Novel coronavirus (COVID-19) standard operating procedure

Running an END OF LIFE medicines reuse scheme in a care home or hospice setting

This scheme is fully endorsed by the National Chief Pharmacist Group and supported by the National Clinical Lead, Palliative & End of Life Care, Wales.

This guidance is correct at the time of publishing. However, it is subject to updates so please use the hyperlinks to confirm you are accessing the most up-to-date information.

Contents

1 Purpose

This standard operating procedure (SOP) supports timely access to essential end of life (EoL) medicines during the COVID-19 pandemic for patients who are being cared for in a care home[1] or hospice setting.[2] In Wales, care homes can offer nursing and personal care or personal care only. The latter may not employ any registered nurses.

This guidance is applicable for use during the COVID-19 pandemic only.[3]

2 Background

2.1 COVID-19

Public Health England has issued guidance on managing COVID-19 for providers of supported living and home care.

2.2 Managing medicines

NICE has issued good practice for managing medicines in care homes. The guidance promotes safe and effective use of medicines in care homes by advising on processes for prescribing (including remote prescribing), handling and administering medicines. It also recommends how medicines (including controlled drugs) should be received, stored and disposed of within a care home setting.

2.3 Recycling/ reuse of patient medicines

In accordance with the Human Medicines Regulations 2012[4] as amended, where a prescription-only medicine is supplied to a person in accordance with a prescription ordered by an appropriate practitioner, it becomes the property of the person named on the prescription. This means in normal circumstances, a medicine prescribed to one person cannot be supplied to another.

It is the accepted position in the UK that the reuse or recycling of one person's prescribed medicines by another is not recommended. The rationale being that once dispensed, the conditions under which medicines have been stored cannot be guaranteed and as such, there is a risk that the quality, safety and efficacy of a medicine may fall below the standard required either in legislation or by professional regulators. Patients' unused medicines would normally be disposed of by returning them to a contracted external company or community pharmacy.

There are increasing concerns about the ability of the supply chain to meet increased demand for EoL medicines during the COVID-19 outbreak; arrangements which in exceptional circumstances, support the appropriate reuse of EoL medicines in care homes and hospices will minimise waste of these medicines should they come into short supply.

Arrangements that support the reuse of medicines are already widely used in hospitals in Wales and have been shown to reduce medicine waste. Reuse of medicines supplied to hospital inpatients is acceptable in situations where storage conditions can be controlled and appropriate record keeping arrangements are in place.

[1] Regulation and Inspection of Social Care (Wales) Act 2016 defines a 'care home' as the provision of accommodation, together with nursing or care at a place in Wales, to persons because of their vulnerability or needs.
[2] Hospice care aims to improve the quality of life and wellbeing of adults and children with a life-limiting or terminal condition. It helps people live as fully and as well as they can to the end of their lives, however long that may be.
[3] The up-to-date status of the COVID 19 pandemic is confirmed at https://www.gov.uk/coronavirus
[4] http://www.legislation.gov.uk/uksi/2012/1916/contents/made

In general, hospices and care homes will be able to provide similar assurances to hospitals regarding the storage and record keeping for medicines. In these situations, it may be appropriate to support the reuse of medicines in limited circumstances in order to avoid unnecessary delays in accessing EoL medicines.

In light of the current unprecedented impact of COVID-19, the UK Department of Health and Social Care (DHSC) has relaxed its previous position to accommodate the reuse of medicines under limited specific circumstances as outlined in this guidance.

The primary concern is to be appropriately assured regarding the quality, integrity and safety of any medicine(s) being considered for reuse.

The most effective means of being assured of a medicine's quality, integrity and safety is for it to be supplied through the regulated supply chain, appropriately labelled for the person for whom it is supplied. However, during the COVID-19 pandemic, it is recognised that it may be possible to assure a medicine's quality such that it can be reused, where formal arrangements are in place. These arrangements should mirror those already in place in hospitals.

This SOP has been developed to support care homes and hospice providers. It offers a framework to run a safe and effective medicines reuse scheme that is in the best interest of patients.

3 Medicines reuse scheme SOP for care homes and hospices

3.1 When would this apply?

Where arrangements are put in place to reuse EoL medicines in hospices and care homes, they can be used **only** during the current COVID-19 pandemic.

3.2 What might constitute a crisis?

Each individual care home or hospice and authorising prescriber must carry out a risk assessment on an individual medicine basis.

In addition any arrangements must ensure that reuse is only considered where:

- Having made an attempt to obtain the required medicines from a local pharmacy/Local Health Board arrangement, out of hours service or the COVID-19 end of life medicine service, no other stocks of the medicine(s) are available in an appropriate timeframe and there is an immediate patient need for the medicine;
- No suitable alternatives for an individual patient are available in a timely manner, i.e. a new prescription cannot be issued and those medicine(s) supplied or if a prescriber is faced with needing EoL medicines for a patient within 2 hours (the delivery turn around time from the COVID-19 EoL Medicines Service)
- The benefits of re-using a medicine outweigh any risks for an individual patient
- The medicine(s) being considered for reuse have been assessed by a registered healthcare professional to meet the requirements in table one below
- The medicine(s) have been authorised for reuse by a prescriber

3.3 Is a medicine suitable for reuse?

The medicines will be identified as suitable for reuse if they are not needed by the resident named on the prescription. This may be after the resident has died or treatment has changed or stopped or the resident has a large enough supply to ensure timely replacement is possible prior to being needed.

The medicine must be checked against the criteria in Table 1 (see below) by a registered healthcare professional.[5]

Where no registered healthcare professional is on site (e.g. in a care home that only offers personal care and has no registered nurses on site), staff in the home, and other members of the multidisciplinary and specialist palliative care teams will need to work together to facilitate the reuse of medicines scheme. Registered healthcare professionals (e.g. pharmacists, pharmacy technicians, general practitioners, community nurses) from other local organisations, such as healthboards, general practices or community settings, can perform this check (this may be done virtually e.g. by Skype or Hospify etc.) and confirm that the medicine is suitable for reuse.

Appropriate records should be kept, including details of the registered healthcare professional that performed the check on suitability for reuse. (See Annex B)

This SOP is not intended to create stock piles of controlled drugs, but to allow the reuse of medicines that are already at the care home and would otherwise be destroyed. Arrangements should be in place to prevent the unnecessary and excessive build-up of medicines in care homes and hospices. What constitutes excessive will be different for each care home and hospice, and will also depend on a range of factors like numbers of residents and storage facilities.

This SOP applies to medicines that have been supplied to patients while in a care home or a hospice, have not been removed from that setting (other than for short periods of up to 24 hours) and have been stored in accordance with good practice guidance on storing medicines in a managed setting. It applies to all EoL medicines in Annex A, providing the criteria in Table 1 is met.

It is for use within a single care home/hospice setting; medicines identified for reuse should not be transferred to another care home or hospice, even those within the same parent organisation.

Table 1 below provide supporting prompts to assist the registered healthcare professional with their decision making. It is advised that any medicines that do not satisfy the criteria are destroyed as per usual protocols. Otherwise, such medicines may be quarantined and used under the exceptional circumstances stipulated in the SOP.

[5] A healthcare professional should be registered with one of the UK's professional regulatory bodies regulated by the Professional Standards Authority.

3.4 Table 1: Criteria to be considered before the medicine can be reused

	Yes	No	Notes
Is the medicine in an unopened primary container that has not been tampered with?			If the contents (including blister strips and sealed individual units such as ampoules) are completely intact, then as long as they match the description of the packaging they were retrieved from (including ensuring batch numbers are the same) they can be considered for reuse. An unopened ampoule is suitable for reuse
Is the medicine in date?			Medicines must be in date. If expired, they must be disposed of as per policy for the safe disposal of surplus, unwanted or expired medicines.
Was the medicine supplied to the patient whilst they became a resident of the care home or hospice?			Medicines can only be reused if they have been retained in the care home or hospice since being dispensed. Medicines that have accompanied the patient from a community setting prior to admission to the care home or hospice must not be reused
Has the medicine been stored in line with the manufacturer's instructions, including any need for refrigeration?			Any medicine that requires refrigeration, or that has a reduced shelf-life once removed from refrigerated storage, must be destroyed if it has not been stored appropriately. Medicines left in unsuitable conditions (e.g. direct sunlight, near radiators) or where appropriate storage cannot be confirmed, must be destroyed.

If the answer to all of the above questions is **yes,** then the risk of reuse may be judged to be minimal. If the answer to **any question** is **no** then the medicine should not be reused. If doubt remains, discuss with an appropriate registered healthcare professionals and local networks to get a wider perspective on the decision.

3.5 Medicines Reuse Process

Once a decision has been made to reuse a medicine, then the following processes (summarised in the flow chart in Section 4 of this SOP) should be followed:

3.5.1 All EoL medicines (contained in Annex A)

1. A log should be maintained of reused stock. The log should include the generic drug name, batch number, strength, formulation, expiry date quantity and details of the registered healthcare professional that assessed the medicine, as a minimum. When the stock is reused, the quantity used should be entered. An example log returns sheet is given in Annex B.

2. Any medicines suitable for reused should be placed in a sealed container and marked as 'suitable for reuse for EoL pathway', to make it clear that the stock should only be reused when stock cannot be obtained from the regulated supply chain

3. Once a medicine has been assessed as being suitable for reuse, the usual processes and governance, as recommended by NICE guideline SC1: Managing medicines in care homes, apply.

4. Any reused medicine would need to be administered according to the direction of a relevant prescriber[6] and recorded by care home or hospice staff in the relevant administration chart.

5. New remote prescriptions should be scanned and emailed before the first dose is given, and a copy of the prescription kept with the patient's records in line with current processes.

6. The administration chart (paper or electronic) should be updated, in line with the direction from the prescriber (in most cases this would be the prescription). The new record should be checked for accuracy and signed by a second trained and skilled member of staff before it is first used. The prescriber does not need to sign the MAR chart.

3.5.2 Controlled drugs

7. Any stock of medication containing schedule 2 controlled drugs should only be retained if it can be stored securely with controlled and limited access (in line with safe storage requirements for controlled drugs).

8. Any schedule 2 controlled drugs must be entered into a separate section of the controlled drugs register and then an entry made when they are reused, as is usual practice.

3.6 Records

9. All records (CD register entries and returned medicines stock, risk assessments) must be kept in line with current legislation.

3.7 Prescribers

10. When medicines are out of stock and there is an immediate need for them, an alternative preparation should be prescribed and dispensed, as is usual practice where possible.

11. Where stock is not available, or the time it would take to obtain stock via an alternative route would be detrimental to patient care, a prescriber can authorise the reuse of suitably assessed medicines that are already at the care home or hospice so they can be used to treat other patients who need them.

12. Reused medicines may be administered to residents in a care home or hospice under the direction of a prescriber, and in line with the terms stipulated in this SOP.

13. In this situation, the direction would normally be in the form of a prescription with an instruction to access the medicines reuse scheme. See Annex D and E.

[6] This can be a verbal direction initially with a written prescription to follow either by email or hard copy

14. If a prescription is issued remotely, it should be scanned and emailed to the care home or hospice by the prescriber (for known medicines shortages) or the community pharmacy as appropriate in each individual case.

3.8 Community pharmacy

15. When medicines are out of stock and there is an immediate need for them, an alternative preparation should be prescribed and dispensed, as is usual practice where possible.

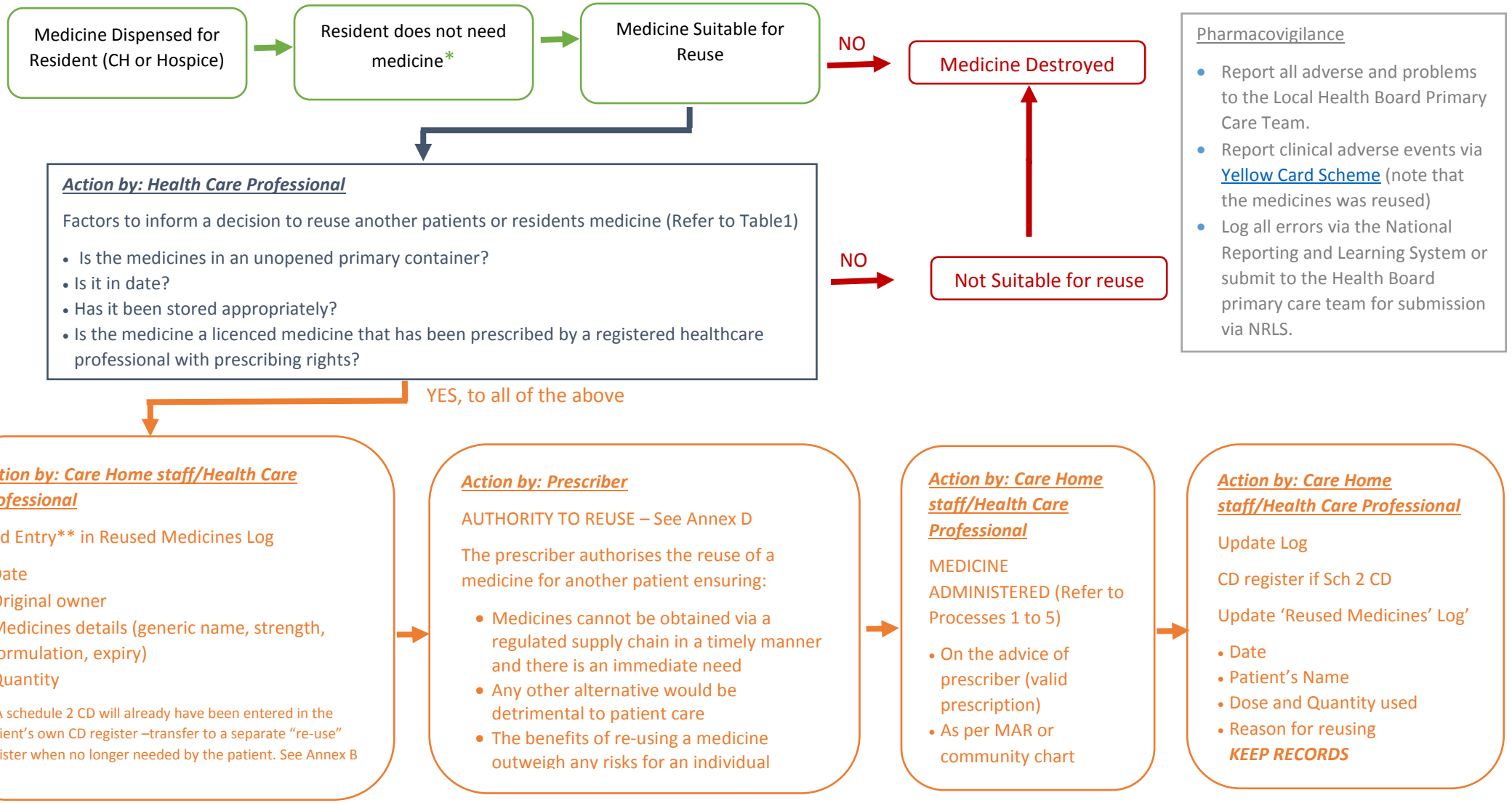
16. Where there is no suitable alternative or a prescription cannot be written for the alternative medicine, the community pharmacy team should alert the care home or hospice and prescriber that it cannot supply the required medication and to suggest accessing alternative health board arrangements.

17. If stock of a reused medicine is available in the care home or hospice, the community pharmacy team should share a copy of the prescription for that medicine with the home.

18. If there are multiple medicines on the prescription (and some are available to dispense) a recommendation to the prescriber that a separate prescription is to be issued for those unavailable and sent to the care home or hospice where it may be used in conjunction with this reuse SOP on receipt of the specified authority from the prescriber.

19. The corresponding MAR chart should be updated as necessary or a recommendation that the All Wales Care Decision Community PRN chart should be used.

4. Medicines re-use pathway



*patient has died/recovered/ switched to an alternative medicine or patient has a large enough supply to ensure timely replacement is possible prior to being needed.

5 Annex A: List of End of Life Medications to be retained

Scheduled 2 – Controlled drugs

- ✓ Diamorphine injection – all strengths (Schedule 2 Controlled Drug)
- ✓ Oxycodone injection – all strengths (Schedule 2 Controlled Drug)
- ✓ Morphine injection – all strengths (Schedule 2 Controlled Drug)
- ✓ Oxycodone liquid – if bottle unopened (Schedule 2 Controlled Drug)
- ✓ Midazolam 10mg/2mL injection
- ✓ Glycopyrronium injection - all strengths
- ✓ Cyclizine 50mg/mL injection
- ✓ Levomepromazine 25mg/mL injection
- ✓ Haloperidol 5mg/mL injection
- ✓ Hyoscine hydrobromide injection - all strengths
- ✓ Hyoscine Butylbromide 20mg/mL injection
- ✓ Morphine 10mg/5mL oral liquid – if unopened bottle cd5
- ✓ Lorazepam 1mg (scored) tablets for SL use if required - cd4

6 Annex B: Template log for care homes and hospices

When a patient is prescribed and receives a medicine it becomes their legal property and so is for their use only.

However, given the COVID-19 pandemic there is a need to ensure as much flexibility as possible to ensure medicines are available to deliver care to patients that is safe and respectful.

Department of Health and Social Care has during the COVID-19 pandemic developed a statement around the reuse of medicine specifically for COVID-19 (see Section 2).

Medicines for reuse				
Date	Patient which medicines originally prescribed to	Medicine details Generic drug name, strength, formulation, expiry date	Quantity	Name, signature and professional number of registered healthcare professional

Reused medicines				
Date	Name of patient	Dose and Quantity of Medicine	Reason for re-using	Name, signature and professional number of registered healthcare professional

7 Annex C –Specific guidance on recording of controlled drugs

Care home or hospice should follow their own policy or standard operating procedure which will detail how to manage controlled drugs. The following process is given as an example:

1. Schedule 2 CDs awaiting destruction will be retained on-site in a CD cabinet, and clearly segregated from all other stock.
2. When no longer needed for a patient the stock should be transferred from the patient's own CD register into a separate "reuse" CD register.
3. When transferring the drug record from the patient own CD register to the reuse CD register the record should be annotated with the following:
   - ✓ Main Register page – *"balance transferred to page x of reuse controlled drug register"*
   - ✓ Reuse register page - *"balance transferred from page x of patient's own CD register"*
4. Deduction and entries should be made in a timely manner, and running balance should always reflect quantities left in the CD cupboard at any point in time

Example 1

Patient A no longer requires medicines and drug record transferred to a new CD register (reuse register) and the medicine is then needed to be used for Resident B.

Page 4	**Main Register – *Resident A***						
Controlled Drug Name: *Morphine Sulphate*		**Form & Strength :** *Injection 10mg/ml*					
Date	**Name**	**Drug**	**Signed**	**Witnessed**	**Amount received**	**Amount used**	**Amount remaining**
Xx/xx/xx	Resident A	Morphine 10mg/ml	AB	DF	Stock check		7
Xx/xx/xx	Resident A	Morphine 10mg/ml	AB	DF		1	6
Xx/xx/xx	Balance transferred to page 8 of reuse controlled drug register	Morphine 10mg/ml	AB	DF		6	0

Page 8	**Reuse CD Register**						
Controlled Drug Name: *Morphine Sulphate*		**Form & Strength :** *Injection 10mg/ml*					
Date	**Name**	**Drug**	**Signed**	**Witnessed**	**Amount received**	**Amount used**	**Amount remaining**
Xx/xx/xx	Balance transferred from page 4 of Main CD register"	Morphine 10mg/ml	AB	EF	Stock check		6
Xx/xx/xx	Balance transferred to page 10 of Main CD register	Morphine 10mg/ml	HI	GK		5	1

Page 10	Main Register – *Resident B*

Controlled Drug Name: *Morphine Sulphate* **Form & Strength :** *Injection 10mg/ml*

Date	Name	Drug	Signed	Witnessed	Amount received	Amount used	Amount remaining
Xx/xx/xx	Balance transferred from page 8 of reuse controlled drug register	Morphine 10mg/ml	AB	DF	Stock check		5
Xx/xx/xx	Resident B	Morphine 10mg/ml	AB	DF		1	4

Example 2

- Resident D has stock and still requires symptom control
- Resident E is waiting supply of medicines, but is deteriorating rapidly and prescriber makes a best interest decision to authorise use of Resident D medicines.

Page 11	Main Register – *Resident D*

Controlled Drug Name: *Morphine Sulphate* **Form & Strength :** *Injection 10mg/ml*

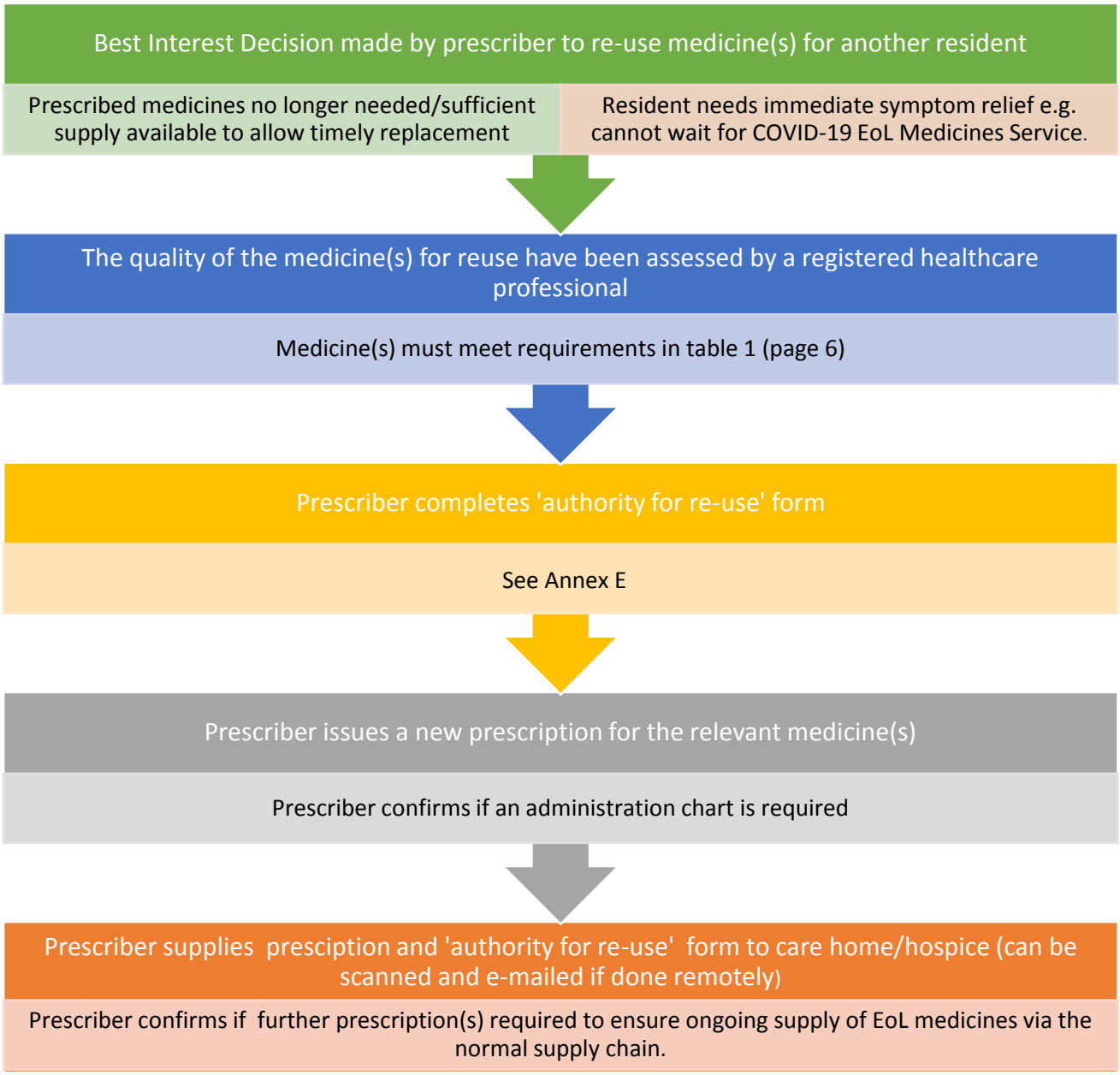
Date	Name	Drug	Signed	Witnessed	Amount received	Amount used	Amount remaining
Xx/xx/xx	Resident D	Morphine 10mg/ml	PD	ED	Stock check		10
Xx/xx/xx	Resident D	Morphine 10mg/ml	PD	ED		1	9
Xx/xx/xx	1 ampoule transferred to page 13 of Main Register	Morphine 10mg/ml	PD	ED		1	8

Page 13	Main Register – *Resident E*

Controlled Drug Name: *Morphine Sulphate* **Form & Strength :** *Injection 10mg/ml*

Date	Name	Drug	Signed	Witnessed	Amount received	Amount used	Amount remaining
Xx/xx/xx	1 ampoule transferred from page 11 of patient own register	Morphine 10mg/ml	PD	ED	1		1
Xx/xx/xx	Resident E	Morphine 10mg/ml	PD	ED		1	0

8 Annex D – Prescriber Medicines Reuse Pathway



9 Annex E – Form of authority for the reuse of medicines (PRESCRIBER)

Prescriber decision aid	**YES ☑**	**NO ☑**
Does the patient's symptoms require immediate treatment and the 2-hour turnaround time for EoL Covid-19 Medicines Service is unacceptable?		
Have alternative methods of obtaining medicine been exhausted?		
Have the medicine(s) being considered for reuse been assessed by a registered healthcare professional to meet the requirements in Table 1 of the SOP?		
Is the reuse of medicines in the patient's best interests? I.e. does the benefits of re-using a medicine outweigh any risks to the patient?		

Resident's Name:	**Date of Birth:**
Reason for re-using medicines:	

Medicine Name	**Strength or Concentrations**	**Form**	**Quantity**

Prescriber Checklist	**YES ☑**	**N/A ☑**
Is a new prescription required for the medicines that are to be reused? (e.g. if the original prescription had multiple medicines and some items are being dispensed by pharmacy)		
Do the medicines need writing up on a community chart/MAR chart?		
Is another prescription required to ensure ongoing supply of EoL medicines via the normal supply chain?		

I authorise the reuse of the listed medicine for the named resident above in line with the *COVID-19 SOP - Running an END OF LIFE medicines reuse scheme in a care home or hospice setting*		
Signed (Prescriber):	Print name:	Date:

Verbal Order Request - Care home/Hospice use only
Verbal order for reuse of medicines received ☐ Name of prescriber authorising reuse: _____ Prescriber professional registration number: _____ Verbal Order received by: _____ Date: _____

10 Annex F – Legal and ethical dilemma for prescribers

Question:
Where do we as clinicians stand legally with regards to authorising the use of EoL medicines for a person different from whom they are prescribed in an emergency situation? I feel really uncomfortable that we are being put in a situation where we would be potentially breaking the law by doing this, even though this would be in the best interests of the person who is distressed.

Answer:
Once a prescription has been dispensed, the medicines then become the property of the patient. However the patient is not authorised under the Misuse of Drugs Act to supply a Controlled Drug to another person unless it is for the purpose of destruction. Once a patient has died, the Controlled Drug becomes part of their estate and, again, the next-of-kin cannot keep possession of it or supply it to anyone except for the purpose of destruction.

The Joint statement from the Chief Executives of statutory regulators of health and care professionals (including the General Medical Council and General Pharmaceutical Council, should be considered.

Therefore, if a prescriber determines the immediate need of EoL medicines for a patient (i.e. sooner than the 2 hours delivery turnaround time from the End of Life COVID-19 Medicines Service) then the following principles should be considered:

- The patient's symptoms require immediate treatment and the 2-hour turnaround time for EoL Covid-19 Medicines Service is unacceptable and all other timely avenues for supply have been exhausted
- Using EoL medicines belonging to another patient will not lead to harm for that patient (i.e. the EoL medicines can be replaced before they are likely to need them)
- The medicines are in date and have been kept in acceptable storage conditions. (Hospices and care homes have procedures in place to store medicines in an appropriate way. Hospice and Care Home staff will follow the criteria within this SOP therefore we can be confident of the quality of any unused medicines in these settings)
- The reasons for the decision to authorise reuse of medicines and the context for the decision must be documented. This documentation must be clear and transparent stating exactly what and why decisions were taken.

In summary, any actions need to be proportionate, transparent and reasonable. Document thoroughly the actions and decision-making principles that have been made.

11 Annex G: Other sources of supporting information

- UK government guidance for care of the deceased with suspected or confirmed COVID-19 https://www.gov.uk/government/publications/covid-19-guidance-for-care-of-the-deceased/guidance-for-care-of-the-deceased-with-suspected-or-confirmed-coronavirus-covid-19
- NHS England and NHS Improvement COVID-19 standard operating procedure for community pharmacy https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-community-pharmacy/
- Marie Curie provide links to supporting guidance and resources https://www.mariecurie.org.uk/professionals/palliative-care-knowledge-zone/proving-good-quality-care/covid-19
- Hospice UK has brought together links to official guidance and resources to provide information on COVID-19 https://www.hospiceuk.org/what-we-offer/clinical-and-care-support/coronavirus-guidance
- Palliative Drugs: collated COVID-19 resources https://palliativedrugs.com
- Health Education England e-learning module: End of Life Care https://portal.e-lfh.org.uk/Component/Details/605650
- Hospice UK – caring for your dying relative at home https://www.hospiceuk.org/docs/default-source/echo/covid-19-echo/covid-19_care-at-home_guide_final.pdf?sfvrsn=2
- Care Quality Commission letter to providers (16 March 2020) https://www.cqc.org.uk/news/stories/routine-inspections-suspended-response-coronavirus-outbreak
- Regulatory approach in challenging circumstances – General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland's joint statement https://www.pharmacyregulation.org/news/regulatory-approach-challenging-circumstances-gphc-and-psni-joint-statement
- Joint statement from chief executives of statutory regulators of health and care professionals https://www.nmc.org.uk/news/news-and-updates/how-we-will-continue-to-regulate-in-light-of-novel-coronavirus/