

Nursing Homes and Residential Care settings for older people

– provision of safe and appropriate patient
care and pharmacy Services

PSI/ICCPE Joint Initiative

Citywest 19th Jan 2012

Leonora O'Brien MPSI – Pharmacy Practice Development Unit, PSI

Agenda

- Introduction/Scene setting - Professional, Legal and Practice Requirements for provision of safe and appropriate care and service to patients in Nursing homes and residential care settings – Leonora O'Brien
- Inspection topics relating to provision of safe and appropriate care and service – Cora O'Connell

Media Headlines

'incidents going unreported'

'significant elder abuse'

'lacking in clinical governance'

'no one in charge'

'staff frightened of reporting concerns for fear of losing their jobs'

'no system of accountability'

Definition of elder abuse:

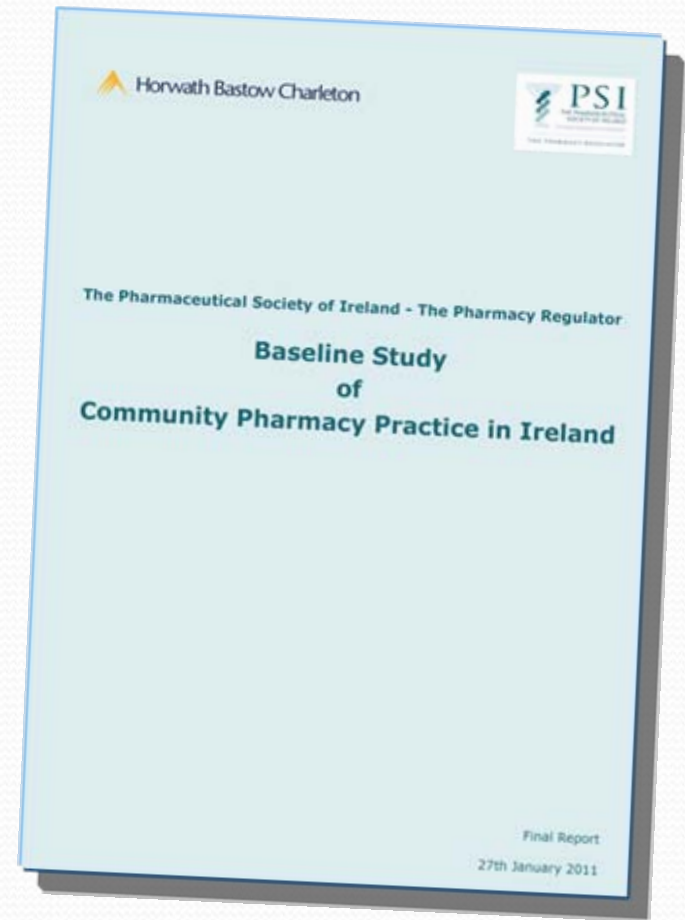
‘A single or repeated act or lack of appropriate action occurring within any relationship where there is an expectation of trust which causes harm or distress to an older person or violates their human and civil rights‘

> 10,000 reports of abuse in last 12 months

- **6 Categories** of abuse: from Physical, to financial abuse
- Highest % of referrals are **Psychological abuse** - can be as simple as disregarding a person, not consulting the patient, Isolation or withdrawal from services
- **Acts of Omission:** Includes failure to provide safe and appropriate service and health care needs
- Even 1 isolated incident = ABUSE

Baseline Study

- 32.7% pharmacies provide pharmacy services to patients in residential care settings;
- Approx 60% pharmacy patients were older people,
- Average 5.4% of all patients in residential care



Professional Responsibilities

- Distress and fear created for these vulnerable patients and their families
- Behoves us as professionals to respond by ensuring we are aware of our obligations; that we carry them out appropriately and find solutions to the challenges
- Act if we encounter sub-standard practice - Health professional's role and obligations as voice, advocate and protection of vulnerable patients
- Reputations of all suffer if we fail to address issues properly, to identify and manage risks, prevent future scandals
- NB keep patient at centre
- NB role of superintendent and supervising pharmacists to show professional leadership

Vision for framework for Irish Health System:

Patient Safety Commission

Knowledgeable patients receiving safe and effective care from skilled professionals in appropriate environments with assessed outcomes

- Pharmacy – part of patient safety and quality framework in Ireland – wider health care reform
- The issues around safe, quality patient care and medicines management are not just pharmacy issues – multi-agency, multi-professional response required.
- PSI engaged with HIQA, HSE at looking at key issues, and also engage with others such Nursing Homes Ireland, other professional regulators, patient advocates to identify and clarify pharmacy issues

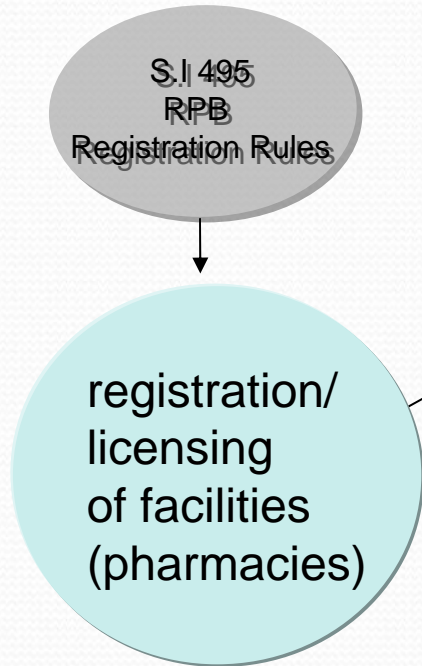
Pharmacy Act 2007

Legislation underpinning safe practice

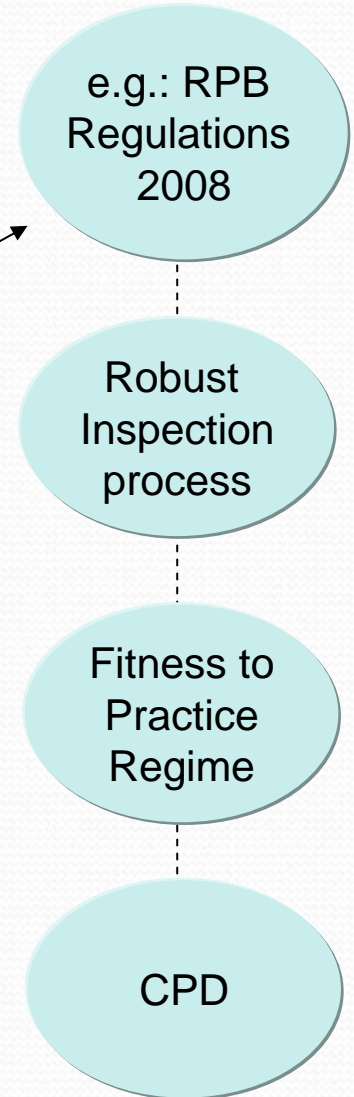
1 Appropriate Environment

2 Clinical governance, management, leadership and accountability

3 Standards



- Pharmacy Act introduced a Clearly defined accountability structure
- Superintendent pharmacist - requirement for RPB
- Ultimate accountability; clinical management, professional policy and safety of service.
- 'personal control' – must be able to demonstrate this control



Guidelines – facilitate compliance with the Act

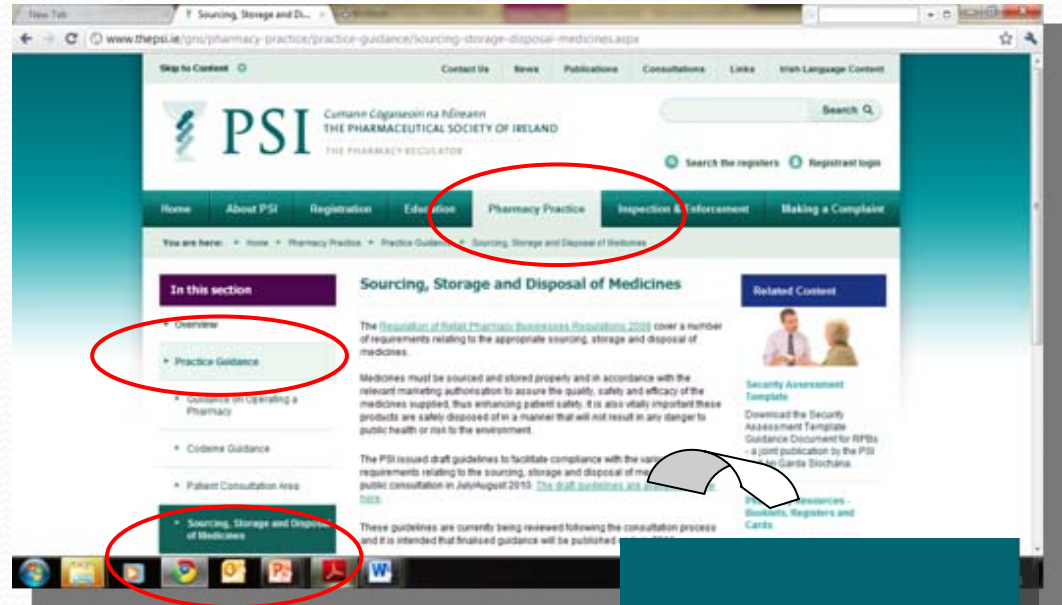
Location on PSI website

- In accordance with the Act, the PSI provides guidelines to facilitate compliance with the Regulation of RPB Regs 2008.

- Publication in line with PSI Service Plan.

- ✓ *PCAs & Non-Rx Codeine Meds*
- ✓ *Sourcing, Storage & Disposal*
- ✓ *By 2012: Premises & Equipment; Regs 9&10: Management & supervision*

- All superintendents expected to comply in full with all professional guidelines, as per signed statutory declaration.



Keeping up to date

Professional responsibility to keep abreast of current developments

➔ 1st Pharmacist Monthly Update
20 December 2011; e Format,
replaces Irish Pharmacy Journal

- Guidance on methadone;
- Superintendent Film following superintendent seminars 2011;
- High Tech guidance re-visit
- Revised BNF wording on Cautionary labels
- IMB drug safety news letter etc

PSI Cumann Cógaiseoirí na hÉireann
THE PHARMACEUTICAL SOCIETY OF IRELAND

Pharmacist Monthly Update Dec 2011

In This Issue

- ▶ PSI Guidance on Methadone Issued
- ▶ High Tech Reminder
- ▶ Superintendent Pharmacist Film
- ▶ New CD Registers/Changes to PSI supply of booklets
- ▶ Revised BNF Wording on Cautionary Labels/Aspirin Warning
- ▶ Tutor Pharmacists for 2012/2013
- ▶ IMB Drug Safety Newsletter December 2011

Welcome message

Dear Pharmacist,
This is the first of a new regular newsletter from the PSI to registered pharmacists. Over the past two years, the PSI has moved to communicating more by email and through its redeveloped website, as this is a more timely, efficient and cost-effective way of communicating with the profession on important and urgent issues. One of the main feedbacks from the profession was a preference that we collate and present non-urgent information for pharmacists into a regular email/newsletter, rather than a series of individual emails, which would also make information more easily retrievable. These newsletters will be archived on the PSI website. Your feedback is welcome at info@thepsi.ie. In 2012 the PSI will also be publishing a quarterly corporate newsletter to all stakeholders including the profession.

PSI Guidance on Methadone Issued

The PSI Council has this month approved [Guidance for Pharmacists on the Safe Supply of Methadone](#) and this document is now available to download from the PSI website.

The purpose of this guidance is to remind and clarify to pharmacists involved in the supply of methadone, and the provision of associated services to patients, of the requirements which must be fulfilled in order to ensure compliance with legal and professional obligations.

The guidance addresses issues including the legal and Code of Conduct considerations relating to the supply of methadone, including the associated prescription requirements, patient counselling and multidisciplinary patient care considerations.

All pharmacists are advised to familiarise themselves with the guidance. Superintendent and supervising pharmacists are advised to review their policies and procedures in light of the guidance and incorporate the relevant elements of the guidance in their updated policies and procedures.

Queries in relation to this guidance or any related matter can be sent to the PSI in writing and preferably by email to info@thepsi.ie.

High Tech Reminder

The PSI would like to highlight to all pharmacists the importance of ensuring compliance with existing guidance and requirements on the management of High Tech medicines. The PSI previously issued guidance in 2008 which is available on the PSI website which highlights that this is a **patient-specific pharmaceutical care and treatment programme**.

Pharmacists are particularly reminded to be cognisant of the requirement to have a **valid prescription** for the dispensing of High Tech medicines and the importance of good planning and management for repeat prescribing. The maximum validity period for any prescription, including High Tech prescriptions, is six months from date of issue, when so indicated. The PSI understands that the term 'lifelong therapy', which has previously been included in these prescriptions and which may have caused some confusion, is to be removed.

Good communication between the various members of the multidisciplinary team caring for these patients should ensure that patients, prescribers and pharmacists are all aware of the patient's care plan and the arrangements for regular therapeutic reviews and appointments and for issuing of further prescriptions (either by the initiating consultant or the patient's GP).

Therefore, for patients on a six-monthly prescription, pharmacists should check in advance of the final dispensing, with either the patient or the prescriber, what the arrangement is for the issuing of a new prescription and whether the patient needs to be reviewed by the initiating consultant prior to this prescription being issued.

Pharmacists involved in providing care and treatment to patients under the High Tech

PSI Guidance specific to nursing homes

- ➔ Practice Notice 1/2010 – Supply by Pharmacists to Patients in residential care settings/Nursing Homes
- ➔ Letter to Superintendent Pharmacists - 2nd March 2010 'Responsibilities to patients living in residential care settings for older people'
- ➔ Letter to Superintendent Pharmacists – 20th April 2011 'Responsibilities to patients living in Nursing Homes and Nursing Units'
- ➔ PPGM – Pharmacy Practice Guidance Manual, Section 3: Residential Home Supply with checklist

Section 3: Guidance for Services and Systems of Operation

RESIDENTIAL HOME SUPPLY

SCOPE

The provision of pharmacy services for a residential care setting is a professional responsibility of a pharmacist. A pharmacist engaged in the provision of pharmacy services to patients in residential care settings should ensure that an equivalent level of care is provided to each and every patient as would be provided at a retail pharmacy practice.

CRITERIA

- The pharmacy must have suitable premises with full product access, including a dispensing counter, storage, shelving, lighting, ventilation and heating or cooling, and a sink, and the premises must be suitable for the provision of pharmacy services.
- The site must be suitable for the provision of pharmacy services and the pharmacy must be able to provide an equivalent level of care to patients in residential care settings.
- A pharmacist should be available to provide an equivalent level of care to patients in residential care settings.
- The pharmacy should have suitable premises with full product access, including a dispensing counter, storage, shelving, lighting, ventilation and heating or cooling, and a sink, and the premises must be suitable for the provision of pharmacy services.
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GUIDANCE

The pharmacist should ensure that the provision of pharmacy services to patients in residential care settings is in compliance with the Code of Conduct for pharmacists and the Pharmacy Act 2007.

20 April 2011

Re: Responsibilities to patients living in residential care settings for older people

Dear Superintendent Pharmacist,

I am writing to you in your responsibilities in respect of the provision of pharmacy services to patients in residential care settings for older people. The provision of pharmacy services to these patients must ensure that they receive the same level of professional care as those patients who attend personally at the pharmacy practice.

02 March 2010

Re: Responsibilities to patients living in residential care settings for older people

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PSI PRACTICE NOTICE 1/2010

Supply by Pharmacists of Medicines to Patients in Residential Care Settings/Nursing Homes

Introduction

The purpose of this Notice is to remind all registered pharmacists involved in the sale or supply of medicines (including prescription-only medicines) to patients who are living in residential care settings/nursing homes of certain requirements which must be fulfilled in order to meet their professional obligations to those patients and to ensure compliance with legal and professional requirements.

The provision of pharmacy services to these patients must ensure that they receive the same level of professional care as those patients who attend personally at the pharmacy practice.

Regulatory Environment

The sale and supply of medicinal products in respect of persons in residential homes is regulated under the Pharmacy Act 2007 and may only be carried out by a registered retail pharmacy business and by or under the personal supervision of a registered pharmacist.

In addition, the pharmacist must be satisfied that he or she complies fully with the requirements of:

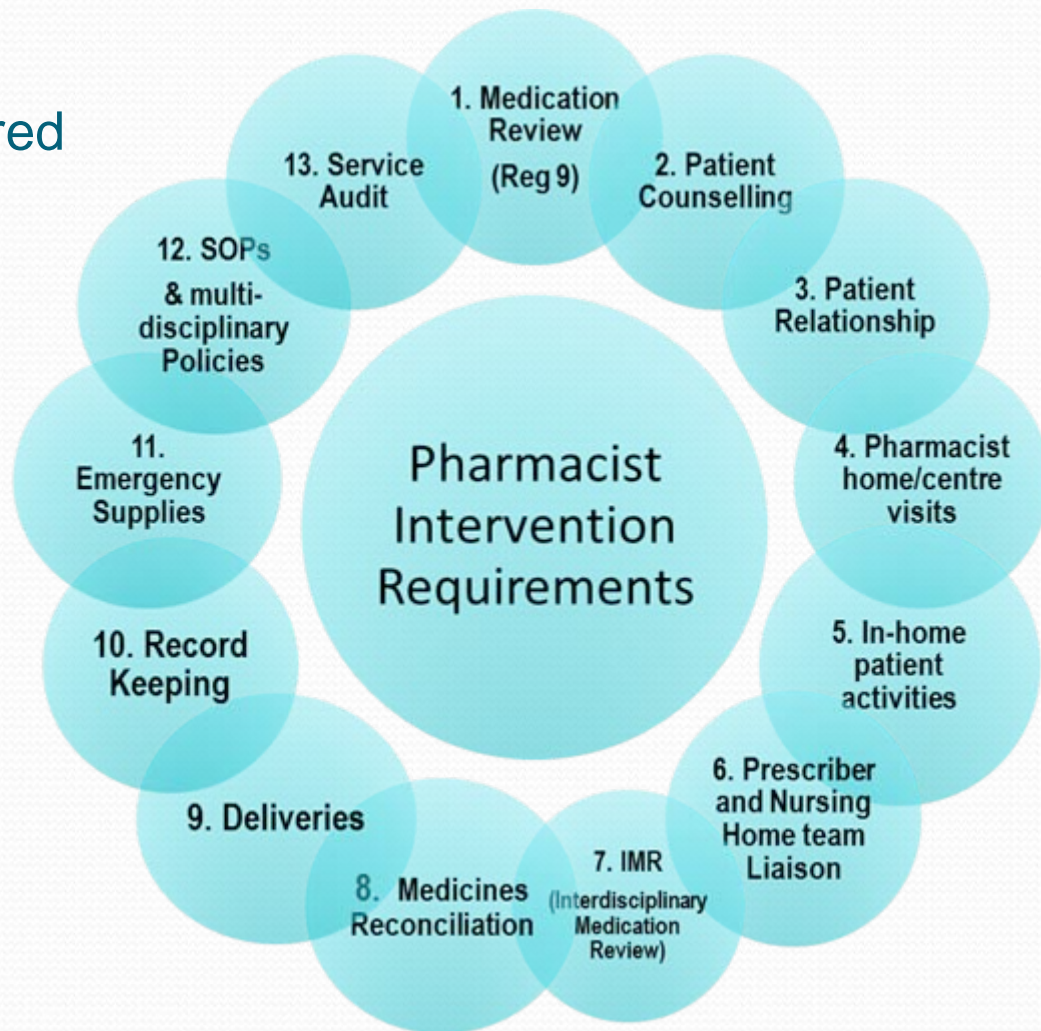
- Pharmacy Act 2007
- Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)
- Guidance issued by the regulator to facilitate compliance with these regulations and/or other legislation
- Medicinal Products (Prescription and Control of Supply) Regulations 2001 to 2009
- Misuse of Drugs Acts 1977 to 2006 and the Orders and Regulations made thereunder.

Pharmacists should also ensure that their professional practice in relation to these patients and their arrangements with the owners, managers and staff of the residential home are in compliance with the Code of Conduct for pharmacists.

Practice Notice

Proactive Implementation Required

On publication of a practice Notice, Superintendent and supervising pharmacists responsibility to identify the elements which need to be implemented within their practice and plan how to update their procedures accordingly



Example map of requirements outlined in nursing home guidance

Practice Notice and Superintendent letters

Outline the fundamentals of good pharmacy practice

- 1) Prescription-only medicines require **valid Rx** to supply (exceptional circumstances emergency supply; personal order of a registered practitioner)
- 2) **Therapeutic review** of prescribed medicines (Reg 9) – (separate out clinical checking and dispensing accuracy checking as separate steps)
- 3) **Patient counseling** which will necessitate visits to attend personally on patients; records of these visits, interventions
- 4) **Adequate pharmacist staff** to carry out and supervise all professional activity of pharmacy. Pharmacist equivalent hours – being looked at across Europe.
- 5) Documented **policies and procedures** – sourcing, storage, dispensing, delivery, supply, records, 3 monthly review, Therapeutic Review and Counselling
- 6) Safe systems and equipment
- 7) **Staff training** – records available for inspection
- 8) **Documented arrangements and procedures agreed with home** incl. records of patient consent where appropriate (for collection / administration / possession of information regarding patient's medication; appropriate representative signatory in cases of compromised patient ability)

9) HIQA Standards **3-monthly review** key to success – ensures inter-disciplinary communication and engagement; provides concrete opportunity for pharmacist to contribute clinical expertise and medicines management expertise. Special consideration to antipsychotics; sedating meds etc.

- HIQA: Independent Authority - reports directly to Minister – drives continuous improvement in Health & Social care services - mandate extends across public, private and voluntary sectors.

- The Standards provide a baseline for care

- NB Standard 14: Medication Management; Standard 15: Medication Monitoring and Review

- Authority's inspections ensure compliance – PSI & HIQA liaise and work together under MoU



Download Standards from:
www.hiqa.ie

10) Legislation - Governing provision of service to patients in nursing homes and residential care

Pharmacy specific

Pharmacy Act 2007 ;
Regulations (S.I. No 488 of 2008); Rules

Medicinal Products (Prescription and
Control of Supply) Regulations 2003 to 2009

Misuse of Drugs Acts

Professional Guidance

Code of Conduct for pharmacists
(Statutory)

Allied and complimentary legislation

Health Act 2007(**Care and Welfare of Residents in Designated Centres for Older People**) Regulations 2009.

Health Act 2007 (**Registration of Designated Centres** for Older People) Regulations 2009.

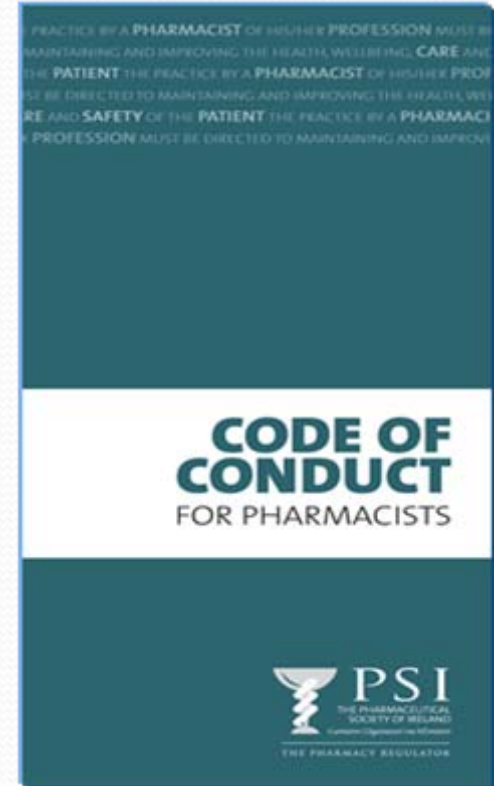
HIQA (Health Information and Quality Authority)
National Quality Standards for Residential Care Settings for Older People in Ireland 2009.

Eg:Standard 15: Medication Monitoring and Review

*“Each resident benefits from his/her medication to increase the quality or duration of his/her life. He/she does **not suffer unnecessarily from illness caused by the excessive, inappropriate or inadequate consumption of medicines**”*


11) Code of Conduct

- No longer ethical code but **Statutory** in nature – sets standard for registration, continued registration/fitness to practise
- Public declaration of these principles and ethical standards
- 6 Principles. Principle One = Primary Principle.
“The practice by a pharmacist of his/her profession must be directed to maintaining and improving the health, wellbeing, care and safety of the patient.”
- Must not permit another person(s) to impair or compromise your ability to observe your statutory obligations under the Code of Conduct
- Superintendent pharmacists must ensure all practices, policies and procedures relating to Nursing Home business relationship(s) and provision of service to patients must facilitate the adherence to the code.



11) Fundamental relationship is between pharmacist and individual patient

- Business contract may be with the Home - ethical, legal and professional duty lies with the patient themselves
- Any collective service agreement(s) must support and facilitate, but not supersede, the need for individual patient care arrangements. Records of such, including patient consent (formal written and informed) records, available for inspection.
- Patient Rights – entitlements around consent, information, dignity
- Patients entitled to equivalent level of care and professional input of pharmacist as would receive if attending pharmacy in person – personal visits to patient on a frequency appropriate to patient need

- 
- Recognise there are practical challenges in meeting these obligations due to nature of care settings, multi-professional and person input, need for team and arrangements with GP, nurses, carers, home owners in order to fulfill obligations
 - In respect of medicines management issues, opportunity for pharmacy profession to demonstrate expertise and leadership and positively influence ongoing responses from other professions and agencies
 - Important to notify PSI / HIQA / HSE / Medical Council or An Bord Altranais of any concerns in relation to medicines management, patient care or certain business arrangements as may be appropriate.

Compulsory related standards in other Jurisdictions:

EG: The Netherlands.

- **Compulsory SOP's** only one small element within QMS.
- All systems and procedures within all pharmacies organisations **externally certified** (e.g. ISO) accredited in order to secure Health Insurer contracts pre-audit also required.
- **Performance Indicators:** Pharmacies grouped in performance clusters. Quality directly linked to reimbursement.
- **Graded PTAM/FTOs** i.e.: local Prescriber – Pharmacist clinical meetings, approx. 7 times a year. Topics: Policies, Formularies, Service
- **Consumer Indexes** - pharmacies are monitored and graded in terms of customer satisfaction and published on web-sites
- **Privacy legislation:** Patient must be informed and the service explained. Patient must be given the opportunity to refuse the service.
- **Professional Guidelines** must be adhered to: example of new 'medication dossier transfer' Guidelines – multidisciplinary Guideline agreed to by 17 different healthcare professions

PSI Guidance on Inspections (ref: Inspection & Enforcement section)

- PSI's Short Guide to Inspections
- Checklist for pharmacy Inspections
- Checklist for new opening inspections



The Pharmaceutical Society of Ireland Short Guide on What to Expect During the Inspection Process

- PSI Authorised Officers (the formal title of the inspectors) will identify themselves at the start of an inspection. All Authorised Officers carry a PSI identity card and their warrant as Authorised Officer, which is their authority to enter pharmacies and other premises. You can ask to see the warrant to assure yourself the person is an Authorised Officer of the PSI.
- On arrival at a pharmacy for inspection, the inspector will first ask to see the pharmacist or pharmacists who are present.
- Most pharmacists will choose to keep the pharmacy open during an inspection, which means that patients and members of the public will need to be attended to during the inspection. The PSI and its Authorised Officers make it clear that patient needs are everyone's priority. During the inspection, the pharmacist will be asked to source particular records or documents for the inspector, but this will be done while ensuring that patients are being dealt with as the priority, and where necessary, the inspector will wait while the pharmacist attends to patients.

So what will the inspectors look for during an inspection?

The PSI has produced a checklist to assist pharmacy owners and pharmacists in preparing for a future inspection and to inform them what to expect during an inspection.

The following areas should be covered in any self-assessment:

- **Premises:** security arrangements, 'keyholding' policy (including policy around the pharmacy not opening when no pharmacist is present), layout to allow for supervision of professional activities and to restrict access to dispensary and medicinal products, patient consultation area; also storage areas, staff areas, bathroom; housekeeping/cleaning records; clean, uncluttered dispensary and professional areas, including proper paper record-filing arrangements.
- Registration certificates (retail pharmacy business and supervising pharmacist) on conspicuous display.



Checklist for a Pharmacy Inspection by the The Pharmaceutical Society of Ireland



The following is a non-exhaustive list of what may be reviewed by an Authorised Officer of the PSI during an inspection of a retail pharmacy business (RPB). This checklist is intended as a self-assessment tool to assist you in preparing for an inspection.

1.0 Registration Certificates		Yes	No
1.1	Has the retail pharmacy business (RPB) the correct certificate of registration and is it prominently displayed to the public?		
1.2	Has the supervising pharmacist the correct certificate of registration and is it prominently displayed to the public?		
2.0 Codeine Containing Products		Yes	No
2.1	Are codeine-containing products stored in the dispensary, out of sight of the public?		
3.0 Policies and Procedures		Yes	No
3.1	Has the RPB a full suite of documented policies and procedures/SOPs? The following are recommended:		
	a) Dispensing, including therapeutic review and patient counselling; high-risk/High Tech medicines		
	b) Storage of medicines		
	c) Sourcing of medicines		
	d) Expiry date checking		
	e) Sale and supply of medicinal products		
	f) Storage and record-keeping for controlled drugs		
	g) Disposal and/or destruction of medicines (including controlled drugs)		
	h) Management of additional services provided (including supply to residential care homes)		
	i) Error and incident management (including error logs)		
	j) Locum induction/communication policy		
	k) Housekeeping and cleanliness of dispensary and shop floor (inc. cleaning records)		
	l) Use of patient consultation area		
	m) Policy on use of child resistant containers		
	n) Keyholding policy (to premises and CD Safe)		
3.2	Is there an implementation date on all SOPs?		
3.3	Is there a review date on all SOPs?		
3.4	Is there evidence that staff have been trained on SOPs?		
4.0 Duty Register		Yes	No
4.1	Has the RPB a duty register/log for the current year?		
4.2	Is the duty register being correctly maintained?		
4.3	Is there professional cover available for all hours of opening?		
4.4	Does the supervising pharmacist provide adequate cover?		



Thank You