OVERVIEW

Each entity using technology to deliver pharmaceutical services to patients is responsible for ensuring it complies with all applicable laws and rules.

This guideline document is intended to provide guidance to licensees and act as a resource. However, this guideline document is not exhaustive, both in content and of technological services considered; and cannot be relied upon or used as a substitute for legal advice.

The following eight areas of focus should be considered when pharmacies are reviewing new technologies and innovative ways to deliver patient care. Using these tenets as guidelines, and the pharmacist’s professional judgement, when drafting internal policies and procedures will help to ensure emerging technologies are not hindered as the rule re-write is underway.

Pharmacies should have policies or procedures that cover the minimum requirements to assure patient safety. These should include the following topics as appropriate for the technology or service:

1. Patient safety
2. Licensing
3. Training
4. Security and confidentiality
5. Record keeping and accountability
6. Quality assurance and improvement
7. Workflow process
8. Emergency procedures.
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Shared Pharmacy Services

Definitions:

Shared Pharmacy Services: A system that allows a participating pharmacist or pharmacy pursuant to a request from another participating pharmacist or pharmacy to process or fill a prescription or drug order, which may include but is not necessarily limited to preparing, packaging, labeling, data entry, compounding for specific patients, dispensing, performing drug utilization reviews, conducting claims adjudication, obtaining refill authorizations, reviewing therapeutic interventions, or reviewing chart orders. (RCW 18.64.011(32))

The following processes are examples to be performed under a shared pharmacy service structure:

- Remote Medication Order Processing
- Workload Balancing
- Central Filling of Prescriptions
- Long-term care shared services

Remote Medication Order Processing: This process includes, but is not limited to, the following:

a. Receiving, interpreting, or clarifying medication orders;

b. Data entry and transferring of medication order information;

c. Performing drug regimen review;

d. Interpreting clinical data;

e. Performing therapeutic interventions, and;

f. Providing information concerning medication orders or drugs.

Workload Balancing: Type of shared service that involves balancing the services between pharmacies in order to ensure drugs or devices are attainable to meet the needs of the patients.

Central Filling of Prescriptions: A pharmacy which is permitted by the state in which it is located to prepare control substances and non-controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed authorized to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

Long Term Care Shared Services: a pharmacy may outsource shared pharmacy services for a long-term care facility or hospice program. The outsourcing pharmacy can fill (satellite) a first dose or partial fill a prescription to meet a patient’s or resident’s immediate needs per RCW 18.64.570.

Licensure:

- In-state pharmacies and pharmacists that utilize shared pharmacy services will need to be licensed as a pharmacy and as a pharmacist in Washington, respectively.
- Out-of-state pharmacies that ship, mail, or deliver legend drugs (including controlled substances) into Washington State shall be licensed as a nonresident pharmacy.
- Pharmacists engaged in shared pharmacy services in a pharmacy which is not licensed as a non-resident pharmacy must be licensed as a pharmacist in Washington State.
• Pharmacists engaged in shared pharmacy services in a pharmacy licensed as a non-resident pharmacy do not need to be licensed as a pharmacist in Washington State.
• Pharmacists engaged in shared pharmacy services, performed from a non-licensed location (ex. Home) must be licensed as a pharmacist in Washington State.

**Patient Safety:**
• Pharmacies should develop processes to ensure patients receive the appropriate medications and are educated on the medications they are utilizing. The use of technology to enhance the safety of dispensing should be outlined in policies and procedures.
• Pharmacies engaged in shared pharmacy services should have internal policies and procedures defining what each pharmacy and pharmacist will be responsible for.
• Pharmacy engaged in shared pharmacy services should consider training, competencies of staff and how reporting of quality outcomes is completed.
• Pharmacists engaged in shared pharmacy services are ultimately responsible for their actions completed during all aspects of the completed prescription or medication order and assumption of the responsibility for the filled prescription or medication order they complete, such as: accuracy of drug, strength, labeling, proper container and other requirements.

**Record keeping and accountability:**
• Pharmacies providing and receiving the services of the shared pharmacy services need to abide by Washington Administrative Code (WAC) 246-869-100 and RCW 18.64.245 (Prescription record requirements); WAC 246-869-070 (Responsible Manager - Appointment); 21 C.F.R. §1304.04 (Maintenance of records and inventories) and any rule, law or regulation pertaining to record keeping and accountability.

**Security & Confidentiality:**
• The pharmacies will share common electronic files or have appropriate technology to allow secure access to the pharmacy’s information system and to provide each pharmacy with access to the information necessary or required to process and fill the medication order.
• The pharmacy’s software information system will maintain the confidentiality of patient information in accordance with the requirements of chapters 18.64, 69.50, 69.41 and 70.02 Revised Code of Washington (RCW) and any applicable federal law.
• The dispensing pharmacy and the central filling pharmacy should have a security and system safeguard designed to prevent and detect unauthorized access, modification, or manipulation of prescription information.

**Operations:**
• Federal regulations, such as CFR 1304 and 1306 should be reviewed (if processing controlled substances) by pharmacies to ensure compliance with all established components of code defining this practice. Additionally, WACs regarding dispensing of prescriptions directly to a patient should be reviewed and compliance ensured.

**Quality Assurance:**
• All pharmacies should consider addition of shared pharmacy services into the overall quality assurance plan.
Kiosks/Vending Machines/Outlets Pharmacies.

- The Commission currently allows the placement of nonprescription medications in vending machines if the owner or operator of the vending machine obtains a Shopkeeper's Registration.
- The Commission does not allow the placement of restricted nonprescription medications in vending machines, e.g., Ephedrine or Dextromethorphan.
- The Commission does not currently allow the placement of a device that dispenses legend drugs directly to patients with no pharmacist physically present. The Commission is considering allowing use of these technologies as part of the rules re-write.
Remote Supervision of Technicians

**Definition:**
The supervision of a pharmacy technician by a pharmacist who is not physically on-site with the pharmacy technician.

**Licensure:**
- Both the pharmacist and the pharmacy technician must be licensed in Washington.

**Patient safety:**
- Pharmacies should have processes in place to ensure the use of audio and visual technologies provides adequate supervision of the work performed by pharmacy technicians.
- Replenishment of ADDDs can be completed through direct supervision with a pharmacist on premises or indirectly by an electronic verification system for managing inventory [WAC 246-874-010 (7) & (18)].
- Appropriate training for all staff involved should be conducted to allow for effective communication between the pharmacy staff.

**Security and Confidentiality:**
- Medication security and patient data would be subject to all appropriate rules and regulations of the licensed space.

**Record keeping and accountability:**
- For medications dispensed to patients, records for the original prescription and refill records should be maintained on the filled prescription or in a separate record book or patient medication record. Such records should be maintained for a period of at least two years and should be made available for inspection to representatives of the pharmacy commission.

**Quality Assurance:**
- The licensee or responsible pharmacy manager should include this practice in the overall quality assurance program of the organization. Adverse events, downtimes and other metrics would be important considerations in the build of the program.