e.g. redeployment of pharmacy staff to the front line or remote working patterns of pharmacy staff.

- The authority to supply homecare medicines should be provided at the highest level that is reasonably practical.
    - Current processes
        - Valid prescription
        - Emergency Supply at the request of a prescriber
    - Pandemic exemption
        - Patient specific supply order generated by Trust approved EPMA system (Fig 1)
        - Patient specific supply order authorised by a Trust approved prescriber and securely transmitted in writing to the homecare provider (Fig 2)
- When dispensing under the pandemic exemption clause 226, the homecare pharmacy never receives a valid original prescription.
- For the avoidance of doubt, if the prescriber is, for whatever reason, not able to prescribe the homecare medicines via the NHS Trust's approved ePMA system, they must follow the alternative for clinical referring centres not using ePMA system.
- NHS Trust Chief Pharmacist is responsible for ensuring appropriate prescribing, prescription/patient specific order validation and administration within their organisation's clinical referring centre(s).
- Where ePMA prescribing is implemented for homecare, the dispensing organisation may accept a statement of compliance relating to their organisation's ePMA system(s)

[3] https://resolution.nhs.uk/covid-19-and-business-continuity/claims-management/

and that appropriate standard operating procedures are in place from the prescribing organisation's Chief Pharmacist.

- Each prescribing organisation and homecare pharmacy is responsible for approving their own SOPs. It is important that proposed deviations to existing processes are communicated in advance of implementation to all parties who may be impacted. It must be clear if proposed changes are permanent updates to current practices or temporary deviations in response to COVID-19.
- Each healthcare professional involved in the implementation of this deviation must understand their responsibilities and be accountable for their own actions.
- It is the responsibility of the NHS clinical referring centre to ensure all high-risk patient specific supply orders are subject to an independent clinical check before being authorised for transmission to the homecare pharmacy. Patient specific supply orders for new registered patients or patients changing to a different therapy are expected to have an independent clinical check.
- Where a valid prescription is not available for a patient new to treatment or new to the homecare services, particular attention must be paid to meeting the requirements of Condition B under the Human Medicine Regulations 2012 Section 226(3).

Process Deviation Guidance

- Homecare provider pharmacy must be confident that an approved prescriber has authorised, and no unauthorised amendments have been made to the prescription form or patient specific supply order that they have received. For the avoidance of doubt, this means
    - in non-ePMA prescribing the prescriber's ink signature is required to authorise the prescription form. Any alternative method of prescriber authorisation of a prescription form or patient specific supply order must be agreed by the Clinical Referring Centre's Chief Pharmacist and the Homecare Pharmacy Superintendent Pharmacist.
    - Each e-mail to homecare providers containing patient specific supply orders must be authorised by a named registered pharmacy professional who takes responsibility for the validity and integrity of the information contained.
    - Only pre-authorised NHSmail[4] email addresses for individual Hospital Trusts and homecare pharmacies must be used to ensure appropriate checks around authenticity and audit trail. Mailboxes must be regularly checked and mailbox contents archived.
- Audit trails of communications sent and received must be maintained by both sending and receiving organisations.
- Authorised prescription forms or ePMA generated patient specific supply orders transmitted to homecare providers as patient specific supply orders under this deviation must be kept and archived by the clinical referring centre for the same length

[4] Other secure modes of e-mail transmission may be specified by NHS Wales, NHS Scotland and NHS Northern Ireland or by exception in England where NHSmail is not available.

of time as required for an original prescription and must be provided to the dispensing pharmacy or relevant regulatory authorities on request.

- There should be no deviation to the current process for managing medication changes after prescriptions have been transmitted or sent to the homecare provider. The homecare provider pharmacy must be notified that the current prescription or patient specific supply order has been superseded and a new prescription or patient specific supply order provided with an indication of the timing for the change e.g. at the earliest opportunity or at time of next dispensing/delivery.
- Both the Trusts and homecare provider must record the number of prescribing events using this HMR Clause 226 pandemic process deviation.
- Any complaints or incidents where the root cause or contributory factors are identified as being related to the use of this MHR Clause 226 pandemic process deviation should be identifiable and reported.

References

- Risk assessment for COVID-19 prescription management deviation
- The Human Medicines Regulations 2012
- Coronavirus Act 2020
- “How we will continue to regulate in light of novel coronavirus (Covid-19)” Statement from General Pharmaceutical Council
- “The interoperability challenge in digital homecare” NCHA position statement
- “Current Status of Electronic Prescribing in Homecare Services” NCHA position Statement
- Joint letter from the Department for Health and Social Care, NHS Resolution, and NHS England and NHS Improvement: clinical negligence indemnity in response to Coronavirus

Acknowledgements

We would like to thank all those contributing to the drafting and review of this document. We would specifically like to acknowledge the support of

Carol McCall

See Mun Wong

Susan Gibert

Ann Slee

Sanjeev Kaushal

Jennifer Bestford

Wing Tang

Keith Farrar

Susan Grieve

Anusha Patel

Disclaimer

History

Version Status	Date	Reason for change	Author(s)
v1.0 Approved	7 Sept 20	New to support NHS COVID-19 pandemic response	NCHA Superintendent Pharmacist Network

Appendix 1

List of Homecare Pharmacies (NCHA Members)

Homecare Provider	Registered Pharmacy Premises	Pharmacy Registration Number
Alcura	Caswell Road, Brackmills Industrial Estate , Northampton, NN4 7PU	1122546
B Braun Avitum Ltd	Unit 8 Warehouse, Brookdale Road,, Thorncliffe Park Estate, Chapeltown, SHEFFIELD, S35 2PW, UK	1122385
Baxter Healthcare Ltd	Units 11/12, Lawnhurst Trading Estate, Ashurst Drive, Stockport, Greater Manchester, SK3 0SD	9010745
Baxter Healthcare Ltd	Salthouse Road, Brackmills Industrial Estate, NORTHAMPTON, Northamptonshire, NN4 7UF	1035483
Baxter Healthcare Ltd	Unit 1, North Orbital Commercial Park, Napsbury Lane, ST. ALBANS, Hertfordshire, AL1 1XB	1101849
Baxter Healthcare Ltd	Caxton Way, Thetford, IP24 3SE	9011091
Calea UK Ltd	Cestrian Court West, Eastgate Way, Manor Park, RUNCORN, Cheshire, WA7 1NT, UK	1092153
Calea UK Ltd	Cestrian Court 2, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, United Kingdom	9011233
Healthcare at Home	Plot 7, Junction Close, Green Lane Industrial Park, Featherstone, Pontefract, West Yorkshire, WF7 6ER	1092334
Healthcare at Home	Fifth Avenue, Centrum 100, Burton On Trent, Staffordshire, DE14 2WS.	1084907
HealthNet Homecare	Unit 3 Ardane Park, Green Lane Industrial Estate, Featherstone, WF7 6EP	1113506
HealthNet Homecare	Units 1&2 Orbit Business Park, Swadlincote, DE11 0WU	9011236
Lloyds Pharmacy Clinical Homecare Ltd	Unit 3&4 Spire Green Centre, Flex Meadow, The Pinnacles, HARLOW, Essex, CM19 5TR, UK	1117146

Lloyds Pharmacy Clinical Homecare Ltd	Unit 4, Scimitar Park, HARLOW, Essex, CM19 5GU, UK	1091717
Lloyds Pharmacy Clinical Homecare Ltd	Unit 3/5, Stoney Gate Road, Station Road Spondon, DERBY, Derbyshire, DE21 7RX, UK	1087393
Lloyds Pharmacy Clinical Homecare Ltd	Units 3/5 Weardale Lane, Queenslie Industrial Estate, GLASGOW, Lanarkshire, G33 4JJ, UK	1098350
Lloyds Pharmacy Clinical Homecare Ltd	BWPC Hub, A A H Pharmaceuticals Ltd, 2 St. Philips Central, Albert Road, St. Philips, Bristol, Somerset, BS2 0XJ, United Kingdom	9010495
Personal Homecare Pharmacy Ltd	11 High View Close, Hamilton Office Park, Leicester, LE4 9LJ. UK	9010129
Pharmaxo	Pharmaxo Pharmacy Services Ltd, 1 Corsham Science Park, Corsham, Wiltshire, SN13 9FU	9011213
Polar Speed Distribution Ltd	Polar Speed Distribution Ltd, 8 Chartmoor Road, Leighton Buzzard, LU7 4WG	1086907
Polar Speed Distribution Ltd	UPS SCS, Birch Coppice Business Park, Danny Morson Way, Dordon, Warwickshire, B78 1SE	9010674
Quest HC	14-16 Phoenix Business Park, Avenue Close, Birmingham, West Midlands, B7 4NU, United Kingdom	9010217
TransCare, B Braun Medical Ltd	Brookdale Road, Thorncliffe Park Estate Chapeltown, SHEFFIELD, South Yorkshire, S35 2PW, UK	1104704

Appendix 2

COVID-19 Prescription Management Process - legal basis for deviation from current homecare prescription management process

Pharmacy professionals want to continue to meet the prevailing legal requirements wherever possible, but it has been recognised by governments and regulators that this may not be possible at this very challenging time of COVID-19 pandemic. The regulations therefore include clauses which allow supply of medicine by pharmacy professionals using allowable deviations from existing practice which would not, in normal, circumstances be appropriate. The current environment is such a time, of government declared pandemic conditions and a serious risk or potentially serious risk to human health meeting the requirements of Condition A of the Human Medicine Regulations 2012 Section 226(3).

In order to meet Condition B of the Human Medicine Regulations 2012 Section 226(3), there are separate deviations for prescribing processes using ePMA and for prescribing processes not using ePMA. The outline of the COVID-19 processes from the NHS perspective are in Figures 1 and 2 respectively. Further process details and legal basis are explained below. An overall risk assessment of the COVID-19 prescription management process has been prepared by NCHA and NHMC.

Throughout this section, it should be understood that the term “prescription” is used to indicate an appropriate patient specific supply instruction which contains sufficient detail to enable the homecare pharmacy to make an appropriate supply of a prescription only medicines, but does not meet the usual understanding of a regulatory compliant prescription. If the “prescription” meets the understanding of a regulatory compliant prescription, this COVID-19 deviation is irrelevant.

The homecare process can be found on page 19 of Royal Pharmaceutical Society Handbook for Homecare Services. The process steps in scope of this COVID-19 deviation are

- Process step 12c: Prescription written by clinical team
- Process step 12d. Clinical pharmacy validation of prescription
- Process step 8: All documentation sent to/collected by homecare provider
- Process step 9: Homecare provider receives prescription

For NHS Clinical Referring Centres using electronic prescription and medicines administration (ePMA) systems

Process step 12c: Authority to supply order from clinical team

Many NHS clinical referring centres have implemented E-prescription and medicines administration (ePMA) systems for use within their hospital Trust. In these organisations it is normal for prescribers to use the ePMA system to “prescribe” medicines for hospital patients in their care. The ePMA system restricts access to approved prescribers and appropriate pharmacy team members.

Current practice is for a member of the pharmacy department to print the patient specific authority to supply orders and to physically present the paper document to the prescriber for application of the prescriber's ink signature to validate the prescription.

Process step 12c: Deviation

The ePMA system record fulfils the requirement of The Human Medicines Regulations 2012 provision 226(3) condition B that

(a) that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person to be treated with it; and

(b) as to the dose which in the circumstances it would be appropriate for that person to take

For the avoidance of doubt, if the prescriber is not able to prescribe the homecare medicines via the NHS Trust's approved ePMA system, follow the alternative deviation for clinical referring centres not using ePMA system.

Process step 12d. Clinical pharmacy validation of authority to supply order

The NHS clinical referring centre's pharmacy team access the ePMA system and identify homecare patient specific orders. Each patient specific order is subject to an independent clinical check and administratively processed in accordance with the local standard operating procedure (see process flow diagram).

Existing governance processes in place to ensure ePMA "prescriptions" cannot be changed after the prescriber's ink signature is applied to the printed prescription.

The patient specific ePMA supply order is "locked" against future changes in accordance with the local standard operating procedure.

A copy of the signed original of the ePMA generated homecare prescription is retained by the NHS clinical referring centre pharmacy team in accordance with local standard operating procedures.

Process step 12d: Deviation

It is the responsibility of the NHS clinical referring centre to perform an appropriate independent clinical check on each patient specific supply order. The dispensing pharmacist will check for significant clinical anomalies, but does not have access to the patient's full clinical record, so the independent clinical check at this stage is an important aspect of homecare clinical governance. If waiting for an independent clinical check would introduce delays to patients obtaining supplies of medicines, a risk base approach must be applied to omission of that check by the clinical referring centre in accordance with local standard operating procedures. It is the responsibility of the NHS clinical referring centre to ensure all high risk patient specific orders are subject to an independent clinical check before being authorised for transmission to the homecare pharmacy.

The NHS clinical referring centre's pharmacy team annotate the EPMA supply order within the EPMA system as required.

The patient specific ePMA supply order is downloaded from the ePMA system e.g. via Microsoft Print to PDF.

The patient specific ePMA supply order is "locked" against future changes in accordance with the local standard operating procedure.

Process step 8: All documentation sent to/collected by homecare provider

The signed -PMA generated homecare prescription physically sent (by post or courier) to the homecare provider pharmacy.

In many cases, to avoid delays or in case originals are "lost" in transit, a copy is sent to the homecare provider via secure e-mail.

Process step 8: Deviation

The patient specific ePMA supply order downloaded from the ePMA system is transmitted from the NHS clinical referring centre to the homecare provider pharmacy by secure e-mail to/from pre-approved e-mail addresses with cover e-mail stating the number of supply orders within the message and confirming the identity and authority of the sender.

For the avoidance of doubt, there is/are no paper document(s) requiring physical transfer to the homecare provider pharmacy.

An audit trail of patient specific supply orders, messages and queries sent/received is kept by the NHS clinical referring centre pharmacy team.

Process step 9: Homecare provider receives prescription

Homecare Provider pharmacy receives an advanced copy of the homecare prescription(s) via secure e-mail.

The ink-signed paper copy of the ePMA supply order physically sent (by post or courier) to the homecare provider pharmacy.

Validity of the copy or original prescription is checked and any queries are resolved via communication with the prescriber and/or NHS clinical referring centre pharmacy team.

The copy or original prescription is processed for dispensing in accordance with the local standard operating procedure. In the case of dispensing from the copy because the original has not yet been received by the homecare pharmacy, the regulatory basis of supply is emergency supply at the request of the prescriber.

Process step 9: Deviation

Homecare pharmacy receives the patient specific ePMA supply order via secure e-mail. The homecare pharmacy team check the identity and authority of the sender as a bone fide source of patient specific supply orders and check the correct number of patient specific supply orders have been received.

The homecare provider pharmacist checks the ePMA supply orders are clear and fulfil the requirement of The Human Medicines Regulations 2012 provision 226(3) condition B that

(a) that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person to be treated with it; and

(b) as to the dose which in the circumstances it would be appropriate for that person to take

Any queries are resolved via communication with the prescriber and/or NHS clinical referring centre pharmacy team.

The patient specific ePMA supply order is processed for dispensing in accordance with the local standard operating procedures.

An audit trail of patient specific supply orders dispensed, messages and queries sent/received is kept by the homecare provider pharmacy team.

For NHS Clinical Referring Centres not using electronic prescription and medicines administration (ePMA) systems

Process step 12c: Authority to supply order from clinical team

Prescription templates are commonly used for homecare services. They are normally prepared by the clinical referring centre pharmacy team as paper-based prescription forms ready for the appropriate prescriber to check and ink-sign.

Process step 12c: Deviation

An appropriate approved prescriber must check and authorise each prescription form. This is normally indicated via an ink signing a printed prescription form. Alternative methods of prescriber authorisation of patient specific supply orders must be approved by the Clinical referring Centre's Chief Pharmacist and the Homecare Pharmacy Superintendent Pharmacist.

The authorised based patient specific supply order fulfils the requirement of The Human Medicines Regulations 2012 provision 226(3) condition B that

(a) that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person to be treated with it; and

(b) as to the dose which in the circumstances it would be appropriate for that person to take

Process step 12d: Clinical pharmacy validation of authority to supply order

Authorised prescription forms are returned by the prescriber to the NHS clinical referring centre's pharmacy team. Each authorised prescription form is subject to an independent check of clinical appropriateness, check the prescriber status is valid, and administratively processed in accordance with the local standard operating procedure.

A copy of the authorised prescription form is retained by the NHS clinical referring centre pharmacy team in accordance with local standard operating procedures.

Process step 12d: Deviation

It is the responsibility of the NHS clinical referring centre to perform an appropriate independent clinical check on each authorised prescription form. The dispensing pharmacist will check for significant clinical anomalies, but does not have access to the patient's full clinical record, so the independent clinical check at this stage is an important aspect of homecare clinical governance. If waiting for an independent clinical check would introduce delays to patients obtaining supplies of medicines, a risk base approach must be applied to omission of that check by the clinical referring centre in accordance with local standard operating procedures. It is the responsibility of the NHS clinical referring centre to ensure all high risk patient specific orders are subject to an independent clinical check before being authorised for transmission to the homecare pharmacy.

In all cases, NHS clinical referring centre pharmacy team must as a minimum validate the identity and authority of the prescriber.

Process step 8: All documentation sent to/collected by homecare provider

The prescription is physically sent (by post or courier) to the homecare provider pharmacy.

In many cases, to avoid delays and in case originals are "lost" in transit, a copy of the authorised prescription form is sent to the homecare provider via secure e-mail.

Process step 8: Deviation

The copy of the authorised prescription form is transmitted from the NHS clinical referring centre to the homecare provider pharmacy by secure e-mail to/from pre-approved e-mail addresses with cover e-mail stating the number of patient specific supply orders within the

message and confirming the identity and authority of the sender, prescribers and clinical checkers.

For the avoidance of doubt, there is/are no paper document(s) requiring physical transfer to the homecare provider pharmacy as the e-mailed copy of the authorised prescription form is recognised patient specific supply order authorising the medicine supply.

An audit trail of patient specific supply orders, messages and queries sent/received is kept by the NHS clinical referring centre pharmacy team including original paper copies of patient specific supply orders and archived for the appropriate retention period and made available on request by the homecare pharmacy or relevant regulatory authority.

Process step 9: Homecare provider receives prescription

Homecare Provider pharmacy receives an advanced copy of the authorised prescription form via secure e-mail.

The authorised prescription form is physically received (via post or courier) into the homecare provider pharmacy.

Validity of the copy or original prescription is checked and any queries are resolved via communication with the prescriber and/or NHS clinical referring centre pharmacy team.

The prescription is processed for dispensing in accordance with the local standard operating procedure. In the case of dispensing from the copy because the original has not yet been received by the homecare pharmacy, the regulatory basis of supply is emergency supply at the request of the prescriber.

Process step 9: Deviation

Homecare Provider pharmacy receives the patient specific supply order via secure e-mail. The homecare provider pharmacy team check

- the identity and authority of the sender as a bone fide source of patient specific supply orders
- check the correct number of patient specific supply orders have been received and
- that the NHS clinical referring centre pharmacy team have confirmed prescriber authority
- that the NHS clinical referring centre pharmacy team have confirmed the patient specific supply orders are appropriate and in accordance with the Human Medicines Regulations 2012 provision 226(3) condition B.

The homecare provider pharmacist checks the patient specific supply order is clear and fulfils the requirement of The Human Medicines Regulations 2012 provision 226(3) condition B that

> *(a) that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person to be treated with it; and*

(b) as to the dose which in the circumstances it would be appropriate for that person to take

Any queries are resolved via communication with the prescriber and/or NHS clinical referring centre pharmacy team.

The patient specific supply order is processed for dispensing in accordance with the local standard operating procedure.

An audit trail of patient specific supply orders dispensed, messages and queries sent/received is kept by the homecare provider pharmacy team.

Appendix 3: Further Background Information

NCHA and the NHS have together been in discussions over a number of years to ensure any deviations to homecare prescribing practice comply with good clinical governance standards. It is widely recognised that existing prescription management processes used in homecare services are cumbersome and require significant manual intervention. NCHA and NHS colleagues have been working to streamline and automate prescription management processes and a digital homecare project which aims to enable e-prescribing in clinical and medicines homecare services is ongoing.

Over the past weeks, there have been further discussions with NHSD, NHSX, DHSC and indirectly with GPhC to explore interpretation and agree whether aspects of the digital homecare project could be implemented options to support COVID-19 response and therefore to avoid the need for this COVID-19 specific pandemic deviation.

All avenues available to request a change in interpretation of the legislation and/or a change in the interpretation of legislation have been explored via NHSX. GPhC have stated granting exemptions (temporary or permanent) to the regulations is not within their jurisdiction. We have been advised that the scale of our issue is not significant enough to get to the parliament time for a temporary legislative change. Hence the need for this deviation to existing practice using the Pandemic supply clause of the Human Medicines Regulations 2012 (226).

The Human Medicines Regulations 2012 provision 226: Emergency sale etc by pharmacist: pandemic diseases

226.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A and B are met.

(2) Condition A is that the supply is made whilst a disease is, or in anticipation of a disease being imminently,—

(a)pandemic; and

(b)a serious risk, or potentially a serious risk, to human health.

(3) Condition B is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied—

(a)that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person to be treated with it; and

(b)as to the dose which in the circumstances it would be appropriate for that person to take

COVID-19 Professional Guidance from Royal Pharmaceutical Society

The Royal Pharmaceutical Society (RPS) has kindly agreed to review this agreement and offer their support of this document, therefore providing another level of support and protection for RPS members.

RPS colleagues have highlighted the following guidance within the RPS Ethical Decision Making Framework[5] and specific COVID-19 guidance[6]. We particularly note the sections "Following of Legislative Requirements" and "Leadership" in place at the time of writing this guidance are reproduced below for convenience only, please refer to the prevailing guidance at the time of reading.

Following of legislative requirements

The law is a minimum standard to allow society to function. It is designed in such a way that it is read as being universally applicable without context. The circumstances being witnessed are exceptional.

So long as a pharmacist is able to account for their decisions, some departure from strict legal requirements may be the right thing to do, for example to reduce the risk of death or reduce intolerable pain.

Guidance from the GPhC[14] highlights that professional judgment is acceptable and encouraged; for example, in the splitting of 100 tablet original packs of paracetamol.

Examples where professionals have to exercise judgment might include missing prescription details, including controlled drug prescriptions, where due diligence has been exercised and the professional is confident that the prescriber's wishes are clear.

Where a prescriber's wishes are less clear, a reasoned decision-making process should be followed, for example, a missing dose on a drug chart could be established by referring to the patient's summary care record, even if the patient has not consented to this. Emergency supply provisions should be used to their fullest to facilitate continuity of patient care.

By contrast, it can never be acceptable for corporate or organisational instructions or 'standard operating procedures' to seek to normalise illegality.

[5] https://www.rpharms.com/about-us/news/details/make-professional-decisions-with-our-backing

[6] https://www.rpharms.com/resources/pharmacy-guides/coronavirus-covid-19/coronavirus-information-for-pharmacists/ethical-decision-making

Leadership

Those in leadership positions should consider their additional responsibilities and demonstrate professional integrity, taking responsibility for making difficult but informed decisions. Organisationally, the most appropriate and experienced individuals should collaboratively make the key decisions, providing direction to more junior staff.

Those in leadership positions have a responsibility to share their experiences and decision making processes wherever possible, to increase engagement and transparency and to prevent unnecessary duplication and wasted time.

Digital Homecare Project

It is recognised that not all hospitals are digital sites with ePMA systems and many are still using paper prescription for medicines homecare. Hospitals that have e-Prescribing and Medicine Administration (ePMA) systems have not implemented e-prescribing for homecare due to expectation from homecare providers that prescriber advanced electronic signatures are included. This means that, despite meeting clinical governance requirements, electronic prescription/patient specific orders generated by Trusts ePMA systems which are valid for dispensing within the prescribing organisation are not routinely accepted when transferred electronically to external homecare pharmacies unless they contain a prescriber's AES.

This key elements under discussion have been

- according to existing practise, homecare prescriptions are generally understood to be "private prescriptions" despite being prescribed by NHS prescribers for NHS patients paid for by the NHS – this is at best counterintuitive. EPMA generated homecare prescriptions are generally understood to be "patient specific orders"[7].
- emergency supply at the request of a prescriber
- ensuring appropriate supply of medicines by homecare pharmacies during pandemic
- interpretation of advanced electronic signature

NCHA Homecare Systems Workshop Proceedings have been published by NCHA. In September 2019, NCHA issued a Briefing note for the Secretary of State for Health and Social Care outlining the need to resolve the interoperability challenge in clinical and medicines homecare services[8].

The Output based Specification has recently been updated by NHS National Homecare Medicines Committee and v9 is due to be published shortly as Appendix 15a of the Royal Pharmaceutical Society Handbook for Homecare Services.

[7] The Human Medicines (Amendment) (No. 2) Regulations 2015

[8] https://www.clinicalhomecare.org/wp-content/uploads/2019/09/Resolving_the_e-prescribing_Interoperability_Challenge_in_Clinical_and_Medicines_Homecare_Services_final220719.pdf