

EXHIBIT 3



Program Statement

OPI: HSD/HPB
NUMBER: P6360.01
DATE: 1/15/2005
SUBJECT: Pharmacy Services

1. **PURPOSE AND SCOPE.** To guide a broad spectrum of operations in the Bureau pharmacy program.

2. **PROGRAM OBJECTIVES.** The expected results of this program are:

An inmate's access to quality, necessary, cost-effective pharmaceutical care will be provided.

3. **DIRECTIVES REFERENCED**

P4100.04 BOP Acquisitions Manual (5/19/04)
P4500.04 Trust Fund/Warehouse/Laundry Manual (12/15/95)
P6010.02 Health Services Administration (1/15/05)
P6013.01 Health Services Quality Improvement Program
(1/15/05)
P6027.01 Health Care Provider Credential Verification,
Privileges, and Practice Agreement Program
(1/15/05)
P6031.01 Patient Care (1/15/05)
P6090.01 Health Information Management (1/15/05)
P6340.04 Psychiatric Services (1/15/05)
P6541.02 Over-the-Counter Medications (11/17/04)

21 CFR Chapter II, Part 1300

4. **STANDARDS REFERENCED**

a. American Correctional Association 4th Edition Standards for Adult Correctional Institutions: 4-4378 (M), 4-4379 (M), 4-4397 (M), 4-4401 (M), and 4-4402

b. American Correctional Association 3rd Edition Standards for Adult Local Detention Facilities: 3-ALDF-4E-17 **(M)**, 3-ALDF-4E-12-1 **(M)**, 3-ALDF-4E-18, 3-ALDF-4E-39, 3-ALDF-4E-42, and 3-ALDF-4E-43

5. **STAFFING.** Each institution will maintain a pharmacy directed by a professionally and legally qualified pharmacist and staffed by a sufficient number of trained personnel, in keeping with the size of the institution and the scope of medical services provided.

Consultant/contract pharmacists, if used, will provide the Health Services Administrator (HSA) with a written monthly report of pharmacy activities. The HSA will maintain this report on file.

6. **STANDARDS OF OPERATION.** Each institution will provide space, equipment, and supplies for the professional and administrative functions of the pharmacy to promote patient safety through the proper storage, preparation, dispensing, and administration of drugs.

a. The Chief Pharmacist will maintain up-to-date reference materials (computer-accessible or print), specifically:

- (1) Drug Information reference (e.g. Facts and Comparisons, American Hospital Formulary Service, MicroMedex, etc.);
- (2) Pharmacology/Pharmacotherapeutics reference (e.g. Goodman/Gilman's, Applied Therapeutics, Harrison's Internal Medicine, Dipiro);
- (3) Drug Interactions;
- (4) Drug Information for Patients; and
- (5) Internet access in the pharmacy.

b. Equipment in the pharmacy will include at least:

- (1) Adequate computer equipment including GroupWise access;
 - The Chief Pharmacist will be the owner of the institution pharmacy mailbox with proxy rights to a designee for leave purposes.
- (2) A refrigerator dedicated to and appropriately labeled, for the storage of medications and biologicals;
- (3) Adequate lighting and ventilation;
- (4) A sink with running water;

- (5) A system to monitor temperature control that meets compendia/Food and Drug Administration (FDA) standards. Medications are considered distressed and must be discarded if temperature controls are not maintained over a 48 hour time frame.
 - There must be either daily temperature control documentation or an electronic temperature control system that alerts staff to values outside standards.
- (6) The Bureau Correctional Institution Pharmacy System (CIPS) computer software system.

c. **Key Control And Accountability.** Only pharmacy staff (pharmacists and pharmacy technicians) and the off-shift duty provider will have keys to the pharmacy. Only the Chief Pharmacist and/or pharmacist-designee(s) will have access to the main stock of controlled substances.

- The key ring for the off-shift duty provider will have a key to the pharmacy, but not to the pharmacy storeroom or any key which would allow them access to main stock medications.
- Access to the controlled substances sub-stock is limited to the staff member who is responsible for the shift inventory of sub-stock. This staff member will sign the "sub-stock inventory certification sheet" for each shift.
- Each institution will develop local procedures for conducting the sub-stock shift inventory.
- The use of automated medication administration cabinets (e.g. SureMed, Pyxis) negates the need for shift inventories and proof of use (disposition) sheets for controlled substances, needles, and syringes.

7. **PROCEDURES AND OPERATIONAL PRACTICES.** The Chief Pharmacist will develop and maintain written procedures and operational practices pertaining to pharmaceutical services, in concert with the medical staff and, as appropriate, with representatives of other disciplines.

a. **Pharmacy and Therapeutics (P&T) Committee.** The Clinical Director (CD) will establish a Pharmacy and Therapeutics (P&T) Committee that will meet at least quarterly. Membership of the P&T Committee will be defined in institution policy and will

include, at a minimum, representatives from the medical (physician), psychiatric (if available), pharmacy, dental, and nursing staff, as well as Health Services Administration.

(1) **Meetings.** The required minimum agenda for this committee meeting includes:

- Determine what drugs on the National Formulary will be available locally;
- Determine what strengths and dosage forms will be available locally;
- Determine if any drugs on the National Formulary should be restricted further (i.e. designated as "Pill Line");
- Discuss and evaluate errors in prescribing, dispensing, and administering medications in the institution;
- Discuss and evaluate Adverse Drug Reactions that occur in the institution;
- Approve Drug Use Evaluations (DUEs) used in the institution;
- Review DUE data and track problems over time;
- Review changes in the National Formulary;
- Present drug information;
- Recommend that a "Request for Addition to Formulary" be completed for a specific drug; and
- Discuss Quality Improvement measures.

(2) **Minutes.** Local P&T Meeting minutes will be made available to all institution health services staff. An electronic copy of the minutes will be sent to the BOP Chief Pharmacist within 30 days of the end of the quarter. Institution P&T Committee Meeting minutes will contain:

- Date of meeting;
- List of attendees;
- Reading and acceptance of previous minutes;
- Policy and Procedure Review;
- Review of past issues;
- Formulary issues;
- Investigational drugs;
- Drug related research projects;
- Monitoring and enforcement activities;
- Medication recalls;
- Medication errors;
- Adverse drug reactions and monitoring;
- Quality Improvement activities;
- Pharmacy interventions;
- Floor stock medications;

- Drug Utilization Review;
- Completed DUEs;
- DUE proposals; and
- Overall and specific pharmaceutical cost trends.

b. **National Drug Formulary.** Each institution will use the Bureau's National Drug Formulary. The National Formulary will be issued following the publication of the National Pharmacy and Therapeutics and Formulary Meeting Minutes.

Authorization for use of items not in the national formulary must be requested from the Medical Director through the BOP Chief Pharmacist, using the "Non-Formulary Drug Authorization" form (BP-S802).

- The form will be completed and sent to the Chief Pharmacist for each medication order requesting a non-formulary item.
- The completed "Non-Formulary Drug Authorization" form will be sent electronically upon receipt of this module from the pharmacy software vendor.
- Emergency requests may be made by phone.
- The institution pharmacy will maintain a copy of all approved and disapproved non-formulary requests. The original will be filed in section 6 of the Health Record.
- Prescribing a formulary medication against a restriction placed on it during the National P&T meeting requires a non-formulary drug authorization unless otherwise stated in the formulary.
- A new non-formulary request is not required for intra-system transfers who previously had a non-formulary medication approved. The approved form, located in Section 6 of the Health Record, will be copied and retained in the pharmacy of the current institution.

The "Request for Addition to Formulary" form (BP-S804) must be used to request a drug item be added to the National Formulary. This form should be routed through the local P&T Committee and then sent to the BOP Chief Pharmacist.

- All requests will be reviewed at the annual National Pharmacy and Therapeutics (P&T) Meeting.

- Recommendations for formulary deletions, restrictions, etc., must also be submitted on this form.

Updates to the National Formulary will be published regularly following National P&T review. Comments and suggestions should be directed to the BOP Chief Pharmacist.

Unless indicated as a non-substitutable product (i.e. negative formulary), proprietary (brand) names are used as examples for identification purposes only. All institutions will use the least expensive A/B rated generic when possible. "Dispense as Written" (DAW) orders will be processed as a non-formulary medication order and must include appropriate justification from the prescriber.

The institution P&T Committee may use a local formulary based on the National Formulary.

- A local formulary can only be more restrictive than the National Formulary. Medications may not be added or restrictions removed.
- Local formularies will be made available to all of the institution's health services staff and consultants.

c. **Training and Education.** Pharmacy personnel will participate in relevant education programs, including orientation of new employees, in-service, and outside continuing education. The institution Chief Pharmacist will maintain participation documentation.

All health care providers performing pill line, physicians, and pharmacy technicians will complete pharmacy orientation as part of the Health Services Orientation. These staff will have documentation in their credentialing file indicating they have completed the Pharmacy Services Orientation, before beginning work in the Pharmacy.

- After completing this orientation, these providers can **administer** medication doses, or **distribute** medication orders to inmates, but they cannot **dispense** medication orders.

d. **Patient Safety.** The institution Chief Pharmacist will ensure there are written procedures in place for patient safety and the control, accountability, and distribution of drugs. These procedures will be reviewed/revised annually, as necessary, and are subject to local negotiation.

- All drugs will be labeled adequately, including the addition of accessory or cautionary statements, and the expiration date, if appropriate.
- Discontinued and outdated drugs and containers with worn, illegible, or missing labels will be returned to the pharmacy for proper disposition.

e. **Dispensing Medication Orders.** Before a medication order is dispensed, a pharmacist will review it prospectively for the following:

- drug/drug interactions;
- drug/disease interactions;
- drug/food interactions;
- therapeutic duplications;
- over use/under use;
- allergies;
- therapeutic appropriateness;
- appropriate dose;
- appropriate route of administration;
- duration of therapy;
- adverse drug reactions;
- proper laboratory monitoring;
- appropriate clinical outcomes; and
- provide the final check of the medication order to ensure it contains the correct drug.

The label will contain the correct directions and patient information pursuant to the medication order. Proper cautionary statements will be included on the vial.

Any items which are changed must be documented in the Health Record justifying the need for the change.

A practitioner with "independent status" (i.e. physician or pharmacist) must check each medication order before it is dispensed to the patient, ensuring the appropriate prospective review has been completed.

- Although dentists have "independent status" they are not allowed to dispense as a majority of medications fall outside the scope of their practice.
- Health care providers, such as MLPs, EMTs, nurses, medical technicians, and pharmacy technicians do not have independent status. As such, health care providers will not be assigned Pharmacist duties.

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- (1) In order to satisfy these requirements during evenings and weekends, each institution will use a "drug administration cabinet". This may be as sophisticated as a Pyxis Medstation, a Meditrol, or a Documed Station, or as simple as a locked, metal cabinet in the urgent care room, or a designated area in the pharmacy.
 - This cabinet will contain a limited number and supply of urgently needed drugs that are commonly used after hours in the institution.
 - These drugs should be in single dose or single day packages but in some cases may be in a three day supply to ensure coverage for weekends and holidays.
 - These medications will be pre-labeled with standard directions and the name and strength of the drug.
- (2) When the after-hours health care provider needs to give an inmate a medication, the following options will be used.
 - (a) The inmate may be placed on pill line to be administered single doses of the prescribed medication until a medication order can be dispensed.
 - (b) The health care provider may access the off-shift drug administration cabinet, remove a pre-packaged container, and:
 - write the inmate's name and number;
 - the date;
 - the provider's name;
 - the expiration date on the package; and
 - distribute it to the inmate.
 - (c) A medication order will be written for the pharmacist to review retrospectively.
 - (d) A log book will be maintained for the off-shift medication cabinet, to record drugs and doses that are distributed from the cabinet. The log book will contain:
 - date;
 - time;

- inmate name;
 - register number;
 - drug;
 - amount dispensed; and
 - provider's signature.
- (e) Where an automated medication distribution system is used as the drug administration cabinet, the distribution/administration report will provide documentation of these occurrences in lieu of the log book.
- (f) The next working day, the pharmacist will:
- enter the order into the pharmacy computer;
 - review the order retrospectively;
 - fill the order for the amount written less the dose(s) distributed or administered by the health care provider;
 - provide a "final check" of the medication order; and
 - dispense the completed order to the inmate.
- (g) The practice agreement for MLPs will state specifically they may access the drug administration cabinet and pill line stock. **Pill line stock will not be bulk stock containers.** Local procedures will specify the system in use at each institution. Pill line stock may include:
- unit-dose packaging appropriately labeled;
 - medication order labeled vials with a seven to 30 day supply of the inmate's medication;
 - heat-sealed blister cards filled or checked by the pharmacist; and
 - automated medication administration cabinets (e.g. Pyxis Envoy).
- (h) Non-pharmacist health care providers will not have access to bulk stock packages that would permit them to actually dispense a medication order or administer doses.
- The only exception to the above is described in Section 9.c.

- (3) Inmates transferring to other institutions in/out of the Bureau will have their medications listed on a Medical Summary of Federal Prisoner/Alien in Transit (BP-S659) form, which is delivered in a timely manner to the pharmacy for processing.

f. **Inspections.** The Chief Pharmacist or designee will conduct at least quarterly inspections of all areas where medications are dispensed, administered, or stored. The Chief Pharmacist will maintain a record of quarterly inspections for at least two years.

g. **Drug Monitoring.** The Chief Pharmacist will provide drug monitoring services keeping with each patient's needs, FDA and manufacturer recommendations, and practices recommended through drug information references.

8. **DEA CONTROLLED SUBSTANCES**

a. **Applicability of Federal Law.** Drug Enforcement Administration (DEA) controlled substances are drugs and drug products under jurisdiction of the Controlled Substances Act of 1970 and are divided into five schedules (I, II, III, IV, and V).

- Nothing in this chapter will be construed as authorizing or permitting any person to engage in any act that is not authorized or permitted under existing federal laws, or that does not meet regulations published in the most recent edition of Title 21, Chapter II, of the Code of Federal Regulations (21 CFR, Part 1300 to end).

Application for a new or renewed registration number under the Controlled Substances Act includes the following procedures.

- (1) To obtain an initial DEA registration number, each Chief Pharmacist will complete and forward a New Application for Registration form (DEA-224), to the BOP Chief Pharmacist for certification.
 - For renewal, Form DEA-224a will be sent to the Central Office, Attn: Chief Pharmacist, BOP, 320 First Street NW, Washington, DC 20853 for certification (there is no cost for new or renewal registration).
 - The BOP Chief Pharmacist will verify fee exemption status.
 - The phone number for DEA registration and renewal is 1-800-882-9539.

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- (2) "Registration Classification" on Form DEA-224 will be checked as "hospital/clinic." There will be only one official registration number for each Bureau institution.
- (3) The DEA registration number will be used only for official federal business.
- (4) The BOP Chief Pharmacist will forward the certified form to the DEA, which will send the new or renewed registration number to the institution.
- (5) The institution Chief Pharmacist will complete and submit these forms. At institutions without a pharmacist on staff, the HSA will retain this responsibility.

b. **Responsibility.** The Chief Pharmacist will be the responsible authority for all DEA controlled substances. The main stock will be kept locked and stored in a vault or safe to which only the Chief Pharmacist and/or pharmacist designee(s) has the combination or keys.

- The HSA will ensure that a duplicate set of keys or combinations of all vaults and safes in the HSU will be sealed in separate envelopes, plainly marked with contents, and filed in the Warden's or security officer's vault or safe.
- The Chief Pharmacist or designee must be present for any inventories, inspections, searches, or shakedowns of the storeroom, vaults or safes.
- The Chief Pharmacist will ensure that all combinations or locks to main stock vaults or safes storing DEA controlled substances are changed:
 - (1) At transfer, reassignment, or termination of applicable HSU administrative or pharmacy personnel, or
 - (2) When unusual circumstances dictate increased internal control measures.

c. **Purchasing/Receiving.** Purchase orders for controlled substances will be prepared by a designated employee without the knowledge or assistance of inmates.

- Controlled substances will be stocked in single-dose packaging when available.

- The Chief Pharmacist will establish a proper system of security for their receipt.

d. **Records.** The pharmacist will maintain adequate main stock records for each controlled substance. Headings will indicate:

- sub-stock unit;
- date;
- record number/P.O. number;
- quantity received;
- quantity issued to sub-stock; and
- balance on hand.

Sub-stock records address the administration of medication on medical/nursing units or on pill line. Sub-stock will have records maintained for proof of use for each DEA controlled substance on hand. Each proof of use sheet will contain:

- name and strength of drug;
- date issued;
- amount issued;
- pharmacy control number;
- department location (if applicable);
- date and amount returned;
- date and time of administration;
- name and number of inmate;
- dosage administered;
- corresponding medication order number (CIPS);
- signature of person administering; and
- balance on hand.

The completed proof of use sheet will be returned to the pharmacy, and kept with controlled substances records.

At the start of each shift, staff will conduct a complete DEA sub-stock inventory in accordance with local procedures. If the inventory is not correct, staff will attempt to resolve the differences immediately.

- The staff member discovering the discrepancy will write a memo to the Chief Pharmacist explaining the event.
- If the discrepancy is not resolved, the Chief Pharmacist or designee, will notify the HSA, to ensure that its possible cause(s) is identified.
- For institutions using a computer driven medication station, the pharmacist will generate sub-stock discrepancy reports daily.

- The pharmacist will review and sign these reports and file them with the controlled substance main stock records.

The staff member completing the sub-stock inventory certification sheet will return it to the pharmacy. The pharmacist will review and retain the forms for two years prior to the last federally mandated biennial inventory. The change of shift record will include:

- date and time of the count;
- signature of off going and oncoming staff; and
- exact quantity of all controlled substances on hand in that sub-stock at that time.

The use of automated medication administration cabinets (e.g. SureMed, Pyxis) negates the necessity for shift inventories, proof of use sheets, and disposition sheets for DEA controlled substances, needles, and syringes.

All inventories and listings in the controlled substance records will be exact using tablets, capsules, vials, etc., not in units of bottles or other bulk measurements.

When a Chief Pharmacist permanently departs from an institution, he/she and the oncoming Chief Pharmacist (or the acting Chief Pharmacist or the HSA) will complete an immediate inventory of:

- main stock controlled substances;
- perpetual inventory;
- purchase orders;
- federal order forms;
- receivers; and
- invoices.

When a newly selected Chief Pharmacist arrives at an institution, he/she and the HSA will complete a similar inventory immediately.

Controlled substances in sub-stocks are to be used for administration only. Any dispensing of controlled substances will be accomplished through main stock.

e. **Security.** The DEA, per 21 CFR Part 1301.72, requires safeguarding and accounting for all controlled substances.

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- Main stock controlled substances will be stored in a vault or safe.
- Sub-stock controlled substances will be stored in a stationary, approved steel cabinet with two separately key-locked steel doors, a safe with a keyed padlock, or an automated medication cabinet (e.g., SureMed, Pyxis).
- When a controlled substance requires refrigeration, the medication must be secured in a locked refrigerator or in a locked drawer within the refrigerator.

f. **Biennial Inventory.** The Controlled Substances Act requires each registrant to make a complete and accurate record of all controlled substance stock on hand every two years. The Chief Pharmacist will complete the biennial inventory on the date mandated by federal law (May 1 of odd-numbered years for institutions registered before May 1, 1971; for institutions registered after May 1, 1971, every two years on the date of the initial inventory).

The actual taking of the inventory will not vary more than four days from the biennial inventory date. The Chief Pharmacist will maintain the inventory with the controlled substances records. The inventory record must:

- (1) List the registrant's name, address, and DEA registration number;
- (2) Indicate the date and time the inventory is taken (i.e., opening or close of business);
- (3) Be signed by the person or persons responsible for taking the inventory;
- (4) Be maintained at the location appearing on the registration certificate for at least two years prior to the last federally mandated inventory;
- (5) List the name of each controlled substance;
- (6) List the dosage form and unit strength of each controlled substance;
- (7) List the number of units in each container of each controlled substance;
- (8) List the number of each container of each controlled substance;

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(9) Separate Schedule II controlled substances from all others; and

(10) Include main stock and all sub-stocks.

g. **Additional Auditing Requirements.** Corrected or amended medication orders may not be processed for controlled substances. A new medication order will be written.

Any record keeping error will be corrected by the person who made the error by drawing one line through the error, writing an explanation directly below, and initialing. Errors may not be "blacked out."

(1) **Theft or Loss.** Any incident of theft or loss must be documented by the individual discovering it. A copy of the documentation will be sent to the Chief Pharmacist for review and filing. The Chief Pharmacist will in turn send a memo to the HSA, with a copy to the Warden. The Warden will notify the DEA via DEA Form 106.

In accordance with 21 CFR 1301.76(b), the DEA Form 106 must contain:

- (a) Name and address of the facility;
- (b) DEA Registration Number;
- (c) Date of the theft;
- (d) The fact that the local police department was notified;
- (e) The type of theft;
- (f) A list of the symbols or cost code (if any) used by the facility; and
- (g) A list of the controlled substance(s) missing.

The report is made in triplicate. The pharmacy keeps the original copy, and forwards the other two copies to the Regional DEA Office.

(2) **Controlled Substances Inventory Team.** The HSA will designate, in writing, a Health Services supervisor as Chair of the Quarterly Controlled Substances Inventory Team. The Controlled Substances Inventory Team will consist of the chair and at least one other supervisor.

- The Chief Pharmacist will be a technical advisor and will be present during the inventory, but may not be a team member.

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- The team will conduct a quarterly count of all main stock controlled substances.
 - Each team member will then sign the Quarterly Controlled Substance Audit Team Certificate form to be filed with the controlled substance records. A copy of this form does not need to be sent to the BOP Chief Pharmacist.
 - This count may be done at anytime within the time frame of the quarter.
- (3) **Quarterly Report.** At the end of each quarter, the Chief Pharmacist will complete a Quarterly Report for Narcotics and other Controlled Substances inventory form. An electronic copy will be submitted to the BOP Chief Pharmacist within 30 days of the end of the quarter. Each quarterly report will reflect the usage pertaining to the following dates (variance from these dates will not be allowed):
- 1st Quarter = October 1 to December 31
 - 2nd Quarter = January 1 to March 31
 - 3rd Quarter = April 1 to June 30
 - 4th Quarter = July 1 to September 30

h. **Disposal.** The Chief Pharmacist or designee will dispose of controlled substances when necessary, in the manner prescribed by the DEA in 21 CFR 1307.21.

This disposal will be accomplished in one of two methods:

- (1) Request from the Special Agent-in-Charge at the Regional DEA Office, in writing, that permission be granted for the facility to self-dispose of controlled substances; or
- (2) By transfer to a DEA approved vendor that is certified to dispose of controlled substances.

9. **DISPENSING AND ADMINISTRATION**

a. **Definitions**

- (1) **Administration** is defined as providing one dose of medication to be applied or consumed immediately.
- (2) **Dispensing** is defined as placing multiple doses in a properly labeled container for use over a period of

time, i.e., filling a medication order. Dispensing is the act of prospectively reviewing the medication order as described in Section 7.e.

- Only pharmacists may dispense medications.

- (3) **Distribution** is defined as physically handing a filled medication order or OTC (over-the-counter) product to an inmate. Any health care provider who has completed the Pharmacy Training and Orientation Program can distribute or administer medications.

b. **Prescribing Restrictions.** All DEA controlled substances, psychiatric medications, and other medications restricted to "physician use only" by the BOP National Formulary prescribed by a MLP must be countersigned by a staff physician before the medication order may be processed and dispensed.

- Local policies will address a process of review in the absence of a full time physician.

c. **Options During the Absence of the Pharmacist.** During periods when a pharmacist is not available (e.g. annual refresher training, CME, etc.) one of the following options will be used:

- **Contracting (Amend Existing Contract).**
Incorporate a requirement for pharmacist back-up coverage in the comprehensive medical contract.
- **Contracting (Establish Separate Contract).**
Contract with a firm that is capable of providing temporary pharmacist services using open market procurement procedures or existing Federal Supply Schedules (FSS). The Bureau of Prisons Acquisition Policy (BPAP), Part 37, stipulates various requirements relating to using private sector temporary services. The Chief Executive Officer and Regional Director must approve a written justification prior to the acquisition.
- **Interagency Agreements.** Establish an interagency agreement with another government agency (e.g., VA or DOD) to provide pharmacist coverage on an "as needed" basis.
- **TDY Within the Bureau.** Arrange/plan for TDY pharmacist assistance from another Bureau institution with more than one pharmacist.

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- **Use PHS Officers from Outside the Bureau.** Secure TDY assistance from PHS officers assigned to other government agencies. (The institution needing the pharmacist is responsible for travel, lodging, and per diem.) The BOP Chief Pharmacist can help identify pharmacists in this category **or** use a PHS inactive reserve corps officer through the BOP-PHS liaison and the PHS Inactive Reserve Coordinator.
- **Obtain the Services of a Second Pharmacist** for larger institutions, particularly those with a satellite camp or FDC. In this situation, pharmacy hours of operation could be extended, vacations, training, and sick leave covered, and quality services can be maintained.

Physicians are responsible for diagnosing and treating patients and may only dispense medications in emergency situations. All of the above options must be actively pursued and exhausted. Institutions without the services of a pharmacist for more than three days will contact the Medical Director for guidance.

d. **Administration.** To ensure that medications are actually consumed at pill line, the following procedures will be followed.

- The pharmacist or pharmacy technician will prepare a CIPS-generated Medication Administration Record (MAR) sheet for use at pill line.
- The person administering the medication will identify each inmate by examining two forms of identification (e.g. photo ID, DOB, registration number, name, etc.) of anyone who arrives to receive medication.
- The inmate will swallow the dose of medication and the water while being observed directly by the staff member.
- The inmate will then show the empty dose cup and water cup to the person conducting pill line before disposal.
- The inmate will be asked to open his/her mouth to show that the medication has not been "cheeked" before leaving the window.
- Medications should not be removed from their packaging or labeling until being administered.

- The administration of medication should be documented in the MAR after it is completed.
- When an inmate refuses to take a prescribed pill line or inpatient administered medication, or is a "no-show," that decision will be documented on the MAR.

Unless local institution security requirements dictate otherwise, medication dispensing will be in light-resistant, moisture-resistant vials and not plastic bags.

e. **DEA Controlled Substances.** The physician or dentist will initiate or countersign the medication order in the health record which will include:

- controlled substance;
- DEA number;
- strength;
- directions; and
- duration of therapy.

Health Services staff may accept a verbal order, but the physician or dentist must countersign the verbal order within 24 hours or by the close of the next workday.

Schedule II controlled substance orders will be valid for 72 hours only (with the exception of detox medications). Schedule III, IV, and V orders may be written for not more than 30 days.

- An exception to this requirement is when DEA controlled substances are used for seizure disorders unless otherwise restricted in the BOP National Formulary. Then, medication orders can be written for up to 180 days.
- All orders for controlled substances used for hypnotic purposes will be valid for not more than seven days.
- All orders for substances (Schedule II - V) used in cases of chronic or terminal illness resulting in unremitting pain not likely to abate in the short term and drugs used for narcolepsy or ADHD will be valid for up to 30 days.
- All such orders must be supported by on-going documentation in the health record or inpatient record.

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Accountability. Consistent with 21 CFR, Part 1300, Section 1304.4, the Chief Pharmacist will maintain all records pertaining to purchase, administration, inventory, and audits for at least two years prior to the most recent federal biennial inventory. These records will be kept in a vault, safe, or other secure area. No other items may be stored with DEA controlled substances or their records.

- Daily, the pharmacist will generate a CIPS controlled substance report. The report will be maintained with other controlled substance documentation in accordance with DEA regulations.

Controlled substances that are damaged, expired, or retrieved from inmates through R/D will be segregated in the safe from other controlled substances.

- A separate "Outdate & Confiscate" log will serve as an inventory as long as the medications are in the facility.

Ordinarily, all DEA controlled substances taken by mouth will be crushed or administered in liquid form. Pharmacy staff will issue crushed medication in single dose packaging already crushed.

f. **Restricted Drugs.** Restricted drugs are defined as non-DEA controlled drugs that may be abused or those that require Directly Observed Therapy (DOT). Ordering, prescribing, dispensing, and accounting for restricted medications will be in accordance with local and Bureau procedures.

The Chief Pharmacist will ensure that medication is not subject to excessive exposure to heat, light, and moisture.

All restricted drugs to be taken by mouth will be administered in single doses, and swallowed in the presence of an employee to ensure that the medication is ingested, in accordance with the procedures outlined in Section 9.d.

g. **Medication Orders.** A medication order is any medication a health care practitioner orders for a patient. A health care practitioner will reevaluate each medication order prior to writing a renewal order.

- All medication orders for chronic care medications are valid for no more than 30 days with five refills totaling 180 days (**except for controlled substances unless used for seizure control and other medications specifically restricted by the BOP National Formulary**).
- When available, the Prescriber Order Entry (POE) will be used to prescribe and process all medication orders. This does not negate the need for the pharmacist to have access to the patient's health record.
- Local CIPS data will be backed up each work day.

All institutions will have a system(s) in place for ensuring medications not picked up by inmates are logged into the CIPS computer system along with documentation in the inmate health record.

The distribution of drug samples within the institution is prohibited.

A staff physician will review and cosign orders written by consultant physicians.

- The pharmacy department will have a means to identify the signatures of all staff practitioners authorized to prescribe.

When an inmate is hospitalized, undergoes surgery, or is transferred from outpatient to inpatient status, or inpatient to outpatient status, current drug orders are to be discontinued automatically.

- Local procedures will determine automatic stop orders for drugs in other circumstances. (Stop order dates for DEA controlled substances are addressed in Section 9.e.

All medications arriving with inmates through receiving and discharge as new commitments will be given to the Chief Pharmacist or designee.

- The Chief Pharmacist will dispose of all DEA controlled substances in a manner prescribed by the DEA.
- Pharmacy staff will dispose of all other medications according to local procedures.

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- During the intake screening process, health care staff will determine the need for any medication orders. The Pharmacy will ensure that adequate supplies are on hand prior to disposal. These medications, if appropriate, will be administered on pill line until the pharmacy is able to obtain the drug(s).
- An inmate may retain medications prescribed by another Bureau institution if they are not otherwise restricted by policy (e.g. controlled substance).

h. Medications for Inmates in Special Housing Units (SHU).

Every workday, the Chief Pharmacist will obtain a list of all inmates placed in a SHU during the previous 24 hours (e.g. SENTRY, Operations Lieutenant). Using this list, the pharmacist will issue current medication(s) and ensure the MAR is available for administration of all restricted medications during SHU rounds.

- Local procedures will be developed and negotiated to retrieve the inmate's confiscated medication. Health Services staff will determine if the medication should be administered or redistributed to the inmate, if appropriate.
- Local policies and procedures will stipulate the medication(s) and amount (number of days) an inmate in SHU may maintain in their cell.
- Under no circumstances will medication be locked up with the inmate's property, thrown in "hot trash," or distributed or administered to an inmate by anyone other than a health care provider.

i. Psychiatric Medication. Refer to Program Statement on Psychiatric Services for procedures on obtaining informed consent, non-compliance, and patient counseling.

Informed consent will be obtained and documented before dispensing or administering psychiatric medication. Ordinarily, the prescribing physician will be responsible for obtaining the informed consent.

- Psychiatric medication for a current DSM Axis III diagnosis does not require an informed consent (e.g. amitriptyline for trigeminal neuralgia or headache disorder), but does require routine patient counseling procedures.

(1) **Continuity of Care.** All institutions will have a system(s) in place for ensuring continuity of care for all inmates receiving psychiatric treatment. This system will include:

- Review of psychiatric history prior to incarceration;
- Review of psychiatric treatment prior to intra-system transfer;
- Monitoring compliance with psychiatric medications; and
- Maintaining documented informed consent in the health record.

(2) **Non-Compliance.** All institutions will have a system(s) in place for timely notification of noncompliance. Such notification will be made to the CD and other relevant mental health staff, such as the Chief of Psychology, treating staff, or contract psychiatrist.

- At Psychiatric Referral Centers (PRCs), the treating psychiatrist and Chief Psychiatrist will be informed of any noncompliance issues.

j. **OTC Medications.** See the Program Statement on Over-the-Counter Medications.

k. **Outdated Medications.** The Chief Pharmacist will maintain adequate records and procedures to ensure that outdated medications are not used.

- Expired medications must be stored separately.
- Expiration dates will be the last day of the month unless otherwise specified.
- Local procedures will be written for disposal of expired medications.

When multi-dose vials of injectable medications are opened, the expiration date will be regarded as the manufacturer's expiration date as long as aseptic technique is used, unless otherwise stated by the manufacturer in the package labeling.

l. **Hormone Maintenance Drugs.** Refer to the Program Statement on Patient Care.

m. **Investigational/Experimental Drugs.** Refer to the Program Statement on Patient Care.

10. **MEDICATION ERRORS**

a. **Definitions**

- (1) A **medication error** is a dose of medication that deviates from the physician's order as written in the inmate's health record or from the expected standard of care, or institution policy and procedures.
 - With the exception of errors of omission, the patient must actually receive the drug for the incident to be classified as a medication error.
- (2) A **potential error** is a mistake in prescribing, dispensing, or planned medication administration that is detected and corrected through intervention, by another health care provider or the inmate, before actual medication administration.
 - Documentation of instances in which an individual has prevented the occurrence of a medication error will help identify system weaknesses and reinforce the importance of multiple checks in the medication use system.

b. **Types of Medication Errors.** Based on the American Society of Health Systems Pharmacists (ASHP) Guidelines, medication errors will be categorized as follows:

- **Prescribing Error.** An incorrect drug selection (based on indicators, contraindications, known allergies, existing drug therapy, and other factors), dose, dosage form, quantity, route, concentration, rates of administration, or instructions for using a drug product ordered or authorized by a physician (or other legitimate prescriber). This includes illegible medication orders that lead to errors that reach the patient.
- **Omission Error.** The failure to administer an ordered dose to a patient before the next scheduled dose, if any.
- **Wrong Time Error.** Administration of a medication outside a predefined time interval from its scheduled administration time.

- **Unauthorized Drug Error.** Administration to the patient of medication not authorized by a legitimate prescriber for the patient.
- **Improper Dose Error.** Administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber or administration of duplicate doses to the inmate.
- **Wrong Dosage Form Error.** Administration to the patient of a medication in a different dosage form than ordered by the prescriber (e.g., intramuscular instead of intravenous).
- **Wrong Drug-Preparation Error.** Medication incorrectly formulated or manipulated before administration.
- **Wrong Administration Technique Error.** Inappropriate procedure or improper technique in the administration of a drug.
- **Deteriorated Drug Error.** Administration of a medication that has expired or for which the physical or chemical dosage form integrity has been compromised.
- **Monitoring Error.** Failure to review a prescribed regimen for appropriateness and detection of problems, or, failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.
- **Compliance Error.** Inappropriate patient behavior regarding adherence to a prescribed medication regimen.
- **Other Medication Errors.** Any medication error that does not fall into one of the above predefined categories.

c. **Applicability and Procedures.** Listed below are the required elements of the institution's Medication Error Program. The Pharmacy Technical Reference Manual (TRM) should be used as a reference for the institution program.

- The monitoring and reporting of medication errors will be conducted in a **blame-free** manner and focus primarily on systems and continuous quality improvement activities rather than on individuals.

(1) **Organizational Responsibilities.** Sufficient personnel must be available to perform tasks adequately and a suitable work environment must exist for preparing drug products.

- Lines of authority will be clearly defined for medication ordering, dispensing, and administration.

A formal Drug Use Evaluation (DUE) program will be integrated and coordinated with the overall institution Quality Improvement Program (QIP). The institution's QIP will include monitoring, evaluation, and resolution of problems in the area of quality and appropriateness of patient care services the pharmacy department provides.

- Pharmacists and others responsible for processing medication orders will have routine access to appropriate clinical information and patients (including medication, allergy and hypersensitivity profiles; diagnoses; pregnancy status; and laboratory values) to help them evaluate the appropriateness of medication orders.

Pharmacists will maintain medication profiles for all patients, both inpatients and ambulatory patients, who receive care at the institution. This profile will include adequate information to allow monitoring of the following:

- medication histories;
- allergies;
- potential drug interactions and Adverse Drug Reactions (ADRs);
- duplicate drug therapies;
- pertinent laboratory data; and
- other information.

The Pharmacy Department must be solely responsible for procuring, distributing, and controlling all drugs used within the organization.

- The preferred administration method is the unit dose drug distribution and control system.

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- Comprehensive policies and procedures that provide for efficient and safe distribution of all medications and related supplies to patients will be established.
- Except in emergencies, all sterile and non-sterile drug products will be dispensed from the pharmacy.
- The storage of non-emergency floor stock medications on the nursing units or in other patient care areas will be limited to OTCs and stat dose quantities of selected drugs.
- Only abbreviations approved in the Program Statement on Health Information Management may be used.

The telephone number of the local **poison control center** will be displayed prominently in the pharmacy and readily available in areas where medications are dispensed/administered.

The pharmacy department, in conjunction with nursing, risk management, QIP, and the medical staff, will conduct ongoing educational programs to discuss medication errors, their causes, and methods to prevent their occurrence.

- (2) **Prescriber Responsibilities.** Prescribers will evaluate the patient's total status and review all existing drug therapy before prescribing new or additional medications.

- Prescribers will be familiar with the medication use system in place within the institution (e.g., the formulary system, DUE programs, allowable delegation of authority, procedures to alert nurses and others to new drug orders, standard administration times, and approved abbreviations).

Medication orders written in the health record and inpatient record, must be complete and will include:

- drug name;
- route and site of administration;
- dosage form;
- dose;
- strength;
- frequency of administration;

- duration of therapy; and
- prescriber's name.

In some cases, a dilution, rate, and time of administration should be specified.

Prescribers will write legible medication orders. An illegible handwritten order will be returned to the prescriber and regarded as a potential error.

Medication orders will include specific instructions rather than using non-standard or ambiguous abbreviations. Specific instructions help differentiate among intended drugs.

- Medication orders will include standard nomenclature, using the drug's name. Avoid locally coined names (e.g., Dr. Doe's compound); chemical names; unestablished abbreviated drug names; acronyms; and apothecary or chemical symbols.
- Always use a leading zero before a decimal expression of less than one (e.g., 0.5 ml).
- A terminal zero will not be used (e.g., 5.0 ml).

Ordinarily, verbal orders will be reserved for emergency situations. When it is impossible for the provider to write the order, the following must occur:

- The health care provider will read the order back to the prescriber to confirm it.
- The health care provider receiving the verbal order will write the order in the patient's health record.
- The prescriber will confirm the order by signing the chart entry within 24 hours or the next working day.

- (3) **Pharmacist Responsibilities.** Pharmacists will participate in drug therapy monitoring and DUE activities to help achieve safe, effective, and rational use of drugs.

Pharmacists must be familiar with the medication use system in place within the institution, including:

- the formulary system;
- DUE programs;
- allowable delegation of authority procedures;
- procedures to alert health care providers and others to new drug orders;
- standard administration times;

Each institution will have a local policy outlining procedures to be followed for "hold" orders.

Before dispensing medications in non-emergency situations, the pharmacist will review an original copy of the written medication order. Pharmacists will have a system for self-checking the reading of medication orders, labeling, and dosage calculations.

- When possible, for high risk drug products, all work should be double checked by another member of the pharmacy staff (e.g., injectable/IV admixtures, cancer medications).

Pharmacists will dispense medications in ready-to-administer dosage forms whenever possible. Pharmacists will ensure timely delivery of medications to the patient care area after receipt of the orders.

- If medications doses are not delivered or therapy is delayed pending resolution of a detected problem (e.g., allergy or contraindications), the pharmacist will inform the health care staff of the delay and the reason.

Pharmacy staff will review medications that are returned to the department. Such review processes may reveal system breakdown or problems that resulted in medication errors (e.g., omitted doses and unauthorized drugs).

c. **Monitoring and Managing Medication Errors.** The staff member identifying the error will report potential and actual medication errors on the Medication Error form (BP-S795). The electronic version of this form will be used when available.

- (1) Physician notification will be made when clinically indicated.

The Medication Error form will be submitted to the institution Chief Pharmacist who will report this information to the QIP Coordinator.

- (2) The QIP coordinator will furnish a copy of the Medication Error Report or a summary of all reports, to the HSA.
- (3) After reviewing the available information, the HSA, Clinical Director, and Chief Pharmacist may determine that immediate intervention (e.g. further education) is necessary to prevent further repeats of the same or similar error, rather than wait on the conclusions of the P&T Committee.

Medication Error Severity Ratings

Level 0	No medication error occurred (<u>potential errors</u> rated Level 0))
Level 1	An error occurred that did not result in patient harm
Level 2	An error occurred that resulted in the need for increased patient monitoring, but no change in vital signs and no patient harm
Level 3	An error occurred that resulted in the need for increased patient monitoring with a change in vital signs but no ultimate patient harm, or, Any error that resulted in the need for increased laboratory monitoring
Level 4	An error occurred that resulted in the need for treatment with another drug or an increased length of stay
Level 5	An error occurred that resulted in permanent patient harm (sentinel event)
Level 6	An error occurred that resulted in patient death (sentinel event)

The QIP coordinator and the Chief Pharmacist will meet at least quarterly to review the forms collected, analyze, and classify the errors, and prepare a Medication Error Review Summary (BP-S796) to report at the P&T Committee.

- This summary will not identify those making the error by name.
- An electronic copy of this summary will be sent to the BOP Chief Pharmacist for informational purposes.

The P&T Committee will suggest process improvements that result from the review. Suggestions may include:

- Conducting organizational staff education;
- Making recommendations for staffing levels;
- Revising policies and procedures, or
- Changing facilities, equipment, or supplies.

d. **Error Resolution.** All errors will be reviewed and researched by the QIP coordinator or Chief Pharmacist.

- The P&T Committee will research errors for correctable administrative and clinical issues and report medication errors in the meeting minutes.

In the large majority of cases, one or more of the following actions are appropriate:

- Error discussion;
- Staff training; and
- Local peer review. (Refer to Program Statement on Credentialing, Privileging and Practice Agreements)

Reviews should focus on the improvement of performance by recognizing errors and developing a plan to minimize future errors.

- A Focus Review Team should evaluate errors resulting in permanent patient harm or death (e.g. sentinel events).

11. **ADVERSE DRUG REACTION REPORTING AND DRUG RECALL.** The Health Services Division participates in adverse reaction reporting programs sponsored by the Food and Drug Administration (FDA) of the Department of Health and Human Services (DHHS).

- Institutions will use the Adverse Drug Reaction Monitoring and Prevention Program outlined in the Pharmacy TRM.
- Drug product defects will be reported in accordance with the FDA drug product problem reporting program.
- A drug recall procedure that can be implemented readily, including provisions for documenting results, will be initiated.
- Adverse Drug Reactions and drug recalls will be reported in the institution P&T Minutes.

12. **RELEASE/TRANSFER MEDICATION.** When an inmate is transferred to a CCC, up to a 90 day supply of current medication will be provided pursuant to a new medication order. The number of days supplied will be determined on a case-by-case basis, dependent upon clinical justification and release planning for the inmate (i.e., insurance, Medicaid, Aids Drugs Assistance Programs (ADAP) availability).

- Unless properly justified, a minimum of 30 days supply of chronic medications will be provided.
- Inmates requiring DEA controlled substances may be considered for transfer to a CCC after institution staff consult with the Community Corrections Manager (CCM) to determine if the respective CCC can accommodate the inmate's special medication needs.

An inmate releasing from custody will be provided a 30 day supply of medication. The medication, with directions, will be given to the releasing officer as indicated by local procedure.

- All release medications will be dispensed in an approved child-resistant container unless waived by the inmate or clinically justified (e.g. disability, etc.).

All intra-system transfers will be provided with a minimum seven day supply of all clinically necessary medications as noted on the Medical Summary of Federal Prisoner/Alien in Transit form (BP-S659).

- On a case-by-case basis, additional medication may be necessary en route to the next institution, with consideration given to length of time, mode of travel, and availability of medication at the next institution.
- All DEA controlled substances and other items subject to abuse will be restricted to minimum quantities.
- An inmate brought in from another Bureau institution (intra-system transfer) may use medication at the receiving institution in accordance with local policy.

A copy of the Medical Summary of Federal Prisoner/Alien in Transit (BP-S659) form may be used to transcribe current medications.

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13. **PRIME VENDOR CONTRACT.** The national contracts for medications and pharmaceutical products are **mandatory**. All institutions will order from these contracts, which are applicable for Federal Supply Schedule (FSS), General Services Administration (GSA), and Blanket Purchase Agreement (BPA) contract pharmaceutical items.

- If the items are identified on the computer database as non-contract items, normal procurement procedures will be used; i.e., purchase from FSS, mandatory source, or open market.

The Chief Pharmacist will implement the prime vendor contract at the institution. Procedures for delivery and receipt of medications will be developed locally in conjunction with the warehouse.

- Questions that cannot be resolved by the Prime Vendor regarding the contract will be directed to the BOP Chief Pharmacist.
- The Chief Pharmacist will ensure institution compliance with the Prime Vendor Procedural Guide. A current guide can be obtained from the Prime Vendor.

Mandatory national contracts exist for selected medications listed in the National Formulary. In these cases, institutions **must** use only the specified brand of the product under contract, when available.

- In order to receive the beneficial contracted price, no institution is authorized to vary from this requirement.

All medications indicated for treatment or manifestations of HIV and AIDS will be listed separately on a purchase order under project number **84-U** if purchased from a vendor **other than** the Prime Vendor. HIV/AIDS medications purchased from the Prime Vendor will use the project number designated to their respective region:

NER	73L	MAR	74L
SER	75L	SCR	76L
NCR	77L	WXR	78L

Medications used to treat Hepatitis C Virus (HCV) infection, such as Interferon Alfa 2B, Interferon Alfa con-1, and ribavirin, will be ordered using project number **31-J**.

Medications other than those to treat HCV or HIV/AIDS will be ordered from the Prime Vendor using the following project number designated to their respective region:

NER	72I	MAR	73I
SER	74I	SCR	75I
NCR	76I	WXR	77I

14. **NEEDLES AND SYRINGES.** The HSA or designee will be responsible for the control of needles and syringes. The importance of proper control and use cannot be overstated.

- **All** unused needles and syringes in sub-stocks will be inventoried on each medically staffed shift. For institutions using computer driven medication stations (e.g. SureMed or Pyxis) for needle and syringe accountability, the shift inventories and disposition sheets are not required.
- Local procedures will specify responsibility for conducting the inventory.
- The time the inventory is conducted will be documented.

The only exceptions to the shift inventory requirement are properly sealed emergency carts or kits or the automated medication cabinets (e.g. SureMed or Pyxis).

- Each institution will develop a policy for inventorying sealed carts on a quarterly basis.

When a discrepancy is noted, a thorough search will be conducted by the finder of the discrepancy, after attempting to resolve the discrepancy, for the missing item(s).

- The finder will report all unresolved discrepancies immediately to the HSA and the Operations Lieutenant.
- After the search, a written memorandum to the HSA and Operations Lieutenant will be prepared by the finder explaining the details.

Local procedures will identify the party responsible for storing needles and syringes. **All** unused sub-stock needles and syringes will be stored in a separate locked cabinet or drawer, within a room locked at all times when staff are not present.

- **All** main stock inventories of sterile needles and syringes will be stored in a secure area, and have a perpetual inventory.
- Each facility will have suitable storage space.

The HSA will ensure a Certificate of Disposition for Control of Needles and Syringes is provided for all areas accountable for these items. The HSA will also ensure local procedures indicate responsibility for requisition of needles and syringes and for recording additions to and uses of inventory.

- Each area of use will have an individualized inventory.
- For institutions using a computer driven medication station, the Activities Report will take the place of the Certificate of Disposition.

The practitioner using or obtaining new supplies of needles and syringes will subtract or add, as appropriate, from the inventory.

- The employee using the needle or syringe will designate on the form the patient's name or reason that the item(s) was used, and sign for the item(s), indicating date and time.
- Employees will not handle disposed/contaminated syringes, needles, scalpels, and other accountable items to conduct a physical count.
- Staff may check out needles/syringes in small quantities for specific indications (e.g. lab, insulin line). All unused needles/syringes will be returned to stock or sub-stock.

Needles and syringes obtained from main stock will be added to the sub-stock inventory and the new totals brought forward. Sub-stock needles and syringes will be requested from main stock via a requisition form.

- Under no circumstance will needles and syringes be stored with controlled substances.

The Certificate for Disposition for Control of Needles and Syringes will be collected by the HSA. This documentation will be retained for two years.

- The HSA will review and maintain each form for spot-check inventories of used needles and syringes.

15. **PATIENT COUNSELING.** The Chief Pharmacist will develop written procedures to address patient counseling by a pharmacist. Physical plant considerations will be factored into this plan. All inmates, whether in the parent institution, SHU, or a satellite facility, will be provided information on their medication. Patient counseling will comply with federal and state regulations.

- This information may take the form of a written medication information sheet and/or oral counseling. Every effort should be made to provide oral counseling when possible.
- Written medication information sheets may be those developed by Bureau pharmacists or those available from pharmacy software program.
- Oral counseling may be done at the pharmacy window, a designated counseling area, or the inmate's cell always being mindful of patient confidentiality.
- The patient counseling will also consider literacy and primary language.

The opportunity for oral counseling by a pharmacist will be offered when new medication is distributed. If not logistically possible, local procedures will provide an avenue for inmates to request counseling.

Patient information to be furnished with new medication orders may include:

- Name of the Drug;
- Indications;
- Dosage Instructions;
- Significant or common Adverse Effects;
- Drug-drug or Drug-food interactions;
- What to do if a dose is missed; and
- Special instructions (i.e. take with food, will discolor urine, etc.)

It is not necessary to furnish patient counseling for each medication refill. However, this provides the pharmacist with an excellent opportunity to check on patient compliance, drug effectiveness, and adverse drug reactions.

Patient information for OTC drugs dispensed by a pharmacist may be on a sheet with other OTC products, and made available in the Health Services Unit.

16. **CHRONIC MEDICATION/SUMMARY SHEET.** The chronic medication/summary sheet is filed under the problem list in Section 2 of the health record. The chronic medication/summary sheet lists current medications.

- Each institution will determine the appropriate format to meet this requirement (i.e., computerized pharmacy records available to the prescriber, etc.).

17. **METHADONE.** The regulations on purchasing, prescribing, and storing of methadone vary depending on the clinical reason for its use. There are currently only three approved uses for methadone within BOP institutions. These uses are:

- Treatment of opiate addicted pregnant inmates;
- Detoxification of opiate addicted inmates; and
- Treatment of severe pain.

a. **Treatment/Detoxification.** Title 42 CFR 8 requires that any healthcare facility using methadone for detoxification or maintenance of opioid addicted patients must have an accredited behavioral health program in order to maintain a valid license for the use of methadone. The responsibility for opioid treatment centers falls under the Substance Abuse and Mental Health Services Administration (SAMHSA).

There are several options available to institutions regarding the use of Methadone.

- (1) Institutions may participate in the DEA Narcotic Addiction Treatment Program by obtaining a methadone license. This license allows institution physicians to treat narcotic addicts with a tapering or withdrawal schedule of methadone for an extended period.

- Inmates will not be maintained on methadone with the exception of pregnant inmates.

Institutions which have a methadone license must store bulk stock methadone in a separate safe from that used to store other controlled substances.

- Methadone ordered under this license may only be used for detoxification purposes. It may not be used for other diagnoses (e.g. pain management).
- All records pertaining to purchasing, prescribing, and administering must be stored separate from other controlled substance records.

- If the institution chooses this method, an application to SAMHSA must be submitted.
 - If the institution chooses to maintain a methadone license the Chief Pharmacist will be responsible for the accreditation process. The institution will be responsible for the corresponding fee.
- (2) For institutions without a methadone license, the DEA allows physicians to prescribe methadone for up to 72 hours, in an emergency, to narcotic addicts.
- The medication order may not be extended or renewed for that individual under any circumstances.
 - This 72 hour window allows for rapid tapering when an inmate coming into the institution has been maintained on methadone in the community.
 - In this instance, the main stock of methadone may be stored with other controlled substances.
 - Documents pertaining to purchase, prescribing, and administering do not have to be stored separately from other Schedule II controlled substances.
- (3) A contract with a local methadone clinic may be pursued to supply methadone for detoxification. All institutions which do not have a methadone license and could conceivably receive a pregnant female on methadone will have a contingency plan, such as this, in place.
- Any pregnant female arriving at the institution on methadone needs to be maintained on methadone until the baby is delivered.
 - Detoxification should be done after delivery. The CD will seek guidance from the BOP Medical Director.
- (4) Institutions may choose non-methadone alternative detoxification protocols either after the 72 hour window explained in subsection 2. above or upon receipt of the inmate.

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b. **Treatment of Pain.** Bureau physicians may prescribe methadone for inmates with severe pain for an extended period. The procedures for prescribing methadone for pain are the same as those described in 9.e.

- When prescribed for severe pain, methadone may be purchased without a methadone license.
- Bulk stock methadone may be stored with other controlled substances.
- Documents pertaining to purchase, prescribing, and administering do not have to be stored separately from other Schedule II controlled substances. However, they must be "readily recoverable."
- Ensure that medication orders for methadone clearly indicate the use for severe/chronic pain in the health record to avoid any confusion or problems during a DEA audit.
- Institutions with a methadone license are not allowed to order methadone used for pain under the methadone detoxification license. These inventories must be kept completely separate.

18. **URGENT CARE CARTS.** An adequate supply of urgent care drugs will be maintained in the pharmacy and in designated areas. The Chief Pharmacist is responsible for all medications located in the urgent care carts and kits, and for the inspection procedures used.

- Approved DEA controlled substances may be maintained on urgent care carts and will be inventoried by pharmacy staff at least quarterly or whenever the urgent care cart seal is broken.
- Information regarding supplies and medication for the urgent care carts, based on the level of emergency care provided, is available from the BOP Chief Pharmacist.

/s/

Harley G. Lappin
Director

EXHIBIT 4

FEDERAL BUREAU OF PRISONS HEALTH SERVICES

NATIONAL FORMULARY Part I

Winter 2018



APPROVED

Jeffery D. Allen, M.D.

Date: 2018.05.31 14:51:26

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Jeffery D. Allen, MD, MEDICAL DIRECTOR

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PART 2

FORMULARY DRUG MONOGRAPHS BY GENERIC	BEMR RX REPORT, SALLYPORT
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Formulary Changes, Winter 2018 Meeting

*** The prescribing of medications against the restrictions, without an approved non-formulary request, is considered an unauthorized use of government funds. The procurement of non-formulary medications or the procurement of formulary medications used outside of formulary restrictions is considered an unauthorized procurement. The prescriber is responsible for justifying the non-formulary request. ***

The following is a summary of the major changes as a result of the Winter 2018 BOP Formulary meeting; please refer to the Winter 2018 National P&T minutes for additional information and detailed discussion regarding all of the changes.

Revisions or changes from the previous year are highlighted in Yellow throughout the document.

bictegravir, emtricitabine, and tenofovir alafenamide (BIKTARVY™)	ADD
Cefdinir (Omnicef™)	ADD
Cefixime (Suprax™)	DELETE
Didanosine	DELETE
Fosamprenavir	DELETE
Haemophilus influenza type b conjugate vaccine (ActHIB™, Hiberix™)	ADD ActHIB™
Lopinavir/Ritonavir	DELETE
Meningococcal vaccines (Menactra™, Menveo™)	ADD Menveo™ ADD Bexsero™
Metoprolol Succinate ER (Toprol XL™)	ADD with inclusionary diagnosis
Nelfinavir	DELETE
Nevirapine	DELETE
Rosuvastatin (Crestor™)	ADD
Sacubitril-Valsartan (Entresto™)	ADD with inclusionary diagnosis
Saquinavir	DELETE
Stavudine	DELETE

National BOP Formulary Mission / Procedural Statement

Purpose:

The formulary system, as defined in the "ASHP Statement on the Formulary System", is a method for evaluating and selecting suitable drug products for the formulary of an organized health-care setting.

The BOP formulary is a list of medications that are considered by the organization's professional staff to ensure high quality, cost-effective drug therapy for the population served. Participants of the Pharmacy, Therapeutics and Formulary Meeting are responsible for the development, maintenance and approval recommendations of the formulary to the BOP Medical Director. Periodically, medications are reassessed and extensively reviewed for inclusion, exclusion, or restrictions in the formulary as applicable per current evidence-based practices and security concerns. Regular maintenance of the BOP formulary ensures optimal treatment options are uniformly consistent and readily available.

The primary goals of BOP Formulary Management are to optimize therapeutic outcomes, optimize cost effectiveness of medications, and to ensure drug usage is conducive within the correctional environment.

Expectations:

1. ALL BOP institutions, including Medical Centers, are expected to abide by the formulary as outlined in the BOP Pharmacy Services Program Statement. It is expected that persons in the review process will NOT be circumvented in the event of a short term absence for non-urgent requests.
2. ALL comments made on the request are expected to be medically appropriate and of a nature conducive to being placed in the medical record.
3. It is expected that non-urgent non-formulary medications will not be initiated until AFTER authorization is received, even if the medication is on the shelf from a previous request. Doing so can be deemed an unauthorized procurement.
4. Prescribers (BOP Physician / MLP / Dentist/ Clinical Pharmacist) are expected to thoroughly justify the request including why the formulary agent cannot be used, and provide pertinent laboratory information. It is expected that non-formulary use criteria will be thoroughly addressed point by point and that all non-formulary justifications/criteria are met.
5. Clinical Directors are expected to support the BOP National Formulary and ensure compliance at their respective institution. The CD is expected to review all requests ensuring that appropriate justification and corresponding non-formulary use criteria are met. It is expected that the CD will allow the pharmacist to appropriately comment and provide pertinent information on the request even if not supportive. It is expected that the CD will disapprove, at the local level, any request which does not meet the non-formulary use criteria.
6. Institution Chief Pharmacists are expected to review all medication orders for formulary compliance. This will include reviewing all non-formulary requests for completeness and appropriate justification, and, if applicable, commenting on information provided by the prescriber regarding non-formulary use criteria. The pharmacist is also expected to provide pertinent information regarding patient compliance for formulary agents, drug cost information, and other comments as they pertain to the request.

7. Institution Administration (HSA, Associate Warden, and Warden) are expected to support and ensure compliance with the BOP National Formulary. Administrative decisions regarding medical care are expected to be consistent with the BOP National Formulary and not conflict with the medically necessary provision of medications and restrictions set forth in the BOP National Formulary.
8. Consultant Physicians are expected to utilize and stay within the guidelines of the BOP National Formulary when making recommendations and to provide specific and adequate justification if formulary medications cannot be utilized.
9. Court Orders: Court orders recommending or ordering specific treatments should be referred to the appropriate BOP attorney(s). All such orders/recommendations are still subject to the non-formulary approval process.
10. It is expected that all institution inventories and ordering procedures will be conducive to acceptable inventory practices (e.g. two week par levels on the shelf maintained with weekly medication ordering).

Compliance:

1. Completion and appropriateness of non-formulary medication requests are a review element of the Clinical Director (CD) Peer Review Process.
2. The Medical Director may request Regional Medical Director follow-up and/or issue a memo to the CD requesting a response and corrective action if problems are identified. This may be prompted by consistent failure of the institution staff to appropriately initiate or complete all elements of the non-formulary request, particularly the required supporting documentation.
3. The Medical Director may issue memos to the institution Warden regarding persistent problems or concerns with respect to the institution's compliance with this process.

Continuity of Care Provision:

There are times when inmates are processed into a facility after normal working hours, weekends, and holidays. In those cases where continuity of care is medically necessary because:

1. There is not a formulary substitute, or
2. Changing to a formulary substitute will not allow for appropriate follow up monitoring until the next workday, **AND**
3. Not providing the medication would pose a significant risk to the patient,

An allowance is given to dispense/administer a non-formulary medication for four days while waiting for non-formulary approval. This four day allowance is to only be utilized for urgent continuity of care purposes, and not for initiating routine/non-emergency non-formulary medications without appropriate approval.

This provision is not a substitute for adequate follow up, monitoring, and initiation of non-formulary medications for patients maintained within the facility for chronic ongoing conditions. It is the prescriber's responsibility to ensure appropriate non-formulary submission prior to the expiration of a current non-formulary request.

Medication orders that do not meet the above continuity of care elements should not be written, entered into the pharmacy software system, or dispensed prior to the appropriate non-formulary approval.

DEFINITIONS / RULES

FORMULARY RULES

BRAND NAME PRODUCTS ARE FOR REFERENCE ONLY
THE LEAST EXPENSIVE GENERIC EQUIVALENT IS TO BE UTILIZED WHEN AVAILABLE, OTHERWISE NON-FORMULARY APPROVAL IS REQUIRED
USE AGAINST SPECIFIC RESTRICTIONS REQUIRES NON-FORMULARY APPROVAL
USE OF FORMULATION NOT SPECIFICALLY INCLUDED (E.G. EXTENDED RELEASE, NASAL, TOPICAL, OPHTHALMIC, RAPID DISSOLVE TABLET, COMBINATION PRODUCT, ETC.) IS NOT AUTHORIZED; REQUIRES NON-FORMULARY APPROVAL

COMPOUNDING

This is defined as the combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the needs of an individual patient. All compounded prescription drugs are deemed "new drugs" within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA).

ALL compounded medications will be considered non-formulary and will go through the same non-formulary and addition to formulary processes as individual, commercially available entities.

DEA CONTROLLED SUBSTANCES

**** ALL CONTROLLED SUBSTANCES ARE RESTRICTED TO PILL LINE ****
** IMMEDIATE RELEASE, NON-ENTERIC COATED, ORAL CONTROLLED SUBSTANCES ARE TO BE CRUSHED PRIOR TO ADMINISTRATION **** IMMEDIATE RELEASE CONTROLLED SUBSTANCE CAPSULES SHOULD BE PULLED APART AND ADMINISTERED IN POWDER FORM **

DIRECTLY OBSERVED THERAPY

A single dose of medication is administered at Pill Line by a qualified employee, and that dose is consumed in the presence of the employee.

EPINEPHERINE AUTO-INJECTOR (EPIPEN™)

Epipen™ may be issued to inmates with known anaphylaxis utilizing the procedure outlined below.

1. Epipen™ is to be entered into BEMR as a pill line item with the recommended sig: - "Inject as directed for severe allergic reaction ** must present this device to pill-line daily for integrity inspection**"
2. The inmate will present the Epipen™ at pill line every day to insure the seal is intact and that no manipulation has occurred.
3. Health services staff will document the encounter in the Medication Administration Record daily.
4. The inmate should be counseled regarding the potential consequences and adverse actions that may occur if tampering is evident or the product is lost or manipulated.

FDA MEDICATION GUIDES AND SIDE EFFECTS STATEMENT

**FDA MEDICATION GUIDES AND DISPLAY OF THE SIDE EFFECTS STATEMENT ARE REQUIRED WITH PRESCRIPTIONS DISPENSED PURSUANT TO INMATES BEING RELEASED, OR SENT TO A RESIDENTIAL REENTRY CENTER (RRC) (E.G. HALF-WAY HOUSE) FDA WEBSITE: <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>

FDA Medication Guides and display of the side effects statement **ARE NOT** required to be provided to the patient when the inmate is:

1. Confined within a BOP institution.
2. Being transferred within BOP (intra-system) or to another correctional entity (inter-system).

FDA Medication Guides and display of the side effects statement ARE required to be provided to the patient when the inmate is:

1. Being released to the community. (including writs and furloughs)
2. Sent to a Residential Reentry Center (RRC) (e.g. Half-Way House).

OVER THE COUNTER MEDICATIONS

Formulary OTC Medications may only be prescribed as a maintenance medication associated with ongoing follow up in a related chronic care clinic and supported by an appropriate and commensurate indication. Refer to the [Formulary OTC Prescribing Criteria Matrix](#).

MEDICAL CENTER ONLY

A restriction placed on some medication requiring that the use of this drug only be within a Federal Medical Center.

MEDICATION RESTRICTIONS

Prescribing restrictions placed on certain medications. Variance from restrictions requires non-formulary authorization.

PILL LINE ONLY

A restriction placed on controlled substances, psychotropics, TB medications, and some other drugs, requiring that a single dose of the drug be administered to an inmate by a qualified employee at a designated time and place. The administration of that dose must be recorded on a Medication Administration Record (MAR) by the employee. A report of medications that are pill line only is available in BOP electronic medical record. There are some medications that are designated as pill line only for certain indications ([see page 11](#)).

MLP REQUIRES COSIGN

A restriction placed on some medications requiring that a physician sign the medical record each time this drug is prescribed. Subsequent medication orders for this drug must also include the signature of a physician.

PLACEBOS - STATEMENT ON USE

Placebos will not be utilized within the Federal Bureau of Prisons.

References:

AMA "Placebo Use in Clinical Practice" statement:

<https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-2.pdf> "In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient-physician relationship, and result in medical harm to the patient".

ASHP "Ethical Use of Placebos in Clinical Practice" (1116) statement

<https://www.ashp.org/-/media/assets/policy-guidelines/docs/policy-positions/policy-positions-ethics.ashx?la=en&hash=EC9E91D6DE66E75BFE873695D19047B991F9B59C> "To affirm that the use of placebos in clinical practice is ethically acceptable only when patients have been informed of and agree to such use as a component of treatment; ..."

NON-SUBSTITUTABLE PRODUCTS

<u>GENERIC DRUG NAME</u>	<u>REQUIRED BRAND PRODUCT</u>
ESTROGENS, CONJUGATED	Premarin™ (Wyeth-Ayerst)
PURIFIED PROTEIN DERIVATIVE	Tubersol™
NIACIN (NF)	Niaspan™ (NF)

LOOK ALIKE / SOUND ALIKE MEDICATIONS

Both the Joint Commission (JC) and the Accreditation Association for Ambulatory Care (AAAH) require health care organizations to identify look-alike / sound alike medications utilized at their site. A Look Alike / Sound Alike medication list is available from ISMP (Institute of Safe Medicine Practices)

Each BOP institution needs to incorporate Look-Alike / Sound-Alike drugs into the agenda of the local Pharmacy & Therapeutics Committee Meetings, and review them on an annual basis. The discussions, decisions, and respective local policy must follow the requirements set forth by accrediting bodies (JC, AAAHC).

This responsibility is deferred to the local level due to the varying missions of our institutions (e.g. Medical Referral Center, ambulatory institution, Detention Centers, implementation of levels of care) and not all institutions carry exactly the same items from the BOP National Formulary.

RESOURCES The Joint Commission www.jointcommission.org

Institute of Safe Medicine Practices www.ismp.org

[ISMP's List of Confused Drug Names](#)

RISK EVALUATION AND MITIGATION STRATEGIES (REMS)

REMS is defined by the FDA as a program to manage a known or potential serious risk associated with a drug or biologic product. Medications with REMS require differing levels of monitoring and control with the most extreme requiring written contracts between the pharmacy/physician and the manufacturer.

Institution pharmacists/physicians should not sign any agreements without first being reviewed by the BOP Chief Pharmacist or designee. The BOP Chief Pharmacist/designee will consult with the BOP Office of General Counsel as appropriate. A list of current REMS drugs can be found at:

<http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>

BOP institutions with patients requiring "specialty pharmacy restricted REMS medications" (e.g., Revlimid™) should contact their Regional Chief Pharmacist or the Chief of Pharmacy Logistics Support for guidance. Institutions may be directed to obtain some complex REMS medications from a single BOP Pharmacy. Institutions and providers should not obtain REMS medications from a non-BOP pharmacy until all internal processes are exhausted and Central Office Pharmacy staff has instructed them to do so.

KEEP ON PERSON (KOP), I.E. SELF-CARRY MEDICATIONS

Medications are generally excluded (i.e., not self-carry eligible) if:

1. Potential for abuse or misuse. (e.g., controlled substances)
2. Injectable drugs.
3. Psychiatric medications. (unless deemed to be very safe when taken in excessive amounts)
4. Most antipsychotics.
5. Close monitoring is required. (e.g., TB meds)
6. Caustic or harmful agents. (e.g., podofilox)
7. Require refrigeration.
8. Packaging can be misused. (e.g., glass container, inhalers with piercing devices)
9. Cost.

NON-CONTROLLED SUBSTANCES RESTRICTED TO PILL LINE

REFER TO BEMR RX DRUG FILE REPORT FOR AN ALL INCLUSIVE LISTING

ANTIEPILEPTIC DRUGS used for treatment of psychiatric disorders

- CARBAMAZEPINE
- DIVALPROEX
- GABAPENTIN - all uses
- LAMOTRIGINE
- LEVETIRACETAM - all non-seizure indications
- OXCARBAZEPINE
- TOPIRAMATE
- VALPROIC ACID

OXYBUTYNIN

PSYCHOTROPIC MEDICATIONS

TRICYCLIC ANTIDEPRESSANTS

****ALL ITEMS ON THIS PAGE ARE RESTRICTED TO PILL LINE ADMINISTRATION.**

**THE PHARMACY AND THERAPEUTICS COMMITTEE AT EACH INSTITUTION SHALL DETERMINE WHICH
ADDITIONAL MEDICATION ITEMS ARE TO BE PLACED ON PILL LINE. HEALTH CARE
PROFESSIONALS MAY ALSO PLACE SPECIFIC PATIENT ORDERS ON PILL LINE. ****

****ANY MEDICATIONS USED TO TREAT TUBERCULOSIS (INCLUDING QUINOLONES AND
OTHER ANTIBIOTICS NOT LISTED ABOVE) MUST BE GIVEN BY DIRECTLY OBSERVED
THERAPY**

NON-FORMULARY CLINICAL CRITERIA/JUSTIFICATION REQUIREMENTS, ALGORITHMS, AND TREATMENTS

Acitretin (Soriatane™)

1. Patients need to have a significant BSA involvement, failed appropriate topical agents, and either failed methotrexate or is a poor candidate for methotrexate.
2. The patient has a teledermatology consult in BEMR with the BOP National Dermatology Consultant
3. Female patients must meet all criteria of the "Do our P.A.R.T" program; however, alternative medications should be sought due to the teratogenicity and long-term effects of acitretin.

Adalimumab (Humira™) - See [Immunomodulator TNF Inhibitors](#)

Adult Attention Deficit Hyperactivity Disorder Medications/ Treatment: atomoxetine (Strattera™), methylphenidate (Ritalin™), amphetamine/dextroamphetamine (Adderall™/Dexedrine™)

1. Failure of non-pharmacologic / Education & Counseling / Psychology Referral to include individual therapy to learn coping, organizational, prioritization, and anger management skills for minimum of 6 months.
2. Failure of ALL formulary noradrenergic re-uptake inhibitors after ADEQUATE trials for a minimum 6 weeks. Patient self-reported trials of medication regimens and doses will not be accepted. All medication trials must occur and be documented within the BOP.
 - a. desipramine/imipramine
 - b. nortriptyline
 - c. venlafaxine
3. Submitted documentation must include/show the following:
 - a. Copy of full psychiatric and psychological behavioral function evaluations
 - b. Evidence (with specific examples) of inability to function in the correctional environment (e.g. incident reports)
 - c. Doses of formulary medications have been maximized
 - d. Six week minimum trial of medication occurred at maximized dose
 - e. Copy of Medication Administration Records (MARs) showing compliance at maximized dose for minimum six week trial
 - f. lab reports of plasma drug levels for desipramine/imipramine and nortriptyline
 - g. History of drug abuse including type of drug (e.g. stimulants, opiates, benzodiazepines, etc.)
4. Additional Notes:
 - a. Only approved on **pill line**.
 - b. **Long acting stimulants** will NOT be approved.
 - c. Contingent to formulation compatibility, stimulant medications will be **crushed** prior to administration.
 - d. Stimulant medications (including atomoxetine) will be our last drug of choice and will only be approved if **function is significantly impaired**.
 - e. The use of stimulant in persons with a history of stimulant **drug abuse** will not be approved.
 - f. See [Bupropion \(Wellbutrin™\)](#) for ADHD use criteria.

Albiglutide (Tanzeum™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Alfuzosin (Uroxatral™)

1. Documentation of significant symptomatic hypotension, orthostatic hypotension, or syncope while receiving terazosin, doxazosin or tamsulosin.
2. Failure of doxazosin 8mg, terazosin 20mg, or tamsulosin 0.8mg daily for a minimum of 6 weeks.

Alirocumab (Praluent™) - See [PCSK9 Inhibitors](#)

Alogliptin (Nesina™) - See [Dipeptidyl Peptidase-4 \(DPP-4\) Inhibitors](#)

Amantadine (Symmetrel™)

1. Parkinson's Disease / syndrome
2. Drug induced extrapyramidal reactions not responsive to trihexyphenidyl or benztropine.
3. Institutional influenza outbreak - approval will be considered on a case by case basis **AFTER** discussion with the National Infectious Disease Coordinator or Chief Physician. Upon determining appropriateness per the CDC guidelines the institution will be advised to apply for non-formulary approval.

Anticoagulants: apixaban (Eliquis™), dabigatran (Pradaxa™), edoxaban (Savaysa™), rivaroxaban (Xarelto™)

1. Patients being treated for atrial fibrillation with an INR that is unable to be stabilized on warfarin therapy despite being enrolled into an anticoagulation clinic
2. Patients previously stabilized on a direct thrombin inhibitor or Factor Xa inhibitor with an appropriate diagnosis. NOTE: NFR for new intakes may be approved for 90 days at care level 1 and 2 institutions and for 30 days at care level 3 and 4 institutions pending appropriate assessment and conversion to warfarin.
3. The expectation is that patients will be converted to warfarin within the time frames listed in the non-formulary use criteria.

Antiepileptic Medications: ethosuximide (Zarontin™), felbamate (Felbatol™), zonisamide (Zonegran™)

Approval of any non-formulary antiepileptic medications will be considered on an individual basis. When requesting approval please provide information necessary for evaluation of the request. This will include:

1. Previous medications, doses, and documented compliance; blood levels when appropriate.
2. EEG or clinical evidence of failure to achieve seizure-free state.
3. Documented adverse effects of formulary medications.
4. Results of any neurologic consultations.

Please be aware that many of the antiepileptic agents have potentially life-threatening side effects under certain conditions, or in some individuals. The prescriber should take special care:

1. To assess and follow the inmate for potential adverse side-effects.
2. Be aware of any potential drug-drug interactions.
3. Adjust dose no more quickly than recommended by the manufacturer.
4. Monitor compliance.

Antifungals - Oral for onychomycosis: itraconazole (Sporanox™), ketoconazole (Nizoral™), griseofulvin, fluconazole (Diflucan™), terbinafine (Lamisil™)

1. Diabetic or circulatory disorders evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation.
2. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil™) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.

Antihistamines - oral: diphenhydramine (Benadryl™), hydroxyzine (Atarax™, Vistaril™), loratadine (Claritin™), cetirizine (Zyrtec™), cyproheptadine (Periactin™), and fexofenadine (Allegra™)

PILL LINE ONLY

1. Formulary - MRC use only, restricted to dialysis only
2. Patients taking antipsychotic medication with extrapyramidal symptoms not responsive to benztropine and trihexyphenidyl (diphenhydramine and hydroxyzine only)
3. Excessive salivation with clozapine (diphenhydramine and hydroxyzine only)
4. Chronic idiopathic urticaria (consider other formulary H2 blockers such as doxepin)
5. Chronic pruritus-associated dialysis (diphenhydramine and hydroxyzine only)
6. Non-formulary use approved via PILL LINE ONLY
7. **Urticaria:** Classified according to etiology or precipitating factor-see Clinical Update article on Urticaria. All potential precipitating factors have been considered and controlled.
8. **Urticaria:** IgE levels and/or absolute eosinophil count in conditions where this is typically seen.
9. Urticaria: Documented failure (ensuring compliance) of steroid pulse therapy (i.e. prednisone 30mg daily for 1 to 3 weeks). **Be aware of any contraindication to steroid use (i.e. bipolar disorder)**

Anti-Obesity Agents: phentermine/topiramate (Qsymia™), lorcaserin (Belviq™), orlistat (Xenical™, Alli™ OTC)

Use must be approved by the BOP Chief Dietician

Apremilast (Otezla™, Celgene™)

Use for psoriasis must be in consultation with BOP teledermatologist.

Use for Psoriatic arthritis:

1. Failure of methotrexate/prednisone, gold or azathioprine.
2. Request must include a rheumatology consult report

Ascorbic Acid (Vitamin C)

Concomitant administration with an imidazole antifungal agent to improve bioavailability by increasing stomach acidity.

Apixaban (Eliquis™) - See [Anticoagulants](#)

Baclofen - See [MUSCLE RELAXANTS](#)

Becaplermin (Regranex™)

1. Patients should have a recent glycosylated hemoglobin (hemoglobin A1c or HbA1c) less than 8. If not, aggressive control of their diabetes should be attempted.
2. Patients should be non-smoking or enrolled in a smoking cessation plan.
3. Stage III or IV (International Association of Enterostomal Therapy for staging chronic wounds) lower extremity diabetic ulcers that extend through the dermis into the subcutaneous tissue or beyond.
4. The wound must have an adequate blood supply measured by Oscillometry (at least 2 units), transcutaneous oxygen pressure (TcpO2 >30 mm Hg) or bleeding with debridement.
5. The wound must be free from infection.
6. If present, lower extremity edema should be treated.
7. The patient must have failed standard therapy for at least 2 months (careful/frequent debridement, moist dressing changes and non-weight bearing).
8. The provider must see the patient on a weekly to biweekly basis for debridement and assessment of ulcer response.
9. The provider must recalculate a new amount of becaplermin gel to be applied at every visit.

Benzodiazepines: Clonazepam & Lorazepam long-term use (> 30 days)

1. Control of severe agitation in psychiatric patients
2. When lack of sleep causes an exacerbation of psychiatric illness
3. Part of a prolonged taper schedule
4. Detoxification for substance abuse
5. Failure of standard modalities for seizure disorders (4th line therapy)
6. Long-term use for terminally ill patients for palliative care (e.g. hospice patients)
7. Adjunct to neuroleptic therapy to stabilize psychosis
8. Second line therapy for anti-mania
9. Psychotic syndromes presenting with catatonia (refer to BOP Schizophrenia Clinical Practice Guideline)
10. Akathisia that is non-responsive to beta blocker at maximum dose or unsuccessful conversion to another antipsychotic agent (refer to BOP Schizophrenia Clinical Practice Guideline)
11. Nausea and Vomiting in Oncology Treatment Patients (Lorazepam only)

Brimonidine 0.1% & 0.15% ophthalmic solution (Alphagan P™)

Documented allergy or sensitivity to brimonidine 0.2 ophthalmic Solution

Budesonide/Formoterol (Symbicort™) - See [Long Acting Beta Agonists \(LABA\)](#) and Long Acting Beta Agonists /Inhaled Corticosteroid (LABA/ICS)

Buprenorphine (Subutex™, Suboxone™) for detoxification

1. Will only be approved for detoxification, NOT for pain or maintenance therapy.
2. Prescribing physician MUST have buprenorphine certification and DHHS - SAMHSA waiver. These must be submitted with request.
3. Only buprenorphine/naloxone (Suboxone™) will be approved.

Bupropion (Wellbutrin™ IR, SR, and XL, Zyban™)

1. Restricted to bipolar depression and/or ADHD.
2. Evidence of proven efficacy through previous treatment with bupropion for bipolar depression and/or ADHD.
3. Patient has no history of diverting bupropion.
4. Patient has no history of seizures.
5. All approvals for bupropion will be for the IR formulation and should be administered crushed and in water.
6. BIPOLAR DEPRESSION USE: Must be maintained on a mood stabilizer and/or antipsychotic.
7. BIPOLAR DEPRESSION USE: Must have failed therapy on at least **three** other formulary agents.
8. BIPOLAR DEPRESSION USE: If patient had a manic episode precipitated by the addition of an antidepressant, failure of additional agents is not necessary.
9. ADHD USE: Failure of non-pharmacologic/education & Counseling/Psychology Referral to include individual therapy to learn coping, organizational, prioritization, and anger management skills for minimum of six months.
10. ADHD USE: Failure of ALL formulary noradrenergic re-uptake inhibitors after ADEQUATE trials for a minimum of six weeks. Patient self-reported trials of medication regimens and doses will not be accepted. All medication trials must have occurred and been documented within the BOP.
 - a. desipramine/imipramine
 - b. nortriptyline
 - c. venlafaxine
11. ADHD USE: Submitted documentation must include/show the following:
 - a. copy of full psychiatric and psychological behavioral function evaluations
 - b. evidence (with specific examples) of inability to function in the correctional environment (e.g., incident reports)
 - c. doses of formulary medications have been maximized or side effects documented
 - d. six week minimum trial of medication occurred at maximized dose
 - e. copy of Medication Administration Records (MARs) showing compliance at maximized dose for minimum six week trial
 - f. lab reports of plasma drug levels for desipramine/imipramine and nortriptyline
 - g. history of drug abuse including type of drug (e.g., stimulants, opiates, benzodiazepines, etc.)
12. Bupropion therapy will not be approved for smoking cessation therapy

Canagliflozin (Invokana™) - See [Sodium-glucose Cotransporter-2 \(SGLT2\) Inhibitors](#)

Certolizumab (Cimzia™) - See [Immunomodulator TNF Inhibitors](#)

Cholinesterase Inhibitors for Alzheimer's disease (AD)

Donepezil (Aricept™) is the non-formulary drug of choice.

1. Request for its non-formulary use requires completion of the "Donepezil Non-formulary Use Criteria Algorithm" form.

Cilostazol (Pletal™)

1. Six months of documented unsuccessful lifestyle modifications (e.g. exercise, smoking cessation).
2. Treatment of cardiovascular disease risk factors.
3. Revascularization cannot be offered or is refused by the patient.

Clonazepam long-term use - See [Benzodiazepines](#)

Clonidine (Catapres™)

1. For use in opiate detoxification only. Oral test dose followed by clonidine patch is preferred protocol mechanism.
2. Dose taper over 2 to 4 days for arriving inmates taking greater than 1 mg per day. Refer to clonidine withdrawal guidance, particularly for patients on concomitant beta blocker therapy. Non-formulary request may be submitted after taper initiated.
3. Use in clozapine induced hypersalivation (CIH) after failure or contraindication to benztropine, amitriptyline, and alpha blocker. NOTE: Including combination therapy with benztropine and an alpha blocker for 12 weeks.
4. Use in Tourette's syndrome.
5. Not to be used in hypertensive urgencies/ emergencies. See Hypertensive clinical practice guidelines and 2006 National P&T Minutes, page 103.

Clonidine Discontinuation Guidance

Discontinuation of most any antihypertensive agent can lead to a corresponding withdrawal syndrome. However, this syndrome is most commonly seen with clonidine, beta-blockers, methyldopa, and guanabenz. The withdrawal syndrome is thought to be caused by sympathetic over activity and includes nervousness, tachycardia, headache, agitation, and nausea. This is usually seen within 36 to 72 hours after cessation of therapy. In rare instances, a rapid increase in blood pressure to pre-treatment levels or above can be seen that could potentially lead to myocardial ischemia. Again, this is rare, especially when patients are not taking above the standard therapeutic doses of these agents. It also appears to occur more often when multiple medications are being withdrawn at the same time.

Abrupt discontinuation of clonidine, in particular those taking greater than 1 mg daily, may result in nervousness, agitation, restlessness, anxiety, insomnia, headache, sweating, palpitation, increased heart rate, tremor, hiccups, muscle pain, increased salivation, stomach pain, nausea and flushing. This may be due in part to the fact that clonidine has been shown to act upon opiate receptors. These effects generally appear within two to three hours after the first missed dose.

Blood pressure may increase in four to eight hours after the first missed dose of clonidine and is associated with a rise in catecholamine plasma concentrations. This potential may be exacerbated after administration of higher doses or continued concurrent therapy with a beta-blocker.

Severe blood pressure increases after clonidine discontinuation can be treated with the reinstitution of clonidine therapy followed by a short, gradual taper over two to four days; IV phentolamine +/- propranolol (propranolol should never be utilized alone as it may further elevate the BP); or utilization of a vasodilator such as hydralazine or diazoxide.

If a patient is taking clonidine concurrently with a beta-blocker, it is best to gradually withdraw the beta blocker, then withdraw the clonidine over two to four days. The beta-blocker can then be reinstituted after clonidine has been successfully withdrawn. Concurrent beta-blocker therapy may exacerbate an increase in blood pressure upon clonidine withdrawal.

Appropriate follow-up to including adjustment of medication management of all patients is essential during this process.

Clopidogrel (Plavix™) - use > 30 days

Clopidogrel indications for use as single antiplatelet agent therapy (in lieu of aspirin):

1. Aspirin allergy (anaphylaxis, bronchospasm)
2. Recurrent non-cardioembolic cerebral ischemia while on aspirin

Clopidogrel indications for use as dual antiplatelet therapy with aspirin (by condition):

1. ACS (NSTEMI, STEMI, unstable angina (UA)) with no revascularization - 1 year
2. Post PCI - 1 year
3. Post CABG - 4 weeks
4. Non-coronary stenting
 - a. Carotid artery stent - similar to PCI

COX-2 Inhibitors: celecoxib (Celebrex™)

Documentation of:

1. Prior history of a serious GI event (hospitalization for perforation, ulcer, or bleed); **OR**;
2. Concurrent use of warfarin (for OA, these patients must ordinarily fail acetaminophen and salsalate prior to receiving a COX-2 inhibitor).

Non-formulary Requests for Cox-II inhibitors will ordinarily not be considered for approval for:

- Lack of response to traditional NSAIDs.
- Dyspepsia or GI intolerance to traditional NSAIDs.
- Patients receiving a proton pump inhibitor.
- Patients receiving low dose aspirin for cardiovascular prophylaxis.
- Patients with known cardiovascular disease.
- Dysmenorrhea.

Cyclobenzaprine (Flexeril™) - See [MUSCLE RELAXANTS](#)

Cyclosporine ophthalmic emulsion 0.05% (Restasis™)

1. Diagnosis of Sjogren's Syndrome
2. Diagnosis of Rheumatoid Arthritis
3. Failed appropriate duration of carboxymethylcellulose (Celluvisc™) containing ocular lubricants via approved non-formulary request.

Dabigatran (Pradaxa™) - See [Anticoagulants](#)

Dapagliflozin (Farxiga™) - See [Sodium-glucose Cotransporter-2 \(SGLT2\) Inhibitors](#)

Darbopoetin Alfa (Aranesp™) - See [Erythropoiesis Stimulating Agents \(ESA's\)](#)

Delavirdine (Rescriptor™)

Patients who have previously tried efavirenz and nevirapine and were changed to delavirdine because of intolerance, adverse effects, or contraindications (e.g. rash or hepatotoxicity with nevirapine; pregnancy with efavirenz) citing specific reasons as to why efavirenz and nevirapine cannot be utilized.

Conversion Recommendations for those entering BOP institution on delavirdine, with undetectable viral load:

1st Alternative: Switch patient from **delavirdine to efavirenz** unless there is a contraindication (e.g. pregnancy). It is recommended that delavirdine therapy be stopped and efavirenz be started at full dose (600 mg HS) the next day.

2nd Alternative: Switch patient from **delavirdine to nevirapine**. Recommendation to stop delavirdine and start nevirapine utilizing dose escalation (e.g. 200 mg daily x 14 days, then 200 mg bid) as if beginning a treatment naive patient. Nevirapine has a higher incidence of rash than delavirdine. There is not 100% cross-reactivity in rash and the rash seems to be related to early blood levels, therefore dose escalation is still recommended. Viral resistance to nevirapine did not occur in clinical trials when patients were given escalating doses.

Delavirdine and nevirapine share resistant mutations so conversion will not lead to increased resistance. If resistance is a concern, on a case by case basis, it may be prudent to give a protease inhibitor (PI) plus nevirapine during the 2 week escalation period. For instance, the decision may depend on viral load; if < 50 for quite some time then no PI; if patient has detectable virus or blips, one may want to cover with a PI (e.g. nelfinavir) during nevirapine escalation. Nelfinavir will add pill burden and diarrhea but no drug interactions or overlapping toxicities exist between nelfinavir and nevirapine.

Inmates entering BOP on a delavirdine-containing regimen, whose viral load is not adequately suppressed, should have their entire HAART regimen re-evaluated in consultation with a specialist.

Dicyclomine (Bentyl™)

1. Clinical diagnosis of IBS AND
2. Three months of fiber (tablets) therapy without relief of symptoms AND
3. Three negative Fecal Occult Blood Tests documented in BEMR, AND
4. At least six months of chronic diarrhea symptoms AND
5. Absence of constipation and/or positive Fecal Occult Blood Test. Any new or renewal orders for dicyclomine must meet the criteria to be dispensed.

Dietary/Herbal Supplements

These agents are not FDA approved and will not be approved.

Difluprednate (Durezol™)

Difluprednate has less ocular effect than prednisolone. Patient case must have potential or actual increase in intraocular pressure for non-formulary request approval.

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: linagliptin (Tradjenta™), alogliptin (Nesina™), saxagliptin (Onglyza™), sitagliptin (Januvia™)

1. Patient has type 2 diabetes
2. Not to be used in combination with GLP-1 agonists.
3. Frequent hypoglycemia on sulfonylurea.
4. Failed maximum tolerated dose of metformin or documented contraindication to metformin.
5. A1C goal not met on therapeutic doses of formulary agents.
6. A1C <9% (if A1C is ≥9%, then insulin therapy is indicated instead of this agent).
7. Criteria 1 through 6 must be met for approval.

Diphenhydramine (Benadryl™) - See [Antihistamines](#)

Dulaglutide (Trulicity™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Dutasteride (Avodart™) -

1. Second line agent for BPH, after failure of alpha blocker.
2. American Urological Association criteria (including symptom score, digital rectal exam, PSA test, urine outflow record) are submitted.
3. Finasteride is the 5-alpha-reductase Inhibitor of choice**
4. Consultation with BOP Chief Psychiatrist and/or Central Office Transgender Clinical Management Team when providing transgender care.

Edoxaban (Savaysa™) - See [Anticoagulants](#)

Empagliflozin (Jaridance™) - See [Sodium-glucose Cotransporter-2 \(SGLT2\) Inhibitors](#)

Enfuvirtide (Fuzeon™) - See [HIV Medication/Treatment](#)

Erythropoiesis Stimulating Agents (ESA's): epoetin Alfa (Epogen™, Procrit™) darbopoetin Alfa (Aranesp™)

All of the following must be true for patient to be eligible for ESA treatment of hepatitis C treatment-related anemia:

1. Patient receiving hepatitis C therapy; AND
2. Patient is one of the following:
 - a. Cirrhotic;
 - b. Pre or post-liver transplant
 - c. HIV/HCV co-infected;
 - d. Receiving HIV triple therapy;
- AND
3. Patient underwent evaluation for other causes of anemia (e.g. bleeding, nutritional deficiency) and has been treated appropriately; AND
4. Patient develops anemia defined as Hgb < 10 g/dL (or as clinically indicated for significant anemia-related signs and symptoms) and persists for at least two weeks after reducing the ribavirin dose to 600 mg/day; AND
5. Patient does not have exclusion criteria: Uncontrolled hypertension or risk for thrombosis.

Etanercept (Enbrel™) - See [Immunomodulator TNF Inhibitors](#)

Etravirine (Intelence™) - See [HIV Medication/Treatment](#)

Evolocumab (Repatha™) - See [PCSK9 Inhibitors](#)

Exenatide (Byetta™), exenatide ER (Bydureon™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Ezetimibe (Zetia™)

1. Must complete and submit Appendix 2, Steps 1-6, Management of Lipid Disorders, BOP Clinical Practice Guidelines.
2. Ezetimibe 10 mg daily can be considered on a non-formulary basis for those patients not meeting their LDL-C goal on simvastatin, lovastatin or atorvastatin 80 mg daily in combination with a bile acid sequestrant (BAS), or the maximally tolerated or recommended daily dose of a statin in combination with a bile acid sequestrant (BAS).
3. If simvastatin, lovastatin, or atorvastatin cannot be used (e.g., due to a drug interaction - CYP 3A4 metabolism) or not tolerated, the maximally tolerated or recommended dose of pravastatin or fluvastatin (e.g. 80 mg/d), in combination with BAS, should be reached prior to considering therapy with ezetimibe.
4. Since there is no evidence to show a benefit with regard to health outcomes with ezetimibe, monotherapy with ezetimibe should be limited to those patients unable to tolerate statins, bile acid sequestrants.

Fenofibrate (Tricor™)

1. Failure of gemfibrozil used for at least 6 months
2. Treatment of hyperglycemic patients. HbA1c should be < 8

3. Triglyceride level must be > 500 after compliance with criteria 1 and 2 above

Filgrastim/pegfilgrastim/tbo-filgrastim (Neupogen™/Neulasta™/Granix™)

1. Adjunctive therapy for cancer chemotherapy.
 - a. Chemotherapy primary prophylaxis for "dose dense" treatment regimen.
 - b. Chemotherapy primary prophylaxis for treatment regimen with 20% or higher risk of febrile neutropenia.
 - c. Chemotherapy primary prophylaxis for patient older than 65, poor performance status, combined chemoradiotherapy, poor nutritional status, advanced cancer, or other serious comorbidities.
 - d. Chemotherapy secondary prophylaxis for patient with history of prior neutropenic complications.
2. All of the following must be true for patient to be eligible for filgrastim treatment of hepatitis C treatment-related neutropenia:
 - a. Patient receiving hepatitis C therapy; AND
 - b. Patient develops neutropenia defined as either
 - i. ANC < 250/mm³; or
 - ii. ANC < 500mm³ with one of the following risk factors for developing infection;
 - a. Cirrhosis, biopsy proven or clinically evident;
 - b. Pre-or post-liver transplant;
 - c. HIV/HCV co-infection
 - d. Receiving HCV triple therapy;AND
 - c. Patient has failed to respond (i.e. neutropenia persists) despite at least two weeks of peginterferon dose reduction.

Fluticasone Oral inhaler (Flovent™)

Must fail two other inhaled corticosteroids with demonstrated compliance.

Fluticasone/Salmeterol (Advair™) - See [Long Acting Beta Agonists \(LABA\)](#) and Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS)

Formoterol (Foradil™) - See [Long Acting Beta Agonists \(LABA\)](#) and Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS)

Gabapentin (Neurontin™)

1. Approved for neuropathic pain after failure of duloxetine, plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
2. Functional status must be documented. If renewal request, the request must indicate that the inmate's functional status has improved with use of gabapentin.
3. Bipolar disorder: Approval will be considered only after documented failure of therapeutic trials of lithium, valproic acid, carbamazepine, and atypical antipsychotics, (alone and in combination), or documented prior response to gabapentin. Failure is defined as recurrence of mania or hypomania during active treatment with therapeutic doses/blood levels of approved medications, with documented compliance, or the presence of adverse side effects. Required documentation includes a mental health evaluation as outlined in the clinical guidelines for psychiatric evaluation, and blood levels (when appropriate) of formulary agents during episodes of recurrent illness.

Recommended Gabapentin Taper

Gabapentin should be tapered over a period of 2 - 4 weeks

Glucagon-like Peptide 1 Receptor (GLP-1) Agonists: albiglutide (Tanzeum™), dulaglutide (Trulicity™), exenatide (Byetta™), exenatide ER(Bydureon™), liraglutide (Victoza™; Saxenda™), lixisenatide (Adlyxin™)

1. Patient has type 2 diabetes.
2. Failed maximum tolerated dose of metformin or documented contraindication to metformin.
3. A1C goal not met on therapeutic doses of formulary agents.
4. A1C <9% (if A1C is ≥9%, then insulin therapy is indicated instead of this agent).
5. Consider in patients with difficulty controlling weight and blood glucose despite appropriate diet and exercise adherence, documentation required including commissary purchases reviewed.
6. Criteria 1 through 4 must be met for approval.

Golimumab (Simponi™) - See [Immunomodulator TNF Inhibitors](#)

Hepatitis C Treatment Algorithm:

"Medical HOLD" will be placed on inmate once Hepatitis C treatment therapy is initiated.

HIV Medications/Treatment: etravirine (Intelence™), maraviroc (Selzentry™), tipranavir (Aptivus™), enfuvirtide (Fuzeon™)

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director

Hormones to maintain secondary sexual characteristics: conjugated estrogens (Premarin™), esterified Estrogens (Menest™), estradiol (Alora™, Climara™, Delestrogen™, Depo-Estradiol™, Estrace™, Estraderm™, Vivelle™), finasteride (Proscar™), spironolactone (Aldactone™) testosterone (Androgel™, Androderm™, Axiron™, Aveed™, Delatestryl™, Depo-Testosterone™, Fortesta™)

1. Consultation with BOP Chief Psychiatrist and/or Central Office Transgender Clinical Management Team when providing transgender care.

Hydroxyzine (Atarax™, Vistaril™) oral - See [antihistamines](#)

Immunomodulator TNF Inhibitors: adalimumab (Humira™), certolizumab (Cimzia™), etanercept (Enbrel™), golimumab (Simponi™), infliximab (Remicade™),

1. Adalimumab is recommended agent before etanercept and golimumab due to better side effect profile and cost effectiveness.
2. Failure of methotrexate/prednisone, gold, or azathioprine.
3. Intolerable side effects of methotrexate where a TNF agent may allow a decrease in methotrexate dose.
4. Request must include rheumatology consult report.
5. All new and renewal prescriptions for dermatologic use requires BOP Teledermatologist consultation.
6. Requests for patients with a TST \geq 5mm or a positive IGRA (interferon gamma release assay) test must be accompanied by evidence of LTBI treatment completion (medication used with ingested dose counts).

Infliximab (Remicade™) - See [Immunomodulator TNF Inhibitors](#)

Insomnia medications: (Ambien™, Lunesta™, Sonata™)

Insomnia is typically a symptom, and not a disease state, and thus the clinical focus should be on identifying and treating the underlying cause (i.e. depression, anxiety, psychosis, poor sleep hygiene, and chronic medical conditions such as diabetes). The long term use of antidepressants or antihistamines for complaints of poor sleep in the absence of another Axis I diagnosis is not appropriate.

Insulin glargine/Insulin detemir, Long Acting Insulin (Lantus™/Levemir™)

1. Recurrent episodes of symptomatic hypoglycemia despite multiple attempts with various insulin dosing regimens. Non-formulary request must include documentation of blood glucose values in the hypoglycemic range (i.e. MARs), and the insulin regimens used. **OR;**
2. Failure to achieve target HbA1c goals despite compliance with an intensive insulin regimen (3 to 4 injections / day) using NPH and regular. Note: The evening dose of NPH should be administered as close to bedtime as staffing and institution procedures permit.) Non-formulary request must include the insulin regimens used, an assessment of compliance (i.e. MARs) and a recent HbA1C result with date.

Insulin Aspart/Insulin lispro, Rapid Acting Insulin (Novolog™/Humalog™)

NOTE: generally speaking insulin lispro and insulin aspart are too short acting to be used safely in most correctional environments.

1. Unable to achieve glycemic control targets with the use of regular insulin, despite multiple attempts with various insulin dosing regimens.
2. Non-formulary request must include the insulin regimens that have been tried and found ineffective, including times of administration.
3. Self-monitoring of blood glucose or immediate access to blood glucose monitoring at all times.
4. Ability to eat a meal immediately (within 15 minutes) after injecting rapid-acting insulin.
5. Patients receiving highly intensive insulin therapy such as q.i.d. administration, including those who would otherwise be candidates for insulin pump therapy.
6. Will be used at Medical Centers only - is not an acceptable transfer medication.

Isotretinoin (Accutane™)

1. iPLEDGE enrollment and requirements located at <https://www.ipledgeprogram.com> Proof of enrollment must be submitted with non-formulary request.
2. Central Office Physician or Regional Medical Director (RMD) have been consulted. This will occur prior to the enrollment of the physician and patient as well as enrollment and fee payment of the institution pharmacy into the iPLEDGE program.

Ketoconazole oral

Ketoconazole tablets are indicated only for the treatment of the following fungal infections: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis in patients in whom other treatments have failed or who are intolerant to other therapies.

Lidocaine Topical Patches (Lidoderm™)

1. Patient is being treated for post-herpetic neuralgia.
2. Patient utilized 4-6 week trial of formulary anticonvulsants and/or tricyclics.
3. Patient will be prescribed other concurrent analgesic therapies effective for neuropathic pain.

Linagliptin (Tradjenta™) - See [Dipeptidyl Peptidase-4 \(DPP-4\) Inhibitors](#)

Linezolid (Zyvox™)

1. IV vancomycin should be utilized when possible.
2. Case by case basis for transition of stable patients receiving IV vancomycin in hospital setting to institution which is unable to provide IV vancomycin.
3. Documentation of culture and sensitivity data must be submitted with non-formulary request.
4. Non-formulary approval will be for pill line administration only due to concerns of expense, compliance, and potential for resistance development.

Liraglutide (Victoza™; Saxenda™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Lixisenatide (Adlyxin™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Long Acting Beta Agonists (LABA) and Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS): salmeterol (Serevent™), formoterol (Foradil™), budesonide/Formoterol (Symbicort™) and fluticasone/salmeterol (Advair™)

1. COPD patients must have failed anticholinergic agent tiotropium (Spiriva™).
2. Continued nocturnal awakenings not managed by medium dose steroid inhaler OR low dose steroid inhaler plus a leukotriene receptor antagonist (i.e. - montelukast).
3. At least severe persistent asthma not controlled by medium dose inhaled corticosteroid alone.
4. Reversibility demonstrated with a short acting beta agonist. Reversibility is characterized by an increase in FEV₁ of greater than 200 mL and greater than 12% from baseline.
5. Not to be utilized as monotherapy.
6. Nebulizer solution will not be approved for use in asthma.
7. Non-formulary requests for long acting beta agonists that meet criteria will be approved for agent on mandatory contract.

Lorazepam long-term use - See [Benzodiazepines](#)

Lorcaserin (Belviq™) - See [Anti-Obesity Agents](#)

Loteprednol etabonate (Lotemax™, Alrex™)

After use of formulary ophthalmic steroid for greater than 28 days.

Maraviroc (Selzentry™) - See [HIV Medication/Treatment](#)

Metaxalone (Skelaxin™) - See [MUSCLE RELAXANTS](#)

Metoclopramide (Reglan™)

1. Restricted to 12 weeks of therapy for all formulations
2. If NFR approved, after 12 weeks, get periodic AIMS testing

Montelukast (Singulair™)

1. **Asthma:** Third line agent in the treatment of asthma. Compliance with other medications must be shown (e.g. oral steroid inhalers)
2. **Allergic Rhinitis:** Third line agent after documented compliance with OTC antihistamine and nasal steroid. Copies of progress notes detailing symptoms and exam findings will be required.
3. **Urticaria:** Montelukast will not be approved for this indication.

Muscle Relaxants: dantrolene (Dantrium™), baclofen (Lioresal™), cyclobenzaprine (Flexeril™), tizanidine (Zanaflex™), metaxalone (Skelaxin™), methocarbamol (Robaxin™), carisprodal (Soma™), chlorzoxazone (Parafon forte DSC™), orphenadrine (Norflex™)

PILL LINE ONLY

Approval for muscle relaxants will be considered for the following cases and all must be administered via PILL LINE:

1. Observable, documented muscle spasm due to:
 - a. Multiple sclerosis
 - b. Spinal cord injury or intrinsic cord lesions (not herniated spinal discs, not low back pain due to muscle spasm)
 - c. Stroke
 - d. Cerebral palsy
2. Approval for baclofen may be considered for intractable pain from neurological conditions, such as trigeminal neuralgia, that has been unresponsive to formulary agents.
3. Metaxalone is last resort skeletal muscle therapy after failure of all other muscle relaxants.

Compliance should be monitored at each visit. These medications are frequently diverted to other inmates due to their mood-altering effects. Abrupt discontinuation of baclofen can precipitate a drug withdrawal syndrome. There are generally no valid indications for long-term use of cyclobenzaprine or similar "muscle relaxants" such as methocarbamol. Lorazepam is recommended for short-term use in acute muscle spasm where sedation is desired.

Naloxone intranasal solution (Narcan™)

1. Prescribed on a case-by-case basis only for inmates with a high risk of opioid overdose who are releasing from BOP custody or transferring to a residential reentry center or home confinement.
2. Nasal dosage form is preferred first-line therapy prior to auto-injector use.
3. When naloxone nasal is prescribed, appropriate education on the risks and symptoms of opioid overdose and the use of naloxone must be provided to the inmate and documented in the medical record.

Narcolepsy Treatment - Stimulant medications: amphetamine, dextroamphetamine, modafinil, methylphenidate, selegiline

1. Documented verification of the inmate's report, to include polysomnography obtained and provided.
2. Patient has failed non-pharmacologic management strategies.
3. Functional impairment with work assignment, institution security, academic needs.
4. Failed treatment with modafinil and fluoxetine (for cataplexy).

Neuraminidase inhibitors: oseltamivir (TamiFlu™), zanamivir (Relenza™)

1. Therapy is only to be offered to patients within 48 hours of exposure. Antiviral therapy is not effective or recommended 48 hours post exposure.
2. Non-Formulary Drug requests for TamiFlu™ will be processed and expedited through Central Office.
3. Treatment requests for outbreaks, prophylaxis, and exposures will be conducted through the Infectious Disease Coordinator. Region, Central Office and approved by the BOP Medical Director for treatment.
4. Note: Stockpile antivirals may only be approved for use by the BOP Medical Director under certain conditions as proclaimed by the World Health Organization.

Nutritional Supplements for oral consumption

1. Request for its non-formulary use requires completion of the ["Nutritional Supplements Worksheet"](#)
2. Failure of medical diets, special diets, and supplemental feeding options available through Food Service, **AND**
3. A documented medical diagnosis affecting nutritional status, **AND**
4. Nutritional Assessment Consult by BOP registered dietician for therapy > 60 days.

Ocuvite/AREDS/I-Caps

1. Item has been previously reviewed in regards to formulary status with ongoing consultation with a BOP ophthalmologist. Offenders wishing to purchase this item should be referred to, and allowed to purchase, from the commissary through a Special Purchase Order (SPO). This is a non-prescription item. The ophthalmic literature remains controversial on the effect on the course of macular degeneration (wet or dry).
2. Refer all renewals of previously approved non-formulary requests to the BOP National Ophthalmology Consultant.

Onychomycosis, oral treatment - See [Antifungals](#)

Orlistat (Xenical™) (Alli™ OTC) - See [Anti-Obesity Agents](#)

Oseltamivir (TamiFlu™) - See [Neuraminidase inhibitors](#)

Oxycodone Controlled Release (Oxycontin™)

1. Must have failed extended release morphine. Failure is defined as unable to titrate dose due to adverse effects unable to be resolved despite aggressive treatment.

PCSK9 Inhibitors: evolocumab (Repatha™), alirocumab (Praluent™)

1. Prescribed for an FDA approved indication only.
2. Failure to achieve cholesterol goals with maximum doses of at least two different HmgCoA reductase inhibitors, OR
3. Unable to tolerate HmgCoA reductase inhibitors.

Phenobarbital (Luminal™)

1. Diagnosis of seizure, **AND**
2. Used in combination with other anticonvulsant medications, **AND**
3. Used as 3rd line agent, **AND**
4. Compliance > 90% maintained

Phentermine/Topiramate (Qsymia™) - See [Anti-Obesity Agents](#)

Prasugrel (Effient™)

1. Does patient have aspirin allergy anaphylaxis, bronchospasm? (Indications for use as a single antiplatelet agent therapy)
2. Does patient have recurrent non-cardioembolic cerebral ischemia while on aspirin?
3. Did patient have ACS: (NSTEMI, STEMI, unstable angina (UA)) with no revascularization - 1 year therapy recommended (indication for use as dual antiplatelet therapy with aspirin)
4. Is patient post PCI - 1 year therapy recommended (indication for use as dual antiplatelet therapy with aspirin)
5. Is patient post CABG - 4 weeks therapy recommended (indication for use as dual antiplatelet therapy with aspirin)
6. Does patient have non-coronary stenting? (indication for use as dual antiplatelet therapy with aspirin)
7. Did patient fail clopidogrel therapy?
8. Is patient on pharmacotherapy that has a major interaction with clopidogrel but does not interact with prasugrel?
9. Patient under the age of 74?
10. Patient weighs 60 kg or more?

Pregabalin (Lyrica™)

1. Diabetic neuropathy - well documented as insufficient functional response to duloxetine plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
2. Postherpetic Neuralgia - well documented intolerance or insufficient functional response at maximally tolerated doses of tricyclic antidepressants and topical analgesics such as capsaicin cream
3. Fibromyalgia - documented diagnosis of fibromyalgia by rheumatologist. Documented insufficient functional response to duloxetine, plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
4. Partial onset seizures - well documented intolerance or insufficient response to at least two other agents (i.e. Carbamazepine, lamotrigine, levetiracetam, phenytoin, topiramate).

Protein Powder/Protein Liquid

1. Request for its non-formulary use requires completion of the ["Nutritional Supplements Worksheet"](#)
2. Failure of medical diets, special diets, and supplemental feeding options available through Food Service, **AND**
3. A documented medical diagnosis affecting nutritional status, **AND**
4. Nutritional Assessment Consult by BOP registered dietician required for every request.

Quetiapine (Seroquel™)

1. Use in psychotic disorder, bipolar disorder, or borderline personality disorders only.
2. Requests must include justification and treatment history in accordance with the Antipsychotic Treatment Algorithm, BOP Clinical Practice Guidelines, Pharmacological Management of Schizophrenia.
3. Non-formulary approvals for oral formulation will be restricted to the IR formulation only. Quetiapine IR must be administered via pill line and crushed prior to administration unless otherwise restricted by package insert.

Quinine

Non-formulary will not be approved for leg cramps.

Restless Leg Syndrome Algorithm

Step 1. Sleep Hygiene - Refer to Sallyport Guidelines

Step 2. Evaluate Drug Therapy - consider medication change or dose reduction of SSRI, TCA, lithium, antihistamines, caffeine, dopamine agonists.

Step 3. Trial of oral iron therapy.

Step 4. Evaluate for secondary causes - iron deficiency, chronic kidney disease, venous insufficiency, neurologic lesions, rheumatic disease, or diabetes - and manage disease states optimally.

Step 5. Treatment with pramipexole, ropinirole, or levodopa/carbidopa.

Rifaximin (Xifaxan™)

1. Treatment of hepatic encephalopathy
2. Patient refractory to lactulose (patient obtained 3 loose stool per day)
3. Patient intolerant to lactulose

Rivaroxaban (Xarelto™) - See [Anticoagulants](#)

Salmeterol (Serevent™) - See [Long Acting Beta Agonists \(LABA\)](#)

Saxagliptin (Onglyza™) - See [Dipeptidyl Peptidase-4 \(DPP-4\) Inhibitors](#)

Sitagliptin (Januvia™) - See [Dipeptidyl Peptidase-4 \(DPP-4\) Inhibitors](#)

Sodium-glucose Cotransporter-2 (SGLT2) Inhibitors: canagliflozin (Ivokana™), dapagliflozin (Farxiga™), empagliflozin (Jardiance™)

1. Patient has type 2 diabetes and established cardiovascular disease.
2. Failed maximum tolerated dose of metformin or documented contraindication to metformin.
3. A1C goal not met on therapeutic doses of formulary agents.
4. A1C <9% (if A1C is ≥9%, then insulin therapy is indicated instead of this agent).
5. Consider in patients with difficulty controlling weight and blood glucose despite appropriate diet and exercise adherence, documentation required including commissary purchases reviewed.
6. Criteria 1 through 4 must be met for approval.

Synvisc™ (Hylan G-F 20), Hyalgan™ (Sodium Hyaluronate)

1. Osteoarthritis of the knee(s) (American College of Rheumatology criteria) confirmed by history, exam, and x-ray.
2. Documented inadequate control of pain or intolerance to adequate trial of acetaminophen (4 grams/day), NSAIDs, and other non-narcotic or narcotic analgesics.
3. Inadequate response to intra articular corticosteroid injections.
4. Inadequate response to bracing and use of canes or crutches.
5. Inadequate response to measures such as weight loss and physical therapy.
6. Surgery is not an option due to concurrent medical conditions that preclude the patient as candidate for surgery. These agents may also be considered as a bridging option before resorting to surgery.

Tbo-Filgrastim (Granix™) - See [Filgrastim](#)

Testosterone (Androgel™, Androderm™, Axiron™, Aveed™, Delatestryl™, Depo-Testosterone™, Fortesta™)

1. Evidence of bilateral orchiectomy, Klinefelter's syndrome, pituitary adenoma, hypothalamic adenoma, or other confirmed disease of the testes, pituitary or hypothalamus.
2. Testosterone supplementation is not approved or continued for unlabeled uses, e.g. strength training, increased libido.
3. A six-month washout period is required for patients with no confirmed disease of the testes, pituitary or hypothalamus.
4. Patient is experiencing significant withdrawal symptoms, e.g. anxiety, depression, mood swings during six-month washout period (60-day taper schedule).
5. Laboratory AND clinical evidence (decrease in energy, mood; decrease in sexual hair, hematocrit, muscle mass and strength, and bone mineral density) of testosterone deficiency is confirmed after the six-month washout period.
6. Use in Gender Dysphoria / Transgender cases will be referred to Central Office Transgender Clinical Management Team for review.
7. Consultation with BOP Chief Psychiatrist and/or Central Office Transgender Clinical Management Team when providing transgender care.

Tipranavir (Aptivus™) - See [HIV Medication/Treatment](#)

Vancomycin, Oral (Vancocin HCl Pulvules™)

1. Use in severe and severe-complicated clostridium difficile infection (CDI) only.
2. Second line agent therapy for non-severe CDI after compliant trial of metronidazole.

Zanamivir (Relenza™) - See [Neuraminidase Inhibitors](#)

Non-Formulary Algorithm for Donepezil (Aricept™) Approval
 (# 1,3,5,9,10 only for renewal)

1. Initial treatment: _____ Follow-up: 3 mo 6 mo 12 mo other _____
 Dose of donepezil: _____
2. Inmate has dementia, Alzheimer's type: (Circle one)
 a. mild b. moderate
 c. Severe - does not qualify for trial. Consider Reduction in Sentence
3. Mini-Mental State Score: _____
 (Other objective measures may be utilized, such as Dementia Rating Scale, however, the same test should be used at each interval to document response to treatment).
 Test _____ Score _____
4. Physical findings: **Please attach copy of most recent exam, must include weight, vital signs, neurologic screening.**
5. Laboratory results: Date: _____

Hgb _____	WBC _____	Plts _____	MCV _____
RDW _____	AST _____	ALT _____	Alk Phos _____
Tot Prot _____	Alb _____	SCR _____	FBG _____
RPR _____	B-12 _____	Folate _____	TSH _____

 U/A: RBC _____ Leukocytes _____ Prot _____ Gluc _____
6. CT head or MRI head results (**attach copy of report**).
7. Major Depression has been effectively treated or ruled out?
 Yes No Current Treatment: _____
8. Delirium has been ruled out by: _____ (Physician) on: _____ (Date):
 Yes No If no, describe: _____

9. List all current medications and their doses and blood levels if appropriate, e.g. lanolin, anti-seizure meds: _____

10. No contraindications to cholinesterase inhibitor (e.g. PUD, asthma, COPD, bradycardia, liver disease, anticholinergic drugs, parkinsonism):
11. Prior treatment with cholinesterase inhibitor?
 Drug(s): _____ Dates: _____
 Outcome: _____
12. Comments: _____

Recommendations by Institution Chief Psychiatrist or Clinical Director: _____

Approved: _____ Medical Director Date: _____

Disapproved: _____ Medical Director Date: _____

Inmate Name: _____ Reg. No: _____

Institution: _____

Worksheet for Use of Nutritional Supplement

Inmate Name:	Register Number:	Institution:																
Date of Birth:	Usual Body Weight – UBW(lb):																	
Weight(lb):	Height(in):	Gender: M / F																
BMI: _____ $BMI = 703 \times [weight(lb) / height^2(in)]$																		
Ideal Weight Range(lb): _____ to _____ <i>Hamwi method: men = 106 lb + 6 lb for each inch >5 ft, women = 100 lb + 5 lb for each inch > 5 ft, then +/- 10% for range</i>																		
Percent Weight Loss(%) , unintentional: Over past month _____, past 3 months _____, past 6 months _____ $Percent\ weight\ loss = (UBW - current\ weight / UBW) \times 100$																		
Medical Diagnoses – check all that apply (must have at least one): <table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> Dysphagia</td> <td><input type="checkbox"/> Burns - % Body Surface Area _____</td> </tr> <tr> <td><input type="checkbox"/> Crohn's Disease</td> <td><input type="checkbox"/> Hunger Strike</td> </tr> <tr> <td><input type="checkbox"/> Alzheimer's Disease</td> <td><input type="checkbox"/> Cancer</td> </tr> <tr> <td><input type="checkbox"/> Swallowing Problems</td> <td><input type="checkbox"/> End Stage Renal Disease on Dialysis</td> </tr> <tr> <td><input type="checkbox"/> Mastication Problems</td> <td><input type="checkbox"/> Multiple Dental Extractions or Extensive Dental Surgery (short term use)</td> </tr> <tr> <td><input type="checkbox"/> Ulcerative Colitis</td> <td><input type="checkbox"/> Chronic Wounds (describe in notes below)</td> </tr> <tr> <td><input type="checkbox"/> Malabsorptive Disorder – Specify _____</td> <td><input type="checkbox"/> Other(s): _____</td> </tr> <tr> <td><input type="checkbox"/> Failure to Thrive</td> <td></td> </tr> </table>			<input type="checkbox"/> Dysphagia	<input type="checkbox"/> Burns - % Body Surface Area _____	<input type="checkbox"/> Crohn's Disease	<input type="checkbox"/> Hunger Strike	<input type="checkbox"/> Alzheimer's Disease	<input type="checkbox"/> Cancer	<input type="checkbox"/> Swallowing Problems	<input type="checkbox"/> End Stage Renal Disease on Dialysis	<input type="checkbox"/> Mastication Problems	<input type="checkbox"/> Multiple Dental Extractions or Extensive Dental Surgery (short term use)	<input type="checkbox"/> Ulcerative Colitis	<input type="checkbox"/> Chronic Wounds (describe in notes below)	<input type="checkbox"/> Malabsorptive Disorder – Specify _____	<input type="checkbox"/> Other(s): _____	<input type="checkbox"/> Failure to Thrive	
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<input type="checkbox"/> Malabsorptive Disorder – Specify _____	<input type="checkbox"/> Other(s): _____																	
<input type="checkbox"/> Failure to Thrive																		
BOP Food Service Diet(s) Tried – check all that apply: <table border="0" style="width: 100%;"> <tr> <td><input type="checkbox"/> Regular</td> <td><input type="checkbox"/> Full Liquid</td> </tr> <tr> <td><input type="checkbox"/> Soft</td> <td><input type="checkbox"/> Pureed</td> </tr> <tr> <td><input type="checkbox"/> Mechanical Soft/Edentulous</td> <td><input type="checkbox"/> Gluten Free</td> </tr> <tr> <td><input type="checkbox"/> Low Residue / Low Fiber</td> <td><input type="checkbox"/> Diabetic Snack</td> </tr> <tr> <td><input type="checkbox"/> Clear Liquid</td> <td><input type="checkbox"/> Snack for Increased Calories</td> </tr> </table>			<input type="checkbox"/> Regular	<input type="checkbox"/> Full Liquid	<input type="checkbox"/> Soft	<input type="checkbox"/> Pureed	<input type="checkbox"/> Mechanical Soft/Edentulous	<input type="checkbox"/> Gluten Free	<input type="checkbox"/> Low Residue / Low Fiber	<input type="checkbox"/> Diabetic Snack	<input type="checkbox"/> Clear Liquid	<input type="checkbox"/> Snack for Increased Calories						
<input type="checkbox"/> Regular	<input type="checkbox"/> Full Liquid																	
<input type="checkbox"/> Soft	<input type="checkbox"/> Pureed																	
<input type="checkbox"/> Mechanical Soft/Edentulous	<input type="checkbox"/> Gluten Free																	
<input type="checkbox"/> Low Residue / Low Fiber	<input type="checkbox"/> Diabetic Snack																	
<input type="checkbox"/> Clear Liquid	<input type="checkbox"/> Snack for Increased Calories																	
Reason(s) Nutritional Needs Could Not be Met Through Food Service Offerings: _____ _____																		
Additional notes: _____ _____																		
Name / Title / Signature of Requestor:		Date:																
Procedure for Submitting Nutritional Supplement Algorithm: <ul style="list-style-type: none"> – Scan into BEMR Document Manager as .pdf file – Attach to BEMR non-formulary request for selected nutritional supplement and/or protein powder/liquid – For nutritional supplement use > 30 days and <u>ALL</u> protein-only supplement requests: a BOP registered dietitian nutritional assessment consult must be attached (completed locally at MRCs or via tele-nutrition at all others) 																		

Non-Sterile Compounding Worksheet

Attach this, with any other required documentation with your NFR request.

Requesting Institution: _____ **Date:** _____

Who is making the compound?

Outside Pharmacy

BOP Pharmacy

Attach copy of medication label
+/- recipe (if will give)

OR,

Pharmacy Name: _____

Pharmacy Phone Number: _____

Pharmacy Address: _____

Rx # (if have): _____

Any Directions/Ingredients they
will give:

Is Compound in BEMR
Already?

1. Go to: Reports -> Drug File
2. Make "Formulary" = ALL
3. Select the box next to
"Compound" towards the
bottom
4. Click "View"
5. Review report and see if desired
compound is listed

NO →

Complete the **MASTER
FORMULATION RECORD
WORKSHEET** on **Page 2**
and submit to the BEMR
Workgroup for addition to
the National Drug File.

YES →

Complete the
**COMPOUNDING RECORD
WORKSHEET** on **Page 3**
and store in Document
Manager **OR** complete any
documentation dictated by
local law, policy, and
procedures.

Label Product per 2011 National P&T Minutes:

- Must enter order into BEMR with our label referencing the medication name, filling pharmacy name, and statement that "inmate is authorized to carry this medication"
- Cannot repackage, instead place non-BOP medication items into a clear plastic bag with the BEMR label affixed to the plastic bag to authorize self-carry.

MASTER FORMULATION RECORD WORKSHEET

Name and Strength of Product: _____ Quantity: _____
 (# of units, volume, weights, etc.)

Intended Use: _____ Intended Route of Administration: _____

Formula:

Ingredient	Quantity	Physical Description	Solubility	Function

Compatibility/Stability Information (Literature Search):

Special Equipment, if any: _____

Calculations:

Method/Directions for Preparation:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

Description of Finished Product: _____

Quality Control Tests:

Beyond-Use Dating/Recommended Storage (Check one):

- ☐ **Solid and Non-Aqueous Formulations** - No later than 25% of the time remaining until the earliest ingredient's expiration date OR 6 months, whichever is earlier
- ☐ **Aqueous Formulations** - No later than 14 days for liquid preparations when refrigerated (36°F to 46°F)
- ☐ **All other Formulations** - No later than 30 days OR duration of therapy, whichever is earlier

Packaging: _____

Labeling: _____
 (Product content and auxiliary labels)

COMPOUNDING RECORD WORKSHEET

Name of Master Formulation Record: _____ Rx#: _____

Date Compounded: _____

Preparer Name: _____

Ingredient	Amount	Manufacturer/Source	Lot #	Expiration Date

Total quantity compounded: _____

Assigned Beyond-Use Date: _____

Solid and Non-Aqueous Formulations	No later than 25% of the time remaining until the earliest ingredient's expiration date OR 6 months, whichever is earlier
Aqueous Formulations	No later than 14 days for liquid preparations when refrigerated (36°F to 46°F)
All other Formulations	No later than 30 days OR duration of therapy, whichever is earlier

Copy of Label:

Description of final preparation: _____

Pharmacist Verification: _____

QC Completed by: _____

Results of QC:

Any QC issues that arose:

Any Reported ADRs:

Urgent Care Cart and Kit Content

MRCs with 24 hour coverage that have a sufficient number of trained staff to perform ACLS 24 hours per day, 7 days per week may elect to stock their Urgent Care Cart with "A" list medications. Care Level III institutions with 24 hour coverage that have sufficient numbers of trained staff to perform ACLS 24 hours per day, 7 days per week wanting to stock "A" list medications must submit a request for a waiver to the Medical Director, BOP - routed through the Regional Medical Director - for approval. All other institutions will stock only medications on the "B" list. Staff using "Urgent Care Cart" supplies for resuscitation should be trained and privileged by the Clinical Director in accordance with established protocols approved by the CD.

Medication	MRCs and approved Care IIIs	All others
Adenosine 6 mg	A	
Amiodarone 50 mg/ml	A	
Aspirin 81 mg	A	B
Atropine 1 mg/10ml	A	
Benztropine inj 1mg/ml	A	B
D5W	A	B
Dextrose 50% injection	A	B
Digoxin 0.5 mg injection	A	
Dopamine 400 mg/5ml	A	
Epinephrine 1:10000 syringe	A	
Epinephrine 1:1000 amps	A	
epinephrine auto-injector 0.3	A	B
Furosemide injection	A	
Glucagon injection	A	B
Glucose Paste/Tabs	A	B
Haloperidol lactate inj 5mg/ml	A	B
Hydrocortisone OR Methylprednisolone injection	A	B
Lactated Ringers	A	B
Lorazepam injection	A	B
Morphine Sulfate injection	A	B
Naloxone 0.4 mg/ml	A	B
Nitroglycerin S.L. 0.4 mg tabs	A	B
Normal Saline	A	B
Procainamide 100 mg	A	
Propranolol 1 mg/ml	A	
Sodium Bicarbonate 50 meq	A	
Sodium Chloride 0.9% injection	A	B
Other items to consider having quick access to in the Urgent Care Room, but not necessarily stored in the cart		
Albuterol Inhaler	A	B
Albuterol Solution	A	B
Charcoal	A	B
Diphenhydramine 50 mg inj	A	B
Nitroglycerin 50 mg/10ml	A	

FORMULARY OTC PRESCRIBING CRITERIA MATRIX 2018

(Please note, although the OTC medication doses recommended by the manufacturer are typically less than prescription doses, the labeling does allow for higher doses if recommended by a clinician.)

Class / Indication	Formulary Agent	Dispense from Pharmacy (if Medically Necessary)	Refer to Commissary	Available Commissary Items
Pain ^{**10} (See OTC Matrix Nomogram – Pain, below as note 10)	- NSAIDS - salsalate- acetaminophen- aspirin **NOTE see comments at end of matrix	Ortho/Rheum diagnosis and followed in a related chronic care clinic ^{**1,2,3} - Acute injury or dental procedure [limit 7 days therapy (no refills) per month] ^{**4} - Inmates being followed in a neurology or pain CCC with migraine diagnosis may receive a short burst of NSAIDS or acetaminophen limited to 7 days (eg 21 tablets) per month for the acute treatment of migraines. Consideration of prophylactic treatment must be documented. - Inmates with a diagnosis/indication of Gout may receive a short burst of NSAIDS limited to 7 days (eg 21 tablets) per fill for the acute treatment of gout flare ups. - Inmates on interferon therapy should be able to receive short burst of acetaminophen to relieve post interferon injection discomfort (for example 3 day supply weekly) while on treatment. NSAIDS should NOT be used in patients with liver disease. or <u>OTC Med Qualified*</u> and medically appropriate	all others	- ibuprofen - naproxen - acetaminophen - aspirin - Midol TM max strength
Eye	- naphazoline-pheniramine eye drops (Visine-A TM) - artificial tears	<u>OTC Med Qualified*</u> and medically appropriate	all others	Allergy eye drops: - naphazoline-pheniramine eye drops (Visine TM A or Opcon TM A) - ketotifen - Artificial tears
Multi-vitamin	- iron - B-6 - calcium - calcium with Vit D - vitamin B-12 tablets - thiamine - folic acid - vitamin D	- anemia, osteoporosis, renal disease, alcohol detox or GI malabsorption diagnosis; or on INH therapy and followed in a related chronic care clinic - Vitamin D – documented deficiency or dermatologist approved sun-restricted conditions (including Lupus, solar urticarial, history of non-melanoma and melanoma skin cancers)	all others	- multivitamin - Vit E - Vit C - calcium - calcium with Vit D - Vit B Complex - Vit D - folic acid
Hemorrhoid	- dibucaine - glycerin-witch hazel topical (Tucks TM) - fiber tablets - docusate	pending hemorrhoid surgery or <u>OTC Med Qualified*</u> and medically appropriate	all others	- dibucaine ointment - hemorrhoidal cream - Tucks TM pads - fiber tablets - docusate
Stomach	- Maalox TM /	<u>OTC Med Qualified*</u> and medically appropriate ^{**5}	all others	- Maalox TM /Mylanta TM

	Mylanta™ - calcium carbonate (Tums™) - Gaviscon™ - MOM - bismuth subsalicylate - simethicone - loperamide - fiber tablets - docusate			antacid tablets - calcium carbonate (Tums™, Roloids™) - Gaviscon™ - MOM - bismuth subsalicylate - simethicone - loperamide - fiber tablets - docusate - methylcellulose (Citrucel™)
H2/PPI**11 (See OTC Matrix Nomogram – H2/PPI Use, below as note 11)	- ranitidine - omeprazole	OTC Med Qualified* and medically appropriate with gastrointestinal diagnosis and followed in a related chronic care clinic**6	all others	- ranitidine - famotidine - omeprazole
Dental	none	acute dental	all others	- anesthetic gel, dental
Anti-histamine, Nasal Steroid Cough and Cold Allergy	- fluticasone nasal spray	OTC Med Qualified* and medically appropriate**9 Non-Formulary - Refer to Use Criteria and OTC Policy	all others	- CTM - loratadine - cough drops - throat lozenges - saline nasal spray - Vicks Vapor Rub™ - guaifenesin syrup - Cromolyn Nasal Spray - triamcinolone nasal spray
Ear	- carbamide peroxide ear drops (Debrox™)	OTC Med Qualified* and medically appropriate	all others	- carbamide peroxide ear drops
Topical	- coal tar - antibiotic ointment - calamine - hydrocortisone - vit A & D - selenium - salicylic acid pads - zinc oxide	OTC Med Qualified* and medically appropriate**8	all others	- coal tar shampoo - sunscreen - antibiotic ointment - calamine - analgesic balm - hydrocortisone - vit A & D - selenium - salicylic acid pads - chapstick - zinc oxide - Lac-Hydrin™
Antifungal	- clotrimazole - miconazole - nystatin	OTC Med Qualified* and medically appropriate skin diagnosis and followed in a related chronic care clinic; x 30 days only per formulary restriction Nystatin – can prescribe for appropriate treatment of yeast infection – max 30 days only per formulary restriction	all others	- clotrimazole - tolnaftate - miconazole - terbinafine (Lamisil™)

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* If inmate is identified as ‘OTC Med Qualified’ (i.e. indigent) in TruFacs and meets guidance in ‘Dispense from Pharmacy’ column, item may only be prescribed up to a 15 day supply (no refills) per month. Refer to PS6541.02 for items available to indigent inmates without an HSU visit.

Note: Refer to current OTC Program Statement for list of medications that can be provided to indigent inmates without signing up for sick call. If a similar medication is not on the indigent OTC list, the inmate may have a short-term prescription.

** 1. Chronic pain conditions with objective abnormalities, e.g. rheumatoid arthritis, osteoarthritis with abnormal x-ray or abnormal findings, - Inmate should be enrolled in Ortho/Rheum chronic care clinic and prescriptions should be written by a clinician and dispensed by the pharmacy for prescription strength medication. For institutions without a pharmacist: inmates who are receiving chronic NSAID or acetaminophen therapy for pain and also receiving an NSAID or acetaminophen for breakthrough pain will be limited to 7 day supply per month of the secondary medication.

2. Chronic pain symptoms without any objective findings (in these cases it is assumed that significant pathology has been ruled out and symptoms are relatively minor) - these patients should be referred to commissary to purchase OTC medications.

3. Acute pain that is relatively minor should be referred to purchase OTC medication from the commissary. This would include minor injuries and headaches.

4. Acute pain that is severe, and short-term post - operative pain management in general should be managed with prescription strength medication written by a clinician and dispensed by the pharmacy ‘acute injury or dental procedure [limit up to 7 days of therapy (no refills) per month]’. Patients with severe pain must receive an appropriate evaluation to rule out causes that require urgent intervention rather than just pain management.

5. Stomach: Short-term laxative and antacid therapy for self-limiting conditions should be referred to the commissary. Non-stimulant laxatives and stool softener therapy may be provided for chronic GI hypo-motility disorders or in conjunction with iron and opioid analgesic orders.

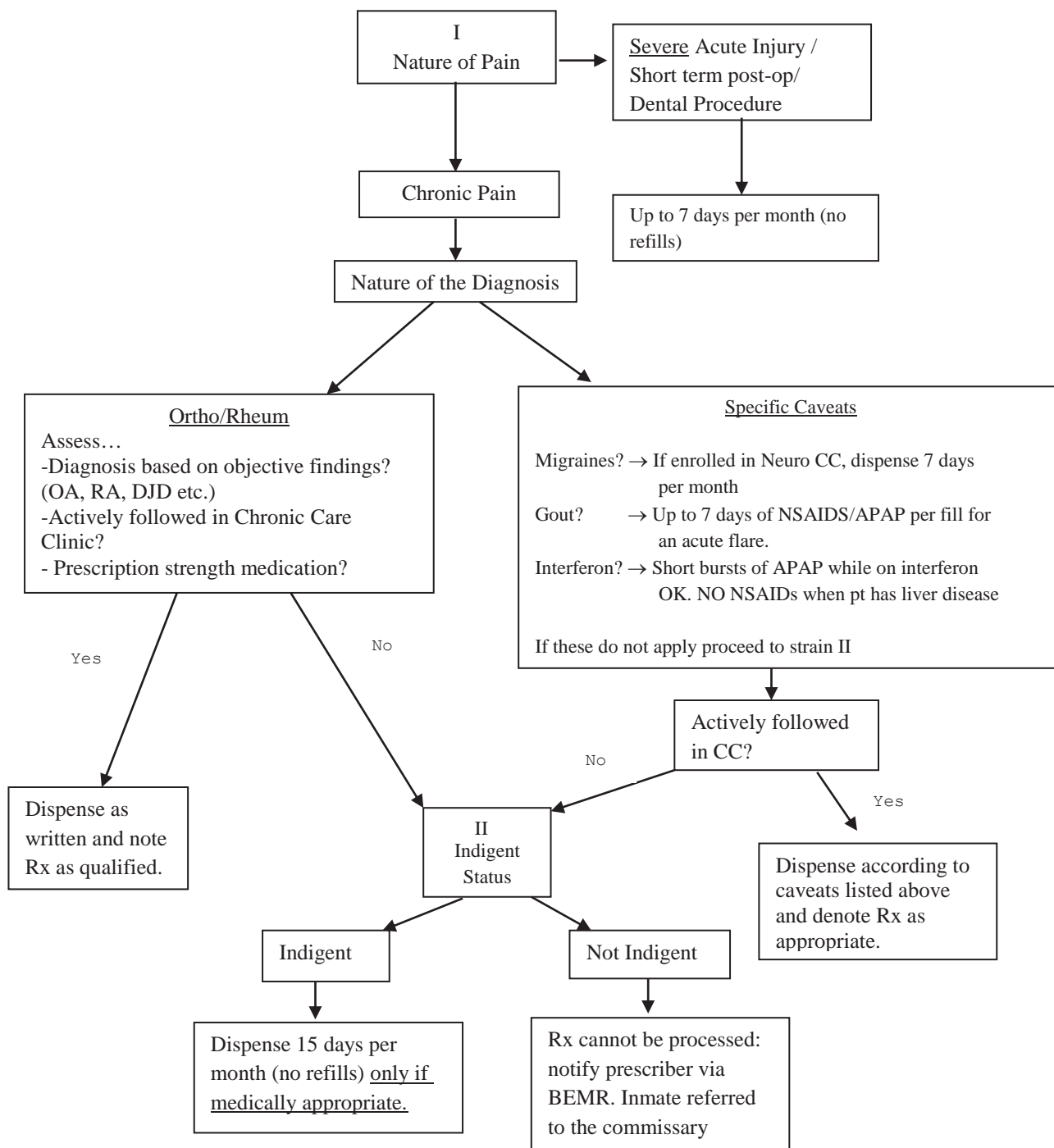
6. H2/PPI’s: **Non-indigent inmates must purchase all OTC strength “Ranitidine or Omeprazole” from the commissary (for: Relief of heartburn, acid indigestion, sour stomach, prn use, QD use for Ranitidine and GERD) unless they are being actively followed in a GI Chronic Care Clinic with documented findings to justify use of these medications for the following: Severe GERD, Zollinger-Ellison Syndrome, Schatzki’s Ring, Barrett’s Esophagitis, Esophageal Stricture, Hiatal Hernia, Previous GI Bypass or Ulcer Surgery, chronic oral steroid use in transplants, Documentation of Chronic need for NSAIDS with Prior History of GI Bleed and Short-Term Treatment of H. Pylori.

7. Non-indigent inmates should be referred to the commissary to purchase OTC eye drops (artificial tears and allergy eye drops) for minor eye conditions (dry eye, red eye, and Pterygium – unless surgical intervention is required). Eye conditions with objective abnormalities, e.g. short-term post-surgical eye procedures, Sjorgren’s syndrome, and prosthetic eye implants – inmates should be enrolled in a general chronic care clinic and followed by an optometrist or ophthalmologist.

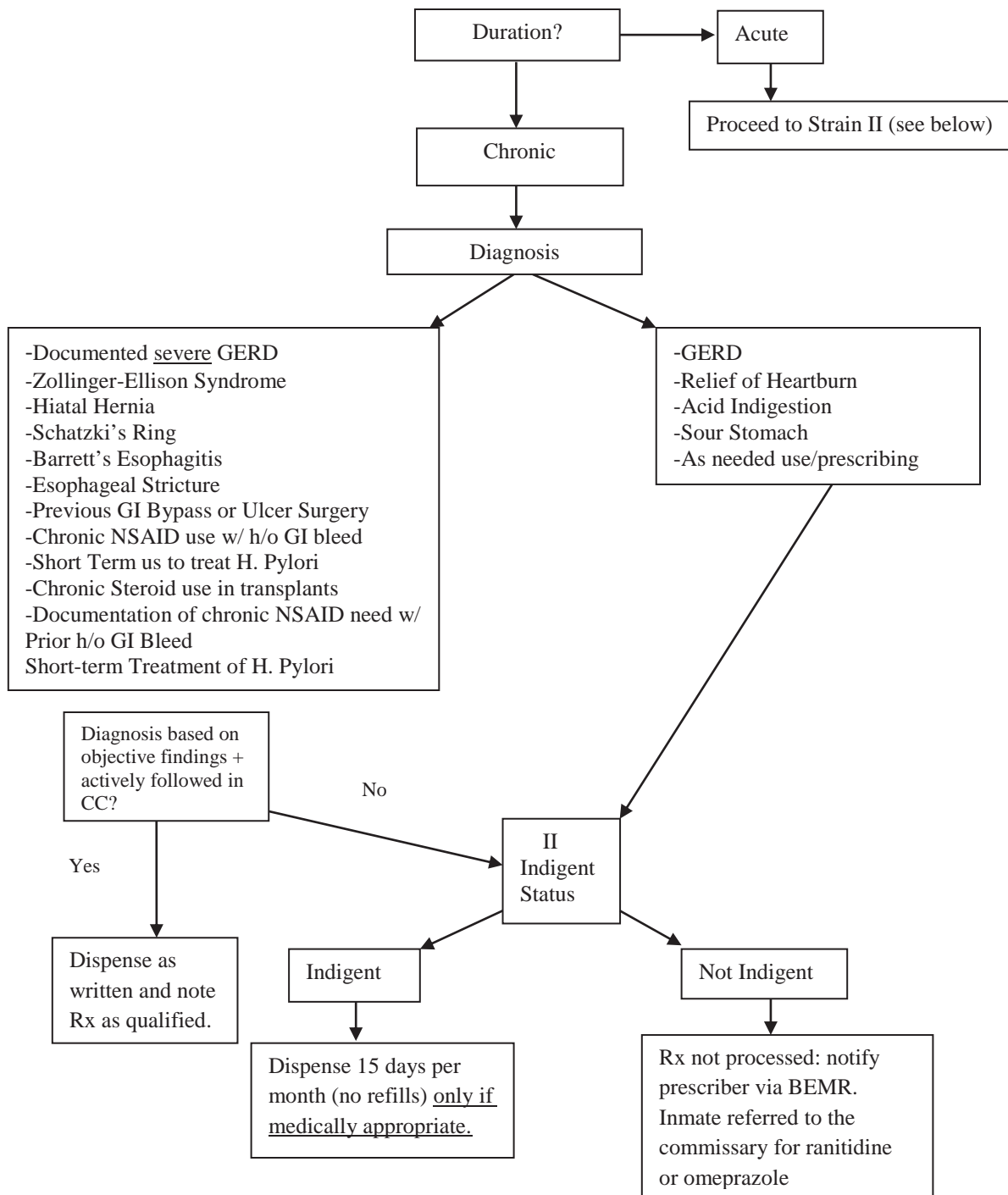
8. Topicals: Non-indigent inmates should be referred to the commissary to purchase OTC topical medications for minor conditions and in accordance with formulary restrictions. Short-term use of topical OTC medications should be purchased from the commissary.

9. Nasal: Non-indigent inmates should be referred to the commissary to purchase OTC nasal sprays for minor symptoms of allergic rhinitis symptoms (rhinorrhea, congestion, and itching). Seasonal use of nasal OTC medications should be purchased from the commissary. Nasal corticosteroid may be provided for chronic allergic rhinitis symptoms with significant adverse effects (significant nasal irritation, persistent epistaxis, pharyngitis), allergic rhinitis with comorbid asthma/serious respiratory disease, or for post-operative use following ENT surgery. Inmates must be enrolled in a general chronic care clinic.

10. OTC Matrix Nomogram – NSAIDs



11. OTC Matrix Nomogram – H2/PPI Use



Hypertensive Emergency & Urgency Guidance

The following is guidance regarding the appropriate management of hypertensive emergencies and urgencies for BOP health care providers. It should be noted that an excessive hypotensive response via unnecessarily aggressive treatment may result in more risk than benefit leading to potential ischemic events such as stroke, myocardial infarction, and blindness. All institutions should provide a local in-service for their providers regarding the appropriate management for these situations. Providers should review the BOP Hypertension Clinical Practice Guideline. Nurses should also reference the BOP nursing protocols when available.

Hypertensive Emergency

Definition: severe hypertension, greater than 180 mmHg systolic or 120 mmHg diastolic, associated with end-organ damage.

Examples: malignant hypertension and hypertensive encephalopathy, ischemic stroke, subarachnoid or intracerebral hemorrhage, acute pulmonary edema, angina pectoris, acute myocardial infarction, aortic dissection, withdrawal of antihypertensive medications, acute increase in sympathetic therapy, pregnancy (preeclampsia or exacerbation of preexistent hypertension).

Goal: immediate, careful reduction in blood pressure utilizing intravenous antihypertensive medications.

Comments: contact emergency responders (911) in cases of hypertensive emergencies. Medical referral center (MRC) providers familiar with management of hypertensive emergencies may choose to initiate intravenous antihypertensive medications depending on availability within institution.

Hypertensive Urgency

Definition: severe asymptomatic hypertension, greater than 180 mmHg systolic or 110-120 mmHg diastolic, with no end-organ damage. Goal: reduce blood pressure to $\leq 160/100$ over several hours to days.

Comments: there is no proven benefit of rapidly reducing blood pressure in patients with severe asymptomatic hypertension and could actually induce cerebral or myocardial ischemia / infarction. All patients should be scheduled for follow up with their primary care provider within several days following an episode of severe asymptomatic hypertension.

Treatment:

1. Allow patient to rest in a quiet room for 15 minutes and repeat blood pressure.
2. If blood pressure is still above 180/110-120, initiate oral treatment.
3. In patients previously **untreated** for hypertension, administer 20 mg furosemide (if normovolemic) or 12.5 mg captopril. May increase dose of furosemide to 40 mg if patient has documented renal insufficiency. Do **NOT** use captopril in pregnant patients.
4. In patients previously **treated** for hypertension, resume medications in noncompliant patients, increase dosage of medications for compliant patients or give 20 mg furosemide.
5. Observe the patient over several hours to ensure blood pressure reduction. Contact the on-call provider if there is no change.

High priority Medical Conditions/Diagnoses

Diabetes Mellitus (high blood sugar)

Hypertension (high blood pressure)

Cardiac problems - history of heart attacks, abnormal heart rhythms, congestive heart failure, or currently having chest pain.

Anyone taking warfarin/Coumadin™ or other blood thinners*

HIV infection

Cirrhosis of the liver

Uncontrolled asthma/COPD (emphysema) or have run out of medications*

Uncontrolled seizures or have run out of seizure medicine*

Any cases of active pulmonary tuberculosis*

Mental health conditions such as bipolar disorder, psychotic disorders (e.g. schizophrenia); any psychiatric condition requiring antipsychotics, mood stabilizers or benzodiazepines are high risk*

Hepatitis C infection - currently being treated with interferon/ribavirin, with or without protease inhibitors*

Medications with withdrawal potential - chronic benzodiazepines, barbiturates, chronic narcotics, etc.*

Dialysis

Cancer receiving active treatment

Antirheumatic DMARDs, non-biologic or biologic (non-urgent)*

* Starred conditions will be less of a priority for transfer consideration if the inmates are being appropriately treated and are able to receive their medications consistently.

Guidance on Therapeutic Substitution on Intake

Introduction

This document provides guidance to local Pharmacy and Therapeutics (P&T) meetings that choose to adopt a process of therapeutic substitution by pharmacists for intake orders. Discussion of therapeutic substitution in this document is limited to intake orders only. Any institution implementing therapeutic substitution must approve of the process through their local P&T.

Therapeutic substitution is defined as the dispensing of a drug that is therapeutically equivalent to, but chemically different from, the drug originally prescribed by a physician or other authorized prescriber. When properly established, a therapeutic substitution program may reduce costs, prevent unnecessary non-formulary requests, increase workplace efficiency, enhance medication access, and improve inventory management.

Requirements

Before initiating a substitution program, each institution's P&T must approve the substitutions included in this document. Documentation of this approval must be included in the institutional P&T minutes which are sent to Central Office. Copies of the institution's substitution program must be available to all providers in Health Services.

NOTE: The listed equivalency tables (see below) have been approved by the National P&T meeting and are the only ones eligible for automatic therapeutic substitution. Requests for additions to the approved list may be submitted for consideration to the National P&T Meeting via the P&T mailbox. As previously noted, these substitutions must be approved by the local P&T before they are used. Any other parameters desired for substitution must be discussed with the prescriber first, on a patient-by-patient basis.

Process

The following process will be adhered to by the pharmacist when performing therapeutic substitution of an intake medication order:

1. After receipt of an intake order for a non-formulary medication that is eligible for automatic therapeutic substitution, the pharmacist will write a BEMR Admin Note using the 'Pharmacy Note' and 'Pharmacy Therapeutic Interchange' designations.
2. All notes will discontinue the non-formulary drug order and add a drug order for the equivalent drug and strength found in the below equivalency tables.
 - a. For pharmacists without a CPA covering the new drug in question, a TO/VO order is required. A co-signature from the prescriber selected on the original intake order is required. OR

- b. For pharmacists with a CPA covering the new drug in question, a regular admin note will suffice with a review by the prescriber selected on the original intake order.
3. For each prescription interchanged, pharmacy staff will manually add the short sig code 'PTI' in the sig field of the new order. (PTI expands to "***Pharmacy Therapeutic Interchange.**")
4. The institution should develop a mechanism to inform the patient of the therapeutic change.
5. Local P&T meetings should periodically review substitution procedures for quality assurance.

Written Order	Formulary Equivalent (Adult dosing only)				
ACE Inhibitors	The following chart will be used to substitute a non-formulary ACE inhibitor for lisinopril.				
	Generic Name	Dose Equivalents (mg/day)			
	<i>Short-acting</i>				
	Captopril	No sub.	No sub.	No sub.	No sub.
	<i>Intermediate-acting</i>				
	Benazepril	5	10	20	40
	Enalapril	5	10	20	40
	Moexipril	-	7.5	15	30
	Quinapril	5	10	20	40
	Ramipril	2.5	5	10	20
	<i>Long-acting</i>				
	Lisinopril	5	10	20	40
	Fosinopril	5	10	20	40
	Perindopril	2	4	4-8	8-16
	Trandolapril	-	1	2	4-8
*Formulary agents in bold.					

Corticosteroids (Inhaled)	<p>The following chart will be used to substitute a non-formulary inhaled corticosteroid for mometasone DPI.</p> <table><tr><th>Generic Name</th><th>Low Daily Dose</th><th>Medium Daily Dose</th><th>High Daily Dose</th></tr><tr><td>Mometasone DPI</td><td>110-220mcg</td><td>330-440mcg</td><td>>440mcg</td></tr><tr><td>Beclomethasone HFA</td><td>80-240mcg</td><td>280-480mcg</td><td>>480mcg</td></tr><tr><td>Ciclesonide HFA</td><td>160-320mcg</td><td>>320-640mcg</td><td>>640mcg</td></tr><tr><td>Budesonide DPI</td><td>180-600mcg</td><td>630-1200mcg</td><td>>1200mcg</td></tr><tr><td>Flunisolide HFA</td><td>320mcg</td><td>>320-640mcg</td><td>>640mcg</td></tr><tr><td>Fluticasone HFA</td><td>88-264mcg</td><td>>264-440mcg</td><td>>440mcg</td></tr><tr><td>Fluticasone DPI</td><td>100-300mcg</td><td>>300-500mcg</td><td>>500mcg</td></tr></table> <p>*Formulary agent in bold.</p> <p>DPI = dry powder inhaler HFA = hydrofluoroalkane</p>	Generic Name	Low Daily Dose	Medium Daily Dose	High Daily Dose	Mometasone DPI	110-220mcg	330-440mcg	>440mcg	Beclomethasone HFA	80-240mcg	280-480mcg	>480mcg	Ciclesonide HFA	160-320mcg	>320-640mcg	>640mcg	Budesonide DPI	180-600mcg	630-1200mcg	>1200mcg	Flunisolide HFA	320mcg	>320-640mcg	>640mcg	Fluticasone HFA	88-264mcg	>264-440mcg	>440mcg	Fluticasone DPI	100-300mcg	>300-500mcg	>500mcg
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Corticosteroids (Nasal)	<p>The following chart will be used to substitute a non-formulary nasal corticosteroid for fluticasone propionate.</p> <table><tr><th>Generic Name</th><th>Dose</th></tr><tr><td>Fluticasone Prop.</td><td>2 sprays EN daily</td></tr><tr><td>Fluticasone Furoate</td><td>2 sprays EN daily</td></tr><tr><td>Beclomethasone</td><td>1-2 sprays EN BID</td></tr><tr><td>Budesonide</td><td>1-4 sprays EN daily</td></tr><tr><td>Ciclesonide</td><td>2 sprays EN daily</td></tr><tr><td>Flunisolide</td><td>2 sprays EN BID/TID</td></tr><tr><td>Mometasone</td><td>2 sprays EN daily</td></tr><tr><td>Triamcinolone</td><td>1-2 sprays EN daily</td></tr></table> <p>*Formulary agent in bold.</p> <p>EN= each nostril</p>	Generic Name	Dose	Fluticasone Prop.	2 sprays EN daily	Fluticasone Furoate	2 sprays EN daily	Beclomethasone	1-2 sprays EN BID	Budesonide	1-4 sprays EN daily	Ciclesonide	2 sprays EN daily	Flunisolide	2 sprays EN BID/TID	Mometasone	2 sprays EN daily	Triamcinolone	1-2 sprays EN daily														
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HMG CoA Reductase Inhibitors (“Statins”)

The following chart will be used to substitute a non-formulary statin:

Generic Name	Dose Equivalents (mg/day)				Ave. Cost/Month
	Intensity:	Low	Medium	High	
Atorvastatin		10	20	40-80	\$1.20
Fluvastatin	20-40	80	-	-	\$75.00
Lovastatin	10-20	40	80	-	\$0.90
Pitavastatin	1	2	4	-	\$109.20
Pravastatin	10-20	40	80		\$2.40
Rosuvastatin		5	10	20-40	\$1.80
Simvastatin	5-10	20	40	80	\$0.90

*Formulary agents in bold

Resources:

1. Professional Resource, Statin Dose Comparison. Pharmacist's Letter/Prescriber's Letter. July 2016.
2. Clinical Resource, ACE Inhibitor Antihypertensive Dose Comparison. Pharmacist's Letter/Prescriber's Letter. November 2016.
3. Clinical Resource, Inhaled Corticosteroid Dose Comparison in Asthma. Pharmacist's Letter/Prescriber's Letter. April 2017.
4. Drug Information Handbook. 26th ed. Wolters Kluwer, Lexicomp; 2017.
5. Univ. of Mississippi Medical Center. [Internet]. Automatic therapeutic interchanges; [cited 2017 Nov 10]. Available from: http://pharmacy.umc.edu/drug_information/autotherapeutic_interchanges.html
6. Good Shepherd Health System (East Texas). [Internet]. Automatic therapeutic interchanges; [cited 2017 Nov 10]. Available from: <http://gsnet.goodshepherdhealth.org/images/newspics/flyer3203131725.pdf>
7. Thomas Jefferson Univ. Hospital. [Internet]. Automatic therapeutic interchanges; [cited 2017 Nov 10]. Available from: <http://hospitals.jefferson.edu/files/nursing-orientation/advanced-practice-files/therapeutic-interchanges.pdf>

8. Upper Peninsula Health System – Marquette, MI. [Internet]. Automatic therapeutic interchanges; [cited 2017 Nov 10]. Available from: <http://ww4.mgh.org/Physicians/Formulary%20Documents/Therapeutic%20Interchanges.pdf>
9. Northern Health, BC Canada. [Internet]. Automatic therapeutic interchanges; [cited 2017 Nov 10]. Available from: <https://physicians.northernhealth.ca/Portals/8/News/documents/TIPListJuly%2023.pdf>
11. Vancouver General Hospital. [Internet]. Automatic therapeutic interchanges; [cited 2017 Nov 10]. Available from: [http://www.vhpharmsci.com/VHFormulary/\(2\)%20VA%20Copy%20of%20BCHA%20Formulary%20THERAPEUTIC%20INTERCHANGE%20PROGRAM.pdf](http://www.vhpharmsci.com/VHFormulary/(2)%20VA%20Copy%20of%20BCHA%20Formulary%20THERAPEUTIC%20INTERCHANGE%20PROGRAM.pdf)
12. Nebraska Pharmacists Association. [Internet]. Automatic therapeutic interchanges; [cited 2018 May 6]. Available from: https://www.npharm.org/files/Resources/MTM/MTM_CPA_TherapeuticInterchangeAbridged.doc
13. Centegra Health System. [Internet]. Automatic therapeutic interchanges; [cited 2018 May 6]. Available from: <http://centegramedsources.com/wp-content/uploads/2017/05/Therapeutic-Interchange-List-2017.pdf>
14. Wang JS, Fogerty RL, Horwitz LI (2017). Effect of therapeutic interchange on medication reconciliation during hospitalization and upon discharge in a geriatric population. PLoS ONE 12(10): e0186075. Available from: <https://doi.org/10.1371/journal.pone.0186075>.
15. University of North Carolina School of Medicine. [Internet]. Antihypertensive Initiation and Titration; [cited 2018 May 6]. Available from: https://www.med.unc.edu/im/files/enhanced-care-files/HTN_Protocol_6.05.pdf

PART II

NATIONAL
BOP FORMULARY

REFER TO BEMR RX
FORMULARY DRUG
FILE REPORT

EXHIBIT 5

DETOXIFICATION OF CHEMICALLY DEPENDENT INMATES

**Federal Bureau of Prisons
Clinical Guidance**

***FEBRUARY 2014
(REFORMATTED JANUARY 2018)***

Federal Bureau of Prisons (BOP) Clinical Guidance is made available to the public for informational purposes only. The BOP does not warrant this guidance for any other purpose, and assumes no responsibility for any injury or damage resulting from the reliance thereof. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are patient specific. Consult the BOP Health Management Resources Web page to determine the date of the most recent update to this document: http://www.bop.gov/resources/health_care_mngmt.jsp.

WHAT'S NEW IN THE DOCUMENT?

NOTE: The formatting of this document, including the renumbering of the tables, was updated in January 2018.

This version of the BOP Clinical Guidance for *Detoxification of Chemically Dependent Inmates* have been revised to be in line with the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)* that was released in May 2013. Additional changes were made as a result of a review by BOP pharmacist staff. Other information was added, based on the *Quick Guide for Clinicians Based on TIP 45: Detoxification and Substance Abuse Treatment*, issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) in 2006.

Among the revisions to the 2009 guidelines are the following:

- **Deletion of what had been *Appendix 2, Selected DSM-IV Criteria Related to Substance Abuse*.**
The DSM-5 criteria have been changed, and the DSM is now copyrighted. Readers are referred to the DSM website at <http://www.dsm5.org/Pages/Default.aspx>.
- **Terminology has been changed to be in line with the DSM-5, for example:**
 - *Substance abuse disorder* has been changed to *substance use disorder*.
 - *Alcohol dependence* has been changed to *alcohol use disorder*.
 - *Benzodiazepine dependence* has been changed to *benzodiazepine use disorder*.
 - *Opiate dependence* has been changed to *opiate use disorder*.
 - *Axis I or Axis II diagnosis* has been changed to *psychiatric disorder*.
- **The discussion of [thiamine replacement](#) (vitamin B1) in the detoxification of alcohol-dependent inmates** has been expanded to cover its critical role in preventing and treating Wernicke-Korsakoff syndrome.
- **Information has been added about the [use of clonidine](#)** in the treatment of alcohol withdrawal.

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1. PURPOSE

The Federal Bureau of Prisons (BOP) Clinical Guidance for *Detoxification of Chemically Dependent Inmates* provides recommended standards for the medical management of withdrawal from addictive substances for federal inmates.

2. INTRODUCTION

Substance use disorders pose a significant and expensive public health problem. Substance abuse affects not only the substance abusers and their families, but also society as a whole—through increases in crime, domestic violence, highway fatalities, incarceration, and health care costs.

Any substance that alters perception, mood, or cognition can be abused. Commonly identified substances of abuse include illicit drugs, alcohol, and certain prescription drugs—which act through their hallucinogenic, stimulant, sedative, hypnotic, anxiolytic, or narcotic effects. Other less commonly recognized substances of abuse include medications with anticholinergic, antihistaminic, or stimulant effects, e.g., tricyclic antidepressants, antiparkinsonian agents, low potency antipsychotics, anti-emetics, and cold and allergy preparations.

Substance use disorders are highly prevalent among inmate populations, affecting an estimated 30–60% of inmates. Drug intoxication and withdrawal may be particularly evident at the time of incarceration. The Bureau of Justice Statistics reports that an estimated 70% of all inmates in local jail facilities in the U.S. had committed a drug offense or used drugs regularly, and an estimated 35% were under the influence of drugs at the time of the offense.

3. DETECTION OF SUBSTANCE ABUSE AND TREATMENT OF WITHDRAWAL

The safe and effective treatment of withdrawal syndromes requires that clinicians be alert to the possibility of substance dependence in all new inmate arrivals at their institutions. A concise overview of detoxification is provided in [Appendix 1](#).

→ The DSM-5 criteria for abuse, intoxication, and withdrawal from selected substances are available at <http://www.dsm5.org/Pages/Default.aspx>.

- **A careful inmate history and clinical assessment is essential.** Substance abusers are rarely accurate in their description of patterns of drug use; they can greatly underestimate or deny their substance abuse, as well as overstate the extent of it. Furthermore, because individuals who abuse substances are likely to be abusing multiple substances, the possibility of more than one addiction must be carefully considered; intoxication from multiple drugs will complicate treatment of the withdrawal syndrome. An overview of the clinical presentations of substance abuse is listed in [Appendix 3, Symptoms and Signs of Drug Abuse](#).
- **Not all substances of abuse produce clinically significant withdrawal syndromes. However, discontinuing substances on which an individual is dependent will likely produce some psychological symptoms.** Withdrawal from substances such as stimulants, cocaine,

hallucinogens, and inhalants can be accomplished with psychological support and symptomatic treatment alone, along with periodic reassessment by a health care provider.

- **The intensity of withdrawal cannot always be predicted.** The addictive nature of a substance is determined by many factors including the physiology, psychology, and neurochemistry of the individual, as well as characteristics of the substance itself. Generally, the most addictive substances are those that are high-potency, that cross the blood-brain barrier quickly, that have a short half-life, and that produce a significant change in the neurochemistry of the brain. These same characteristics also tend to make a slow and safe withdrawal from the substance more difficult, especially if the substance being abused is used as treatment in the detoxification process. **Frequent clinical assessments, along with indicated treatment adjustments (in both dose and frequency) are imperative.**
- **Substances that produce dangerous withdrawal syndromes for individuals with physiological dependence include alcohol, sedative/hypnotics, and anxiolytics.** Withdrawal from narcotics is not generally considered dangerous, except in pregnant women and the medically debilitated; however, narcotic withdrawal does result in significant symptomatology, which can be markedly reduced with targeted therapies.
- **Whenever possible, the clinician should substitute a long-acting medication for short-acting drugs of addiction.** A safe withdrawal plan entails, when feasible, substituting a long-acting, cross-tolerant substance and gradually tapering that substance (not more rapidly than 10–20% per day—depending on the substance and the setting available for detoxification).
- **Every effort should be made to ameliorate the inmate's signs and symptoms of alcohol or drug withdrawal.** Adequate doses of medication should be used, with frequent reassessment. Inmates experiencing withdrawal should also be kept as physically active as medically permissible.
- **Initiation of withdrawal should be individualized.** Substance abuse often leads to significant medical sequelae including liver disease, chronic infections, trauma, cognitive impairment, psychiatric disorders, nutritional deficiencies, and cardiac disease. Detoxification and withdrawal are stressors, and may exacerbate or precipitate medical or psychological decompensation. In some cases, medical stabilization may be preferred to resolve the immediate crisis prior to initiating withdrawal.
- **To the greatest extent possible during detoxification, the provider should control the inmate's access to the prescribed medication regimen.** Overdose with either the prescribed medication or with other drugs is always a possibility. Administration of all controlled medications should be directly observed in a pill line. In addition, consider direct observation of ancillary medications (e.g., clonidine). Inmates should be counseled on the dangers of supplementing their detoxification regimens with over-the-counter medications, prescription medications diverted from other inmates, or illicit drugs and alcohol.
- **Detoxification alone is rarely adequate treatment for alcohol and other drug dependencies.** Inmate education regarding the detoxification process is a necessary component of a successful detoxification plan. In addition, clinicians should conduct periodic assessments to detect the development of any psychiatric symptoms such as depression, suicidal thinking, or underlying psychosis. Inmates should be considered for follow-up psychological support through group therapy, individual counseling, 12-step recovery meetings, or similar programs. These services provide alternative methods of coping with the stresses that trigger alcohol or

drug abuse. Psychology staff can also determine whether referrals to drug education or to nonresidential or residential drug treatment programs are indicated.

- Symptoms and signs of conditions that require immediate medical attention are listed in **TABLE 1** below:

TABLE 1: SYMPTOMS AND SIGNS OF CONDITIONS REQUIRING IMMEDIATE MEDICAL ATTENTION

<ul style="list-style-type: none"> • Change in mental status • Increasing anxiety • Hallucinations • Temperature greater than 100.4°F (these patients should be considered potentially infectious) • Significant increases and/or decreases in blood pressure and heart rate • Insomnia 	<ul style="list-style-type: none"> • Abdominal pain • Upper and lower gastrointestinal bleeding • Changes in responsiveness of pupils • Heightened deep tendon reflexes and ankle clonus, a reflex beating of the foot when pressed rostrally, indicating profound central nervous system irritability and the potential for seizures
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4. MANAGEMENT OF INMATES WITH COMPLICATING MEDICAL AND PSYCHIATRIC CONDITIONS

Careful consideration should be given to inmates with co-morbid medical and psychiatric conditions, since these patients are at greater risk for severe withdrawal symptoms and complications.

- **Brain injury:** Inmates with a history of brain injuries of any type are more likely to suffer seizures and/or delirium during detoxification, and therefore require closer monitoring.
- **Co-morbid seizure disorder:** The presence of an underlying seizure disorder needs to be considered when tapering from benzodiazepines, barbiturates, and alcohol. Patients with pre-existing seizure disorders will be more susceptible to seizures as their medications are tapered; a slower taper is indicated for these inmates.
- **Cardiac disease:** Inmates with cardiac disease are more sensitive to sympathetic hyperactivity, so careful monitoring and control of symptoms is essential. A slower taper is also indicated for these inmates.
- **Liver and kidney diseases:** Inmates with liver or renal disease may metabolize drugs and medications more slowly; as such, they require closer monitoring for drug toxicity and possible adjustments as treatment regimens are tapered.
- **Psychiatric disorders:** Inmates with pre-existing psychiatric conditions may suffer an exacerbation of their illness during detoxification. A collaborative treatment effort with psychology and psychiatry staff is warranted for management of these inmates. Inmates without pre-existing psychiatric illness may also experience significant psychological distress during detoxification, including the development of suicidal ideation, plan, and intent. A careful assessment of the inmate's mental status, with particular attention to thoughts of self-harm, should be part of every inmate evaluation during detoxification.

- **Elderly inmates:** Elderly inmates are at increased risk of complications during detoxification. The elderly are less likely to show marked sympathetic hyperactivity during withdrawal, but they are just as likely to suffer a severe withdrawal syndrome. Detoxification in the elderly is further complicated by these factors: a greater need for prescription drugs and the potential for drug-drug interactions; a greater risk of drug toxicity from slower drug metabolism; and the higher incidence of complicating medical conditions such as heart disease and cognitive disorders. Careful monitoring, ongoing titration of medications, and inpatient hospitalization for complicated patients may be necessary.
- **Pregnancy:** Pregnancy significantly complicates detoxification efforts. Many medications cross the placenta and/or are secreted in breast milk. Careful consideration must be given to the known and unknown effects of medications on the fetus or infant, and these must be weighed against the risks of detoxification. Pregnant women generally should be maintained on their medications throughout their pregnancy, but each case is unique and should be managed in close consultation with an obstetrical specialist. Pregnant women on methadone ordinarily should not be detoxified, as this increases the risk of miscarriage and premature labor. Refer to the BOP Pharmacy Services Program Statement with regards to methadone. Pregnant women with alcohol dependence should be managed in an inpatient setting, due to the risk of miscarriage during detoxification.
- **Risk of suicide:** The frequency of suicide attempts is substantially higher among patients with a substance use disorder. Frequent and thorough patient assessments are indicated during the withdrawal period with particular attention to thoughts of self-harm.
- **Short-stay inmates:** Inmates with short sentences, or with lengths of stay that are thirty days or less, generally should not be detoxified off benzodiazepines or barbiturates if these agents are currently medically indicated. However, opiate detoxification can be completed safely in less than two weeks, and alcohol detoxification is a necessity for all inmates who present with alcohol dependence or withdrawal.

5. PLACEMENT OF INMATES FOR DETOXIFICATION

Detoxification can be safely and effectively accomplished for inmates in a variety of housing placements, including: locked jail units, general population, observation cells in the health services unit, and Special Housing Units, or when necessary as inpatients in a community hospital or Medical Referral Center (MRC). The specific housing placement should be determined on a case-by-case basis, in accordance with BOP policy and through multidisciplinary recommendations made by health care, psychology, and custody staff. The optimal placement will depend on the type of substance abuse, the severity of the withdrawal syndrome, the inmate's co-morbid medical and psychiatric conditions, security concerns, and the resources of the institution.

If an inmate is placed in a locked unit or Special Housing Unit for detoxification, their medications, medical assessments, and ongoing monitoring must all be provided in a timely manner. If detoxification in a locked unit or Special Housing Unit cannot be accomplished with these assurances, strong consideration should be given to one of two options: *either* inpatient detoxification *or* medical stabilization and maintenance, with postponement of attempts at

detoxification. Transferring patients from mainline facilities to MRCs for the management of withdrawal is not typically indicated or necessary.

All medications prescribed for the treatment of withdrawal should be administered via directly observed therapy at pill lines. Ideally, dosing should be three times a day or less, so as to accommodate pill lines at most institutions.

6. ALCOHOL WITHDRAWAL

DIAGNOSIS OF ALCOHOL USE DISORDERS

SCREENING

As the initial step in diagnosing alcohol use disorders, all incoming inmates should be screened for a history of alcohol use. Inmates presenting with alcohol intoxication should be presumed to have alcohol use disorder until proven otherwise. Despite the difficulty in obtaining an accurate history from an intoxicated inmate, a full assessment should be attempted.

WITHDRAWAL SYNDROME

The alcohol withdrawal syndrome can develop in any individual who has a history of regular, heavy use of alcohol, has a known dependence on alcohol, or has clinical signs of intoxication. Alcohol withdrawal syndromes can be mild, moderate, or life-threatening. The severity of an individual's alcohol withdrawal syndrome is difficult to predict, although a history of problems with withdrawal makes it likely that a similarly severe withdrawal syndrome will occur again. Individuals with a high blood alcohol level (>100 mg/dL) and concurrent signs of withdrawal are at particularly high risk for a severe withdrawal syndrome.

Uncomplicated alcohol withdrawal is generally completed within five days. Alcohol withdrawal symptoms can develop within a few hours of decreasing or discontinuing use. Symptoms generally peak within 24–36 hours after abstinence begins. Early signs and symptoms of withdrawal include gastrointestinal distress, anxiety, irritability, increased blood pressure, and increased heart rate. Later, symptoms of moderate intensity develop, including insomnia, tremor, fever, anorexia, and diaphoresis. Withdrawal seizures can occur at various times during alcohol withdrawal, but generally begin within 48 hours of the last drink. Withdrawal delirium, “delirium tremens,” usually begins 48–72 hours after the last drink. If allowed to progress, delirium can result in changes in consciousness, marked autonomic instability, electrolyte imbalances, hallucinations, and death. With appropriate intensive treatment, mortality from delirium tremens is markedly reduced (to 1% or less).

➔ *In many alcoholics, the severity of withdrawal symptoms increases after repeated withdrawal episodes. This is known as the **kindling phenomenon**, and suggests that even patients who experience only mild withdrawal should be treated aggressively to reduce the severity of withdrawal symptoms in subsequent episodes. Kindling also may contribute to a patient's relapse risk and to alcohol-related brain damage and cognitive impairment.*

PATIENT EVALUATION

A careful patient history and physical examination by a clinician is indicated for all inmates suspected of clinically significant alcohol use:

- An assessment should be made of the frequency of alcohol use, length of time used, amount used, symptoms of withdrawal when use is decreased or discontinued, and the date and amount of alcohol last consumed.
 - If alcohol use disorder is suspected, further inmate history should cover, in part: other substances used, signs and symptoms of gastritis or gastrointestinal hemorrhage, history of trauma (especially head trauma), liver disease, history of seizure disorder, pancreatitis, psychiatric illness, and suicidal ideation.
 - Physical examination is necessary to evaluate the inmate for the aforementioned conditions, as well as to assess vital signs, possible cardiac and lung disease, and neurologic and mental status.
 - Laboratory evaluation should include a complete blood count, comprehensive serum chemistry panel, urine toxicology (for medical reasons, not correctional), and a pregnancy test for women.
 - The medical indications for other studies such as a chest radiograph, electrocardiogram, viral hepatitis serologies, and screening for sexually transmitted diseases should be based on the individual assessment.
 - Inmates may be brought to the Health Services Unit for assessment of intoxication after being given a breathalyzer test by a correctional officer. Although performance of this test remains the function of Correctional Services, the results are medically relevant and should be ascertained and assessed by the clinician.
- ➔ *Prior to initiating treatment, the inmate's status should be scored using the Clinical Institute Withdrawal Assessment of Alcohol, revised (CIWA-Ar), (BP-S708.060). The CIWA-Ar is an evidence-based scoring system that should be used over time to objectively assess the severity and progression of alcohol withdrawal symptoms. The CIWA scoring system and a sample record for CIWA-Ar scores are provided in [Appendix 2](#).*

TREATMENT OF ALCOHOL WITHDRAWAL

Inmates experiencing alcohol withdrawal should be counseled by a health care provider on the signs and symptoms of withdrawal, the anticipated treatment plan, and patient responsibilities.

- Specific treatment strategies for alcohol withdrawal should be determined by the condition of the individual inmate, and should be reviewed and approved by a physician.
- Educational information in [Appendix 6, Patient Information – Detoxification from Alcohol](#) should be used when appropriate.

THIAMINE REPLACEMENT

All inmates with suspected alcohol use disorder should be treated with thiamine (vitamin B1), 100 mg either orally or intramuscularly, daily for at least 10 days, up to 4 weeks for those at high risk for malnutrition. Due to the potential dire consequences of non-compliance, oral doses should be administered at pill line.

Thiamine replacement should always precede administering parenteral glucose to persons with alcohol intoxication; otherwise, the glucose infusions can precipitate Wernicke-Korsakoff syndrome and the severe cardiovascular complications associated with thiamine deficiency discussed below.

- **Wernicke encephalopathy:** Characterized by confusion, lethargy, inattentiveness, impaired memory, vision changes (e.g., nystagmus), and ataxia. Often undetected and under-diagnosed, untreated Wernicke's encephalopathy can advance to Korsakoff psychosis.
- **Korsakoff psychosis:** Characterized by impaired memory (particularly new memory formation), hallucinations, and confabulation. Korsakoff psychosis is associated with significant morbidity and a 15–20% fatality rate.

BENZODIAZEPINE THERAPY

Benzodiazepines are the mainstay of alcohol withdrawal treatment in the correctional setting. Benzodiazepine treatment for alcohol withdrawal in the BOP should be based on the CIWA-Ar score ([Appendix 2](#)), in accordance with the guidelines shown in **TABLE 2** below.

➔ *Patients actively seizing as a result of alcohol withdrawal, or showing signs of delirium tremens, should be immediately treated with benzodiazepines.*

TABLE 2. OVERVIEW OF TREATMENT OF ALCOHOL WITHDRAWAL, BASED ON CIWA-AR SCORE

CIWA-Ar Score	Level of Withdrawal	Recommended Treatment
<10	MILD	Supportive, non-pharmacologic therapy and close monitoring are indicated (unless patient has history of alcohol withdrawal seizures or co-morbid cardiovascular conditions).
10–15	MODERATE	Medication (lorazepam) is indicated to reduce symptoms and the risk of major complications.
>15	SEVERE	Strong consideration should be given to hospitalizing inmates who exhibit severe symptoms, as they are at increased risk for serious complications.

Lorazepam is the recommended benzodiazepine for managing alcohol withdrawal in most inmates:

- Lorazepam does not require cytochrome oxidation for metabolism, so its clearance is not impaired by liver disease, a common co-morbidity for inmate populations. This is in contrast to other benzodiazepines such as chlordiazepoxide, diazepam, and clonazepam, which are metabolized in the liver and can accumulate with slow metabolizers or with liver disease.
- Another benefit of lorazepam is that it can be administered orally, intravenously, or intramuscularly—unlike diazepam and chlordiazepoxide, which should NEVER be given intramuscularly because of erratic absorption.
 - ▶ Ambulatory alcohol detox is normally managed with oral benzodiazepines. For the most part, intramuscular administration should be avoided, due to variable drug absorption.
 - ▶ IV access should be established in all patients who are at risk of severe withdrawal. All patients with seizures or delirium tremens should be given IV benzodiazepines. IV administration should only be considered in the hospital/inpatient setting.

- **TABLE 3** outlines lorazepam dosing recommendations based upon CIWA-Ar scores.
 - ▶ For inmates with **moderate to severe withdrawal**, symptom-triggered therapy based upon CIWA-Ar scores (see [Appendix 2](#)) is recommended and has been shown to require less overall benzodiazepine use.
 - ▶ A fixed-dose schedule is recommended for inmates with **mild withdrawal** who are being treated with lorazepam because they have either a history of alcohol withdrawal seizures or co-morbid cardiovascular conditions.
- ➔ For information about benzodiazepine dependence, see [Section 7, Benzodiazepine Withdrawal](#).

TABLE 3. RECOMMENDED SCHEDULE FOR LORAZEPAM TREATMENT OF ALCOHOL WITHDRAWAL

MILD WITHDRAWAL (CIWA-Ar Score = 8–9)	MODERATE WITHDRAWAL (CIWA-Ar Score = 10–15)	SEVERE WITHDRAWAL (CIWA-Ar Score >15)
★ All inmates with alcohol withdrawal should be treated with thiamine (100 mg orally or intramuscularly) daily for at least 10 days. Thiamine replacement must be completed <u>before</u> administration of parenteral glucose.		
Most Inmates		
Repeat CIWA-Ar every 4–8 hours, until CIWA-Ar score has remained less than 10 for 24 hours without medication.	<ol style="list-style-type: none"> 1. Administer lorazepam every hour: 2–4 mg IM, PO, or IV. 2. Repeat CIWA-Ar in one hour (90 minutes, if giving lorazepam orally). 3. Repeat lorazepam 2–4 mg every 60–90 minutes until CIWA-Ar score is less than 10. Then, discontinue lorazepam. 4. Repeat CIWA-Ar every 4–8 hours until the score has remained less than 10 for 24 hours. If the score rises again within this 24-hour period, repeat steps 1–3 above. 	<p>Hospitalization for inpatient detoxification and monitoring is strongly suggested.</p> <p>Lorazepam is administered according to the same schedule as described under “Moderate Withdrawal.” However, an increase in frequency of both lorazepam and CIWA-Ar may be indicated.</p> <p>Lorazepam can be given up to 2–4 mg IV, as frequently as every 15–20 minutes.</p>
Inmates with History of Alcohol Withdrawal Seizures		
Generally, inmates with a history of alcohol withdrawal seizures will present with signs and symptoms of moderate-to-severe withdrawal. Do not give anti-seizure medications unless the inmate also has an underlying seizure disorder. Carbamazepine may be useful in treating patients with a history of alcohol withdrawal seizures (see below).		
Suggested initial regimen: * Days 1–2: Lorazepam 2 mg, 3x daily Days 3–4: Lorazepam 2 mg, 2x daily Day 5: Lorazepam 2 mg, single dose (AM or HS) Days 1–6: Monitor 3x daily with CIWA-Ar.**	Same as above.	Same as above.
(Table 3 continues on next page.)		

MILD WITHDRAWAL (CIWA-Ar Score = 8–9)	MODERATE WITHDRAWAL (CIWA-Ar Score = 10–15)	SEVERE WITHDRAWAL (CIWA-Ar Score >15)
(Table 3 continued from previous page.)		
Inmates with Co-Morbid Cardiovascular Conditions		
Conditions include: hypertension, angina, congestive heart failure, or history of myocardial infarction or stroke.		
<p>Consider lorazepam treatment, even if only mild withdrawal symptoms.</p> <p>Suggested initial regimen: *</p> <p>Days 1–2: Lorazepam 1–2 mg, 3x daily</p> <p>Days 3–4: Lorazepam 1–2 mg, 2x daily</p> <p>Day 5: Lorazepam 1–2 mg, single dose (AM or HS)</p> <p>Days 1–6: Monitor 3x daily with CIWA-Ar.**</p>	Same as above.	Same as above.
<p>* In these cases, the dose of lorazepam may need to be decreased if the inmate experiences somnolence, ataxic gait, slurred speech, or other signs of medication intoxication.</p> <p>** If the CIWA-Ar score is greater than or equal to 10 at any time, follow the steps for “Moderate Withdrawal” or “Severe Withdrawal.”</p>		

CARBAMAZEPINE

Carbamazepine may be used to treat alcohol withdrawal symptoms in patients who have a history of alcohol-related seizures.

- Carbamazepine dosing is generally started at 600 to 1,200 mg on the first day in divided doses and is generally tapered to 0 mg over 5 to 10 days.
- The following tapered dosing schedule can be used: **Day 1** = 600–800 mg; **Day 2** = 500 mg; **Day 3** = 400 mg; **Day 4** = 300 mg; and **Day 5** = 200 mg.

Carbamazepine is just as effective as the benzodiazepines in generally healthy individuals with mild-to-moderate alcohol withdrawal. However, a limitation of carbamazepine is its interaction with multiple medications that undergo hepatic oxidative metabolism. Thus, carbamazepine may be less useful in older patients or in those with multiple medical problems.

ADJUNCTIVE TREATMENTS OF ALCOHOL WITHDRAWAL

- **Many of the symptoms of alcohol withdrawal are caused by increased sympathetic activity. CLONIDINE has been used successfully to attenuate these symptoms.** A variety of dosing schedules for clonidine have been used to suppress acute symptoms of alcohol withdrawal. Generally, a dose of 0.1 to 0.2 mg every 8 hours is adequate to control symptoms. The dose can generally be tapered over 3–5 days as symptoms subside. Decreased renal function may necessitate more frequent monitoring and lower doses.
 - ➔ *Clonidine’s usual side effects include hypotension and somnolence. Treatment with clonidine requires careful monitoring of vital signs, as well as increased vigilance for other withdrawal problems.*
 - **Clonidine should only be used for mild withdrawal symptoms.** Clonidine will mask the symptoms of withdrawal and artificially lower the CIWA-Ar score, without decreasing the

risk for seizures or delirium tremens. Therefore, clonidine should NOT be utilized for moderate or severe withdrawal.

- ▶ **Patients in active substance withdrawal are at increased risk of suicide, and clonidine is fatal in overdose.** Extra care is therefore warranted, including monitoring inmates for thoughts of self-harm and limiting its administration to pill line with direct observation. Consider administering crushed immediate-release tablets to prevent “tonguing” or “cheeking” of the medication.
- ▶ **If a patient is taking clonidine concurrently with a beta-blocker,** it is best to gradually withdraw the beta-blocker, and then withdraw the clonidine over two to four days. The beta-blocker can then be reinstituted after clonidine has been successfully withdrawn. Concurrent beta-blocker therapy may exacerbate an increase in blood pressure upon clonidine withdrawal.
- **Anti-seizure medications may have a use in the treatment of alcohol withdrawal, especially in those individuals with underlying seizure disorders.** In such cases, anti-seizure medications should be given in therapeutic doses with careful attention to blood levels. Anti-seizure medications do not replace the need for benzodiazepines in the treatment of alcohol withdrawal and will not prevent the development of delirium tremens.
- **Individuals in alcohol withdrawal often develop fluid imbalances, electrolyte abnormalities, and hypoglycemia.** Careful attention to these issues can prevent significant medical complications. Treatment may require the use of intravenous fluids, glucose (after appropriate thiamine replacement), and electrolytes.
- **Individuals with alcohol dependence frequently suffer from malnutrition.** Short-term supplementation with a daily multivitamin (containing folate) is advisable if malnutrition is suspected. Refer to BOP National Formulary non-formulary use criteria for multivitamins.
- **Hypomagnesemia may develop during alcohol withdrawal.** However, routine magnesium supplementation has not been proven to be medically necessary, and is not recommended.

7. BENZODIAZEPINE WITHDRAWAL

DIAGNOSIS OF BENZODIAZEPINE USE DISORDERS

- Benzodiazepine withdrawal syndrome can begin within a few hours of last drug use (especially when using short-acting drugs), but may take several weeks to resolve. **Because of the high risk of delirium, seizures, and death, benzodiazepine withdrawal should always be treated.**
- **Physiological dependence on benzodiazepine is diagnosed through a careful determination of several factors:** type of medications used, length of time used, amount used, reasons for use, symptoms that occur when doses are missed or medication is discontinued, and date and amount of drug last used. **Physiological benzodiazepine dependence can occur even when the medication is taken only as prescribed** and may not include any significant biopsychosocial consequences. Physiological dependence develops within 3–4 weeks of regular use.
- Although recreational use and abuse of benzodiazepines does occur, most inmates who present with benzodiazepine dependence had been prescribed these medications previously to

treat a psychiatric disorder. Previously treated psychiatric symptoms are likely to recur during detoxification from benzodiazepines. **Therefore, a full psychological or psychiatric evaluation is indicated for inmates who have developed drug dependence while taking prescribed benzodiazepines.** Subclinical signs of withdrawal (e.g., insomnia and anxiety) may take months or years to resolve and usually should be treated with a non-addictive medication before they dominate the clinical picture. It may be necessary to delay benzodiazepine detoxification until the inmate has been on a therapeutic dose of an antidepressant or other appropriate medication for several weeks.

- The withdrawal syndrome from benzodiazepines is similar to that of alcohol and barbiturates, with the time course depending on the half-life of the substance used. The fact that individuals with benzodiazepine dependence often concurrently abuse alcohol further complicates their withdrawal course.

SIGNS AND SYMPTOMS OF BENZODIAZEPINE WITHDRAWAL

Inmates with suspected benzodiazepine withdrawal should be given a targeted physical examination that includes vital signs and an evaluation of cardiovascular, neurologic, and mental health status. Laboratory evaluations should include a complete blood count, comprehensive serum chemistry panel, urine toxicology (for medical reasons, not correctional), and a pregnancy test for women.

➔ *No objective measure or scoring system has been validated to assess benzodiazepine withdrawal; however, the patient's symptoms usually indicate how far the withdrawal syndrome has progressed, as outlined in TABLE 4 below. **Do not use the CIWA-Ar for assessing benzodiazepine withdrawal.***

TABLE 4. SYMPTOMS OF BENZODIAZEPINE WITHDRAWAL

STAGE	SYMPTOMS
Early Withdrawal	Increased pulse and blood pressure, anxiety, panic attacks, restlessness, and gastrointestinal upset.
Mid Withdrawal	In addition to the above, may progress to include tremor, fever, diaphoresis, insomnia, anorexia, and diarrhea.
Late Withdrawal	If left untreated, a delirium may develop with hallucinations, changes in consciousness, profound agitation, autonomic instability, seizures, and death. Patients showing signs of late (severe) withdrawal should be hospitalized.

TREATMENT OF BENZODIAZEPINE WITHDRAWAL

The general principle of substituting a long-acting medication for a short-acting one is especially important in the treatment of benzodiazepine withdrawal. Many inmates will present with histories of chronic use of Xanax (alprazolam) or Ativan (lorazepam), both high-potency, short-acting substances. Attempts at tapering these substances for detoxification often lead to significant withdrawal symptoms and can be unsuccessful, resulting in a full-blown withdrawal syndrome.

Benzodiazepines with long half-lives, such as clonazepam, are generally used for benzodiazepine detoxification. However, they can accumulate and cause excessive sedation or intoxication.

Careful monitoring is absolutely necessary, especially in the initial stages of changing the inmate to the longer-acting medication.

Inmates experiencing benzodiazepine withdrawal should be counseled by a health care provider on the signs and symptoms of withdrawal, the anticipated treatment plan, and patient responsibilities. Educational information in [Appendix 7, Patient Information – Detoxification from Benzodiazepines](#), should be used when appropriate. Specific treatment strategies for benzodiazepine withdrawal should be determined by the condition of the individual inmate, and should be reviewed and approved by a physician.

The following guidance should be taken into consideration:

- **Clonazepam treatment:** Clonazepam is a high-potency medication with a half-life of greater than 24 hours; it is well-tolerated and easy to administer. Clonazepam can be substituted for other benzodiazepines, according to the dose equivalencies listed in [Appendix 4, Benzodiazepine Dose Equivalents](#). It is generally begun on a three-times-a-day schedule; however, because of the long half-life, some dosing schedules for tapering may be successfully accomplished through once-daily dosing. The frequency can be adjusted according to appropriate withdrawal symptom monitoring. Individuals metabolize clonazepam at different rates; therefore, the dose equivalencies will not hold for all inmates and must be individualized according to the inmate's response. As in alcohol withdrawal, sympathetic hyperactivity is an early sign of benzodiazepine withdrawal. Control of these symptoms is accomplished with adequate dosing of the cross-tolerant medication.
- **Monitoring:** During the first three days of treatment, the inmate should be examined for withdrawal symptoms and have vital signs taken at least every 8 hours. If the inmate becomes over-sedated or intoxicated, the dose can be lowered until the inmate is more alert, so long as vital signs remain in the normal range. Stabilization may take two to three days on the new medication. After the inmate's condition has stabilized, the clonazepam can be given twice-daily, and then tapered gradually.
- **Tapering:** The tapering schedule will depend on several factors, including the setting in which the inmate is treated and the presence of co-morbid medical or psychiatric conditions.
 - ▶ **If the inmate is hospitalized,** the medication can be tapered by 10% per day. Throughout the tapering schedule, inpatients should continue to be evaluated for withdrawal symptoms every 8 hours.
 - ▶ **Outpatients** should not be tapered any more rapidly than by 10% every three to five days, or 25% per week. Outpatients should be evaluated daily for at least the first week, or as their condition indicates.

As the taper nears the end, it may be necessary to slow it further if anxiety or insomnia develop. These symptoms can continue for many months after detoxification has been safely completed. Referral to psychological services for supportive care, as well as stress management, sleep hygiene, and relaxation training, may be helpful both during and after the detoxification process. Psychology or psychiatry staff should closely monitor the inmate during detoxification if a co-morbid psychiatric disorder is present.

ADJUNCTIVE TREATMENTS OF BENZODIAZEPINE WITHDRAWAL

- **Psychological and psychiatric treatments are often necessary in the management of patients physiologically dependent on benzodiazepines.** The nature of those treatments will depend on the individual's needs. Inmate education regarding the withdrawal process, expected symptoms, and possible recurrence of psychiatric symptoms is essential.
- **Beta-blockers (e.g., propranolol) and alpha-2 adrenergic medications (e.g., clonidine) have sometimes been used to attenuate the sympathetic hyperactivity associated with benzodiazepine withdrawal. However, these drugs are not routinely recommended.** They mask the very symptoms that signal an inadequate dosage of the cross-tolerant medication, and thereby place the inmate at increased risk for developing severe withdrawal. If the inmate is already on one of these medications for other medical conditions, such as hypertension, increased vigilance is necessary to prevent severe withdrawal symptoms from developing.
- **Anti-seizure medications are generally not indicated for treating withdrawal from benzodiazepines.** Carbamazepine has been shown to have some efficacy in treating benzodiazepine withdrawal, but it has many drug-drug interactions and significant side effects, and can be problematic in patients with liver disease. Inmates with underlying seizure disorders should have their seizure medication adjusted to therapeutic blood levels. Seizure medication levels should be monitored throughout the detoxification process.
- **SAMHSA recommends chlordiazepoxide as an alternative to clonazepam** for substitution of a long-acting medication for a short-acting one, or switching to a long-acting barbiturate such as phenobarbital.

8. BARBITURATE WITHDRAWAL

DIAGNOSIS AND SIGNS/SYMPTOMS OF BARBITURATE WITHDRAWAL

- Barbiturates generally have short half-lives, and withdrawal symptoms can develop within a few hours of the last dose.
 - Discontinuation of barbiturates produces a withdrawal syndrome essentially identical to that of alcohol and benzodiazepines, and can similarly result in significant morbidity and mortality if left untreated.
 - Unlike benzodiazepines, barbiturates have a narrow therapeutic margin, above which toxicity and respiratory depression quickly develop.
 - Although tolerance develops to the sedative and euphoric effects of barbiturates, little tolerance develops to respiratory depression.
 - Withdrawal from barbiturates progresses as shown in **TABLE 5** below.
- ➔ *Due to the severity of barbiturate withdrawal, a low threshold should exist for admission to a local hospital if needed.*

TREATMENT OF BARBITURATE WITHDRAWAL

The general principles and physical assessments used in benzodiazepine withdrawal also apply to the management of barbiturate withdrawal.

TABLE 5. SYMPTOMS OF BARBITURATE WITHDRAWAL

STAGE	SYMPTOMS
Early Withdrawal	Increased pulse and/or blood pressure, anxiety, panic attacks, restlessness, gastrointestinal distress.
Mid Withdrawal	Tremor, fever, diaphoresis, insomnia, anorexia, diarrhea.
Late Withdrawal	Changes in consciousness, profound agitation, hallucinations, autonomic instability, seizures. Any signs or symptoms of late withdrawal should prompt hospitalization.

Inmates experiencing barbiturate withdrawal should be counseled by a health care provider on the signs and symptoms of withdrawal, the anticipated treatment plan, and patient responsibilities. Educational information in [Appendix 8, Patient Information – Detoxification from Barbiturates](#) should be used when appropriate.

Inmates experiencing barbiturate withdrawal should always be actively medicated. Specific treatment strategies for barbiturate withdrawal should be determined by the condition of the individual inmate, and should be reviewed and approved by a physician. The following guidance should be taken into consideration:

- Substitute phenobarbital for the drug of abuse in equivalent doses as per [Appendix 5, Barbiturate Dose Equivalents](#).
- Administer phenobarbital on a four-times-a-day schedule. It may be necessary to establish a non-standard pill line time to meet the need for directly observed administration of phenobarbital.
- Stabilize the inmate on the baseline dose for three days, followed by tapering the dose by no more than 10% every three to five days.
- Assess the inmate's condition and vital signs at least every 8 hours during the first three days of treatment; then, at least every day for the first week; and then as the inmate's condition dictates. If this level of monitoring is not possible, consult the Regional Medical Director for advice, or consider admitting the patient to a local hospital.
- For outpatients, consider slowing the taper toward the end of the withdrawal schedule.
- Inpatients may be tapered as quickly as 10% of their drug dosage per day.

ADJUNCTIVE TREATMENTS FOR BARBITURATE WITHDRAWAL

- **Symptoms of anxiety and insomnia may continue for months after the safe completion of detoxification.** Inmate education is paramount. Referral to psychology services for stress management, relaxation training, and sleep hygiene may be indicated for certain inmates.
- **Beta-blockers and clonidine will mask withdrawal symptoms and complicate management.** As such, these drugs are not routinely recommended in adjunctive treatment for barbiturate withdrawal. Inmates with seizure disorders should have anti-seizure medications maintained in the therapeutic range and should have blood levels checked frequently throughout the detoxification process.

9. OPIATE WITHDRAWAL

DIAGNOSIS OF OPIATE USE DISORDERS

The diagnosis of opiate dependence is made through a careful patient history and physical examination.

The history should focus in part on the following information:

- Types of drugs used, route of use, length of time drugs have been used, symptoms when drugs have been stopped or decreased, and date and amount of last drug use.
- Review of risk factors, symptoms, and previous testing for bloodborne pathogens: hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
- Determination of past medical history and review of symptoms for medical conditions associated with chronic opiate use such as malnutrition, tuberculosis infection and disease, trauma, skin infections, endocarditis, and sexually transmitted diseases.

The physical examination should include, in part, an evaluation of the inmate's vital signs and cardiopulmonary status for evidence of fever, heart murmur, or hemodynamic instability. In addition, there should be a focused examination of the skin for signs of scarring, atrophy, infection, and the stigmata of endocarditis.

The laboratory evaluation should include a complete blood count, comprehensive serum chemistry panel, urine toxicology, and a pregnancy test in women. Other studies such as hepatitis serologies, HIV testing, electrocardiogram, chest x-ray, and screening for sexually transmitted diseases could be conducted, depending on the individual historical findings and physical examination.

Medical detoxification is considered the standard of care for individuals with opiate dependence. Opiate withdrawal is rarely dangerous except in medically debilitated individuals and pregnant women. Pregnant women taking opiates should be treated with methadone or maintained on methadone, since detoxification increases the risk of miscarriage and premature labor. Symptoms of withdrawal from short-acting opiates such as heroin can develop a few hours after the last use, peak within 36–72 hours, and subside over 5–10 days. Longer-acting opiates such as methadone produce a more protracted withdrawal syndrome, beginning in 24–48 hours, peaking in 72 hours, and subsiding over 1–3 weeks.

Early signs of opiate withdrawal include: rhinorrhea, diaphoresis, lacrimation, yawning, dilated pupils, and increased temperature. Later signs include: anorexia, nausea, vomiting, diarrhea, tenesmus, goose flesh, weakness, increased blood pressure and pulse, agitation, restlessness, and severe muscle and bone pain.

TREATMENT OF OPIATE WITHDRAWAL

Patients with opiate use disorders often express significant fear and anticipatory anxiety regarding detoxification. Inmates experiencing opiate withdrawal should be counseled by a health care provider on the signs and symptoms of withdrawal, the anticipated treatment plan, and patient responsibilities. Educational information in [Appendix 9, Patient Information – Detoxification from Opiates \(Narcotics\)](#) should be used when appropriate.

Treatment is aimed at reducing the signs and symptoms of withdrawal, and may or may not include the use of a substitute narcotic such as methadone. Specific treatment should always be determined by the condition of the individual inmate, and should be reviewed and approved by a physician. The following guidance should be taken into consideration.

METHADONE TREATMENT

The federal Narcotic Addict Treatment Act of 1974 restricts the use of methadone in the treatment of opiate dependence to facilities that are appropriately licensed as a Narcotic Treatment Program for maintenance or detoxification with methadone. Methadone can be provided without an institutional license for up to three days while arranging for an appropriate referral of the patient to a licensed facility. This three-day allowance cannot be renewed or extended.

In accordance with the above requirements, methadone can be substituted for any other opiate. Because methadone has a long half-life, accumulation can occur over the first few days while a steady state is reached, which can result in an iatrogenic overdose and death due to respiratory depression.

Methadone used for opiate detoxification should ordinarily be administered in accordance with the following guidance:

- Methadone can be given in doses of 5–10 mgs orally, every 4–6 hours as needed to control objective signs of withdrawal, to a maximum dose of 40 mg/day.
- Frequent monitoring for respiratory depression and over-sedation is necessary until the inmate is stabilized.
- Once signs of withdrawal are controlled and the inmate is stabilized over two to three days, then begin tapering the methadone at a rate of 10% per day.
- Clonidine is usually given in conjunction with the methadone to minimize withdrawal symptoms.

CLONIDINE TREATMENT

Clonidine is an acceptable alternative for opiate detoxification and should be considered if the institution does not have a methadone license or when otherwise medically indicated. Clonidine is usually used together with other medications for symptomatic relief during detoxification. Clonidine will suppress many of the symptoms of withdrawal, including sympathetic hyperactivity, nausea, vomiting, diarrhea, cramps, and sweating; however, it has no effect on muscle or bone pain, insomnia, or severe drug craving.

Clonidine is ordinarily administered in accordance with the following guidance:

- ➔ *Clonidine can cause hypotension and somnolence (increasing risk of injury), and is fatal in overdose.*
- Clonidine can be given in doses of 0.1–0.2 mg orally, three to four times daily. Directly observed therapy (pill line) is strongly encouraged. Crushing of the tablets should also be considered.
- Clonidine patches can be utilized in mild withdrawal cases and are left on for seven days.
- Vital signs should be carefully monitored before each dose of clonidine.
- Withhold clonidine if systolic BP drops below 90 mm Hg or if bradycardia develops.
- Maintain baseline clonidine dosing for two to three days; then, taper off over five to ten days.

BUPRENORPHINE TREATMENT

Buprenorphine is a mixed agonist-antagonist agent. It can be used for maintenance therapy for opioid dependent patients, or for helping opioid-dependent patients achieve abstinence from opioids. Detoxification of inmates who have been using buprenorphine as maintenance therapy can be accomplished in an outpatient setting over several days. Tapering the patient will be accomplished by other opioid agents. A special license is required to prescribe buprenorphine. This medication is not routinely used in the BOP. Refer to the National BOP Formulary for current non-formulary use criteria for buprenorphine.

ADJUNCTIVE TREATMENTS FOR OPIATE WITHDRAWAL

Symptomatic treatment for opiate withdrawal should be provided over five to ten days, using standard doses of the following medications unless otherwise contraindicated:

- Nonsteroidal anti-inflammatory agents are used for pain and fever.
- Antidiarrheals and anti-emetics are used to control gastrointestinal symptoms.
- Benzodiazepines are used for insomnia and restlessness.
- Buspirone has shown efficacy in reducing anxiety and symptoms associated with opioid withdrawal, and may be prescribed as needed on a case-by-case basis.

Many inmates with opiate dependence have experienced multiple episodes of withdrawal prior to incarceration, and are typically highly anxious during opiate withdrawal, even when symptoms are well-controlled. Psychological support is often necessary to help ease these anxieties. The inmate's mental health status should be monitored on an ongoing basis during withdrawal. Referrals to psychology and psychiatry staff should be initiated as warranted.

10. COCAINE/STIMULANTS

Inmates with a dependency on cocaine or other stimulants generally do not require treatment in an inpatient setting. The cessation of this substance does not always cause specific withdrawal symptoms. However, symptoms may be severe enough to require clinical intervention. For most inmates who use cocaine or other stimulants, medications are not ordinarily indicated as an initial treatment for withdrawal or dependence, as none have shown efficacy. Inmates are treated symptomatically.

- ➔ *SAMHSA recommends that patients withdrawing from stimulants should be monitored closely for depression/suicidality, as well as prolonged QTc intervals and seizures, which may be additional complications of stimulant withdrawal. An EKG is recommended during cocaine withdrawal to monitor for cardiac complications.*

11. INHALANTS

Inhalants are commonly used to obtain a quick high. Substances such as paint thinner, cleaners, and glue can be breathed in through the nose—a process known as *huffing*. The various symptoms associated with huffing include dizziness, impaired coordination, slurred speech, unsteady gait, lethargy, blurred vision, and even stupor or coma. There are no general lab tests for patients suspected of inhaling a substance. Treatment is generally supportive, but in the case of an overdose, emergency support may be necessary, as well as increased observation to monitor vital signs.

DEFINITIONS

COMPREHENSIVE SERUM CHEMISTRY PANEL includes, at minimum: glucose, electrolytes, BUN, creatinine, albumin, bilirubin, AST, and ALT.

CROSS-TOLERANCE is the ability of one drug or substance to act as a physiologic substitute for another. Using a cross-tolerant substitute allows the dependent individual to “detox” without experiencing a withdrawal syndrome.

DETOXIFICATION is the medically managed withdrawal of individuals from a substance on which they are physiologically dependent.

KINDLING, a phenomenon in which the severity of withdrawal symptoms increases after repeated withdrawal episodes, is experienced by many alcoholics. This phenomenon suggests that even patients who experience only mild withdrawal should be treated aggressively to reduce the severity of withdrawal symptoms in subsequent episodes. Kindling also may contribute to a patient’s relapse risk and to alcohol-related brain damage and cognitive impairment.

PHYSIOLOGICAL DEPENDENCE exists if a physiological withdrawal syndrome develops when a medication, drug, or other substance is discontinued. Individuals may develop physiological dependence without developing pathological substance dependence. For example, taking prescribed benzodiazepines for a psychiatric condition over a prolonged period can lead to physiological dependence, without other symptoms of substance dependence developing.

SUBSTANCE refers to any chemical that is mood- or mind-altering; it can include street drugs, inhalants, and prescription and over-the-counter medications, as well as nicotine, caffeine, and alcohol.

SUBSTANCE DEPENDENCE is a “cluster of physiological, behavioral, and cognitive symptoms indicating that an individual continues to use a substance” (DSM-5), despite serious social, financial, emotional, behavioral, or physical consequences. Physiological dependence may or may not develop in individuals who are substance-dependent. The terms *substance dependence* and *addiction* are used interchangeably.

TOLERANCE is the “need for markedly increased amounts of the substance to achieve intoxication,” or a “markedly diminished effect when using the same amount.” (DSM-5).

WERNICKE-KORSAKOFF SYNDROME is caused by a deficiency in thiamine (vitamin B1), commonly depleted in people with alcohol use disorders due to altered gastrointestinal absorption or a diet lacking sufficient thiamine. Thiamine is critical for the prevention and treatment of Wernicke’s encephalopathy, a neurological disorder that manifests as ataxia, ophthalmoplegia, and confusion. **Thiamine is a cofactor in normal glucose metabolism and should be administered before the administration of glucose.** If left untreated, this encephalopathy may progress to permanent cognitive impairment known as Korsakoff’s psychosis, for which there is no known treatment.

WITHDRAWAL SYNDROME is the characteristic group of signs and symptoms that typically develop after a rapid, marked decrease or discontinuation of a substance on which an individual is dependent. The severity and duration of the withdrawal syndrome is determined by a number of factors: the type of substance, as well as its half-life and duration of action; the length of time the substance has been used, the amount used, and whether other substances are also used; the presence of other medical and psychiatric conditions; and other individual biopsychosocial variables.

REFERENCES

American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed. Washington, DC: American Psychiatric Association; 2013. Available at: <http://www.dsm5.org/Pages/Default.aspx>

Ait-Daoud N, Malcolm RJ, Johnson BA. An overview of medications for the treatment of alcohol withdrawal and alcohol dependence with an emphasis on the use of older and newer anticonvulsants. *Addict Behav.* 2006;31:1628.

American Psychiatric Association Practice Guidelines [homepage on the internet]. *Practice guideline for the treatment of patients with substance use disorders*, 2nd ed., May 2006. Available at: http://www.psychiatryonline.com/pracGuide/pracGuideTopic_5.aspx

Asplund CA, Aaronson JW, Aaronson HE. 3 regimens for alcohol withdrawal and detoxification. *J Fam Pract.* 2004;53:545-54. Available at: <http://www.jfponline.com/Pages.asp?AID=1730>

Becker HC. Kindling in Alcohol Withdrawal. *Alcohol Health & Research World.* 1998; 22:25-33. Available at: <http://pubs.niaaa.nih.gov/publications/arh22-1/25-34.pdf>

Buydens-Branchey L, Branchey M, Reel-Brander C. Efficacy of buspirone in the treatment of opioid withdrawal. *J Clin Psychopharmacol.* 2005;25:230–236.

Carbamazepine: alcohol withdrawal. Off-label drug facts. *Facts & Comparisons 4.0*. St. Louis, MO: Wolters Kluwer Health, Inc; 2008.

Center for Substance Abuse Treatment. Detoxification from alcohol and other drugs. *Treatment Improvement Protocol (TIP) Series*, Number 19. U.S. Department of Health and Human Services Publication No. (SMA)95-3046. Washington, D.C.: US Government Printing Office; 1995. Available at: <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.39784>

College of Psychiatric and Neurologic Pharmacists. *2012–2013 BCPP Examination Review and Recertification Course*. Available at: <http://cpnp.org/bcpp/products/review>

Miller N, Doot M, Kasser C, et al. *Detoxification: Principles and Protocols (Topics in Addiction Medicine, Volume 1, Number 2)*. Chevy Chase, MD: American Society of Addiction Medicine;1997.

Malcolm R, Myrick H, Roberts J, Wang W, Anton RF, Ballenger JC. The effects of carbamazepine and lorazepam on single versus multiple previous alcohol withdrawals in an outpatient randomized trial. *Gen Intern Med.* 2002;17(5):349–355.

Mayo-Smith M, et al. Pharmacological management of alcohol withdrawal: a meta-analysis and evidence-based practice guideline. American Society of Addiction Medicine Working Group on Pharmacological Management of Alcohol Withdrawal. *JAMA.* 1997;278(2):144–51.

Silbergleit R, Durkalski V, Lowenstein D, et al. Intramuscular versus intravenous therapy for prehospital status epilepticus. *N Engl J Med*. 2012; 366(7): 591– 600. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/22335736>

Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. *Quick Guide for Clinicians Based on TIP 45: Detoxification and Substance Abuse Treatment*. 2006. Available at: <http://store.samhsa.gov/shin/content/SMA06-4225/SMA06-4225.pdf>

Sullivan JT, Sykora K, Schneiderman J, Naranjo CA, Sellers EM. Assessment of alcohol withdrawal: The revised Clinical Institute Withdrawal Assessment for Alcohol Scale (CIWA-Ar). *British Journal of Addiction* 1989;84:1353–57.

U.S. Department of Justice, Bureau of Justice Statistics [homepage on the internet]. Prison Statistics. Available at: <http://www.bjs.gov/>

Weaver MF. Treatment of sedative-hypnotic drug abuse in adults. *UpToDate*. 2009;17.1.

APPENDIX 1. DETOXIFICATION OVERVIEW

This chart is designed to be used only as a quick reference guide. For complete information, see the indicated section in these guidelines.

SUBSTANCE (section in guidelines)	MONITORING	PRIMARY TREATMENT	SEVERITY OF WITHDRAWAL	HOSPITALIZATION?
ALCOHOL (Section 6)	CIWA-Ar Score: As frequently as every hour	<ul style="list-style-type: none"> • Lorazepam • Thiamine 	Low to high; can be fatal	As needed for moderate to severe withdrawal
BENZODIAZEPINES (Section 7)	Vital Signs: Three times a day for 3 days	<ul style="list-style-type: none"> • Clonazepam 	Low to high; can be fatal	As needed for late withdrawal
BARBITURATES (Section 8)	Vital Signs: Three times a day for 3 days	<ul style="list-style-type: none"> • Phenobarbital 	Low to high; can be fatal	As needed for late withdrawal
OPIATES (Section 9)	Vital Signs: Daily; more often if clonidine used	<ul style="list-style-type: none"> • Methadone • Clonidine • Symptomatic 	Low to high	Usually not necessary
COCAINE (Section 10)	Vital Signs: As needed	<ul style="list-style-type: none"> • Symptomatic 	Low to high	Usually not necessary

APPENDIX 2. ALCOHOL WITHDRAWAL ASSESSMENT AND TREATMENT FLOWSHEET

Guidelines for using the [Alcohol Withdrawal Assessment and Treatment Flowsheet](#) on next page:

1. **Early intervention for a CIWA-Ar score of 8 or greater** provides the best means of preventing the progression of withdrawal. The CIWA-Ar scale is the most sensitive tool for assessing a patient who is experiencing alcohol withdrawal.
2. **Use the attached *Alcohol Withdrawal Assessment and Treatment Flowsheet*** to document the patient's vitals and CIWA-Ar scores, as well as the administration of PRN medications.
3. **Follow the Assessment Protocol** shown at the top of the flowsheet. Record the date, time, vitals, and the CIWA-Ar ratings and Total Score each time the patient is assessed.
4. **To calculate the Total CIWA-Ar Score**, rate the patient according to each of the 10 CIWA-Ar criteria, and then add together the 10 ratings. Each criterion is rated on a scale from 0 to 7 (except for "Orientation and Clouding of Sensorium," which is rated on a scale from 0 to 4). The clinician can select any rating from 0 to 7 (or 0 to 4, in the case of "Orientation"), even for criteria where not every number on the rating scale is defined.

AUG 2009

ALCOHOL WITHDRAWAL ASSESSMENT AND TREATMENT FLOWSHEET

U.S. DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF PRISONS

Assessment Protocol a. Assess vitals and CIWA-Ar. b. If total CIWA-Ar score ≥ 8 , repeat every hour. Once the CIWA-Ar score < 8 , then repeat every 4–8 hours until score has remained < 8 for 24 hours. c. If initial Total CIWA-Ar score < 8 , repeat CIWA every 4–8 for 24 hours. d. If indicated, administer PRN medications per BOP protocol.	Date								
	Time								
	Pulse								
	RR								
	O ₂ sat								
	BP								
Use the CIWA-Ar Scale to assess and rate each of the following 10 criteria.									
Nausea/Vomiting: Rate on scale of 0–7. 0 - none; 1 - mild nausea, no vomiting; 4 - intermittent nausea; 7 - constant nausea, frequent dry heaves and vomiting									
Tremors: Have patient extend arms and spread fingers. Rate on scale of 0–7. 0 - no tremor; 1 - not visible, but can be felt fingertip-to-fingertip; 4 - moderate with arms extended; 7 - severe, even with arms not extended									
Anxiety: Rate on scale of 0–7. 0 - none, at ease; 1 - mildly anxious; 4 - moderately anxious or guarded, so anxiety is inferred; 7 - equivalent to acute panic states, as in severe delirium or acute schizophrenic reactions									
Agitation: Rate on scale of 0–7. 0 - normal activity; 1 - somewhat normal activity; 4 - moderately fidgety and restless; 7 - constantly paces or thrashes about									
Paroxysmal Sweats: Rate on scale of 0–7. 0 - no sweats; 1 - barely perceptible sweating, palms moist; 4 - beads of sweat obvious on forehead; 7 - drenching sweats									
Orientation & Clouding of Sensorium: Ask, "What day is this? Where are you? Who am I?" Rate on scale of 0–4. 0 - oriented; 1 - cannot do serial additions, uncertain about date; 2 - disoriented to date by no more than 2 days; 3 - disoriented to date by > 2 days; 4 - disoriented to place and/or person									
Tactile Disturbances: Ask, "Have you experienced any itching, pins and needles sensation, burning or numbness, or a feeling of bugs crawling on or under your skin?" Rate on scale of 0–7. 0 - none; 1 - very mild itch, P&N, burning, numbness; 2 - mild itch, P&N, burning, numbness; 3 - moderate itch, P&N, burning, numbness; 4 - moderate hallucinations; 5 - severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous hallucinations									
Auditory Disturbances: Ask, "Are you more aware of sounds around you? Are they harsh? Do they startle you? Do you hear anything that disturbs you or that you know isn't there?" Rate on scale of 0–7. 0 - not present; 1 - very mild harshness or ability to startle; 2 - mild harshness or ability to startle; 3 - moderate harshness or ability to startle; 4 - moderate hallucinations; 5 - severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous hallucinations									
Visual Disturbances: Ask, "Does the light appear to be too bright? Is its color different than normal? Does it hurt your eyes? Are you seeing anything that disturbs you or that you know isn't there?" Rate on scale of 0–7. 0 - not present; 1 - very mild sensitivity; 2 - mild sensitivity; 3 - moderate sensitivity; 4 - moderate hallucinations; 5 - severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous hallucinations									
Headache: Ask, "Does your head feel different than usual? Does it feel like there is a band around your head?" Rate on scale of 0–7. Do not rate dizziness or lightheadedness. 0 - not present; 1 - very mild; 2 - mild; 3 - moderate; 4 - moderately severe; 5 - severe; 6 - very severe; 7 - extremely severe									
Total CIWA-Ar Score: (8–9 = mild withdrawal; 10–15 = moderate withdrawal; >15 = severe withdrawal)									
Indications for PRN Medication: Please follow the protocol in BOP <i>Clinical Practice Guidelines for Detoxification of Chemically Dependent Inmates</i> for use of lorazepam and other medications for withdrawal. See Table 2 and Section 6, Alcohol Withdrawal .									
Medication administered? (see Medication Administration Record) Yes/No:									
Time of PRN medication administration:									
Assessment of response: (CIWA-Ar Score 30–60 minutes after medication administered)									
Provider initials:									

Inmate Name _____
Reg No. _____
Date of Birth ____/____/____
Institution _____

Signature/Title	Initials	Signature/Title	Initials

APPENDIX 3: SYMPTOMS AND SIGNS OF DRUG ABUSE*

DRUG	ACUTE INTOXICATION AND OVERDOSE	WITHDRAWAL SYNDROME
HALLUCINOGENS LSD ¹ ; psilocybin; mescaline; PCP ² ; STP ³ ; MDMA ⁴ ; Bromo-DMA ⁵	Pupils dilated (normal or small with PCP); BP elevated, heart rate increased, tendon reflexes hyperactive; temperature elevated; face flushed; euphoria, anxiety or panic; paranoid thought disorder; sensorium often clear; affect inappropriate; time/visual distortions; visual hallucinations; depersonalization With PCP: drooling, blank stare, mutism, amnesia, analgesia, nystagmus (sometimes vertical), ataxia, muscle rigidity, impulsive/often violent behavior.	None
CNS STIMULANTS amphetamines; cocaine; methylphenidate; phenmetrazine; phenylpropanolamine; most anti-obesity drugs	Pupils dilated and reactive; respiration shallow; BP elevated; heart rate increased; tendon reflexes hyperactive; temperature elevated; cardiac arrhythmias; dry mouth; sweating; tremors; sensorium hyperacute or confused; paranoid ideation; hallucinations; impulsivity; hyperactivity; stereotypy; convulsions; coma	Muscular aches; abdominal pain; chills, tremors; voracious hunger; anxiety; prolonged sleep; lack of energy; profound psychological depression, sometimes suicidal; exhaustion
CANNABIS GROUP marijuana; hashish; THC ⁶ ; hash oil	Pupils unchanged; conjunctiva injected; BP decreased on standing; heart rate increased; increased appetite; euphoria, anxiety; sensorium often clear; dreamy, fantasy state; time-space distortions; hallucinations rare	Nonspecific symptoms including anorexia, nausea, insomnia, restlessness, irritability, anxiety
OPIOIDS heroin; morphine; codeine; meperidine; methadone; hydromorphone; opium; pentazocine; propoxyphene	Pupils constricted (may be dilated with meperidine or extreme hypoxia); respirations depressed; BP decreased, sometimes shock; temperature decreased; reflexes diminished to absent; stupor or coma; pulmonary edema; constipation; convulsions with propoxyphene or meperidine	Pupils dilated; pulse rapid; gooseflesh; abdominal cramps; muscle jerks; "flu" syndrome; vomiting, diarrhea; tremulousness; yawning; anxiety
CNS SEDATIVES barbiturates; benzodiazepines; glutethimide; meprobamate; methaqualone	Pupils in mid position and fixed (but dilated with glutethimide or in severe poisoning); BP decreased, sometimes shock; respiration depressed; tendon reflexes depressed; drowsiness or coma; nystagmus; confusion; ataxia, slurred speech; delirium; convulsions or hyper-irritability with methaqualone overdosage; serious poisoning rare with benzodiazepines alone	Tremulousness; insomnia; sweating; fever; clonic blink reflex; anxiety; cardiovascular collapse; agitation; delirium; hallucinations; disorientation; convulsions; shock
ANTICHOLINERGICS atropine; belladonna; henbane; scopolamine; trihexyphenidyl; benztropine mesylate; procyclidine; propantheline bromide	Pupils dilated and fixed; heart rate increased; temperature elevated; decreased bowel sounds; drowsiness or coma; flushed, dry skin and mucous membranes, sensorium clouded; amnesia; disorientation, visual hallucinations; body image alterations; confusion	Gastrointestinal and musculoskeletal symptoms

¹ LSD = d-lysergic acid diethylamide⁴ MDMA = 3,4 methylenedioxymethamphetamine² PCP = phencyclidine⁵ Bromo-DMA = 4 Bromo-2,5dimethoxyamphetamine³ STP = 2,5-dimethoxy-4-methylamphetamine⁶ THC = delta-9-tetrahydrocannabinol

* Mixed intoxications produce complex combinations of signs and symptoms.

APPENDIX 4: BENZODIAZEPINE DOSE EQUIVALENTS

The dose equivalencies and half-lives shown below are estimates only. Dosages may need to be adjusted based on clinical findings, as well as on other factors such as age that affect the metabolism of benzodiazepines. For example, liver disease can decrease metabolism and thereby increase the accumulation of the benzodiazepine. The presence of active metabolites will also increase the half-life of the medication. Generally, the older the person, the slower the metabolism and the longer the half-life. For example, the half-life of flurazepam in an elderly individual may be as long as 200 hours.

GENERIC NAME (Trade Name)	EQUIVALENT DOSE (mg)	HALF-LIFE (hours)
Alprazolam (<i>Xanax</i>)	0.5–1	6–15
Chlordiazepoxide (<i>Librium</i>)	25	24–48
Clonazepam (<i>Klonopin</i>)	1–2	30–40
Clorazepate (<i>Tranxene</i>)	7.5–15	30+
Diazepam (<i>Valium</i>)	10	20–50
Estazolam (<i>ProSom</i>)	1	10–24
Flurazepam (<i>Dalmane</i>)	15–30	50–200
Lorazepam (<i>Ativan</i>)	1–2	10–20
Oxazepam (<i>Serax</i>)	10–30	5–10
Temazepam (<i>Restoril</i>)	15–30	3–20
Triazolam (<i>Halcion</i>)	0.25	1–5
Zolpidem (<i>Ambien</i>)	10–20	2–5
REFERENCE: Weaver MF. Treatment of sedative-hypnotic drug abuse in adults. <i>UpToDate</i> . 2009;17.1.		

APPENDIX 5: BARBITURATE DOSE EQUIVALENTS

Dose equivalencies are estimates, and dosages should be adjusted according to clinical response. Barbiturates have a narrow therapeutic window, such that toxicity can develop quickly at dosages above what is needed to manage withdrawal symptoms. Long-term use produces tolerance to the sedative and euphoric effects, but without a concurrent tolerance to respiratory depression. Careful attention to vital signs, particularly respiratory status, is imperative during withdrawal and detoxification.

Note: Phenobarbital is the drug of choice for detoxification from most barbiturates and barbiturate-like medications. *One exception is meprobamate.* Meprobamate itself can be used to detoxify inmates dependent on meprobamate.

BARBITURATES	
Generic Name (<i>Trade Name</i>)	Equivalent Dose (mg)
Amobarbital (<i>Amytal</i> , others)	100
Butabarbital (many combinations)	100
Butalbital (<i>Fiorinal</i> , others)	100
Pentobarbital (<i>Nembutal</i> , others)	100
Phenobarbital (<i>Donnatal</i> , others)	30
Secobarbital (<i>Seconal</i> , others)	100
BARBITURATE-LIKE DRUGS	
Generic Name (<i>Trade Name</i>)	Equivalent Dose (mg)
Chloral Hydrate (many)	250–500
Ethchlorvynol (<i>Placidyl</i>)	200–500
Glutethimide (<i>Doriden</i> , others)	250
Meprobamate (<i>Miltown</i> , others) (see Note above)	400
Methaqualone (<i>Quaalude</i> , others)	300
REFERENCE: Weaver MF. Treatment of sedative-hypnotic drug abuse in adults. <i>UpToDate</i> . 2009;17.1.	

APPENDIX 6: PATIENT INFORMATION – DETOXIFICATION FROM ALCOHOL

Your medical team has determined that you will need medical care in order to safely withdraw from alcohol. By being an active partner in your own treatment, you can help the withdrawal process be more effective and more comfortable. Treating your body's dependence on alcohol is only the first step towards a sober and healthy life style. Psychology staff and/or drug treatment counselors will work with you to develop a plan for long-term recovery. You may also find it helpful to attend AA (Alcoholics Anonymous) meetings at your institution.

What kind of withdrawal symptoms will you get?

It is impossible to know what symptoms of alcohol withdrawal any one person will experience. So much depends on your own physical condition. If you had problems when you stopped drinking before, you are likely to have at least some of those same symptoms again. The symptoms of alcohol withdrawal can include stomach upset, anxiety, mood swings, increased blood pressure, increased heart rate, insomnia, tremor, fever, loss of appetite, heavy sweating, hallucinations, seizures, and, in rare cases, death.

What kind of medical care will you get?

Alcohol withdrawal can be safely managed with medical help. You will be given thiamine (a vitamin) to take regularly for several days. It is very important that you take the thiamine as prescribed to prevent permanent brain damage.

To determine what other medications you need, and how much, your medical team will be examining you regularly for signs of withdrawal. Sometimes, medications such as lorazepam (Ativan) are used to prevent serious complications like high blood pressure, seizures, or confusion. Clonidine is another medication that is often used to treat high blood pressure. It will reduce your blood pressure and heart rate, as well as help with tremor, anxiety, and sleeplessness. If clonidine is prescribed for you, it is very important to take it on schedule. In fact, you must take all of your medications just as prescribed. They will be provided through pill line. If you miss a dose, let the medical staff know immediately.

Help yourself leave alcohol behind:

1. **Be honest about your use of alcohol and other substances.** This will help assure the best treatment for you.
2. **Immediately report any unusual symptoms to your medical team,** such as chest pain, hallucinations, fainting, seizures, or suicidal thinking.
3. **Take your medications on schedule and as prescribed.** They can prevent serious complications. If you miss a dose, let your medical team know as soon as possible.
4. **Stay busy and active during the day.** This will help keep your mind occupied and help you sleep better at night.
5. **Meet with psychology staff about other treatment options** such as drug treatment, relaxation training, and stress management.

By working with your medical team, you can help your withdrawal go as smoothly as possible. However, no matter how carefully the process is managed, you are still likely to have some mild symptoms such as trouble with sleeping and nervousness. Sometimes, these symptoms will continue for weeks or perhaps months. Be sure to seek help from medical and psychology staff if you find your symptoms to be troublesome.

APPENDIX 7: PATIENT INFORMATION – DETOXIFICATION FROM BENZODIAZEPINES

Your medical team has determined that you will need medical care in order to safely withdraw from benzodiazepines (tranquilizers). By being an active partner in your own treatment, you can help the process be more effective and more comfortable. Treating your body's dependence on benzodiazepines is only the first step towards a healthy life style. If you have been prescribed benzodiazepines for a nervous condition, psychiatry and psychology staff will develop a new treatment plan for your condition that does not require the use of addictive medications. If you have been taking benzodiazepines in an abusive pattern, psychology staff and/or drug treatment counselors will work with you to develop a plan for long-term recovery. You may also find it helpful to attend NA (Narcotics Anonymous) meetings at your institution.

What kind of withdrawal symptoms will you get?

It is impossible to know what symptoms of benzodiazepine withdrawal any one person will experience. So much depends on your own physical condition. If you had problems when you stopped taking the medication before, you are likely to have at least some of those same symptoms again. It is *not* safe to suddenly stop taking benzodiazepines. The symptoms of benzodiazepine withdrawal can include stomach upset, anxiety, mood swings, increased blood pressure, increased heart rate, insomnia, tremor, fever, loss of appetite, heavy sweating, hallucinations, seizures, and, in rare cases, death.

Benzodiazepine withdrawal can be safely managed with medical help. You may be given the same medication you have been taking, or the medical staff may determine that it is safer to substitute another benzodiazepine. Either way, it is very important for you to take your medication just as prescribed to prevent serious complications such as high blood pressure, seizures, delirium, and even death. Your medical team will be examining you regularly for signs of withdrawal so they can determine the correct dose of your medication. Your medication will be provided through pill line. If you miss a dose, let the medical staff know *immediately*.

Help yourself leave benzodiazepines behind:

1. **Be honest about your use of benzodiazepines and other substances.** This will help assure the best treatment for you.
2. **Immediately report any unusual symptoms to your medical team,** such as chest pain, hallucinations, fainting, seizures, or suicidal thinking.
3. **Take your medications on schedule and as prescribed.** They can prevent serious complications. If you miss a dose, let your medical team know as soon as possible.
4. **Stay busy and active during the day.** This will help keep your mind occupied and help you sleep better at night.
5. **Meet with psychology staff about other treatment options** such as drug treatment, relaxation training, and stress management.

By working with your medical team, you can help your withdrawal go as smoothly as possible. However, no matter how carefully the process is managed, you are still likely to have some mild symptoms such as trouble with sleeping and nervousness. Sometimes, these symptoms will continue for weeks or perhaps months. Be sure to seek help from medical and psychology staff if you find your symptoms to be troublesome.

APPENDIX 8: PATIENT INFORMATION – DETOXIFICATION FROM BARBITURATES

Your medical team has determined that you will need medical care in order to safely withdraw from barbiturates. By being an active partner in your own treatment, you can help the process be more effective and more comfortable. Treating your body's dependence on barbiturates is only the first step towards a healthy life style. If you have been prescribed barbiturates for a nervous condition, psychiatry and psychology staff will develop a new treatment plan for your condition that does not require the use of addictive medications. If you have been taking barbiturates in an abusive pattern, psychology staff and/or drug treatment counselors will work with you to develop a treatment plan for long-term recovery. You may also find it helpful to attend NA (Narcotics Anonymous) meetings at your institution.

What kind of withdrawal symptoms will you get?

It is impossible to know what symptoms of barbiturate withdrawal any one person will experience. So much depends on your own physical condition. If you had problems when you stopped taking the medication before, you are likely to have at least some of those same symptoms again. It is *not* safe to suddenly stop taking barbiturates. The symptoms of barbiturate withdrawal can include stomach upset, anxiety, mood swings, increased blood pressure, increased heart rate, insomnia, tremor, fever, loss of appetite, heavy sweating, hallucinations, seizures, and, in rare cases, death.

Barbiturate withdrawal can be safely managed with medical help. You may be given the same medication you have been taking, or the medical staff may determine that it is safer to substitute another barbiturate. Either way, it is very important for you to take your medication just as prescribed to prevent serious complications such as high blood pressure, seizures, delirium, and even death. Your medical team will be examining you regularly for signs of withdrawal so they can determine the correct dose of your medication. Your medication will be provided through pill line. If you miss a dose, let the medical staff know *immediately*.

Help yourself leave barbiturates behind:

1. **Be honest about your use of barbiturates and other substances.** This will help assure the best treatment for you.
2. **Immediately report any unusual symptoms to your medical team,** such as chest pain, hallucinations, fainting, seizures, or suicidal thinking.
3. **Take your medications on schedule and as prescribed.** They can prevent serious complications. If you miss a dose, let your medical team know as soon as possible.
4. **Stay busy and active during the day.** This will help keep your mind occupied and help you sleep better at night.
5. **Meet with psychology staff about other treatment options** such as drug treatment, relaxation training, and stress management.

By working with your medical team, you can help your withdrawal go as smoothly as possible. However, no matter how carefully the process is managed, you are still likely to have some mild symptoms such as trouble with sleeping and nervousness. Sometimes, these symptoms will continue for weeks or perhaps months. Be sure to seek help from medical and psychology staff if you find your symptoms to be troublesome.

APPENDIX 9: PATIENT INFORMATION – DETOXIFICATION FROM OPIATES (NARCOTICS)

Your medical team has determined that you will need medical care in order to safely withdraw from opiates. By being an active partner in your own treatment, you can help the process be more effective and more comfortable. Treating your body's dependence on opiates is only the first step towards a healthy life style. If you have been prescribed opiates for a medical condition, your medical team will develop a new treatment plan for your condition that does not require the use of addictive medications. If you have been taking opiates in an abusive pattern, psychology staff and/or drug treatment counselors will work with you to develop a treatment plan for long-term recovery. You may also find it helpful to attend NA (Narcotics Anonymous) meetings at your institution.

What kind of withdrawal symptoms will you get?

It is impossible to know what symptoms of opiate withdrawal any one person will experience. So much depends on your own physical condition. If you had problems when you stopped taking opiates before, you are likely to have at least some of those same symptoms again. The symptoms of opiate withdrawal can include a runny nose, tearing of the eyes, yawning, dilated pupils, fever, loss of appetite, nausea, vomiting, diarrhea, abdominal cramps, sweating, goose flesh, increased blood pressure, increased heart rate, nervousness, restlessness, and muscle and bone pain.

Opiate withdrawal can be safely managed with medical help. To determine what medications you need, and how much, your medical team will be examining you regularly for signs of withdrawal. Medications such as methadone or clonidine may be used to help with some of the symptoms. Clonidine is usually used to reduce your blood pressure and heart rate, as well as help with nausea, vomiting, diarrhea, cramps, and sweating. You may be given other medications to help with bone and muscle pain, nausea, diarrhea, and insomnia.

If clonidine is prescribed for you, it is *very* important to take it on schedule. In fact, you must take all of your medications just as prescribed in order to reduce the considerable discomfort caused by opiate withdrawal. Even with effective treatment you are likely to experience some withdrawal symptoms. Your medications will be provided through pill line. If you miss a dose, let the medical staff know immediately.

Help yourself leave narcotics behind:

1. **Be honest about your use of opiates and other substances.** This will help assure the best treatment for you.
2. **Immediately report any unusual symptoms** to your medical team, such as chest pain, fainting, severe diarrhea, vomiting, or suicidal thinking.
3. **Take your medications on schedule and as prescribed.** They can prevent serious discomfort. If you miss a dose, let your medical team know as soon as possible.
4. **Stay busy and active during the day.** This will help keep your mind occupied and help you sleep better at night.
5. **Meet with psychology staff about other treatment options** such as drug treatment, relaxation training, and stress management.

By working with your medical team, you can help your withdrawal go as smoothly as possible. However, no matter how carefully the process is managed, you are still likely to have some mild symptoms, such as trouble with sleeping, nervousness, drug craving, and physical discomfort. Sometimes anxiety and insomnia will continue for weeks or months. Be sure to seek help from medical and psychology staff if you find your symptoms to be troublesome.

EXHIBIT 13



JAIL-BASED MEDICATION-ASSISTED TREATMENT

PROMISING PRACTICES, GUIDELINES, AND RESOURCES FOR THE FIELD

October 2018

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To find this resource online, visit www.ncchc.org/jail-based-mat.

To request MAT-related technical assistance, visit www.rsat-tta.com/On-Site-TA-Teleconferences/Training-and-Technical-Assistance-Request-Form.aspx.



This project was supported by Contract Number DJBP0700C0B0SN511010, awarded by the National Institute of Corrections, and Grant Number 2016-MU-BX-K021, awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Office of Justice Programs, which also includes the Bureau of Justice Statistics, the SMART Office, and the Office for Victims of Crime. Points of view or opinions in this document are those of the authors and do not represent the official position or policies of the United States Department of Justice.

NATIONAL SHERIFFS' ASSOCIATION

FOREWORD

Jails have become a revolving door for individuals struggling with mental health and substance use disorders. More than 10 million individuals pass through jails around the country annually, with at least half of those individuals having substance use disorders, half of whom are opioid abusers. Individuals suffering with mental health and substance use disorders come in and out of the jail, with arrests, incarceration, and release to the community, where the abuse restarts and the cycle continues when they commit another crime. Without effective intervention, this drives our nation's crime rate dramatically, while those who are most vulnerable remain sick. Jails not only oversee individuals struggling with substance use disorders and withdrawal, but are also in a unique position to initiate treatment in a controlled, safe environment.

Historically, it has not been the responsibility of the sheriffs and jail administrators to be primary providers of substance use disorder treatments. But with thousands of Americans dying every week from drug overdoses and those recently released from jail among the most defenseless, the situation has changed—sheriffs have taken on the challenge.

In 2017, the nation's sheriffs resolved to support the most current, evidence-based substance use disorder treatment within their jails to respond to the opioid and drug epidemic. Sheriffs have become this nation's pioneers in establishing medication-assisted treatment (MAT) programming, expanding jail MAT programs into 30 states at present.

The following guidelines introduce what has been learned from the sheriffs' and jail administrators' innovative use of MAT, describing the essential components of these programs and analyzing the latest research on how these programs are best implemented, as well as the medications approved for opioid use disorders. The guidelines are a result of the extraordinary collaboration of our federal, national, and private partners. Our nation's sheriffs and jail administrators are deeply appreciative for their contributions and commitment to assisting the jails in addressing the opioid epidemic for our justice-involved populations.

Jails represent perhaps the most unique place to get individuals off drugs and on the path to long-term recovery. But jails can only help individuals begin that journey—communities must shepherd those in need through that journey. As illustrated by the examples of several successful jail programs captured in the guidelines, the sheriffs and jail administrators reach beyond the walls of their jails to collaborate with treatment and support services in the community to ensure that what has begun in jail continues upon release.

We hope that sheriffs and jail administrators will find the *Promising Practices, Guidelines, and Resources* helpful in making these programs available to those who so desperately need them for their health and well-being as well as the safety of our communities.



Jonathan F. Thompson
Executive Director and CEO
National Sheriffs' Association

NATIONAL COMMISSION ON CORRECTIONAL HEALTH CARE

FOREWORD

As my colleague Jonathan Thompson notes, jails are on the front lines of the opioid epidemic in the United States.

Over the past 40 years, sheriffs and jail administrators across the country have sought to improve the quality of health services provided to the individuals in their care. In the mid-1970s, 30 jails served as the pilot sites for the first health services standards for correctional settings and an accompanying accreditation program. Today, the National Commission on Correctional Health Care (NCCHC) continues to help jails address the most complex problems in health services, including care for individuals suffering from mental illness and substance use disorder. In addition to its standards for jail health services, NCCHC also offers standards and accreditation specifically for opioid treatment programs.

As this publication makes clear, pharmacotherapy—i.e., medication-assisted treatment (MAT)—is widely held to be a cornerstone of best practice for recovery from substance abuse. Effective treatment, including MAT, particularly when coupled with evidence-based behavioral treatment, improves medical and mental health outcomes and reduces relapses and recidivism.

MAT provides a significant opportunity to help individuals with substance use disorder, especially those who participate in a community-based opioid treatment program (OTP). OTPs are licensed facilities that provide methadone and often other MATs for individuals diagnosed with an opioid-use disorder. Effective treatment for substance use disorder, including long-term MAT, has been shown to reduce drug use, overdose, and mortality. Fundamentally, it is key to halting the national epidemic of drug abuse, particularly opioid use disorder, and interrupting the costly cycle of recidivism resulting from this underlying disorder. We encourage sheriffs and our jail-based colleagues to take the lead in this effort.



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ACKNOWLEDGMENTS

So many people and organizations made the document *Jail-Based Medication-Assisted Treatment: Promising Practices, Guidelines, and Resources for the Field* possible. Although it is not feasible to recognize each of these contributions individually, the National Sheriffs' Association (NSA) and the National Commission on Correctional Health Care (NCCHC) would like to highlight the distinctive roles of several people involved in this two-year effort.

First, the NSA and NCCHC staffs would like to thank the co-chairs of the project: Ruby Qazilbash, Associate Deputy Director, Bureau of Justice Assistance, and Stephen Amos, Chief of the Jails Division, National Institute of Corrections. They initiated this effort and provided the leadership to realize a vision of consensus around issues that initially seemed to many as hopelessly complex and controversial.

An initiative of the scope and complexity of *Jail-Based Medication-Assisted Treatment: Promising Practices, Guidelines, and Resources for the Field* never would have gotten beyond the concept phase without considerable funding and technical support. Officials from the U.S. Department of Justice (specifically, the Bureau of Justice Assistance and the National Institute of Corrections), the Office of National Drug Control Policy, the National Institute on Drug Abuse, and the Substance Abuse and Mental Health Services Administration (SAMHSA) demonstrated how the federal government can effectively partner at the state and local levels.

The staffs of the NSA and NCCHC are enormously indebted to Project Director and principal author Andrew Klein, PhD, of the Advocates for Human Potential, Inc. No other expert in the country knows more about the application of medication-assisted treatment (MAT) in correctional settings than Dr. Klein. He contributed his expertise, ideas, and suggestions about how to improve access to MAT and made substantial contributions to the design and early drafts of this document.

Through his thoughtful engagement and input of the project partners, Dr. Klein brought to life a document that will be of significant service to the field. In addition, special recognition goes to Jennie M. Simpson, PhD, Office of Policy, Planning, and Innovation, SAMHSA, who provided invaluable technical knowledge and input. A third crucial contributor is Kevin Fiscella, MD, MPH, an addiction medicine expert who serves on the NCCHC board of directors; he is a professor in the department of family medicine at University of Rochester, New York.

The NSA and NCCHC are grateful to the members and staff of the organizations that composed the roundtable discussion and provided a bedrock of strategic expertise: the American Probation and Parole Association, the National Association of Counties, the American Jail Association, the National Association of Drug Court Professionals, the Massachusetts Sheriffs' Association, the California State Sheriffs' Association, the Texas Sheriffs' Association, the Rhode Island Department of Corrections, the Kentucky Department of Corrections, the American Society of Addiction Medicine, the National Governors Association, the Council of State Governments Justice Center, The Pew Charitable Trusts, New York University School of Medicine, and Sam Houston State University.

Finally, the NSA and NCCHC staffs and project partners thank the many correctional, addiction, and mental health professionals who strive daily to provide a better quality of life to people in their charge. Their devotion to providing the best possible services to people with substance use disorders can enhance the security and the well-being of our communities. It is for them that this document has been written.

WHAT'S IN IT FOR ME AS A CRIMINAL JUSTICE EXECUTIVE?

Medication-assisted treatment (MAT), utilizing the U.S. Food and Drug Administration (FDA)-approved medications methadone, buprenorphine, or naltrexone, is considered a central component of the contemporary standard of care for the treatment of individuals with opioid use disorders (OUDs).¹ It may also be used for individuals with co-occurring mental illnesses, in consultation with a physician.

Two-thirds of people in jail meet the criteria for drug dependence or abuse.

—Bureau of Justice Statistics

Evidence strongly supports that the use of MAT increases the likelihood of successful treatment for individuals with OUDs² and reduces morbidity and mortality. Research has begun to show that adding MAT to the treatment of those involved in the criminal justice system confers the same benefits and also reduces recidivism.³

These findings are particularly relevant for criminal justice decision makers—including sheriffs and corrections department officials—given that Bureau of Justice Statistics

surveys found that nearly two-thirds (63 percent) of people in jail meet criteria for drug dependence or abuse. Many of these individuals have OUDs and could benefit from access to MAT, a combination of behavioral interventions and medications that have been shown to decrease opioid use, increase treatment retention, reduce overdose, and reduce criminal activity.⁴

By thoughtfully and carefully including MAT, when appropriate, as a tool in the range of jail-based treatment options, the value proposition to criminal justice executives may include:

- Stemming the cycle of arrest, incarceration, and release associated with substance use disorders (SUDs), as individuals with SUDs return to the community without connection to treatment.
- Contributing to the maintenance of a safe and secure facility for inmates and staff.
- Reducing costs: Comprehensive drug treatment programs in jails are associated with reduced system costs.⁵ According to the 2018 Substance Abuse and Mental Health Services Administration (SAMHSA) TIP 63: Medications for Opioid Use Disorders, “Data indicate that medications for OUD are cost effective and cost beneficial.”⁶



***Medication-assisted treatment (MAT)**—utilizing the FDA-approved medications methadone, buprenorphine, or naltrexone—is considered a central component of the contemporary standard of care for the treatment of individuals with opioid use disorders.*

Most important, MAT can help rebuild and save the lives of those with substance use disorders:

- By facilitating continued access to MAT for individuals who are on prescribed FDA-approved MAT, correctional agencies can minimize the risk of postrelease overdose and death. For individuals with OUDs who were not receiving MAT prior to arrest, correctional facilities can offer MAT prior to release, taking into account individual preferences and clinician judgment. Importantly, facilities should offer all three MAT options.
- When MAT is not feasible (e.g., the individual is facing transfer to a facility that does not offer MAT), FDA-approved medications (e.g., methadone or buprenorphine) should be used to provide medically managed opioid withdrawal.
- Considering that the criminal justice system is the largest source of organizational referrals to addiction treatment,⁷ justice leaders have a unique and valuable opportunity to facilitate the path to recovery.

Notwithstanding the increasing evidence and formal support from many prominent public health and public safety organizations (including the NSA and NCCHC), substance use treatment providers—both inside and outside of the criminal justice system—have been slow to add MAT to their treatment regimens. In 2011, the Washington County, Maryland, jail became the first to introduce MAT for nonpregnant women and for men. Other county jails and state departments of corrections (DOCs) in Missouri, Pennsylvania, and Massachusetts followed suit.

However, as of January 2018, 20 state DOCs did not offer MAT in their drug treatment programs for incarcerated individuals beyond limited methadone maintenance for pregnant women. Out of several thousand local and county jails, fewer than 200 in 30 states provide MAT, and the protocol is primarily limited to the provision of injected naltrexone immediately before individuals are released back into the community. Jails that provide MAT for pregnant women typically discontinue it postpartum, although this is not the recommended standard of medical care (C. Sufrin, personal communication, September 27, 2018).

RESOURCE GOAL

A main goal of this resource is to support and inform institutional and community corrections leaders and personnel as they consider MAT for individuals with SUDs at various stages of engagement with the criminal justice system: pre- and posttrial and upon reentry, with or without supervision. While evidence-based findings on MAT programs specifically for this population continue to grow, the contents of this resource are based on the currently available research on MAT and the use of MAT in correctional settings, programming for SUD across the criminal justice system, and, most important, the experiences of expert justice leaders and practitioners who have pioneered the application of MAT in these agencies and institutions. (See *Appendix III: Advisory Roundtable Membership* for the roster of experts who contributed time, talents, and guidance to this resource.)

HOW TO USE THIS RESOURCE

To advance informed consideration and support for the appropriate use of jail-based MAT, this document includes the following:

- **An overview** of general tenets and best practices associated with developing, implementing, and sustaining a jail-based MAT program. This outline of key issues and questions is well-suited for a quick read by criminal justice executives.
- **A deeper exploration of the topics** highlighted in the overview, including existing standards, related guidelines, and examples from the field. While suitable for (and hopefully of interest to) the range of readers, given the sometimes technical and detailed nature of the content, this section may be most appropriate for MAT program developers and practitioners involved in hands-on activities.
- **Programs in action**, providing a window into several real-world, jail-based MAT programs, including outcomes and lessons learned.
- **Tools, treatment programs, references, and supporting documentation** related to MAT.

OVERVIEW

BEST PRACTICES AND GUIDELINES FOR JAIL-BASED MEDICATION-ASSISTED TREATMENT

CLIENT ENROLLMENT IN A JAIL-BASED MAT PROGRAM

- ALL INDIVIDUALS ENTERING A JAIL SHOULD BE SYSTEMATICALLY SCREENED FOR SUBSTANCE USE DISORDERS, INCLUDING ANY HISTORY OF ALCOHOL/SEDATIVE OR OPIOID WITHDRAWAL.
- THE DECISION TO OBTAIN MEDICATION FOR OPIOID OR ALCOHOL USE DISORDERS, AND THE SPECIFIC MEDICATION CHOSEN, SHOULD BE THE INDIVIDUAL'S, AFTER CONSULTATION WITH MEDICAL AND TREATMENT PROVIDERS, NOT IMPOSED BY A JUSTICE OR TREATMENT AGENCY.
- INDIVIDUALS SHOULD BE CLINICALLY ASSESSED BY A QUALIFIED TREATMENT PROVIDER TO DETERMINE WHETHER MAT IS CLINICALLY INDICATED.

THE CORRECT MEDICATION, DOSAGE, AND LENGTH OF TREATMENT DETERMINED FOR A CLIENT IN MAT

- ASSISTING INDIVIDUALS WITH CHOOSING THE MEDICATION THAT IS RIGHT FOR THEM REQUIRES SHARED DECISION MAKING.
- CERTAIN WIDELY AGREED-UPON CONSIDERATIONS SHOULD BE DISCUSSED AND CONSIDERED PRIOR TO DETERMINING THE APPROPRIATE MEDICATION (OR SWITCHING MEDICATIONS), DOSAGES, AND LENGTH OF TREATMENT.
- CLIENTS SHOULD BE ROUTINELY TESTED TO ENSURE RECEIPT OF THE APPROPRIATE PRESCRIBED DOSAGE OF MEDICATIONS.

MAT FOR PREGNANT WOMEN

- PREGNANT WOMEN WITH OPIOID AND ALCOHOL USE DISORDERS REQUIRE SPECIALIZED SERVICES TO PREVENT AND REDUCE HEALTH RISKS DURING PREGNANCY.

MEDICATION ALONE IS NOT THE ANSWER: THE FORCE MULTIPLIER OF PARTNERSHIPS AND SUPPORT SERVICES

- FOR MAXIMUM BENEFITS IN THE TREATMENT OF OPIOID AND ALCOHOL USE DISORDERS, COUPLE MAT WITH COUNSELING AND THE APPROPRIATE WRAPAROUND SERVICES.
- JAILS IMPLEMENTING COMPREHENSIVE MAT PROGRAMS—AND THE CLIENTS THEY SERVE—WILL BENEFIT FROM COLLABORATIVE RELATIONSHIPS WITH COMMUNITY-BASED TREATMENT, MAT, AND OTHER BEHAVIORAL HEALTH PROVIDERS.

MAT PROGRAM COMPONENTS: ASSEMBLING THE RIGHT TEAM, SAFEGUARDS, PROTOCOLS, AND STRUCTURE FOR A SUCCESSFUL JAIL-BASED PROGRAM

- CORRECTIONAL STAFF SHOULD RECEIVE TRAINING AND EDUCATION ABOUT MAT.
- RESIDENTIAL CORRECTIONAL FACILITIES, AS WELL AS COMMUNITY TREATMENT PROVIDERS, SHOULD HAVE SPECIFIC SAFEGUARDS TO PREVENT THE DIVERSION OF AGONIST MEDICATIONS⁸ (FOR EXAMPLE, METHADONE) AND TO SAFEGUARD PARTICIPATING INDIVIDUALS.
- COMMUNITY-BASED TREATMENT AND MEDICATION PROVIDERS SHOULD BE CAREFULLY SELECTED. CORRECTIONAL AGENCY COLLABORATION MAY BE REQUIRED TO ENCOURAGE PROVIDERS TO MEET THE NEEDS OF REFERRED INDIVIDUALS.
- CORRECTIONAL PERSONNEL SHOULD REFER CLIENTS TO PRESCRIBING PROVIDERS AND OTHER TREATMENT PROVIDERS WHO HAVE THE REQUIRED CERTIFICATION AND ARE KNOWLEDGEABLE ABOUT ADDICTION, SUBSTANCE ABUSE, OR BEHAVIORAL HEALTH PROGRAMS, AND THE ROLE OF MEDICATION IN SUBSTANCE USE TREATMENT.
- THERE ARE PRETRIAL AND POSTTRIAL MAT PROGRAMS.

THE IMPORTANCE OF CLIENT SCREENING TO ADDRESS TREATMENT CONTINUATION, WITHDRAWAL, AND RELAPSE

- SYSTEMS SHOULD BE IN PLACE TO ENSURE CONTINUATION OF METHADONE OR BUPRENORPHINE WHEN APPROPRIATE.
- MEDICALLY MANAGED WITHDRAWAL PROTOCOLS SHOULD BE IN PLACE TO SUPPORT SCREENING FOR WITHDRAWAL SEVERITY AND POLYSUBSTANCE USE, MONITORING, AND MEDICAL MANAGEMENT OF SYMPTOMS.
- JAIL MAT PROGRAMS SHOULD INCLUDE ONGOING MONITORING THROUGH DRUG SCREENING AND OTHER DIVERSION/RISK MITIGATION STRATEGIES.

ENGAGING MEDICAID AND POSTRELEASE FINANCIAL ASSISTANCE

- JAILS FACILITATING MAT SHOULD ENGAGE THEIR STATE MEDICAID AGENCIES AND OTHER PUBLIC PAYERS TO FACILITATE HEALTH CARE COVERAGE.

EXPLORE IN-DEPTH

BEST PRACTICES AND GUIDELINES FOR JAIL-BASED MEDICATION-ASSISTED TREATMENT

CLIENT ENROLLMENT IN A JAIL-BASED MAT PROGRAM

ALL INDIVIDUALS ENTERING A JAIL SHOULD BE SYSTEMATICALLY SCREENED FOR SUBSTANCE USE DISORDERS, INCLUDING ANY HISTORY OF ALCOHOL/SEDATIVE OR OPIOID WITHDRAWAL.

Receiving screening should be conducted immediately upon acceptance into jail custody. Screeners should explain the reason for the questions, e.g., “We ask these questions to ensure you receive appropriate treatment while you are here.” Questions should address physical and mental health, prescribed medications including MAT, previous drug or alcohol treatment, recent drug or alcohol use including types and amount, and current or past history of drug or alcohol withdrawal. Individuals showing evidence of intoxication or who report MAT or past or current drug or alcohol use should be referred to medical for further evaluation.

THE DECISION TO OBTAIN MEDICATION FOR OPIOID OR ALCOHOL USE DISORDERS, AND THE SPECIFIC MEDICATION CHOSEN, SHOULD BE THE INDIVIDUAL’S, AFTER CONSULTATION WITH MEDICAL AND TREATMENT PROVIDERS, NOT IMPOSED BY A JUSTICE OR TREATMENT AGENCY.

FDA-approved MAT medications vary, as do their impact, and they are available through different channels and administered in different manners. Options should be tailored and individualized, and individuals should receive complete information to make informed decisions in consultation with a medical and treatment team.

INDIVIDUALS SHOULD BE CLINICALLY ASSESSED BY A QUALIFIED TREATMENT PROVIDER TO DETERMINE WHETHER MAT IS CLINICALLY INDICATED.

When the results of an appropriately administered needs assessment indicate that an individual needs treatment (and that treatment can be provided), law enforcement officers, probation and parole agents, judges, and correctional officers do not determine the clinical needs of the individual.

RELATED PROFESSIONAL GUIDELINES

The American Society of Addiction Medicine (ASAM) advises physicians treating patients with opioid use disorders that “(t)he choice of available treatment options for addiction involving opioid use should be a shared decision between clinician and patient.” ASAM continues: “Clinicians should consider the patient’s preferences, past treatment history, and treatment setting when deciding between the use of methadone, buprenorphine, and naltrexone in the treatment of addiction”⁹

In accordance with federal law (21 CFR §1306.07), office-based opioid treatment (OBOT), which provides medication on a prescribed weekly or monthly basis, is limited to buprenorphine. Clinicians should consider a patient’s psychosocial situation, co-occurring disorders, and risk of diversion when determining whether an opioid treatment program or OBOT is most appropriate. OBOT may not be suitable for patients with active alcohol use disorder or sedative, hypnotic, or anxiolytic use disorder (or those who are in treatment for addiction involving the use of alcohol or other sedative drugs, including benzodiazepines or benzodiazepine receptor agonists). It also may be unsuitable for persons who regularly use alcohol or other sedatives but do not have addiction or a specific substance use disorder related to that class of drugs. The prescribing of benzodiazepines or other sedative-hypnotics should be used with extreme caution in patients who are prescribed methadone or buprenorphine for the treatment of an opioid use disorder.



This is particularly important when it comes to prescribing medications, including those for alcohol and OUDs. All medications carry different risks and benefits for different individuals; treatment decisions, including medication, should be based on what has been proven to work and what is most likely to benefit the individual patient.

Clinical assessments for MAT begin with a general assessment for SUDs. Such assessments allow tailoring of treatment to a person's withdrawal symptoms, often helping to reduce the amount of medication needed. Several instruments have been developed for such purposes:

- The **Clinical Opiate Withdrawal Scale (COWS)**, an 11-item scale, is used to reproducibly rate common signs and symptoms of opiate withdrawal and monitor these symptoms over time.¹⁰
- The **Clinical Institute Withdrawal Assessment of Alcohol Scale**, revised (CTWA-Ar),¹¹ a five-item scale, is used to measure symptoms of alcohol withdrawal.
- The Rand Corporation-developed ***Procedures for Medication-Assisted Treatment of Alcohol or Opioid Dependence in Primary Care*** for NIDA¹² includes scales for opiate dependence (pp. 75–77) and alcohol dependence (pp. 24–25), which describe the symptoms associated with these use disorders. The RAND publication was revised when the DSM-5 replaced the DSM-IV criteria for these disorders to indicate that its scales could still be used to assess the appropriateness of treatment. The Rand publication also includes sample checklists for pre-injection naltrexone for alcohol use disorder (p. 15) and pre-initiation of buprenorphine/naloxone (p. 65). The former includes, for example, “Patient is motivated to reduce or stop alcohol use” (p. 15). The latter includes, for example, “perform a urine drug screen (expect positive for opioid[s] but be cautious if positive for benzodiazepines)” (p. 65).
- **Texas Christian University (TCU) Drug Screen V** is an updated version of the TCU Drug Screen II and is also based on the DSM-5. The TCU Drug Screen V screens for mild to severe substance use disorder and is particularly useful when determining an individual's placement and level of

care in treatment.¹³ The TCU Drug Screen V also has an opioid supplement to identify the needs of people with opioid use disorders and the specific risk of an overdose that a person may be facing.

THE CORRECT MEDICATION, DOSAGE, AND LENGTH OF TREATMENT DETERMINED FOR A CLIENT IN MAT

ASSISTING INDIVIDUALS WITH CHOOSING THE MEDICATION THAT IS RIGHT FOR THEM REQUIRES SHARED DECISION MAKING.

No one medication will guarantee that an individual will sustain long-term recovery from opioid or alcohol use disorders, and there are currently no definitive guidelines to reliably match an individual to the optimal medication.¹⁴ Nor is there a set period during which any of the medications must be taken to correlate with long-term recovery. The medication and the length of its use must be matched to the needs of the individual. The decision about which medicine is best for which person should be made jointly among the individual, a physician or medical provider, and a treatment provider or knowledgeable counselor.

However, correctional withdrawal alone actually increases the chances the person will overdose following community release due to loss of opioid tolerance.¹⁵ For this reason, all individuals with OUD should be considered for MAT. Both methadone and buprenorphine have been shown to reduce mortality.¹⁶ In addition, all persons with OUD should be offered naloxone (Narcan) kits that can be used to reverse an overdose.¹⁷

Before any specific medication is considered, the individual needs to be assessed. The person should then be introduced to the full array of FDA-approved medications and the rules that govern how each is obtained and used, as well as the need for accompanying treatment, support, and appropriate services. All potential adverse reactions to the medications should be fully disclosed, including consequences of continued drug use. It is important that the potential adverse consequences be presented in a manner and with a vocabulary that the individual can understand. This may require alternative or supplementary explanations by persons other than physicians.

It should also be explained that agonist medications—i.e., buprenorphine and methadone—cannot be abruptly discontinued, unlike naltrexone. Although the length of time that treatment with medication is required needs to be individualized, generally individuals should be advised that relapse can occur if the medication is stopped too soon.

A physical examination to determine general health is also part of the assessment.¹⁸ The physical exam should include a drug test and tests for medical conditions, including tuberculosis and liver conditions. People who use drugs are at a high risk of contracting HIV, hepatitis, and other diseases.



After the assessment, the physician and the patient should discuss the best course of treatment, including which medication the patient should take and what dosage may be appropriate. Substance abuse counselors, or, with permission, close family members or friends may be valuable participants in treatment planning, monitoring, and support. Because the number of MAT providers is limited, especially in rural communities, not all FDA-approved medications may be available to all individuals in the community.

Oral naltrexone for the treatment of OUDs is often adversely affected by poor medication adherence. Clinicians should reserve its use for patients who are able to comply with special strategies to enhance their adherence (for example, observed dosing). Extended-release injectable naltrexone reduces, but does not eliminate, issues with medication adherence. It should be noted that individuals may be provided with oral naltrexone for several days prior to injections of naltrexone to ensure that there are no negative reactions to the medication, although this practice is not advised or required by the FDA. Of the medications on the market, the least amount of research is available for naltrexone. Two recent studies have found that once individuals have their first injection of naltrexone, their retention and relapse rates are the same as those taking buprenorphine with naloxone; however, they are more likely to initially balk at the treatment than those who sign up for buprenorphine,¹⁹ in part because of the need for a 7- to 14-day medically supervised withdrawal before starting naltrexone.

CERTAIN WIDELY AGREED-UPON CONSIDERATIONS SHOULD BE DISCUSSED AND CONSIDERED PRIOR TO DETERMINING THE APPROPRIATE MEDICATION (OR SWITCHING MEDICATIONS), DOSAGES, AND LENGTH OF TREATMENT.

OUD medications include the following:

METHADONE

Methadone is recommended for patients who are physiologically dependent on opioids, are able to give informed consent, and have no specific contraindications for agonist treatment, including the taking of benzodiazepines, when prescribed in the context of an appropriate plan that includes psychosocial intervention. Electrocardiograms can be done on patients prior to starting methadone to prevent risk

of sudden death in those with a prolonged QT (required time for ventricular and repolarization) interval.

The usual daily dose of methadone ranges from 60 to 120 milligrams (mg). Some patients may respond to lower doses, and some patients may need higher doses.

Methadone can be prescribed only by licensed opioid treatment programs. While some jails have obtained OTP licenses, most will need to partner with a community-based OTP. There are two exceptions to DEA methadone regulations. First, methadone may be dispensed daily for up to three days for the purpose of ensuring treatment continuity (e.g., the community OTP is closed on weekends or the individual is serving weekends). The second exception applies to correctional facilities that are "licensed by both the state and DEA as a clinic, a hospital, or a hospital/clinic." These licensed facilities may use methadone when needed to effectively treat medical conditions, psychiatric conditions, alcohol withdrawal, or pregnancy. However, few correctional facilities have such clinic/hospital licenses.²⁰

BUPRENORPHINE

Buprenorphine is recommended for opioid-dependent patients and can be prescribed outside of OTPs by physicians, nurse practitioners, and physician assistants who have obtained buprenorphine licenses (also called "waivers").²¹

Individuals should wait until they are experiencing moderate opioid withdrawal before taking the first dose to reduce the risk of precipitated withdrawal. Generally, buprenorphine initiation should occur at least 6 to 12 hours after the last use of heroin or other short-acting opioids or 24 to 72 hours after the last use of long-acting opioids such as methadone. Home-based induction is recommended only if the patient or prescribing physician is experienced with the use of buprenorphine.

Buprenorphine doses after induction and titration should be, on average, ≥ 8 mg per day. The FDA approves dosing to a limit of 24 mg per day, but there is limited evidence regarding the relative efficacy of higher doses. In addition, the use of higher doses may increase the risk of diversion.

Buprenorphine tapering and discontinuation is a slow process, and close monitoring is recommended. Buprenorphine tapering is generally accomplished over several months.

When a switch from buprenorphine to naltrexone is being considered, 7 to 14 days should elapse between the last dose of buprenorphine and the start of naltrexone to ensure that the patient is not physically dependent on opioids prior to starting naltrexone.

When a switch from buprenorphine to methadone is being considered, there is no required time delay because this switch does not typically result in any type of adverse reaction.

Patients who discontinue agonist therapy and resume opioid use should be made aware of the risks.



SWITCHING FROM METHADONE TO BUPRENORPHINE

Some correctional institutions may not be equipped to provide methadone, which may require switching individuals from methadone to buprenorphine with or without naloxone. Individuals with OUDs can safely be switched from methadone to buprenorphine maintenance. According to SAMHSA's *Quick Guide for Physicians: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*:

Induction of patients from long-acting opioids (e.g., methadone) onto buprenorphine should be managed by physicians experienced with the procedure. Patients taking methadone should have their dose tapered to 30 mg or less per day for at least 1 week before buprenorphine induction. Twenty-four hours must elapse between the final dose of methadone and the first dose of buprenorphine. The first dose of buprenorphine should be 2 mg of monotherapy. A second 2 mg dose can be given and repeated up to 8 mg per day if signs of withdrawal appear.

The guide goes on to chart the steps in the induction from Day 2 and forward. When an individual has no withdrawal symptoms, minimal side effects, and no uncontrollable cravings, he or she is considered stabilized. During stabilization (1 to 2 months), adjustments in the dose and frequent physician–patient contact help establish the proper level of medication. Until full stabilization is achieved, weekly assessments are indicated. Doses of buprenorphine/naloxone may be increased in 2/0.5–4/1 mg increments until stabilization is achieved. Nearly all patients stabilize on daily doses of 16/4–24/6 mg; some may require up to 32/8 mg daily. The maintenance phase follows.

The same SAMHSA guide advises that “(a)ppropriate dosages of buprenorphine are more effective than low dosages (20–35 mg) of methadone. A buprenorphine dosage of 8–16 mg/day is equivalent to about 60 mg/day of methadone.”

The *ASAM Practice Guidelines* highlights the following:

“Patients switching from methadone to buprenorphine in the treatment of opioid use disorder should be on low doses of methadone before switching medications. Patients on low doses of methadone (30 to 40 mg per day or less) generally tolerate transition to buprenorphine with minimal discomfort, whereas patients on higher doses of methadone may experience significant discomfort when switching medications. Generally, buprenorphine initiation should occur at least 6 to 12 hours after the last use of heroin or other short-acting opioids or 24 to 72 hours after their last use of long-acting opioids such as methadone. Buprenorphine doses after induction and titration should be, on average, at least 8 mg per day. The FDA approves dosing to a limit of 24 mg per day, and there is limited evidence regarding the relative efficacy of higher doses. In addition, the use of higher doses may increase the risk of diversion.”²²

NALTREXONE

Naltrexone is a recommended treatment for preventing the relapse of OUDs. Naltrexone does not require a special license to prescribe. Oral formula naltrexone may be considered for patients where adherence can be supervised or enforced. Extended-release injectable naltrexone may be more suitable for patients who cannot be observed or supported when taking their medication daily.

There is no recommended length of treatment with oral naltrexone or extended-release injectable naltrexone. The duration depends on clinical judgment and the patient's circumstances. Because there is no physical dependence associated with naltrexone, it can be stopped abruptly without withdrawal symptoms. Importantly, patients should be informed that discontinuation of naltrexone is associated with enhanced sensitivity to opioids and heightened risk of overdose. The FDA warning label for extended release naltrexone states: “It is important that patients inform family members and the people closest to the patient of this increased sensitivity to opioids and the risk of overdose.”²³

Switching from naltrexone to methadone or buprenorphine should be planned, considered, and monitored. Switching from an antagonist such as naltrexone to a full agonist (methadone) or a partial agonist (buprenorphine) is generally less complicated than switching from a full or partial agonist to an antagonist, because there is no physical dependence associated with antagonist treatment and, thus, no possibility of precipitated withdrawal. Patients being switched from naltrexone to buprenorphine or methadone will not have a physical dependence on opioids; therefore, the initial doses of methadone or buprenorphine should be low.

A patient should not be switched until a significant amount of naltrexone is no longer in his or her system. This requires a 1-day wait for oral naltrexone and a 30-day wait after a naltrexone injection.

WHAT THE RESEARCH SUGGESTS REGARDING DIFFERENT OPIOID MEDICATIONS

A Cochrane study of 31 experimental trials of high to moderate quality involving 5,430 participants examined the use of buprenorphine compared with a placebo and then compared it with methadone. The authors concluded the following:

Buprenorphine is an effective medication in the maintenance treatment of heroin dependence, retaining people in treatment at any dose above 2 mg, and suppressing illicit opioid use (at doses of 16 mg or greater) based on placebo-controlled trials.

However, compared with methadone, buprenorphine retains fewer people when doses are flexibly delivered and at low fixed doses. If fixed medium or high doses are used, buprenorphine and methadone appear no different in effectiveness (retention in treatment and suppression of illicit opioid use); however, fixed doses are rarely used in clinical practice so the flexible dose

results are more relevant to patient care. Methadone is superior to buprenorphine in retaining people in treatment, and methadone equally suppresses illicit opioid use.²⁴

Studies have also compared the mortality risk in and out of treatment with methadone and buprenorphine. Researchers examined 19 eligible cohorts, following 122,885 people treated with methadone over 1.3 to 13.9 years and 15,831 people treated with buprenorphine over 1.1 to 4.5 years.

Overdose mortality evolved similarly, with pooled overdose mortality rates of 2.6 and 12.7 per 1,000-person years in and out of methadone treatment (unadjusted out-to-in rate ratio 4.80, 2.90 to 7.96) and 1.4 and 4.6 in and out of buprenorphine treatment.

The authors concluded:

Retention in methadone and buprenorphine treatment is associated with substantial reductions in the risk of all cause and overdose mortality in people dependent on opioids. The induction phase onto methadone treatment and the time immediately after leaving treatment with both drugs are periods of particularly increased mortality risk²⁵

There have been far fewer studies of naltrexone use. One national study found that use of oral naltrexone was associated with higher risk of mortality than methadone.²⁶ A 2017 study was conducted to evaluate the long-term safety, tolerability, and treatment outcomes of injectable naltrexone. The small study of fewer than 49 screened opioid-dependent individuals screened by health care professionals concluded that “(l)ong-term (2 years) (of injections) was associated with no new safety concerns” The NIDA study described above of a larger sample found that “(a)ll recorded overdose events, fatal or nonfatal, occurred among participants assigned to usual treatment (0 events in the extended-release naltrexone group vs. 5 in the usual-treatment group from week 0 to 25, $p=0.10$; 0 vs. 7 events from week 0 to 78, $p=0.02$); no overdoses occurred in the extended-release naltrexone group after discontinuation of the agent.”²⁷ A recent study compared use of methadone, buprenorphine, and extended-release naltrexone among patients who had previously survived an overdose.²⁸ Findings showed that use of methadone or

buprenorphine was associated with reduction in death, but the use of naltrexone was not. Small numbers and inclusion of both oral and injectable naltrexone limit firm conclusions regarding this drug’s effect on mortality.

Only two studies have compared buprenorphine and injectable naltrexone, as mentioned previously. Both found that, once begun, the medications were equally effective in terms of retention over 6 months. The larger NIDA study found that “a monthly shot of naltrexone (sold as Vivitrol) is as effective as its main competitor, the daily pill of buprenorphine and naloxone (sold as Suboxone).” Researchers found that about half of the people with opioid addiction who took either drug remained free from relapse 6 months later. However, because naltrexone required abstinence for 7 to 10 days, 28 percent of those assigned naltrexone did not follow through and receive their first injections. For those who did, 52 percent subsequently relapsed, as opposed to 56 percent who relapsed on buprenorphine with naloxone.²⁹ As previously noted, the ASAM National Practice Guideline states:

Oral naltrexone for the treatment of opioid use disorder is often adversely affected by poor medication adherence. Clinicians should reserve its use for patients who would be able to comply with special techniques to enhance their adherence, for example, observed dosing. Extended release injectable naltrexone reduces, but does not eliminate, issues with medication adherence.

LENGTH OF TREATMENT

Research indicates that the length of time an individual should spend on medication varies and needs to be reassessed with the medical staff, considering the individual’s medical history and situation. Opioid use disorder is a chronic condition representing alterations in brain function.³⁰ Relapse rates are common and often fatal. Long-term MAT is often required in the same way that long-term medications are needed for other chronic conditions such as diabetes or high blood pressure.

Both SAMHSA³¹ and ASAM³² have suggested guidelines for determining when and how medication should be discontinued. The latter, for example, concludes that there is no recommended time limit for treatment with buprenorphine, methadone, or naltrexone. It advises, however, that “buprenorphine taper and discontinuation is a slow process and close monitoring is recommended.” Further, discontinuation is generally accomplished over several months and “patients and clinicians should not take the decision to terminate treatment with buprenorphine lightly” (p. 34). Similarly, ASAM holds that “the optimal duration of treatment with methadone has not been established; however, it is known that relapse rates are high for most patients who drop out; thus, long-term treatment is often needed” (p. 30). For both oral and injectable naltrexone, ASAM concludes that the duration of treatment should depend on the response of the individual patient, the patient’s individual circumstances, and clinical judgment (p. 37).



RELATED FEDERAL GUIDELINES

Federal Guidelines for Agonist Maintenance in Opioid Treatment Program (OTP) Settings

- 1. Maintenance treatment.** An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), that a person is currently addicted to an opioid drug and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment, that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.
- 2. Maintenance treatment for persons under age 18.** A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term medical withdrawal (detoxification) or drug-free treatment within a 12-month period to be eligible for methadone maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant state authority consents in writing to such treatment.
- 3. Maintenance treatment admission exceptions.** If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction . . . for patients released from penal institutions with a documented history of opioid use disorder (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).
- 4. Medically managed withdrawal treatment.** An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term medically managed withdrawal by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful medically managed withdrawal episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two medically managed withdrawal treatment episodes in one year.

Data show that treatment retention is reduced when patients are tapered off MAT prematurely.³³ For some patients, MAT could be indefinite.³⁴ NIDA describes addiction medication as an “essential component of an ongoing treatment plan” to enable individuals to “take control of their health and their lives.”³⁵ For methadone maintenance, 12 months of treatment is the minimum, according to NIDA.³⁶

The first long-term follow-up of patients treated with buprenorphine/naloxone for addiction to opioid pain relievers found that half were abstinent at 18 months after starting therapy. After 3 ½ years, the number reporting abstinence rose to 61 percent. At each follow-up interview, patients who were currently receiving the medication were much more likely to report abstinence compared with those not taking medication. Only 6.6 percent of the patients maintained abstinence after a brief course of medication (2 weeks of medication, 2 weeks to taper off, and 2 months follow-up). Those who relapsed during this phase were provided with 12 weeks of medication followed by 4-week tapering and 2-month follow-up. Nearly half of these patients achieved abstinence during their last 4 weeks; however, fewer than 10 percent were still doing well at the end of the 2-month follow-up. At 18 months, 30 months, and 42 months, patients who were engaged in MAT had markedly higher odds of positive outcomes. At 42 months, the advantage associated with MAT had narrowed but was still large, 79.6 percent abstinence versus 50.8 percent abstinence. During the study, patients reported abstinence only for the prior 30-day period. Many who relapsed reentered MAT and then were able to remain abstinent for at least the 30 days at reporting periods.³⁷

After piloting the use of injected naltrexone, the Pennsylvania Department of Corrections’ MAT program, which initially recommended 6 months of injections, now recommends a full year of injections. A study of individuals involved in the criminal justice system provided with injected naltrexone for 6 months found that those receiving the injections had significantly fewer relapse events, a higher rate of opioid-negative urines, and less-serious adverse events, including fatal and nonfatal overdoses, than those engaged in abstinence-only treatment. However, those treated with 6 months of naltrexone injections had outcomes similar to those not treated after a year. This suggests that more than 6 months of injections may be indicated for longer-term abstinence.³⁸

ALCOHOL USE DISORDER

Three drugs are approved by the FDA to treat alcohol use disorder (AUD): disulfiram, acamprosate, and naltrexone. An Agency for Healthcare Research and Quality review of 167 studies of medical treatment of AUD in outpatient settings found evidence to support the use of naltrexone and acamprosate, but insufficient evidence to support the use of disulfiram.³⁹ Specific to incarcerated populations, there is less research available on the use of MAT for alcohol use disorder, except for a few older studies on the use of disulfiram during community supervision.

- **Disulfiram:** Although disulfiram has been in use for many years, it is no longer considered a first-line treatment choice. Its action interferes with the breakdown of alcohol by the liver, resulting in adverse physical responses to any intake of alcohol. The National Institute on Alcohol Abuse and Alcoholism clinical guidelines state: “The utility and effectiveness of disulfiram are considered limited because compliance is generally poor when patients are given it to take at their own discretion.”⁴⁰ Its use is limited to highly motivated patients and those who can be directly observed while they take the medication. It is contraindicated for patients who are still drinking. Disulfiram is available only with a prescription.
- **Acamprosate:** Acamprosate can be prescribed by physicians or nurse practitioners and, in some states, by physician assistants and psychologists. Although not all patients respond to acamprosate, research suggests it is more likely to be effective for patients who are abstinent from alcohol before acamprosate is initiated, and it is more likely to benefit patients who intend to abstain from alcohol completely rather than for those who plan to reduce their alcohol use. Acamprosate has been successful in European studies at increasing abstinence rates. It works by relieving some of the anxiety and dysphoria associated with postacute withdrawal from alcohol.
- **Naltrexone:** Systematic reviews show that naltrexone is effective for treating alcohol use disorder. It appears to be comparable to acamprosate.⁴¹



agonist, or an antagonist, by taking other drugs or increasing doses of prescribed medications. If persons try to overcome the blocking effects of naltrexone by ingesting increasing amounts of opioid medications or heroin, they are at a high risk of overdosing. The utilization of drug testing also can ensure that a person is taking medication and not diverting it.

MAT FOR PREGNANT WOMEN

PREGNANT WOMEN WITH OPIOID AND ALCOHOL USE DISORDERS REQUIRE SPECIALIZED SERVICES TO PREVENT AND REDUCE HEALTH RISKS DURING PREGNANCY.

Opioid withdrawal during pregnancy is associated with miscarriage, premature delivery, and other serious complications. The American College of Obstetricians and Gynecologists (ACOG) recommends against opioid withdrawal during pregnancy.⁴⁵ MAT is readily available to stabilize pregnant women with OUDs during pregnancy.

Studies find that women who use substances during pregnancy have elevated risk of early birth, babies with lower birth weights, and more problems during labor and delivery. However, stopping opioids too quickly during pregnancy is also risky. Opioids cross the blood barrier to the developing fetus. If the pregnant woman suddenly quits, the fetus also experiences withdrawal and dangerous complications can result. Children of women treated for OUDs with opioid replacement therapies during pregnancy have improved birth outcomes.⁴⁶

Methadone maintenance for pregnant women is an accepted best practice that has been used safely for years and has been widely researched.⁴⁷ As with any treatment, there are some risks, but they are weighed against the consequences of untreated opioid addiction, including withdrawal and relapse.

Infants exposed to opioids in utero may experience withdrawal symptoms at birth, sometimes severe enough to require medication and delay discharge from the hospital.

MEDICATION DOSAGES

Appropriate doses vary for these medications, except for naltrexone and disulfiram, where the dose is standard. Dosing is an individualized medical decision. In some instances, low doses of methadone, for example, have been found less effective for keeping users in treatment than higher doses.⁴²

CLIENTS SHOULD BE ROUTINELY TESTED TO ENSURE RECEIPT OF THE APPROPRIATE PRESCRIBED DOSAGE OF MEDICATIONS.

SAMHSA's *Federal Guidelines for Opioid Treatment Programs*⁴³ requires programs to “provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient, in maintenance treatment, in accordance with generally accepted clinical practice.”

There are several different ways to test for drugs, including alcohol. As described by ASAM, “Drug tests do not detect drug use in general.” Instead, drug tests identify specific drugs or drug classes as well as drug metabolites in biological matrices that are represented in particular test panels. Drugs can be identified in any matrix; the most common matrices for typical testing purposes include urine, blood, and oral fluid.”⁴⁴

Because of the risk of overdose, it is important to ensure that individuals not try to circumvent the stabilizing or blocking effects of their medication, whether it be an agonist, a partial

This condition is known as neonatal abstinence syndrome (NAS). Infants born to mothers treated with methadone or buprenorphine are also at risk of NAS but are less likely to be preterm or have low birth weight. Opioid-exposed infants can be monitored and managed in most hospitals. Women receiving medications are usually encouraged to breastfeed because the benefits greatly outweigh the very small trace amounts of medication that may be found in breast milk.⁴⁸

There are fewer long-term studies of safety and effectiveness of buprenorphine during pregnancy, but some suggest that buprenorphine reduces NAS.⁴⁹ ACOG supports treating pregnant women with buprenorphine if they are already on it or prefer it.⁵⁰ Pregnant women should generally receive only the single-drug formula, without added naloxone.

Women with opioid use disorders who are under community supervision should be referred to treatment providers that offer specialized services for pregnant and postpartum women. They require an intensive level of support after delivery to prevent relapse, and many will benefit from additional services, including parenting skills training and supports or family reunification planning.⁵¹

Pregnant women with alcohol use disorders should receive medically managed withdrawal treatment from alcohol as soon as possible. Fetal alcohol spectrum disorders and fetal alcohol effects occur in a small but significant proportion of babies born to women who drink heavily during pregnancy. Alcohol consumption during the first trimester is a particularly high risk. Because some women who drink heavily during the first trimester may not know they are pregnant, treatment providers should include pregnancy tests if clients are unsure.

In custody settings, women are usually screened for pregnancy on intake, but women with a history of substance use should also be screened for pregnancy in community corrections. All women who come in contact with the criminal justice system should be educated about the risks of substance use during pregnancy, including the provision of tobacco cessation support and services (which all public and private health insurance plans are now required to cover).⁵²



EXISTING STANDARDS AND GUIDELINES

- *A Collaborative Approach to the Treatment of Pregnant Women With Opioid Use Disorders*. SAMHSA, 2016. <https://store.samhsa.gov/shin/content//SMA16-4978/SMA16-4978.pdf>
- *Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants*. SAMHSA, 2018. <https://store.samhsa.gov/shin/content//SMA18-5054/SMA18-5054.pdf>
- *Advancing the Care of Pregnant and Parenting Women With Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance*. SAMHSA, 2016. <https://www.regulations.gov/document?D=SAMHSA-2016-0002-0001>
- *Opioid Use Disorders and Medication-Assisted Treatment in Pregnancy*. National Center on Substance Abuse and Child Welfare, n.d. <https://ncsacw.samhsa.gov/resources/opioid-use-disorders-and-medication-assisted-treatment/default.aspx>
- *Pregnancy and Postpartum Care in Correctional Settings*. Carolyn Sufrin, MD, PhD. Endorsed by the American College of Obstetricians and Gynecologists and should be construed as ACOG clinical guidance. <https://www.ncchc.org/filebin/Resources/Pregnancy-and-Postpartum-Care-2018.pdf>
- *Standards for Health Services in Jails*. National Commission on Correctional Health Care, 2018. <https://www.ncchc.org/jail-prison-standards>
- *Standards for Opioid Treatment Programs in Correctional Facilities*. National Commission on Correctional Health Care, 2016. <https://www.ncchc.org/opioid-treatment-programs-2>
- *State Standards for Pregnancy-related Health Care and Abortion for Women in Prison*. American Civil Liberties Union, 2016. <https://www.aclu.org/state-standards-pregnancy-related-health-care-and-abortion-women-prison-0>





MEDICATION ALONE IS NOT THE ANSWER: THE FORCE MULTIPLIER OF PARTNERSHIPS AND SUPPORT SERVICES

FOR MAXIMUM BENEFITS IN THE TREATMENT OF OPIOID AND ALCOHOL USE DISORDERS, COUPLE MAT WITH COUNSELING AND THE APPROPRIATE WRAPAROUND SERVICES.

All FDA-approved medication for the treatment of substance use disorders is intended to be used in conjunction with counseling and behavioral therapies, although some research has found that providing MAT when counseling is not immediately available (for example, when a patient is on a waiting list) still improves outcomes.⁵³

Treatment programs can include both group and individual counseling to accommodate the diverse needs of participants. Both cognitive behavioral therapy and therapeutic communities have been found to be effective treatment modalities for individuals in correctional facilities.⁵⁴

Most behavioral therapies found to be effective in addressing alcohol and SUDs are for specific drugs of abuse and have been studied primarily in community settings. Their use in correctional settings requires adjustments and modifications. Once such therapies are implemented, it is imperative that justice programs evaluate whether they have maintained fidelity to the essential elements of the treatments found to be effective and that the program, as modified and implemented, achieves results commensurate with those found in the research.

Many programs have found manualized treatment interventions to be effective, offering structure and consistency. They are also easy to use and can help focus sessions (although implementation should guard against over-restrictiveness), and counselors need to incorporate personal style and creativity in their use.⁵⁵ The quality of the interpersonal relationships between staff members and participants, along with the skills of the staff, are as important to risk reduction as the specific programs in which individuals participate.⁵⁶

In addition to access to appropriate medication, the SAMHSA Federal Guidelines for Opioid Treatment Programs requires the following considerations in assessing client treatment and services: (1) Each patient accepted for treatment at an opioid treatment program shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. (2) The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. (3) The treatment plan also must identify the frequency with which these services are to be provided. (4) The plan must be reviewed and updated to reflect the patient's personal history; his or her current needs for medical, social, and psychological services; and his or her current needs for education, vocational rehabilitation, and employment services.⁵⁷

Inadequately treated substance use disorder is a key risk factor for recidivism. A best practice includes treatment that also addresses recidivism risk factors.

The concept of RNR [risk-need-responsivity] is considered a best practice for corrections professionals⁵⁸ and has been shown to effectively reduce recidivism by as much as 35 percent in certain settings.⁵⁹ Research has shown that non-adherence to the RNR principles in service delivery is not only ineffective but can also be detrimental to offender treatment outcomes.⁶⁰

One study examining the effectiveness of treatment programs reported a substantial negative correlation ($r = -.28$) between risk level and treatment effect size for a program that did not adhere to RNR principles.⁶¹

JAILS IMPLEMENTING COMPREHENSIVE MAT PROGRAMS—AND THE CLIENTS THEY SERVE—WILL BENEFIT FROM COLLABORATIVE RELATIONSHIPS WITH COMMUNITY-BASED TREATMENT, MAT, AND OTHER BEHAVIORAL HEALTH PROVIDERS.

By maintaining collaboration and regular communication, the jail and the treatment providers can work together to optimize success and enhance the prospects of long-term recovery for each shared client. Although a person must ultimately be motivated to pursue recovery, research provides "overall support for the dictum that legally referred clients do as well or better than voluntary clients in and after treatment."⁶² Jail personnel using motivational interviewing can assist in helping individuals commit to their recovery, even if the initial motivation for treatment came from wanting to avoid conviction, wanting to avoid a jail or prison sentence, or being ordered to seek treatment as a condition of probation or parole.

EXAMPLE FROM THE FIELD

A New York jail relies on a state treatment court where most individuals choose buprenorphine as their medication. The court maintains an evolving list of approved providers based on the probation department's experiences. For example, providers who communicate effectively and cooperate with the probation department remain on the list; those who do not are removed. Almost all of the probationers receive their medication at outpatient programs designated by the officers. A small number receive it directly from physicians. All participants also must attend the outpatient program for counseling and other services.⁶³

judge or a district attorney) have reservations about addiction medication, "MAT programs can succeed if the program views clinical decisions as the province of clinicians."⁶⁴

Because agonist medication is so highly valued among incarcerated individuals with OUDs, correctional administrators may be tempted to view its use as a reward for "good behavior" for select individuals and may resist allowing access to all people in need. Medication and other forms of behavioral health treatment should not be used as rewards, nor their withholding as a punishment. Loss of privileges or confinement are more appropriate alternatives.

RESIDENTIAL CORRECTIONAL FACILITIES, AS WELL AS COMMUNITY TREATMENT PROVIDERS, SHOULD HAVE SPECIFIC SAFEGUARDS TO PREVENT THE DIVERSION OF AGONIST MEDICATIONS⁶⁵ (FOR EXAMPLE, METHADONE) AND TO SAFEGUARD PARTICIPATING INDIVIDUALS.

The incorporation of MAT programming, especially in jails, can raise challenges based on the medication options available.

Dispensing medications for the treatment of OUDs in facilities that have no previous experience handling and storing them requires preparation and education. Precautions must be exercised to guard against the illicit diversion of agonist medications. Some studies have found that these medications are both effective for jail populations and are subject to diversion. A study of an in-prison buprenorphine program found that buprenorphine "can facilitate community treatment entry. However, concerns remain with in-prison treatment termination due to attempted diversion of medication."⁶⁶ Yet facilities that do not offer opioid agonist treatments may unwittingly, and paradoxically, be promoting diversion among inmates with OUDs who would benefit from such treatment.

MAT PROGRAM COMPONENTS: ASSEMBLING THE RIGHT TEAM, SAFEGUARDS, PROTOCOLS, AND STRUCTURE FOR A SUCCESSFUL JAIL- BASED PROGRAM

CORRECTIONAL STAFF SHOULD RECEIVE TRAINING AND EDUCATION ABOUT MAT.

MAT programs, like all other programs, work best when program staff members are supportive. For example, studies have found that drug courts that have buy-in from their whole teams have a more positive view of their own programs. However, even in courts where key players (for example, a



Agonist medications must be counted, recorded, and stored in locked cabinets. Administering each dose takes a few minutes, and patients must be closely observed to lessen the possibility of diversion. Any missed dose must be documented and returned to the locked cabinet. Prior to initiating administration of the medications, staff members must be trained and a protocol must be developed to accommodate the additional responsibilities entailed. The FDA approved a monthly injectable form of buprenorphine sold under the brand name Sublocade. Use of injectable buprenorphine avoids diversion and minimizes postrelease interruption of treatment. It requires refrigeration and must be used within 7 days after being warmed to room temperature.

Special care must be taken in the storage of medications, both for security and to make sure that the medications are used before their expiration dates. For example, injectable naltrexone must be refrigerated and then allowed to warm to room temperature before mixing, followed by intramuscular injection. Once at room temperature, the drug must be used within 7 days or discarded. Medical staff members must be reassured about potentially increased liability for the prescription and dissemination of these medications and informed about the possibility of increased workloads.

Although the following guidelines address only opioid treatment programs, the *Federal Guidelines for Opioid Treatment Programs* (42 CFR Part 9) notes that referred community-based treatment programs should take explicit measures to prevent the diversion and abuse of the dispensed agonist medications, particularly with regard to allowing clients to take medication unsupervised.

To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

1. Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and state and federal holidays.
2. Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use, beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling MAT for unsupervised use.
 - No recent abuse of drugs (opioid or nonnarcotic), including alcohol
 - Regularity of clinic attendance
 - Absence of serious behavioral problems at the clinic

- Absence of known recent criminal activity (e.g., drug dealing)
- Stability of the patient's home environment and social relationships
- Length of time in comprehensive maintenance treatment
- Assurance that take-home medication can be safely stored within the patient's home
- Assurance that the rehabilitative benefit the patient derived from a decreased frequency of clinic attendance outweighs the potential risks of diversion

3. Such determinations and the basis for such determinations, consistent with the criteria outlined in paragraph (i)(2) of this section, shall be documented in the patient's medical record. If it is determined that the patient is responsible in handling MAT, the following restrictions apply:
 - During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week, and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.
 - In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is two doses per week.
4. No medications shall be dispensed to patients in short-term medically managed withdrawal treatment or interim maintenance treatment for unsupervised or take-home use.
5. OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner designed to reduce the risk of accidental ingestion, including childproof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 et seq.).⁶⁷

EXAMPLE FROM THE FIELD

Rhode Island Department of Corrections Distribution of Buprenorphine Protocol, April 22, 2016: "If at any time a correctional officer suspects or observes an inmate putting their hands around their mouth, a mouth check will be immediately performed to determine the presence of the buprenorphine; a strip search of the inmate will/may be performed to ensure compliance with this procedure; and if contraband is discovered (medication cheeked or transferred to another area), the inmate will be issued a disciplinary action."

COMMUNITY-BASED TREATMENT AND MEDICATION

PROVIDERS SHOULD BE CAREFULLY SELECTED.

CORRECTIONAL AGENCY COLLABORATION MAY BE REQUIRED TO ENCOURAGE PROVIDERS TO MEET THE NEEDS OF REFERRED INDIVIDUALS.

Most SUD treatment programs across the country (88.9 percent) have not yet incorporated access to MAT, either within their programs or in partnership with medical providers.⁶⁸ The specific and separate requirements for the provision of buprenorphine and methadone have contributed to the fragmentation of MAT access for persons with OUDs. Jails, therefore, must often search out community-based agencies that provide MAT as well as appropriate treatment and services for individuals to be released to the community. The Pennsylvania Department of Corrections, for example, has issued a directive that it “will no longer do business with service providers who do not, at all levels, support the use of medication-assisted treatment.”⁶⁹

In selecting and working with a referral agency to better serve correctional clients, justice agencies should be advised by the Federal Guidelines for Opioid Treatment Programs, March 2015, issued by SAMHSA.⁷⁰ The guidelines emphasize that community-based agencies should offer recovery-oriented systems of care, in addition to medication, and specify that:

OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services.⁷¹ These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

1. OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients; to contribute to the appropriate treatment plan for patients; and to monitor patient progress.
2. OTPs must provide counseling on the prevention of exposure to, and the transmission of, HIV disease for each patient admitted or readmitted to maintenance or medically managed withdrawal treatment.
3. OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to need such services.⁷²

In the United States, the treatment of opioid dependence with medications (including the use of buprenorphine) is governed by the Certification of Opioid Treatment Programs, 42 Code of Federal Regulations (CFR) 8.⁷³ Associated treatment standards include frequent office visits (weekly in early treatment), concurrent counseling, urine drug testing (including testing for buprenorphine and metabolites), and recall visits for pill counts if diversion is suspected.

Regarding practitioners dispensing narcotic drugs for narcotic treatment, the Comprehensive Addiction and Recovery Act of 2016 amended Section 303 of the Controlled Substances Act as follows: “In the prescriber’s notification to the Secretary of HHS of their intent to prescribe buprenorphine, they must certify that the practitioner is a qualifying practitioner; they have the capacity to provide directly, by referral, all drugs approved by the FDA for the treatment of opioid use disorder, as well as appropriate counseling and other ancillary services.”

CORRECTIONAL PERSONNEL SHOULD REFER CLIENTS TO PRESCRIBING PROVIDERS AND OTHER TREATMENT PROVIDERS WHO HAVE THE REQUIRED CERTIFICATION AND ARE KNOWLEDGEABLE ABOUT ADDICTION, SUBSTANCE ABUSE, OR BEHAVIORAL HEALTH PROGRAMS, AND THE ROLE OF MEDICATION IN SUBSTANCE USE TREATMENT.

Policies, procedures, and agreements with community providers should ensure that there is no interruption of MAT following correctional release and referral to community MAT providers. Many licensed SUD treatment programs complete an assessment that includes whether MAT may be indicated. If a program does not have a physician on staff, clients may be referred to a physician or a certified OTP that can prescribe, dispense, and/or administer the appropriate medication. This underscores the need to exercise care in making referrals to SUD treatment programs that can conduct proper pharmacotherapy assessments, directly provide the most appropriate medication, and deliver counseling and recovery support services. Access to opioid medications may be limited in the community, especially in rural areas.⁷⁴ Telemedicine is approved in some states for buprenorphine prescribing, particularly in rural areas.⁷⁵

THERE ARE PRETRIAL AND POSTTRIAL MAT PROGRAMS.

JAIL-BASED PRETRIAL MAT PROGRAMS

Most individuals’ entry into jail occurs after arrest and arraignment, pending trial or case resolution for those not able to raise bail or who are ordered held for trial. Traditionally, little programming has been available for these individuals because their stay is limited and they have not been convicted of a crime. However, the opioid epidemic has inundated jails with an increased number of individuals under the influence of opioids. Jails have become de facto detoxification (i.e., medically managed withdrawal) centers.

Once individuals have gone through medically managed withdrawal, many jails are in a unique position to initiate treatment for these individuals, launching them on the path to long-term recovery. An increasing number of jails have begun to establish treatment programs for these individuals. In addition to medically managed withdrawal services, these jails have established medical screening for MAT as well as in-jail provision of these medications to promote continued abstinence from illicit opioids upon release. To ensure continuity of treatment, these jails link released individuals to treatment, support, and medical providers in the community. However, medically managed withdrawal is not treatment. In fact, withdrawal is associated with high risk for overdose and death following release, underscoring the need for MAT.



There is a dual incentive for incarcerated individuals to take advantage of these programs: Not only can their participation lead to recovery in the long term, but in the short term, their participation can influence prosecutors and courts to consider noncustodial treatment alternatives once they return to court for further hearings. In many jurisdictions, prosecutors and courts let defendants know at arraignment that they will take into consideration the defendants' participation in a jail pretrial program to resolve their criminal cases. Although many defendants may be more concerned with avoiding custodial sentences than long-term abstinence and recovery, research has shown that successful treatment is not dependent on voluntary entry into treatment.⁷⁶

However, if it is likely that a prosecutor and a court will not consider a noncustodial sentence, beginning agonist treatment pretrial may not be indicated if the individual is expected to return to jail for a long period of time or be sentenced to prison.

Before an individual is enrolled into a jail's MAT program, he or she is educated about the medications offered and the associated choices to be made (as described earlier). The jail then introduces concurrent initial drug counseling and sets up referrals in the community for follow-up counseling as well as continued access to medication.

An increasing number of jails provide agonist medications for incoming individuals who are already prescribed these medications, especially if they are not expected to remain in jail for prolonged periods of time. While certified medical

personnel can dispense buprenorphine, methadone must be dispensed by a licensed methadone clinic. For this reason, most jails rely on community methadone clinics to come to their facilities daily to dispense medication under the supervision of the jail authorities rather than becoming licensed methadone providers in their own right.

JAIL-BASED POSTTRIAL MAT PROGRAMS

Many more jails provide posttrial MAT for sentenced individuals. Generally, access is provided for those who are also enrolled in a facility's drug treatment program. These posttrial MAT differ from the pretrial programs in that most participants do not need to undergo medically managed withdrawal before entry. If an individual has been allowed to continue prescribed agonist medications before entrance into the jail, some programs allow him or her to remain on these medications, but generally for only a year. After that, the individual is medically tapered off the agonist medication.

Most of these jail programs offer naltrexone shortly before individuals' reentry into the community, either when released on parole or when no further correctional supervision is needed. However, some also offer naltrexone maintenance for several months before release. These jails provide either oral naltrexone daily for approximately 1 month, followed by injectable naltrexone immediately before release, or up to 3 months of monthly injections prior to release. Although there have been no studies on the effectiveness of extended naltrexone maintenance before prerelease injections, it is thought that such maintenance will result in better follow-through after release. Many correctional programs have found that, although individuals sign up for naltrexone 2 or 3 months before release, they often change their minds when it is time for the injections. Despite prolonged abstinence while incarcerated, it is reported that for some, anticipation of imminent release triggers drug cravings and drug dreams, making them anxious and/or resistant to committing to the month's abstinence that the injections will promote. It is thought that the provision of naltrexone months before release will prevent renewed cravings and anxiety and encourage individuals to enroll in the naltrexone MAT program and continue the medication after release.

Two studies provide some support for this rationale. Both found that when individuals receive the first injection before release from jail, they are significantly more likely to have a second injection compared to those whose first injection is given immediately after release.⁷⁷ This suggests some significance to initiating the medication before release.

Similarly, a randomized clinical trial of buprenorphine maintenance that compared individuals who began receiving the medication while in jail with those who received it upon release found that the former approach was associated with more days in buprenorphine treatment in the designated community treatment program during the 12-month postrelease assessment. However, the study did not find an association with superior outcomes in terms of reduction of heroin or cocaine use or criminal behavior.⁷⁸

In addition, research makes it clear that receiving MAT in jail along with treatment is associated with better follow-up in the community than treatment alone. For example, a randomized controlled trial of methadone maintenance and counseling for some inmates compared with counseling only found that in the year following release, those who had methadone and counseling spent 7 times as many days in treatment for drugs during the postrelease year. None of the counseling-only participants continued in treatment for the entire year, whereas 37 percent of the methadone participants remained in treatment for that year. The counseling-only individuals were also significantly more likely to test positive for opioids 12 months postrelease.⁷⁹

These findings are relevant because individuals are at a significantly increased risk of an overdose death during the first 2 weeks postrelease.⁸⁰ Use of methadone and buprenorphine substantially reduces this risk.⁸¹

To ensure the continuity of medication after release, it is essential that funding be arranged. If medication is to be paid for through the state Medicaid program, individuals should be enrolled before release so there is no gap between release and eligibility to access the needed medication. If health coverage requires prior approval for certain medications, it should be arranged before release for the same reason. In addition to financing medication, jails should facilitate participants' first postrelease community treatment appointments.

Several jail-based MAT programs have created recovery support case manager positions to bridge the gap between institutions and communities. These case managers meet with individuals before release and remain available for support and assistance for up to a year after release. Among other duties, recovery support case managers may accompany released individuals when they first enter treatment programs, meet with medical providers, or engage in other recovery-related activities. Unlike probation or parole officers, the case managers' function is solely to provide support, and their engagement by the released individuals is voluntary.

THE IMPORTANCE OF CLIENT SCREENING TO ADDRESS TREATMENT CONTINUATION, WITHDRAWAL, AND RELAPSE

SYSTEMS SHOULD BE IN PLACE TO ENSURE CONTINUATION OF METHADONE OR BUPRENORPHINE WHEN APPROPRIATE.

Jails should establish systems to ensure that detainees and sentenced inmates who had been receiving MAT, particularly methadone and buprenorphine, prior to their arrest have MAT continued when feasible.⁸² Withdrawal of methadone or buprenorphine increases the risk for adverse consequences. Avoidable potential consequences include onset of withdrawal symptoms (requiring medical management and monitoring), increase in disciplinary problems⁸³, drop out from treatment postrelease⁸⁴, and dramatic increases in overdose-related deaths

postrelease among those not maintained on MAT.⁸⁵ In Rhode Island, when MAT continuation was implemented in jails and prisons statewide, postrelease deaths dropped by 60 percent.⁸⁶

MAT continuity can be ensured through appropriate policies and procedures, memoranda of understanding with community programs, established lines of communication with community prescribers, and systems for obtaining MAT and for supervised administration of MAT. Communication upon jail entry is necessary to confirm dosing with the community program or prescriber. Systems for obtaining MAT must be consistent with federal and state regulations. Dosing should be directly supervised to minimize diversion.

Prerelease communication with community prescribers is needed to avoid interruption in dosing. For methadone, this often means requesting that the community OTP "guest dose" the patient in jail—i.e., provide take-out doses of methadone that are secured by the jail and administered under jail supervision. For buprenorphine, this often means prescription of buprenorphine by jail medical staff who are waived to prescribe it and direct observation of its administration. Alternatively, jails can obtain a license as an OTP program.⁸⁷ Prerelease communication with community treatment programs helps to ensure that patients are scheduled with an immediate appointment with the community prescriber, thus avoiding a postrelease interruption in MAT.

MEDICALLY MANAGED WITHDRAWAL PROTOCOLS SHOULD BE IN PLACE TO SUPPORT SCREENING FOR WITHDRAWAL SEVERITY AND POLYSUBSTANCE USE, MONITORING, AND MEDICAL MANAGEMENT OF SYMPTOMS.

Medically managed withdrawal utilizing prescribed, FDA-approved medications may be necessary when a person transitions to a controlled setting or begins treatment with naltrexone. In custody settings, especially jails, this must be addressed early in the intake process (ideally, within hours of admission) to reduce the risk of medical complications and fatalities. Withdrawal symptoms may begin within 4 to 6 hours of the last opioid use and may last for up to several months.⁸⁸ Jails should have protocols in place to identify people who might require medically managed withdrawal services. It is of equal importance to have a plan to engage them in treatment. Medically managed withdrawal by itself is not treatment.⁸⁹ While in some instances, withdrawal can be a step toward treatment, this is largely not the case in correctional settings, where the risk of death from overdose is extremely high.

A person entering a correctional institution on a prescribed medication should be allowed to continue for a reasonable period. If the incarceration will be for more than a year, the individual can be tapered off the medication under medical supervision and then restarted 30 days prior to release in order to minimize risk of postrelease overdose and death. Research has found that forced detoxification of prescribed opioid medication, such as methadone, can undermine an individual's willingness to engage in MAT in the future, compromising the likelihood of long-term recovery.⁹⁰

Another issue to be aware of is polysubstance use. It is unwise to assume that an individual who reports a history of opioid use is exempt from the potentially life-threatening consequences of alcohol or benzodiazepine withdrawal. Opioid-dependent individuals are likely to use other substances, including alcohol, and may increase their alcohol consumption when they attempt to curtail opioid use. Universal withdrawal severity screening, institutional or community-based, of all persons entering corrections with an established or suspected history of substance use is widely recommended.⁹¹

The use of a standardized brief withdrawal severity assessment can help to stratify risk levels:

- **Low**—should be monitored but does not require medical attention
- **Medium**—requires immediate medical attention but does not have complicating medical conditions
- **High**—requires immediate medical attention and intensive monitoring because of other medical conditions that elevate risk⁹²

STANDARDS, GUIDELINES, AND INFORMATION ON WITHDRAWAL SEVERITY SCREENING

- ***Guide to Developing and Revising Alcohol and Opioid Detoxification Protocols.*** Kevin Fiscella, MD, MPH, for the National Commission on Correctional Health Care, 2015. www.ncchc.org/filebin/Resources/Detoxification-Protocols-2015.pdf
- ***Detoxification of Chemically Dependent Inmates.*** Federal Bureau of Prisons clinical practice guidelines, February 2014. www.bop.gov/resources/pdfs/detoxification.pdf
- ***TCU Drug Screen V Opioid Supplemental.*** Texas Christian University, September 2017. <https://ibr.tcu.edu/forms/tcu-drug-screen>
- ***TIP Series 45: Detoxification and Substance Abuse Treatment.*** Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, 2006. <https://store.samhsa.gov/product/TIP-45-Detoxification-and-Substance-Abuse-Treatment/SMA15-4131>
- ***Opioid Substitution Treatment in Custodial Settings—A Practical Guide.*** World Health Organization and United Nations Office on Drugs and Crime, 2008. www.unodc.org/documents/balticstates/Library/PrisonSettings/OST_in_Custodial_Settings.pdf
- ***Managing Opiate Withdrawal: The Wows Method.*** CorrectCare, Summer 2016. www.ncchc.org/filebin/CorrectCare/30-3-Wows.pdf

Even people who do not require medical attention should have easy access to ample, drinkable fluids.

Common factors that can elevate risk levels include a history of delirium tremens or withdrawal-associated seizures, a history of traumatic brain injury, advanced age, major medical or psychiatric comorbidity, and pregnancy.⁹³ Outpatient medically managed withdrawal treatment is not uncommon for individuals withdrawing from opioids.⁹⁴

In custody settings, the medical consequences of acute withdrawal from alcohol or chemically related sedative/hypnotic drugs (for example, benzodiazepines or barbiturates) can be reduced or eliminated when sound protocols are implemented and followed.⁹⁵ Symptoms of opioid withdrawal should be treated in accordance with correctional health care guidelines. Although deaths from inadequately treated withdrawal are uncommon, such deaths are on the rise.

Although medically managed withdrawal is not treatment and relapse is likely to occur without long-term follow-up services, assisting individuals in custody who are withdrawing from substances is an ethical and medical responsibility. ASAM criteria, endorsed by SAMHSA in its TIP 45: Detoxification and Substance Abuse Treatment, suggests “that for alcohol, sedative-hypnotic, and opioid withdrawal syndromes, hospitalization (or some form of 24-hour medical care) is often the preferred setting for medically managed withdrawal, based on principles of safety and humanitarian concerns. When hospitalization cannot be provided, then a setting that provides a high level of nursing and medical backup 24 hours a day, 7 days a week is desirable.”

Medications combined with psychological support are the standard for medical practice and improve recovery outcomes. To get the best results from medically managed withdrawal, an individual should be immediately connected with medication and counseling. Many medications are used to help ease withdrawal symptoms. The Federal Bureau of Prisons offers clinical guidelines for safe, medically managed withdrawal from alcohol, opioids, barbiturates, and other substances.⁹⁶ These practice guidelines do not differ significantly from community-based medically managed practices. Withdrawal should be assessed using the validated scales previously discussed. It should be treated using FDA-approved medications. These include methadone (when provided through an OTP), buprenorphine, or lofexidine. Systematic reviews suggest that clonidine has some benefit in relieving withdrawal symptoms but is less effective than opioid agonists.⁹⁷

All correctional facilities should make naloxone (Narcan) kits available in the event of an overdose. Ideally, all individuals with OUDs should leave their facilities with such a kit (or a prescription for one). Following an overdose, the individual and his or her family should be educated in how to administer this lifesaving drug.⁹⁸

Alcohol withdrawal is usually treated with short-term, gradually tapering doses of long-acting benzodiazepines. Medications include clonidine; thiamine, also called vitamin B1; and carbamazepine, an antiseizure medication. All

medications should be administered under the supervision of trained medical personnel, particularly considering that many individuals entering corrections may suffer from liver disease, a condition that contraindicates the use of certain medications.

JAIL MAT PROGRAMS SHOULD INCLUDE ONGOING MONITORING THROUGH DRUG SCREENING AND OTHER DIVERSION/RISK MITIGATION STRATEGIES.

Alcohol and drug use during treatment should be carefully monitored as outlined in NIDA's *Principles of Drug Abuse for Criminal Justice Populations*.⁹⁹ Individuals trying to recover from alcohol and drug addiction may experience a relapse and return to drug use. This is considered a part of the recovery process for people with SUDs. Those on MAT, like others in SUD treatment, may relapse, take other drugs, or misuse prescription medication. Individuals on antagonist drugs such as naltrexone may switch to cocaine or other drugs that are not blocked by naltrexone.

Different people have different triggers for relapse, and treatment providers work to identify such triggers. Common triggers include mental stress and associations with peers and social situations linked with drug use. An undetected relapse can progress to serious alcohol and drug misuse and potential overdose. When detected, relapses can present opportunities for therapeutic intervention. Monitoring alcohol and substance use through urinalysis or other objective methods, as part of treatment or criminal justice supervision, provides a basis for assessing and providing feedback on the participant's treatment progress. It also provides opportunities to intervene to change unconstructive behavior and to determine rewards and sanctions to facilitate change and modify treatment plans according to progress. For individuals on medications, it can also ensure that they are taking the correct dosages.

In addition to urine tests, correctional and treatment agencies can employ a range of methods to monitor for return to drug use, including pill or strip counting and behavioral observations. These methods are generally not dissimilar from those used to monitor illicit drug use by other non-MAT participants. Most correctional agencies perform the monitoring themselves and do not rely on treatment programs or correctional health providers.

Once a patient is released from jail, the method and extent of monitoring depends on the type of medication. Patients prescribed buprenorphine typically take home a month's worth of medication, which requires more vigilant monitoring. Methadone patients, on the other hand, typically take their doses in liquid form under observation by clinic medical staff and do not self-administer medication at home until they are well stabilized to safeguard against misuse. Naltrexone cannot be diverted when it is injected by a health care provider, and oral naltrexone has no abuse potential.

States with an operational prescription drug monitoring program (PDMP) collect all Schedule II, III, and IV (and, in some states, Schedule V) controlled substance prescription data that can be accessed by authorized users, including physicians

and pharmacists. By regularly checking the PDMP, providers can become aware if a patient receives a controlled substance from another prescriber and address the possible return to drug use. Every state and the District of Columbia now has an operational PDMP (although Missouri's is not statewide; it is operated by the St. Louis County Department of Public Health and is joined by other counties/jurisdictions). A list of the capabilities for each PDMP can be found at <http://www.pdmpassist.org/content/state-profiles> and at <http://www.pdmpassist.org/content/pdmp-maps-and-tables>.

Jails report a major challenge in terms of contraband drugs, including agonist medications used for opioid treatment. For example, the Ohio Department of Rehabilitation and Correction reported that in December 2016, based on random drug tests conducted on 5 percent of the prisoners, 1 in 20 tested positive for illicit drugs, with marijuana being most common, followed by Suboxone.¹⁰⁰ While many jails have provided methadone to pregnant women for decades, and currently some jails and prisons regularly provide agonist medications to their inmates, at least one jail has found that its MAT program appears to have reduced the demand for illicit drugs within its institutions. However, the same department underscores that the provision of agonist medication requires daily procedures for monitoring the medication dissemination by both nursing and correctional staff.¹⁰¹ An integrated jail/prison system found that continuation of methadone improved postrelease engagement in treatment and reduced disciplinary problems among inmates.^{102, 103}

ENGAGING MEDICAID AND POSTRELEASE FINANCIAL ASSISTANCE

JAILS FACILITATING MAT SHOULD ENGAGE THEIR STATE MEDICAID AGENCIES AND OTHER PUBLIC PAYERS TO FACILITATE HEALTH CARE COVERAGE.

Lack of insurance or gaps in insurance coverage inhibit the use of MAT. For example, according to a 2016 U.S. Government Accountability Office report,¹⁰⁴ out-of-pocket costs for sublingual buprenorphine for individuals who lack insurance coverage for medications can range from \$200 to \$450 a month. The cost of injectable naltrexone can be triple that cost. State Medicaid programs may not reimburse for all three of the approved OUD medications. In some states that cover all or some of the medications, there is a shortage of physicians willing to prescribe medications for persons with substance use disorders.¹⁰⁵ Some states have stringent prior authorization requirements governing the coverage of medications such as buprenorphine or extended-release injectable naltrexone. For example, Idaho requires preauthorization to receive Medicaid coverage for Suboxone, Vivitrol, or oral naltrexone. A breakdown of state coverage (including medications) is contained in *A Comprehensive Listing of What States Cover for Substance Use Disorder* (see <http://www.rsat-tta.com>).¹⁰⁶

Correctional or treatment agency staff members can help ensure that individuals receive the coverage needed to utilize MAT programs, including available state-subsidized medications.

Federal law and regulations do not require states to terminate Medicaid enrollment when a person is incarcerated, but the law does prohibit federal payments for that person's health care costs while he or she is in prison or jail (excluding the inpatient exception). Guidance from the Centers for Medicare & Medicaid Services (CMS) in April 2016 clarifies that states must accept applications from people who are incarcerated and enroll or reenroll them if determined eligible. It encourages states to suspend enrollment or coverage by using markers or other indicators in the claims processing system that help ensure that claims submitted by states are denied for disallowed services provided to people in prisons and jails. Whatever method is used, CMS states that a suspension must be lifted when this exclusion no longer applies—for example, upon a person's release, or when he or she is admitted to a medical institution for treatment that falls within the inpatient exception.¹⁰⁷

In addition, if an individual obtains employment and no longer qualifies for Medicaid, he or she may not be able to afford the subsidized premiums or copays. Such an individual may need additional assistance, such as pharmaceutical company coupons or access to generic versions of buprenorphine.

There are programs for reduced-price medications, some from the pharmaceutical industry itself. There are also federal and state government programs. Congress established the 340B program to allow certain covered entities that serve large numbers of uninsured patients to obtain drugs from pharmaceutical suppliers at the same discounted rates that Medicaid pays (i.e., 25 to 50 percent less). The following website lists 340B-covered entities by state: <http://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>. Also, some states fund MAT medications for programs that serve correctional populations out of state block grant funding or state appropriations. More than 1,200 Federally Qualified Health Centers are located in inner cities and rural areas and serve uninsured and low-income individuals. Many offer buprenorphine based on discounted fees. The nearest center can be located via <https://findahealthcenter.hrsa.gov>.

THE DIFFERENT TYPES OF ASSISTORS INCLUDE THE FOLLOWING:

- **Navigators**—Navigators receive extensive training from CMS and are responsible for providing unbiased information about public and private health insurance programs in a culturally competent manner. They regularly report on their outreach and consumer education activities and accomplishments. In plan year 2018, the Navigator Program is evolving: Navigators will be encouraged to leverage volunteers as well as strategic partnerships with public and private organizations to identify individuals who would benefit from Exchange coverage. These updates leverage practices from private sector-focused programs like those within Medicare Advantage.
- **Non-navigator assistors (in-person assistors)**—These serve a function similar to navigators, providing in-person assistance and informing consumers about coverage options, but funding for assistors is more flexible than navigator funding. Many states opt to train staff members of existing community-based agencies to carry out in-person assistor duties.
- **Certified application counselors (CACs)**—CMS designates organizations to certify counselors who perform these functions. CACs complete pre-service training and receive ongoing in-service training via CMS webinars and newsletters. They comply with privacy and security standards but have fewer reporting requirements.
- **Brokers, agents, and contracted assistors**—Brokers usually act on behalf of the consumer and are compensated by insurers or consumers. Agents are compensated by insurers. Some states contract with brokers or agents to act as “navigators.” They may be required to forgo compensation or abide by other guidelines that mitigate potential conflicts of interest.

JAIL-BASED MEDICATION-ASSISTED TREATMENT PROGRAMS IN ACTION

SACRAMENTO COUNTY JAIL, CALIFORNIA

ORIGIN AND DEVELOPMENT OF THE PROGRAM

In 2013, the Sacramento County Sheriff's Department Reentry Services Bureau, Sacramento Probation Department, and Correctional Health Services began a pilot program to provide substance use treatment with the administration of naltrexone to a select group of inmates with a history of opiate dependence and/or acute alcohol abuse. The pilot group showed great success. As a result, the program was made available to all consenting inmates who qualified.

PROGRAM PARTICIPATION PROCEDURES

Program participants are identified by self-referrals, reentry specialists, inmates with known drug/alcohol use histories, and referrals from outside sources. When an inmate is identified as a possible program participant, the following screening process is used:

1. A reentry specialist meets with the inmate to explain the program and to obtain consent to proceed.
2. A signed copy of the Sacramento County Correctional Health Services and WellSpace Health Vivitrol Consent Form is placed in the inmate's file, a second copy is forwarded to the reentry resource officer, and a copy is sent to County Health Services and WellSpace Health (the postrelease medical program).
3. Verification is made of participation in a substance use treatment program. If the inmate is not participating in a program, the reentry specialist will coordinate enrollment with the reentry resource officer.
4. Probation verification is made, although probation status is not required for participation.
5. The inmate is referred to the Department of Human Assistance eligibility specialists for eligibility verification for Covered California or other health insurance pursuant to the Affordable Care Act.
6. Correctional Health Services conducts a medical evaluation of the inmate to approve participation in the program.
7. When participation is approved by Correctional Health Services, the doctor prescribes naltrexone to the participant and ensures that the first injection is scheduled for 35 to 40 days prior to release and the second injection for 7 days prior to release.
8. The reentry specialist notifies WellSpace Health of the participant's anticipated injections and release from custody. An appointment is scheduled for the third injection prior to release.
9. The assigned reentry specialist serves the participant postrelease for the duration of his/her use of naltrexone. Reentry services continue based on need after the individual discontinues naltrexone or completes the recommended 6-month participation.
10. If the participant is serving a period of supervised release, the reentry resource officer ensures that the reentry specialist coordinates the individual's program participation with his or her probation officer of record.

OUTCOMES

Of the first 174 total program participants, 54 have been arrested for new offenses (31 percent).

MIDDLESEX JAIL AND HOUSE OF CORRECTION, MASSACHUSETTS

ORIGIN AND DEVELOPMENT OF THE PROGRAM

The Middlesex Sheriff's Office (MSO) Medication-Assisted Treatment and Directed Opioid Recovery (MATADOR) program encourages long-term recovery to improve health outcomes and reduce recidivism. The program, in its current form, was launched in October 2015. The prior attempt at a MAT program resulted in programmatic failure but yielded insights for MATADOR's eventual success. The original Vivitrol program failed because it was missing many of the factors now known to be integral to a successful MAT program:

- The original program lacked buy-in from the correctional officials tasked with overseeing its success.
- It lacked a data collection/performance measures component.
- It had a very limited network of health providers who participated in MAT involving Vivitrol.
- It needed critical casework follow-up to assist participants with navigating medical appointments, health insurance coverage, and other issues associated with life back in the community.

The failure of the initial MAT program provided an opportunity to improve in three areas that became implementation milestones:

- The need for a navigator or recovery coach to remain in touch postrelease
- The need for real-time data to provide areas in need of improvement
- Increased participation by community health providers

PROGRAM DEVELOPMENT

MATADOR has evolved significantly since its October 2015 inception date. One of the major drivers of its success has been the increased participation of community health care providers and substance use counseling centers. The MATADOR program began with four community providers willing to accept patients and administer naltrexone injections. As of May 2017, that number had expanded to 35 providers, 70 support program locations, and four drug courts. In addition to the community support necessary to initiate and sustain a successful MAT program, key stakeholders include data

experts, medical/mental health treatment providers, dedicated recovery navigators/coaches, and courts willing to accept MAT as a legitimate form of relapse prevention and recidivism reduction.

Many MATADOR participants begin with medically managed withdrawal. Just under half (42 percent) of the intakes have drug addictions so severe that they need to be detoxed when they arrive—76 percent of them have some type of opioid in their systems. Following medically managed withdrawal, officers and program staff members provide drug treatment and casework services to treat those suffering from addiction issues. As part of that process, inmates are educated on all forms of MAT, including injectable naltrexone. Individuals interested in participating in MATADOR are educated on program specifics and receive medical screening prior to enrollment.

Prior to release, a participant is given an injection and is in touch with the navigator, who schedules follow-up medical and treatment visits. When an inmate is released from the facility, the program begins in earnest.

At its inception, the MATADOR program required one full-time employee (FTE) as a recovery support navigator and ½ FTE for data collection/analysis. Both initial positions were internal assignments and considered an investment in the program. As the program expanded, a second navigator was hired to keep up with demand. In addition, the program benefited from a grant award that uses Byrne JAG funding to secure two substance use treatment beds for program participants and 20 hours per week for a research assistant to collect data.

It was originally anticipated that the MSO's Residential Substance Abuse Treatment unit would be a natural feeder into the MATADOR program; however, data show that most program participants in the last 3 to 5 months have sought out the program after learning about it through word of mouth in the general population.

The MATADOR program director is a licensed nurse practitioner in the process of becoming a licensed recovery support navigator. Through this unique combination of training and expertise, the program provides clinical/medical guidance while establishing the rapport necessary for a successful postrelease relationship between the participant and the navigator. Potential participants are educated in all forms of MAT (Vivitrol, Suboxone, and methadone) and, if chosen, are provided with only Vivitrol (first injection prerelease) behind the walls of the Middlesex Jail and House of Correction.

The MATADOR team has gone to great lengths to establish open lines of communication with health care providers in the community, including identifying a primary point of contact at each community health care provider's and support program's office. This allows for a streamlined flow of information and, when necessary, the adjustment of treatment options,

services, and health insurance plans. Communication between the health care provider and the program is initiated when the program navigator notifies a provider of a new participant and schedules a medical follow-up appointment. If an appointment is missed, the MSO's research team is notified via phone call. The health care provider attempts to reengage the participant; failure to do so results in a call to a navigator, who attempts to reach the individual separately.

MATADOR team meetings provide ongoing communication among the MSO's research staff, executive staff, and navigators to ensure program integrity. The MATADOR program navigator works in conjunction with nearly 90 community health care providers, support programs, and drug courts throughout Massachusetts. The engagement and collaboration of these critical health care and criminal justice stakeholders have made a key difference in the success of the program reboot.

OUTCOMES

Of the 370 individuals who have completed the program, 81 percent had not been rearrested for new crimes as of January 2018.

LOUISVILLE METRO DEPARTMENT OF CORRECTIONS, KENTUCKY

ORIGIN AND DEVELOPMENT OF THE PROGRAM

The Louisville Metro Department of Corrections (LMDC) began experiencing a significant influx of high-need drug users among the jail population. Heroin-related arrests skyrocketed from 120 in 2010 to 1,501 arrests in 2014. In 2015, the county had the most overdose deaths of any Kentucky county (268) and the most heroin-related overdose deaths (131). In 2016, LMDC was funded to expand the in-jail substance use treatment program Enough is Enough and MAT (Vivitrol) for eligible opioid addicts returning to the community.

IMPLEMENTATION

In the spring of 2016, LMDC partnered with Correct Care Solutions (CCS), its contracted medical/mental health provider, to launch its MAT program. Flowcharts, consent-to-treat forms, and informational handouts were developed, and training for medical staff was provided. Originally, the program was designed to be provided only to inmates who were active participants in Enough is Enough, a 90-day voluntary drug treatment program. Shortly thereafter, staff members realized

that the program would also benefit inmates who could not be enrolled in Enough is Enough because of shorter incarceration periods. LMDC partnered with the courts and prosecutors to refer pretrial inmates interested in Vivitrol treatment and continued treatment in the community in lieu of further custodial sentencing. A senior social worker/coordinator for the MAT program established contacts with community providers who committed to taking on the task of the care continuum for MAT program participants.

Although the program started slowly, it quickly gained momentum and speed once word spread to the jail population. State funding pays for hepatic function panel (liver enzyme) labs, drug screens, Vivitrol injections, and days inmates participate in the Enough is Enough program.

Once an inmate has volunteered as a potential participant for MAT who will be released from LMDC custody within a month, the program coordinator requests hepatic function panel labs to be collected by medical staff members. Once the lab results return, the doctor or nurse practitioner clears or denies prescription based on the results. If prescription is denied, the referral source and the inmate are notified. If cleared, approximately 1 week before the potential release date, the program coordinator conducts a drug screen and has the inmate sign consent-to-treat and release-of-information forms. At that time, medical staff members are informed that the inmate is ready to receive Vivitrol. The nurse administers the naltrexone (pill) and, after the inmate is observed for possible side effects, the first Vivitrol injection is administered. The program coordinator forwards the lab results and the signed consent form to the community provider, and the inmate receives an appointment for follow-up care.

OUTCOMES

As of January 2018, 200 individuals have graduated from either the pretrial or posttrial MAT program. Of these, 47 percent have remained arrest-free in the community; only 4 percent of the individuals were arrested more times after release than before they entered the program.

LESSONS LEARNED

The program must:

- Develop effective collaboration with community providers.
- Keep ongoing meetings with all involved for troubleshooting purposes and progress discussions (LMDC holds biweekly meetings to discuss the program).
- Keep open and continued discussions with the judges, prosecutors, and public defenders.

SNOHOMISH COUNTY JAIL, WASHINGTON

ORIGIN AND DEVELOPMENT OF THE PROGRAM

The Snohomish County Jail initiated its buprenorphine MAT program in January 2018, beginning with a buprenorphine/naloxone (marketed as Suboxone) detox program. The program became necessary because of a huge increase over the past few years in people being arrested who were addicted to opioids. The jail's 24-bed medical unit was overwhelmed with individuals in need of medically managed withdrawal.

PROGRAM DEVELOPMENT

The jail found it was conducting withdrawal watches for 40 to 50 percent of those arrested, mostly for opioids. The medical unit was operating at more than 200 percent capacity. To ease cravings and mitigate the symptoms of withdrawal, the jail began Washington State's first pilot program to provide medically managed withdrawal with Suboxone. Individuals feel the ameliorative effects of 8 mg of buprenorphine within 30 minutes to 2 hours, and it takes 5 days before they are tapered off. Before receiving buprenorphine, individuals complete urine screens and medical exams to screen out those on other drugs, including benzodiazepines and alcohol, or those who have liver disease and other conditions.

The use of the medication has allowed the jail to move these individuals to the general population to free up medical beds and ease the correctional resources required for this special unit. The use of buprenorphine for medically managed withdrawal also introduces the individuals to MAT and gives them a picture of what treatment could include when they leave jail. Upon release, detoxed individuals are connected with treatment and medication providers in the community. Pregnant inmates are provided with buprenorphine without naloxone (marketed as Subutex).

If entering individuals are already on prescribed methadone or buprenorphine, they are maintained until they leave the jail, even if sentenced for the 3 to 6 months typically imposed for jail inmates.

Once through medically managed withdrawal, inmates who will be at the jail for at least 6 weeks (including those sentenced as well as those held pretrial) are offered Suboxone treatment 10 to 14 days before they are released. Three jail staff nurse practitioners and a physician at the jail prescribe the medication for both medically managed withdrawal and maintenance. The nurses carefully provide the medication each day under the supervision of correctional officers who provide direct supervision of inmates.

When individuals are released, they are picked up at the door by a community provider who continues to provide medication and counseling. At their release, the jail provides a prescription for 3 days of Suboxone, which gives the treatment provider time to begin prescribing. It generally takes a day for those on Medicaid to have it reinstated, so medication costs are initially covered by the treatment provider.

These same community providers also conduct group and individual counseling for the in-house jail treatment program, so those referred postrelease are already familiar with them. The jail has four community treatment providers to whom inmates are referred upon release.

Initially, the jail limited the program to 25 inmates to ensure smooth implementation and protection against any diversion of the medication. The inmates selected are well-known to the jail staff, since most have been in and out of jail previously for opioid abuse.

OUTCOMES

The pilot is too new to generate long-term outcome data. However, officials say the medically managed withdrawal program is easing the strain on deputies by getting inmates into the general population quicker and is much more humane. As the health administrator reported to local media, "They started their medication yesterday and within a couple hours were night and day difference. They went from vomiting, nausea, diarrhea, body aches to feeling well, eating, drinking, and wanting to shower. So, big difference."¹⁰⁸ Although the jail pays for the Suboxone tablets, the overall cost of the medication is less than the amount the jail paid for the medications previously used to ease withdrawal symptoms.

RHODE ISLAND

CORRECTIONAL FACILITIES

ORIGIN AND DEVELOPMENT OF THE PROGRAM

The Rhode Island Department of Corrections (RIDOC) operates a combined jail/prison system. Data documented that 21 percent of the state's overdose victims in 2014 and 2015 were incarcerated in the 2 years prior to death (up from 9 percent in 2009). More than 250 individuals were entering the system on agonist medication, either methadone or buprenorphine.

Traditionally, RIDOC allowed inmates on methadone to be maintained on their doses for an initial 30 days. That time span was increased to 60 days several years ago. After that period, inmates were tapered off the medication.

In 2016, as the opioid epidemic grew across the state, RIDOC initiated a program to target this high-risk population. All incoming inmates are screened and assessed for MAT. Now, MAT is initiated upon commitment, as needed, or continued for individuals already on methadone or buprenorphine for 6 to 12 months. For those not on agonist maintenance, naltrexone is provided prior to release.

IMPLEMENTATION

This program required an immediate increase in staffing for substance use disorder services. RIDOC hired three temporary chemical dependency professionals to initiate the screening of detainees upon arrival and to conduct follow-up assessments on those identified as needing it. RIDOC worked with The Providence Center, a treatment program, to place two recovery coaches to work with inmates involved in the MAT program. All levels of RIDOC staff, from the director to frontline nurses and correctional officers, are involved in the program. RIDOC encouraged collaboration among security, medical, and behavioral health personnel, as well as outside vendors. In addition, RIDOC engaged MAT community vendors to ensure continued care and medication upon release for all three FDA-approved opioid medications.

Internal communication is supported by the establishment of a MAT process team; weekly and biweekly meetings are held with administration, security, rehabilitative services, and medical staff members. External communication is supported by members of the MAT process team serving on committees such as the treatment subcommittee of the Governor's Overdose Prevention and Intervention Task Force and the Narcan distribution subcommittee.

Each day, inmates are organized into separate medical lines to be provided with methadone or buprenorphine, carefully monitored by correctional officers. At first, buprenorphine was provided in pill form but it was switched to strips (Suboxone) that dissolve faster and are less easily diverted by inmates. The strips are counted every shift to prevent diversion.

Initially, security staff were resistant to the use of Suboxone out of concern for diversion. The medical director and several staff members met with the jail warden and other administrators to educate them about MAT and to listen to concerns. These meetings went a long way in alleviating fears about the program.

OUTCOMES

During the 12 months between October 1, 2016, and September 30, 2017, RIDOC provided MAT to 896 individuals. Of these, 63.5 percent were on MAT at entry and were continued on MAT, and 36.5 percent were initiated on MAT soon after entry. Most (61 percent) received methadone, and 39 percent received buprenorphine. After release, at least 72 percent were confirmed to have continued with MAT—95 percent of those who were on it at time of entry and 32 percent of those induced after entry. Research showed that this program reduced postrelease deaths by 60 percent and all opioid-related deaths in the state by more than 12 percent.¹⁰⁹

APPENDIX I: SUBSTANCE USE DISORDER SCREENING TOOLS

The National Institute on Drug Abuse (2015) offers a list of screening tools that have been found to be effective for adults and adolescents.

FOR ALCOHOL

- Alcohol Screening and Brief Intervention for Adolescent and Youth: A Practitioner's Guide
- Alcohol Use Disorders Identification Test (AUDIT)
- Alcohol Use Disorders Identification Test-C (AUDIT-C)
- Brief Screener for Tobacco, Alcohol, and Other Drugs (BSTAD)
- Center for Adolescent Substance Abuse Research: CRAFFT
- CRAFFT (Part A)
- Helping Patients Who Drink Too Much: A Clinician's Guide
- NIDA Drug Use Screening Tool
- NIDA Drug Use Screening Tool: Quick Screen
- Screening to Brief Intervention (S2BI)

FOR DRUGS

- Brief Screener for Tobacco, Alcohol, and Other Drugs (BSTAD)
- CRAFFT
- CRAFFT (Part A)
- DAST 20: Adolescent Version
- Drug Abuse Screen Test (DAST-10)
- NIDA Drug Use Screening Tool
- NIDA Drug Use Screening Tool: Quick Screen
- Opioid Risk Tool
- S2BI

APPENDIX II: SUBSTANCE USE DISORDER TREATMENT PROGRAMS

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

NIDA lists the following substance use disorder treatment programs:

- Behavioral therapies, including multisystemic therapy (MST)¹¹⁰
- Cognitive behavioral therapy (CBT)
- Community reinforcement approach (CRA) plus vouchers
- Contingency management (CM) interventions/motivational incentives
- Family behavior therapy (FBT)
- The Matrix Model
- Motivational enhancement therapy (MET)
- Therapeutic communities (TC)
- Twelve-step facilitation therapy

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

SAMHSA lists the following research-based alcohol and substance use disorder treatment programs for youth (aged 18–25) and adults (aged 26–55) in correctional facilities:

- Buprenorphine Treatment Practitioner Locator¹¹¹
- Correctional therapeutic community (CTC) for alcohol and substance abusers 6 months from prison release
- Creating Lasting Family Connections Fatherhood Program (CLFCFP), family reintegration for men
- Forever Free for women
- Helping Women Recover and Beyond Trauma for Women (manual-driven treatment)
- Interactive journaling
- Living in Balance (LIB) (manual-based)
- Moral Reconation Therapy (MRT) (cognitive behavioral approach)
- Opioid Treatment Program Directory¹¹²

- Texas Christian University (TCU) Mapping-Enhanced Counseling (MEC), a communication and decision-making technique to support the delivery of treatment services¹¹³

U.S. DEPARTMENT OF JUSTICE

Crime Solutions, the Justice Department registry of research-based programs and practices, lists the following practices as “effective,” mostly for reducing drug and substance use, specifically for individuals involved in the criminal justice system:

- Incarceration-based therapeutic communities for adults (effective for reducing crime and delinquency)
- Mentoring at-risk youth (effective for reducing crime and delinquency, promising for reducing drug and substance use)
- Motivational interviewing for substance use (effective for reducing drug and substance use)
- Opiate maintenance therapy for dual heroin-cocaine abusers (effective for reducing drugs and substance use for heroin/opioids)

Crime Solutions also includes the following practices found to be “promising,” also mostly for reducing drug and substance use:

- Adult drug courts (reducing crime and delinquency)
- Cognitive behavioral therapy for moderate to high-risk adults (reducing crime and delinquency)
- Incarceration-based narcotics maintenance treatment (reducing drug and substance use but no effect on crime and delinquency)¹¹⁴

It should be noted that the practices involving MAT have not been shown to be effective in reducing crime and delinquency outcomes. However, as noted in MAT’s description of “meta-analysis outcomes” relating to the finding that incarceration-based narcotics maintenance treatment has not been found to be effective in reducing crime and delinquency, this finding is influenced by the presence of a negative outlier. When this outlier is removed, the difference is no longer significant in terms of recidivism.¹¹⁵

APPENDIX III: ADVISORY ROUNDTABLE

MEMBERSHIP

Advisory Roundtable, February 3, 2017

FEDERAL PARTICIPANTS

- Co-Chair Stephen Amos, Chief, Jails Division, National Institute of Corrections
- Co-Chair Ruby Qazilbash, Associate Deputy Director, Bureau of Justice Assistance
- Anita Grant, Captain, United States Public Health Service, National Institute of Corrections
- Sandora Cathcart, Correctional Program Specialist, National Institute of Corrections
- Ronald Taylor, Chief of the Prisons Division, National Institute of Corrections
- Tim Jeffries, Senior Policy Advisor, Bureau of Justice Assistance
- DeAnna Hoskins, Policy Advisory, Bureau of Justice Assistance
- June Sivilli, Division Chief, Public Health & Public Safety, Office of National Drug Control Policy
- Nataki MacMurray, Public Health & Public Safety Analyst, Office of National Drug Control Policy
- Sidney Hairston, Public Health Advisor, Division of Pharmacological Therapies, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration
- Jennie Simpson, Policy Advisor, Substance Abuse and Mental Health Services Administration
- Annie Hollis, Health Insurance Specialist, Division of Benefits and Coverage, Centers for Medicare and Medicaid
- Tisha Wiley, Health Services Administrator, National Institute on Drug Abuse

REPRESENTATIVES FROM MODEL MAT PROGRAMS

PRISONS

- Chris Bina, Director, Pharmacy Services, Health Services Division, Bureau of Prisons
- Chris Mitchel, Assistant Deputy Commissioner, Massachusetts Department of Correction
- Kevin Pangburn, Director, Division of Substance Abuse, Kentucky Department of Corrections
- Jennifer Clarke, Medical Programs Director, Rhode Island Department of Corrections
- Shannon Robinson, Senior Psychiatry Supervisor, California Department of Corrections and Rehabilitation

SHERIFFS/JAILS

- Brad Rose, Sergeant, Sacramento County Sheriff's Department, California
- Peter Koutoujian, Sheriff, Middlesex County House of Correction, Massachusetts
- Dennis Wilson, President, Sheriffs' Association of Texas, Sheriff of Limestone County, Texas
- Carolina Montoya, Director, Office of Rehabilitation Services, Miami-Dade County Department of Corrections and Rehabilitation, Florida
- Cornita Riley, Jail Administrator, Orange County, Florida

DRUG COURTS

- Kimberly Kozlowski, Project Director, Syracuse Community Treatment Court & Onondaga City Family Treatment Court
- Hon. Robert Ziemian, District Court Judge, Massachusetts

POLICE/ PRETRIAL DIVERSION

- Fred Ryan, Chief, Arlington, Massachusetts, Police Council Chair, Police Assisted Addiction Recovery Initiative
- Elizabeth Simoni, Executive Director, Maine Pretrial Services
- Kathleen O'Toole, Chief of Police, Seattle, Washington

PROBATION AND PAROLE

- Sue De Lacy, Administrative Manager, Orange County Probation, California
- Alison Morgan, Deputy Director, Colorado Department of Parole

CORRECTIONAL AND RELATED ASSOCIATIONS

- Veronica Cunningham, Executive Director, American Probation and Parole Association
- Maeghan Gilmore, Program Director, Health, Human Services and Justice, National Association of Counties
- Jonathan Thompson, Executive Director, National Sheriffs' Association
- Jessica Vanderpool, Special Projects Director, National Sheriffs' Association
- Wayne Dickey, President, American Jail Association, Administrator, Brazos County Jail, Texas
- James Martin, Accreditation Specialist, National Commission on Correctional Health Care
- Beth Haynes, Manager, Quality and Science, American Society of Addiction Medicine
- Jeffrey Locke, Senior Policy Analyst, Homeland Security & Public Safety Division, National Governors Association

RESIDENTIAL SUBSTANCE ABUSE TREATMENT TRAINING AND TECHNICAL ASSISTANCE

- Facilitator, Andrew Klein, Project Director, Advocates for Human Potential
- Steve Valle, President, AdCare Criminal Justice Services
- Lisa Talbot Lundrigan, RSAT Faculty (ACA), Vice President, AdCare Criminal Justice Services
- Neal Shifman, President & CEO, Advocates for Human Potential
- Niki Miller, Senior Research Associate, Advocates for Human Potential

POLICY RESEARCH ORGANIZATIONS AND RESEARCHERS

- Richard Cho, Director of Behavioral Health, Council of State Government Justice Center
- Cynthia Reilly, Director of Prescription Drug Abuse Project, The Pew Charitable Trusts
- Joshua Lee, Associate Professor, New York University School of Medicine
- Mary Alice Conroy, Distinguished Professor of Psychology, Clinic Director, Sam Houston State University

REFERENCES

1. National Institute on Drug Abuse. (2016). Advancing addiction science, effective treatment for opioid addiction. <https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction>
- Substance Abuse and Mental Health Services Administration. (2018). Tip 63: Medications for opioid use disorders. (HHS Publication No. [SMA] 18-5063EXSUMM). Rockville, MD. <https://store.samhsa.gov/product/SMA18-5063EXSUMM>
2. Gelber, S., & Rinaldo, D. W. (2013, June). Report III: FDA-approved medications indicated for the treatment of opioid dependence: Literature reviews on effectiveness and cost-effectiveness, Treatment Research Institute (TRI), 2013. In American Society for Addiction Medicine (Ed.), Advancing Access to Addiction Medications. http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final
- National Institutes of Health. (1997, November 19). Effective medical treatment of opiate addiction. NIH Consensus Statement, 15(6), 15–17. <http://consensus.nih.gov/1997/1998TreatOpiateAddiction108PDF.pdf>
- Executive Office of the President, Office of National Drug Control Policy. (1996, March). Treatment protocol effectiveness study. <https://www.ncjrs.gov/ondcppubs/publications/treat/trmtprot.html>
- National Institute on Drug Abuse. (2016, November 1). Effective treatments for opioid addiction. <https://www.drugabuse.gov/effective-treatments-opioid-addiction-0>
- Fu, J. J., Zaller, N. D., Yokell, M. A., Bazazi, A. R., & Rich, J. D. (2013, May–June). Forced withdrawal from methadone maintenance therapy in criminal justice settings: A critical treatment barrier in the United States. *Journal of Substance Abuse Treatment*, 44(5), 502–505. doi: 10.1016/j.jsat.2012.10.005
- Kakko, J., Svanborg, K. D., Kreek, M. J., & Heilig, M. (2003, February 22). 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: A randomised, placebo-controlled trial. *The Lancet*, 361(9358), 662–668. doi: 10.1016/S0140-6736(03)12600-1
3. Cornish, J. W., Metzger, D., Woody, G. E., Wilson, D., McLellan, A. T., & Vandergrift, B. (1997). Naltrexone pharmacotherapy for opioid dependent federal probationers. *Journal of Substance Abuse Treatment*, 14, 529–534.
- Dolan, K. A., Shearer, J., White, B., Zhou, J., Kaldor, J., & Wodak, A. D. (2005). Four-year follow-up of imprisoned male heroin users and methadone treatment: Mortality, re-incarceration and hepatitis C infection. *Addiction*, 100, 820–828.
- Gordon, M. S., Kinlock, T. W., Schwartz, R. P., Fitzgerald, T. T., O’Grady, K. E., & Vocci, F. J. (2008). A randomized clinical trial of methadone maintenance for prisoners: Findings at 6 months post-release. *Addiction*, 103, 1333–1342.
- Kinlock, T. W., Gordon, M. S., Schwartz, R. P., & O’Grady, K. E. (2008). A study of methadone maintenance for male prisoners: Three-month postrelease outcomes. *Criminal Justice & Behavior*, 35, 34–47.
- Lee, J., McDonald, R., Grossman, E., McNeely, J., Laska, E., Rotrosen, J., & Gourevitch, M. N. (2015). Opioid treatment at release from jail using extended release naltrexone. *Addiction*, 110(6), 1008–1014.
- Magura, S., Lee, J. D., Hersherberger, J., Joseph, H., Marsch, L., Shropshire, C., & Rosenblum, A. (2009). Buprenorphine and methadone maintenance in jail and post-release: A randomized clinical trial. *Drug & Alcohol Dependence*, 99, 222–230.
- O’Brien, C. P., & Cornish, J. W. (2006). Naltrexone for probationers and prisoners. *Journal of Substance Abuse Treatment*, 31, 107–111.
- Rich, J. D., McKenzie, M., Larney, S., Wong, J. B., Tran, L., Clarke, J., ... Zaller, N. (2015). Methadone continuation versus forced withdrawal on incarceration in a combined U.S. prison and jail: A randomized, open-label trial. *The Lancet*, 386(9991), 350–359.
- Stallwitz, A., & Stover, H. (2006). The impact of substitution treatment in prisons—A literature review. *International Journal of Drug Policy*, 18, 464–474.
4. Pope, L. (2018, January 24). The role of jails in combatting the opioid crisis (Think Justice blog). Vera Institute of Justice. <https://www.vera.org/blog/the-role-of-jails-in-combatting-the-opioid-crisis>

5. National League of Cities and National Association of Counties. (2016). A Prescription for Action: Local Leadership in Ending the Opioid Epidemic. <http://opioidaction.org/report>
6. SAMHSA, op. cit. ES-3.
7. Smith, K., & Strashny, A. (2016, April 26). Characteristics of criminal justice system referrals discharged from substance abuse treatment and facilities with specially designed criminal justice programs. The CBHSQ Report. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. https://www.samhsa.gov/data/sites/default/files/report_2321/ShortReport-2321.html
8. An agonist is a drug that activates certain receptors in the brain. Full agonist opioids activate the opioid receptors in the brain fully, resulting in the full opioid effect. Examples of full agonists are heroin, oxycodone, methadone, hydrocodone, morphine, and opium. An antagonist is a drug that blocks opioids by attaching to the opioid receptors without activating them. Antagonists cause no opioid effect and block fully agonist opioids. Examples are naltrexone and naloxone. Naloxone is sometimes used to reverse a heroin overdose. Buprenorphine is a partial agonist, meaning that it activates the opioid receptors in the brain, but to a much lesser degree than a full agonist. https://www.naabt.org/faq_answers.cfm?ID=5
9. Wesson, D. R., & Ling, W. (2003). The clinical opiate withdrawal scale (COWS). *Journal of Psychoactive Drugs*, 35(2), 253–259.
10. Cunningham, C., & Fishman, M. The ASAM national practice guideline for the use of medications in the treatment of addiction involving opioid use. <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-pocketguide.pdf?sfvrsn=0>
11. Sullivan, J. T., Sykora, K., Schneiderman, J., Naranjo, C. A., & Sellers, E. M. (1989). Assessment of alcohol withdrawal: The revised Clinical Institute Withdrawal Assessment for Alcohol scale (CIWA-Ar). *British Journal of Addiction*, 84, 1353–1357.
12. Heinzerling, K. G., Ober, A. J., Lamp, K., De Vries, D., & Watkins, K. E. (2016). SUMMIT: Procedures for medication-assisted treatment of alcohol or opioid dependence in primary care. The RAND Corporation and the National Institute on Drug Abuse. http://www.integration.samhsa.gov/clinical-practice/mat/RAND_MAT_guidebook_for_health_centers.pdf
13. Institute of Behavioral Research. (2014). Texas Christian University Drug Screen V. <https://libr.tcu.edu/forms/tcu-drug-screen/>
14. Clark, K. J. (n.d.). PCSS MAT training, MAT in the OTP setting: Integrating the three approved medications (methadone, buprenorphine, ER naltrexone), Slide 41, American Society of Addiction Medicine. <http://pcssmat.org/wp-content/uploads/2014/09/ASAM-PCSS-MAT-KClark-yo-updated-final-revision3.pdf>
15. Binswanger, I. A., Blatchford, P. J., Mueller, S. R., & Stern, M. F. (2013). Mortality after prison release: Opioid overdose and other causes of death, risk factors, and time trends from 1999 to 2009. *Annals of Internal Medicine*, 159(9), 592–600.
16. Sordo, L., Barrio, G., Bravo, M. J., Indave, B. I., Degenhardt, L., Wiessing, L., ... Pastor-Barriuso, R. (2017). Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of cohort studies. *BMJ*, 357, j1550.
17. Walley, A. Y., Xuan, Z., Hackman, H. H., Quinn, E., Doe-Simkins, M., Sorensen-Alawad, A., ... Ozonoff, A. (2013). Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: Interrupted time series analysis. *BMJ*, 346, f174.
18. Standards for opioid treatment programs in correctional facilities. (2016). Standard O-E-02 Health Assessments. Chicago, IL: National Commission on Correctional Health Care.
19. Tanum, L., Klemmetsby Solli, K., e-Huma Latif, Z., Saltyte Benth, J., Opheim, A., Sharma-Haase, K., & Kunø, N. (2017). Effectiveness of injectable extended-release naltrexone vs. daily buprenorphine-baloxone for opioid dependence: A randomized clinical noninferiority trial. *Journal of the American Medical Association Psychiatry*. 74(12):1197–1205. <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2657484>
20. Diversion Control Division, Drug Enforcement Administration, U.S. Department of Justice. Narcotic Treatment Programs Best Practice Guideline. <https://www.dea/diversion.usdoj.gov/pubs/manuals/narcotic/appendixa/treatment.htm>
21. For information for physicians on the waiver application and management process to prescribe or dispense buprenorphine for opioid dependency treatment, see <https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver>.
22. Cunningham, C., & Fishman, M. The ASAM national practice guideline for the use of medications in the treatment of addiction involving opioid use. <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-pocketguide.pdf?sfvrsn=0>
23. Highlights of prescribing information [for Vivitrol]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021897s020s023lbl.pdf
24. Mattick, R. P., Breen, C., Kimber J., & Davoli, M. (2014, February). Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence, Cochrane. http://www.cochrane.org/CD002207/ADDICTN_buprenorphine-maintenance-versus-placebo-or-methadone-maintenance-for-opioid-dependence

25. Sordo, L., Barrio, G., Bravo, M. J., Iciar Indave, B., Degenhardt, L., Wiessing, L., Ferri, M., & Pastor-Barriuso, R. (2017, April 26). Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of cohort studies, *BMJ*, 357, j1550.
26. Gibson, A. E., Degenhardt, L. J., (2007). Mortality related to pharmacotherapies for opioid dependence: a comparative analysis of coronial records. *Drug and Alcohol Review*, 26(4), 405-410.
27. Lee, J., Friedmann, P. D., Kinlock, T. W., Nunes, E. V., Boney, T. Y., Hoskinson, R. A., & O'Brien, C. P. (2016, March 31). Extended-release naltrexone to prevent opioid relapse in criminal justice offenders. *New England Journal of Medicine*, 374, 1232–1242.
28. Larochelle, M. R., Bernson, D., Land, T., Stopka, T. J., Wang, N., Xuan, Z., & Walley, A. Y. (2018). Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: a cohort study. *Annals of Internal Medicine*, 169(3), 137-145.
29. Lee, J., Friedmann, P. D., Kinlock, T. W., Nunes, E. V., Boney, T. Y., Hoskinson, R. A., & O'Brien, C. P. (2016, March 31). Extended-release naltrexone to prevent opioid relapse in criminal justice offenders. *New England Journal of Medicine*, 374, 1232–1242.
30. Volkow, N. D., Koob, G. F., & McLellan, A. T. (2018). Neurobiologic advances from the brain disease model of addiction. *New England Journal of Medicine*, 374(4), 363-371.
31. Substance Abuse and Mental Health Services Administration. (2016). Sublingual and transmucosal buprenorphine for opioid use disorder: Review and update. SAMHSA Advisory, 15(1), 1–12. <http://store.samhsa.gov/shin/content//SMA16-4938/SMA16-4938.pdf>
32. American Society of Addiction Medicine. (2015, June 1). The ASAM national practice guideline for the use of medications in the treatment of addiction involving opioid use. <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>
33. Fiellin, D. A., Schottenfeld, R. S., Cutter, C. J., Moore, B. A., Barry, D. T., & O'Connor, P. G. (2014, December). Primary care–based buprenorphine taper vs. maintenance therapy for prescription opioid dependence: A randomized clinical trial. *JAMA Internal Medicine*, 174(12), 1947–1954. doi: 10.1001/jamainternmed.2014.5302
34. Center for Substance Abuse Treatment. (2005). Medication-assisted treatment for opioid addiction in opioid treatment programs. Treatment Improvement Protocol (TIP) Series 43 (HHS Publication No. [SMA] 12-4214). Rockville, MD: Substance Abuse and Mental Health Services Administration. <http://store.samhsa.gov/product/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs/SMA12-4214>
- D. Mee-Lee (Ed.). (2013, October 24). The ASAM criteria: Treatment criteria for addictive, substance-related, and co-occurring conditions (e-page 293). Rockville, MD: American Society of Addiction Medicine. (Noting that “the notion that the duration of treatment varies . . . is a foundational principle of the ASAM criteria.”)
35. National Institute on Drug Abuse. (2016, November 1). Effective treatments for opioid addiction. <https://www.drugabuse.gov/effective-treatments-opioid-addiction-0>
36. National Institute on Drug Abuse. (2018, January 17). Principles of drug addiction treatment: A research-based guide (third edition). <https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition>
37. Potter, J. S., Dreifuss, J. A., Marino, E. N., Provost, S. E., Dodd, D. R., Rice, L. S., & Weiss, R. D. (2015). The multisite prescription opioid addiction treatment study: 18-month outcomes. *Journal of Substance Abuse Treatment*, 48(1), 62–69.
- Weiss, R. D., Potter, J. S., Griffin, M. L., Provost, S. E., Fitzmaurice, G. M., McDermott, K. A., & Carroll, K. M. (2015). Long-term outcomes from the National Drug Abuse Treatment Clinical Trials Network Prescription Opioid Addiction Treatment Study. *Drug and Alcohol Dependence*, 150(1), 112–119.
38. Lee, J. D., Friedmann, P. D., Kinlock, T. W., Nunes, E. V., Boney, T. Y., Hoskinson, Jr., R. A., & O'Brien, C. P. (2016, March 31). Extended-release naltrexone to prevent opioid relapse in criminal justice offenders. *New England Journal of Medicine*, 374, 1232–1242. doi: 10.1056/NEJMoa1505409
39. Agency for Healthcare Research and Quality. (August 2016). Pharmacotherapy for adults with alcohol use disorder in outpatient settings. <https://effectivehealthcare.ahrq.gov/topics/alcohol-misuse-drug-therapy/policymaker>
40. Peitras, S., Azur, M., & Brown, J. (2015, November 25). Review of medication-assisted treatment guidelines and measures for opioid and alcohol use (Appendix B, Table B 1 from SAMHSA and NIAAA: Brief guide to medication for the treatment of alcohol use disorder). <https://aspe.hhs.gov/system/files/pdf/205171/MATguidelines.pdf>
41. Cochrane Primary Care. Naltrexone effective for alcohol dependence. <https://www.cochranepriarycare.org/pearls/naltrexone-effective-alcohol-dependence>
42. Centers for Disease Control and Prevention. (2003, July 18). Incorporating HIV prevention into the care of persons living with HIV. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5212a1.htm>
43. Federal Guidelines for Opioid Treatment Programs. <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>
44. American Society of Addiction Medicine. (2013, October 26). Drug Testing: A White Paper of the American Society of Addiction Medicine (ASAM). <http://www.asam.org/docs/default-source/public-policy-statements/drug-testing-a-white-paper-by-asam.pdf>
45. American College of Obstetricians and Gynecologists. Opioid use and opioid use disorder in pregnancy. <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Opioid-Use-and-Opioid-Use-Disorder-in-Pregnancy>

46. Center for Substance Abuse Treatment. (2009). Substance abuse treatment: Addressing the specific needs of women. Treatment Improvement Protocol (TIP) Series, No. 51. (HHS Publication No. [SMA] 14-4426). <http://store.samhsa.gov/shin/content/SMA14-4426/SMA14-4426.pdf>
47. American College of Obstetricians and Gynecologists. (2012, May). ACOG Committee Opinion No. 524: Opioid abuse, dependence, and addiction in pregnancy. *Obstetrics & Gynecology*, 119(5), 1070–1076. <https://www.ncbi.nlm.nih.gov/pubmed/22525931>
48. National Institutes of Health, U.S. National Library of Medicine. (2015). Neonatal abstinence syndrome. www.nlm.nih.gov/medlineplus/ency/article/007313.htm
49. Jones, H. E., Martin, P. R., Heil, S. H., Kaltenbach, K., Selby, P., Coyle, M. G., & Fischer, G. (2008, October). Treatment of opioid-dependent pregnant women: Clinical and research issues. *Journal of Substance Abuse Treatment*, 35(3), 245–259. doi: 10.1016/j.jsat.2007.10.007
50. American College of Obstetricians and Gynecologists. (2012, May). ACOG Committee Opinion No. 524: Opioid abuse, dependence, and addiction in pregnancy. *Obstetrics & Gynecology*, 119(5), 1070–1076. <https://www.ncbi.nlm.nih.gov/pubmed/22525931>
51. Unger, A., Metz, V., & Fischer, G. (2012). Opioid dependent and pregnant: What are the best options for mothers and neonates? *Obstetrics and Gynecology International*, Article ID 195954. doi: 10.1155/2012/195954
52. National Commission on Correctional Health Care. (2014, October 19). Women's health care in correctional settings (position statement). <http://www.ncchc.org/womens-health-care>
- American College of Obstetricians and Gynecologists. (2011, November, reaffirmed 2016). Health care for pregnant and postpartum incarcerated women and adolescent females. Committee Opinion, Number 511. <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Pregnant-and-Postpartum-Incarcerated-Women-and-Adolescent-Females>
53. Sigmon, S. C., Ochalek, T. A., Meyer, A. C., Hruska, B., Heil, S. H., Badger, G. J., & Higgins, S. T. (2016, December 22). Interim buprenorphine vs. waiting list for opioid dependence. *New England Journal of Medicine*, 375, 2504–2505. doi: 10.1056/NEJMc1610047
54. Crime Solutions, the U.S. Justice Department National Institute of Justice registry of evidence-based programs. <https://www.crimesolutions.gov/>
55. Godley, S. H., White, W. L., Diamond, G., Passetti, L. L., & Titus, J. C. (2001). Therapist reactions to manual-guided therapies for the treatment of adolescent marijuana users. *Clinical Psychology Scientific Practice*, 8, 405–417. doi: 10.1093/clipsy.8.4.405
56. Dowden, C. & Andrews, D. A. (2004, April 1). The importance of staff practice in delivering effective correctional treatment: A meta-analytic review of core correctional practice. *International Journal of Offender Therapy and Comparative Criminology*, 48 (2), 203–214. doi: 10.1177/0306624X03257765
57. Substance Abuse and Mental Health Services Administration. (2015, March). Federal guidelines for opioid treatment programs. (HHS Publication No. [SMA] PEP15-FEDGUIDEOTP). Rockville, MD. <http://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf>
58. Taxman, F., Thanner, M., & Wesburd, D. (2006, January 1). Risk, need, and responsivity (RNR): It all depends. *Crime & Delinquency*, 61(9), 1.
59. Bonta, J., & Andrews, D. (2007). Risk-Need-Responsivity model for offender assessment and rehabilitation, 2007–06. Canada: Public Safety Canada & Carleton University.
60. Lowenkamp, C., & Latessa, E. (2005). Increasing the effectiveness of correctional programming through the risk principle: Identifying offenders for residential placement. *Criminology & Public Policy*, 4(2), 263–290.
61. Andrews, D., Bonita, J., & Wormith, S. (2011, June). The Risk-Need-Responsivity (RNR) Model: Does adding the good lives model contribute to effective crime prevention? *Criminal Justice Behavior*, 38(7), 735–755.
62. Anglin, M. D., Prendergast, M., & Farabee, D. (1998, March 23–25). The effectiveness of coerced treatment for drug-abusing offenders. Presented at the Office of National Drug Control Policy's Conference of Scholars and Policy Makers. Washington, DC.
- Coviello, D. M., Zanis, D. A., Wesnoski, S. A., Palman, N., Gur, A., Lynch, K. G., & McKay, J. R. (2013, April). Does mandating offenders to treatment improve completion rates? *Journal of Substance Abuse Treatment*, 44(4), 417–425. doi: 10.1016/j.jsat.2012.10.003
63. Friedman, S., & Wagner-Goldstein, K. (2015). Medication-assisted treatment in drug courts: Recommended strategies. Center for Court Innovation, State of New York Unified Court System, and Legal Action Center. <https://lac.org/wp-content/uploads/2016/04/MATinDrugCourts.pdf>
64. Ibid.
65. An agonist is a drug that activates certain receptors in the brain. Full agonist opioids activate the opioid receptors in the brain fully, resulting in the full opioid effect. Examples of full agonists are heroin, oxycodone, methadone, hydrocodone, morphine, opium, and others. An antagonist is a drug that blocks opioids by attaching to the opioid receptors without activating them. Antagonists cause no opioid effect and block fully agonist opioids. Examples are naltrexone and naloxone. Naloxone is sometimes used to reverse a heroin overdose. Buprenorphine is a partial agonist, meaning that it activates the opioid receptors in the brain, but to a much lesser degree than a full agonist. https://www.naabt.org/faq_answers.cfm?ID=5

66. Gordon, M. S., Kinlock, T. W., Schwartz, R. P., Fitzgerald, T. T., O'Grady, K. E., & Vocci, F. J. (2014, September 1). A randomized controlled trial of prison-initiated buprenorphine: Prison outcomes and community treatment entry. *Journal of Drug and Alcohol Dependence*, 142, 33–40. doi: 10.1016/j.drugalcdep.2014.05.011
67. Substance Abuse and Mental Health Services Administration. (2015, March). Federal guidelines for opioid treatment programs. (HHS Publication No. [SMA] PEP15-FEDGUIDEOTP). <https://store.samhsa.gov/product/PEP15-FEDGUIDEOTP>
68. Substance Abuse and Mental Health Services Administration. (2014). National Survey of Substance Abuse Treatment Services (N-SSATS): 2013. Data on Substance Abuse Treatment Facilities. (BHSIS Series S-73, HHS Publication No. [SMA] 14-489). Rockville, MD. Retrieved from https://www.samhsa.gov/data/sites/default/files/2013_N-SSATS/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services.pdf
69. Pennsylvania Department of Corrections. (2015, October). MAT expansion plan: PA DOC strategies for expanding the use of MAT for justice-involved individuals. <http://www.cor.pa.gov/General%20Information/Documents/Medication%20Assisted%20Treatment/MAT%20Expansion%20Plan.pdf>
70. Substance Abuse and Mental Health Services Administration. (2015, March). Federal guidelines for opioid treatment programs. (HHS Publication No. [SMA] PEP15-FEDGUIDEOTP). Rockville, MD. Available at <http://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf>
71. Cognitive behavioral therapies should be considered specifically for correctional populations.
72. Substance Abuse and Mental Health Services Administration. (2015, March). Federal guidelines for opioid treatment programs. (HHS Publication No. [SMA] PEP15-FEDGUIDEOTP). Rockville, MD. <http://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf>
73. For more information on these standards, visit <https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs>.
74. Gordon, A. J., Lo-Ciganic, W. H., Cochran, G., Gellad, W. F., Cathers, T., Kelley, D., & Donohue, J. M. (2015, November–December). Patterns and quality of buprenorphine opioid agonist treatment in a large Medicaid program. *Journal of Addiction Medicine*, 9(6), 470–477. doi: 10.1097/ADM.0000000000000164
75. Substance Abuse and Mental Health Services Administration. (2015). National Survey of Substance Abuse Treatment Services (N-SSATS): 2014. Data on Substance Abuse Treatment Facilities. (BHSIS Series S-79, HHS Publication No. [SMA] 16-4963). http://www.samhsa.gov/data/sites/default/files/2014_National_Survey_of_Substance_Abuse_Treatment_Services/2014_National_Survey_of_Substance_Abuse_Treatment_Services/2014_National_Survey_of_Substance_Abuse_Treatment_Services.pdf
76. Telepractice Standards for OASAS Designated Providers. New York State Office of Alcoholism and Substance Abuse Services. <https://www.oasas.ny.gov/regs/documents/TelepracticeStandards.pdf>
77. Coviello, D. M., Zanis, D. A., Wesnoski, S. A., Palman, N., Gur, A., Lynch, K. G., & McKay, J. R. (2013). Does mandating offenders to treatment improve completion rates? *Journal of Substance Abuse Treatment*, 44(4), 417–425. <http://doi.org/10.1016/j.jsat.2012.10.003>
78. Friedmann, P. D., Ducharme, L. J., Welsh, W., Frisman, L., Knight, K., Kinlock, T., & Pankow, J. (2013, December 19). A cluster randomized trial of an organizational linkage intervention for offenders with substance use disorders: Study protocol. *Journal of Health and Justice*, 1(6). doi: 10.1186/2194-7899-1-6
- Friedmann, P. D., Wilson, D., Knudsen, H. K., Ducharme, L. J., Welsh, W. N., Frisman, L., & Vocci, F. J. (2015, March). Effect of an organizational linkage intervention on staff perceptions of medication-assisted treatment and referral intentions in community corrections. *Journal of Substance Abuse Treatment*, 50, 50–58. doi: 10.1016/j.jsat.2014.10.001
- Welsh, W. N., Knudsen, H. K., Knight, K., Ducharme, L., Pankow, J., Urbine, T., & Friedmann, P. D. (2016, January). Effects of an organizational linkage intervention on interorganizational service coordination between probation/parole agencies and community treatment providers. *Journal of Administration and Policy in Mental Health and Mental Health Services Research*, 43(1), 105–121. doi: 10.1007/s10488-014-0623-8
79. Gordon, M., Kinlock, T. W., Schwartz, R. P., O'Grady, K. E., Fitzgerald, T. T., & Vocci, F. J. (2017). A randomized clinical trial of buprenorphine for prisoners: Findings at 12-months post-release. *Drug and Alcohol Dependence*, 172, 34–42.
80. Merrill, E. L., Kariminia, A., Binswanger, I. A., Hobbs, M. S., Farrell, M. Marsden, J. ... Bird, S. M. (2010). Meta-analysis of drug-related deaths soon after release from prison. *Addiction*, 105(9) 1545-1554.
81. Green, T. C., Clarke, J., Brinkley-Rubinstein, L., Marshall, B., Alexander-Scott, N., Boss, R., & Rich, J. D. (2018). Postincarceration fatal overdoses after implementing medications for addiction treatment in a statewide correctional system. *JAMA Psychiatry*, 75(4) 405-407.
82. Substance use disorder treatment for adults and adolescents (position statement). (2016). Chicago, IL: National Commission on Correctional Health Care. <https://www.ncchc.org/substance-use-disorder-treatment-for-adults-and-adolescents>
83. Moore, K. E., Oberleitner, L., Smith, K. M. Z., Maurer, K., & McKee, S. A. (2018). Feasibility and effectiveness of continuing methadone maintenance treatment during incarceration compared with forced withdrawal. *Journal of Addiction Medicine*, 12(2), 156–162.
84. Rich, J. D., McKenzie, M., Larney S., Wong, J. B., Tran, L., Clarke, J., ... Zaller, N. (2015). Methadone continuation versus forced withdrawal on incarceration in a combined U.S. prison and jail: A randomised, open-label trial. *Lancet*, 386(9991), 350–359.

85. Alex, B., Weiss, D. B., Kaba, F., Rosner, Z., Lee, D., Lim, S., ... MacDonald, R. (2017). Death after jail release: matching to improve care delivery. *Journal of Correctional Health Care*, 23(1), 83-87.
86. Green, T. C., Clarke, J., Brinkley-Rubinstein, L., Marshall, B., Alexander-Scott, N., Boss, R., & Rich, J. D. (2018). Postincarceration fatal overdoses after implementing medications for addiction treatment in a statewide correctional system. *JAMA Psychiatry*, 75(4) 405-407.
87. Standards for opioid treatment programs in correctional facilities. (2016). Chicago, IL: National Commission on Correctional Health Care.
88. Kinlock, T. W., Gordon, M. S., Schwartz, R. P., Fitzgerald, T. T., & O'Grady, K. E. (2009, October). A randomized clinical trial of methadone maintenance for prisoners: Results at 12 months post release. *Journal of Substance Abuse Treatment*, 37(3), 277-285.
89. Alderks, C. (2017, August 22). Trends in the use of methadone, buprenorphine, and extended-release naltrexone at substance abuse treatment facilities: 2003-2015 (update). The CBHSQ Report. Retrieved from the Substance Abuse and Mental Health Services Administration website: https://www.samhsa.gov/data/sites/default/files/report_3192/ShortReport-3192.html
90. Substance Abuse and Mental Health Services Administration. (2006). Detoxification and substance abuse treatment. Treatment Improvement Protocol (TIP) Series, No. 45. (HHS Publication No. [SMA] 134131). <https://store.samhsa.gov/shin/content/SMA13-4131/SMA13-4131.pdf>.
- Roberts, A., Hayes, A., Carlisle, J., & Shaw, J. (2007). Review of drug and alcohol treatments in prison and community settings: A systematic review conducted on behalf of the Prison Health Research Network. England: University of Manchester.
91. Rich, J. D., McKenzie, M., Larney, S., Wong, J. B., Tran, L., Clarke, J., & Zaller, N. (2015, July 25). Methadone continuation versus forced withdrawal on incarceration in a combined U.S. prison and jail: A randomised, open-label trial. *The Lancet*, 386(9991), 350-359. doi: 10.1016/S0140-6736(14)62338-2.
- Maradiaga, J. A., Nahvi, S., Cunningham, C. O., Sanchez, J., & Fox, A. D. (2016, March). "I kicked the hard way. I got incarcerated." Withdrawal from methadone during incarceration and subsequent aversion to medication-assisted treatments. *Journal of Substance Abuse Treatment*, 62, 49-54. doi: 10.1016/j.jsat.2015.11.004
92. Wilcox, T. (2016, Summer). Managing opiate withdrawal: The WOWS method. *CorrectCare*. <http://www.ncchc.org/filebin/CorrectCare/30-3-WOWS.pdf>
- Substance Abuse and Mental Health Services Administration. (2016). Pocket guide: Medication-assisted treatment of opioid use disorder (HHS Publication No. [SMA] 16-4892PG). <http://store.samhsa.gov/product/Medication-Assisted-Treatment-of-Opioid-Use-Disorder-Pocket-Guide/SMA16-4892PG>
93. Fiscella, K. (2015, September). Guide to developing and revising alcohol and opioid detoxification protocols. <http://www.ncchc.org/filebin/Resources/Detoxification-Protocols-2015.pdf>
94. Fiscella, K., Moore, A., Engerman, J., & Meldrum, S. (2004). Jail management of arrestees/inmates enrolled in community methadone maintenance programs. *Journal of Urban Health: Bulletin of the New York Academy of Medicine*, 81(4), 645-654.
95. Substance Abuse and Mental Health Services Administration. (2006). Detoxification and substance abuse treatment. Treatment Improvement Protocol (TIP) Series, No. 45. (HHS Publication No. [SMA] 134131). <https://store.samhsa.gov/shin/content/SMA13-4131/SMA13-4131.pdf>
96. Federal Bureau of Prisons. (2014, February). Detoxification of chemically dependent inmates: Federal Bureau of Prisons clinical practice guidelines. <https://www.bop.gov/resources/pdfs/detoxification.pdf>
97. Cochrane. Clonidine, lofexidine, and similar medications for the management of opioid withdrawal. http://www.cochrane.org/CD002024/ADDICTN_clonidine-lofexidine-and-similar-medications-management-opioid-withdrawal
98. Centers for Disease Control and Prevention. Reverse overdose to prevent death. <https://www.cdc.gov/drugoverdose/prevention/reverse-od.html>
99. Fletcher, B., & Chandler, R. (2014, April). Principles of drug abuse treatment for criminal justice populations: A research-based guide. National Institute on Drug Abuse, No. 11-5316. https://www.drugabuse.gov/sites/default/files/txcriminaljustice_0.pdf
100. Johnson, A. (2017, April 16). Addiction drug Suboxone is popular prison contraband. *Columbus Dispatch*. <http://www.dispatch.com/news/20170416/addiction-drug-suboxone-is-popular-prison-contraband>
101. Rhode Island Department of Corrections. (2016, April 22). Distribution of suboxone protocol, women's facility, 9.14-8, 18.20-2 & 18.52-3, April 22, 2016; (2016, April 16). Distribution of suboxone protocol SOP, supplements policy, 9.14-8, 18.20-2 & 18.52-3.
102. Rich, J. D., McKenzie, M., Larney, S., Wong, J. B., Tran, L., Clarke, J., ... Zaller, N. (2015). Methadone continuation versus forced withdrawal on incarceration in a combined U.S. prison and jail: A randomised, open-label trial. *Lancet*, 386(9991), 350-359.
103. Moore, K. E., Oberleitner, L., Smith, K. M. Z., Maurer, K., & McKee, S. A. (2018). Feasibility and effectiveness of continuing methadone maintenance treatment during incarceration compared with forced withdrawal. *Journal of Addiction Medicine*, 12(2), 156-162.
104. U.S. Government Accountability Office. (2016, September). Opioid addiction: Laws, regulations, and other factors can affect medication-assisted treatment access: Report to the Majority Leader, U.S. Senate. <http://www.gao.gov/assets/690/680050.pdf>

105. Haffajee, R. L., Bohnert, A. S. B., Lagisetty, P. A. (2018). Policy pathways to address provider workforce barriers to buprenorphine treatment. *American Journal of Preventive Medicine*, 54(6S3), S230-S242. [https://www.ajpmonline.org/article/S0749-3797\(18\)30074-6/fulltext](https://www.ajpmonline.org/article/S0749-3797(18)30074-6/fulltext)
106. Miller, N. (n.d.) A Comprehensive Listing of What States Cover for Substance Use Disorder, including Medications. www.rsat-tta.com
107. Council of State Governments Justice Center. Critical Connections —Getting people leaving prison and jail the mental health care and substance use treatment they need: What policymakers need to know about health care coverage, p. 22. <https://files.csgjusticecenter.org/critical-connections/Critical-Connections-Full-Report.pdf>
108. Scott, H. (2018, January 24). Snohomish County taking new approach to opioid crisis. Seattle: MYNorthwest. <http://mynorthwest.com/878895/snohomish-co-opioid-crisis>
109. Green, T. C., Clarke, J., Brinkley-Rubinstein, L., Marshall, B., Alexander-Scott, N., Boss, R., & Rich, J. D. (2018). Postincarceration fatal overdoses after implementing medications for addiction treatment in a statewide correctional system. *JAMA Psychiatry*, 75(4) 405-407.
110. National Institute on Drug Abuse. (2018, January 17). Principles of drug addiction treatment: A research-based guide (3rd edition). <https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition>. These programs are described in Appendix II.
111. For more information about this resource, please see <https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator>.
112. For more information about this resource, please see <http://dpt2.samhsa.gov/regulations/smalist.aspx>.
113. National Institute on Drug Abuse. (2018, January 17). Principles of drug addiction treatment: A research-based guide (3rd edition). <https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition>
114. National Institute of Justice. (n.d.). All programs & practices. <http://www.crimesolutions.gov/Programs.aspx#practices>
115. Ojmarh, M., Wilson, D. B., & MacKenzie, D. L. (2012, November 1). The effectiveness of incarceration-based drug treatment on criminal behavior: A systemic review. *Campbell Systematic Reviews*, 18. doi: 10.4073/csr.2012.18



ABOUT THE NATIONAL SHERIFFS' ASSOCIATION

Chartered in 1940, the National Sheriffs' Association (NSA) is a professional association dedicated to serving the Office of Sheriff and its affiliates. NSA represents thousands of sheriffs and deputies in our nation's 3,300 jails, as well as other law enforcement and public safety professionals and concerned citizens nationwide. Guided by a board of directors and 17 committees, NSA addresses the full range of issues of importance to law enforcement in fulfillment of its mission to support and enhance the professionalism of those whose job it is to serve and protect. It provides its 20,000-plus members with a wide range of services, information, trainings and technical assistance, including a professional magazine, an e-newsletter, and an annual and winter conference. <http://www.sheriffs.org>



ABOUT THE NATIONAL COMMISSION ON CORRECTIONAL HEALTH CARE

NCCHC is a not-for-profit 501(c)(3) organization working to improve the quality of care in our nation's jails, prisons, and juvenile detention and confinement facilities. NCCHC establishes standards for health services in correctional facilities, operates a voluntary accreditation program for institutions that meet these standards, produces and disseminates resource publications, offers a quality review program, conducts educational trainings and conferences, and offers a certification program for correctional health professionals. NCCHC is supported by the major national organizations representing the fields of health, law and corrections. <http://www.ncchc.org>

TO FIND THIS RESOURCE ONLINE, VISIT WWW.NCCHC.ORG/JAIL-BASED-MAT.

TO REQUEST MAT-RELATED TECHNICAL ASSISTANCE

Visit the Residential Substance Abuse Treatment (RSAT) for State Prisoners Program Training and Technical Assistance page at www.rsat-tta.com/On-Site-TA-Teleconferences/Training-and-Technical-Assistance-Request-Form.aspx. This website is funded through a grant from the Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice.

EXHIBIT 15



NATIONAL DRUG CONTROL STRATEGY

A Report by the
Office of National Drug Control Policy

JANUARY 2019

NATIONAL DRUG CONTROL STRATEGY

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The negative consequences of the trafficking and use of illicit drugs, along with the toll that drug misuse and abuse is taking across America, have endangered too many communities, ruined too many families, and taken the lives of too many of our fellow Americans.

The Trump Administration's *National Drug Control Strategy* is focused on reversing these developments, saving American lives, and setting our Nation on a path to being stronger, healthier, and drug-free. This *Strategy* is intended to guide and focus Federal government efforts along three complementary lines of effort. First, we must reduce the size of the drug-using population by preventing initiates to illicit drug use through education and evidence-based prevention programs. Second, we must reduce barriers to treatment services so that access to long-term recovery is available for those suffering from substance use disorder. And finally, we must drastically reduce the availability of these drugs in the United States through law enforcement and cooperation with international partners to lessen the negative effects of drug trafficking that impact the safety of our communities and the well-being of our citizens.

While this *Strategy* reflects the President's top priority to address the current opioid crisis and reduce the number of Americans dying from these dangerous drugs, it also sets us on the path to develop further the capability, knowledge, and infrastructure to respond to the evolving nature of the drug threat as we move deeper into the twenty-first century.

This is a *Strategy* of action. It reflects our understanding of the complex interplay between the availability of drugs in the U.S. market and their use, anticipates changes in the drug environment in both the public health and law enforcement domains, and allows us to adapt our actions and make lasting progress against this historic national security, law enforcement, and public health challenge. Most importantly, it demands our full effort and a relentless focus on delivering results. The American People should expect nothing less.

A handwritten signature in black ink, reading "James Carroll".

James W. Carroll
Director of National Drug Control Policy

NATIONAL DRUG CONTROL STRATEGY

“We will work to strengthen vulnerable families and communities, and we will help to build and grow a stronger, healthier, and drug-free society.”

—PRESIDENT DONALD J. TRUMP

INTRODUCTION

The drug crisis our country faces today is unprecedented. It has evolved over the past several decades and has steadily worsened with time. Every state and county, and every socioeconomic group in our country, is directly affected by the negative consequences of illicit drug use. However, today we can see American ingenuity across the Nation, sparked by the commitment to save lives, at work to establish lasting solutions to this monumental problem. Law enforcement and public health innovators working side-by-side at the local level, assisted and inspired by families who have lost loved ones to the scourge of drug use, resourced by government agencies at every level working with private sector partners, are already making a difference. This *National Drug Control Strategy*, the Trump Administration’s first, establishes the President’s priorities for addressing the challenge of drug trafficking and use, now and in coming years. It also provides the strategic direction necessary for the Federal government to prevent initiates to drug use through education and evidence-based prevention, provide treatment for those suffering from the disease of addiction so they can reach long-term recovery, and reduce the availability of these dangerous drugs in every American community.

The President’s top priority is to address, head on, the current opioid crisis and reduce the number of Americans dying from these dangerous drugs. This crisis alone has resulted in more American deaths in just two years than in the course of the entire Vietnam War. In 2017, there were more than 70,200 drug overdose deaths in the United States according to the Centers for Disease Control and Prevention (CDC). More than 47,500 of these deaths involved an opioid, and more than half of these deaths involved a synthetic opioid such as illicit fentanyl or one of its analogues. From 2014 to 2017, the number of deaths attributed to synthetic opioids like fentanyl and its analogues increased 413 percent, and these synthetic opioids are now involved in more deaths than any other drug such as prescription opioids, heroin, or cocaine. Along with the current opioid crisis, overdose deaths involving heroin, cocaine, methamphetamine, and prescribed opioid painkillers have all increased since 2014 as well, and many of these deaths involved more than one drug.

The Trump Administration is matching the magnitude of today’s historic crisis with a historic level of focus and resources. In addition to providing an array of Federal grants across the spectrum of drug issues the President increased resources in his Fiscal Year (FY) 2019 Budget dedicated to the opioid crisis, held two opioid summits at the White House, established *The President’s Commission on Combating Drug Addiction and the Opioid Crisis* (herein referred to as the Commission) via Executive Order in March 2017, and announced his *Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* in March 2018.

NATIONAL DRUG CONTROL STRATEGY

While confronting today's drug crisis to arrest its growth and reduce its effects, we must also further develop the capability, knowledge, and infrastructure to respond to the evolving nature of the drug threat as we move deeper into the twenty-first century. Drug traffickers will continue to attempt to secure ever-greater profits by expanding their customer base, reducing overhead, and mitigating risks to their supply chains. The exponential growth in the availability and use of synthetic drugs in the United States, especially synthetic opioids like fentanyl and its analogues, provides a window into the likely future of drug use and trafficking. Drug trafficking organizations can avoid the costly process of harvesting illicit crops and producing plant-based drugs by the much cheaper and faster process of chemical synthesis. Potent synthetic drugs can be smuggled across our borders in small quantities that can be more easily concealed than bulkier plant-based drugs. They can also be purchased cheaply on the dark web using cryptocurrencies that provide anonymity, and shipped into the United States through international mail or as express consignment shipments. The combination of low production cost, the anonymity of the darkweb and cryptocurrencies, and drugs with higher potency than plant-based drugs, creates a favorable risk-reward structure that drug traffickers will embrace to an even greater degree in the years to come.

Along with the emergence of the greater availability and trafficking of synthetic drugs, we must also confront an emerging crisis of cocaine availability and use in the United States. The increased cultivation of coca and production of cocaine in Colombia, the source of more than 90 percent of the cocaine in the U.S. market, has once again reached record levels. Moreover, the suspension of aerial eradication programs in Colombia during its peace process, from 2015 until today, has led to even greater yield from coca plants, resulting in increased production and purity levels. Cocaine use in the United States started rising again after many years of decline. From 2016 to 2017, overdose deaths in which cocaine was the primary contributing drug increased 34 percent according to the CDC, and the National Survey of Drug Use and Health (NSDUH) shows that in 2017 past-month users of cocaine aged 12 and above increased from 1.9 million Americans to 2.1 million and new initiates to cocaine use increased to 1 million, averaging approximately 2,800 per day.

Given the current drug crisis facing America, and the President's priorities, this *Strategy* adopts a strong bias toward *action*. It focuses on leveraging our understanding of the complex interplay between the availability of drugs in the U.S. market and their use, anticipating changes in the drug environment in both the public health and law enforcement domains, and adapting our actions to seize the initiative to make lasting progress against this historic challenge. The global drug trafficking enterprise is vast, dynamic, and adaptable, but it is not without vulnerabilities. It is only through a unified effort in which the Federal government works with, and in support of, creative and resourceful individuals and organizations across the country, that can we address this complex national security, law enforcement, and public health problem.

STRATEGIC OBJECTIVE AND ASSUMPTIONS

This *Strategy* is focused on achieving one overarching strategic objective:

Building a stronger, healthier, drug free society today and in the years to come by drastically reducing the number of Americans losing their lives to drug addiction in today's crisis, and preparing now to dominate the drug environment of the

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future. This will be done by preventing initiates to drug use, providing treatment services leading to long-term recovery for those suffering from addiction, and aggressively reducing the availability of illicit drugs in America's communities.

This *Strategy* consists of three interrelated elements designed to achieve the President's goal of building and fostering a stronger, healthier, and drug free society: prevention, treatment and recovery, and reducing the availability of drugs in America. The single and most important criterion of success is saving American lives, and achieving that objective requires the Federal government to work with partners at the state, local, and tribal levels; the healthcare sector; industry; foreign partners; and every concerned American citizen to advance our Nation's efforts to promote and maintain healthy lifestyles, and help build and grow safe communities free from the scourge of drug use and addiction.

This *Strategy* makes several key assumptions:

- Deliberate, sustained, and well-coordinated education and prevention efforts will, over time, reduce the number of Americans who initiate illicit drug use.
- Better prescribing practices and the expansion of alternatives to prescription drugs that hold a high potential for addiction and abuse will have a positive effect on reducing the number of initiates to illicit drug use.
- Increasing the availability of treatment services for substance use disorder will lead to a greater number of Americans achieving sustained recovery and reduce the size of the illicit drug market and demand in the United States.
- Reducing the availability of illicit drugs in the United States will enable public health efforts to take hold, increasing the potential for successful prevention and treatment efforts.
- Aggressive and versatile drug trafficking organizations will respond to sustained pressure placed upon them by disruption, dismantlement, interdiction efforts and judicial/prosecutorial efforts, and will adapt their production and trafficking methods to minimize risk and maximize profit.

STRATEGY IMPLEMENTATION

The three fundamental elements that form the heart of this *Strategy*—prevention, treatment and recovery, and reducing availability—are complementary and mutually supporting. Reducing the size of the illicit drug using population involves **preventing** initiates to illicit drug use through education and evidence-based prevention programs. Providing **treatment services leading to long-term recovery** for those suffering from substance use disorder, often using medication-assisted treatment (MAT) combined with therapy, moves people out of the active user population and on the path to recovery. By reducing the number of individuals who use illicit drugs through prevention and treatment, we can diminish the market forces pulling illicit drugs across our borders and into our communities. Simultaneously, we must drastically reduce the **availability** of these drugs in the United States. Increased availability increases the opportunity for individuals to initiate drug use, and the path from first use to chronic use can be brutally short, particularly for potent and highly addictive drugs like opioids. By reducing availability we not only lessen the negative ancillary effects of drug trafficking that impact the safety of

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our communities and the well-being of our citizens, we also relieve the pressure on the public health domain in its prevention and treatment efforts. Reducing the size of the illicit drug-using population through prevention and treatment, together with reducing the availability of drugs in the United States through law enforcement and cooperation with international partners, are complementary efforts that inform and support one other, and will set the Nation on the path to being strong, healthy, and drug-free.

This *Strategy* is not intended to enumerate every activity the Federal government and key stakeholders must execute in order to achieve the President's strategic objective. Rather, it articulates the President's drug control priorities and sets the strategic direction for the Administration to take measures to prevent Americans, especially our future generations, from falling into the cycle of drug use and addiction; to provide Americans who suffer from substance use disorders with world class treatment and recovery services; and to protect America's citizens from the negative effects of drug trafficking and use. It also provides Federal drug control departments and agencies the strategic guidance they need for developing their own drug control plans and strategies, and it ensures programming and resource decisions about Federal drug control budget dollars are allocated in a manner consistent with the Administration's priorities.

PREVENTION

Preventing drug use before it starts is a fundamental tenet of a comprehensive approach to drug control. The science of prevention has evolved and significantly improved, and decades of research show that prevention works when implemented through evidence-based programs focused on specific audiences. Early intervention through informational media campaigns and community support mechanisms can alter the trajectory of young people in a positive direction and increase protective factors while reducing risk factors. Studies show that addiction is a disease that can be prevented and treated through sound public health interventions. Evidence-based prevention is most effective when it is carried out over the long-term with repeated interventions to reinforce original prevention goals.

Combining two or more evidence-based elements in a comprehensive prevention program is more effective than a single activity alone. Moreover, these early investments pay large dividends in substantially reduced treatment and criminal justice costs, saving taxpayer dollars while reducing the number of young people whose lives are tragically affected by early substance abuse.

As the Commission noted, "substance abuse prevention is a process which requires a shift in the behavior, culture, and community norms." The Commission emphasized the three categories of prevention intervention that target risk factors and increase protective measures: universal interventions that attempt to reduce specific health problems across all people in a particular population by reducing a variety of risk factors and promoting a broad range of protective measures; selective interventions delivered to particular communities, families, and children who, due to their exposure to certain environmental considerations, are at increased risk of substance misuse; and appropriate interventions directed to those already involved in a risky behavior such as substance misuse, or are beginning to demonstrate problems but have not yet developed a substance use disorder.

Implementing a Nationwide Media Campaign

Mass media campaigns are most effective when developed with coherent, credible, evidence-based messages grounded in behavioral science research. The Administration is already addressing the unmet need of a compelling and universal information campaign to educate our Nation on the drug-related vulnerabilities of our youth and other at-risk populations. The Administration implemented the *RxAwareness* campaign as a first step to address this problem, and augmented that initiative by launching a national substance abuse prevention media campaign, *The Truth About Opioids*. This major effort will reach audiences not targeted by *RxAwareness* by addressing topics related to the speed at which chronic substance use can develop, the drastic measures those suffering from substance use disorder will take to feed their addiction, and the need to reduce the stigma associated with addiction and treatment for substance abuse.

The media campaign is principally focused on opioids that are killing so many of our citizens. Prevention messages targeting youth are being disseminated through social media and other popular platforms utilized by young people. As the campaign moves forward, its messaging will use data analytics to determine appropriate messaging based on target population and substance, and will employ communication and marketing methods such as market segmentation, demographic data on users, and multiple formats and languages for individuals with disabilities and individuals with limited English proficiency. The campaign will be augmented by science-based primary prevention across multiple sectors using approaches that effectively engage students, parents, schools, health care systems, faith communities, social service organizations, and other sectors, in the development and implementation of community and school-based prevention initiatives.

Addressing Safe Prescribing Practices

There is a compelling need for additional research on, and the implementation of, evidence-based guidelines for the dosages and duration of prescription opioid treatment for injuries and post-surgical pain management. This is particularly important for patients with a history of substance abuse or at elevated risk for drug misuse. Additionally, information on viable alternatives for particular surgeries and pain-related conditions, along with an examination of health care coverage for alternative treatment, will advance efforts to reduce overall opioid prescribing in the United States. Government experts, the healthcare sector, the research community, and stakeholder organizations all play key roles in addressing these needs to build evidence on effective treatment and periodically updating prescriber guidelines. Moreover, clinical guidelines and best practices should be standardized in provider training programs and continuing medical education programs for those who prescribe and administer opioids such as surgeons, emergency medicine providers, and emergency medical technicians.

In 2016, CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain* for using opioids to treat chronic pain intended to improve communication between the primary care provider and the patient regarding the risk and benefits of these treatments and to improve the effectiveness of pain management treatment in general. The *Guideline* focus on three areas: determining when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinua-

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tion; and assessing the risk and harms of opioid use. The Administration will build on the CDC *Guideline* and safe prescribing practices by: working with key stakeholders to develop model statutes, regulations, and policies that ensure informed patient consent prior to an opioid prescription for chronic pain; coordinating the development of a national curriculum and standard of care for opioid prescribers that supplements the CDC's *Guideline* and focuses on primary care physicians; and developing a model training program to be disseminated to all levels of medical education on the screening for substance use and health status to identify at-risk patients. Mental illness often occurs together with substance use disorders. Underpinning these initiatives is the awareness that patients with chronic pain must receive the best medical care available to ameliorate their suffering and enable them to enjoy the best possible quality of life, while simultaneously reducing the likelihood that patients will become addicted to these treatment regimens.

Expanding the Use of Prescription Drug Monitoring Programs

A Prescription Drug Monitoring Program (PDMP) is a proven means to increase accountability in opioid prescribing practices and prevent patients from receiving opioids and other controlled medications that may have adverse interactions with opioids from multiple providers. In some states where PDMP checking is optional, providers report difficulty using their PDMP due to lack of integration with electronic health records (EHR) which interrupts workflow and can result in decreased use. Providers also cite lack of interstate data-sharing and concerns about patient confidentiality as reasons not to use the PDMP. In those cases where states' integration services are made available, the service can be costly. Currently, at least two PDMP data sharing hubs exist and many states share data. However, two distinct but related issues make data sharing challenging. First, a patchwork of different state laws governing data sharing has thus far prevented the development and execution of a nationwide PDMP capability. The problem of being unable to share data includes Federal healthcare providers attempting to access PDMP data who encounter similar difficulties dealing with various state laws. Second, even in those cases where there are not legal impediments to sharing data, interoperability challenges to sharing these data exist resulting from the two different data sharing platforms. Improving interoperability within the clinical data workflow, and making PDMP data from neighboring states more accessible, can improve the likelihood that providers will consult the PDMPs. In the coming years, we will build on existing research regarding barriers to nation-wide PDMP implementation, and employ various strategies to support PDMP integration and data sharing, including efforts that address the legal and interoperability challenges, as well as measures to incentivize states to make checking of PDMPs mandatory for all providers.

Strengthening the Capacity of State, Local, and Tribal Communities to Identify and Prevent Substance Abuse

Family, friends, and local communities are the first line of defense in preventing substance abuse, and positive adult involvement in children's lives reduces the likelihood of drug use. As the Commission concludes, "With tools for teachers and parents to enhance youth knowledge of the dangers of drug use, early intervention strategies can be implemented for children with environmental and individual risk factors." Parents and primary caregivers must understand that they can make the most significant difference in the child's attitudes and values regarding the use of drugs. Religious organizations are also an

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integral part of the community response to substance abuse, and clergy and faith-based organizations have been successful at keeping youth away from drugs, as well as providing successful support when they have turned to drug use. This strategy will support and reinforce the positive resources that family, friends, and the community can bring to bear on this crisis at both the prevention as well as the treatment and recovery levels. Parents are historically under-represented in prevention programs despite the fact that parent-based programs play a vital role in delaying the onset and use of alcohol and other drugs. This is true for school outreach programs as well.

Enhancing Research and the Development of Evidence-Based Prevention Programs

The National Academies of Sciences, Engineering, and Medicine outline three categories of prevention intervention: universal, selective, and indicated. These interventions have been studied based on targeted populations and risk factors, and, as the Commission observes, “When evidence-based programs are selected for specific populations and implemented with fidelity, they can be effective. Prevention programs need to be tested for scalability, fidelity, and sustainability after research champions are no longer present to drive the programs.”

Advancing our capability to prevent drug use before it starts will require, among other things, the more widespread adoption and use of evidence-based methods to identify at risk individuals using strategies that allow for screening, brief intervention, and referral to treatment. This is especially important for adolescents and young adults from middle school through college. In addition, we must increase opportunities to educate and inform child welfare professionals and healthcare providers about the early signs of substance abuse and identify resources to support pregnant and parenting women, children of parents with substance abuse disorders or addiction, and children born with neonatal abstinence syndrome (NAS). Where evidence about prevention interventions for a population or substance is lacking, we must work to build evidence on effective approaches.

Continuing to Strengthen ONDCP’s Drug Free Communities (DFC) Program

ONDCP’s Drug-Free Communities (DFC) Support Program, created by the Drug-Free Communities Act of 1997, undergirds the Administration’s focus on preventing and reducing youth substance use at the community level. The DFC Program provides grants to community coalitions to strengthen the infrastructure among local partners to create and sustain a reduction in local youth substance use. Since the DFC Program’s inception, findings from evaluations of the DFC program found that DFC-funded community coalitions have reduced youth substance use. According to the DFC’s 2018 National Cross-Site Evaluation Report, on average DFC-funded community participants cut alcohol use by 19 percent and prescription drug abuse by 18 percent among high school students in their communities. The DFC Program will conduct semiannual training to ensure coalitions have the resources and skillset they need to strengthen the prevention infrastructure within their communities and among their local partners to effectively prevent and reduce youth alcohol, tobacco, marijuana and (illicit) prescription drug use. This training will provide DFC-funded community coalitions with the resources and tools they need to develop local and sustainable prevention initiatives.

Expanding Drug Take-Back Across the Country

The Drug Enforcement Administration's (DEA's) twice-yearly Take-Back Day serves as an opportunity for citizens to dispose of unused and unneeded prescription drugs and a chance to support community drug prevention efforts. Although year-round take-back programs are expanding, including some by retail drug stores, the DEA program remains an important element of public awareness aimed at reducing the amount of unused medications available for potential diversion and misuse. Expanding the number of registered collectors, including hospitals and law enforcement centers, would allow states and municipalities to reduce their reliance on the Federal government for collection, disposal, and transportation. The DEA and other Federal partners should work to engage state, local, and tribal governments to raise awareness of the importance of disposing unused medications, expand the number of permanent disposal sites across the country, and increase the opportunity for their citizens to do so safely and easily.

Conclusion

Decades of research and data demonstrate addiction is a preventable disease. Today, we face a compelling need to invest in a comprehensive approach to preventing drug abuse, one which emphasizes concrete and lasting policy change at the Federal, state, tribal, and community levels. The Administration will focus its efforts and work across the government to empower communities, youth, parents, caregivers, and families to come together to create sustainable programs, policies, and practices to combat drug abuse. We know that every dollar we invest in research-based substance abuse prevention programs has the potential to save much more in treatment and criminal justice system costs and enhance the overall quality of life for communities and their citizens.

TREATMENT AND RECOVERY

Addiction is a chronic medical condition that affects the brain by causing distinct cognitive, behavioral, and physiological changes. There is a need to improve the availability of treatment while concurrently enhancing the quality of that treatment. Research shows that treatment is most effective when it addresses addiction as a chronic condition requiring continuing services and support structures over an extended period of time. This can be accomplished with ongoing outpatient services provided through opioid treatment, or more intensive initial services such as detoxification and residential treatment, followed by continued care and recovery support in the community. Every individual needs an assessment and individualized treatment plan to address their needs as they relate to opioid and other substances use disorders.

Unfortunately, most people who need treatment do not seek it. According to the NSDUH, in 2017 an estimated 20.7 million Americans aged 12 or older needed treatment for a substance use disorder, but only 4 million received any kind of treatment and only 2.5 million received that treatment at a specialty facility—a disparity known as the “treatment gap.” In some cases treatment capacity is simply not available, and in others people do not fully acknowledge their need for treatment. Therefore, in addition to expanding treatment capacity, there is a need to engage with those people who need treatment but, for whatever reason, are not seeking it. As a Nation, we must encourage people who need treatment to seek it, create greater access to treatment, and ensure there is adequate capacity to accommodate the need.

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The Administration prioritizes several distinct initiatives to achieve these goals. First, a proactive response to overdoses to ensure that the patient can enter into a treatment program designed to meet his or her individual needs. Second, consistently using evidence-based approaches to treatment and making Medication-Assisted Treatment (MAT) a standard of care for opioid addiction. This includes increasing the number of physicians providing high-quality, evidence-based treatment for opioid use disorders with MAT, and increasing the availability of MAT for incarcerated individuals. Expanding treatment infrastructure will enable us to increase the initial treatment for the vast majority of people who require treatment but are unable or unwilling to obtain it. Third, examining ways to expand and encouraging the expansion of treatment insurance while reducing reimbursement barriers to encourage those on the margins of accepting treatment to make the positive decision to begin a treatment regimen. Finally, the expanded use of Drug Courts and diversion programs will foster entrance into treatment programs and away from the cycle of destructive and self-defeating behaviors that is the hallmark of the disease of addiction. Addressing these and other challenges will require a comprehensive multi-year strategy to educate the public and policymakers, reduce stigma and misunderstanding of addiction, better integrate substance abuse screening and treatment into mainstream health care, build and stabilize the addiction treatment workforce, increase access to treatment, and foster more effective approaches to care for substance use disorders.

Improving the Response to Overdose

Naloxone is an opioid antagonist medication that can rapidly reverse an opioid overdose. However, there are varying levels of access to naloxone throughout the country. Most states have protocols to expand access to naloxone, such as by allowing dispensing of naloxone under a standing physician's order. The Food and Drug Administration is working to facilitate the development of nonprescription naloxone, by creation and testing of appropriate consumer-friendly Drug Facts labeling. The Commission recommended that all law enforcement personnel in the United States be equipped with naloxone, model legislation be provided to states to allow naloxone dispensing via standing orders, and Good Samaritan laws be enacted to empower the public to provide help. However, even simple rescue breathing can keep a person alive until help arrives, and devices like pocket masks can protect a rescuer while saving someone's life using rescue breathing until naloxone can be administered. We will begin to increase public awareness of the importance of rescue breathing in the event of an opioid overdose in those cases when naloxone is not available as a critical live-saving measure. Moreover, we must do more to ensure that the reversal of a potentially fatal overdose is not just another event in a long and protracted struggle with an addiction to dangerous drugs, but rather the first important step toward effective treatment and the path to sustained recovery.

Enhancing Evidence-Based Addiction Treatment

We must ensure that health care providers screen for substance use disorders and know how to appropriately counsel or refer patients they encounter with such a disorder. Treatment models that demonstrate the best outcomes incorporate behavioral, psychosocial, and pharmacological elements, and are tailored to the specific circumstance of the individual. The ability to provide a pathway to evidence-based treatment for those who need it depends on skilled and well-trained providers who are appropriately

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credentialed and licensed. This must include a complete evaluation for opioid use disorder and other substance use disorders by a qualified medical professional; access to MAT as a deliberate choice made by a qualified professional in consultation with the patient; simultaneous access to relevant psychosocial treatments such as therapy and relapse prevention; the treatment of co-occurring mental disorders that many patients with substance use disorder suffer from such as Post-Traumatic Stress Disorder (PTSD), depression, and anxiety disorders; and the treatment of co-occurring medical conditions such as cardiac, infectious, and dermatologic issues often associated with prolonged drug use. Additionally, identifying and treating pediatric patients with early substance use disorder can prevent their transition to longer and more severe drug use, potentially saving their lives. Therefore, we must scale up adolescent addiction screening and treatment in pediatrician and family medicine settings.

Eliminating Barriers to Treatment Availability

Individuals with substance use disorders, including opioid addiction, should have access to evidence-based treatment. Fewer than half of the privately funded substance use disorder treatment facilities offer MAT, and only a third of patients with opioid use disorders have access to those treatments. This is especially true in rural areas where the compelling need for access to treatment far exceeds its availability. The Administration will work across the Federal government to remove barriers to substance use disorder treatments, including those that limit access to any forms of FDA-approved MAT, counseling, certain inpatient/residential treatment, and other treatment modalities. All primary care providers employed or funded by the Federal government should screen for alcohol and drug use disorders and, if the patient requests it, provide substance use treatment or a referral for such treatment within 24-48 hours.

Increasing the Size of the Addiction Service Workforce, and Treatment and Recovery Infrastructure

Critical shortages in trained and professional addiction service providers is one of the many factors contributing to the treatment gap. The addiction service workforce currently employs varying styles of service delivery. Promoting training, professional incentives for entering the workforce, and establishing a greater level of standardization for care will equip the addiction service workforce to provide support services across all settings, from prevention through treatment and recovery. Opioid and other addictions require intensive interventions through a team-based approach that includes recovery coaches and medical professionals in hospitals and primary care offices, and includes the full range of health professionals such as drug counselors, behavioral health technicians, health educators, physician assistants, and community health workers. Growing our addiction service workforce requires apprenticeship opportunities for a range of addiction treatment professions. This will enable the more rapid increase of available care professionals than reliance on standard training regimens alone, and enable them to provide addiction treatment services for screening, intervention, and recovery support across the continuum of care, to enhance team treatment for individuals with substance use disorders. Furthermore, increased standardization of care and its associated training will help professionalize the field through credentialing, and provide mentoring opportunities for those patients who successfully complete their treatment and want to assist in the recovery of others.

Leveraging Drug Courts and Diversion Programs

Providing individuals arrested for non-violent drug-related offenses the opportunity to participate in a Drug Court program or outpatient treatment while under supervision is increasingly becoming the practice throughout the country. From 2009 to 2014 the number of Drug Courts in the United States increased by 24 percent, reaching 3,057, and by June 2015 the number of Drug Courts reached 3,142 per the Department of Justice. Recently, some pioneering police departments began diverting individuals addicted to drugs directly to treatment in lieu of arrest. Many communities are adopting pre-arrest diversion programs and other law enforcement diversion and deflection models, in which those struggling with addiction can walk into a participating police station 24 hours a day for police-assisted rapid treatment entry. The Administration supports these innovative programs and will scale up support for State, Tribal, and local drug courts in order to provide offenders struggling with addiction access to evidence-based treatment as an alternative to or in conjunction with incarceration, or as a condition of supervised release.

Increasing Employment Opportunities for Those in Recovery

Americans in stable recovery from addiction deserve fair consideration for any job for which they are qualified. Today, millions of Americans from all walks of life are in recovery. Many of these individuals have past misdemeanor or felony drug-related criminal convictions that can impede or prevent them from securing employment for which they are fully qualified, even after having paid their debt to society and having emerged from the shadow of addiction. In addition to the obstacles created by a past criminal conviction, those in recovery can face long-lasting barriers to employment due to laws that prohibit the hiring of individuals with a past drug conviction in certain settings. These legal restrictions can create additional difficulties for those seeking to fully rejoin the community and sustain a life in recovery. The Administration will work across the Federal government and the private sector to increase hiring opportunities for those in recovery. This will include providing the best information to employers on the overall benefits of bringing these individuals back into our workforce, developing best practices to increase their employment prospects, and increasing the availability of safe housing that enables those in recovery to hold a full-time job and take their place in the American workforce.

Expanding Access to Peer Recovery Support Services

Peer recovery support services provide the bridge between formal systems and services and community-based support networks. When provided through a Recovery Community Organization (RCO), these services can be offered prior to, during, after, and sometimes in lieu of treatment. These RCOs and peer recovery support workers provide urgently needed services. The country needs to quickly increase the number of peer recovery support workers, including those who are in MAT and recovery programs. This workforce serves a dual function; it helps develop the national peer recovery support services infrastructure, and it provides employment opportunities for people in recovery who are well-suited to make this kind of contribution. Furthermore, while the number of Collegiate Recovery Programs (CRPs) on the campuses of large public universities, private higher education institutions, and community colleges has increased rapidly over the past decade, they are still the exception rather than the rule. Every higher

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education campus in America could potentially benefit from some type of CRP. Adolescent recovery support services are especially scarce and of tremendous value to youth, given the importance of peer networks to their social development. Recovery high schools and alternative peer group models hold great promise for meeting the needs of youth, either in active recovery or in encouraging youth to seek it, and we must encourage their increased use across the Nation.

Expanding the Scientific Understanding of Peer Recovery Support Services

While much is known about the process of addiction and about interventions to help address it, less is known about the recovery process and its various trajectories, components, and stages. A better understanding of this process will help in the design and targeting of both clinical and recovery support service interventions that are stage-and trajectory-specific. More research is needed to design and target clinical and recovery support interventions and strategies for long-term recovery. However, while the positive anecdotal evidence of the near-term effectiveness of recovery support service models is strong, rigorous, empirical research is required on their long-term effectiveness, the characteristics of those who benefit most from them, and peer recovery support services' role within and impact on broader systems and communities.

Reducing Stigma and Making Recovery Possible

Americans in recovery are a vital part of every community in the United States, and they seek the same things other Americans want and need—a good job, a safe place to live, the fellowship of a faith community, and the companionship of neighbors and friends. The millions of Americans in long-term recovery from addiction demonstrate that recovery is possible, and they share the message that while addiction is a chronic disease, treating it is possible. In doing so, they help lift the stigma, misunderstanding, and shame that prevent too many Americans from seeking help for substance use disorders. By promoting, supporting, and celebrating recovery, we can reduce stigma and offer hope and encouragement to those struggling with this incredibly difficult disease. Many people in recovery have also dedicated their lives to helping others affected by substance abuse as recovery coaches and counselors, a critically important and growing component of the addiction service workforce. The Administration will continue in its efforts to better educate the public, healthcare professionals, and policymakers on the science of addiction and the promise of recovery, and how stigma and misunderstanding can undermine efforts to reduce drug use and its consequences.

Conclusion

Untreated substance abuse can result in violence, crime, and risky behavior that jeopardizes the health and safety of individuals, families, and communities. The moment a person is ready and willing to enter treatment can be fleeting and infrequent. In addition to matching the individual with the most appropriate care model, efforts to expand treatment must include the capability to act quickly on the demand for treatment whenever and wherever the opportunity is presented. Anytime someone seeking help for addiction calls a treatment center, doctor's office, hospital, health clinic, or other medical facility,

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that person should immediately be referred to some level of assistance. Even if a treatment slot is not immediately available, recovery coaches, peer counseling groups, and families who have learned about addiction can provide help until the right treatment opportunity becomes available. It is in everyone's best interest—affected individuals, their families, and the Nation—for high-quality, evidence-based drug treatment to become more easily accessible. The current opioid crisis highlights the urgent need to encourage those who need treatment to seek it, rapidly increase treatment admissions for opioid addiction, improve treatment retention, and increase the number of individuals who successfully achieve sustained recovery. It is also essential to eliminate the stigma, misunderstanding, and legal and regulatory barriers that delay or prevent treatment access and impede recovery. In addition to saving lives and helping people in recovery achieve their full potential, these changes will help ensure that the significant public investment in treatment pays off in terms of long-term recovery.

REDUCING THE AVAILABILITY OF ILLICIT DRUGS IN THE UNITED STATES

Almost all of the illicit drugs causing American deaths are produced outside the United States and trafficked across the Nation's borders and, increasingly, through the international mail and express consignment carriers. Large and established Drug Trafficking Organizations (DTOs) and foreign producers shipping drugs into the United States threaten the health and safety of our communities by exposing our citizens to substances such as fentanyl, heroin, cocaine, and methamphetamine, which kill tens of thousands of Americans each year. The increased use of illicit drugs burdens the U.S. health care system and leads to lost productivity and civil engagement. Moreover, drug trafficking sustains a vast domestic and international criminal enterprise that enables corruption, undermines governance, has a destabilizing effect on our partner nations, and funds a range of illicit activities. Law enforcement agencies at all levels—Federal, state, local, and tribal—have achieved considerable success in combating drug trafficking and use, yet traffickers continue to refine their methods and adopt new techniques for delivering potent illicit drugs to our communities. Responding to the aggressive trafficking and distribution techniques of DTOs is an urgent national security and law enforcement priority.

The non-medical use of prescription drugs presents another dimension of the availability problem. Many active drug users report obtaining prescription drugs from friends, family members, and in some cases, healthcare providers. The overprescribing of prescription drugs, the diversion of prescription drugs for non-medical use, and the lack of accountability or oversight in prescribing practices increase the availability of prescription drugs in America's homes and workplaces, making it far too easy for them to fall into the wrong hands. Moreover, drug dealers exploit the demand for prescription medicines and traffic in counterfeit pills containing heroin, fentanyl, or one of its analogues. These drugs are difficult to distinguish from legitimate prescription medicines, and because they are most often milled and pressed in variable formulations in clandestine locations, increase the chance for accidental overdose.

Disrupting, Dismantling, and Defeating Drug Traffickers and Their Supply Chains

While DTOs often are involved in poly-drug trafficking and other criminal activity, the unprecedented rise in deaths from the opioid crisis demands that we prioritize U.S. government efforts on the individuals and groups involved in the smuggling and sale of the most deadly drugs such as synthetic opioids and heroin. As these organizations continue to modify their techniques and operations in an attempt to reduce risk and maximize profit, we must anticipate and then respond to emerging changes in the drug trafficking environment, identify and exploit vulnerabilities in the illicit drug supply chain, and seize the initiative from drug traffickers in order to disrupt their activities and dismantle the infrastructure they use to sustain their illicit enterprise. Along with aggressive actions to prevent the further expansion of these criminal enterprises in our country, we must also work with foreign partners to attack criminal networks, principally those in the Western Hemisphere, whose drug trafficking and associated criminality directly impact migration and border security issues affecting the United States.

Working with International Partners

The U.S. Government will focus its diplomatic efforts to encourage partner nations to produce results that match the growing threat from illicit drugs. Consistent with the *National Security Strategy*, we will prioritize assistance with partners who are aligned with U.S. interests, are showing results, and building the capacity to address these threats independent of U.S. assistance programs. This will require partners' renewed commitment to disrupt the illicit supply chain through the interdiction and seizure of the illicit drug supply, illicit funds, and weapons; eradicate poppy and coca plants; find and dismantle the labs used for all illicit drug processing; develop and sustain robust law enforcement and justice systems; maintain the rule of law and ferret out corruption; and arrest and prosecute drug traffickers operating within their own land borders, territorial waters, and airspace. These efforts are not only important in their own right but will complement, and be informed by, a strong domestic public health response to the crisis aimed at reducing the use of these drugs in the United States. We will continue to work bilaterally with the primary drug producing and trafficking countries most affecting the United States, emphasizing our shared responsibility for today's drug problems and the strong desire for tangible progress in the years to come. Regional relationships will be an important part of our international approach going forward, allowing us to share information and harmonize our drug policies in the face of a constantly changing threat. Moreover, we will take full advantage of the strong multilateral framework that exists to address the global drug problem, particularly in terms of supporting the three international drug control conventions and providing leadership in the processes for internationally scheduling, controlling, and monitoring illicit drugs and their precursor chemicals.

Combating Illicit Internet Drug Sales

Over the past two years, illicit drug sales on both the clear and the dark web have further expanded the illicit drug market, allowing individuals to purchase dangerous drugs directly from their manufacturers instead of through established trafficking organizations, and have them shipped directly to their homes. We must disrupt the ability of drug traffickers to exploit the anonymity, distance, and financial trans-

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action reliability provided through internet sales by degrading the implicit trust between buyer and seller required for illicit on-line transactions. We must use existing authorities to their maximum effect to successfully target drug traffickers and their enablers by employing both passive and active measures to disrupt and exploit illicit drug related activities operating on both clear and dark webs. Contesting drug marketplaces in the cyber domain and disrupting the use of cryptocurrencies for illicit drug sales will require a coordinated and well-resourced framework of relationships, laws and regulations, procedures, and capabilities. This will allow us to identify and target the network of actors involved, and prosecute those who use the open or dark webs to market, sell, and purchase illicit drugs. Developing a drug cyber defense capability, and exercising it to achieve sustained effort against the internet drug market, will erode this implicit trust and disrupt illicit operations on the clear and dark webs over time.

Focusing Federal Government Effort Against Illicit Drug Delivery Through the Mail and Express Consignment Networks

We must complement our efforts against internet drug sales with a sustained effort to disrupt the flow of illicit drugs shipped through the international mail and express consignment environments. This requires developing the policy and regulations, international relationships, facility infrastructure upgrades, and technology required to aggressively target, detect, and intercept illicit drugs transported through the international mail and express consignment environments both internationally and domestically. We must work with our international partners to develop the ability to share Advance Electronic Data for all international shipments, in accordance with the *President's Opioid Initiative*, and continuously refine targeting algorithms to identify and interdict international shipments before they depart the source country and at U.S. Ports of Entry. We must help critical partner countries develop the ability to detect and intercept illicit drugs in their domestic mail and express consignment systems before those drugs depart for the United States and enter the U.S. mail or commercial carrier system. Finally, we must develop next generation technology and screening capabilities to increase our ability to detect illicit drugs once they enter the mail and express consignment systems within the country, and improve testing capability to determine the precise type and source of illicit drugs seized. This investment in science, technology, resources, and international relationships is necessary to determine the type, source region, production location, and route traveled for all illicit drugs seized by the United States and its international partners.

Interdicting the Flow of Drugs Across the Physical Borders and into the United States

Along with the new challenge of drug trafficking via internet sales and mail and express consignment delivery, drugs continue to flow across our land borders and through the maritime and air routes. Stopping these flows must remain part of our comprehensive interdiction efforts. The historically high levels of cocaine production in Colombia, along with heroin and methamphetamine production in Mexico, combined with the vast number of routes and conveyances into the United States, make the challenge of combating drug trafficking across our physical borders no less daunting than it has been for the past several decades. Federal agencies should expand efforts in the detection and monitoring of the air and maritime approaches to the United States; the detection of illicit drugs and precursor chem-

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icals being shipped in commercial containers; and interdiction of plant-based drugs such as heroin, cocaine, and marijuana, as well as synthetic drugs and their precursor chemicals, along the Nation's land borders. Moreover, this increased effort must be complemented by increased effort and cooperation from foreign partners who can contribute vital information on trafficking patterns and assets to seize drugs bound for the United States.

Disrupting and Dismantling the Illicit Drug Production Infrastructure

The United States and Mexico have expanded cooperation to address the common threat of illicit opioids, and both governments agree that reducing the supply of heroin, methamphetamine, and fentanyl is a shared responsibility. Mexico is increasing its efforts to eradicate poppy fields more effectively, destroy clandestine laboratories, and interdict heroin and other drugs before they reach the U.S. border. The U.S. Government provides training to Mexican law enforcement officers, analysts, chemists, and military personnel to identify and safely dismantle clandestine drug laboratories that produce heroin, methamphetamine, and fentanyl, and how to address the dangers synthetic drugs present to law enforcement.

Expanding coca cultivation and cocaine production in Colombia and the broader Andean region must continue to be addressed in a comprehensive manner. Key elements of cooperation with proven partners such as Colombia and Peru include increasing all forms of eradication, alternative development and economic opportunities, interdiction, investigation and prosecution, judicial support, and public health cooperation, all of which must be long-term and sustainable. Since coca fields differ in their level of productivity, this approach will be most successful if collectively focused in areas of high-yield coca cultivation. Unfortunately, these areas generally have limited government services and lingering security concerns, and will require concerted effort over several years to keep partner nations focused on the issue and turn the rising tide of cocaine production.

Within the United States marijuana cultivation on public lands, and within National Forest System lands in particular, is a significant issue. Cultivation activities not only sustain the illicit marijuana trade but also produce large volumes of hazardous materials that pose a significant risk to the public and the environment. Wildlife, soil, and vegetation are often contaminated by the various hazardous substances involved in the cultivation process. Personnel conducting enforcement, cleanup, and regulatory activities, as well as the public, are at considerable health risk from exposure to these chemicals. Continued firm action is required against the exploitation of the Nation's public lands through increased detection, disruption, reclamation, and prosecutions.

The majority of illicit synthetic drugs available in the United States are manufactured abroad. New illicit synthetic drugs and the precursor chemicals used to make them originate predominantly in China, although most of the methamphetamine available in the United States is manufactured in Mexico. Increased collaboration with Mexico, China, and other partners on shared drug priorities can help disrupt drug trafficking networks, along with the corrupt or compromised systems that support them, and reduce the availability of dangerous synthetic drugs in the United States. The United States will continue bilateral exchanges with China, Mexico, Colombia, and other source and transit countries to reduce production and trafficking of synthetic drugs destined for markets in the United States and support collaboration with international partners impacted by drugs from the very same sources.

Leveraging the Full Capabilities of Multi-Jurisdictional Task Force Programs

The High Intensity Drug Trafficking Areas (HIDTA) Program provides assistance to law enforcement agencies operating in areas determined to be critical drug-trafficking regions of the United States. HIDTAs provide an umbrella to coordinate Federal, state, local, and tribal drug law enforcement agencies' investigations, and act as neutral centers to manage, de-conflict, analyze, provide intelligence, and execute drug enforcement activities in their respective regions. With the recent inclusion of Alaska, the first new HIDTA in 17 years, the 29 regional HIDTAs now include designated areas in all 50 states, Puerto Rico, the U.S. Virgin Islands, and the District of Columbia. The regional HIDTAs bring together more than 21,000 Federal, state, local, and tribal personnel from 500 agencies through 800 enforcement, intelligence, and training initiatives, all designed to disrupt illicit drug trafficking and dismantle criminal and drug trafficking organizations. The Administration will ensure strong support for counterdrug enforcement, including by supporting Federal participation in multi-jurisdictional task forces and enhancing support for information sharing at all levels. This will ensure that national data systems receive input from state, local, and tribal agencies, and that these agencies, in turn, have access to data compiled by Federal agencies that can prove vital to their own investigations.

Interrupting the Financial Activities of Drug Traffickers

Illicit drugs enter the United States from global suppliers as the result of a long and complex process involving manufacture, concealment, movement, purchase, and delivery. The illicit drugs may change hands several times during the process, and this often necessitates the transfer of money, either as payment for services or for delivery of the final product. Traditionally, street-level sales of illegal drugs are conducted with cash, creating immediately liquid assets that are almost impossible to track. As technology and money laundering methods have adapted over the years to circumvent Anti-Money Laundering regulations, drug traffickers have initiated many new techniques to enable the traditional method of hard currency transactions. Although some of these methods create additional investigative evidence, emerging technologies continue to outpace banking regulations and consistently provide drug traffickers the means to launder large amounts of their illicit proceeds.

Most of the revenue generated from illegal drug sales in the United States is maintained at the retail level of drug distribution. However, illicit proceeds that flow back to international sources of drug supply are most often used to finance other illegal activities or the next cycle of illegal drugs to be directed into our communities, posing a continual threat to the country. These funds also corrupt and weaken the government infrastructure of source and transit countries, limiting those governments' ability to combat Transnational Criminal Organizations (TCOs), escalating violence, and threatening the stability of the governments we partner with to counter illicit activity. We will combat this threat and target the drug proceeds that motivate criminal activity by attacking TCOs' financial capital; preventing the circulation, transfer, and concealment of their illicit proceeds; and ultimately decreasing their wealth and their incentive to function.

Enhancing Law Enforcement Capacity

Success in reducing the availability of illicit drugs in our country requires building the capacity and tools to fully understand, and relentlessly respond to, the increased drug threat we face. As stated in our *National Security Strategy*, this capacity building includes national-level strategic intelligence and planning capabilities to improve the ability of departments and agencies to work together to combat TCOs, particularly those who traffic drugs at home and abroad. We must improve our capability to dismantle TCOs as a whole through greater coordination and focus, directly benefiting our counterdrug efforts. Improved strategic planning must be informed by better strategic intelligence on transnational organized crime and global criminal networks, fusing law enforcement and Intelligence Community information and intelligence to create the most complete picture available of criminal networks. We must use that information to identify and exploit vulnerabilities in drug trafficking networks using the full range of law enforcement capabilities including criminal prosecutions, financial disruption tools such as asset forfeiture proceedings, and security operations to remove the profits from crime. Moreover, we must maintain pressure on these organizations over time and prevent them from regenerating their capabilities. We must also emphasize both actions that lead to prosecutions—to reduce networks' ability to operate, through the investigation, arrest, and prosecution of critical personnel—and those that lead to the long-term disruption of network operations such as the seizures of illicit drugs, precursor chemicals, illicit funds, and weapons.

Our conventional focus on targeting high-level individuals within the hierarchy of well-organized and sophisticated DTOs must evolve toward identifying and targeting vulnerable critical components of more fluid and dynamic organizations such as financial facilitators, corrupt officials, and key transporters, to affect a significant disruption of DTO activities, targeting key nodes to attack the entire network through its enablers. Degrading and defeating criminal networks that have become more resilient because they are decentralized, redundant in capabilities and capacities, and compartmentalized, requires identifying the key nodes enabling DTO operations and simultaneously targeting them for maximum effectiveness over time. Agile interagency and international coordination will allow for better detection of changes in the trafficking supply chain, which will support intelligence-driven operations against identified vulnerabilities, from drug production to delivery to the end user.

Conclusion

The increased availability and use of illicit drugs is taking far too many American lives. It burdens the U.S. health care system and leads to lost productivity and civil engagement here at home, and global drug trafficking sustains a vast domestic and international criminal enterprise that enables corruption and destabilizes partner nations abroad. America's drug crisis has created a complex national security, law enforcement, and public health challenge for the Nation, and this challenge will remain with us for the foreseeable future. We must leverage the full capabilities of the U.S. intelligence and law enforcement communities, our military, domestic law enforcement and criminal justice capabilities, and sustained engagements with the governments of key partner nations and international organizations to stop the flow of these drugs across our borders and into our communities, and use that capability to posture ourselves for an ever-evolving drug trafficking environment. Our actions will include disrupting the evolving illicit supply chain, decreasing the volume of drugs being sold over the internet; decreasing

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the cultivation of illicit crops like poppy and coca as well as the volume of illicit drugs being produced for export to the United States; increasing the amount of illicit drugs seized before entering the United States; increasing the amount of forfeited assets; increasing the number of convictions for drug-related crimes; and increasing the pace of emerging dangerous substances being reviewed and scheduled for domestic and international controls.

Achieving the President's objective of reducing the number of Americans losing their lives to drug addiction in today's crisis, and preparing now to dominate the drug environment of the future, requires deliberate actions focused on clear priorities and tangible outcomes to reduce the availability of drugs in our Nation. However, lasting success requires those actions to complement, and be informed by, a strong domestic public health response to reduce the use of these drugs in the United States which makes possible enormous profits for drug traffickers and fuels the illicit drug market. Bold and decisive national security, law enforcement, and public health efforts are needed to lift the Nation from the shadow of drug use and move toward the President's goal of a stronger, healthier, and drug free society today and in the years to come.

METRICS

Because this *Strategy* focuses on outlining a high-level approach rather than enumerating all of the key tasks and activities that organizations at the Federal, State, local and Tribal levels must undertake in order to stem the tide of this crisis, it is important to employ some broad measures of performance and effectiveness to guide the *Strategy's* implementation. This not only ensures the necessary policies, priorities, and objectives of drug control agencies and interagency partners are adequately aligned and resourced to advance the President's drug control priorities, but also serves to identify those areas where a refinement of the *Strategy* may be necessary to close an identified gap, or areas where a shift in specific agency resources can attain greater effects in achieving the President's overarching strategic objective.

This requires that we focus on effects and not simply performance. While a performance measure represents the specific characteristic or aspect of the program or policy used to gauge successful performance of a specific task, effectiveness represents the aggregate progress, of multiple agencies contributing to achieving tangible improvement through their programs, initiatives, and policies. Doing so requires linking actions taken on the front end of the global supply chain to reduce the availability of illicit drugs in the United States with measurable effects on the health and safety of our communities.

Measures of Performance

- Educate the public, especially adolescents, about drug use, specifically opioids increase, mandatory prescriber education and continuing training on best practices and current clinical guidelines; and increase PDMP interoperability and usage across the country
- Encourage expanded access to evidence-based addiction treatment in every state, particularly Medication-Assisted Treatment for opioid addiction; support legislative changes to allow

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Medicaid to reimburse certain residential treatment at facilities with more than 16 beds; and encourage states to apply for state Medicaid demonstration projects that address barriers to inpatient treatment as a part of a comprehensive opioid/substance use disorder strategy

- Significantly reduce the availability of illicit drugs in the United States by preventing their production outside the United States, disrupt their sale on the internet, and stop their flow into the country through the mail and express courier environments, and across our borders

Measures of Effectiveness

- The number of Americans dying from a drug overdose is significantly reduced within five years
- Nationwide opioid prescription fills are reduced by one-third within three years, and within five years all healthcare providers have adopted best practices for opioid prescribing
- Evidence-based addiction treatment, particularly Medication-Assisted Treatment for opioid addiction, is more accessible Nationwide for those who need it
- The production of plant-based and synthetic drugs outside the United States has been significantly reduced, illicit drugs are less available in the United States as reflected in increased price and decreased purity, and drug seizures at all U.S. ports of entry increase each year over five years