Pharmaceutical Services and Medication Management Guide

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ICE

ICE Health Service Corps

FOREWORD

This U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) Pharmaceutical Services and Medication Management Guide supplements:

- IHSC Directive 09-02, *Pharmaceutical Services and Medication Management*

The IHSC chief pharmacist and regional pharmacy consultants developed and maintain the *Pharmaceutical Services and Medication Management Guide*. The guide explains concepts, assigns responsibilities, and details procedures for the provision of pharmaceutical services.

The intended audience is IHSC health service staff who support health care operations within ICE-owned and contracted detention facilities.

STEWART D SMITH

Stewart D. Smith, DHSc, FACHE
ERO Assistant Director
ICE Health Service Corps

Digitally signed by STEWART D SMITH
Date: 2023.08.16 09:41:31 -04'00'

Date

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A. Introduction.

IHSC pharmacists work as part of an interdisciplinary team with other health care professionals providing health care to patients within U.S. Immigration and Customs Enforcement (ICE) detention facilities. Pharmacists' responsibilities include adjudicating medication orders, dispensing medication, counseling, educating staff and patients, and monitoring the use of medications. Pharmacists follow IHSC Clinical Practice Guidelines and the IHSC Attachment 09-02 A-01, *National Formulary* located in the IHSC Policy Library. IHSC pharmacists enter into collaborative practice agreements (CPAs) with physicians to manage a variety of disease states, medications, and provide preventive health services. These physician-pharmacist partnerships expand access to care and improve clinical outcomes.

1. **Components of the Pharmacy Program:**

   The IHSC Pharmacy Program consists of pharmacies located throughout the United States. The IHSC Health Operations Unit assigns each IHSC pharmacy to either the Eastern, Central, or Western Region. A regional pharmacy consultant (RPC) leads each region and works directly with the IHSC chief pharmacist to streamline pharmacy operations and communications. Lead pharmacists in each region report directly to their respective RPC. The IHSC chief pharmacist and regional pharmacy consultants meet regularly to discuss pharmacy related issues and provide direction and leadership to the IHSC Pharmacy Program.

2. **Clinical Pharmacist Program:** The IHSC Clinical Pharmacist Collaborative Practice Program attains optimal clinical patient outcomes and maximizes patient safety through pharmacists delivering direct patient care. Under CPAs, clinical pharmacists (CPs) perform patient assessments; use prescriptive authority to order, interpret and monitor laboratory tests; conduct clinical assessments and develop therapeutic plans; provide care coordination and other health services for wellness and prevention of disease; and develop partnerships with patients for ongoing care. Pharmacists who provide direct clinical care to patients must maintain a CPA with a supervising physician as specified in Section XI of this Guide.

3. **Remote Pharmaceutical Services Program:** IHSC-staffed facilities use the IHSC Remote Pharmaceutical Services Program (RPS) to provide pharmaceutical services to cover pharmacists' leave of absence and vacancies at IHSC-staffed pharmacies across the United States. The IHSC RPS program coordinator recruits IHSC pharmacists to voluntarily cover IHSC-staffed pharmacy sites without a pharmacist, and in some cases, without a pharmacist or pharmacy technician. The RPS has two processes to provide pharmaceutical services: remote fill or remote verification. The RPS program coordinator determines the process to use based availability of appropriate pharmacy personnel.
    a. Remote fill: used when the IHSC site is without a pharmacist and a pharmacy technician. With this process, the covering pharmacist fills prescription orders, ships them to the site and answers all clinical pharmacy questions.
    b. Remote verification: preferred when the IHSC site has a pharmacy technician on-site but is without a pharmacist. The covering pharmacist reviews all orders, verifies all medications filled by the pharmacy technician via video conferencing software and answers all clinical pharmacy questions.
4. **Antibiotic stewardship:** The Antibiotic Stewardship Committee members have backgrounds that include, but are not limited to, epidemiology, medicine, pharmacy, infection control, and dentistry. The committee's aim is to advise on appropriate use of antibiotics across all IHSC-staffed facilities. Committee members evaluate antibiotic practices through drug reviews, provide feedback and recommendations to clinical staff, and develop clinical tools to facilitate appropriate prescribing practices (e.g., antibiograms, Quick Sheet for Empiric Antibiotic Use). In addition, the committee routinely educates staff through interactive case-based presentations.
5. **Pharmacy Information Technology Workgroup**: The workgroup supports field pharmacists and participates in IHSC Health Information and Technology Unit initiatives. The workgroup consists of experienced IHSC pharmacists who serve as electronic Health Record Pharmacy project officers and several understudy officers.

These officers test software updates, educate field officers, maintain user registries, manage drug file entries, execute the national formulary, and in conjunction with software vendors, problem solve multi-faceted issues arising across the electronic health record landscape. Additionally, they lead information technology (IT) hardware and software product changes and improvements, while refining the electronic health record vision and guiding future planning.

II. PHARMACY OPERATIONS

IHSC pharmacies maintain procedures for the procurement, dispensing, distribution, accounting, and disposal of pharmaceuticals.

A. Equipment

Pharmacy equipment includes:

a. Computers and peripherals, defined as one workstation per pharmacy staff member, at least one laptop computer, one mobile phone per pharmacist, at least one landline phone, and appropriate printers.

b. At least one generator-connected power outlet.

c. A dedicated and appropriately labeled refrigerator for the storage of medications and biologics. Refrigerators may be either a compact, under the counter style or a large standalone unit. If the pharmacy has a household-grade combination refrigerator/freezer unit, staff may only use the refrigerator component for medication storage. Refrigerators used to store biologicals or vaccines must be pharmaceutical grade and connected to backup/generator power.

d. A sink with hot and cold running water.

e. Adequate HVAC and lighting to maintain U.S. Pharmacopeia (USP) standards for room temperature medication storage.

f. A system to monitor temperature control (i.e., room, refrigerator, and freezer, if present) that meets compendia, U.S. Food and Drug Administration (FDA), or state vaccines for children (VFC) standards, as applicable.

g. Adequate shelving, storage, and counter space.

h. Appropriate reference materials such as journals, books, electronic or internet-based references.

B. Staffing

1. A licensed pharmacist (supervisory lead pharmacist or lead pharmacist) directs the pharmacy department at IHSC-staffed facilities. The clinical director (CD), in consultation with the health services administrator (HSA), guides pharmacy service operations, in accordance with IHSC policy and standards. The IHSC chief pharmacist, regional clinical director, or the deputy medical director, provides technical and administrative supervision.
2. Pharmacy department staffing includes staff pharmacists, contract pharmacists, and pharmacy technicians depending on facility needs. In pharmacy departments with two or more U.S. Public Health Service (PHS) pharmacists, one is the supervisory lead pharmacist, and the remaining are staff pharmacists. The staff pharmacists work under the direction of the supervisory lead pharmacist. The clinical director (CD) or designee provides clinical oversight for the lead and clinical pharmacists.
3. A pharmacist supervises technicians who work in the pharmacy. The lead pharmacist must remain aware of all the technician's activities involving the handling of medications. The lead pharmacist ensures all duties assigned to the technician are consistent with their training and experience.

C. Coverage during Pharmacist Absence

1. The respective RPC, in consultation with the IHSC chief pharmacist, determines options for covering a pharmacist's absence.
2. Options include remote verification, remote filling from another IHSC pharmacy, providing on-site TDY pharmacist support, arranging for approved mail order pharmacy coverage, or obtaining the services of a contract pharmacist after receiving approval and coordination via the IHSC Staffing Contract Management Program.

a. Remote verification - Only facilities with an on-site pharmacy technician may use the remote verification process to cover a pharmacist's absence. In this case, pharmacy technicians prepare prescriptions in the absence of an on-site pharmacist. A remote pharmacist, physician, or dentist for dental prescriptions, verifies prescriptions before the pharmacy technician dispenses or administers the medication. The on-site technician enters the medication order into the Correctional Institution Pharmaceutical System (CIPS) for dispensing. A remote pharmacist verifies the prescription order, and either a remote pharmacist or an on-site physician reviews or verifies the filled prescriptions prior to dispensing. The prescription labels must contain the initials of both the pharmacy technician and the verifying pharmacist, physician, or dentist. For dental prescriptions, a physician or dentist reviews or verifies the prescriptions prior to dispensing. The physician or dentist must initial each medication container to indicate they reviewed or verified the completed prescription. The remote pharmacist must use a camera and a secure video-conferencing system to verify the filled prescriptions.

b. Remote Fill Services - An IHSC pharmacist located remotely at a different IHSC-staffed facility fills and mails prescriptions to a pharmacy that does not have a pharmacist, a pharmacy technician, or physician present.

D. Orientation

1. A regional or supervisory lead pharmacist must orient all incoming pharmacy personnel within 60 days of hire. The orientation develops an understanding of the purpose, function, and responsibilities of the department within IHSC. See Pharmacy Staff Initial/Annual Competency Forms in References.
2. The newcomer orientation takes approximately four weeks to complete and must include the following:
   a. Introduction to existing department staff.
   b. Explanation of job description and duties.
   c. Explanation of expected levels of job performance.
   d. Review of IHSC directives, guides, and operations memoranda.
   e. Completion of all required training elements.
   f. Orientation to pharmacy areas and procedures.

g. Completion of the facility orientation requirements, per local facility leadership.

3. The respective RPC must provide an abbreviated orientation for pharmacists in multidisciplinary positions, prior to their first temporary duty (TDY) or remote verification assignment.

E. Competency

1. An assessing official completes competency assessments for all pharmacy staff, using the Pharmacist Competency Assessment Form. The assessing official initiates and places the completed competency assessments in the staff member's credential file within 60 days of hire. Pharmacy staff complete assessments each year.

2. Pharmacists in multidisciplinary positions must complete a competency assessment prior to their first TDY or remote verification assignment with their respective RPC. Designated assessing officials conduct competency assessments for pharmacy staff in accordance with the below table. See Section XI.D, which addresses competencies for clinical pharmacists.

Table 1. Assessing Officials by Position Title.

Staff Member	**Assessing Official**
Lead pharmacist	Regional pharmacy consultant
Staff pharmacist	Supervisory lead pharmacist
Pharmacy technician	Lead pharmacist
Pharmacists in multidisciplinary positions	Regional pharmacy consultant
Contract staff pharmacist	Lead pharmacist

F. Pharmacy Services and Recordkeeping

1. **Regulations and Standards**: The lead pharmacist is responsible for the purchase, inventory, and record keeping of all Drug Enforcement Administration (DEA) controlled substances and IHSC restricted items stored in the pharmacy.
2. **DEA Registration:** The lead pharmacist secures and maintains a current hospital or clinic DEA registration number. In the absence of a pharmacist, the RPC performs this duty. DEA registration forms and tools are available via the DEA website. Health services staff must communicate any changes in DEA registration status and DEA registration issues or concerns to the respective RPC.
3. **State Licensure:** As a federal agency, IHSC pharmacies do not maintain state pharmacy licenses. Staff refer questions related to state pharmacy licensure requirements to the IHSC chief pharmacist.
4. **Inventory:** Pharmacies can choose not to carry certain IHSC National Formulary medications due to local practice trends or storage constraints. Each pharmacy should stock at least one drug in each drug class on the IHSC National Formulary. The pharmacist and local Pharmacy and Therapeutics (P&T) Committee manage the pharmacy inventory to ensure the facility provides appropriate, efficient, and cost-effective pharmaceutical care.

G. Procurement of Medications

1. IHSC pharmacy staff purchase medications under a federal contract from the Veterans Affairs (VA) Pharmaceutical Prime Vendor Program (PPV). The IHSC chief pharmacist approves mail order contract pharmacies to fill prescriptions as a backup system, during the absence of a pharmacist or to obtain pharmaceuticals unavailable via the VA PPV. In clinics with insufficient prescription volume to justify an on-site pharmacist, the pharmacist is unavailable, or the position of the pharmacist is vacant, health service staff use mail order or remote pharmaceutical services to process prescriptions.
2. If a product is unavailable from the sources listed above, health service staff obtain it from a local pharmacy using the IHSC pharmacy benefits manager program (Script Care).

Pharmacy staff must procure specialty medications unavailable from standard sources through pharmacy leadership and the IHSC Resource Management Unit (RMU).

H. Receipt of Medications

IHSC pharmacy staff must review all medications received against the supplier's invoice to ensure the correct quantity, condition, and product expiration date.

I. Storage of Medications

1. The facility HSA and lead pharmacist ensure the pharmacy and drug storage areas are secure, and access is limited to approved IHSC staff designated in the local operating procedures. The HSA works with the facility administration to ensure pharmacy and drug storage areas have adequate locking devices.
2. **Emergency Medications and Supplies:** Each facility must store emergency drugs and medical supplies in a locked cart or cabinet accessible only to the health care provider in charge. The lead pharmacist and nurse manager track inventory for the contents of the emergency/night cabinet. Health services staff must document any changes to the inventory. The facility's HSA must designate a staff member to inspect the cart for expired items at least monthly. Pharmacy staff must replace short-dated medications in a timely manner.
3. **Patient Workers:** Patients are not allowed access to the pharmacy or drug storage areas.
4. **Authorized Staff Access and Key Control**: Only the pharmacist, pharmacy technician, and physician may access the pharmacy using keys or door lock combinations. Pharmacy technicians must have access to the pharmacy to ensure continuity of care in the absence of the pharmacist. The facility lead pharmacist, IHSC RPC, IHSC chief pharmacist, or facility clinical director grant temporary access to the pharmacy in emergencies. Pharmacies that serve as both the pharmacy and the directly observed therapy (DOT) medication distribution area provide access to health services staff to perform the DOT medication distribution process. Pharmacy personnel must implement security measures to restrict access to medications stored in the pharmacy (e.g., locking cabinets).

5. **Storage:** Pharmacy personnel store drugs by route of administration, in alphabetical order, by generic name, and dosage form:
    a. Oral – inhalant.
    b. Oral – internal.
    c. Otic.
    d. Nasal – inhalant.
    e. Controlled substances.
    f. Abusable supplies.
    g. Flammable items.
    h. Thermolabile items.
6. **Security:** Pharmacies must have the following features:
    a. A secure perimeter.
    b. Access limited to authorized staff.
    c. Solid walls from floor to ceiling with a solid ceiling.
    d. A secure entrance door with a high security lock.
    e. A secure medication storage area.
7. **Checklist:** The pharmacist develops a facility-specific checklist to document monthly inspections and maintains completed copies in the pharmacy files. The pharmacist documents problems or deficiencies identified during the monthly inspections and corrects issues when possible. The pharmacist reports unresolved problems or deficiencies to the HSA.
8. **Non-dispensable inventory:** Pharmacy personnel must ensure drug storage and medication areas do not have outdated, discontinued, or recalled medications, except in a designated area for disposal.
9. **Overstock:** The pharmacist must return surplus medication to the Veterans Affairs (VA) Prime Pharmaceutical Vendor (PPV) as saleable merchandise for full credit whenever possible.
10. **Expired Medication:** The pharmacist marks a secure area within the medical facility to store expired drugs pending acceptance by the contracted reverse distributor. If the expired drug is a controlled substance, the pharmacist returns the drug via reverse distributor or disposes it according to DEA regulations.

11. **Damaged Medication:** The pharmacist marks damaged medication, e.g., keep on person (KOP) medication returns, as pharmaceutical waste and separates the item for disposal via the appropriate vendor. If the damaged drug is a controlled substance, the pharmacist must dispose of it according to DEA regulations.

12. **Temperature Monitoring**: Pharmacy personnel maintain all medications within the temperature range indicated by the manufacturer that is appropriate for long-term storage. Pharmacy staff must:

    a. Maintain room temperatures between 68° Fahrenheit (F) and 77° F (excursions permitted between 59° F and 86° F). Staff can store medications stable at room temperature at "cool" temperatures, between 46° F and 59° F, or refrigerated, unless otherwise specified in the individual monograph or on the label.

    b. Maintain medications labeled as "keep refrigerated" between 36° F and 46° F. Pharmacy personnel must post signs on the exterior of refrigerators and freezers designated for medication storage stating that refrigerators and freezers are not for food storage.

    c. Maintain medications labeled as "keep frozen," at a temperature within the manufacturer's recommendations for each medication, typically between -58° F and 5° F.

    d. The pharmacy staff must use an electronic temperature recorder or data logger to document temperature readings of refrigerators and freezers, including on days the pharmacy is closed. The lead pharmacist or designee may contact the IHSC RPC to determine the stability of medications when temperatures go out of range.

    e. Facilities participating in the VFC program must adhere to VFC program storage and documentation standards.

III. PRESCRIPTIONS

A. Authorized Prescribers

1. Pharmacy personnel only process medications ordered by an authorized prescriber. APPs and CPs prescribe only under an IHSC-approved collaborative practice agreement. The following disciplines may prescribe medications for patients at IHSC-staffed facilities:

a. Physicians.

b. Dentists.

c. Nurse practitioners (NP).

d. Physician assistants (PA).

e. Clinical pharmacists.

2. Licensed contract providers may prescribe medications for patients referred to them for care. The facility lead pharmacist orients new prescribers to the IHSC formulary process, and instructs them how to access the IHSC National Formulary found in the IHSC Policy Library.

B. Written Prescriptions

1. Prescribers write all in-house prescriptions under the "Plan" section of the electronic health record, within the subjective-objective-assessment-plan (SOAP) format.
2. Prescribers order medications by their generic name from a list available in the electronic health record. If a prescribed medication is not listed, the provider should contact the local pharmacist. The local pharmacist should then contact the pharmacy IT workgroup members to add the medication to the master medication list.
3. Brand name products that have "A" rated generics available require a completed and approved Request for Non-Formulary Medication Form (Form IHSC 067). Pharmacists must fill prescriptions with "A" rated generic products listed in the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Bio similarity or Interchangeability Evaluations or Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, unless the brand name product from the VA PPV is more cost effective.
4. Prescribers may write prescription orders for up to 180 days, if within the limits of federal law. The deputy medical director can authorize prescriptions that exceed 180 days if within the limits of federal law in specific circumstances.
5. IHSC does not authorize "hold" orders.

6. The ordering provider communicates urgent medication initiations, discontinuations, or changes to the pharmacy staff, in addition to documentation in the electronic health record.
7. Medication order start dates:
    a. Prescribers must date controlled substance prescriptions on the day they are issued (21 CFR 1306. 05 (a)). Providers notate “Do not dispense until: MM/DD/YYYY” or “Start Date: MM/DD/YYYY” on the prescription as applicable.
    b. The initial start date for medication orders can correspond with when the pharmacy reopens.
    c. Prescribers must discontinue a medication before entering a new order for it.
    d. Prescribers can only post-date pre-procedure or scheduled taper orders.
    e. Health services staff must not enter more than one post-dated order, per medication, per patient, at a time.
8. Each prescription must include the following information:
    a. Date of order.
    b. Patient's name and alien registration number.
    c. Drug name, dosage form, strength, and quantity.
    d. Directions for use.
    e. Reason or medical condition for which the medication is prescribed (i.e., “for pain” or “for diabetes”).
    f. Refill information, when appropriate.
    g. Provider's stamped name, title, and legal signature or approved electronic entry of name.
    h. Provider’s DEA registration number or facility DEA registration number with provider suffix, when ordering a controlled substance. (CFR title 21 part 1306, CFR title 21 part 1301.22, CFR title 21 part 1301.23)

C. Verbal/Telephone Orders

1. A physician, dentist, APP or CP can order a prescription verbally. A verbal order to administer a one-time dose of medication is a chart order, not a prescription. Verbal orders to administer consecutive doses of a medication are prescriptions.
2. Providers only use verbal prescription orders:
   a. When they are off-site.
   b. After-hours.
   c. During emergency situations, to continue medications until a provider evaluates the patient.
   d. When delayed medication administration delays giving the medication may cause significant suffering, injury, or death to the patient.
3. Prescribers communicate verbal medication orders for an urgent or emergent medication to a pharmacist, licensed vocational nurse (LVN), licensed practical nurse (LPN), registered nurse (RN), NP, or PA. The person taking the verbal order must transcribe it in the health record and read it back to the provider. The provider verbally confirms that the order is correct by repeating it again. The person taking the order notes in the patient's electronic health record that the provider read back and verified the order. The responsible prescriber or designee must co-sign prescriptions within 72 hours.
4. Pharmacy personnel carry out verbal orders for the administration of a controlled substance in accordance with the guidance in Section IV.A. of this guide.

IV. DEA CONTROLLED SUBSTANCES AND RECORD KEEPING

A. Prescriptions

1. Only physicians, dentists, APPs, or CPs who meet the following criteria order prescriptions for a controlled substance:
   a. Authorized to prescribe scheduled medications, in accordance with their state license and scope of practice.
   b. Authorized to prescribe scheduled medications, in accordance with their IHSC collaborative practice agreement.

c. Registered under the Controlled Substances Act or is exempt from registration. IHSC federal and contract providers who operate under their facility's DEA-controlled substance registration certificate are exempt from individual registration.

2. Prescribers must enter all orders for controlled substances in the electronic health record and print a hard copy. The prescriber must sign the written prescription (wet-ink signature) and provide it to the pharmacist. When the prescriber is off-site, they must wet-ink sign the hard copy, and fax or mail it to the pharmacist for dispensing.
3. Providers can fax prescriptions for Schedules III-V controlled substances to the dispensing pharmacy. The fax is an original prescription if the provider has wet ink signed the prescription. Providers cannot fax prescriptions for Schedule II controlled substances. Pharmacies must have the hard copy, wet ink signed prescription to dispense Schedule II controlled substances.
4. Pharmacists who provide remote pharmaceutical care services may use a scanned image of the original signed hard copy prescription for verification. The pharmacist must file the written hard copy prescription at the dispensing pharmacy.
5. Pharmacists can dispense verbal orders of Schedule III-V controlled substances from a provider. Pharmacists can administer a controlled substance before the receipt of an electronic or written order. The pharmacist must transcribe oral prescriptions and include all information for a valid prescription except the provider's signature. The provider must document the order in the electronic health record. Prescribers must limit verbal orders for controlled substances to the amount or duration needed to treat the patient until the provider issues a signed, wet-ink prescription.
6. Prescribers who issue verbal prescriptions for Schedule II-controlled substances must write a prescription within 72 hours authorizing the verbal order. Providers must deliver the signed prescription to the pharmacist within seven calendar days of issuance. Providers should issue a new prescription if the patient requires further treatment with a scheduled medication.

7. A physician must cosign the hardcopy of all controlled substances prescribed by APPs and CPs. A physician must document consultation with the APP or CP in the electronic health record as a telephone encounter if they cannot cosign the hardcopy. Medications requiring authorization or concurrence include those continued from intake or prescribed outside of the pharmacy's operational hours. APPs and CPs, in accordance with their state licensure and scope of practice, can renew orders for controlled substances to treat chronic conditions. APPs must request a chart review by their supervising physician at least every 90 days for patients who require extended treatments with controlled substances.
8. Providers must date and sign-controlled substance prescriptions on the day they are issued. Providers may notate "Do not dispense until: MM/DD/YYYY" or "Start date: MM/DD/YYYY" on the prescription as applicable.
9. During hours when the pharmacy is closed, or in the absence of the pharmacist, only a physician or a contract pharmacy can dispense a controlled substance. Nurses may administer a controlled substance upon orders of an authorized prescriber.

B. Recordkeeping

1. Pharmacists must maintain all records concerning controlled substances for at least two years, for inspection and copying by authorized DEA officials (e-CFR Title 21, Chapter II, Part 1304.04). Pharmacy personnel must keep records and inventories of Schedule II controlled substances separate from other pharmacy records. Pharmacy personnel must keep records and inventories of Schedule III, IV, and V controlled substances separate from ordinary business records. Pharmacy personnel must keep financial records for seven years. The pharmacist must maintain the following records for two years from the date of creation (National Archives and Records Administration retention schedule N1-567-12-001:
    a. Official order forms (DEA Form-222) for receipt and sale of Schedule II controlled substances.
    b. Receipts and invoices for Schedule II, III, IV, and V controlled substances.
    c. All inventory records of controlled substances, including the initial and biennial inventories.

d. Records of controlled substances distributed or dispensed (i.e., hardcopy prescriptions).

e. Report of Theft or Loss of Controlled Substances (DEA Form-106).

f. Registrant Record of Controlled Substances Destroyed (DEA Form-41).

g. Records of transfers of controlled substances between pharmacies.

h. Current facility DEA registration certificate.

2. **Prescriptions:** The pharmacist must file completed paper prescriptions using one of the following methods:

   a. Two separate files, one for Schedule II drugs dispensed and another for Schedule III, IV, V, and non-controlled drugs dispensed.

      - Pharmacy staff must mark prescriptions for Schedule III, IV, and V substances with a red "C," not less than one inch high.

   b. Pharmacy staff must create three separate files, one for Schedule II drugs dispensed, one for Schedule III, IV, and V drugs dispensed, and one for non-controlled drugs dispensed.

3. **DEA Form 222 & Schedule II Invoices** - pharmacists must:

   a. Use a DEA Form 222 or electronic controlled substance ordering system to purchase or transfer Schedule II controlled substances.

   b. Order the DEA Form 222 directly from the DEA. The DEA Form 222 is a single form with preprinted information unique to each IHSC pharmacy. DEA Form 222s are serially numbered and sent in batches of three.

   c. Complete each DEA Form 222 without error, otherwise, the supplier will reject the order.

   d. Track all DEA Form 222s, including voided, used, and unused forms, and store the forms in a secure location.

   e. Report the serial numbers for lost DEA Form 222s and return unused forms to the nearest DEA office.

   f. File and retain executed DEA Form 222s in the pharmacy in accordance with federal recordkeeping standards. Pharmacy staff must attach the executed DEA Form 222 to the respective invoice for filing.

4. **Completing a DEA Form 222** - the pharmacist must:
    a. Complete Part one and Part two of the DEA Form 222 and make a copy for the pharmacy's records.
    b. Mail or deliver the original DEA Form 222 to the supplier.
    c. Complete Part five on the retained copy of the DEA Form 222. Only the lead pharmacist, or pharmacist granted a power of attorney, can sign a DEA Form 222. IHSC RPCs can provide copies of power of attorney forms for staff pharmacists.
    d. Review, sign, file, and store orders and invoices for controlled substances in the pharmacy.
5. **Monthly Inventory**: The pharmacist maintains a perpetual inventory control system for controlled substances and abusable supplies (e.g., syringes, needles, scalpels, and suture kits) stored in the pharmacy. The pharmacist conducts a physical inventory of all controlled substances stored in the pharmacy at least monthly on the last working day of each month. The pharmacist conducts the physical inventory of controlled substances with a non-pharmacy staff member who does not have recurring access to medication storage areas, such as the HSA, assistant HSA (AHSA), or facility health care program manager.
6. The pharmacist must generate a monthly printout from the VA PPV listing all controlled substances ordered during the month. The pharmacist compares this list against the on-site records to validate and account for all medications ordered during the month. The VA PPV and monthly inventory report must match. The pharmacist and HSA (or non-pharmacy designee) jointly sign the completed monthly count and the VA PPV print out. The pharmacist maintains a copy of the signed monthly inventory report and VA PPV print out with the controlled substance records. The IHSC RPCs periodically audit controlled substances records.
7. **Biennial Inventory**: The pharmacist conducts a biennial inventory of all controlled substances in accordance with DEA regulations and using the following criteria:
    a. The pharmacist maintains and files the inventory with the controlled substances records.

b. The biennial inventory includes all controlled substances in the pharmacy and medical facility.

c. The pharmacist must complete the inventory at least every two years.

d. The pharmacist conducts the inventory either at the beginning or end of the workday, on any date, within two years of the previous biennial inventory.

e. The pharmacist records the inventory on either an approved DEA form or a locally generated form that includes: the drug name, dosage form, strength, and quantity of each controlled substance. The record must also include the pharmacy name, address, telephone number, inventory date and time, printed name, title, and legal signature of the pharmacist who conducted the inventory.

8. **Transfer of Custody:** Changes in custody of controlled substances that involve health services staff, custody employees, or ICE employees require a written transfer of custody. The departing and arriving custodian pharmacists should complete a joint written and signed inventory, whenever possible.

   a. This written transfer of custody must include the name of departing and arriving custodians; date and time of inventory; listing of the medication's name, strength, and dosage form; and the amount of medication at the time of transfer. Pharmacists document this information in the perpetual inventory log.

   b. If a joint inventory is not possible, the physician or designee (HSA or AHSA) accepts custody until the arrival of the custodian pharmacist. The designee ensures compliance with transfer of custody requirements in the absence of a pharmacist.

   c. For inter-departmental transfers where both departments maintain perpetual inventories, both the issuing and receiving parties must co-initial at least one perpetual inventory record.

   d. Health services staff must document controlled substances from or for patients entering and departing the facility using a Controlled Substance Chain of Custody Form (IHSC Form 927).

The receiving health service staff member must initiate and sign an IHSC 927 controlled substance chain of custody form immediately, for incoming controlled substances that were not accompanied by an appropriate transfer of custody form. Health services staff must transfer incoming controlled substances to custody for storage in the patient's property, as soon as the medication is available through IHSC dispensing procedures.

9. **Change of Address.** When a pharmacy moves to a new physical location, or the postal address changes at the same location, the lead pharmacist must obtain a new DEA certificate reflecting the new address or location. The facility's lead pharmacist must notify the DEA about a change in address before the effective date of the move. Pharmacy personnel may relocate the controlled substance only after securing prior approval from the regional HSA, IHSC chief pharmacist, and DEA field office.

V. COMPLIANCE, MONITORING AND CONTROL

A. External Monitoring

IHSC pharmacy services must comply with relevant laws and regulations to provide medical and pharmaceutical care to noncitizens in ICE custody. This includes accrediting body standards and all appropriate national standards of practice. The facility lead pharmacist secures and maintains a current facility DEA registration number. In the absence of an on-site lead pharmacist, the RPC performs this duty.

B. Pharmacy Inspections

The pharmacist or trained designee must physically inspect all drug areas monthly to ensure the absence of expired, recalled, or deteriorated drugs; proper drug storage conditions; and compliance with manufacturers' storage recommendations. The pharmacist or designee must report to the HSA and respective RPC all problems or deficiencies that they cannot reconcile or correct.

The pharmacist or trained designee must:

a. Physically examine the medications in the urgent care cart monthly, and each time that the security seal on the cart is broken. Any IHSC employee who breaks the security seal on the urgent care cart and removes a medication must immediately notify the pharmacy to restock.

b. Monitor after-hours cabinet (AHC) medication usage on a regular basis and review utilization no less than once a month.

c. Monitor the proper condition of storage of drugs.

d. Ensure compliance with the United States Pharmacopeia Compendia and manufacturer recommendations. The pharmacist must report all identified problems to the HSA and IHSC RPC. The HSA, facility lead pharmacist, or IHSC RPC must formulate and initiate corrective action plans, as appropriate.

e. Complete the inspection checklist: Pharmacists must use a locally developed, clinic specific, standardized inspection checklist to document internal pharmacy inspections. The pharmacist must maintain completed copies in the pharmacy for a minimum of two years (e-CFR Title 21 Chapter II Part 1304.04).

f. Conduct the biennial inventory of controlled substances: The pharmacist must conduct a biennial inventory of all DEA controlled substances at least every two years in accordance with DEA regulations.

g. Report all medication errors: Pharmacy personnel must report medication errors on the incident reporting document under categories that include but are not limited to the wrong patient, wrong drug, wrong dose, wrong administration time, or omission of a medication. The individual responsible for the error, or whoever discovers the error, must verbally notify the prescriber of the medication error and complete an incident report. The individual who discovers the error must notify the CD or assigned physician, dentist, APP, or CP to determine if follow-up is needed. The CD or assigned physician, dentist, APP, or CP documents their decision and the patient's status in the electronic health record as appropriate. The IHSC incident reporting system will automatically forward the completed incident report to the HSA.

h. Conduct risk assessments: The pharmacist must conduct risk assessment activities based on IHSC national guidance and locally identified problem areas. This may include but is not limited to literature reviews, drug utilization reviews, and local performance improvement (PI) studies.

i. When there is no on-site pharmacist, an IHSC consultant pharmacist or designee documents inspections and consults at least quarterly.

C. Pharmacy Reports

The pharmacist must report medication errors using the Incident Reporting Tool and submit as directed. The pharmacist must also complete and forward a MedWatch Report (Form FDA 3500) to the FDA after each reportable adverse event or product problem. The pharmacist must retain a copy of the MedWatch Report for local pharmacy files.

The pharmacist must prepare and send the following reports through the HSA to the respective RPC, and the IHSC chief pharmacist:

a. Monthly report: The pharmacist must submit a report of monthly workload statistics for the previous month by the 10th day of each month. This report must include monthly drug expenditures, number of prescriptions filled, number of night cabinet medications issued, and number of multiple dose pre-packs prepared.

b. Monthly controlled substances report: as described in Section 4.B, a report of the monthly controlled substances inventory. The report includes purchases and utilization data. The facility HSA or designee so-signs the report.

D. Local Pharmacy and Therapeutics Committee

A facility pharmacist chairs the local P&T Committee, a committee that includes representatives from nursing, dental, mental health, a physician (CD if available), and an APP. The facility HSA or AHSA, and quality improvement/risk management representatives are optional, but recommended. The local P&T committee:

a. Meets quarterly, as needed.

b. Discusses topics that include, but are not limited to, drug recalls, medication usage trends, and medication related problems or concerns.

c. Determines which drugs the local pharmacy will stock from the IHSC National Formulary.

d. Determines more stringent local restrictions than identified in the IHSC National Formulary.

e. Determines the need for, and assesses the results of, drug utilization evaluations (DUEs).

f. Determines contents of the after-hours medications supply, and additions to the emergency medication supply beyond the minimum requirements specified in pharmacy SharePoint page under resources.

g. Annually, compiles a list of medications to present to the National P&T Committee for IHSC National Formulary addition, deletion, or modification.

h. Maintains local meeting minutes.

VI. DRUG FORMULARY

A. IHSC National Formulary

1. IHSC-staffed facilities can use medications included in the IHSC Attachment 09-02 A-01, *National Formulary* located in the IHSC Policy Library. IHSC-staffed facilities restrict how providers use medications. The IHSC National Formulary lists brand names for illustrative purposes; it does not endorse any trademarked product. IHSC staff must use "A" rated generics over their brand name equivalent if it is more cost effective.
2. Physicians, APPs, and CPs must use formulary medications, unless there are significant clinical reasons stated in the patient's electronic health record for the non-formulary medication. If a patient arrives on a non-formulary medication and there is a formulary substitute, the provider must switch to the formulary product. Exceptions to this requirement include:
   a. Documented failure of therapy with the formulary medication.
   b. Documented allergy to the formulary product.
   c. Known contradiction to the formulary product.
   d. Other clinically significant justification noted in the patient's electronic health record that would justify the non-formulary medication.
   e. Health service staff must inform the patient when their medications change.

3. The “Physician Use Only” restriction applies to medications that require a physician’s approval for initiation and renewal. If the patient arrives with “Physician Use Only” medications, an APP can continue the medication until an IHSC physician determines the appropriateness of the medication.
4. The “Physician Initiation Only” restriction applies to medications that require a physician’s approval for initiation. An APP or CP may continue this medication without obtaining the physician’s approval. If the patient arrives with “Physician Initiation Only” medications, an APP may continue the medication until an IHSC physician determines the appropriateness of continuing the patient on a medication in this category. APPs and CPs can continue “Physician Initiation Only” medications in the electronic health record from specialist providers in the community. Health services staff can locate the approved IHSC Attachment 09-02 A-01, *National Formulary* located in the IHSC Policy Library.
5. IHSC considers all compounded medications, including topical and parenteral preparations, as non-formulary items. Approved compounded preparations must follow the appropriate U.S. Pharmacopeia (USP) standards for the route of administration.
6. The IHSC Formulary for non-IHSC-staffed facilities lists medications approved for use in non-IHSC-staffed facilities only. Please see the non-IHSC formulary on the IHSC public-facing webpage for more information.
7. Providers who wish to receive an exemption to, or modification of, a restriction listed in the formulary must submit a nonformulary medication request as shown in the next section.

B. Non-Formulary Medications

1. Providers must request authorization for use of non-formulary medications. The CD and RPC must approve the request before initiating the medication, unless there is a compelling medical need, expected adverse effects, or increased risk of injury, illness, or death. Providers must submit the IHSC Form 067 or the eCW Non-Formulary Request Form, and provide appropriate justification for their treatment request to the local pharmacist. The local pharmacist adds cost and local product availability information, and submit the completed form to the #IHSC_NFR_RX distribution list.
2. A non-formulary approval remains in effect until ICE releases the patient from custody. IHSC does not require a new non-formulary request for the continuation of therapy for: intra-system transfer patients who previously had a non-formulary medication approved; or patients, who take an approved non-formulary medication, and leaves then returns to ICE custody within 90 days.
3. Non-formulary request submission process:
    a. The requesting provider completes a non-formulary request form in collaboration with the local clinical director and pharmacist.
    b. The pharmacist sends the non-formulary request via e-mail to the IHSC Nonformulary Request inbox at (b)(6),(b)(7)(C) @ice.dhs.gov.
    c. RPCs adjudicate all requests except for the following:
        - The RPC designates a field pharmacist to complete non-formulary request reviews in their absence.
        - If the RPC recommends denial of a psychotropic medication, upon appeal, the RPC consults with the chief psychiatrist or designee to determine approval or denial.
        - Complex medical cases such as infectious disease or oncology, high-cost medications exceeding $20,000/month, and appeals of denied non-formulary requests. The RPC consults with the infectious disease consultant (for IHSC-staffed facilities only), regional clinical director, or deputy medical director, to determine approval or denial.

d. The adjudicating pharmacist returns the completed non-formulary request form, approved or denied, via e-mail to the initial requestor and the requesting facility's pharmacist.

e. Medical records staff enter the completed non-formulary request forms, whether approved or disapproved, into the non-formulary requests folder of the patient's electronic health record.

VII. PRESCRIPTION PREPARATION

A. Availability of Prescriptions

Pharmacy staff must ensure needed medications are available 24 hours a day, seven days a week. Based on the patient's immediacy of need, this system includes:

1. A facility pharmacist dispensing a prescription.
2. Acquiring the medication from the after-hours stock available when a pharmacist is not present.
3. Using the patient's personal supply until the facility can obtain the medication.
4. Obtaining the medication from a mail order pharmacy (external or internal).
5. Obtaining the medication from a local retail pharmacy via Script Care.

B. Prescription Documentation

1. Pharmacy personnel document the following information for each prescription prior to dispensing:
   a. Prescription number.
   b. Name and title of pharmacist or designee.
   c. Date and military time of filling.
   d. Any clarifying information.
2. Prescription medication labels must include the following information:
   a. Medical clinic name and address.
   b. Pharmacy phone number.

c. Prescription number.

d. Date of prescription filling.

e. Patient name and alien registration number.

f. Drug name, strength, and quantity.

g. Directions for use.

h. Prescriber's name and title.

i. Pharmacist's name or initials.

j. DEA cautionary information if a scheduled medication.

k. Appropriate auxiliary labels, when required.

C. Medication Containers

1. Pharmacy personnel must transfer medications purchased in glass containers to medically appropriate plastic containers, prior to dispensing to patients for KOP use. Pharmacy staff must dispense nitroglycerin tablets in their original glass container to maintain potency and efficacy.
2. Pharmacy personnel must transfer medications purchased in metallic containers, such as topical creams or ointments, to plastic containers, administered solely via pill-line, or dispensed directly to patients, as determined by the facility's local pharmacy and therapeutics committee.
3. Pharmacy staff must dispense all medications intended for use outside the facility in child-safe packaging, unless exempt from the Poison Prevention Packaging Act, or if the patient submits a written request to receive discharge or transfer medications with easy-open lids. Non-pharmacy staff must replace easy-open lids with child-resistant lids, if dispensing medications for internal use, for KOP or pill-line; or when used as travel or transfer supplies.

D. After-Hours Medication

1. The pharmacist will ensure that an after-hours cabinet (AHC) is available in the clinic.
   a. Locking cabinet: The AHC is a locking cabinet or cart for use after the pharmacy closes.

b. Stored alphabetically: Pharmacy personnel store medications alphabetically by generic name and separate categories (e.g., injectable, oral, topical).

c. Log: The pharmacy staff must implement a log system that the IHSC chief pharmacist approves for accountability of medication usage (i.e., the provider or nurse who removes an item completes a log). The log must adhere to one of the two templates authorized by pharmacy leadership. The log must include two patient identifiers, such as name and alien ID number; the medication name, strength, formulation, and quantity removed; the date and time of removal; the authorizing provider; the staff removing the item; and a witness to the removal. Health service staff must properly document medications issued by the AHC to ensure accountability.

d. Pharmacy and therapeutic par levels: The local pharmacy and therapeutic committee determine the local par levels for the medications stocked in the after-hours supply.

e. Templates: Approved after-hours log templates can be found on the IHSC Pharmacy SharePoint page in the resources folder.

2. Pharmacies must prepack pharmaceuticals to meet medical facility requirements. All prepackaged medication labels must detail the drug name, dosage form, strength, quantity, general directions for use, lot number, expiration of the bulk bottle (if not visible on the item or unit-dose packaging), and expiration date. The expiration date must be within six months of the prepackage date, or the manufacturer's expiration date if unit-dose packaging is unbroken, or if less than 12 months of shelf life remains. Upon issue, health service staff must label the prepackaged medication with the date of issue, patient name, alien registration number, general directions for use, and prescriber name and title. Health services staff administer AHC medications on a dose-by-dose basis via the pill line. Authorized health services staff distribute prepackaged items as KOP if verified by a pharmacist prior to placement in the AHC.

E. Pharmacy Benefits Network

For urgent prescriptions, health service staff use the Script Care Pharmacy Benefit program to obtain pharmacy services from a participating local pharmacy. This process allows the facility to obtain the medication immediately without a co-payment.

The pharmacy bills IHSC HQ directly using the Script Care billing system.

1. The provider or designated health care staff should call in or fax the prescription order to a local participating pharmacy when obtaining medication via the Script Care Pharmacy Network.
2. Health service staff should complete the Script Care Pharmacy Benefits Letter template and fax it to the participating pharmacy (see Reference D). The provider must coordinate with the pharmacist or facility HSA to pick up or deliver the new prescription. Each facility has an individual group number. Facility-specific letters are stored in the resources folder on the IHSC Pharmacy SharePoint.
3. The staff should call the local pharmacy to confirm receipt of the fax or provide the necessary prescription information as follows:
   a. Patient's name.
   b. Patient's date of birth.
   c. Drug name.
   d. Drug strength.
   e. Dosage form.
   f. Route of administration.
   g. Directions for use.
   h. Quantity.
   i. Authorizing provider.
   j. Provider's national provider identification (NPI) number available at NPI Registry Search.
   k. Clinic phone number.
   l. Staff member's name.

VIII. PRESCRIPTION DISPENSING

A. Keep on Person

1. Patients do not prepare, dispense, or administer medication, except for self-medication programs approved by the facility administrator and responsible physician.

The pharmacist, HSA, CD, and nurse manager must develop and implement a distribution system for KOP medications at each facility. IHSC does not charge patients for pharmaceuticals.

2. Patients may only possess medications ordered by, or reviewed and approved by, IHSC health care staff. The facility administrator and responsible physician establishes the self-medication program or over the counter (OTC) medications purchased through an IHSC-approved commissary program. Patients may receive up to a 30-day supply of KOP medication. Pharmacy personnel may dispense medications that are available only as a single unit-of-use (e.g., albuterol inhaler) as an unbroken unit, even if the days' supply is greater than 30. KOP medications exclude all other medications requiring distribution through the pill line per the IHSC National Formulary.
3. Health care staff may inspect medications containing potentially hazardous materials (e.g., needles) on a regular basis in accordance with local facility procedures.

   Patients must not at any time possess:

   a. Controlled substances.
   b. Medications for the treatment of tuberculosis.
   c. Medications requiring distribution through the pill line process per the IHSC National Formulary.
   d. More than a single unit or container of a particular medication at any given time.
   e. Medications without a label displaying the medication information and identification of the patient to whom it was dispensed.
4. Health services staff verify two types of patient identification prior to dispensing KOPs or providing pharmaceutical services. Identification measures include reviewing information on the patient identification wrist band, identification card, patient date of birth, asking the patient to state their name, or requesting the patient's complete or partial alien registration number. Health service staff document KOP medication distribution by using a KOP signature log or appropriate documentation in the electronic health record.

5. Health services staff verify two types of patient identification prior to dispensing KOPs or providing pharmaceutical services. Identification measures include reviewing information on the patient identification wrist band, identification card, patient date of birth, asking the patient to state their name, or requesting the patient's complete or partial alien registration number. Health service staff document KOP medication distribution by using a KOP signature log or appropriate documentation in the electronic health record.
6. Physicians, dentists, APPs, and CPs must counsel the patient upon initiation of drug therapy by verbal instruction, written materials, or a combination of both. Medication counseling includes relaying: the name of medication; purpose or pharmacological action of the medication; directions for use including frequency of administration; significant side effects or interactions; and any other relevant information. Medication counseling materials are available in both English and Spanish for most medications contained in the formulary. Pharmacists can contact the RPC regarding the availability of the materials in other languages.

B. Directly Observed Therapy - Pill Line

The facility HSA, CD, nurse manager, and lead pharmacist must develop and implement a distribution system for supervised dosing of restricted medications in accordance with the IHSC 03-16 G-01, *Medication Administration Guide* located in the IHSC Policy Library. Procedures at each medical facility must take into consideration staffing, hours of operation, equipment, and space.

1. The following medical disciplines may administer direct observed medications to patients:
   a. Physicians.
   b. Dentists.
   c. NPs.
   d. PAs.
   e. RNs.
   f. LPNs.
   g. LVNs.

h. Pharmacists may administer medication in accordance with their state license and deputy medical director or designee approval.

2. The following medications must be administered through direct observation:

   a. All controlled substance medications.

   b. All tuberculosis treatment medications.

   c. Any other medications for which the local P&T committee establishes restrictions to mitigate the risk of abuse or diversion.

   d. Any medication that requires staff monitoring to ensure individual patient compliance, per the physician, dentist, APP, or CP.

   e. Oral medications provided to a patient in segregation, except for nitroglycerin. The prescriber may initiate or continue KOP status for topical creams and ointments; inhalers and spacers; suppositories; and eye, ear and nasal medications; unless the prescriber deems pill line use necessary. Prescribers make exceptions for KOP use of other medications on an individualized basis and must document the exception in the health record.

C. Medication Refills

Pharmacists must ensure patients can request and receive refills in a timely manner. Pharmacists can utilize the sick call process, use paper request forms, or establish a regular window for in-person requests. Pharmacy staff must determine the patient's need of a refill need before dispensing. Pharmacy personnel should not automatically refill KOP medication orders that are valid. Rather, the patient should request refills through the appropriate process designated by the facility.

D. Medication Renewals

Pharmacy staff must regularly alert providers of impending medications that are expiring by issuing the "Script Expiration Report" from the Correctional Institution Pharmacy Software (CIPS) Program. Providers review the report and patient health records to determine if they should continue or alter medication orders.

IX. CONTINUITY OF CARE

A. Intake Screening Medications

1. Patients who enter IHSC-staffed facilities on a verifiable prescription medication should continue to receive the medication. Health services staff document justification for an alternate treatment plan in the electronic health record. Custody staff must turn in all medications brought into IHSC-staffed facilities by patients to the health services staff during the intake health screening. Health services staff examine the medications, document the medications in the patient's health record, and consult with a medical provider, to determine if the medications are still necessary and appropriate for the patient, in accordance with the policies and procedures specified in IHSC Directive 03-16, *Medication Administration* and the associated IHSC 03-16 G-01, *Medication Administration Guide* located in the IHSC Policy Library.
2. All incoming medications are the property of the patient. Health services staff must transfer patients' personal medications to custody staff. Custody staff must place the medications into the patient's property, provided the patient does not have access to them, unless the patient agrees that destruction of the medication is appropriate.
3. If the provider determines the patient requires a medication when the pharmacy is closed, the intake nurse coordinates with the pill-line staff to continue the medication on the "pill-line." The pill-line staff administer the medication on a dose-by-dose basis until the pharmacist can process the new prescription. Health care staff can use the patient's personal medications as an interim supply, if the facility does not stock the medication or a comparable substitute. The pill-line staff must return all unused medication to the patient's property as soon as the pharmacy procures and dispenses the medication.
4. Health services staff may use only medications that are properly labeled on the tablet or capsule to indicate a legitimate manufacturer. Patients may keep short acting beta-agonist inhalers and sublingual nitroglycerin that are in their possession.

B. Transfer Medications

1. Pharmacy staff are responsible for the preparation of medication travel packs during pharmacy business hours, as determined by the facility's pharmacy local operating procedures or staffing schedule. Medications dispensed directly to patients upon release from custody require child resistant packaging. Pharmacy staff may provide non-child resistant packaging if the patient consents and the pharmacy staff member documents the packaging method in the medical record; or the product is exempt under the Poison Prevention Packaging Act (1970). Providers may designate a medication as "Not Required for Travel" during the initial order. Any medication order without this designation must be in the patient's travel or transfer medication supply. Pharmacists must dispense transfer or discharge supplies, and controlled substances, in accordance with the days' supply quantity requirements below, or through the duration of the written prescription, whichever is shorter.

   In the absence of a pharmacist or after pharmacy operating hours:

   a. Health services staff use the patients' pill-line supply as travel medications, if the medication supply is sufficient, and the prescription was verified and dispensed in accordance with IHSC policy.

   b. IHSC physicians verify and dispense travel medication prescriptions prepared by an IHSC pharmacy technician.

   c. Health services staff use the after-hours cabinet for travel medication supplies.

   d. Health services staff use after-hours procedures to obtain a medication supply from a local pharmacy.

2. Patients transferred from one detention facility to another must receive the following quantities of medication:

   a. A 15-day supply of medications as ordered by the prescribing authority.

   b. At least a 30-day supply of medications for the treatment of latent tuberculosis.

   c. At least a 40-day supply of HIV medications.

   d. A seven-day supply of insulin syringes for patients with an active order for insulin.

e. An unbroken unit for medications that are available only as a single unit-of-use (e.g., albuterol inhaler).

f. The CD may prescribe a greater supply after the RPC gives concurrence.

C. Discharge Medications

Patients released from ICE custody must receive the following medication quantities:

a. A 15-day supply of medication as ordered by the prescribing authority.

b. Up to a 90-day supply, on a case-by-case basis, based on the clinical director's judgement and specific patient circumstances.

c. A 30-day supply of medication for patients treated for HIV/AIDS or latent tuberculosis.

d. A seven-day supply of insulin syringes for patients with an active insulin order.

e. An unbroken unit for medications that are available only as a single unit-of-use (e.g., albuterol inhaler).

f. The CD, or designee, may prescribe a greater supply but must secure concurrence from the RPC.

X. NATIONAL PHARMACY AND THERAPEUTICS (P&T) COMMITTEE

A. Committee Responsibilities

The National P&T Committee ensures quality and cost-effective support of pharmacy-related clinical and administrative services, and compliance with national standards. This includes, but is not limited to:

a. Developing and maintaining a national formulary of pharmaceuticals.

b. Evaluating clinical data, literature, and field input to guide formulary modification.

c. Reviewing and re-evaluating the list of items available on urgent care carts and in first aid kits.

d. Reviewing reported drug experience and drug defect reports.

e. Providing recommendations regarding pharmacy directives, equipment, and space for effective and efficient pharmacy and medical supply management.

B. Committee Meeting

1. The committee membership consists of the following voting members:
   a. Chairperson - IHSC deputy medical director.
   b. Committee director - IHSC chief pharmacist.
   c. IHSC RPCs; regional clinical directors; IHSC chief APP and regional APPs; IHSC chief dentist and regional dentists; IHSC chief nurse and regional nurse managers; IHSC chief psychiatrist; senior psychiatric APP; and specialty consultants (i.e., infectious disease, cardiology).
   d. The committee chair and committee director determine further membership.
2. Members meet at least annually. The committee director discusses recommendations and follow-up requirements with the chairperson and prepares and disseminates an agenda at least five days prior to each scheduled meeting.
3. The committee director keeps a permanent record of minutes and associated documentation of activities on file. The committee director disseminates copies of minutes to committee members, the HSA and CD at each IHSC-staffed site.
4. HSAs disseminate meeting minutes to all medical staff. A copy of the meeting minutes and formulary document are made available to IHSC staff on the Pharmacy SharePoint site.

XI. CLINICAL PHARMACY COLLABORATIVE PRACTICE PROGRAM

A. Program Overview

1. The IHSC Clinical Pharmacist Collaborative Practice Program leverages pharmacists who deliver direct patient care, to optimize clinical patient outcomes and maximize patient safety. CPs manage disease states, provide clinical consultation and medication management services.

2. CPs manage disease states under collaborative practice agreements. They review, evaluate, and decide a patient's drug therapies. Disease state management involves selecting therapies to achieve the desired patient outcome. CPs perform patient assessments; use prescriptive authority; order, interpret and monitor laboratory tests; formulate clinical assessments and develop therapeutic plans; coordinate care and provide other health services to promote wellness and prevent disease; and develop partnerships with patients for ongoing care.
3. Board certified pharmacists provide clinical consultation services for patients located at remote sites. Pharmacists order medications, laboratory testing, and special needs accommodations. Any IHSC provider may refer or request services. The facility's supervising physician serves as the CP's collaborating physician. CPs located at facilities without an on-site physician may collaborate with their facility's acting clinical director or regional clinical director.
4. CPs provide medication management services. Their scope of practice includes:
    a. Review a patient's medical record to assess past drug use and medication compliance history.
    b. Measure and review patient vital signs.
    c. Conduct a focused physical examination and patient assessment.
    d. Order, interpret, monitor, and evaluate laboratory test results related to drug therapy. Tests include basic metabolic panel (BMP), comprehensive metabolic panel (CMP), complete blood count (CBC), liver function test (LFT), culture, drug levels, and sensitivity tests.
    e. Formulate a diagnosis for acute and chronic health conditions.
    f. Develop therapeutic plans and initiate, adjust, and discontinue medication regimens in accordance with IHSC treatment protocols.
    g. Counsel and develop partnerships with patients regarding drug therapy decisions and concerns. Additionally, provide care coordination, medication and disease state education, and other health care services to promote wellness and disease prevention.
    h. Assess the need for vaccinations, and order and administer immunizations.

i. Document clinical encounters in the IHSC Electronic Health Record. Medical documentation includes subjective data, objective data, assessments, and recommendations for treatment, referral, or follow-up.

5. The IHSC Medical Executive Committee grants CPs the authority to prescribe IHSC formulary medications, unless otherwise approved through the IHSC non-formulary approval process.

6. IHSC authorizes CPs to prescribe any IHSC formulary OTC medication. All licensed pharmacists have extensive education and training in common medical conditions and OTC medication treatments. CPs prescribe or administer IHSC formulary prescription medications as appropriate and approved by the U.S. Food and Drug Administration. The CP must follow the established IHSC non-formulary process to prescribe nonformulary medications. CPs prescribe controlled substances within the limits of their state licensure and IHSC policy or obtain co-signature by their collaborating physician. All CPs order and administer vaccinations in accordance with their state licensure and as clinically indicated by the Centers for Disease Control (CDC) Advisory Council on Immunization Practices recommendations.

B. Program Oversight

1. The IHSC chief pharmacist and the IHSC RPCs provide oversight and direction for the IHSC Clinical Pharmacist Collaborative Practice Program. The collaborating physician provides oversight for individual CPs, as CPs collaborate with multiple physicians in accordance with their facility's practice environment and state licensure requirements.

2. The chief pharmacist:

   a. Supervises and manages the IHSC clinical pharmacy program.

   b. Maintains and updates the IHSC forms specific to clinical pharmacy practice.

   c. Serves as a resource for the initiation of clinical pharmacist CPAs at IHSC-staffed facilities.

3. The IHSC RPCs:

   a. Monitor and report clinical pharmacy program performance measures reported by CPs.

   b. Conduct weekly case management sessions with CPs if needed.

c. Serves as a resource for the initiation of clinical pharmacist CPAs at IHSC-staffed facilities.

C. Qualifications, Credentialing, and Privileging

Pharmacists who wish to practice under a CPA must undergo credentialing, competency, and Medical Executive Committee reviews and approvals for authority to practice. Credentialing is a process that reviews the CP's qualifications, including career history, licensing, education, and training. See IHSC Directive 01-44, *Credentialing and Privileging* located in the IHSC Policy Library, for more information.

The IHSC Credentialing and Privileging Unit credentials and grants clinical pharmacists authority to practice under a collaborative practice agreement.

1. **Credentialing**: Pharmacists must meet one of the following requirements, in addition to their qualifying degree, to provide clinical care through a collaborative practice agreement:
   a. Certification in medication therapy management (MTM).
   b. National specialty board certification (e.g., BCPS, BCACP).
   c. American Society of Health System Pharmacists (ASHP)-accredited Post-Graduate Pharmacy Residency (PGY1).

Pharmacy specialty board certification is the highest professional credential for a clinical pharmacist and reflects extensive knowledge and understanding of acute and chronic condition diagnostic criteria and therapeutics. Completed the year after graduation, pharmacy residency programs exposure pharmacists to different clinical environments within a health care system. MTM certification indicates a pharmacist has completed training above the baccalaureate or PharmD level in appropriate management and documentation of care for acute and chronic illnesses.

2. **Competency:** The IHSC chief pharmacist, RPC, or the CP's collaborating physician or designee, conducts an initial competency assessment using the IHSC clinical pharmacist competency assessment form. The pharmacist must include the completed competency assessment in their credential file before the CP can submit a CPA for approval. This process repeats at least annually for the duration of the CPA.

3. **Authority to Practice:** Upon completion of the credentialing and competency process, the collaborating physician completes a CPA with the CP to authorize them to provide direct patient care services. CPs and physicians must agree on the disease states the CPs manage. IHSC pharmacists who are not federal employees or uniformed service officers may only enter a CPA with a physician who is licensed in the same state, unless the pharmacist's state of licensure or other federal legislation permits multi-state CPAs. Once all collaborating physicians, including the Medical Executive Committee, complete and approve the CPA and credentialing documents, the CP becomes an authorized IHSC clinical pharmacist.
4. The chief pharmacist or their designee notifies the IHSC electronic medical record team to change the CP's profile to that of a medical provider in the electronic health record. This change permits the CP to order medications and document therapies.
5. The HSA keeps a copy of the CPA in the pharmacist's credential folder. The IHSC Credentialing and Privileging Unit (ICPU) keeps a copy of all CPAs for all clinical pharmacists in their credentialing folder at IHSC headquarters. CPs and collaborating physicians must renew the agreement annually. The CPA is terminated if:
    a. IHSC no longer employs either the collaborating physician or CP.
    b. The CP is unable to maintain their board certification.
    c. At the request of the CP, collaborating physician, IHSC chief pharmacist, or IHSC deputy medical director.

D. Collaboration and Supervision

1. CPs are independent providers during their pharmacy duties but must operate under general physician supervision when performing direct patient care. General supervision is the availability of an appointed physician to consult with the CP and participate in chart review as noted in IHSC policy. The supervision can be face-to-face, telephonic, electronic, or written. This supervision does not require direct physical oversight but requires physician collaboration with the CP. The CP must participate in weekly case management discussions with the RPC or program designee, for three months after initiating a CPA. IHSC waives the case management review requirement for CPA renewals.

2. IHSC encourages pharmacists with and without board certification to practice under CPAs. CPs who are not board certified must discuss their scope of practice with their authorizing physician and specifically determine the disease states they can address. For all CPs, after the CP completes the initial patient encounter and formulates a treatment plan, the CP assigns their completed encounter to the collaborating physician for review and co-signature in the electronic health record. All initial encounters, critically abnormal laboratory test results (alert values), new diagnoses, and their respective treatment plans require review and co-signature by the collaborating physician. The collaborating physician or designee then reviews the encounter note, and provide feedback to the CP within 72 hours.

E. Clinical Care

CPs provide disease state management through medication therapy, preventative medicine, and nutritional and wellness education. The individual collaborative agreements between CPs and collaborating physicians specify the disease states CPs may diagnose and treat. Board-certified CPs are generally authorized to manage any previously diagnosed acute or chronic condition that is primarily managed by medication. In addition, CPs may provide patient assessment, diagnosis, and treatment of minor acute conditions, as delineated in their collaborative practice agreement.

CP intervention intends to achieve definitive outcomes that improve patients' quality of life. Outcomes include curing a disease; eliminating or reducing a patient's symptomatology; eliminating or reducing medication risks and adverse events; arresting or slowing a disease process; preventing a disease or symptomatology; and ensuring medication use is cost effective. Pharmacists must follow IHSC medical director-approved clinical guidelines, and nationally accepted disease state treatment guidelines for conditions where no IHSC medical director approved guideline exists.

F. Outcomes and Peer Review

IHSC requires peer review and drug use evaluation by all pharmacists who practice under a CPA. Peer review procedures for CPs are detailed in IHSC Directive 01-46, *Multidisciplinary Peer Review* located in the IHSC Policy Library. CPs must track applicable patient outcomes included in the IHSC National Performance Measures and report outcomes to the chief pharmacist or designee annually. CPs also record and provide clinical outcomes data to the PHS National Clinical Pharmacy Specialist Committee (NCPSC) to attain and maintain NCPS certification.

G. Referrals

IHSC APPs, physicians, or behavioral health providers may assign individual patients to the CP for follow-up care after they complete the patient's health assessment (PE-S or PE-C). CPs and collaborating physicians can add any patient to the CP's patient panel whose vital signs, lab values, diagnoses, or medications fall within the parameters of the CPA for weekly electronic health record report reviews without a physician or APP referral. After authorization from the collaborating physician, the CP requests consultation from the pharmacist for patients within their care.

XII. CONTINUITY OF OPERATIONS

A. Considerations

IHSC-staffed facilities face several hazards, including security threats, geologic events, severe weather, and manmade disasters. Responses to these disasters include continued operations at critical staff levels or without essential services, facility evacuation, or sheltering in place. Pharmacists are not expected to determine the type of response during an emergency but must provide assistance, if called upon. During a declared emergency or hazardous situation, pharmacy staff members execute the facility's emergency response plan and make efforts to continue pharmaceutical care. Staff must prioritize personal and patient safety over inventory and equipment. If an IHSC pharmacy suffers structural damage, the pharmacy leadership determine the disposition of the inventory. Any floodwater in a pharmacy or extended exposure to temperatures outside USP standards renders the entire stock unusable.

B. Hazardous Situations

1. **Interruption of Critical Services**: When faced with an interruption in critical services such as power or telecommunications outages, pharmacists have several options to maintain continuity of operations. In preparation, pharmacy staff should save copies of the IHSC pharmaceutical services directive and guide and important documents, such as the facility's DEA registration and off-line prescription spreadsheet, to their laptop hard drive (C:/ drive).
2. **Electronic Health Record Service or Network Connectivity Interruption**: If the electronic health record is unavailable for more than two hours during a business day, physicians, dentists, APPs, and CPs must order medications on hard copy prescriptions. The physicians, dentists, APPs, and CPs must document all written medication orders in the patient's health record on an SF-600 form and transcribe the prescription on an IHSC prescription form. All hard copy prescriptions must be complete and accurate, in accordance with Section III.B. of this guide.
3. If a network outage does not affect electronic health record and pharmacy systems, pharmacists should utilize government-issued smartphones to generate a Wi-Fi hotspot to connect to the ICE network through a virtual private network (VPN). Pharmacists use this method to access electronic pharmacy and electronic health record systems to process prescriptions.
4. If a system outage affects both the electronic health record and the pharmacy system, and a hotspot and VPN cannot restore connectivity, pharmacy staff should dispense prescriptions offline and record the prescriptions in an Excel database. The database should include all information required by IHSC Directive 09-02, *Pharmaceutical Services and Medication Management* located in the IHSC Policy Library.
5. Pharmacy staff should print prescription labels using an offline (USB port) printer and generate medication guides from Lexi-Comp, as required by the FDA. Offline printers or network printers that function with a USB cable can print labels. These devices do not store data or require additional encryption. Pharmacy staff should install off-line printer drivers as a precautionary measure to reduce disruption during an emergency. Installation must happen prior to an emergency, as driver installation requires administrative privileges and network connectivity. It is not possible to install drivers during an outage and network drivers are not compatible with USB port use.

6. When network connection and electronic health record services resume, physicians, dentists, APPs, and CPs must order the medications and electronically prescribe in the electronic health record to maintain an accurate medication list. Pharmacy staff must record the original prescription in the pharmacy system and add an "Rx Note" that it was originally filled off-line.

7. **Power Loss:** All IHSC pharmacies must maintain an uninterrupted power source (UPS) to prevent data loss during generator tests and provide battery backup capability in the event of an extended power loss. During a power interruption, if the facility generator does not provide emergency power within 5 to ten minutes, pharmacy operations should rapidly adapt to conserve power and extend the amount of time they can provide pharmaceutical services. Pharmacy staff must power down desktop computers and large network printers to minimize unnecessary power consumption.

    a. Pharmacy staff should only use a UPS to power laptop computers, smart phones, and USB-connected printers operating network interruption procedures. Other electronic devices should remain powered off or in sleep mode to conserve battery life.

8. **Evacuation**: IHSC pharmacy staff must maintain preparedness to evacuate their facility. During a facility evacuation, medication orders from IHSC physicians, dentists, APPs, and CPs at the sending site remain valid for 30 days from the patient's transfer date; any IHSC receiving facility can fill the order. If the patient returns to the original IHSC facility within 30 days, the order remains valid until its original expiration date.

    a. Urgent or Emergent Evacuation

        Pharmacy staff should ensure continuity of pharmaceutical care operations by prioritizing the survival of critical supplies and medications during urgent or emergency facility evacuations, as conditions permit. Emergent evacuations generally require staff to evacuate immediately, and urgent evacuations occur with less than 24 hours' notice. An example of an emergent evacuation would be in response to a fire within the facility, while an urgent evacuation would occur in response to an approaching brushfire. Pharmacists prepare "evacuation bags" with emergency pharmacy supplies in areas at high risk for sudden geologic or severe weather events.

These supplies include, but are not limited to:

- Government-issued laptop computers.
- Government-issued smartphones.
- Offline/USB-capable portable printer.
- Blank printed prescription forms.
- Blank printed prescription labels.
- Blank medication administration records.
- Envelopes, vials, and lids.
- Controlled substance perpetual inventory forms.
- Syringes and intravenous (IV) supplies.

b. Emergency medications.

- Insulin.
- Narcotics/controlled substances.
- Nitroglycerin.
- Antibiotics.
- IV fluids.

9. Facilities at high risk for evacuation should maintain supplies of lockable and temperature-controlled mobile containers to ensure rapid transfer of pharmaceutical inventory. The lead pharmacist must notify pharmacy leadership as soon as practicable following an urgent facility evacuation to request assistance, including the deployment of TDY staff.
10. Planned Facility Evacuation (>24 hours' notice). During a planned evacuation, the following processes must occur:
    a. Pharmacy leadership notification.
    b. The IHSC chief pharmacist and RPCs coordinate with the regional HSAs and Health Operations Unit chief to determine the feasibility of deploying TDY staff to an evacuating or receiving facility. Pharmacy leadership also coordinates the provision of remote pharmacy assistance.

c. Pharmacy staff process and dispense travel medications for all patients with acute or chronic medical conditions either remotely or on-site. Staff should ship the medication directly to the patient's sending or destination facility, depending on the circumstances. The pharmacist at the sending facility notifies the pharmacist at the receiving facility of pending transfers at the earliest opportunity. If an IHSC facility reverts to the use of paper medication administration records (MARs) due to a critical service interruption, pharmacy staff should print and include duplicate patient MARs or MAR labels with travel medication packs. Original MARs must not travel with the patients. Pharmacy staff at the sending facility retain the original MARs for record-keeping.

d. Secure pharmacy inventory:

- Pharmacy inventory may remain in place if the risk of flooding, structural damage, or extended loss of power is low. If the inventory is vulnerable to damage, pharmacy staff should protect government property by following the steps below, as appropriate:

  - Physically moving the pharmacy's medication inventory to another IHSC-staffed facility.
  - Prioritize shipment of vulnerable medications to another IHSC-staffed facility - refrigerated, high-cost, national shortage or backorder, or hard-to-acquire medications.
  - Elevate sensitive equipment 36 inches above floor level.
  - Secure all sharp instruments and bulk controlled substances in a locked safe or cabinet within the locked pharmacy.
  - IHSC pharmacists accompanying patients or inventory to another IHSC-staffed facility should maintain custody of the pharmacy laptop and smartphone.
  - Pharmacy staff transferring controlled substances should prepare the medications in tamper-resistant packaging for shipment. An IHSC pharmacist or physician must maintain secure and continuous custody of controlled substances until shipment or acceptance by the receiving facility.

11. **Shelter-in-Place:** IHSC can order staff at an ICE facility to shelter in place during an emergency. During a shelter-in-place event, pharmacy staff members either remain in the pharmacy or proceed to a safe and secure area within the facility as directed by on-site leadership. Pharmacy staff should secure the pharmacy and its inventory prior to moving to a safer location if it is safe to do so.

    a. The lead pharmacist must notify pharmacy leadership of planned shelter-in-place responses as soon as practicable. The notification enables the timely deployment of TDY pharmacist assistance.

    b. Pharmacists dispense 24- to 48-hour supplies of pill-line medications for KOP administration during a planned shelter-in-place event.

12. **Critical Staffing Shortage:** IHSC pharmacists, HSAs, or clinical directors must communicate with their respective RPC when pharmacies operate or plan to operate at less than 35% of their staffing model. During a critical staffing period, health services staff may receive cross training to assist with pharmacy technician duties. A pharmacist, or CD in the absence of a pharmacist, must verify all prescription orders prepared by non-pharmacist staff members prior to dispensing. Remote verification, remote fill, or TDY support can assist the pharmacy.

    a. If none of the above options are viable during a federal or state-declared emergency, a pharmacy technician or cross-trained health services staff member prepares urgent prescriptions on-site. An off-site pharmacist must verify the prescription using a secure videoconference line.

    b. The IHSC chief pharmacist and deputy medical director, in cooperation with facility administrative and clinical leadership, authorize facilities to expand KOP privileges in situations where excess patient movement contributes to an increased risk of patient harm or unsafe workload for on-site staff. In these situations, an IHSC physician, dentist, APP, and CP authorizes patients to self-administer (KOP) medications that are normally restricted to pill-line in the IHSC formulary. To authorize these medications as KOP, the physician, dentist, APP, and CP must document as such in each prescription. Pharmacists cannot dispense more than a two-week supply for an initial KOP fill, followed by another two-week supply before dispensing a 30-day supply. Psychiatric providers must provide written authorization for other providers to change their pill-line orders to KOP.

c. These privileges only impact medications in the below drug classes:

- Antidepressants [except for bupropion].
- Anticonvulsants for the treatment of epilepsy/seizure disorders.
- Antiretrovirals for the treatment of HIV or Hepatitis B.
- Buspirone.
- Oral anticoagulants.
- Tacrolimus.

C. Recovery Process

When returning to a facility after an evacuation or loss of critical services, pharmacy staff must conduct a complete inventory and inspect the pharmacy for damage. Pharmacy staff dispose of compromised pharmaceuticals via a reverse distributor or hazardous waste vendor, as appropriate.

Responding pharmacy staff members and pharmacy leadership should participate in an after-action review with the Public Health, Safety, and Preparedness Unit staff to determine successes, failures, and opportunities for process improvement.

XIII. PHARMACIST IMMUNIZATION SERVICES

IHSC pharmacists provide immunization services to patients without a provider order, in accordance with U.S. Centers for Disease Control and Prevention (CDC) guidelines and the pharmacist's state licensing board. To do so, pharmacists must complete appropriate immunization administration training. IHSC pharmacy personnel must administer immunizations to patients in accordance with national IHSC vaccination clinical guidelines.

Pharmacy technicians administer immunizations to patients under pharmacist supervision following successful completion of the American Pharmacist Association (APhA) Pharmacy-Based Immunization Administration by Pharmacy Technicians course.

XIV. REFERENCES

A. Forms

The following forms are available in the IHSC Approved Forms Library:

a. Pharmacist Initial and Annual Competency Form.

b. Pharmacy Technician Initial and Annual Competency Form.

c. Non-Formulary Medication Request Form.

d. Controlled Substances Custody Log.

B. Clinical Pharmacist CPA form

The clinical pharmacist CPA form are available on the IHSC Pharmacy SharePoint under IHSC Clinical Pharmacy CPA Forms.

C. After-Hours Medication Logs

Night cabinet/cart logs approved by IHSC pharmacy leadership are available on the IHSC Pharmacy SharePoint under the After-Hours Log Templates sub-folder.

D. Required Emergency Medications

The list of required emergency medications required by IHSC pharmacy leadership is available on the IHSC Pharmacy SharePoint under the Resources folder.

E. Script Care Forms

The following forms and resources are available on the IHSC Pharmacy SharePoint under the Pharmacy Benefits Letter folder.

1. Facility-Specific Pharmacy Benefits Letters.
2. List of Participating Pharmacies.

F. Site Visit Inspection Report

The pharmacy site visit inspection checklist used by the RPCs is available on the IHSC Pharmacy SharePoint under the Resources folder.

G. Continuity of Operations Reference Table

The pharmacy emergency preparedness and continuity of operations reference table is available on the IHSC Pharmacy SharePoint under the Continuity of Operations subfolder.

H. Clinical pharmacist scope of practice

The CPA for each clinical pharmacist is found at IHSC Clinical Pharmacy CPA Forms.