

Standards for Medicines Management for Nurses and Midwives



Bord Altranais agus
Cnáimhseachais na hÉireann
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DRAFT FOR CONSULTATION

(Inside Page Front Cover)

Standards for Medicines Management (2015) supersedes Guidance to Nurses and Midwives on Medication Management (An Bord Altranais, July 2007). This document comes into effect (insert date).

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Note the term 'patient' has been used in these Standards to represent a person who uses health and social care services. Similar terms of 'client', 'consumer', 'person', 'resident', 'service user', 'mother', 'baby' and 'child' described in nursing and midwifery practice are represented by the term patient.

Abbreviations

EMA	European Medicines Agency
HIQA	Health and Information Quality Authority
HPRA	Health Products Regulatory Authority
HSE	Health Service Executive
ISBAR	Identify, Situation, Background, Assessment, Recommendation
MPAR	Medicines Prescription Administration Record
MDA	Misuse of Drugs Act
NMBI	Nursing and Midwifery Board of Ireland
PODs	Patient's Own Drugs
PPPG	Policies, Procedures, Protocols and Guidelines
PSI	Pharmaceutical Society of Ireland
RNP	Registered Nurse Prescriber
SALAD	Sound Alike Look Alike Drugs

Glossary

For the purposes of these Standards the following words and phrases are explained.

Adherence

Adherence to medicines is defined as the extent to which the patient's action matches the actions recommended.

Administration of medicines: the administration to a patient or by a patient of a medicinal product (medicine) onto or into their body for therapeutic, diagnostic, prophylactic or research purposes.

Adverse event: is a preventable failure at any stage of the medicines management process that leads to, or has the potential to lead to, harm to the patient. Since adverse drug events are the most frequent type of preventable adverse event, patient safety must be a key component of the culture and quality of medicines management (Expert Group on Safe Medicines Practice, Council of Europe 2006)

Adverse reaction: "...a response to a medicinal product which is noxious and unintended" (p 74 European Directive 2010).

Adverse reaction – suspected: is when "... there is at least a reasonable possibility of there being a causal relationship between a medicinal product and an adverse event." (p 74 European Directive 2010)

Authorised medicine prescribed for an unauthorised indication: is a medicine which is prescribed outside the terms of its marketing authorisation, and which is not specified in the summary of product characteristics. This was previously known as 'off-label prescribing'.

Black triangle: the inclusion of an inverted black triangle in the package leaflet is to alert healthcare professionals and patients that the medicine is subject to additional monitoring by European Medicines Agency (EMA). This inclusion does not mean that a medicine is unsafe, but rather that the medicine is new to the market or that further data is needed –

for example, on long-term use in real clinical practice. The purpose of the symbol is to actively encourage patients and healthcare professionals to report any suspected side effects observed with these medicines. The list of medicines under additional monitoring is available from the Health Products Regulatory Authority (HPRA) website.

Brand name - innovator's name, proprietary product name, medicine speciality product name, medicinal speciality product name: the special name given for marketing purposes to any ready-prepared medicine placed on the market in a special pack. A brand name may be a protected trademark.

Clinical trial (Clinical study): is any systematic study on pharmaceutical products in human subjects whether in patients or other volunteers, in order to discover or verify the effects of and identify any adverse reaction to, investigational products, and to study the absorption, distribution, metabolism and excretion of the products with the aim of ascertaining their efficacy and safety.

Complementary and alternative therapies: are "...a group of diverse medical and healthcare systems, practices and products that are not generally considered part of the conventional medicine."

Compliance: refers to the degree or extent of conformity by the patient to the recommendations about day-to-day treatment by the provider with respect to the timing, dosage and frequency of the prescribed medicine.

Computer generated prescription: a prescriber enters the prescription details onto the computer following which a copy of the prescription is printed out and the prescriber signs the prescription to include their registration number and gives it to the patient.

Concordance: is a shared process leading to the agreement of the overall aims of any prescribed drug treatment and how they are to be achieved.

Crushing medicine: involves rendering it from a solid in the form of a tablet or pill to a powder form in order to assist with administration to the patient.

Dispensing: the process starting from the receipt of a prescription request, assessment of the request, review of medicines therapy and health information, the preparation of the product, recording the prescription, and delivery of the final product with appropriate counselling (PSI, 2008)

Exempt medicine: is an unauthorised medicine which is supplied on foot of a prescription or order from a registered doctor or dentist, for use by individual patients under their care in order to fulfil the special needs of those patients. (HPRA 2014)

Formulary: a listing of approved medicines for prescription and use in the healthcare organisation.

Guideline: defined as a principle or criterion that guides or directs action. Guideline development emphasizes using clear evidence from the existing literature, rather than expert opinion alone, as the basis for advisor materials. (HSE 2011)

Hand written prescription: a written prescription is handwritten on a single pre-printed form usually taken from a prescription pad. All handwritten prescriptions must be written in ink.

High-Alert medications: are medications that bear a heightened risk of causing significant patient harm when they are used in error. (Institute of Safe Medication Practices, 2014)

Immunisation: the process whereby a person is made immune or resistant to an infectious disease (RCPI 2013).

Maximum: greatest possible quantity or value attainable.

Medicine administration compliance aids/monitored dosage systems: different names are used to describe medication administration compliance aids, such as monitored dosage systems, blister packs, medication systems, unit dose packages and multi-dose packages, and dose administration aids.

Medication protocols: are written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medication protocol involves the authorisation of the nurse or midwife to supply and administer a medication to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment.

Medicine reconciliation: the process of creating and maintaining the most accurate list possible of all medications a person is taking - including drug name, dosage, frequency and route - in order to identify any discrepancies, deletions, omissions, additions and to ensure any changes are documented and communicated, thus resulting in a complete list of medications.

Medicines review: a structured critical examination of a patient's medicines with the objective of reaching an agreement with the patient about optimising the impact of medicines and minimising the number of medication-related problems and reducing waste.

Must: commands the action a nurse or midwife is obliged to take from which no deviation whatsoever is allowed.

Omission: failure to do something, especially something that a person has a moral or legal obligation to do.

Pharmacy top-up: system of supply in which pharmacy staff maintain unit stock levels.

Placebo: a pharmacologically inert substance that has no physiological effect.

Policy: is a written statement that indicates clearly the position and values of the organisation on a given subject. (HSE 2011)

Preferred drug: is selected following a thorough evaluation of the available evidence. The Preferred Drugs Initiative in Ireland identifies a single 'preferred drug' within a therapeutic drug class and offers prescribers useful guidance on selecting, prescribing and monitoring a drug for a particular condition.

Prescribing modalities: an all-inclusive term used to describe the various methods of writing a prescription or issuing a medication order.

PRN as required medicines: *Pro re nata* is a Latin phrase that is commonly used in medication management to mean 'as needed' or 'as the situation arises'. It is generally used as the initialism PRN to refer to those prescribed medicines that are not scheduled on a regular basis.

Procedure: a written set of instructions that describe the approved and recommended steps for a particular act or sequence of events. (HSE 2011)

Protocol: a written plan that specifies procedures to be followed in defined situations. It represents a standard of care that describes an intervention or set of interventions. Protocols are more explicit and specific in their detail than guidelines, in that they specify who does what, when and how. (HSE 2012)

Remote or telephone orders: in exceptional circumstances, where there is an immediate unplanned clinical need and the prescriber is unable to issue a new prescription in person at that time, the nurse or midwife may need to accept a remote/telephone order from a medical practitioner.

Self-administration: hospital and residential care: involves the independent use of a medication by patient in a manner that supports the management and administration of their medicines.

Serious reportable events: "patient death or serious disability associated with a medication error by the healthcare provider but excluding reasonable differences in clinical judgement involving drug selection and dose." (p 29, HSE 2014)

Should: indicates a strong recommendation to perform a particular action from which deviation in particular circumstances must be justified.

Sound-Alike Look-Alike Drugs (SALAD): medicines that have similar-sounding names or a similar appearance.

Standards: are authoritative statements developed, monitored and enforced by the NMBI that describe the responsibilities and conduct expected of nurses and midwives and their involvement with medicines across all healthcare settings.

Transcription: is an act by which medicinal products are written from one form of direction to administer to another.

Transportation of medicines by nurses or midwives: refers to the nurse or midwife carrying prescribed medicinal products from one location to another for administration to a patient in the home situation.

Unregulated healthcare worker: a person who is not statutorily regulated and is employed within a healthcare, residential or community setting and whose role includes a component of direct patient care and the performance of delegated care activities, supported in organisational policy.

Standards Listing

Definition of Medicines Management:

“The facilitation of safe and effective use of medicines.”

These standards for medicines management are authoritative statements developed, monitored and enforced by the Nursing and Midwifery Board of Ireland. The standards describe the responsibilities and conduct expected of nurses and midwives in their involvement with medicines across all care settings. They are intended for use alongside the policies, procedures, protocols and guidelines (PPPGs) of the health service organisation.

Standard 1

Patients have a right to receive their medicines from a nurse or midwife who understands the purpose of the drug regimen and its associated risks and benefits. You should support the patient in taking their medicines safely within an agreed model.

Standard 2

You must be aware of your legal and professional responsibility and accountability with regard to medicines management to ensure that patients receive the maximum benefit from their medicines.

Standard 3

You should have access to medicines based on patient need, and there are local systems in place to support this.

Standard 4

You must understand the purpose of the prescription or medicines order, and be absolutely clear as to the written or printed directions. Also, you should seek further information, advice and guidance if necessary before administering any medicinal product.

Standard 5

You are accountable for all actions and omissions relating to your role in administering a prescribed medicine.

Standard 6

Following the administration of a medicine, you must monitor that the desired effect of the medicine has been achieved, and participate in a review of the medicines.

Standard 7

You may decide to withhold a medicine based on a specific clinical rationale or respecting the patient's own decision to refuse their medicines.

Standard 8

You must adhere to the requirements of the Misuse of Drugs Acts and Regulations, given the serious nature of the drugs and their potential for misuse or abuse, follow a strict regimen of control of these substances at all times.

Standard 9

You must have a thorough understanding of the factors involved in adverse events or reactions. You must also recognise the high importance of reporting every medicine-related error, whether actual or potential, and implement remedial action.

Standard 10

You must understand the rationale for the drug prescription and the potential side effects of the drug in order to be able to identify, intervene and report a suspected adverse event or reaction.

Standard 11

You must work with the patient and, where appropriate, their families and carers in medicine reconciliation. You must also work in association with other healthcare professionals to ensure that people do not suffer unnecessarily from the excessive, inadequate or inappropriate use of medicines.

Standard 12

You should understand the complex factors that influence the patient's decision-making process and adherence regarding their medicines. Education should be provided to the patient and their family in relation to the use of medicines. It should be explained to the person in a way that is accessible and understandable.

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Introduction

This guidance document framed around twelve standards for medicines management has been developed to support nurses and midwives in the delivery of safe and effective care for patients. The Nursing and Midwifery Board of Ireland have worked in partnership with the Office of the Nursing and Midwifery Services Director of the HSE. The standards and accompanying practice guidance have been written following extensive consultation with nurses and midwives, and in response to recent developments related to medicines management in Ireland. An Expert Advisory Panel contributed to the development of the document to help ensure its accuracy and evidence-base.

The standards have been developed to support you and aim to:

- advise you on how you should provide care to patients, their families and society;
- help you identify the medicines management needs of your patients, so that you can maintain the relevant skills, knowledge and behaviours to safeguard patients (protect the public) in their use of medicines;
- guide you on providing information to patients, and their carers and families where appropriate, on the risks and benefits of their medicines;
- support you to work alongside the other members of the healthcare team to ensure that the patient achieves the maximum benefit from their medicines;
- help you, within a culture of positive reporting to be open and honest in promoting the safe use of medicines;
- help you promote a culture of shared decision-making in which patients are provided with the information they need to make informed choices about their medicines and how they decide to take them.

Context

Medicines have had a significant impact on the health and welfare of people, and continue to play an integral role in the prevention and treatment of illness and the promotion of well-being in our society.

However, the use of medicines has changed in recent years due to:

- the proliferation of the use of medicines – more than a quarter of people in Ireland over the age of 50 are taking five or more medicines;
- the increase in the range and variety of medicines available, and the prescribing of medicines for preventative reasons as well as curative;
- the use of many medicines or ‘polypharmacy’ in people with chronic illness, people with multiple comorbidities, and older people;
- the introduction of nurse and midwife prescribing with Registered Nurse Prescribers now practicing in a range of nursing and midwifery services working at all levels and across diverse clinical areas and specialities;
- the establishment of a national medicines management programme to promote the safe, effective and cost-effective use of medicines; and
- the understanding that less than half of patients follow their prescription or take their medicines according to instructions.

This guidance from the Nursing and Midwifery Board (replaces the 2007 Guidance to Nurses and Midwives on Medication Management) is supported by the NMBI and HSE on-line learning programme (hyperlink to be inserted).

These standards have been written to support you in your roles and responsibilities for medicines management. As members of the inter-professional health and social care team, you are well placed to assist patients in the safe, effective and ethical use of medicines.

Standard 1

Patients have a right to receive their medicines from a nurse or midwife who understands the purpose of the drug regimen and its associated risks and benefits. You should support the patient in taking their medicines safely within an agreed model.

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Section 1 Professional and Legal Matters

Introduction

Medicines management is directed and influenced by many factors. These include professional, legal and ethical considerations. Professional healthcare regulation, medicines legislation and ethical principles such as consent and autonomy of the patient all form part of these factors.

The inter-professional role of other healthcare disciplines also impacts medicines management. The healthcare system and practice environments and the resources and policies of the individual health service organisation also specify medicines management. Models of care delivery – such as person- or patient-centred care, the social model, and task-oriented care – contribute to how medicines are managed across the healthcare services. The influence of evidence-based information and education is pivotal in facilitating an individual's ongoing competency with medicines and enhancing patient safety. Attention to the safety, effectiveness and cost-effectiveness of medicines supports quality medicines management by nurses and midwives.

Standard 2

You must be aware of your legal and professional responsibility and accountability with regard to medicines management to ensure that patients receive the maximum benefit from their medicines.

Professional Practice

Professional factors with respect to medicines management evolve from professional regulation, as established by the Nurses and Midwives Act of 2011 and the NMBI statutory functions for standard setting and provision of guidance. The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives (the Code) (2014) and the Scope of Nursing and Midwifery Practice (currently under review) serve as the building blocks for the NMBI's regulatory framework.

The Code guides nurses and midwives in their day-to-day practice and helps them to understand their professional responsibilities in caring for patients in a safe, ethical and effective way. The five principles of the Code:

- Respect for the dignity of the person
- Professional responsibility and accountability
- Quality of practice
- Trust and confidentiality
- Collaboration with others

underpin the Code's ethical values and related standards of conduct and practice. Nurses' and midwives' medicines management practices should be informed by the Code's guidance and standards.

The Scope of Nursing and Midwifery Practice Framework (the Scope) is the second building block in the framework. The scope of practice for nurses and midwives in Ireland is determined by legislation, European Union directives, international developments, social policy, national and local guidelines and individual levels of competence. Important considerations for determining the scope of nursing and midwifery practice also relate to the professions' role in medicines management.

These considerations include:

- Competence
- Responsibility, accountability and autonomy
- Continuing professional development
- Support for professional nursing and midwifery practice
- Delegation and supervision
- Practice setting
- Collaborative practice
- Expanded roles
- Emergency situations

The Code and the Scope form the foundation for this document on medicines management. Nurses' and midwives' responsibilities, activities and accountability with medicines should be guided by the established ethical values, standards of professional

conduct and scope of practice considerations. Additionally, nurses' and midwives' documentation and communication of care encompassing medicines management should be carried out in a clear, objective, accurate and timely manner within a legal and ethical framework.

The nurse and midwife must practise according to the legislation governing nursing and midwifery practice (Nurses and Midwives Act 2011 and accompanying Rules) and the current standards and policies of regulatory health and social care bodies and health service organisations.

Nurses' and midwives' legal and professional accountability for medicines management requires knowledge of the relevant statutes and legislation regarding the practices of prescribing, dispensing, storing, supplying and administering scheduled medicines. This includes controlled, prescription-only, pharmacy sale and non-prescription over-the-counter medicines including those available only from a pharmacy and those on the general sales list.

The NMBI acknowledges that health service providers' requirements may dictate specific policies, procedures, protocols and guidelines (PPPGs) regarding medicines management. The health service provider, healthcare regulators and professional organisations have a responsibility to the patient to assure safe, effective and ethical medicines management practices.

PPPGs should be developed, implemented and monitored in a collaborative inter-professional manner by nursing, midwifery, medical, pharmacy and management staff where health care is provided. In addition, the drugs and therapeutics and medication safety committees (where available) should be consulted for their input regarding the organisation's policies, protocols and guidance involving medicines. Other relevant departments, such as risk management and quality and safety, could also be consulted for their input.

Legislation that directs nursing and midwifery medicines management practice

Some medicines management components are specifically authorised in legislation. The sections below provide an overview in relation to the key areas of prescribing, dispensing, supplying and administering medicines. Other legislation, such as for MDA controlled drugs, are referred to in other sections of this document.

Prescribing

Medical practitioners and dentists are authorised through the *Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (Statutory Instrument (SI) 540 of 2003)* to prescribe medicines.

The Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3) and the Medicinal Products (Prescription and Control of Supply) Amendment Regulations 2007 (SI 201) provide the legal authority to nurses and midwives to prescribe medicines. The following conditions must all be satisfied for this prescriptive authority to be legal:

- The nurse or midwife is 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).
- The medicine is one that would be given in the usual course of the service provided in the health service setting in which the nurse or midwife is employed.
- The prescription is issued in the usual course of the provision of that health service.

The Regulations allow a health service provider to set further conditions for the nurse or midwife's prescriptive authority. Additionally, the Misuse of Drugs (Amendment) Regulations 2007 (SI 200) provides a specific schedule of MDAs (Schedule 8) for use by the registered nurse prescriber (RNP). (Refer to Appendix X for detailed listing.)

The NMBI has established Practice Standards and Guidelines for the RNP as part of the regulatory framework for this expanded scope of practice. The RNP must read the Standards for Medicines Management in association with the current version of the Practice Standards.

Dispensing

Legislation regarding the dispensing and supply of medicines form part of the regulations for retail pharmacy businesses which is provided for in the Pharmacy Act 2007. (There are separate dispensing regulations for MDA controlled Schedule 1, 2 and 3 medicines). The Pharmaceutical Society of Ireland (PSI) is the responsible regulator for enforcing and monitoring these and other regulations which authorise the registered pharmacist to review medicines for appropriateness and potential adverse effects prior to supplying and dispensing medicines.

The medicines legislation does not refer to the dispensing of medicines by nurses and midwives. Best practice suggests that medicines should be dispensed by the pharmacist in the best interest of the patient.

Supplying and Administering

There are several pieces of legislation which provide for the supply and administration of medication which are the two main activities of medicines management performed by nurses and midwives (presented in detail in Section 2).

Key pieces of legislation include:

- Irish Medicines Board (Miscellaneous Provisions) Act 2006
- Medicinal Products (Prescription and Control of Supply) Regulations 2003
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005
- Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007.

Collaboration with Others in Medicines Management

Collaboration with Others, a key principle of the NMBI Code, applies to the standards of medicines management. Nurses and midwives share responsibility with colleagues from other healthcare disciplines for providing safe quality healthcare; collaborating and working together to achieve safe and effective management of the patient's medicines.

The responsibilities of medicines management incorporate the assessment, diagnosis, planning, implementation and evaluation of the nursing and midwifery process involving the patient, and, where appropriate, the patient's family and carers.

As part of the overall individualised care of the patient, nurses and midwives may be required to delegate to, supervise and educate nursing and midwifery students, as well as unregulated healthcare workers. The primary motivation for the delegation of any aspect of medicines management should be based on serving the interests and needs of the patient.

The health service provider must have PPPGs and accompanying governance arrangements in place which authorise and support nurses and midwives in the delegation and supervision of any aspect of medicines management. In addition, there should be appropriate resources in place to underpin delegated roles and tasks. These elements form part of the employer's organisational accountability.

The nurse and midwife must consider their individual accountability when making a decision to delegate a medicines management task to someone who is not a registered nurse or midwife (draft NMBI 2015). The Scope and its decision-making framework provide key guidance and consideration for nurses and midwives about delegation and supervision.

Personal Health and Medicines Management

Nurses and midwives are responsible for their own health and well-being. If they become aware that their health is affecting their ability to practise safely, they must get help in managing their condition (NMBI 2014). Advice and support should be sought from their general practitioner. Additional supports for nurses and midwives include occupational health services and employee assistance programmes.

Nurses or midwives who require a medicine for a personal health condition should acquire it in an appropriate way. It is not permissible for a nurse or midwife to remove medicine from their workplace for personal use or for supplying to their family, friends or significant

others. This is applicable to all forms of medicines (for example, prescription medication including analgesics, antibiotics and over-the-counter medication).

It is not permissible for a nurse or midwife to ask a work colleague with prescriptive authority to write a prescription for them. In addition, nurses or midwives who remove medicines from their place of employment for personal use may be subject to:

- employment disciplinary procedures,
- criminal charges,
- a fitness to practise inquiry by NMBI.

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Section 2 Components of Medicines Management

Ordering and acquisition of medicines

Standard 3

You should have access to medicines based on patient need and there are local systems in place to support this.

Each organisation should have their own systems for ordering and acquisition of medicines.

Practice guidance

Medicines can be classified as either 'stock' medicines, where the supply is held by the individual unit for use on any patient as required, or as 'named patient' / 'non-stock' medicine. In the latter, the supply is labeled for, and may only be used by, the named patient.

In any defined setting, there should be clear policies, procedures, protocols or guidelines for:

- ordering both stock and non-stock items,
- pharmacy top-up,
- ward staff requisition,
- *ad hoc* ordering,
- obtaining medicines from other settings,
- the safe supply of medicines for patients on leave,
- the ordering and handling of medicines for patients on admission, transfer and discharge.

There should be a defined list or formulary for stock medicines. The functions of the Drug and Therapeutics Committee (or local equivalent group) include management of the approved medicine list or hospital/unit formulary.

Supply of medicines

A nurse or midwife may supply medicines under the direction of a registered medical practitioner or a registered nurse prescriber in the course of a service provided by a

hospital other than a hospital providing community mental health services (which is limited to three days' supply). This activity is authorised in the Irish Medicines Board (Miscellaneous Provisions) Act, 2006 and the Medicinal Products (Prescription and Control of Supply) Regulations, 2003 as amended.

Practice guidance

Local, written PPPGs should be observed when a nurse or midwife is to supply a medicine. The PPPGs should include directions on labelling of medicines as per Article 9(2) of the Regulations.

Consideration should be given to the further education and training required by a nurse or midwife involved in the supply of medicines.

Circumstances may arise when the nurse or midwife may be required to supply a medicine that has not been dispensed by a pharmacist. An example of this is the use of a medication protocol to supply and administer a specific medicine such as vaccinations. In these situations, the nurse or midwife must be aware of their responsibilities regarding this practice in the context of medicines management. (Refer to Appendix 1 for medication protocol framework).

The nurse or midwife must consider the scope of practice decision-making framework and specific medication protocol where applicable in determining their own competence to undertake this activity.

Dispensing

Dispensing is the process starting from the receipt of a prescription request, assessment of the request, review of medicines therapy and health information, the preparation of the product, recording the prescription, and delivery of the final product with appropriate counselling (PSI, 2008).

The General Medical Services Scheme provides for general practice dispensing services in certain limited circumstances where there is no pharmacy in an area and patients are

unable to access prescribed medicines from retail pharmacies. Practice nurses working in those general practices which dispense medicines should adhere to local PPPGs. Best practice suggests that medicine should be dispensed by the pharmacist.

Enabling a supply of medicines out of hours by nurses and midwives

Circumstances may arise in healthcare services when a medicine that has been prescribed and a supply is needed but there is no on-call pharmacy service with a pharmacist available to dispense the prescription. The activities enabling a supply of medicine should be differentiated from dispensing, (which is the pharmacist's role). It is termed 'enabling' because the nurse or midwife needs access to a supply of those medicines that have already been assembled, checked and recorded by a pharmacist.

Practice guidance

The nurse and midwife manager should work in partnership with the pharmacist:

- to ensure that there is an adequate supply of medicines for their area;
- to audit the nature of all access to the pharmacy by nursing and midwifery staff, in order to keep this to a minimum;
- to ensure that medicines which may be needed out-of-hours are identified and held in a designated area;
- where there is a need for enabling a supply out-of-hours this should be done on foot of a pharmacy requisition rather than the MPAR or drug Kardex;

Local PPPGs should be developed to support the enabling of a supply of medicines in the absence of the pharmacist. This includes the safe custody of the pharmacy keys and recording their use as required.

Storage of medicines

In order to provide a safe and secure environment for the delivery of medicines, the nurse and midwife must be familiar with local PPPGs on the security of all medicines, including:

- MDA controlled drugs,
- medicines which require refrigeration,
- medical gas cylinders,
- patients' own medicines in the general hospital,

- medication that is self-administered by patients,
- prescription forms which provide access to medicines,
- medicines keys.

Practice guidance

There should be a process:

- for receiving and checking the medicine delivery order before it is locked away;
- outlining staff actions to be taken and who should be notified when dealing with discrepancies in medicine orders received; and
- to underpin medicine security measures (including keyholder access).

Transportation of medicines by nurses and midwives

Transporting medicines refers to the nurse or midwife carrying prescribed medicines from one location to another for administration to a patient in the home situation.

Where a nurse or midwife does not have access to the patient's own medicines, they may have to transport medicines (see Section 3 for guidance on transporting scheduled controlled drugs). It is considered good practice for nurses or midwives to develop PPPGs in partnership with general practitioners, pharmacists and the palliative care team to establish an adequate provision of medicines in the person's home.

Practice guidance

The nurse or midwife should be in possession of, or have access to, a medication order or prescription for the individual patient. A remote prescribing method is acceptable when the treatment is immediately necessary to:

- save a life,
- avoid serious deterioration in health,
- alleviate otherwise uncontrollable pain or distress,
- change or adjust a drug dosage.

The nurse or midwife may transport medicines to a patient who is unable to collect their medicines, provided that the patient can be safely identified and that they are conveying a prescribed medicine for the same individual.

There should be a local PPPG to support safe and efficient access to necessary medicines for individual patients.

The nurse or midwife should keep records as they work and maintain an up-to-date account of the dispensing, prescribing and administration of these medicines based on local PPPGs.

Prescribing Modalities

Prescribing modalities is an all-inclusive term used to describe the various methods of writing a prescription or issuing a medicine order. As nurses and midwives experience the increasing use of technologies in health care, it is important they understand the differences between different types of prescriptions and other medicine orders.

Specific standards for prescription writing must be adhered to as required by legislation.

The Medicinal Products (Prescription and Control of Supply) 2003 as amended, directs what must be written on a medicine prescription. A prescription is required to:

- be in ink and signed by the person issuing it with his/her usual signature and be dated by him/her;
- include the address of the person issuing it except in the case of a health prescription/GMS,
- clearly indicate the name of the person issuing it and state whether they are a registered medical practitioner, registered dentist, registered nurse prescriber: and
- specify the name and address, and age if under 12, of the person for whose treatment it is issued.

In order to be called a prescription, the order must be signed by a prescriber (everything else may be printed but the original signature in ink is a legal requirement).

Standard 4

You must understand the purpose of the prescription or medicines order, and be absolutely clear as to the written or printed directions. Also, you should seek further information, advice and guidance if necessary before administering any medicinal product.

Practice guidance

The nurse or midwife who is administering medicines on foot of a prescription should be satisfied that the prescription is clear and unambiguous.

It is recommended that all prescriptions should:

- be written legibly in black ink or otherwise so as to be indelible
- be dated
- state patient GMS /unit number (if applicable)
- state the patient's full name, age, date of birth, room number/ward name/unit/house or have the resident's address label affixed
- state any known allergies, or if none, it should be noted
- have direction written in English, using only approved abbreviations
- use the generic name of the medicine and preparations. In circumstances where a specific preparation is indicated by the patient's clinical condition, it should state the brand name and 'Do Not Substitute'
- state the names of medicines and preparations in full, using approved titles only
- state clearly if the medicine will need to be crushed
- state the duration of prescription
- be signed by the prescriber.

If amending or correcting the prescription, the prescriber should rewrite the prescription in full.

The prescriber should never use a decimal point before a trailing zero – for example, 5mg is correct, not 5.0mg. Always use a whole zero before a decimal when the dose is less than a whole unit – for example, 0.5ml is correct, not .5ml. The use of the decimal is only otherwise acceptable to express a range – for example, 0.5 to 1mg.

All medicines administration records/drug Kardexes should be rewritten if they become dirty, torn or disfigured or where the chart is full. This should be done in a manner that preserves confidence in the accuracy of the records.

Handwritten prescriptions

A written prescription is handwritten on a pre-printed form usually taken from a prescription pad. All handwritten prescriptions must be written in ink.

Computer generated prescriptions

A prescriber enters the prescription details onto the computer. following which a copy of the prescription is printed out and the prescriber signs the prescription to include their registration number and gives it to the patient.

Remote or telephone orders

These were formerly described as 'verbal orders'.

In exceptional circumstances, where there is an immediate unplanned need in the clinical situation and the prescriber is unable to issue a new prescription in person at that time, the nurse or midwife may need to accept a remote/telephone order from a medical practitioner.

Remote/telephone orders have a higher potential for errors as these orders can be misheard or misinterpreted. Safety is the overriding principle in accepting remote or telephone orders.

Remote prescribing: acute hospital services

The only time a remote/telephone order for medicines is acceptable in acute hospital services should be when there is an immediate unplanned patient need. The nurse or midwife should use ISBAR to frame the case for the medical practitioner. The nurse or midwife must provide context for the doctor (such as allergies, laboratory values, other medicines, and medical conditions).

Practice guidance

The medical practitioner is responsible for documenting the written order on the medicines administration record within an acceptable timeframe – usually 12 hours as determined by the hospital's PPPG.

A RNP may not communicate a remote/telephone medicine order.

The justification and rationale for accepting a remote or telephone medicine order should be documented by the nurse or midwife involved to establish the clinical judgement exercised in the immediate unplanned situation.

Generic drug names should be used when drug orders are given; abbreviations should be avoided.

A record of the telephone order should be documented in the appropriate section of the patient's records in accordance with local PPPGs.

The order must be stapled or otherwise securely attached to the medicines administration record/drug Kardex.

Remote prescribing: community and residential care

Similar to the acute hospital environment, nurses or midwives in community and residential services may need access to a remote prescription where the medical practitioner is not based on site.

Practice guidance

Remote prescriptions may be utilised when the treatment is immediately necessary to:

- save a life,
- avoid serious deterioration in health,
- alleviate otherwise uncontrollable pain or distress,
- change or adjust a drug dosage.

The nurse or midwife must provide and document the context for the medical practitioner. (This may include the use of the ISBAR tool, patient's level of consciousness, medical history, allergies, laboratory data, current medicines, vital signs and urine output.)

A registered nurse prescriber should not communicate a medication order through the use of a remote or telephone order.

A nurse or midwife who accepts a remote order should understand the purpose of the medicine prescribed. They should also have sufficient knowledge of the indications and contraindications for administration and monitoring and reporting the patient's condition. Local PPPGs should be developed to support the safe use of remote/telephone orders.

Use of facsimile/email

Facsimile (fax)

Although a medical order received by fax is not the actual prescription, the nurse or midwife should treat it with the same due diligence as if it were.

Practice guidance

The nurse or midwife receiving a fax to support a change in the patient's need for a prescription should ensure that the prescription is legible and includes the following:

- the patient's name
- the patient's date of birth
- the name of patient's medical practitioner
- the generic name of the medicine or preparation or brand name, if necessary the name, dose, form, frequency, quantity of medicine
- the signature and licence number of the prescriber
- the date
- the duration of prescription

If any of the above information is not clearly understandable, the medical practitioner or the pharmacist should be contacted for clarification.

The original prescription should be supplied to both nurse or midwife and the pharmacy by the medical practitioner within 72 hours.

The medical practitioner should also document the changes on the appropriate care document according to local PPPGs within 72 hours.

Electronic mail/email

The nurse or midwife may need to accept a remote prescription for patients in different environments –, for example, the islands, isolated and rural areas, patients' own homes, community hostels and similar settings. Therefore, the use of information technology such as email may be more accessible where a fax machine is not available. Local PPPGs should be developed and agreed by the multidisciplinary team.

Transcription

Transcribing is an act by which medicinal products and instructions are written from one form of direction to another (Nursing and Midwifery Council, 2010)

It is recognised that transcribing of any clinical information is a high-risk activity, and there are serious risks of inadvertent transcription errors or duplication of medicines.

Practice guidance

A nurse or midwife who transcribes a prescription is professionally accountable for their decision to transcribe, and for the accuracy and the safety of the transcribed information. It is expected that nurses and midwives engaged in transcription have the clinical knowledge to recognise a potentially dangerous dosage or therapeutic duplication.

This activity should be directed by local health service PPPGs which must stipulate required systems – that is, a second nurse or midwife or pharmacist should independently verify the prescription transcribed in order to minimise the risk of error.

The nurse or midwife should attach a copy of the original prescription issued by the prescriber to the transcribed Medicines Prescription Administration Record (MPAR) for

reference by the pharmacist. The transcribed MPAR should be signed by the general practitioner prior to the nurse or midwife administering the medicine.

The activity of transcribing should be supported by PPPGs and be audited on a regular basis.

Medication protocols

Medication protocols are written directions that allow for the supply and administration of a named medicine by a nurse or midwife in identified clinical situations. A medication protocol involves the authorisation of the nurse or midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An example of this are nurse-led vaccination programmes in schools.

The legislative basis for medication protocols for the supply and administration of medicines is the Medicinal Products (Prescription and Control of Supply) Regulations of 1996, as amended, which provides authority for hospitals to utilise medication protocols in order to meet patient need for medicines management.

Practice guidance

Medication protocols must be developed based on evidence of best practice. The medication protocol should identify who is responsible and competent to implement the protocol. The protocol should be specific about what is allowed and not allowed under its terms. It should also include a date for the protocol to be reviewed.

Medication protocols must be supported by locally agreed PPPGs.

Refer to Appendix 1 for additional guidance and the medication protocol template.

Nurses and midwives giving advice related to medicines management by telephone

Practice guidance

Discharged patients

The nurse or midwife who gives medicine management advice by telephone to a discharged patient should be supported by clear evidence-based protocols and clinical guidelines that have been developed by the multidisciplinary team involved in the delivery of the service. The nurse or midwife should:

- ensure the advice given to the patient on the telephone meets the same professional standard as for any patient;
- ensure the telephone consultation is limited to information or instruction that falls within their scope of practice and best available evidence;
- adhere to the local PPPGs on providing and documenting telephone advice.

Other Healthcare Professionals

- The nurse or midwife giving medicines management advice by telephone to other healthcare professionals should: be supported by clear evidence-based protocols and clinical guidelines that have been developed by the multidisciplinary team involved in the delivery of the service;
- be competent to use their professional judgment in a given clinical situation; document their advice and send a copy by fax or email to their colleague;
- be supported by local PPPGs.

PRN as required medicines

Pro re nata is a Latin phrase that is commonly used in medicines management to mean 'as needed' or 'as the situation arises'. It is generally used as the abbreviation **PRN** to refer to those prescribed medicines that are not scheduled on a regular basis.

Practice guidance

PRN prescriptions should state: circumstances, interval, maximum dose in 24 hours and review date.

The decision to administer medicines prescribed as PRN is taken by the nurse or midwife based on the patient's clinical need. The exact time the medicine was given and the amount given should be recorded on the medicine chart.

As part of the medicines review process, the multidisciplinary team may decide to include certain medicines on a PRN basis, in order to plan for any likely patient need.

Psychotropic medicines – (used to treat the symptoms of mental disorders) may be prescribed on PRN basis. In these situations best practice would support the “3 T” approach, that is:

- the drug treatment should have a specific **target** symptom
- the starting dose should be low and **titrated** upwards
- the treatment should be time limited.

Supply including over-the-counter products

A nurse or midwife may supply medicines under the direction of a registered medical practitioner or a registered nurse prescriber in the course of a service provided by a hospital other than a hospital providing community mental health services, (which is limited to three days' supply). This activity is authorised in the Irish Medicines Board (Miscellaneous Provisions) Act, 2006 and the Medicinal Products (Prescription and Control of Supply) Regulations, 2003 as amended.

Practice guidance

Local PPPGs should be observed when a nurse or midwife is to supply a medicine. PPPGs should include directions on labelling of medicines as per Article 9(2) of the Regulations.

Consideration should be given to the further education and training required by any nurse or midwife involved in the supply of medicines.

Circumstances may arise when the nurse or midwife may be required to supply a medicine that has not been dispensed by a pharmacist. In these situations, the nurse or midwife must be aware of the responsibilities involved with this practice in the overall management of medicines.

Supply by wholesale dealing - Community Midwives

Supply by way of wholesale dealing means that a community midwife in the course of their professional practice may obtain a supply of a medicine without a prescription. This is authorised through the Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended.

A midwife providing community-based midwifery care may obtain and have in their possession, a supply of the following medicines for use in their practice:

- Ergometrine maleate
- Lidocaine
- Oxytocin (for use in the 3rd stage of labour/management of postpartum haemorrhage)
- Oxytocin and Ergometrine maleate (Syntometrine)
- Naloxone hydrochloride (for use in reversing the effects of pethadine and pentazocine – See section 3)
- Nitrous oxide and oxygen(Entonox)
- Phytomenadione (Konakion) –
- Therapeutic oxygen
- Such fluids for intravenous infusion that may be required for the management of haemorrhage

Practice guidance

There should be established PPPGs between the community midwife and the pharmacist –whom the midwife is seeking the supply from for the provision of the service.

Each community midwife should obtain a requisition book for the purposes of documenting:

- the supply of these medicines obtained from a pharmacist on an “as needed basis” to include:
 - Name and address of the pharmacist from whom the drug was obtained
 - Total quantity and form of the medicine
 - Batch numbers
- return of unused medicines for disposal
- return of medicines which have expired.

The sections on transportation of medicines and storage apply in these situations of wholesale supply.

Self-administration of medicines

Self-administration of medicines involves the independent use of a medicine by a patient in a manner that supports the management and administration of their medicines.

Residential Care Services

Self-administration of medicines for people living in residential care settings is an important part of maintaining their independence. The option for individuals who would prefer to manage their own medicines is recognised as best practice. The National Quality Standards for Residential Care Settings for Older People in Ireland state that older people residing in nursing homes may self-administer medications where the risks have been assessed and their competence to self-administer is confirmed (HIQA 2014). The National Quality Standards: Residential Services for People with Disabilities reinforce the importance of self-administration by stating that a resident should take “*responsibility for their medicines unless he/she wishes otherwise*” (page 89, HIQA, 2013).

Exclusion criteria should be agreed to protect people at risk from self-harm, people sectioned under the Mental Health Act 2001, people who are unable to give consent or who refuse consent, and people who find self-administration a burden.

Practice guidance

Health service providers should have local PPPGs for self-administration of medicines which should detail the assessment of the resident, ongoing surveillance, documentation requirements and the storage and supply of medicines.

The nurse or midwife, in collaboration with other members of the multidisciplinary team, is responsible for the initial and continued assessment of residents who are self-administering medication. The nurse or midwife also has an ongoing responsibility for recognising and acting on changes.

A risk assessment should be undertaken and the outcomes recorded in the resident's care plan. The risk assessment should consider the differing levels of administration support a resident may need. These levels are outlined here:

- 0 Resident not self-administering
- 1a Resident self-administers the medicines with full supervision
- 1b Resident requests medication from the nurse at the appropriate time
- 1c Residents may carry their own relieving device (such as an inhaler or anti-angina spray)
- 2 Resident administers medicine without supervision

The assessment process should include an evaluation of the resident's ability to self-administer as appropriate in conjunction with pharmacy support. There should be ongoing assessment, at agreed intervals or when the person's condition changes, of their ability to perform this activity.

Appropriate, safe and secure storage should be provided for medicines, with day-to-day access limited to the resident. The medicines should be provided in a suitable medicines administration system, and the nurse or midwife should ensure that the resident can open and close the medicine containers safely.

The nurse or midwife should help the resident to understand their medicines.

Information sheets should use the name of the medicines that the person is familiar with. This may necessitate a *Do Not Substitute* prescription.

The practice of self-administration of medications should be evaluated and audited at regular intervals.

Acute Hospital and Hospice Settings

There are a number of advantages in supporting patients to self-administer their medicines while they are an in-patient in an acute hospital or hospice. Self-medication allows patients to stay as near to their own routine as possible, participate in medicines review, and allows for re-education if the routine is incorrect. The use of Patients' Own Drugs (PODs) means that patients bring their medicines with them in a patient medicines bag when they transfer from one environment to another.

Practice guidance

Health service providers should have local PPPGs for self-administration of medicinal products, which should detail:

- assessment of patients,
- informed consent,
- ongoing surveillance,
- the documentation requirements,
- the storage and supply of PODS.

Where appropriate, a cognitive assessment to determine the patient's suitability for self-medication should be carried out. This assessment should be documented in the healthcare record (HSE 2014).

Where patients consent to self-administration of their medicines, it should be made clear to them that they can withdraw consent at any time.

Patients share the responsibility for their actions relating to self-administration of their medicines. The patient should be adequately informed and supervised, and given access to pharmacy support, so that they adhere to the medicines therapy and treatment plan. This should be recorded in the care plan.

Nurses and midwives are responsible for the continued assessment, monitoring and evaluation of patients who are self-administering medicines. They also have ongoing responsibility for recognising and acting upon changes in a patient's condition.

Appropriate, safe and secure storage should be provided for the PODs.

The nurse or midwife should help the patient to understand their medicines and make sure that they have access to a supply if they are transferred or discharged. Information sheets should use the name of the medicines that the person is familiar with. This may necessitate access to a *Do Not Substitute* prescription.

The practice of self-administration of medications should be evaluated and audited at regular intervals in the healthcare setting.

Administration of Medicines

The administration of a medicinal product (medicine) onto or into the human body, to a patient or by a patient for therapeutic, diagnostic, preventative or research purposes.

Standard 5

You are accountable for all actions and omissions relating to your role in administering a prescribed medicine.

Practice guidance

With respect to the administration of a medicine, the nurse or midwife must only administer a medicine in a safe context. That is, the nurse or midwife should only administer a medicine if:

- they have knowledge of the patient's current health status and plan of care;
- the prescription is clear and unambiguous and they have access to information on medicines;
- they have the consent and participation of the patient;
- they comply with the Ten Rights of Medicines Management (as detailed below).

Prior to the administration of medicines, the nurse and midwife must:

- know the patient's medicines history, current medicines regimen and whether the patient has been taking or receiving them;
- assess the general condition of the patient to confirm the appropriateness of the medicine to be administered.

The nurse or midwife must:

- **have access** to a prescription that is clear and unambiguous
- have access to medicines information from the Summary of Product Characteristics, Irish Medicines Formulary, British National Formulary, a mobile assist drug interaction tool, the pharmacist or the prescriber
- determine the potential for interactions between:
 - the prescribed medicines
 - the prescribed medicines and dietary products
 - the prescribed medicine and any other additional non-prescribed medicine

The nurse or midwife must **communicate with the patient** to:

- ensure that the patient is aware of the intended purpose of the medicine being administered as well as the potential adverse events/reactions
- ensure that the patient consents to the prescribed medicines.

THE TEN RIGHTS

1. Right patient
2. Right reason
3. Right drug
4. Right route
5. Right time
6. Right dose
7. Right form
8. Right action
9. Right documentation
10. Right response

BOX 1. The ten rights of medicine administration
(adapted from The nine rights of medication administration. Elliot and Liu 2014)

The nurse or midwife who is administering the medicines must:

1. be certain of the identity of the patient to whom the medicine is being administered by verifying the identification wristband, photograph or name and date of birth on the medicine chart. (Right patient)
2. understand the intended purpose of the medicines to be administered. (Right reason)
3. confirm that the name of the dispensed medicine to be administered corresponds with the generic or brand name of the prescribed medicine and they must only administer a viable medicinal product – that is, properly packaged and within its expiry date. The nurse or midwife must also check, both by asking the patient and checking the allergy status box on the medicines chart, whether the patient has a known and recorded allergy to the prescribed drug. (Right Drug)
4. administer the medicine via the prescribed anatomical route and site (Right route);
5. administer the medicine at the prescribed time and prescribed intervals (Right time)
6. confirm, through arithmetical calculation, that the dose of the medicine being administered concurs exactly with the dose prescribed. Where the local PPPGs identify this process for high risk medicines, the dose must be independently verified. (see section on double checking) (Right dose)
7. confirm that the form of medicine that has been dispensed matches with the specified route of administration. (Right form)
8. ensure the medicine is prescribed for the appropriate reason, and state to the patient the action of the medication and why it is prescribed (Right action)
9. sign, date and retain all documentation recording the administration of each medicine in the medicines administration chart (or other document directing the administration of a medicine). The chart must only be signed to record a medicine has been administered once the medicine administration has been witnessed. (Right documentation)
10. observe the patient for adverse effects, and assess the patient to determine that the desired effect of the medicines has been achieved (Right response).

Nursing and Midwifery Students

A nursing or midwifery student should only administer a medicine to a patient:

- under the supervision of a registered nurse or midwife;
- when they the student, agree to undertake the administration;
- on gaining the patient's consent.

Monitoring

Monitoring the efficacy of any medication is an integral part of the nurse or midwife's role. If the medicine does not achieve the desired effect, or results in the onset of adverse events or reactions, the nurse or midwife must:

- maintain a record of the patient's clinical status to ensure that their safety has not been or will not be compromised;
- record the adverse events or reactions in the patient's care plan;
- report to the authorised prescriber;
- ensure that the patient is fully informed about their progress and are involved in making decisions regarding their ongoing care;
- report suspected adverse reactions to HPRA.

Standard 6

Following the administration of a medicine, you must monitor that the desired effect of the medicine has been achieved, and participate in a review of the medicines.

Refer to Section 5 for further guidance on the nurses' and midwives' role in medicines review.

Double Checking/Independent Verification

An independent, double check of any medicines is termed independent verification. The nurse or midwife conducts their own calculation of the medicines and then compares with a colleague.

Practice guidance

- Double-checking the administration of medicines is not a statutory requirement.

- For the administration of high-risk medicines, along with those medicines whose dosage can change or requires complex arithmetical calculations, local PPPGs may require a system of independent verification.

It is recognised that there are circumstances in care delivery settings where the nurse or midwife is not working alongside other registrants – for example, working in the community, residential care units or on night duty. Local PPPGs should be available to support the nurse or midwife in the safe management of medicines.

Preparing a medicine for administration

Except when a dose administration appliance is being used, a medicine should only be prepared for administration immediately before its prescribed administration time and not in advance unless required (for example, reconstitution).

A nurse or midwife should not administer any medicine which has been prepared by another practitioner.

Administration a Non-Prescribed Medicine in an Emergency

Administering a non-prescribed medicine is allowed for in an emergency where the nurse or midwife recognises that:

- in order to reduce the threat or potential threat to a patient's life, the patient requires the administration of a non-prescribed medicine and there is no immediate access to a person with the appropriate prescribing authority;
- the nurse or midwife adheres to the local PPPGs relating to the administration of a non-prescribed medicine in the event of an emergency.

Use of medicines administration compliance aids/monitored dosage systems

Different names have been used to describe medicines administration compliance aids, such as monitored dosage systems, blister packs, medication systems, unit dose packages, multi-dose packages and dose administration aids.

Compliance aids are designed not only to aid self-administration by patients, but also to support the safe administration of medicines in healthcare settings.

Practice guidance

- The patient's individual requirements should be assessed to ensure there are no contraindications related to using the compliance aid.
- The nurse or midwife must assess the patient's suitability and understanding of how to use an appropriate compliance aid safely and accurately. Systems for evaluation of the appropriateness of the compliance aid should be documented in local PPPGs, based upon the patient's condition and prescribed medicines.
- The ability of the nurse or midwife to quickly and correctly identify a specific medicine among several medicines in a package is essential. References and resources should be readily accessible for the nurse or midwife to confirm prescribed medicines in the compliance aid with identifiable drug information.

Withholding and omission of medicines

Standard 7

You may decide to withhold a medicine based on a specific clinical rationale or respecting the patient's own decision to refuse their medicines.

Withholding a medicine is when the nurse or midwife makes a professional decision that there are clinical reasons why they should not proceed with administering a specific medicine.

Omission of medicines, where a nurse or midwife either does not have access to the supply or does not take steps to obtain the drug, is an organisational rather than a professional issue that should be viewed as an untoward occurrence and documented as a medication error.

Practice guidance

In the event that the nurse or midwife intentionally withholds the administration of a prescribed medicine, the nurse or midwife must:

- ensure that the omission of the medicine is recorded in the patient's medicine administration chart;

- document the event in the patient's care plan along with the reason why the medicine was intentionally withheld;
- inform the patient's medical practitioner in addition to the authorised prescriber;
- maintain a record of the patient's clinical status to ensure that their safety has not been compromised;
- document that the patient has been told why the medicine has been intentionally withheld;
- support the patient to remain involved in the decision-making regarding the ongoing clinical management of medicines.

Patient refusal of medicines

A patient may indicate to the nurse or midwife that they do not wish to take a medicine that is being offered on foot of a prescription as part of their agreed plan of care. Because a patient has a legal right to refuse medicines, the nurse or midwife can only recommend, advise, or suggest that the patient takes their medicine.

Practice guidance

If the patient refuses the medicine, the nurse or midwife must:

- ensure that the refusal of the medicine is recorded in the patient's medicine administration chart;
- document the event in the patient's care plan stating the reason why the medicine was refused by the patient;
- inform the patient's medical practitioner in addition to the authorised prescriber;
- maintain a record of the patient's clinical status to ensure that their safety has not been/is not compromised;
- document that the patient and/or family/carers understand potential health implications for refusing the medicine and are involved in the decision-making regarding the ongoing medicines management plan.

Disposal and return of medicines

The activities associated with the removal and disposal of medicines that are no longer required or are no longer suitable for their intended use

Practice guidance

Nurses and midwives should:

- ensure that all medicines that are no longer required should be returned to the pharmacy, whether hospital or community for disposal;
- not offer to arrange for disposal of medicines on behalf of patients;
- follow procedures for safe removal and destruction of unwanted, damaged, out-of-date or part-used medicines. Such procedures are required in all locations where medicines are stored and administered.

Immunisations and Vaccinations

Immunisation is the process whereby a person is made immune or resistant to an infectious disease (RCPI 2013). A vaccine is any preparation intended to produce immunity to a disease by stimulating the production of antibodies. (RCPI 2013)

Immunisation and vaccination are accepted mechanisms in public health for the prevention and eradication of infectious disease. Nurses and midwives are key health professionals involved in providing immunisations to patients and communities in the promotion of public health and prevention of infectious disease.

Registered Nurse Prescribers can prescribe immunisations and vaccinations that have been authorised by the HPRA.

Practice guidance

Nurses and midwives involved in immunisation programmes (including vaccination prescribing and administration) must maintain their competency and current knowledge with all aspects of this practice. This encompasses:

- Vaccine handling and delivery
- Storage and stock control
- Obtaining consent
- Proper technique of administration
- Recognition and intervention with side effects, adverse events and/or complications post immunisation

- Management of anaphylaxis
- Medication Protocol Framework and use

The nurse or midwife should be able to manage adverse reactions including anaphylaxis as first line providers in these emergency situations. Anticipation of this may require basic life-support training, additional resources, skills and equipment. Anaphylaxis may also necessitate the administration of emergency medicines (for example, epinephrine) and nurses and midwives should be knowledgeable about treatment with these medicines. Health service providers should have an organisational PPPG on immunisation/vaccination addressing these areas to support best practice by nurses and midwives.

DRAFT

Section 3 MDA Scheduled Controlled Drugs

Introduction

This section sets out the requirements under the Misuse of Drugs Acts and subsequent regulations for the administration by registered nurses and midwives of MDA Scheduled controlled drugs to patients across care settings.

Standard 8

You must adhere to the requirements of the Misuse of Drugs Acts and Regulations, and given the serious nature of the drugs and their potential for misuse or abuse, follow a strict regimen of control of these substances at all times.

Legislation

The Misuse of Drugs Acts, 1977 and 1984 and the Misuse of Drugs Regulations, 1988, as amended, determine the conditions of production, manufacture, possession, supply, importation and exportation of controlled drugs. The drugs are categorised into five schedules with different controls applicable to each category. The legal term for these drugs is the abbreviation 'MDA' accompanied by the appropriate schedule of the drug. These schedules are listed in Appendix 2.

Supply and possession of MDA Scheduled Controlled Drugs to and within institutions

In institutions where a pharmacist is not employed, the director of nursing/midwifery (or designate director) may be supplied with MDA Scheduled controlled drugs. In these circumstances, before delivering any MDA Scheduled controlled drug, the supplier must receive a written requisition that complies with the general requirements for requisitions and is countersigned by a medical practitioner employed or engaged by the institution.

The nurse or midwife manager in charge of a ward, theatre, unit or department may be supplied with an MDA Scheduled controlled drug, solely for the purpose of administration to patients in that ward, theatre, unit or department, on foot of a requisition issued by them in accordance with the directions of a medical practitioner.

In circumstances where the pharmacist (or director/acting director of nursing/midwifery where a pharmacist is not employed) supplies an MDA Scheduled controlled drug to the nurse/ midwife manager (or designee) they must:

- obtain a requisition signed by the nurse/ midwife manager (or designee) that clearly specifies the total quantity of the drug to be supplied;
- mark the requisition in such a way to show that it has been complied with;
- keep the requisition for two years in the pharmacy which supplied the MDA Scheduled controlled drug.

Supply and possession of MDA Scheduled controlled drugs to and within private hospitals or private nursing homes

The Misuse of Drugs Regulations, 1988 Article 8 (1) (a) does not apply to private hospitals and private nursing homes. Therefore, they have no authority to be in possession of MDA Scheduled controlled drugs or to be supplied with such drugs.

Supplies of MDA Scheduled drugs for patients in private hospitals and private nursing homes should be obtained by way of a medical prescription as if the patients were in their own homes. Private hospital and private nursing home patients are considered to be in the same position as a patient in their own home.

Private hospitals and private nursing homes may hold licenses under the Misuse of Drug Acts, 1977 and 1984. These licenses legally permit the supply, distribution and control of MDA Scheduled drugs for private hospitals and private nursing homes similar to the arrangements in use in where no pharmacist is available.

Management of MDA Schedule 2 Controlled Drugs

Practice guidance

The following additional guidelines are provided as evidence of best practice with the management of MDA Schedule 2 controlled drugs:

- The health service provider's local PPPGs for MDA Schedule 2 controlled drugs may require two people, one of whom is a nurse or midwife, to administer MDA Schedule 2 controlled drugs. This is not a statutory requirement.
- It is recommended that local health service providers should consider including requirements expected for the requisitioning, receipt, checking, preparation, administration, storage, record keeping, stock checks, transport, or disposal and destruction of these drugs when establishing local PPPGs for MDA Schedule 2 controlled drugs.
- Local health service providers should also consider whether these activities are to be witnessed and, if so, by whom (that is, another nurse or midwife or other members of the healthcare team).
- Access to the keys of controlled drugs storage should be the subject of approved local PPPGs for MDA Schedule 2 controlled drugs, bearing in mind responsibility and accountability issues. The nurse or midwife or their nurse/midwife manager or designee should keep the keys of the MDA Schedule 2 controlled drugs storage on their person.
- Local PPPGs should be in place for monitoring and checking a stock balance at each transaction of MDA Schedule 2 controlled drugs. At changeover of shifts, a nurse or midwife from each shift should complete the count of these MDA Schedule 2 controlled drugs.
- Appropriate documentation of the administration of MDA Schedule 2 controlled drugs should be entered in the patient's chart or notes and in the controlled drugs register of the ward, theatre, unit, department or care setting.
- The nurse or midwife manager should keep requisition copies (or a note) detailing the requested MDA Schedule 2 controlled drugs submitted to the pharmacist or nursing/midwifery director who supplies the drugs.

Community care involving MDA Schedule 2 Controlled Drugs

Nurses and midwives practising in the community who are administering MDA Schedule 2 controlled drugs to a patient for whom they have been prescribed should communicate with the prescriber to ensure that the patient's requirements for these drugs are regularly and frequently reviewed.

Residential Care Settings

All MDA Schedule 2 controlled drugs (except those for self-medication) are administered by a nurse. The receipt, administration, management and disposal of MDA Schedule 2 controlled drugs is recorded in accordance with NMBI guidelines, HIQA guidelines and the Misuse of Drugs Acts 1977 and 1984. MDA Schedule 2 Controlled drugs (excluding those for self-medication) are secured in a manner that meets legislative requirements as set out by the Misuse of Drug Regulations 1988 as amended.

All Care Environments

Each of the activities concerned with MDA Schedule 2 controlled drugs must be described in an Approved Health Service Provider's PPPG. Nurses and midwives should comply with and follow the Approved Health Service Provider MDA Schedule 2 controlled Drug PPPG within their organisation or care setting.

Transport of MDA Schedule 2 Controlled drugs in the community

Where the patient resides in the community:

- Nurses and midwives are authorised to transport the MDA Schedule 2 controlled drug to a person for whom the drug has been properly prescribed for and dispensed by a pharmacist.
- Nurses and midwives are not otherwise permitted to have the MDA Schedule 2 controlled drug in their possession or storage.
- Nurses and midwives should ensure the MDA Schedule 2 controlled drugs are transported safely and securely to the patient's home.
- Once in the patient's home, the nurse or midwife should sign the patient drug record card and it should be witnessed that the MDA Scheduled 2 controlled drug has been received by the patient. Where a second nurse or midwife is not available, another competent person may witness receipt – for example, a carer.

Where the patient is being transported in the community:

- The MDA Schedule 2 controlled drug must be dispensed by the pharmacist to the patient on an individual basis as per the written prescription.

- The drugs should not be supplied from the stock of the MDA Schedule 2 controlled drugs onsite.

It is the responsibility of the patient or their family to return for destruction unused or expired MDA Schedule 2 controlled drugs to the pharmacy from which they were dispensed. MDA Schedule 2 controlled drugs should be destroyed in such a way that they cannot be retrieved, reconstituted or used.

Community-based midwifery and MDA Schedule 2 Controlled drugs

A community-based midwife is authorised by exemptions to the *Misuse of Drugs (Amendment) Regulations, 2007* to have in their possession pethidine or pentazocine for their practice.

There are specific requirements for this possession. A written order is signed by the midwife and countersigned by a medical practitioner or registered nurse prescriber practising in their area.

The medication order must state:

- the name and address of the midwife,
- the total quantity of the drug to be supplied, and
- the purpose for which it is required.

A record must be kept in a book by the midwife of any supply of pethidine that they obtained and administered. The record must include:

- the name and address of the person from whom the drug was obtained,
- the total quantity of the drug obtained, and
- the form in which it was obtained.

After administering the pethidine to the patient, the midwife must enter into the register book:

- the name and address of the patient,
- the total quantity administered, and
- the form in which it was administered.

Each of the activities concerned with MDA Schedule 2 controlled drugs must be described in an Approved Health Service Provider PPPG. Midwives should comply with and follow the Approved PPPG for MDA Schedule 2 controlled Drugs within their organisation or care setting. A record of administration of the MDA Schedule 2 controlled drugs should also be kept in the patient's records.

The Register for MDA Schedule 2 Controlled drugs must be retained for a minimum of two years from the date in which the last entry was made.

Storage of MDA medicines

All medicines should be stored in a secure manner, either in a locked cupboard or room. They should be stored in the appropriate environment as indicated on the label or packaging of the medicine or as advised by the pharmacist.

Best practice and local decision suggests that MDA Schedule 2 Controlled drugs should be locked in a separate cupboard or container from other medicines to ensure further security. Where practicable, the safe custody provisions relating to medicines in pharmacy legislation should be followed.

Misuse, Abuse or Theft of MDA Schedule 2 Drugs

Approved Healthcare Provider PPPGs must be made available and accessible to nurses and midwives across all healthcare settings for the detection and management of the misuse, abuse and or theft of MDA Schedule 2 drugs involving staff or patients.

Section 4 Patient Safety

Introduction

The role of the nurse and midwife in safe medicines management encompasses understanding the purpose of the patient's medicine regimen, supporting the safe administration of medicines, monitoring the effectiveness of medicines and the patient's understanding and adherence. It is not solely a mechanistic automatic task, but ensures that the patient gets the maximum benefit from the medicines they need while, at the same time, minimising the potential for harm.

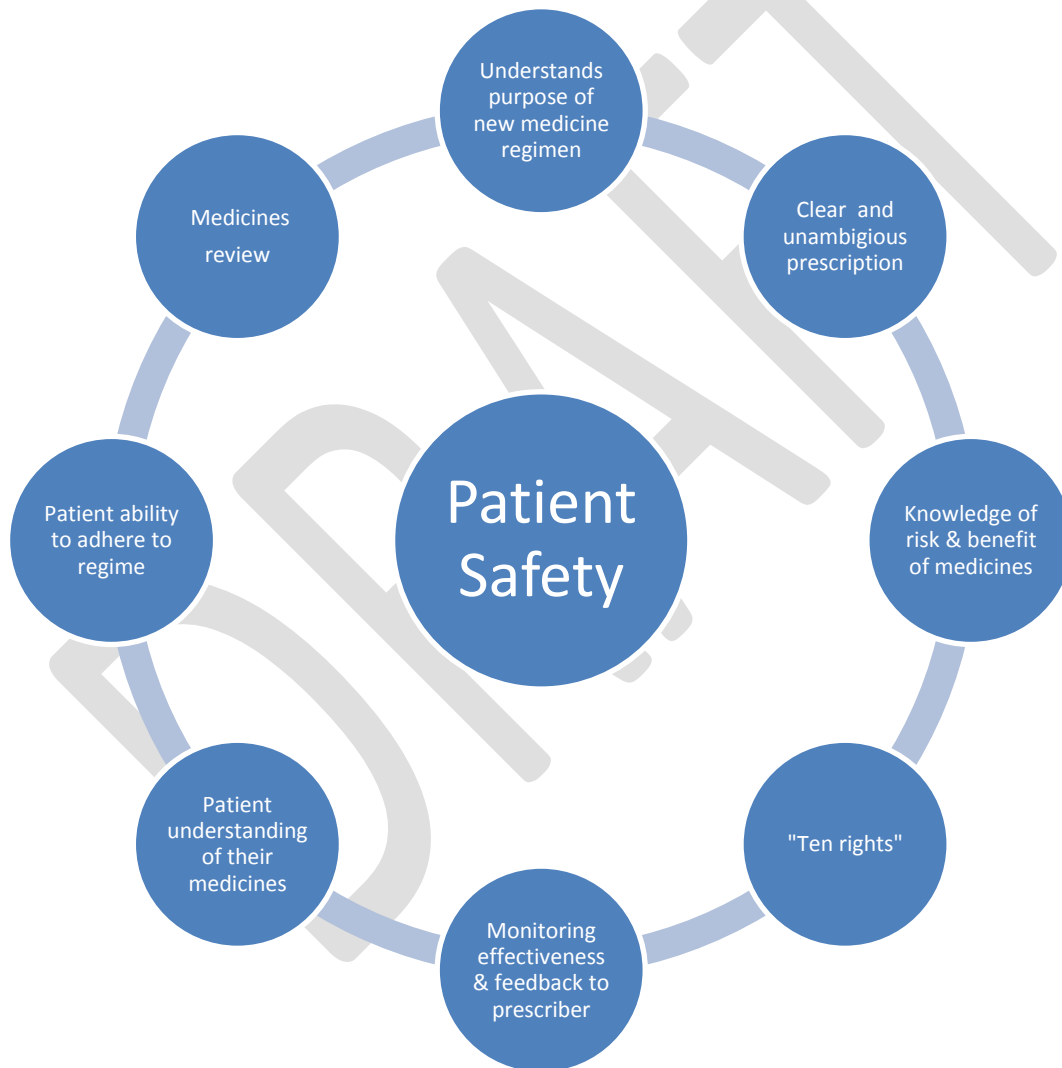


FIGURE 1 PATIENT SAFETY CYCLE

The Nurses and Midwives Act 2011 emphasises the key role in maintaining the health, safety and welfare of the public. Patient safety must be the priority in every setting, and has been defined as the freedom from accidental injury.

The nurse and midwife:

- Understands the purpose of the patients' medicines regimen;
- Can read the prescription clearly;
- Understands the risks and benefits of each medicine;
- Adheres to the "Ten Rights" for the safe administration of medicines;
- Monitors the effectiveness of specific medicines;
- Ensures that the patient understands their medicines including discussion on quality of life issues;
- Discusses the potential difficulties with adherence to regimen;
- Advises on medicines management follow up and review.

Standard 9

You must have a thorough understanding of the factors involved in adverse events or reactions. You must also recognise the high importance of reporting every medicine-related error, whether actual or potential, and implement remedial action.

Adverse Events

An adverse event is a preventable failure at any stage of the medicines management process that leads to, or has the potential to lead to, harm to the patient. Since adverse drug events are the most frequent type of preventable adverse event, patient safety must be a key component of the culture and quality of medicines management (Council of Europe 2006).

An adverse drug event is a medicine-related adverse event which can be further classified as:

A. Medicine Error

Any error in the prescribing, dispensing or administration of a drug, regardless of whether there are adverse consequences or not

B. Potential Adverse Drug Event (Previously termed 'near miss') An error or close call that had the potential to cause an adverse drug event, but did not, either by interception or chance.

It is important that an open culture exists to encourage the immediate reporting of errors or incidents in the administration of medicines. However, this does not negate the responsibility and accountability of nurses and midwives to adhere in a diligent manner to PPPGs on safe medicines management and maintain their professional competence.

All adverse events should be seen as opportunities to assess practice, identify what went wrong, learn from the event and institute changes to the medicines management cycle.

Practice guidance

- Upon noting an adverse event, the nurse and midwife must immediately give priority to the safety of the patient and monitor their health status to limit or prevent further harm.
- Nurses and midwives have a duty to report all adverse events, not only medicine errors, but also those situations where no harm occurred and the patient was unaffected or unaware of a problem.
- Nurses and midwives must recognise and report all untoward occurrences using the local medicine error reporting system where such exists.
- The causes of adverse events are complex and require that robust reporting systems are in place which will:
 - capture relevant information;
 - investigate the circumstances and run-up to the event;
 - report to the patient, the prescriber and the line manager or employer;
 - instigate remedial action plans for all events;

All healthcare areas should have local PPPGs on adverse event reporting and the dissemination of findings.

The prevention, detection and reduction of adverse events should be a collaborative process amongst the healthcare team, since errors may reflect a problem with the system and may involve other professions and departments.

Strategies to prevent Adverse Events

- Use generic drug names, where appropriate
- Understand safe and rational prescribing for individual patients
- Work with pharmacists and prescribers in medicines reconciliation
- Demonstrate knowledge of High- Alert medications
- Demonstrate knowledge of Sound Alike Look Alike Drugs (SALADs)
- Develop checking habits and work with a colleague for independent verification when calculation skills are required
- Involve patients in the safe use of medicines
- Encourage clear, accurate and factual documentation
- Ensure access to an up-to-date paper-based or online British National Formulary and other authoritative sources of current product information and guidance – for example, the Irish Medicines Formulary, HPRA medicines information, European Medicines Agency website.
- Report and learn from errors

Table 1 Strategies to prevent adverse events

Identifying and Reporting Adverse Reactions

Standard 10

You must understand the rationale for the drug prescription and the potential side effects of the drug in order to be able to identify, intervene and report a suspected adverse event or reaction.

a. Adverse reactions have been defined as:

“... a response to a medicinal product which is noxious and unintended”

(European Directive 2010, p74).

Directive 2010/84/EU of the European Parliament and of the Council recommends that the definition of the term ‘adverse reaction’ should be amended to ensure that it covers noxious and unintended effects resulting not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse and abuse of the medicinal product.

b. Suspected Adverse Reaction is when:

“There is at least a reasonable possibility of there being a causal relationship between a medicinal product and an adverse event.”

(European Directive 2010, p74).

Practice guidance

- If a nurse and midwife observes an adverse reaction or suspected adverse reaction, they must give immediate priority to the patient’s safety and monitor their health status to limit or prevent further harm.
- The nurse or midwife should report the suspected adverse reaction to the prescriber who can advise on any intervention needed.
- Local risk management procedures should indicate steps to be followed in the event of an adverse reaction with regard to reporting and subsequent actions.
- In addition to prescribers, nurses and midwives, any person involved in patient care may report issues relating to the safety and quality of healthcare products to the

HPRA. This includes patients, carers, members of the public and all healthcare professionals.

Serious Reportable Events

Serious reportable events are described as:

“...unambiguous, largely preventable, and serious, as well as adverse, indicative of a problem in a healthcare setting’s safety systems, or important for public credibility or public accountability...”

(National Quality Forum 2011, p2)

These are also termed ‘never events’.

In medicines management, a serious reportable event is:

“... patient death or serious disability associated with a medication error by the healthcare provider but excluding reasonable differences in clinical judgement involving drug selection and dose.”

(HSE 2014, p29)

Practice guidance

- Following a ‘never event’, nurses and midwives are expected to report such events to risk managers and participate in subsequent investigation.
In addition, they should cooperate with the introduction of identified changes. This is critical to the prevention of future serious reportable events.
- Nurses and midwives should participate in the learning strategies which are applied in the service from every event that occurs.

Generic Substitution

Generic substitution, under The Health (Pricing and Supply of Medical Goods) Act 2013, permits pharmacists to substitute medicines which have been designated as interchangeable by the HPRA. Previously, when a specific brand of medicine was prescribed for a patient, a pharmacist could only supply that specific brand.

The Act allows pharmacists to substitute different versions of some prescribed medicines which are often less expensive generic versions of brand name medicines. The medicines must be included in a list of interchangeable drugs published by the HPRA.

If the patient needs a particular brand of medicine for medical reasons, the prescriber can write 'Do not Substitute' on the prescription and the proprietary or brand name medicines will be dispensed.

Practice guidance

The nurse or midwife should demonstrate knowledge of the safety issues relating to generic prescribing, and the implications of generic substitution.

Exempt medicines

An exempt medicine is an unauthorised medicine which is supplied on foot of a prescription or order of a registered doctor or dentist, for use by individual patients under the prescriber's direct responsibility in order to fulfil the special needs of those patients (HPRA 2014).

Medicines prescribed, dispensed, supplied and administered in Ireland are required to have a marketing authorisation from the HPRA or from the European Medicines Agency (EMA). However, the Medicinal Products (Control of Placing on the Market) Regulations 2007, as amended, provide certain exemptions that legally allow a registered medical practitioner or registered dentist to prescribe a medicine that does not have this authorisation. They were previously known as '*unauthorised*' or '*unlicensed*'.

The exemptions from authorisation allow for:

- Medicines supplied as part of an approved clinical trial.
- Medicines sold or supplied based on a valid prescription from the medical practitioner or dentist for use by an individual patient who is under the doctor or dentist's direct care.

The prescriber has the professional responsibility for the clinical use of the exempt medicine.

- A nurse or midwife has authority to administer an exempt medicine only when it has been prescribed by a medical or dental practitioner.
- Currently, RNPs are not permitted to prescribe exempt medicines.

Authorised Medicine Prescribed for an Unauthorised Indication

This was previously known as 'off-label prescribing'. It is where an authorised medicine is prescribed for an illness or condition that is not listed on the medicine's summary of product characteristics.

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 an authorised medicine for an unauthorised indication.

There is no restriction in the relevant medicines regulations for a registered medical or dental practitioner to prescribe an authorised medicine for an unauthorised indication.

Prescribing by a RNP of an authorised medicine for an unauthorised indication must be in accordance with Regulation 5A of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 as amended.

A nurse and midwife has authority to administer an authorised medicine for an unauthorised indication once it has been prescribed by a registered medical, dental practitioner or nurse prescriber.

Practice guidance

The decision to prescribe, supply or administer such medicines should be justified by evidence-based practice. Information should be available for, or be sought by, the nurse and midwife to supply or administer the medicine safely.

- Prior to commencement of treatment with an exempt medicine or authorised medicine for an unauthorised indication, informed consent must be obtained.
- The nurse or midwife should refer to the prescriber or pharmacist if they have questions or concerns regarding the indications for its use by the patient.
- The nurse or midwife must have an understanding of the reasons for administering the medicine, particularly as it relates to the assessment and evaluation of the effectiveness of the prescribed medicine for the patient.

- The nurse or midwife should have sufficient knowledge of the medicine to educate the patient or family member.
- The use of exempt medicines and unauthorised indications for authorised medicines should be supported by local PPPG. RNPs have additional guidance as presented in The Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (An Bord Altranais, 2010) and The National Policy for Nurse and Midwife Medicinal Product Prescribing (HSE, 2012).
- If an exempt medicine is prescribed as part of a clinical trial, additional guidance and information should be sought from the clinical investigator and the associated clinical research nurse where applicable.
- The European Communities (Clinical Trials on Medicinal Products for Human Use) 2004 as amended, lay down the principles and detailed guidelines which should be adhered to when undertaking clinical trials.

Crushing Medicine

The crushing of medicines involves rendering it from the solid form of a tablet or capsule to a powder form in order to assist with administration to the patient.

Since crushing of medicine renders it an exempt medicine, nurses and midwives should only administer crushed medicines to their patients on foot of a prescription from a registered medical or dental prescriber. A general authorisation on the MPAR to crush medicines does not meet the requirements under legislation for exempt medicines. It should be authorised for each individual medicine. RNPs are not authorised to prescribe exempt medicines.

Practice guidance

If the nurse or midwife determines that a change in the form of the medicine is necessary for safe administration to the patient, they should consult with the medical practitioner and pharmacist to discuss alternative preparations or forms of administration for the patient.

Crushing of medicines should be avoided if:

- the action of crushing alters the medicine's absorption rate and/or stability such as sustained, delayed or extended forms

- the crushed form has an unacceptable taste
- it causes a local irritant effect
- it results in a failure of the medicine to reach the site of action
- it leads to an occupational health and safety concern such as exposure to a radioactive, cytotoxic substance or teratogenicity.

If no alternative to crushing is available, such as liquid form or another medicine, then the nurse or midwife should ensure that:

- the medicine is prescribed by the medical practitioner in the patient's MPAR;
- the need to crush the medicine is discussed with the patient;
- there is a PPPG to support the practice of crushing oral medications, to include
 - guidelines and decision-making on the rationale for individual patient events,
 - Identifying and addressing health and safety issues that may result from crushing the medicine;
- crushed medication is added to a small amount of suitable foodstuff (according to the resident's preference) such as teaspoon of yoghurt or jelly.
- Crushed medicines can only be added to foodstuff if there is evidence that this is a suitable method of administration and does not adversely affect the bioavailability of the medicine, absorption, stability.
- medicines should not be added to beverages or meals;
- they understand the reasons for administering the medicine, particularly as it relates to the assessment and evaluation of the effectiveness of the prescribed medicine for the patient;
- they document the rationale for crushing the medicine and record the alternatives considered;
- there is access to an updated list of medicines which should not be crushed
- crushing the medicines is not being (and should never be) used as a mechanism to disguise or covertly administer medicines.

Covert administration of medicine

Covert administration of medicine refers to when a medicine is administered in a disguised form to a patient without their knowledge or consent.

- Nurses and midwives must not engage in the practice of covert administration of medicines. There are specific provisions in the Mental Health Act 2001 in relation to continued administration of medicines in the treatment of mental disorder for a period longer than three months for adults and children. Nurses and midwives should use existing legal and best practice frameworks for individual patient situations. These frameworks include Assisted Decision-Making Capacity Bill (2013), the HSE National Consent Policy, Quality Framework for Mental Health Services in Ireland – (National Mental Health Services Standards) relevant organisational policy, associated capacity assessment tools and the NMBI Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.

Covert administration and children

A child's capacity to make decisions advances over time and depends on their age and developmental stage. In situations where children have not yet achieved capacity to make their own decisions, medication is usually administered with the consent of their parents or legal guardians. In supporting parents' administering medications to their children, the nurse or midwife should review with the parent the necessity of giving medications covertly and encourage them to speak with a pharmacist before crushing medicines or mixing it with food or beverages.

Complementary and Alternative Therapies

When describing health approaches with non-mainstream roots, the words 'alternative' and 'complementary' are used interchangeably, but the two terms refer to different concepts, namely:

Complementary generally refers to using a non-mainstream approach together with conventional medicine.

Alternative refers to using a non-mainstream approach in place of conventional medicine.

Where a nurse or midwife is providing complementary and alternative therapies, they should ensure that such therapies do not adversely affect conventional medicines that the patient has been prescribed.

Practice guidance

- The nurse or midwife should assess a patient for both past and present use of complementary and alternative therapies and document this in the care plan.
- This information should be communicated to the members of the healthcare team involved in the patient's care, with special consideration to both the prescriber and the pharmacist.
- The nurse or midwife using complementary and alternative therapies should be competent in the specific therapy, and have undergone an education programme that provides them with the required skills and knowledge to practise such therapies.
- Where a nurse or midwife is providing complementary and alternative therapies, it should be evidence-based and informed consent should be documented in the care plan.
- Ensure that there are organisational PPPGs to underpin the safe use of complementary and alternative therapies for the safety and well-being of the patient.

Placebo

A placebo is pharmacologically inert substance that has no physiological effect.

Practice guidance

Administering placebos to patients in the absence of informed consent is not an acceptable practice for nurses or midwives.

Clinical Trials

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

If medicine is prescribed and administered to a patient as part of a clinical research trial, guidance and information should be sought from the clinical investigator or the associated clinical research nurse or midwife. This should include the monitoring and reporting of adverse events or reactions in accordance with clinical trial protocol.

SECTION 5 Quality Assurance: developing high quality and safe services

Optimising the use of medicines is central to the quality of patient care, and encompasses the safe, effective and cost-effective use of medicines. Medicines need to be prescribed rationally, administered safely and their effectiveness monitored to ensure that the patient receives the maximum benefit and achieves the best outcomes.

This section discusses various evidence-based quality approaches that support the safe and rational use of medicines.

Medicines Reconciliation

Standard 11

You must work with the patient and, where appropriate, their families and carers in medicine reconciliation. You must also work in association with other healthcare professionals to ensure that people do not suffer unnecessarily from the excessive, inadequate or inappropriate use of medicines.

Medicines reconciliation is the process of creating and maintaining the most accurate list possible of all medicines a person is taking – including drug name, dosage, frequency and route – in order to identify any discrepancies, deletions, omissions, additions and to ensure any changes are documented and communicated, thus resulting in a complete list of medicines (HIQA 2014).

Medicines reconciliation is a continuous process that should involve the multidisciplinary healthcare team. It aims to provide patients with the correct medicines at all points of transfer within and between health and social services. It can be considered complete when each medication that a person is taking has been actively continued, discontinued, held or modified at each point of transfer, and these details have been communicated to the next care provider.

There are three steps in the medicines reconciliation process:

1. Collecting: involves the collection of the medication history and other relevant information about the patient's medicines.

Residential Care:

Pre-admission PPPGs should be in place to ensure that the resident's circumstances, medicines, treatment and ongoing support by medical and other professionals is provided to the person-in-charge (HIQA 2014). Prior to discharge or transfer to another facility, such information should be provided by the person-in-charge to the subsequent care provider (HIQA 2014).

Acute Care Setting: Discharge and Transfer to Hospital: Pre-admission or Admission.

The nurse or midwife should obtain an accurate pre-admission medicines list to reflect the therapies a patient actually used before admission to hospital. This should include prescriptions, over-the-counter medicines, nutritional support and other therapies such as herbal products (HSE 2014).

2. Checking: this is the process of ensuring that the medicines, doses, frequency times and routes that are prescribed for the patient are correct. The nurse or midwife should:
- reconcile the pre-admission medicines list with the admission list prescribed on the MPAR and resolve any anomalies;
 - record details of the patient's community pharmacy, where relevant;
 - review the patient's pre-admission medicines list where appropriate in order to identify any problems associated with current drug therapy;
 - document the patient's allergy status (including 'no known allergy' status), the type and details of known allergies and any previous adverse drug reactions (HSE 2014).
3. Communicating: is the final step in the process where any changes that have been made to a patient's prescription are documented, dated and communicated to the person to whom the patient's care is being transferred.

The nurse or midwife should document, date and communicate any changes that have been made to the patient's prescription. The record should be ready to be communicated to the patient and the next person responsible for the medicines management care of that person and should include:

- when a medicine has been started and for what reason;
- the intended duration of the treatment;
- when a medicine has been stopped and for what reason;
- when a medicine has been held and for what reason;
- when a dose has been changed and for what reason;
- when the frequency or timing has been changed and for what reason.

Practice guidance

- The nurse or midwife should undertake a complete medicines history with the patient and collect all relevant information about the patient's medicines. This medicines history should be collected from the most recent and reliable source. Where possible, the information collected should be cross-checked and verified.
- The nurse or midwife recording the information should always record the date the information was obtained and the source of the information. Where there appears to be a discrepancy between what the patient is currently prescribed and what the patient is actually taking, this should also be recorded by the nurse or midwife. If it can be established, the reason for any variation should be recorded also.

Medicines Review

Medicines review is increasingly recognised as a cornerstone of high-quality medicines management. Medicines review is a way of optimising therapy, improving health outcomes for the patient and reducing the likelihood of medicines-related morbidity and mortality.

Medicines review is now understood to be a collegial approach whereby the prescriber, nurse or midwife and pharmacist work together to support the patient with the safe use of their medicines.

Medication review has been defined as:

‘...a structured, critical examination of a patient’s medicines with the objectives of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste.’

(Task Force on Medicines Partnership and the National Collaborative Medicines Management Services Programme, 2002)

Practice guidance

The nurse or midwife should be aware of the different levels of medicines review in clinical practice (Room for Review, 2002)

Level 0 **Ad hoc:** unstructured opportunistic review

Level 1 **Prescription review:** a technical review of a list of patient’s medicines

Level 2 **Treatment review:** a review of medicines with patient’s full notes

Level 3 **Clinical medication review:** face-to-face review of medicines with the patient

The nurse or midwife should:

- Talk to the patient about their opinions and expectations of the medicines regime.
- Assess the patient’s daily activities and mental status, their laboratory reports, hospital visits, personal viewpoint.
- Discuss with the patient any barriers to filling their prescriptions and taking the dispensed medicines.

Medicines Metrics

Metrics are parameters or measures of quantitative assessment used for measurement and comparison or to track performance. Patient data can be collected and risk adjusted to ensure meaningful comparison across the system.

Medicines metrics focus on key clinical markers for safety that should be standards in any service. Medicines metrics are among those most likely to be sensitive to differences in nursing input and are, therefore, potentially good indicators of safety (Griffiths et al. 2008; Doran 2011).

Practice guidance

Nurses and midwives should ensure that they:

- understand each individual medicines metric and be satisfied that it is fit for purpose before any data collection commences;
- ensure that all patients in the clinical area have received the explanatory information;
- ensure that patients have signed a consent form that they are willing to participate in the medicines metrics collection;
- ensure the confidentiality of the data collected;
- report immediately any safety issues highlighted by the data collection to their line manager and take remedial action;
- ensure that they follow local PPPGs.

Preferred Medicines

The National Medicines Management Programme has established a system of Preferred Drugs. The Preferred Drugs initiative identifies a single 'preferred drug' within a therapeutic drug class, and offers prescribers useful guidance on selecting, prescribing and monitoring this drug for a particular condition. Prescribers are encouraged to make the preferred drug their drug of first choice when prescribing a drug from that therapeutic class.

A preferred drug is selected following a thorough evaluation of the available evidence. Factors considered in the evaluation process include, but are not limited to, clinical efficacy and effectiveness, dosing and administration, drug interactions, side effects, cost, national prescribing trends, and national and international clinical guidelines.

Practice guidance

The nurse or midwife should be familiar with the current list of preferred drugs and their safety guidance prior to the administration of medicines.

Information on the preferred drugs is available on www.hse.ie/yourmedicines.

Patient and family/carer information

Consideration should be given to the appropriate timing of teaching, including patient or carer readiness to learn. Teaching should be undertaken in a respectful and dignified manner.

Standard 12

You should understand the complex factors that influence the patient's decision-making process and adherence regarding their medicines. Education should be provided to the patient and their family in relation to the use of medicines. It should be explained to the person in a way that is accessible and understandable.

Practice guidance

The nurse or midwife should include patient education as an integral component of the safe, effective and cost-effective use of medicines. Patient education is an ongoing, multidisciplinary approach which should be documented in the patient's care plan and included in all admission, transfer and discharge information.

Best practice would indicate that this information and education should include:

- The various generic and brand names, formulations and routes of administration of each medicinal product
- The expected mechanism of action of the medicine
- Indications and goals of therapy for each medicine
- The provision of understandable and usable information
- Principal risks and benefits of the medicine
- Signs and symptoms of potential adverse effects and actions to take if they occur
- Possible interactions of the medicine with other medicinal products, particular foods or other substances
- Specific plans for monitoring therapy and adjusting doses
- Recommendations for follow-up and reporting of potential side effects or adverse reactions
- Instruction never to share any medicine and information on harm associated with sharing any medicine

- Safe and secure storage of medicines in the home
- Documentation of all education regarding self-management in the patient's healthcare records

Medicines Compliance, Adherence and Concordance

One of the problems in achieving patient-centred medicines management is that a high proportion of patients do not always take their medicines in the way the prescription was intended.

Non-compliance can be either unintentional (where the patient simply forgot to take a prescribed medicine) or intentional (where the patient consciously decides not to). In the latter case in particular, causes of non-compliance are complex. Complicated dose regimens, polypharmacy and side-effects may be significant contributory factors.

Medicines adherence describes a presumed agreement between prescriber and patients regarding the prescription and the prescriber's rationale for the medicines regime. It may be defined as the extent to which the patient's action in taking their medicines matches the prescription (NICE, 2009).

Concordance describes a shared process leading to the agreement of the overall aims of any prescribed drug treatment and how they are to be achieved. Throughout this process, the patient is able to participate and is ultimately able to influence the outcome. It is suggested that achieving concordance between prescriber and patient is more likely to lead to higher rates of compliance (RPSGB, 1997).

Practice guidance

- The nurse or midwife should assess the patient's current medicines compliance and discuss the overall aims of any medicines treatment regime and how they are to be achieved.
- The nurse or midwife should ensure that the patient has a safe level of knowledge relating to their medicines in the form of information that is understandable to the individual.

- The nurse or midwife should ensure that the patient has access to a current prescription on discharge and has access to obtaining their medicines from the pharmacy.
- The nurse or midwife should ensure that the patient has a current list of their medicines and appropriate safety information.

DRAFT

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Appendices

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Appendix 1

Framework for Medication Protocols (revised from 2007 Guidance)

Medication protocols are written directions that allow for the supply and administration of a named medicine¹ by a nurse or midwife in identified clinical situations. A medication protocol involves the authorisation of the nurse/midwife to supply and administer a medication to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect.

Care (involving medicines), for the most part, should be founded and provided on an individual explicit basis for the patient. However, the supply and administration of medicines under medication protocol can support more timely delivery of quality health care and optimally utilise the skills of healthcare professionals. The use of a medication protocol should be reserved for those situations when it offers an advantage for the patient care and where it is consistent with appropriate professional relationships. Medication protocol use should be considered in the context of the clinical situation, safety assurance for the patient and acceptance of accountability by the healthcare professional involved. Medication protocols must be developed based on evidence of best practice and supported locally by the multidisciplinary healthcare team. In operationalising a protocol, a nurse or midwife who is authorised to supply, is also responsible for administration of the medication. This activity cannot be delegated.

The NMBI supports the development of medication protocols using a nationally recognised template based on international evidence and best practice. The responsibility for developing and quality-assuring medication protocols rests with health service providers. It is important that local PPPGs are devised to support the development and implementation of any medication protocols for patients.

¹ Controlled drugs cannot be supplied under protocol owing to restrictions in the Misuse of Drugs Act 1984 and subsequent Regulations

Medication Protocol Framework Template

1. Critical elements

1.1 Name of the organisation and/or department where the protocol applies.

1.2 Date the protocol comes into effect and a review date and/or expiration date.

1.3 Names and signatures of protocol author(s) and reviewers, which should include the chair of the drugs and therapeutic committee (if relevant), the medical consultant, a pharmacist and nurses/midwives working within the clinical area.

1.4 Name(s) and signature(s) of the employing authority that is authorising the implementation of the protocol (for example, health service provider).

2. Clinical criteria

2.1 Clinical condition for use of the protocol:

2.1.1 Definition of the clinical condition including the criteria for confirmation of the condition.

2.1.2 Clearly define in what circumstances the protocol applies.

2.2 Relevant international and national guidelines/evidence-based practice.

2.3 Inclusion criteria for patient/service-user treatment using the protocol.

2.4 Exclusion criteria for patient/service-user treatment using the protocol.

2.5 Actions to be taken for those who are excluded from the protocol, whether by the above exclusion criteria or because the patient/service-user does not wish to receive treatment using the protocol.

2.6 Description of circumstances and referral arrangements when further advice or consultation is required.

2.7 Documentation requirements of the protocol to include specific details of where the supply or the supply and administration of the medication is to be recorded.

3. Details of medication to be supplied

3.1 Name of medication, legal classification, dosage, maximum total dosage, quantity, route and frequency of administration and the minimum and maximum period over which the medication should be administered.

3.2 Warnings, including cautions, contraindications, interactions and side effects.

3.3 Potential adverse reactions and procedures for treatment of same.

3.4 Procedure for reporting adverse drug reactions to the Irish Medicines Board.

3.5 Procedure for the reporting and documentation of errors and near misses involving the medication.

3.6 Validated reference charts to be available in circumstances where calculation of dose is required.

3.7 Mechanism for storage of medication and for obtaining supply.

3.8 Resources and equipment necessary for care under the protocol to be specified. This is dependent on the assessment requirements and best practice guidelines identified for the clinical condition. All involved staff should be familiar with the availability and location of resuscitative equipment.

3.9 Audit process to identify appropriate use of the protocol or unexpected outcomes.

4. Patient care information

4.1 The advice (including written) to be given to the patient or carer before and/or after treatment.

4.2 Medication information to be provided to the patient or carer using the authorised patient information leaflet if one is available. It should include relevant warnings including possible side effects and potential adverse reactions.

4.3 Details of any necessary follow-up action and referral arrangements. This should be as specific as possible, to include how the process of referral is to be done, with whom, when and where it should occur.

5. Staff authorised to use protocol

5.1 Name(s) and signature(s) of nurses/midwives authorised to use the medication protocol, including any necessary criteria:

5.1.1 Professional qualifications, training, experience and competence seen as necessary and relevant to the clinical condition treated using the medication protocol.

5.1.2 Requirements for staff for continuing training and education for supplying medication using the specific protocol.

Appendix 2

Schedules of MDA Controlled Drugs

MDA Schedule 1 Controlled Drug

A special license is required for any activity in respect of these drugs. In practice, such activities are strictly limited to scientific research or forensic analysis. Examples of these drugs are: coca leaf, raw opium, and the major hallucinogenic drugs.

MDA Schedule 2 Controlled Drug

A license is required for the import and export of these drugs and those entitled to produce, supply or possess them are listed. Possession without an appropriate authority is an offence. A pharmacist may supply to a patient only on the authority of a prescription written in the prescribed form. Record-keeping requirements (including an MDA Schedule controlled drug register) apply in full. Destruction must be witnessed and the safe custody maintained. Examples of MDA Schedule 2 controlled drugs are opioids (morphine and diamorphine), amphetamines and synthetic opioids (pethidine, methadone, fentanyl) and specific preparations of cannabis extract.

MDA Schedule 3 Controlled Drug

Less strict controls apply to this schedule of drugs. Record-keeping requirements in a MDA Schedule controlled drug register do not apply. Destruction of the drug does not need to be witnessed. The safe custody provisions are applicable to these drugs, as are the MDA controlled drug prescription writing requirements. Most barbiturates, some potent analgesics, minor stimulants and two benzodiazepines-flunitrazepam and temazepam are examples.

MDA Schedule 4 Controlled Drug

Control of these drugs is minimal and in practice they should be supplied in accordance with the Medicinal Products (Prescription and Control of Supply) Regulations, 2003. Recording keeping in an MDA controlled drug register, the retention of invoices and the safe custody regulations do not pertain to drugs in this schedule. Most benzodiazepines and phenobarbitone or methylphenobarbitone preparations containing not more than 100 milligrams per dosage unit and no other controlled drug.

MDA Schedule 5 Controlled Drug

This MDA schedule lists medicinal products exempt from most restrictions under the Regulations. Invoices regarding these products must be retained for two years. The list includes but is not limited to:

- preparations (not being a preparation designed for administration by injection) when compounded with one or more other ingredients and which contains a total of not more than 100 milligrams of the substance or substances. The substances are; containing codeine, nicocodeine, nicodicodine, norcodeine, acetydihydrocodeine, ethylmorphine, pholcodine and their respective salts. mixed with other substances and containing less than 100mg per dosage unit or not more than 2.5% in individual preparations.
- Preparations of dihydrocodeine (not being injections) containing not more than 10mg per dosage unit of dihydrocodeine as base and, in the case of undivided preparations, not more than 1.5% as base.
- Preparations of cocaine containing not more than 0.1% calculated as cocaine base
- Preparations of medicinal opium or morphine, containing not more than 0.2% calculated as anhydrous morphine base
- Preparations of diphenoxylate containing not more than 2.5mg of diphenoxylate calculated at base and a quantity of atropine sulphate equivalent to at least 1% of the dose of diphenoxylate (e.g. Lomotil)
- Preparations for oral administration containing not more than 135mg of dextropropoxyphene (e.g. Distalgesic, Doloxene Co.)

MDA Schedule 8 Controlled Drugs

This schedule establishes which drugs registered nurse prescribers (RNPs) are legally entitled to prescribe within schedules 2 and 3.

PART 1 – DRUGS FOR PAIN RELIEF IN HOSPITAL FOR:

1. A person with a probable myocardial infarction
2. A person after trauma suffering from acute or severe pain
3. A person requiring post-operative pain relief in a hospital who has had either 1 or 2

Drug	Route of Administration
Morphine Sulphate	Oral, Intravenous, Intramuscular
Codeine Phosphate	Oral

PART 2 – DRUGS FOR PALLIATIVE CARE

Drug	Route of Administration
Morphine Sulphate	Oral, Subcutaneous
Hydromorphone	Oral, Subcutaneous
Oxycodone	Oral, Subcutaneous
Buprenorphine	Transdermal
Fentanyl	Transmucosal, Transdermal
Methylphenidate	Oral
Codeine Phosphate	Oral

PART 3 – DRUGS FOR MIDWIFERY

Drug	Route of Administration
Pethidine	Intramuscular

PART 4 – DRUGS FOR NEONATAL CARE IN HOSPITAL

Drug	Route of Administration
Morphine Sulphate	Oral, Intravenous
Fentanyl	Intravenous

Appendix 3

Useful Resources

Health Information and Quality Authority Unit 1301, City Gate, Mahon, Cork

Email: info@hiqa.ie

Website www.hiqa.ie

The Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2

Email infor@hpra.ie

Website: www.hpra.ie

Irish Medication Safety Network,

Email: enquiries@imsn.ie

Website: www.ismn.ie

National Medicines Information Centre, St James's Hospital, James's Street Dublin 8

Email nmic@stjames.ie

Website www.nmic.ie

National Centre for Pharmacoeconomics, Rialto Gate, St James's Hospital. James's Street, Dublin 8.

Email: info@ncpe.ie

Website: www.ncpe.ie

National Poisons Information Centre. Beaumont Hospital PO Box 1297 Beaumont Road, Dublin 9.

Email details on website.

Website: www.poisons.ie

The Pharmaceutical Society of Ireland, PSI House, 15-19, Fenian Street, Dublin 2.

Email: infor@thepsi.ie

Website: www.thepsi.ie

Appendix 4

Relevant Legislation, National Policies and Standards (To be completed)

European Communities (Clinical Trials on Medicinal Products for Human Use) 2004 as amended.

Health Act 2007

The Health (Pricing and Supply of Medical Goods) Act 2013

Irish Medicines Board (Miscellaneous Provisions) Act 2006

Medicinal Products Prescription and Control of Supply Regulations 1996 as amended

Medicinal Products (Control of Placing on the Market) Regulations 2007 as amended,

Medicinal Products (Control of Advertising) Regulations 2007

Mental Health Act 2001

Misuse of Drugs Acts 1977 and 1984

Misuse of Drugs Regulations 1988 as amended

Nurses and Midwives Act 2011

Pharmacy Act 2007

Assisted Decision-Making Capacity Bill (2013),

HSE National Consent Policy

HIQA National Standards for Safer Better Health Care

HIQA National Quality Standards for Residential Care Settings for Older People in Ireland.

HIQA National Standards for Residential Services for Children and Adults with Disabilities

HIQA National Standards for Children's Residential Centres

HIQA National Standards for Residential Services for Children with Disabilities

HIQA Guidance for Health and Social Care Providers: Principles of Good Practice in Medication Reconciliation

Mental Health Commission Quality Framework for Mental Health Services in Ireland – (National Mental Health Services Standards)

Royal College of Physicians of Ireland Immunisation Guidelines for Ireland

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