

# ASHP Guidelines on Pharmacy Services in Correctional Facilities

Correctional facilities include county, state, and federal jails, prisons, and detention centers whose populations may be adult or juvenile, U.S. citizen or noncitizen, sentenced inmates or detainees awaiting judicial proceedings. They may be managed directly by the relevant jurisdiction, run by a private company providing services under contract, or a combination of the two. Case law and historical precedent have established the inmate-patient's right to healthcare, notably in *Estelle v. Gamble*<sup>1</sup> and more recently in *Brown v. Plata*.<sup>2</sup> (Incarcerated individuals served by correctional pharmacists are referred to as *inmate-patients* in these guidelines; some jurisdictions may prefer other terms.) Correctional facilities should provide, at a minimum, a basic, humane, and appropriate level of healthcare services, consistent with community standards of care and made available to inmate-patients 24 hours a day, as needed. An important component of this basic provision is safe and effective pharmacist-provided patient care. As such, it is recommended that all correctional facilities obtain the services of a pharmacist.<sup>3</sup>

The size and scope of individual correctional facilities vary greatly. The concepts, principles, and recommendations contained in this document are intended to be generally applicable. In settings that may not have the ability to obtain the services of one or more full-time pharmacists, part-time, contract, or consultant pharmacists maintain the same basic obligations and responsibilities as their full-time counterparts in larger settings.

Correctional pharmacy practice, defined herein, encompasses many aspects of community, hospital, and consultant pharmacy practice while remaining a unique and distinct field of pharmacy practice. These guidelines are intended to address aspects unique to correctional pharmacy practice and detail the valuable clinical services and leadership provided by pharmacists in this arena.

Pharmacists who practice in correctional settings are responsible for maintaining familiarity with community standards of care, as well as the *Standards for Health Services* promulgated by the National Commission on Correctional Health Care<sup>4,5</sup> and the standards of the American Correctional Association.<sup>6,7</sup> Other pertinent guidelines of ASHP, the National Commission on Correctional Health Care, and the American Correctional Association should be reviewed as well as regulations and laws set by applicable federal, state, and local jurisdictions. Pharmacists who practice in correctional settings must also be familiar with the current literature, laws, and regulations governing confidentiality, consent, and other aspects of correctional healthcare that may differ from standard pharmacy practice.

The pharmacy director, in conjunction with the medical director or other responsible health authority and the correctional institution's administrators, should develop policies and procedures that complement these guidelines and add institution-specific details.

## The Pharmacy Director

A licensed pharmacist in good standing with a state board of pharmacy recognized by the National Association of Boards

of Pharmacy should be appointed the pharmacy director of the facility. He or she should be available, at a minimum, on a consulting basis. Pharmacist staffing should be proportionate to the healthcare needs of the facility.<sup>8</sup>

If the only pharmacy services provided are those of a consultant pharmacist, the consultant pharmacist must assume the role of the pharmacy director. If the correctional facility contracts with a vendor who provides pharmacy services, the vendor should designate and provide support for a pharmacist to assume the role of pharmacy director of the institution, with the associated responsibilities.<sup>9</sup>

The pharmacy director assumes responsibility for pharmacy operations and application of policy as approved by the responsible health authority and administration of the correctional facility and/or pharmacy vendor.

## Therapeutic and Clinical Policies

Commensurate with the expanding role of clinical pharmacists, correctional pharmacists are well positioned to serve in an active role on the inmate-patient's medical team and provide direct patient care to improve health outcomes and minimize the risk of harm. Pharmacists can provide a plethora of services to correctional facilities and information on topics including but not limited to drug interactions, nutrition counseling and drug-nutrient interactions, food and drug allergies, drug abuse and withdrawal treatment, prenatal pharmaceutical care for pregnant women, disaster planning and response, emergency medications, proper antidotes for overdoses or poisonings, screening for and management of chronic diseases, mental health, anticoagulation, transitions of care, and medical devices and supplies. Correctional pharmacists should be involved in the administration of the annual influenza vaccine and other indicated vaccines to staff and inmate-patients. A pharmacist should be involved in the care of all inmate-patients with chronic infectious disease, especially tuberculosis, human immunodeficiency virus (HIV) infection, and viral hepatitis, to ensure proper drug therapy management of these complex conditions common to the correctional environment. Improper pharmaceutical management of these patients can contribute to disease outbreaks and the development of lifelong drug resistance.

The pharmacy director or a pharmacist designee should be a member of the institutional pharmacy and therapeutics (P&T) committee or its equivalent. A formulary should exist in accordance with the ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System and the ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System.<sup>10,11</sup>

Drug products selected for formulary inclusion should serve the needs of the inmate-patient population, be consistent with national clinical guidelines, and be as cost-effective as possible.<sup>12</sup> Institutional safety and security should also be considered when analyzing formulary options and restricted-use criteria. The correctional pharmacist must be aware that certain medications and delivery devices can be sold, bartered, abused, or modified into weapons or para-

phernalia for drug use. The therapeutic benefits must be weighed against the risk of harm in cooperation with correctional services staff. Dosage forms such as liquids and injections should be considered for drugs identified as having abuse potential. However, pharmacists should advocate that cost and potential safety risks are not the sole determinants for drug product selection. Procedures should exist for the provision of nonformulary medications when medically appropriate.

For correctional institutions that offer a commissary or general store that sells medications or drug products, a pharmacist should be permitted to provide input into which nonprescription medications are made available for purchase. To prevent possible overdose, purchase quantity limits should be considered. The pharmacy director may determine which (if any) nonprescription medications are available from the pharmacy for inmate-patients who cannot afford them. The pharmacy director should also be involved in ensuring that the nonprescription medications are appropriately stored, and he or she should inspect any areas where medications are kept at regular intervals to ensure the integrity of these medications.

Regular consultation with the facility's medical, nursing, and mental health staff and leadership should occur, especially for maintaining policies and procedures for the use of psychotropic medications, medications for the treatment of infectious and communicable diseases, and other diseases or medical conditions common to the specific inmate-patient population, as necessary.<sup>13</sup> Pharmacists should provide input into antibiotic stewardship and infection-control policies and procedures pertinent to medication use and contact with medical supplies. Pharmacists should also be utilized appropriately in clinical decision-making, quality and safety improvement, policy and procedure development, drug regimen review, medication-use evaluation,<sup>14</sup> and direct patient care, in accordance with their skills and qualifications.<sup>15</sup>

## Personnel

The pharmacy director should oversee pharmacy personnel and retain appropriate supervisory controls for support personnel, ensuring that pharmacy services are available commensurate with the needs of the facility. A pharmacist should visit and inspect the medication areas in the facility as required by policy but no less than quarterly.

Sufficient support personnel should be available to maximize the use of pharmacists in tasks requiring professional judgment.<sup>16</sup> Pharmacy technicians used as support personnel must meet jurisdictional requirements. Pharmacy technicians should have completed a pharmacy technician training program accredited by ASHP and the Accreditation Council for Pharmacy Education, obtained Pharmacy Technician Certification Board certification, and be in good standing with the state board of pharmacy.<sup>17</sup> When faced with a shortage of qualified pharmacy technicians, the health authority may need to consider the use of other legally qualified personnel with appropriate training and credentials to support pharmacy and departmental operations.

All personnel involved in the pharmaceutical distribution process should possess comparable education, training, licensure, and certifications to those of their community counterparts. The competencies, credentials, and licensure of all pharmacy staff should be maintained, inspected, and

developed through ASHP-accredited residencies, relevant continuing-education activities, and advanced clinical training. Eligible pharmacists are encouraged to pursue board certification and credentialing as a certified correctional health professional through the National Commission on Correctional Health Care.<sup>4,5</sup> Pharmacists in correctional settings are encouraged to instruct or precept student pharmacists and pharmacy residents, as resources permit, to expose students and residents to correctional pharmacy as a potential career path.

## Fiscal Resources

The pharmacy director or his or her designee should be involved in the appropriate administrative committee or board that establishes the budget for pharmacy department operations. Pharmacists serving correctional institutions should strive to provide high-quality care to inmate-patients while managing expenses. The ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems provides a framework for cost-effectiveness decisions.<sup>12</sup>

The annual pharmacy budget can be forecast by weekly average utilization multiplied by 52 weeks. It should account for the total inmate capacity, average daily inmate population, demographics and health status of the inmate population, regional variability of disease burden, unforeseen needs, drug shortages, variability in drug pricing, and the disproportionate number or severity of patients with chronic or communicable diseases at the institution.<sup>18</sup>

## Medication Purchasing and Control

Control of medications as they enter and move within the institution is an essential element of pharmacy operations in the correctional setting. Adequate methods to ensure that the appropriately trained staff members are involved in meeting these responsibilities should be established.

A pharmacist should be responsible for purchasing and controlling all prescription drug products. The responsibility, if any, for the ordering, issuance, accountability, and monitoring of other products that may be dispensed by or stored in the pharmacy should be made clear in policy. These items may include nonprescription medications, diagnostic and drug-related devices, needles, syringes, batteries, eyeglasses, contact lenses, and medical or surgical devices such as supplies for wound or ostomy care, suture and surgical kits, dental equipment, prosthetics, shoe inserts, compression garments, splints, and similar items. Accountability may include electronic controls, physical counts, and perpetual inventories.

The pharmacy director is responsible for selecting reputable and appropriate sources from which to obtain drug products and for ensuring that all drug products meet applicable legal requirements. Additional guidance on the obligations of drug product suppliers and purchasers appears in the ASHP Guidelines for Selecting Pharmaceutical Manufacturers and Suppliers.<sup>19</sup> Pharmacists must use professional judgment and prudence when considering the practice of redispensing unused medications or determining whether to allow inmate-patients to use medications brought in from outside the facility. These practices are not generally

recommended, as the medications may have been adulterated or stored under improper conditions.

## Drug Product Distribution

Inmate workers should not be utilized at any point in the distribution process. An ideal drug product distribution system will vary from one institution to another but should include as many of the following components as possible.<sup>20</sup> The drug distribution system will

- Be safe and cost-effective.
- Foster drug control and active drug-use monitoring by utilizing medication administration records to reduce medication errors and adverse drug reactions.
- Provide ongoing processes for the monitoring and reporting of adverse drug reactions and the detection and prevention of medication errors.
- Implement a unit dose or unit-of-use drug distribution and control system for all drug products used in directly observed therapy; to the extent practical, these items should be purchased or packaged in single-unit or unit dose packages or manually unit dosed with appropriate labeling.<sup>21</sup> Blister packaging, often called blister cards or bingo cards, may also be used for this purpose, provided they are appropriately labeled.
- Allow for the recovery of larger quantities of medications dispensed to inmate-patients to self-carry or keep on their person, after the discontinuance of orders or in compliance with automatic stop orders.
- Monitor and prevent the dispensing of unusually large quantities of medications, especially sufficient doses to potentially enable suicide attempts; individuals who are determined to be at high risk for suicide should be identified to the appropriate medical providers, including pharmacists.
- Provide opportunities for population-based reporting and analysis.
- Utilize modern, secure, and functional electronic hardware and software for data management and automated drug dispensing in accordance with the ASHP Guidelines on the Safe Use of Automated Dispensing Devices.<sup>22</sup>
- Allow access to patient medication records only to authorized personnel with a need for access.
- Protect patient confidentiality throughout the distribution process, especially for patients receiving medications for sensitive conditions (e.g., sexually transmitted infections, HIV).<sup>23</sup>
- Grant pharmacists full access to review and enter clinical interventions and documentation into the inmate-patient's medical record to ensure patient safety and the appropriateness of medication orders.<sup>24</sup>
- Require that the pharmacist review all medication orders before the first dose is dispensed, with the exception of emergency situations.
- Document refills and chain of custody from receiving to dispensing to the end user or destruction in accordance with state and federal laws and regulations.
- Detect and document patterns of inmate-patient medication behavior (e.g., use, misuse, refusal to use) in the patient's medical record.

- Allow for continuity of care both outside and within different areas of an institution.
- Minimize or eliminate the ability of inmate-patients to transfer, barter, trade, or share medications.
- Minimize unauthorized use of medications by anyone other than the intended patient, including pilferage by other inmates and staff. Multiuse containers and devices must not be shared among multiple inmate-patients.
- Deter the act of cheeking (pretending to but not actually swallowing a medication) through the use of injectable, immediate-release, or liquid medications; by crushing tablets and floating them in water (if appropriate); and by performing visual mouth checks.
- Have mechanisms to replace medication that is confiscated by staff or lost and alert the pharmacist to provide appropriate counseling for inappropriate medication behaviors such as stockpiling and cheeking.
- Account for situations unique to or made more complex by the nature of the correctional environment, such as an institutional lockdown, disease outbreaks, utility outages, and floods.

## Medication Administration

In correctional settings, the responsibility of medication administration is sometimes assigned to appropriately trained nonhealthcare personnel if traditional administration by nurses is impracticable. The Standards of the National Commission on Correctional Health Care address this issue in greater detail.<sup>4,5</sup>

The pharmacy director should participate in the development of medication administration forms and ensure that all relevant information is incorporated into the forms, including medications administered, doses, frequency of administration, start and stop dates, and medication allergies. These forms should be stored electronically or kept in an area inaccessible to inmates.

The pharmacy director is responsible for creating policies and procedures for how medication will be administered to inmate-patients assigned to work details or work-release programs; being transported or escorted to a court hearing or other proceeding; or assigned to special housing units, segregation from the general population, or other special settings. Procedures should also be in place to ensure continuity of medication therapy upon transfer or release, within the capacity and limitations of the institution. For example, upon release, inmate-patients could either be issued an actual supply of medications proportionate to the anticipated time that they will need to reestablish care in the community or have their discharge prescriptions transmitted to a community pharmacy, compliant with the laws and regulations of both the transmitting and receiving state with the approval of the prescribing medical provider.

## Education

Pharmacists in correctional settings are encouraged to take an active role in training facility and fellow healthcare staff on issues of pharmacist-provided patient care and pharmacy policies and procedures within the institution. Staff educational programs should include information on indications,

administration, and the proper use of medications stocked for emergency use; monitoring for adverse events and allergic reactions; documentation; accountability; confidentiality; drug information; and the importance of adherence to medication regimens. The important role of correctional facility officers and their expectations as first responders in medical emergencies should be emphasized.

Pharmacists should also provide appropriate counseling to inmate-patients through the provision of language- and age-appropriate educational materials, direct counseling, small-group meetings, or other technological means (e.g., videoconferencing, telehealth) as available.<sup>25</sup> Poor health literacy is common among inmates, and efforts should be made to address and improve their understanding of their health and well-being while incarcerated. Inmate-patients should have reasonable access to drug information or pharmacist consultation upon request and within an acceptable time period to allow them to make informed choices regarding their own care. Pharmacists with the qualifications necessary to administer direct patient care services or medication therapy management should be authorized to do so, assuming that legal requirements are met and necessary collaborative practice agreements are in place.

## Research

Performance of prospective and retrospective research is needed to advance the practice of correctional pharmacy and provide evidence-based rationales for clinical decisions and programs. However, inmates are federally protected as subjects in medical research as a result of the inherent loss of autonomy associated with incarceration and historical abuses.<sup>26</sup> The responsibility for ethical research begins with the professionalism of the primary investigators, including research pharmacists. All research with the potential to impact patient care must include provisions for informed consent and be approved by the institutional review board or its equivalent at all institutions involved, with special attention to medicolegal issues, ethics, criminology, and the endemic patient population.<sup>27</sup>

Adherence to federal regulations on medical research in correctional facilities is essential.<sup>28</sup> Extreme care should be taken to prevent situations in which inmates are or may appear to be coerced, rewarded, or penalized for their participation or nonparticipation in research. A common principle is that the inmate population should not bear the actual or possible risk burden of the research if it is unequal to the actual or possible benefits that this population stands to gain from the research.<sup>29</sup> All correctional research that involves medications should be conducted in consultation with a pharmacist, at a minimum.

## Facilities

Several models of onsite and remote pharmacy facilities exist in the correctional environment and provide effective pharmacist patient care services. Pharmacy services may be provided in the absence of an onsite pharmacy. The definition of a pharmacy in the context of a correctional facility may or may not match the legal definition of a pharmacy for state or federal regulatory purposes, and associated registration requirements may differ. If the pharmacy is located

onsite, it should be located within or in an area contiguous to the space provided for other healthcare services in order to accommodate interdisciplinary cooperation in patient care and facilitate inmate-patient perception of the pharmacy as a provider of healthcare services. Facilities and equipment should be adequate to accommodate appropriate security of all drug products, especially controlled substances. Only pharmacists designated by the pharmacy director should have access to the pharmacy. These pharmacists may possess keys, combinations, or trackable, secured electronic entry to the pharmacy and controlled substance safes. If state law allows, an authorized administrator may also possess these items. However, emergency access to the pharmacy for medical reasons should be minimized or eliminated through night stock medication availability or an emergency medication cart or locker maintained by a pharmacist. If urgent entry to the pharmacy must occur for nonmedical situations, such entries must be documented and reviewed by the pharmacy director.

Adequate and secure networked computers and electronic systems should be present with appropriate access to software to include electronic medical records, drug information resources, and programs necessary for the pharmacist to complete assigned tasks and duties.<sup>30</sup>

The safety and physical security of pharmacy staff should be priorities. All pharmacy staff should be appropriately equipped and trained to use communication devices, correctional tools, and self-defense techniques in accordance with institutional policy. Institutional correctional staff should ensure that all safety and security equipment is functional and well maintained. Pharmacy staff should not be asked to perform correctional duties outside their abilities or scope of training, except in emergencies, and should be trained and included in emergency drills and contingency planning. Procedures to address safety concerns to administrators should be in place.

## Drug Storage

The pharmacy director is responsible for ensuring that medications are securely stored in every location in which they are kept in order to deter misuse and abuse. All drug products must be stored in accordance with the manufacturer's and/or *United States Pharmacopeia* requirements. Expired drug products must be segregated from those that remain in drug storage areas and must never be dispensed to inmate-patients. Refrigeration, freezers, and warmers should be adequate and functional, with appropriate monitoring and record keeping.

The number of areas where medications are stored should be kept to a minimum, and access to these areas should be off-limits to inmates and accessible only by approved and appropriately trained staff. The designated pharmacy personnel should inspect these areas on a consistent basis as determined by the pharmacy director. Controlled substances must be processed and stored in a manner consistent with the *Pharmacist's Manual* released by the Drug Enforcement Administration.<sup>31</sup> Theft and losses, especially suspected diversion, must be promptly reported to the appropriate regulatory agencies and to management of the correctional facility.



## Reporting and Documentation

The pharmacy director should provide and explain reports of pharmacy activities to administration, other medical staff, and other stakeholders at regular intervals, depending on the level of pharmacy services provided. The pharmacy director is also responsible for maintaining and reviewing documentation for accuracy, especially medication administration records. Reports should be stored securely in hard copy or secure electronic format and for an appropriate period of time.

Basic reporting and documentation include

- The quantity and costs of drugs and services furnished,
- Destruction of unusable or outdated medications,
- Inventory value and quantities,
- Records of meetings with administrators, physicians, midlevel providers, nurses, and other staff, as well as changes implemented as a result of those meetings,
- Minutes of P&T committee (or equivalent) meetings,<sup>11</sup>
- Medication administration records,
- Actions taken on drug recalls or shortages,
- Results of quality-control and quality-improvement activities, such as drug-use evaluations and chart reviews,
- Reports generated as required by applicable state and federal laws regulating the practice of pharmacy, unless otherwise exempt or inapplicable, and
- All forms required by the Drug Enforcement Administration.

## Policies and Procedures

Following policies and procedures closely ensures safe, fair, consistent, and equitable distribution of pharmacist-provided patient care and ensures accountability. A written policies and procedures manual should be created to address specific aspects of pharmacy practice in each correctional facility or complex, including but not limited to the areas detailed in these guidelines. This manual should be reviewed and updated by the pharmacy director at least annually and signed by the administrator of the correctional facility and medical director or other responsible health authority. The manual should also address

- Transportation and storage of inmate-patients' medications within and among facilities and units.
- Security of drug products, especially controlled substances and drug-related items with needles and syringes.
- Contingency plans for maintaining accessibility of medications and services in the event of a lockdown, disaster, riot, or other emergency.
- The use of emergency kits of medications in life-threatening situations. The maintenance of such items should be the responsibility of a pharmacist, and their use should always be reported to the pharmacy director as soon as practical.
- Procedures in place to protect patient privacy. Correctional institutions must comply with the Health Insurance Portability and Accountability Act, though there are some minor differences regarding the sharing

of health information and notification of privacy practices for inmate-patients.<sup>32</sup>

- Destruction procedures for expired, unused, or wasted drugs and controlled substances in accordance with the environmental regulations of the state or jurisdiction.
- The use of investigational drugs within the facility.<sup>33</sup>

ASHP acknowledges that individuals make personal moral decisions about capital punishment but opposes pharmacists' participation in capital punishment and affirms that pharmacists have a right to decline to participate in capital punishment without retribution.<sup>34</sup> Correctional pharmacists are committed to helping inmate-patients achieve optimal health outcomes.

## Conclusion

High-quality pharmacist-provided patient care in correctional institutions contributes to the overall correctional mission of jails and prisons and to improving public health and reducing health disparities.<sup>35-37</sup> The pharmacy director and pharmacy staff should attempt to build and maintain positive relationships with other healthcare staff and institution administration to facilitate open and productive lines of communication. Adherence to detailed policies and procedures, together with ongoing surveillance and quality improvement, will create an environment that is conducive to safe and effective inmate-patient care. Improvements in health status and health behavior that occur due to the interventions of a pharmacist can begin a cascade of lasting benefits for inmate-patients and prepare them to return to their communities and to society.

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