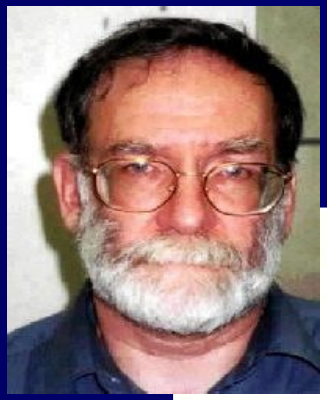
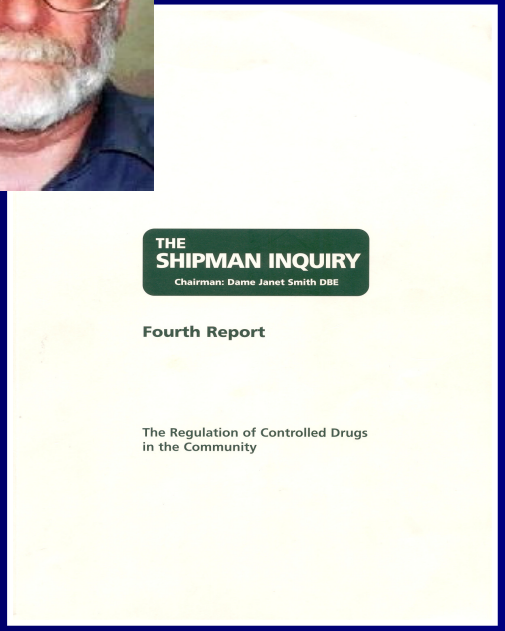
The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

Background





- On 31 January 2000, Harold Shipman was convicted of murder of 15 patients. However actual death toll around 200.
- Inquiry chaired by Dame Janet Smith
- 6 reports including recommendations

Shipman Inquiry

- Fourth Report – Regulation of Controlled Drugs in the Community
- Fifth Report – Safeguarding patients: Lessons from the Past – Proposals for the Future
- Dame Janet Smith praised the centralised nature of the inspection arrangements for controlled drugs in NI
- Recommendations from 4th and 5th reports can be seen in Health Act 2006 and The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

- Made 5 June 2009 under Health Act 2006
- Similar to England/Scotland/Wales Regulations
- Into operation 1 October 2009
- Maximise structures and processes already in place and use these to develop systems that will ensure the safe management and use of controlled drugs
- Formalises existing arrangements

Four parts

- Preliminaries (Reg 1 & 2)
  - Includes definitions of terms
- Accountable Officers (Reg 3-18)
  - Who they are and what they do)
- Premises and inspections (Reg 19-21)
- Co-operating and Sharing Information (Reg 22-31)

Designated Bodies

- Reg 3 refers to Designated Bodies
  - Regional Board
  - 5 Trusts
  - NIAS
  - Independent Hospitals (includes hospices)
- Reg 4 requires each Designated Body to appoint an Accountable Officer (AO)

Accountable Officers

- Register held by department
- "fit, proper and suitably experienced person" (Reg 4)
- "the person does not routinely supply, administer or dispose of controlled drugs as part of his duties" (Reg 5)
- In specified circumstances may be shared by two or more Designated Bodies (Reg 5)

Removal of AO (Reg 6)

- Designated Body may remove AO if
  - He no longer satisfies the criteria
  - Or he is unfit to be an AO
    - Through wilful breach of duties or due to negligence or incompetence
  - Or the Body is acting according to other arrangements it has related to employment/engagement of AO

Designated Officers (DOs)

- Not defined in legislation
- Appointed by Designated Body to assist Accountable Officer to fulfil their statutory obligations regarding safer management and use of controlled drugs
- Guidance does not specify how many DOs can be appointed or their individual roles

AO Resources (Reg 7)

- Designated Bodies must provide resources to AO to enable him to carry out his responsibilities.
  - Includes funds, access to, and use of IT, accommodation and staff

Setting the Scene for AOs

- Two points to note about AO responsibilities and the frequent wording of the Regs:
  - "An accountable officer shall –
    - "establish and operate, or ensure that his designated body establishes and operates, appropriate arrangements…
    - "Ensure that any person acting on behalf of, or providing services under arrangements made with, his designated body establishes and operates appropriate arrangements…"

Safe Management and Use (Reg 9)

- AO must secure, by appropriate arrangements, the safe management of controlled drugs (CDs)
- AO must ensure that arrangements are reviewed

Safe Management and Use (Reg 9)

- AO must ensure that the arrangements comply with misuse of drugs legislation.
- AO must ensure that there are in place adequate and up-to-date SOPs* to secure safe management of CDs.
  - Matters to be covered in SOPs* are specified.

*Standard Operating Procedures

Destruction and Disposal (Reg 10)

- AO must secure, by appropriate arrangements, the safe destruction and disposal of CDs.

Monitoring and Auditing (Reg 11)

- AO must ensure that appropriate arrangements are in place for monitoring and auditing the management and use of CDs.

Monitoring and Auditing (Reg 11)

- Arrangements must provide for
  - Analysing prescribing data
  - Alerting the AO of any complaints or concerns involving the management of CDs
  - An incident reporting system for adverse incidents involving CDs
  - Analysing, and responding to, adverse incidents involving CDs

Declarations and Self-Assessments (Reg 12)

- The Board AO, the Department and the RQIA have the power to request periodic declarations and self-assessments from specified parties.

- These declarations and self-assessments shall state whether CDs are handled, and how they are managed and used.

Training and information (Reg 13)

- AO must ensure that appropriate arrangements are in place:
  - for training, from time to time, those who handle CDs to enable them to carry out their responsibilities
  - for providing information, and where appropriate, training on local SOPs when a person first becomes involved in handling CDs
  - for informing persons when any local SOPs are reviewed or amended.

Monitoring and Auditing (Reg 14)

- AO must ensure that appropriate arrangements are in place for:
  - monitoring and auditing the management and use of CDs by relevant individuals
  - monitoring and assessing the performance of relevant individuals related to the management and use of CDs
- The arrangements must provide for
  - recording concerns in accordance with Reg 15
  - assessing and investigating concerns as per Reg 16
  - determining if there are concerns which should be shared under Reg 25

Recording Concerns (Reg 15)

- AO must ensure that appropriate arrangements are in place for recording concerns about incidents that involved, or may have involved, improper management or use of CDs by a relevant individual
- The minimum information required is specified
- Records may be on paper or electronic
- Access to the information is to be restricted

Dealing with Concerns (Reg 16)

- AO must ensure that appropriate arrangements are in place in his Body for assessing and investigating concerns
- This may include assistance from other Responsible Bodies

Dealing with Concerns (Reg 16)

- The Responsible Bodies for Reg 16 are:
  - A Designated Body
  - The Department
  - The Counter Fraud Unit (CFU) of the RBSO
  - The PSNI (police)
  - The RQIA
  - A Regulatory Body

Dealing with Concerns (Reg 16)

- The AO must ensure that he, or his Body, keeps records of:
  - requests made to other AOs or Responsible Bodies to investigate concerns
  - any assessments or investigations of concerns
  - any notifications made under Reg 25 (duty to disclose information)

Taking Action (Reg 17)

- AO must ensure that appropriate arrangements are in place for ensuring appropriate action is taken for the purposes of protecting patients and the public when concerns appear to be well-founded

Taking Action (Reg 17)

- Actions the AO may take include:
  - requesting advice, support, mentoring, training from specified individuals (e.g. CIR at Department)
  - implementation of an SAI procedure
  - referral of concerns to a regulator/police/CFU
  - sharing/requesting information (Regs 25 and 26)
  - request the Local Intelligence Network (LIN) to set up an incident panel to investigate and make recommendations

Sharing Information (Reg 18)

- AO must ensure that appropriate arrangements are in place for ensuring proper sharing of information in accordance with Regs 25 and 26

Local Intelligence Network (LIN) (Reg 18)

- The Department shall direct AOs to establish a LIN for sharing information regarding the management and use of controlled drugs
- The network shall include the following types of bodies:

- the Department
- the Regional Board
- an HSC Trust
- the NIAS
- the RQIA
- CFU of RBSO
- PSNI (police)
- A Regulatory Body

Local Intelligence Network

- Develop communication between Responsible Bodies
- Held quarterly
- Share concerns within set guidelines (Occurrence Reports)
- Collate and disseminate learning points from concerns/incidents

Periodic Inspections (Reg 19)

- AO must ensure that appropriate arrangements are in place for ensuring periodic inspections of premises:
  - used in connection with controlled drugs
  - which are not subject to inspection by RQIA or the Department
- Persons authorised to inspect by the Designated Body must be authorised in writing
- Records must be maintained on paper or electronically

Inspections

- Statutory inspection bodies to provide assurances to Accountable Officers, where appropriate, to reduce duplication of inspections.
- Assurances can be taken by AO when inspected by external bodies

Relevant Premises (Reg 20)

- The premises which various types of AOs or authorised staff members may inspect are prescribed.
- In addition, premises of persons acting on behalf of the Designated Body, or providing services to it, are included
- Constables or persons authorised by the Department may also enter and inspect

Private Dwellings (Reg 21)

- Staff of the Department, the RQIA or Designated Bodies may enter certain specified premises without the presence of a constable.

Responsible Bodies (Reg 22)

- Responsible Bodies are identified for co-operation:
  - a Designated Body
  - the Department
  - the RQIA
  - RBSO
  - PSNI (police)
  - a Regulatory Body

Relevant Persons (Act and Reg 23)

- Section 19 of the 2006 Act identifies as relevant persons
  - Health care professionals
  - Other employees
  - Others

  who engage in any activity carried on by the DB or by a body or person acting on behalf of it or providing services under arrangements made with the DB which involve or may involve the management or use of controlled drugs
- The Reg prescribes:
  - Doctors, dentists, midwives, nurses, pharmacists, and staff providing services to private patients
  - residential care home and nursing home managers, or the persons carrying them on, or persons engaged in any activities carried on by the registered persons

Co-operation and Relevant Persons (Reg 24)

- Responsible Bodies must co-operate in:
  - Identifying cases in which action may need to be taken
  - Considering issues relating to taking action
  - Taking action

Disclosing Information (Reg 25)

- The circumstances where, and purposes for which, information may be disclosed by a Responsible Body to another Responsible Body are prescribed
- Confidential information relating to, and identifying, patients must be treated in accordance with the Regulation
- Certain information regarding assessments or investigations of concerns must be notified to specified persons and Bodies
- Notification is not required where investigation or civil or criminal proceedings would be prejudiced, or where disclosure is prohibited by an enactment

Records and Disclosure (Reg 28)

- The nature of the records to be kept relating to disclosures (Reg 25 and 26) is prescribed
- Records may be kept on paper or electronic form

Occurrence Reports (Reg 29)

- AO must give a quarterly Occurrence Report to the chair of the LIN
- This must provide details of any concerns that his Body has in relation to the management and use of CDs or
- Confirmation of “no concerns”

Safety of Patients and Public (Reg 30)

- AOs may make recommendations to their own or other Responsible Bodies as to action that should be taken to protect patients and public
- If the concern relates to a relevant person who is not providing services to, or under arrangements with, a Designated Body, the chair of the LIN shall
  - seek to take reasonable steps to protect patients and public
  - where appropriate refer the matter to a relevant Responsible Body (e.g. a regulator, or PSNI [police])

Disclosure in Good Faith (Reg 31)

- Protection of a person from civil proceedings resulting from disclosures of information in good faith under certain Regs 25, 26, 29 or 30)

What is happening?

- Legislation comes into operation
  - 1 October 2009
- Date of first LIN
  - 1 December 2009
- Other forums for sharing information
  - Cross Border Intelligence Group
  - National Controlled Drugs Group
- Self-assessments/declarations
- Periodic and routine inspections