

## Institutional Pharmacy Practice

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## Objectives

- To discuss the regulation of institutional pharmacy practice in Washington
- To differentiate between federal and state regulation

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## Medicare, Medicaid, What's the difference?

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|--|--|
| ■ Medicare   | ■ Medicaid   |
| ■ Currently very limited pharmacy benefit (until 2006)                   | ■ Rx Drugs are optional but every state provides                       |
| ■ Only Rx drugs that patient can not self administer                     | ■ All drugs included BUT can have limits                               |
| ■ (e.g. injectable anticancer drugs, drugs administered by MD, RN, etc.) | ■ (e.g., prior approval, pref. Rx list, etc. BUT no formulary allowed) |

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## Medicare, Medicaid, What's the difference?

- |   |  |
|---|--|
| ■ Medicare  | ■ Medicaid                                 |
| ■ Federal funds only  | ■ State funds plus Federal matching funds. |
| ■ Insurance companies contracting with Medicare set reimbursement.  | ■ States set reimbursement                 |
| ■ Feds may NOT negotiate with drug companies for price concessions. | ■ States get rebates from drug companies   |

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## Medicare Modernization Act

- New Rx coverage 05/04 "Discount" cards
- Medication Therapy Management (MTM)
- 01/06 Rx coverage (Part D)
- RPh and Others
- Optional
- Fee based on effort
- Monthly Premium
- Co-pays
- Tiered Disp Fees

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## Medicare Rules

- Medicare rules are called:
- The Conditions of Participation (CoP)
- Every hospital, nursing home, home health agency, kidney dialysis center, ambulatory surgical center, etc. that wants to treat Medicare patients MUST comply with the Conditions of Participation that are appropriate to that type of facility

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## Medicare Rules

- CMS contracts with State agencies to inspect for compliance with CoP.
- Washington State Dept. of Health
  - Hospitals, Hospice, Home Health, Amb. Surg. Ctr, Clinical Laboratories, dialysis centers
- Washington DSHS
  - Nursing Homes
- These agencies also inspect for State Licensing laws/rules compliance.

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## Medicare Rules

- Currently there are no CoPs for ambulatory pharmacy services
- Pharmacies that are located in or that provide pharmacy services to a Medicare participating facility must meet the CoPs

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- 1. Pharmacy Management
  - Meet needs of patients
  - Pharmacy directed by licensed RPh
  - Drug storage under competent supervision
  - Medical Staff responsible for P & P to minimize errors (may delegate to phcy)

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (a) Pharmacy or Rx storage area must be administered in accordance with accepted professional principles.
  - P & P followed, Records in detail, employees acting within scope of practice, control over drugs, distribution, written reports, minutes of meetings, job descript.

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (2) Adequate personnel to insure quality services, including emergencies
  - Sufficient number & training of staff

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (3) Current & accurate records on receipt & disposition of controlled subs.
  - Records readily retrievable, trace movement of CS, RPh is responsible
- (b) Delivery of Services
- Must be consistent with policies, Fed and State laws

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (1) Compounding, dispensing under supervision of RPh
  - (Surveyors interview various staff)
- (2) Drugs in locked storage area
  - Availability of Keys?

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (3) Outdates, mislabeled, unusable Rx not available for patient use.
- (4) Handling of drugs when RPh not available
- (5) Automatic Stop Orders on Drugs
  - Orders get re-written after surgery, transfer, etc.
- (6) ADR, Rx Errors, Administration errors, reported to attending & QA program

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (7) Abuses & losses of CS must be reported to RPh, CEO, DEA etc.
- (8) Info on drug interactions, Rx therapy, side effects, etc must be available to professional staff
  - Current drug references are available

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (9) Formulary system must be established by medical staff

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## Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.23 Nursing Services
- These are the drug related responsibilities of nursing but pharmacy retains some responsibility
- (c Drugs prepared & administered in accordance with laws, prescribers orders, and standards of practice
- (1) Rx administered by nurses

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## Joint Commission on Accreditation of Healthcare Organizations

- JCAHO Accreditation means a hospital is deemed to meet Medicare COP.
- Choice made by Congress 1965
- JCAHO Standards have changed significantly since 1965 but Medicare's standards have not.
- Should deemed status continue?

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## Joint Commission on Accreditation of Healthcare Organizations

- If hospital is JCAHO accredited, State does NOT inspect EXCEPT State may inspect for State laws/rules compliance.

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## Joint Commission on Accreditation of Healthcare Organizations

- JCAHO focuses heavily on Rx issues
- Now requires elimination of certain abbreviations
- Now requires reconciliation of patient's meds on admission and discharge AND communication with future caregivers
- Community pharmacies should be getting discharge information

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## Prescription Writing Abbreviations to avoid JCAHO

- U (for unit)
  - Mistaken for 0, 4, cc
- IU (intl. Unit)
  - $\mu$
- Q.D. or Q.O.D.
  - Mistaken for each other or period = 1
- Trailing zero 1.0 mg
  - Period is missed
- Lack of leading zero
  - .1 mg period gets missed.
- MS
- MS04
- MgSO4
  - Morphine sulfate or magnesium sulfate
- $\mu$ g (microgram)
  - Mistaken for milligram use **mcg**

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## Prescription Writing-Abbreviations to avoid

- HS – (bedtime or half strength)
  - Mistaken for each other
- q hs mistaken for every hour
- T.I.W (3 times per week)
  - Mistaken for tid, twice/wk
- AS, AD, AU for ears
  - Mistaken for OS, OD, OU (eyes)
- S.C. or S.Q. (for subcutaneous) mistaken for sublingual or 5 every
- Write SubQ or full word
- D/C (for discharge)
- Mistaken for discontinue
- cc (for cubic centimeter) mistaken for U (units)

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## What is JCAHO going to do about use of prohibited abbr.?

- Pass if use of these is “sporadic” (<10%) or if written confirmation of what prescriber meant is in chart.
- Otherwise need plan for improvement to meet requirement in short time period.

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## Joint Commission on Accreditation of Healthcare Organizations

- Accreditation is expensive!
- Most small hospitals are NOT accredited
- If not accredited Then:
  - Medicare contracts with State Agencies to inspect for compliance with COP
  - WA Dept of Health has contract in WA

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## Inspection of Hospitals

- DOH Facilities Staff inspects for
  - Medicare
  - State Licensing
- DOH accepts BoP Pharmacy Inspections to determine if hospital meets Rx standards.
- DOH spends time in rest of hospital

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## BoP Inspection/rules

- WAC 246-873
- All hospitals Must have Rx license
- RPh in charge
- May be consultant
- Adequate staff
- Inspect Rx storage
- RPh responsible for ALL drugs



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## WA Hospital Rules, cont.

- RPh shall review original order or a direct copy before administration EXCEPT:
  - In an Emergency
  - In compliance with WAC 246-873-050
    - Absence of a RPh
- Designated RN may obtain Rx from pharmacy leave copy of order & stock bottle or Unit Dose package of drug removed.

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## WA Hospital Rules, cont.

- Emergency Outpatient Prescriptions
- Pre-pack meds for ED
- Try to make system as foolproof as possible
- Labels completed by nurse or MD
- Retain order for RPh review
- MD must dispense if CS EXCEPT:
  - 10 Rural hospitals (see 246-873-060)

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## WA Hospital Rules, cont.

- Administration of Drugs
- Administered by licensed persons
- Verbal orders limited
- Patient's own drugs
  - Identified by RPh
  - Administered on specific order
  - If not used must be stored
  - May be given back at discharge but could retain if hazardous to patient's health
- Investigational drugs under control of Pharmacy

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## WA Hospital Rules, cont.

- Provision of drugs
  - Usually unit dose form in larger hospitals
  - CS usually supplied as floor stock with proof of use sheets
  - Usually stock bottles (floor stock) in rural hospitals
  - Drugs are ordered via chart orders rather than prescriptions
  - Pharmacy should be getting copy of the orders

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## Long Term Care Facilities

- Skilled Nursing Facilities (SNF)
  - Medicare & Medicaid
- Intermediate Care Facilities (ICF) & IMR
  - Medicaid only
- Boarding Homes
  - Medicaid only
- Assisted Living Centers
  - Medicaid only

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## Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- Although JCAHO accreditation is available to nursing homes, but very few are accredited AND it does NOT provide deemed status.

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## Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- See 42 CFR 483.60 Pharmacy Services
- SNF may either provide drugs or contract for pharmacy services
- (Washington does not allow SNF to stock drugs except emergency kit.)
- Therefore, all SNFs contract with RPh's
- May separate Rx provider from consultation service

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## Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- Perverse incentives for Reviewing RPh
  - Reduce unnecessary drugs
  - Less drugs = less reimbursement
- Rx review reports go to
  - DNS, Administrator, Medical Director

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## Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- Provision of Drugs
  - Dispensed as individual prescriptions but may be Rx or chart order
  - Usually packaged in 30 day blister cards
  - Pharmacies usually provide computerized medication administration records (MAR) for use by nurses
  - Doctors sign off on orders monthly
  - Original Rx required for Schedule II

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## Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- (a) Must meet drug needs of all patients
- (b) must provide services of RPh who
  - Provides consultation on all aspects of Rx services
  - Establishes records system for CS
  - Determines that Rx records are in order

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## Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- (c) The drug regimen of each resident must be reviewed each month by the pharmacist.
- Rule adopted in 1973
- The first clinical pharmacist service required by Federal rule
- Followed by OBRA 90 and MTM in 2003

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## Washington NH Rules

- Rx Services Cte. (same as Medicare)
- RPh consultant
- Rx services
- Controlled Substances
  - III separate from others
  - Except in UD system
- OTC's stock bottles labeled with Patient's names

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## Washington NH Rules

- Emergency kit authorized
- Locked drug storage
- Poisons other hazards stored separately
- On site reviews of storage by RPh
- Labeling requirements
  - Different from outpatients
  - CS Schedule on Label

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## Washington NH Rules

- Record books for II & III
  - 24 hour counts for II
  - Weekly counts for III
- Destroy left over CS
  - Problem with Dept. of Ecology
- Continuity of Rx therapy
- OK to provide Rx for patient leaves

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## NH Controlled Substances

- BoP Rule allowing stock supplies of CS so that NH can use reverse distributors BOP to issue CS registration # to pharmacy for NH using Pharmacy Name and NH address.

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## Other Long Term Care Facilities

- Institutions for the Mentally Retarded
  - Fircrest School
  - Rainier School
- Usually have full time pharmacy service
- Function like hospital pharmacies but may use combination of floor stock, individual prescriptions or bingo cards

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## Other Long Term Care Facilities

- Adult Family Homes/Boarding Homes
- Theoretically patients need less RN supervision than SNF patients
- Usually supplied by community phcy
  - Individual prescriptions
  - Some bingo cards
- Patients may self administer OR non-licensed staff may *assist* them to self administer

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## Other Long Term Care Facilities

- Adult Family Homes/Boarding Homes/Assisted Living
- Theoretically patients need less RN supervision than SNF patients
- Usually supplied by community pharmacy
  - Individual prescriptions
  - Some bingo cards
- Patients may self administer OR non-licensed staff may *assist* them to self administer
- No RPh review of meds required except when filling prescriptions.

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## Parenteral Products for Non-Hospitalized Patients 246-871

- Rules adopted in 1990 as Home IV pharmacies were being developed.
- Need P & P describing activities of Phcy
- Meet Physical Requirements
  - Class 100 environment (IV Hood)
    - Laminar Flow for IVs
    - Vertical Flow for Chemotherapy drugs
- Hood certification annually

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## Parenteral Products for Non-Hospitalized Patients, cont.

- Pharmacist in Charge
  - Trained in specialized functions
  - Supportive personnel trained
  - RPh available 24/7

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## Parenteral Products for Non-Hospitalized Patients, cont.

- Drug Distribution
  - Information on Rx
  - Profile information
  - Label information
  - Identification of preparer & checking RPh
  - 24 hour phone number to contact RPh

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## Parenteral Products for Non-Hospitalized Patients, cont.

- Delivery Service
  - Timely delivery
  - Temperature Controls
  - Instructions for disposal of unused IV
  - Disposal of infectious waste
  - Emergency kit for RN use
  - Authorized by MD
  - Ekit use Protocol to be approved by BOP

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## Parenteral Products for Non-Hospitalized Patients, cont.

- Antineoplastic drugs
  - Vertical laminar flow hood
  - Protective apparel
  - Safety containment
  - Disposal of waste
  - Written procedures for spills
  - Package to minimize accidents
- NOTE: WISHA inspects for safety of personnel working with these drugs.

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## Parenteral Products for Non-Hospitalized Patients, cont.

- Clinical Services
  - Prescriber-Nurses-Pharmacists understand roles & responsibilities
  - Medication use review needed
  - RPh access to clinical & lab data on patient
  - Patient training for self administration if needed
  - Any new medication must be monitored during first dose to avoid anaphylaxis.

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## Parenteral Products for Non-Hospitalized Patients, cont.

- Quality Assurance (QA) Program
  - Medication errors
  - Adverse drug reactions
  - Patient satisfaction
  - Product sterility
  - Written documentation of testing samples for microbial contamination
  - Test for pyrogens if bulk compounding is done using non-sterile products
- Justify any expiration dates assigned to products

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## Questions?

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