

Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (3rd Edition)



Bord Altranais agus
Cnáimhseachais na hÉireann
Nursing and Midwifery Board of Ireland

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This document is an interim document while awaiting the updated *Requirements and Standards for Nurses and Midwives with Prescriptive Authority*.

The *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority 3rd Edition* replace the *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority, 2nd Edition (2010)*. They come into effect on 28/02/2018.

Introduction

Prescriptive authority for nurses and midwives is founded on a dual framework of medicines legislation and associated regulation and professional regulation. Medicines legislation and regulations are the first framework, providing specific legal authority for a nurse or midwife to prescribe. The Nursing and Midwifery Board of Ireland (NMBI), the statutory regulatory body for nurses and midwives, has established the second framework, the professional regulation and guidance for the registered nurse or midwife prescriber (as per its function under the *Nurses and Midwives Act 2011*).

Medicines legislation for nurse and midwife prescribing

The primary legislation - the *Irish Medicines Board (Miscellaneous Provisions) Act, 2006* - provides for amendments to medicines regulations by Ministerial order for nurses and midwives to prescribe medications. The *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007 (Statutory Instruments, (S.I.) No. 201 of 2007)* and the *Misuse of Drugs Regulations 2017 (S.I No. 173 of 2017)* (this revokes the 2007 Misuse of Drugs (Amendment) Regulations) specify the legislative requirements/conditions for prescribing of medicinal products by nurses and midwives. A number of conditions must be satisfied for this authority.

They are summarised as follows:

1. The nurse/midwife must be employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home)
2. The medicinal product is one that would be given in the usual course of service provided in the health service setting in which the nurse/midwife is employed
3. The prescription is issued in the usual course of the provision of that health service
4. NMBI registration number (also known as the Personal Identification Number (PIN)) must be stated on the prescription.

Reference must be made to the individual regulations for full details

In addition, the 2007 regulations allow a health service provider to determine further conditions for the prescriptive authority of the nurse or midwife. The prescribing of MDA-controlled drugs, is as detailed in the *Misuse of Drugs Regulations, 2017* which stipulates conditions for Schedule 8 and restrictions for prescribing Schedule 4 and 5 MDAs. (This is outlined in Practice Standard 4).

Professional regulation and guidance for nurse and midwife prescribing

The NMBI provides for the registration, control and education of nurses and midwives and for other matters relating to their practice of nursing and midwifery and sees its overall responsibility to be in the interest and protection of the public. Prescribing is an expansion of a nurse's or midwife's scope of practice, beyond the skills, competence and knowledge an individual practitioner possesses at the point of registration.

The professional regulatory framework for nurse or midwife prescribing is established through the *Nurses Rules, 2007*, amended by the Nurses Rules 2010 and Nurses and Midwives Rules 2013 which allows for the creation of a division of the Register for Nurse and Midwife Prescribers. *Requirements and Standards for Education Programmes for Nurses and Midwives with Prescriptive Authority* (An Bord Altranais, 2007) defines the competencies to be attained through successful completion of the programme.

Building upon these foundations are the remaining elements of the Board's framework, which are:

- *Decision-Making Framework for Nurse and Midwife Prescribing* (An Bord Altranais 2007) (See Appendix 3)
- *Collaborative Practice Agreement (CPA)* (NMBI 2016)
- NMBI guidance documents:
 - *Guidance to Nurses and Midwives on Medication Management* (2007)
 - *Recording Clinical Practice Guidance to Nurses and Midwives* (2002)
 - *Practice Standards for Midwives* (2010)
 - *The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives* (2014)
- *Scope of Nursing and Midwifery Practice Framework* (2015)
- *Collaborative Practice Agreement Guidance For Nurses and Midwives With Prescriptive Authority* (4th Edition, 2016)
- *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority* (2018)

Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority

The professional responsibilities of the nurse and midwife are addressed in the *Practice Standards and Guidelines* that follow and should be viewed as the overarching mechanism with which a nurse or midwife is expected to practice. These specific standards, along with the Decision-Making Framework, CPA and guidance documents, outline the requirements of NMBI for the registered nurse or midwife prescriber. *The Practice Standards and Guidelines* augment the clinical governance structures required at local and national levels to support safe and professional practices for the implementation of nurse and midwife prescribing.

Prescribing practice involves a number of complex skills including comprehensive consultation, diagnosis, information giving and accurate documentation. Consultation with a patient/service-user during the prescribing process and the correct completion of a prescription enhances patient/service-user safety and reduces the likelihood of a medication error (World Health Organisation, 1994; Smith, A, Latter S. and Blenkinsopp, A. 2014)

The rationale for providing these standards and guidelines is as follows;

1. Safe and effective prescribing practice will lead to improved patient/service user outcomes and reduce the incidence of adverse events related to medication.
2. The role of the nurse or midwife prescriber is undertaken in an interdependent system which recognises the expertise of the registered nurse or midwife prescriber and avails of the professional knowledge of medical, nursing and pharmacy colleagues (NMBI and HSE, 2015).
3. Nurses and midwives with prescriptive authority are prescribing a wide range of medications across diverse patient/service-user populations that have the potential to interact.

Two key elements in good prescribing practice are minimising risk and maximising effectiveness (Naughton, C. et al 2013) In minimising risk it is important to note that prescribing is a complex process and may be associated with adverse events and unintended consequences. Therefore, it is important that the Nurse or Midwife Prescriber has a thorough understanding of the medication that is being prescribed including possible side-effects and the interaction the medication may have with other medications. It is also important that risk is minimised through comprehensive and accurate recording of the prescribing consultation. Although it is recognised that risk cannot be fully eliminated the nurse or midwife prescriber should take all steps to ensure that risk is minimised. In maximising effectiveness it is good practice to monitor the impact of the medicinal product prescribed.

It is also essential in the prescribing consultation to respect the patient's/service user's choice. There are two principles in this regard: first the nurse or midwife prescriber should listen to the patient's/service user's concerns and needs and, secondly, they should ensure that the patient/service user is educated and informed so that s/he understands his/her medication regimen (Naughton, C. et al. 2013).

Objectives:

The objectives for the Practice Standards are to:

- Provide nurse and midwife prescribers with professional guidance for prescriptive authority including medication management
- Enable nurse and midwife prescribers to demonstrate the key competencies and related principles to ensure safe, competent, effective and ethical practice
- Ensure appropriate mechanisms of clinical and self-governance are in place relating to the nurse or midwives prescriber's scope of practice
- Outline a regulatory framework for nurses and midwives for the continuum of their prescribing authority/practices
- Assure the public of the competence and professional accountability required of the nurse or midwife prescriber by the NMBI

Each practice standard is described and is accompanied by supporting rationale(s), guidance for practice and reference to *Recording Clinical Practice Guidance to Nurses and Midwives* (An Bord Altranais, 2002).

The standards and guidelines outlined in this document are intended as a guide towards best practice, but should always be used in conjunction with professional judgement.

Practice Standard 1. Clinical Decision-Making Process

Nurse and midwife prescribing is underpinned by a number of principles. These include the nurse and midwife's scope of practice, their Collaborative Practice Agreement (CPA) (NMBI 2016), their core competencies and their decision-making processes. A systematic clinical decision-making process should inform the decision to prescribe.

Rationale

Nurse and midwife prescribers are referred to the *Decision-Making Framework for Nurse and Midwife Prescribing (Appendix 3)*. This algorithm outlines the decision-making pathway that should be followed by a nurse or midwife prescriber.

The *Decision-Making Framework for Nurse and Midwife Prescribing* highlights the importance of the following in informing the nurse or midwife's decision to prescribe:

- Ensure that prescribing is within the nurse's or midwife's scope of practice and competency
- Prescribing is undertaken following an assessment of the patient/service user
- The nurse or midwife has gathered evidence to determine a treatment plan for the patient/service user
- The nurse or midwife has determined the required pharmacological/non-pharmacological treatment option(s) for the patient/service user
- The nurse or midwife initiates the treatment decision in discussion with and agreement by the patient/service user (and/or carer if applicable) providing a comprehensive description of the treatment prescribed including expectations of treatment and side effects if any
- The nurse or midwife ensures that record keeping is accurate and up-to-date.
- The nurse or midwife prescriber documents the treatment plan including the prescribed medication monitoring, evaluation and follow up care
- The nurse or midwife prescriber refers and the patient/service user to the appropriate Health Care Professional if required.

Associated competencies

Domain 1. Professional/Ethical Practice

1.3 Practices within a framework of professional accountability and responsibility in relation to prescribing.

Domain 2. Holistic Approaches to Care and Integration of Knowledge

2.2 Plans care in consultation with the patient/service-user taking into consideration the therapeutic regimes of all members of the interdisciplinary team.

Practice Standard 2.

Communication and History Taking

The responsibility of prescriptive authority requires the nurse or midwife prescriber to effectively and efficiently communicate with the patient/service user and to complete an accurate and comprehensive medication history.

Rationale

Communicating with a patient/service user and comprehensive history taking are fundamental principles of safe and effective prescribing practice. The quality of the consultation with the patient/service user is central to outcomes such as correct diagnosis, effective treatment, concordance, medication adherence, quality and safety. The complexity, depth of information and duration of a consultation is dictated by the individual patient's/service user's needs. The underlying principle is that the information is sufficient to allow the formulation of an appropriate plan of care. A comprehensive medication history is important to reduce the possibility of prescribing errors associated with collecting incomplete medication histories (Cullinane, O'Mahony and Byrne, 2016).

Guidance for Practice

There are a number of important areas that normally should be considered within the consultation. These include the following:

- Assess and clarify a patient's/service user's clinical condition including an evaluation of their reason for presentation for treatment and the patient's/service user's presenting symptoms
- An appropriate physical examination should be carried out if clinically indicated (as per local health service provider policy)
- Assess the patient's/service user's management of the presenting problem to date and whether they have experienced any previous episodes of the presenting problem
- Undertake an assessment of the patient's/service user's current and past medication history
- Medication history should include an assessment of the following:
 - Medicines currently prescribed
 - Over-the-counter medicines (OTC). Patients/service-users may not recognise that medicines they buy over the counter are important and may result in drug interactions.
 - Herbal remedies
 - Homeopathic medicines
 - Medicines taken that have been prescribed for others
 - Dietary, vitamin or food supplements.

- The patient's/service user's medication should be assessed both by asking the patient/service user and/or their family if appropriate³ and reviewing the patient's/service user's health care records. Patients/service users on multiple medications may not be aware of the name or dosage of their current regimen therefore it is good practice to check all available sources of information (WHO, 2009).
- Ask the patient/service user or their family if appropriate and also refer to the patient's/service user's health care records for documented medication allergies, other forms of allergies, medication sensitivities and adverse drug reactions.
- Ask the patient/service user, if appropriate, about their level of adherence to their current medication regimen (Fitzgerald, 2009).
- Be aware of any precautions that need to be taken into consideration when prescribing, for example if the patient/service user is pregnant or breastfeeding.
- Be aware of potential drug interactions with the patient's/service user's existing condition(s)⁴
- When prescribing the nurse or midwife should take into account the issue of polypharmacy, the possibility of cognitive impairment and whether the patient/service user has any associated co-morbidities (Agrawal et al, 2009).
- If relevant, order and review diagnostic, radiological and laboratory tests and interpret results in relation to provisional diagnosis and proposed treatment plan.
- Smoking, alcohol history and illicit drug use should also be considered due to the potential interaction between these substances and medicinal product prescribed (Young, Duggan and Franklin, 2009).
- Social circumstances, occupational and family history are also important elements of a comprehensive medication history.
- Review the diagnosis in the context of the patient's/service user overall clinical and medication history and presentation.
- Take into consideration the patient's/service user's overall care plan.

In the event there is a decision to prescribe a medicinal product as part of the patient's/service user's care plan, there are a number of principles that normally should be taken into account during the prescribing consultation process (WHO, 2009; Beckwith and Franklin, 2011). These include:

- Only prescribe if the nurse or midwife prescriber has assessed the patient/service user and has a valid clinical relationship with the patient/service user
- Communicate clearly with patients/service users in a language that they understand. Patients/ service users should normally be provided with the following information:

3 Relevant sources should be referred to in this regard. For example the patient's consultant or GP, hospital or community pharmacist, Health Products Regulatory Authority (HPRA), Summary of Product Characteristics (SmPC) and patient information leaflets.

4 It should be noted that individual health service providers/employers may have specific policies for documenting care and prescribing practices

- A rationale for the prescription
- Name of the medicinal product
- Purpose of the medicinal product
- Dose and frequency with which medicinal product is to be taken
- Route of administration
- Additional medicinal product instructions, for example to take medicinal product with food, or potential interactions between the medicinal product prescribed and other medicinal products/substances including OTC products
- Possible side-effects of their medicinal product
- When to come back or what to do if they have a concern about their medicinal product
- Include and encourage patients/service users to be actively involved in the prescribing process
- Decide whether it is appropriate to prescribe, not to prescribe or alter medicinal products.
- Monitor, if appropriate, the patient's/service user's response to medicinal product.

Associated competencies

Domain 2. Holistic Approaches to Care and Integration of Knowledge

- 2.1 Conducts a systematic holistic assessment of patient/service-user needs.
- 2.2 Plans care in consultation with the patient/service-user taking into consideration the therapeutic regimes of all members of the interdisciplinary team.
- 2.3 Implements planned nursing/midwifery care/interventions to achieve the identified outcomes of the plan of care.
- 2.4 Evaluates patient/service-user progress toward expected outcomes and review plans in accordance with evaluation data and consultation with the patient/service-user.
- 2.5 Demonstrates and integrates knowledge of medicinal products for safe medication management and prescribing practices.

Domain 3. Interpersonal Relationships

- 3.1 Establishes and maintains caring therapeutic interpersonal relationships with individuals/ service- users/groups/ communities for safe and effective prescribing.

Domain 4. Organisation and Management of Care

- 4.1 Effectively manages the nursing/midwifery care of service-users/groups/communities.

Practice Standard 3.

Documentation

The *Decision-Making Framework for Nurse and Midwife Prescribing* (Appendix 3) gives reference to systems of documentation for patient/service user care and prescribing, e.g. patient/service user case notes and medicinal product administration records. Individual health service providers/employers may have specific policies for documenting care and prescribing practices (including requirements for clinical audit of practice).

The clinical consultation and referral pathway of the nurse or midwife prescriber should be noted in the CPA. Nurses and Midwives are referred to NMBI documents *Recording Clinical Practice Guidance to Nurses and Midwives* (An Bord Altranais, 2002) and midwives are referred to the document *Practice Standards for Midwives* (NMBI, 2010). The principles of documenting and recording the care delivered to patients/service-users outlined in these documents also pertain to the standards of recording that should occur within prescribing practice.

The depth and detail of information recorded in a consultation is dependent on the context, circumstances and individual characteristics of the patient/service user. If the consultation is a first consultation (no previous health care record), or a previous record with new, unresolved or deteriorating symptoms or a consultation after a prolonged period of time, then a full comprehensive clinical assessment should be carried out and the detail must be recorded in the associated consultation documentation. This is regardless of whether the consultation takes place face to face or by telephone.

Rationale

It is the responsibility of the nurse or midwife prescriber to comprehensively record their prescribing consultation. This allows for the episode of care related to prescribing to be communicated to other healthcare professionals, keeps an accurate record of the consultation and ensures the safety of the patient/service user. The document *Guidance to Nurses and Midwives on Medication Management* (An Bord Altranais, 2007) addresses the importance of an interdisciplinary approach to medication management; this is especially critical in the role as a nurse or midwife prescriber.

Guidance for Practice

- The nurse or midwife prescriber must document all prescribing decisions and actions. The context of all consultations should be described with reference to a patient's/service user's age, gender, primary condition and reason for presentation for treatment
- All episodes of nurse and midwife prescribing should be recorded in the patient's/service user's health care records⁵. This ensures clear communication of treatment with medical and other healthcare professionals
- Accurate and comprehensible communication is central to preventing prescribing errors. Therefore, it is important that all written communication is legible, unambiguous and does not lead to misunderstanding between health care professionals
- Entries made in error should be bracketed and have a single line drawn through them so that the original entry is still legible. Amendments should be signed and dated with a rationale provided. Correction fluids should not be used
- A nurse or midwife prescriber making a referral or consulting with another member of the healthcare team should clearly identify, his/her name, title and position
- Documentation of the prescribing consultation should occur during or immediately after the prescribing consultation
- In exceptional circumstances it may be necessary to record the consultation retrospectively. However, this retrospective record should occur within 24 hours post consultation. The first date and time recorded should reflect the date and time of the current entry. The record should clearly indicate that it is a retrospective entry with the date and time of the original consultation also recorded
- In the event of a case review or audit it is essential that reviewers can distinguish between concurrent and retrospective entries in order to establish accurate information on the sequence of events and assess the reliability of entries
- Regular audit of documentation is an integral part of maintaining quality prescribing practice.

⁵ HSE Standards and Recommended Practices for Healthcare Records Management (HSE, 2011 pg. 21) recommend that: 'All records relating to the patient shall be kept in a unified healthcare record file. The structure shall facilitate documentation of the chronology of events and all significant consultations, assessments, observations, decisions, interventions and outcomes. The structure shall also facilitate the monitoring of standards, audit, quality assurance and the investigation of complaints.'

The following should normally be documented in the patient's/service user's health care records:

- All entries should have both the date (day/month/year) and time (using the 24 hour clock) of the consultation recorded (HSE, 2011). The date and time are important especially in instances where the patient's/service user's care and/or condition is changing frequently
- The patient's/service user's age, date of birth, gender, address and medical record number
- The purpose of the consultation and rationale for decisions made in relation to the prescriptive episode. This should include the rationale for either issuing the prescription, changing the current medication regime (including discontinuing medication) or a decision not to prescribe
- Name of medication prescribed, discontinued, dose changed or OTC medication recommended by the nurse or midwife prescriber.
- Instructions and advice given by the nurse or midwife prescriber to the patient/service user regarding their medication.
- Dose, frequency, route and the duration that the medication should be taken for.
- Advice provided to the patient/service user in the event of side effects or deterioration in their condition.
- Date and/or time of proposed review or if no review is required
- During a review record the outcome and efficacy of medication prescribed.
- Patient/ service user known drug allergies or adverse drug reactions. If the patient/service user has no known allergies this must also be documented
- All consultations should be signed by the nurse or midwife prescriber. They should also include the nurse and midwives name (printed) and NMBI Personal Identification Number (PIN).

Note: It is not necessary to duplicate information already recorded in the patient's/service user's health care records however, it is the responsibility of the individual nurse or midwife prescriber to ensure and indicate in the current consultation that they are aware of the patient's/service user's medical history, drug allergies and current medication and that this information is up-to-date prior to prescribing medication (Beckwith and Franklin, 2011; Drennan et al. 2009).

Associated competencies

Holistic approaches to care and integration of knowledge

- 2.2 Plans care in consultation with the patient/service-user, taking into consideration the therapeutic regimes of all members of the interdisciplinary team.
- 3.2 Collaborates with all members of the health care team and documents relevant information.

Practice Standard 4.

Prescription writing

Prescription writing

Specific standards for prescription writing must be adhered to as required by legislation and the health service provider/employer (including Drugs and Therapeutics Committee) policy. This also pertains to the safe keeping and accountability associated with prescription pads.

Medicines regulations pertaining to prescription writing by the nurse or midwife prescriber include:

- *Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (S.I. 540 of 2003)*
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007 (S.I. 201 of 2007)*

In summary, these regulations require the prescription to:

- Be legible
- State the full name of the person issuing it and include NMBI PIN
- The prescription (including computer-generated prescriptions) must be in indelible ink
- The prescription must be dated and signed by the nurse or midwife prescriber with her/his usual signature
- The full name and address of the patient/service user must be on the prescription
- If a patient/service user is under the age of 12 years, the date of birth is required.

Prescriptions should be written using only approved abbreviations.

Prescription writing for (schedule 4 and 8) controlled drugs

The Misuse of Drugs Regulations, 2017 (Government of Ireland, 2017) states the particular requirements that must be met for a RNP to issue a prescription for Schedule 4 and 5 MDA drugs and a named schedule 2 or 3 MDA drug. (Schedule 8).

- Schedule 8 provides a detailed listing of the drugs, routes of administration and conditions for which Schedules 2 or 3 MDA drugs can be prescribed by a nurse or midwife prescriber (Appendix 2)
- The nurse or midwife prescriber does not have legal authority to prescribe any other Schedule 2 or 3 MDA drug which is not listed in Schedule 8, nor write for a different route of administration of the named drug, nor prescribe for any condition/situation not named in Schedule 8.
- The nurse or midwife prescriber must adhere to the *Misuse of Drugs Regulations (2017)* and the *NMBI Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority 3rd Edition* (NMBI, 2018) when prescribing MDA drugs.

- When prescribing MDA drugs, the nurse or midwife prescriber must ensure the prescription:
 - is in ink or otherwise so as to be indelible
 - clearly indicates the RNP's full name, including the first name
 - states the NMBI PIN
 - is signed by him/her with his/her usual signature
 - is dated by him/her
 - specifies the nurse or midwife prescriber's address and telephone number
 - specifies the name, including the first name, and address of the person for whose treatment it is issued
- The prescription must specify in the nurse or midwife prescriber's handwriting:
 - The name of the controlled drug to be prescribed
 - The dose of the controlled drug to be taken by the person for whose treatment the prescription is issued
 - In the case of a prescription for a controlled drug which is a preparation the nurse or midwife prescriber must include
 - The form and, where appropriate, the strength of the controlled drug to be supplied, and
 - Either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units, as appropriate, to be supplied, and
 - In the case of a prescription for a controlled drug which is not a preparation, the total quantity (in both words and figures) of the controlled drug to be supplied
 - In the case of a prescription for a total quantity to be dispensed in instalments, the number of instalments and the intervals at which instalments may be dispensed.
- The specific criteria to be included on a prescription for Schedule 2 and 3 controlled drugs also applies to controlled drugs in Schedule 4 Part 1 of the Misuse of Drugs Regulations 2017, i.e. most benzodiazepines and Z-drugs:
 - the name of the drug
 - dose
 - pharmaceutical form
 - strength (where appropriate)
 - the total quantity of the controlled drug to be dispensed **written in both words and figures**
- Controlled drugs in Schedule 4 Part 1 are not required to be handwritten.

A prescription for controlled drugs cannot be repeated but may be dispensed in instalments by the direction of the prescriber.

Rationale

Prescription writing is an important component of the role of the nurse or midwife prescriber. A prescription is primarily an instruction from a prescriber to a dispenser and as such should be clear, legible and indicate precisely the treatment prescribed (WHO, 1994). This will ensure that the possibility of errors occurring is reduced and that patients/service users have a good understanding of the treatment prescribed. The nurse or midwife prescriber must adhere to legal requirements for prescription writing of scheduled prescription medicinal products and MDA controlled drugs. A prescription for a scheduled medicinal product, including MDA's, must be correctly and accurately written, as it may otherwise result in difficulties for dispensing of the prescribed medicinal product by the pharmacist and/or supply and administration to the patient/service user.

Guidance for Practice

- It is recommended that the generic or non-proprietary name of the medicinal product be used on the prescription. However, it is acknowledged that with some medicinal products the proprietary name may need to be used
- When recording the strength/dosage of the medicinal product it is recommended that internationally and nationally accepted abbreviations only be used. It is also good practice to identify the maximum daily dose of the medicinal product
- It is good practice to identify when the medication should be discontinued or if long-term medication is prescribed a review date must be indicated
- It is important to ensure that the instructions regarding the medicinal products are understood and agreed by the patient/service-user
- It is important that the nurse or midwife prescriber ensures that the written prescription is legible on all copies
- Corrections must only be made by re-writing the prescription. Use of correction fluid or deleting with a pen is prohibited.

Associated competencies

Professional/ethical practice

1.3 Practices within a framework of professional accountability and responsibility in relation to prescribing.

Holistic approaches to care and integration of knowledge

2.5 Demonstrates and integrates knowledge of medicinal products for safe medication management and prescribing practices.

Interpersonal relationships

3.2 Collaborates with all members of the health care team and documents relevant information.

Practice Standard 5.

Prescribing for self, family and significant others

Prescribing for self, family and/or significant others is prohibited by a nurse or midwife prescriber. There should be an established nurse or midwife prescriber to patient/service user relationship when prescribing for another individual. A blurring of professional and personal boundaries of care and accountability results and represents a conflict of interest. Writing and issuing a prescription for personal use or for a family member or significant other must not be undertaken by a nurse or midwife prescriber regardless of circumstances.

The individual requiring a prescribed medicinal product should be referred to/directed to another appropriate registered prescriber (e.g. General Practitioner) or where health services are provided.

Rationale

Prescribing must take place in the context of providing nursing/midwifery care to an identified patient/service user requiring the services of the health service provider. The medicines regulations - *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007 and Misuse of Drugs Regulations, 2017* - provide specific requirements for nurses and midwife prescribers to issue a prescription which must be adhered to in the provision of health care.

Ethically, prescribing in this manner is not objective and is not best practice. Serious concerns may arise about the misuse/abuse of medicinal products and inappropriate prescribing. A nurse or midwife prescriber prescribing for self, family and significant others is in violation of these standards.

Associated competencies

Professional/ethical practice

- 1.1 Practices in accordance with legislation and professional guidance affecting nursing/midwifery practice.
- 1.3 Practices within a framework of professional accountability and responsibility in relation to prescribing.

Practice Standard 6.

Repeat prescribing

The nurse or midwife prescriber should be knowledgeable of the medicinal products regulations relating to the supply/dispensing of medicinal products in instalments for the duration of individual prescriptions. Repeat prescribing may arise in situations where the original issued prescription was issued and the patient/service user requests or requires a continued course of medication. This may typically occur in the treatment of chronic health conditions.

In these instances of repeat prescribing for continued treatment, there should be an established nurse or midwife prescriber to patient/service user relationship when prescribing. The nurse or midwife prescriber should undertake an appropriate assessment of the need for continued treatment with the prescribed medicinal product. This decision-making should be documented. It should include a discussion with the patient/service user of perceived effectiveness and adherence to the treatment plan.

The nurse or midwife prescriber should acknowledge her/his scope of practice for prescribing, recognising any limitation of competence/knowledge and refer the patient/service user to the appropriate practitioner for evaluation concerning the repeat prescription if required.

Rationale

There should be regular review and appropriate clinical assessment of the patient/service user condition for continuing a specific medication in accordance with the overall treatment plan. Although the nurse or midwife prescriber may not have determined the initial need/diagnosis warranting the medicinal product prescription, s/he is responsible for conducting a relevant assessment and decision in determining the appropriateness of a repeat/continued prescription. The issue of timely and appropriate medicinal product review has been identified as a significant factor in ensuring patient/service user safety and appropriate prescribing.

Associated competencies

Holistic approaches to care and integration of knowledge

- 2.1 Conducts a systematic holistic assessment of patient/service-user needs.
- 2.4 Evaluates patient/service-user progress toward expected outcomes and reviews plans in accordance with evaluation data and consultation with the patient/service-user.
- 2.5 Demonstrates and integrates knowledge of medicinal products for safe medication management and prescribing practices.

Practice Standard 7.

Prescribing of off-label and exempt medicinal products

Off-label Medicinal Product

Definition: Off-label use refers to the use of an authorised medicinal product outside the terms of its marketing authorisation (MA). It is the prescribing of the medicinal product that is off-label, rather than the medicinal product itself. (HSE, 2017) There is no impediment in the relevant legislation or professional regulation to a nurse or midwife prescriber prescribing a medicinal product for off-label use. The issuing of a prescription for an off-label indication must be in accordance with Regulation 5A of the *Medicinal Products (Prescription and Control of Supply) Regulations 2003* as amended.

Rationale

The nurse or midwife prescriber is legally and professionally accountable and responsible for prescribing practices as mandated by the medicinal product legislation and the NMBI professional standards.

Off-label prescribing as defined above is not prohibited by the medicines regulations. The *Medicinal Products (Control of Placing on the Market) Regulations 2007* as amended do not prohibit the sale, supply, manufacture, possession or procuring the sale, supply, manufacture of a medicinal product for off-label use. It is permissible for an authorised medication to be supplied from a prescription issued by any prescriber, including where it has been prescribed for off-label use.

Guidance for Practice

In tandem with the legislative requirements the nurse or midwife prescriber should be aware of best practice guidance and organisational policy when prescribing for off-label use. As with all decisions in prescribing medicinal products, the prescribing for off-label use must be within the nurse or midwife prescriber's scope of practice.

The nurse or midwife prescriber should be knowledgeable of best practice for prescribing medicinal products for off-label use. This includes determining:

- if there is an alternative authorised medicinal product that could be prescribed;
- if the medicinal product is regularly used to treat patient/service users in the nurse or midwife prescribers area of clinical practice
- if the specific medicinal product is listed within the health service provider's prescribing guidelines (where such guidelines exist).

The nurse or midwife prescriber must include the prescribing of any medicinal products for off label use on the relevant section of the CPA. The health service provider's organisational policy for nurse or midwife medicinal product prescribing should detail the process for reviewing and approving the prescribing of medicinal products for off-label use by a nurse or midwife prescriber. The NMBI supports the use of the Nurse/ Midwife Medicinal Product Prescribing Form (HSE, HPRA, 2017- Toolkit) (or a similar tool) as a guide for the governance structures required for health service providers to authorise nurse or midwife prescribers to prescribe medicinal products for off-label use. This ensures the safety and quality of care for patients and service users requiring the prescription of a medicinal product for off-label use.

Exempt Medicinal Product

Definition: An exempt medicinal product (EMP) is a medicinal product that is not authorised in Ireland either by the Health Products Regulatory Authority (HPRA), or in the case of a centrally authorised medicinal product, by the European Medicines Agency (EMA), but which can be legally supplied in response to a *bona fide* unsolicited order, formulated in accordance with the specifications of a registered medical practitioner or registered dentist for use by their individual patients on her/his direct personal responsibility, in order to fulfil the special needs of those patients (Medicinal Products (Control of Placing on the Market) Regulations 2007 as amended).

The *Medicinal Products (Control of Placing on the Market) Regulations, 2007* provide statutory authority for a medical practitioner to treat a patient under her/his care, using exempt medicinal products. The prescribing of exempt medicinal products by nurse or midwife prescribers is **not** provided for in current medicinal products legislation and regulation. Therefore this action is outside the nurse's or midwife's scope of practice for prescriptive authority. A patient/ service user need for a prescription for an EMP should be referred to the appropriate medical practitioner.

Associated competencies

Professional/ethical practice

- 1.1 Practices in accordance with legislation and professional guidance affecting nursing/ midwifery practice.
- 1.2 Practices within the limits of own competence and takes measures to develop and maintain own competence.
- 1.3 Practices within a framework of professional accountability and responsibility in relation to prescribing.

Practice Standard 8.

Prescribing by means of other than an original prescription

Regulation 7(5) (b) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) requires that a prescription be an 'original'.

There is however provisions provided for under Regulation 8 of the aforementioned Regulations, for the emergency supply of certain prescription only medicines other than in accordance with a prescription, in emergency circumstances where an original prescription cannot be furnished immediately.

Rationale

Regarding the provision of an emergency prescription Regulation 8 of the Medicinal Products Prescription and Control of Supply Regulations 2003, as amended states:

- "8. (1) It shall not be a contravention of regulation 5(1) or regulation 7 for a person keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the Pharmacy Acts, 1875 to 1977 to supply a medicinal product otherwise than in accordance with a prescription where -*
- (a) the authorised person by whom or under whose supervision the product is to be supplied has been requested to supply the product for a particular patient by a registered medical practitioner, registered dentist or registered nurse who by reason of an emergency is unable to furnish a prescription immediately, [Amended by 2007 Amendment Regulations]*
 - (b) the practitioner or nurse concerned has undertaken to furnish a prescription within 72 hours, [Amended by 2007 Amendment Regulations]*
 - (c) the product is supplied in accordance with the directions of the practitioner or nurse requesting it, and [Amended by 2007 Amendment Regulations]*
 - (d) subject to paragraph (3), the product is not a controlled drug specified in Schedule 1, 2, 3 or 4 to the Misuse of Drugs Regulations 1988 or any amendment thereof."*

Associated competencies

Professional/ethical practice

- 1.1 Practices in accordance with legislation and professional guidance affecting nursing/ midwifery practice.
- 1.2 Practices within the limits of own competence and takes measures to develop and maintain own competence.

Practice Standard 9.

Separation of responsibilities in the medication management cycle

a. Separation of prescribing and administering of medications

The nurse or midwife prescriber should separate the activity of prescribing a medicinal product and the subsequent action of administering the medicinal product. Another individual should undertake the administration component of the medication management cycle, especially in the case of MDA drugs. This is safe practice, providing for the typical safety checks within the medication management cycle.

Whilst acknowledging the fundamental principles associated with the separation of responsibilities for prescribing and administering a medicinal product, the nurse or midwife prescriber may be involved in a cross over and merging of these activities as part of her/his provision of patient/service user care. Where this cross over occurs this practice should be recorded in the CPA. The CPA should outline the auditing of such practices as part of the overall audit of prescriptive practices.

b. Separation of prescribing and supplying

The nurse or midwife prescriber should not undertake to both prescribe and supply a medicinal product as part of providing episodes of patient/service user care. There should be clear separation of these activities. There may be circumstances arising when the nurse or midwife prescriber may be required to supply a medicinal product. In these situations, the prescriber should be aware of her/his responsibilities with this practice in the overall context of medication management.

Whilst recognising the separation of responsibilities for prescribing and supplying medicinal products as a fundamental principle, the nurse or midwife prescriber may be involved in a cross over and merging of these activities. Where this cross over occurs this practice should be recorded in the CPA. The CPA should outline the auditing of such practices as part of the overall audit of prescriptive practices.

Rationale

Best practice advocates the separation of responsibilities in the systems associated with medication management. The pharmacist has a particular role and expertise for dispensing, as does the nurse or midwife involved with supply and/or administration of medicinal products. Distinct separation of responsibilities and activities in the medication management cycle provides for greater patient/service user safety.

Associated competencies

Holistic approaches to care and integration of knowledge

2.5 Demonstrates and integrates knowledge of medicinal products for safe medication management and prescribing practices.

Interpersonal relationships

3.2 Collaborates with all members of the health care team and documents relevant information.

Organisation and management of care

4.1 Effectively manages the nursing/midwifery care of service-users/groups/communities.

Practice Standard 10.

Influence of outside interests (relationships with pharmaceutical representation or similar organisations)

The nurse or midwife prescriber should prescribe in an appropriate, ethical manner, based on the best interests of the patient/service user only. She/he should not be influenced by factors such as financial support by pharmaceutical and/or health care interests.

Rationale

The *Code of Professional Conduct and Ethics for Registered Nurses and Midwives (NMBI, 2014)* states:

“The nurse or midwife must not accept any gifts or favours from patients, healthcare and pharmaceutical companies that could:

- Reasonably give the impression that you are providing someone with preferential treatment;
- Influence your professional integrity; or
- Cause a conflict of interest-where your private interests might interfere with your professional responsibility to your patient

Nursing/midwifery practices should always be based on the principles identified within the *Code of Professional Conduct and Ethics for Registered Nurses and Midwives. The Scope of Nursing and Midwifery Practice Framework (NMBI, 2015)* refers to the values of nursing and midwifery practice and the relationship to the patient/service-user based on trust, understanding, compassion and support.

Associated competencies

Professional/ethical practice

1.1 Practices in accordance with legislation and professional guidance affecting nursing and midwifery practice.

Personal and professional development

5.1 Acts to enhance the personal and professional development of self and others.

Practice Standard 11.

Continuing professional development and competency

NMBI through its Requirements and Standards for the Education Programme for Nurses and Midwives with Prescriptive Authority (2007) and professional guidance refers to the nurse or midwife prescribers professional and personal responsibility to maintain individual competency for prescribing practice. There is an obligation for the nurse or midwife prescriber to commit to, and engage in, continuing professional development relating to assurance of competency for her/his prescribing practices.

Health service providers/employers have a responsibility to provide support and access to continuing professional development and assessment of competence. The nurse and midwife prescriber must be aware of the professional regulatory and organisational requirements for his/her continued competence for maintaining prescriptive authority.

Rationale

Competence is understood as: the attainment of knowledge, intellectual capacities, practice skills, integrity and professional and ethical values required for safe, accountable and effective practice as a registered nurse or registered midwife (NMBI, 2015).

The nurse or midwife prescriber accepts personal responsibility for professional development and the maintenance of professional competence. This is achieved by engaging in continuing professional development, audit of practice, and peer review.

Upon entry to the division of the Register for Nurse or Midwife Prescriber, it is acknowledged that the applicant has attained the competencies of prescriptive authority through the completion of the education programme. S/he has been deemed competent to prescribe as per the Higher Education Institutions Marks and Standards for the theoretical and clinical elements of the programme.

Associated competencies

Organisation and management of care

4.1 Effectively manages the nursing/midwifery care of service-users/groups/communities.

Personal and professional development

5.1 Acts to enhance the personal and professional development of self and others.

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Competencies for Prescriptive Authority

Domain 1. Professional/Ethical Practice

Performance Criteria:

1.1 Practices in accordance with legislation and professional guidance affecting nursing/midwifery practice

Indicators:

- Practices within the legislation and professional regulation and guidelines relevant to his/her scope of practice and care setting
- Integrates accurate and comprehensive knowledge of ethical principles and the Code of Professional Conduct within the scope of professional practice in the delivery of nursing/midwifery care involving medicinal products and prescribing
- Accepts personal accountability for prescribing decisions and actions, understanding the legal implications of doing so

Performance Criteria:

1.2 Practices within the limits of own competence and takes measures to develop and maintain own competence

Indicators:

- Recognises own abilities and level of professional competence
- Conducts self audit of practice incorporating reflective practice/thinking to identify prescribing competence within the nurse/midwife's scope of practice
- Maintains current knowledge of advances in practice, pharmacotherapeutics and emerging safety concerns related to prescribing
- Consults appropriately with medical practitioner and/or pharmacist for patient/service-user¹ when individual nurse/midwife perceives limitations in his/her knowledge of prescribing
- Identifies a mechanism to support continuing professional development needs

Performance Criteria:**Indicators:**

1.3 Practices within a framework of professional accountability and responsibility in relation to prescribing

- Adheres to legislation, professional regulation and guidelines and employing organisations standards/policies for prescriptive authority
- Complies with the requirements/policies of the employing organisation for:
 - reporting medication errors/incidents and near misses
 - audit of prescribing patterns/practices
- Complies with the requirements of the employing organisation and the Irish Medicines Board for reporting adverse drug reactions
- Understands and applies the mechanisms of the HSE National Shared Services Primary Care Reimbursement Service for prescribing

Domain 2. Holistic Approaches to Care and Integration of Knowledge

Performance Criteria:**Indicators:**

2.1 Conducts a systematic holistic assessment of patient/service-user needs

- Performs a comprehensive assessment of the patient/service-user encompassing history taking, physical examination and identification of health risk factors
- Comprehends the health conditions² being managed, their natural progress and how to assess the severity of condition
- Assesses the relationship between health condition and current medication plan
- Requests and interprets relevant diagnostic tests and procedures to inform appropriate and safe prescribing
- Evaluates the use of complementary therapies by the patient/service- user for safety and potential interactions

Performance Criteria:

2.2 Plans care in consultation with the patient/service-user taking into consideration the therapeutic regimes of all members of the interdisciplinary team

Indicators:

- Critically utilises assessment data with expert clinical decision-making skills to formulate a diagnosis and plan of care based on scientific rationale, evidence based standards of care and practice guidelines supporting the maintenance and promotion of health
 - Integrates appropriate non-pharmacologic interventions into a plan of care and advises the patient/service-user on the use of such interventions
 - Involves patient/service-user or carer as active participants in decision- making process and plan of care that is mutually agreed
 - Initiates appropriate and timely consultation and/or referral when the problem exceeds the nurse/midwife's scope of practice and expertise
-

Performance Criteria:

2.3 Implements planned nursing/midwifery care/interventions to achieve the identified outcomes of the plan of care

Indicators:

- Implements care based on knowledge, skills and competence within his/her scope of practice
 - Considers appropriate diagnostic and therapeutic interventions as part of ongoing plan of care
 - Provides guidance and advice regarding the agreed care/interventions to the patient/service-user
-

Performance Criteria:

2.4 Evaluates patient/service-user progress toward expected outcomes and review plans in accordance with evaluation data and consultation with the patient/service-user

Indicators:

- Evaluates and provides evidence based rationale for clinical decision and nursing/midwifery intervention with regard to pharmacological/nonpharmacological treatment choice or referral to medical practitioner if applicable
- Schedules appropriate follow-up care to monitor the patient/service- user and evaluate their response to treatment

Performance Criteria:**Indicators:**

2.5 Demonstrates and integrates knowledge of medicinal products for safe medication management and prescribing practices

- Integrates accurate and comprehensive knowledge of the Guidance to Nurses and Midwives on Medication Management within the scope of professional practice in the delivery of nursing/midwifery care involving medicinal products and prescribing
- Identifies and utilises current medicinal products information in the provision of individualised care
- Utilises expert knowledge of pharmacokinetics and pharmacodynamics to determine appropriate dosage, dosage form, route and frequency of administration of medications based on relevant individual patient/service-user characteristics (i.e. age, gender, co-morbidity, culture)
- Identifies and integrates appropriate monitoring systems for medication safety and efficacy in the care plan
- Demonstrates an understanding of the potential for unwanted effects, (e.g. adverse drug reactions [ADRs], drug interactions, special precautions and contraindications), and actions to avoid/minimise and manage them
- Understands the potential for misuse of drugs
- Applies the principles of evidence-based practice, and clinical and cost-effectiveness
- Recognises the public health issues related to medicinal product use
- Considers non-pharmacological approaches to modifying disease and promoting health where appropriate

Domain 3. Interpersonal Relationships

Performance Criteria:

3.1 Establishes and maintains caring therapeutic interpersonal relationships with individuals/service-users/groups/communities for safe and effective prescribing

Indicators:

- Discusses with patient/service-user assessment findings and treatment options recognising relevant individual patient/service-user characteristics (i.e. age, gender, co-morbidity, culture) and expectations
- Assesses the patient/service-user understanding of and own responsibility in their care plan, involving carers where appropriate
- Facilitates the patient/service-user in self management of condition and prescribed treatment
- Communicates sensitively, respecting patient/service-users' emotions and concerns

Performance Criteria:

3.2 Collaborates with all members of the health care team and documents relevant information

Indicators:

- Identifies the roles and responsibilities of other health care professionals in the prescribing process
- Establishes relationships with other health care professionals based on understanding and mutual respect
- Maintains comprehensive documentation and patient/service-user records of plan of care within a legal and ethical framework
- Participates in interdisciplinary team collaboration relating to the patient/service-user's care plan
- Establishes mechanisms for consultation regarding practice decisions and referral pathways

Domain 4. Organisation and Management of Care

Performance Criteria:

4.1 Effectively manages the nursing/
midwifery care of service-users/groups/
communities

Indicators:

- Demonstrates quality assurance and quality management in prescribing through a structure of audit and report
- Integrates the principles of clinical risk management and health and safety in prescribing practice
- Identifies health promotion priorities and implements health promotion strategies for patient/service-user groups in the area of clinical practice

Domain 5. Personal and Professional Development

Performance Criteria:

5.1 Acts to enhance the personal and professional development of self and others

Indicators:

- Demonstrates a commitment to life-long learning
- Accepts personal responsibility for professional development and the maintenance of professional competence
- Maintains current knowledge of advances in scope of practice associated with prescribing and medication management
- Develops professional links with others practising in the same specialist area
- Informs and empowers patients/service-users and communities to protect, maintain and promote health
- Contributes to the learning experience of colleagues through support, supervision and teaching in medication management
- Contributes to professional and health policy at local, regional and national level in promoting safe and effective medication practices
- Uses the outcomes of audit of prescribing practices to improve service provision

Appendix 2

Controlled Drugs in Schedule 8 which practitioners who are registered nurses or registered midwives may prescribe within schedules 2 and 3 - Misuse of Drugs Regulations, 2017

PART 1 Drugs for pain relief in hospital

Drug	Route of administration
Buprenorphine	Transdermal
Codeine phosphate	Oral
Dihydrocodeine	Oral
Fentanyl	Intranasal, Intravenous, transdermal, transmucosal, subcutaneous, sublingual/buccal
Morphine sulphate	Intramuscular, intravenous, oral, subcutaneous
Morphine tartrate	Intramuscular, intravenous, subcutaneous
Oxycodone	Oral, subcutaneous, intravenous
Pethidine	Intramuscular, intravenous, subcutaneous

PART 2 Drugs for palliative care

Drug	Route of administration
Buprenorphine	Transdermal
Codeine phosphate	Oral
Fentanyl	Intranasal, Intravenous, transdermal, transmucosal, subcutaneous, sublingual/buccal
Hydromorphone	Oral, subcutaneous
Methylphenidate	Oral
Morphine sulphate	Intramuscular, oral, subcutaneous
Morphine tartrate	Intramuscular, subcutaneous
Oxycodone	Oral, subcutaneous

PART 3 Drugs for purposes of midwifery

Drug	Route of administration
Pethidine	Intramuscular

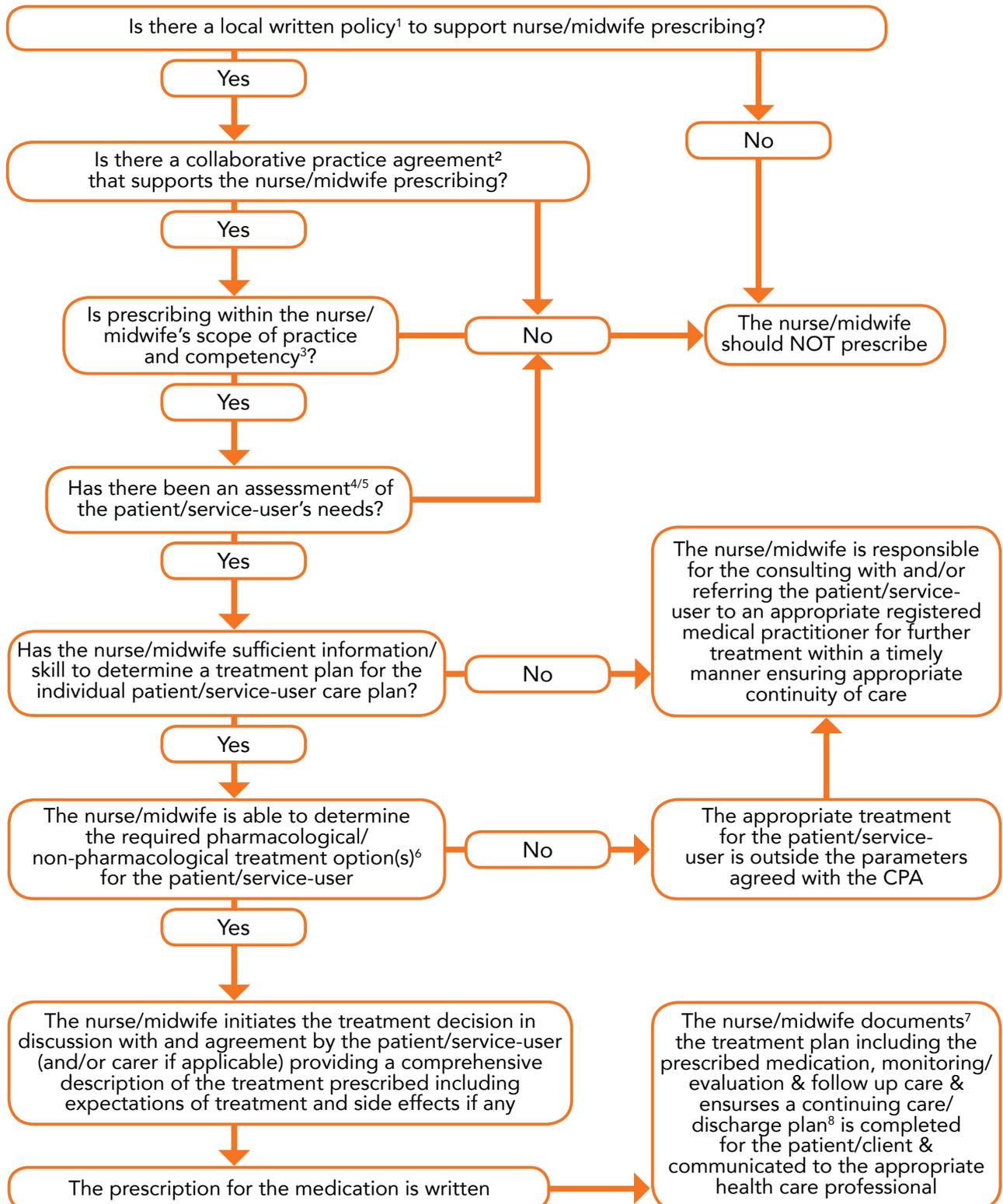
PART 4 Drugs for neonatal care

Drug	Route of administration
Fentanyl	Intravenous, transdermal, transmucosal
Morphine sulphate	Intramuscular, intranasal, intravenous, oral, subcutaneous
Morphine tartrate	Intramuscular, intravenous, subcutaneous

PART 5 Drugs for use in mental health or intellectual disability

Drug	Route of administration
Methylphenidate	Oral

Decision-Making Framework for Nurse and Midwife Prescribing



Explanatory Notes overleaf

Decision Making Framework

Explanatory Notes

- 1 Policy identifies the structures that authorise and provide a framework for the practice of nurse/midwife prescribing in the organisation. This may include reference to the involvement of Drugs and Therapeutics, Risk Management and Clinical Governance Committees.
 - 2 The collaborative practice agreement (CPA) is drawn up with the agreement of the nurse/midwife, the registered medical practitioner, and the employer outlining the parameters of the nurse/midwife's prescribing authority (his/her scope of practice). Refer to the An Bord Altranais publication Collaborative Practice Agreement for Nurses and Midwives with Prescriptive Authority (2007).
 - 3 Scope of practice and competency – Does the nurse/midwife meet the requirements and standards set by An Bord Altranais through completion of the education programme for nurse/midwife prescribing? Is he/she on the Division of the Register of Nurse Prescribers as maintained by An Bord Altranais? Is the RNP undergoing continuing professional development in prescribing practice to enable competency assessment?
 - 4 Assessment includes:
 - Physical examination
 - History taking (including medications)
 - Clinical diagnostic decision* (diagnosis, hypothesis)
 - 5 Orders and interprets laboratory and other diagnostic tests – e.g. bloods and spirometry.
 - 6 If the patient/service-user's assessed needs exceed the nurse/midwife's scope of practice, the patient/service-user is referred to the appropriate registered medical practitioner.
 - 7 Documentation and record keeping for RNPs should be outlined in local policy e.g. prescription writing including prescription pad responsibilities, medication administration record and patient/service-user's individual case notes; supporting material for clinical audit of the RNP's prescribing practice.
 - 8 Continuing care/Discharge plan – Monitoring of therapeutic effect of the prescribed treatment by the registered medical practitioner/RNP and other team members.
- * An example: a nurse with prescriptive authority is working in the diabetic day care centre. Her patient population includes individuals with known diagnoses of insulin dependent diabetes. A patient presents with a pattern of hyperglycemia. The nurse through her assessment skills checks for ketones in the urine and for any source of infection. She also enquires about any recent changes in the patient's diet. Based on this information the nurse make a clinical diagnostic decision regarding the elevated blood sugars and the insulin dose is adjusted appropriately.





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