# TITLE 30: PROFESSIONS AND OCCUPATIONS PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

# ARTICLE L AMBULATORY SURGERY CENTERS AND MULTI-PROVIDER CLINICS

- 1. For purposes of this Article, an ambulatory surgery center (ASC) or multi-provider clinic (MPC) shall mean a facility where medical procedures or services are performed or provided by multiple practitioners for outpatients. Examples would include but would not be limited to an ambulatory surgery center, a medical doctor's office/clinic, or a dental office. An ASC/MPC advisory pharmacist refers to any Mississippi licensed pharmacist who reviews processes and ensures appropriate reconciliation of controlled substances at least monthly on site in an ASC or MPC. The ASC/MPC is responsible for complying with all applicable regulations of the Mississippi Board of Pharmacy as well as other state and federal regulatory agency requirements.
- 2. Every ASC/MPC shall obtain an ASC/MPC permit from the Mississippi Board of Pharmacy for every location where controlled substances are administered by multiple providers/practitioners under one DEA number. This permit along with a DEA registration allows the ASC/MPC to order controlled substances for the facility to be used by multiple providers/practitioners under one clinic DEA number. Such a permit shall be obtained by applying for a permit on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee. This requirement does not apply to ASC's or clinics with only a single provider where the provider's registration is based at that location. All ASC/MPC permits will expire on December 31 of each year and shall be renewed annually by submitting a renewal application and renewal fee. Any renewal application received after December 31<sup>st</sup> of the renewal period will be assessed a \$50.00 late fee prior to renewal. ASC/MPC permits are not transferable or assignable. There are two subcategories for ASC/MPC permits: outpatient surgery center/clinic pharmacy and outpatient surgery center/clinic.
  - A. Ambulatory Surgery Center/Multi-Provider Clinic Pharmacy Services (fee \$300)
    - (1) This permit should be used when a pharmacist is integrated into the daily workflows of the facility including ordering and stocking of medications and clinical support but is not an actual dispensing pharmacy. Additionally, a controlled substance permit is required.
    - (2) See Institutional Pharmacy Regulations
  - B. Ambulatory Surgery Center/Multi-Provider Clinic (fee \$100)
    - (1) Requires there to be at least a monthly arrangement with a pharmacist onsite to review processes and ensure appropriate reconciliation of controlled substances. The pharmacist reviews appropriate records for ordering, storage, and other record keeping requirements and documentation of administration, wastage, and disposal of medications in accordance with documented policies and procedures of the ASC/MPC.
    - (2) This permit will serve as the controlled substance permit required by statute.
- 3. Advisory Pharmacist Requirement.
  - A. A permit for an ASC/MPC shall not be issued or renewed unless the advisory pharmacist is licensed in this state.

- B. If the license of the advisory pharmacist becomes void or inactive due to surrender, revocation, suspension, restriction or for any other reason, or if the license of the advisory pharmacist is removed from the permit of the ASC/MPC for any reason, application must be made for a new permit with another advisory pharmacist within fifteen (15) days.
- C. Failure to submit an application with the new advisory pharmacist within fifteen (15) days shall render the permit inactive and the ASC/MPC shall not conduct any activities using the controlled substances that were obtained pursuant to the permit and the corresponding DEA registration until a new permit is issued to the ASC/MPC with a new advisory pharmacist on the permit.
- D. The failure to obtain a new advisory pharmacist within the required fifteen (15) day time period shall be reported to DEA by the Mississippi Board of Pharmacy.

#### 4. Record Keeping

- A. Every ASC/MPC permit issued by the Board of Pharmacy shall keep complete and accurate records of acquisition and disposition of all controlled substances. These records shall include:
  - (1) Complete and accurate records of receipt of all controlled substances
  - (2) Complete and accurate records of disposition of all controlled substances
- B. Records of acquisition and disposition must be maintained for a period of at least 2 years. These records shall be kept in such a manner that an audit will show the beginning inventory and record of acquisition of controlled substances to balance with controlled substances on hand and record of disposition of controlled substances.
- C. Unless authorized by the Federal Drug Enforcement Administration to maintain records of controlled substances at a location other than the location permitted by the Mississippi Board of Pharmacy, these records shall be maintained at the permitted location. All records pertaining to controlled substances shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy.
- D. The ASC/MPC advisory pharmacist shall provide a monthly report outlining any findings from their review. This document shall be signed by the medical director or designee and dated. The facility must maintain these reports for a period of two (2) years, and a copy must be available for inspection upon request.

#### 5. Storage

- A. All drug products shall be maintained and stored in such a manner that maintains the integrity of the product.
- B. All containers from which drugs are administered must be properly labeled.
- C. Outdated drugs shall be removed from general stock and returned to a reverse distributor licensed with the Mississippi Board of Pharmacy or destroyed onsite following DEA rules for onsite destruction and use of DEA Form 41.

#### 6. Security

A. In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. A securely locked, substantially constructed area shall be provided for storage of all controlled substances. Controlled substances for return to a MS licensed reverse distributor or for onsite destruction as described above shall be maintained in the drug storage area of the clinic and segregated from general stock until

proper disposition of such controlled substances is made. Controlled substances, thus maintained in the drug storage area, shall be kept in a locked cabinet, drawer, or other suitable locked container and only authorized personnel shall have access to the drug storage area.

## 7. Inventory

- A. A perpetual inventory shall be maintained on all Controlled Substances, Schedule II-V.
- B. The medical director shall develop inventory listings of drugs to be included in specified areas and assure that:
  - (1) Such drugs are available therein, properly stored and labeled
  - (2) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements
  - (3) Each drug stored in these areas shall be assigned a "par value" and each addition or withdrawal by authorized persons shall be properly documented.
- C. If a facility has a loss of controlled substances, a complete inventory of all remaining controlled substances shall be made within forty-eight (48) hours of discovery of the loss of controlled substances. This inventory shall be dated and signed by the ASC/MPC staff conducting the inventory.
- D. The advisory pharmacist shall be notified within twenty-four (24) hours of discovery of any discrepancy in counts or the loss of any controlled substances. The advisory pharmacist shall notify the Board immediately upon his/her notification with a plan to investigate the loss. A written report shall be submitted to the Mississippi Board of Pharmacy within fifteen (15) days; this written report shall include a copy of the inventory required by this ARTICLE.
- E. When a facility has a change in ownership or a change in the advisory pharmacist listed on their permit (pharmacist-in-charge), or is permanently closed, a complete inventory shall be made of all controlled substances at the time of the change. A copy of this inventory shall be kept with other records of controlled substances in the facility and a copy shall be sent to the office of the Board of Pharmacy. When a facility is permanently closed, the advisory pharmacist (pharmacist-in-charge) shall notify the Board in writing within fourteen (14) days by what means and as to whom controlled substances were transferred or disposed of.
- F. Every facility permitted by the Mississippi Board of Pharmacy shall take an annual inventory of all controlled substances on hand on or about May 1 but no later than May 15. A facility may conduct the controlled substance inventory at another date as long as the annual inventory is conducted during the same period each year. This inventory shall be maintained with the other controlled substance records of the facility.

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- 2. Every ASC/MPC shall obtain an ASC/MPC permit from the Mississippi Board of Pharmacy for every location where controlled substances are administered by multiple providers/practitioners under one DEA number. This permit along with a DEA registration allows the ASC/MPC to order controlled substances for the facility to be used by multiple providers/practitioners under one clinic DEA number. Such a permit shall be obtained by applying for a permit on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee. This requirement does not apply to ASC's or clinics with only a single provider where the provider's registration is based at that location. All ASC/MPC permits will expire on December 31 of each year and shall be renewed annually by submitting a renewal application and renewal fee. Any renewal application received after December 31<sup>st</sup> of the renewal period will be assessed a \$50.00 late fee prior to renewal. ASC/MPC permits are not transferable or assignable. There are two subcategories for ASC/MPC permits: outpatient surgery center/clinic pharmacy and outpatient surgery center/clinic eonsultant.
  - A. Ambulatory Surgery Center/Multi-Provider Clinic Pharmacy Services (fee \$300)
    - (1) This permit should be used when a pharmacist is integrated into the daily workflows of the facility including ordering and stocking of medications and clinical support but is not an actual dispensing pharmacy. Additionally, a controlled substance permit is required.
    - (2) See Institutional Pharmacy Regulations
  - B. Ambulatory Surgery Center/Multi-Provider Clinic Consultant (fee \$100)
    - (1) Requires there to be at least a monthly arrangement with a pharmacist onsite to review processes and ensure appropriate reconciliation of controlled substances. The pharmacist reviews appropriate records for ordering, storage, and other record keeping requirements and documentation of administration, wastage, and disposal of medications in accordance with documented policies and procedures of the ASC/MPC.
    - (2) This permit will serve as the controlled substance permit required by statute.
- 3. Consultant Advisory Pharmacist Requirement.
  - A. A permit for an ASC/MPC shall not be issued or renewed unless the <del>consultant</del> <u>advisory</u> pharmacist is licensed in this state.

- B. If the license of the consultant advisory pharmacist becomes void or inactive due to surrender, revocation, suspension, restriction or for any other reason, or if the license of the consultant advisory pharmacist is removed from the permit of the ASC/MPC for any reason, application must be made for a new permit with another consultant advisory pharmacist within fifteen (15) days.
- C. Failure to submit an application with the new consultant advisory pharmacist within fifteen (15) days shall render the permit inactive and the ASC/MPC shall not conduct any activities using the controlled substances that were obtained pursuant to the permit and the corresponding DEA registration until a new permit is issued to the ASC/MPC with a new consultant advisory pharmacist on the permit.
- D. The failure to obtain a new consultant advisory pharmacist within the required fifteen (15) day time period shall be reported to DEA by the Mississippi Board of Pharmacy.

#### 4. Record Keeping

- A. Every ASC/MPC permit issued by the Board of Pharmacy shall keep complete and accurate records of acquisition and disposition of all controlled substances. These records shall include:
  - (1) Complete and accurate records of receipt of all controlled substances
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- B. Records of acquisition and disposition must be maintained for a period of at least 2 years. These records shall be kept in such a manner that an audit will show the beginning inventory and record of acquisition of controlled substances to balance with controlled substances on hand and record of disposition of controlled substances.
- C. Unless authorized by the Federal Drug Enforcement Administration to maintain records of controlled substances at a location other than the location permitted by the Mississippi Board of Pharmacy, these records shall be maintained at the permitted location. All records pertaining to controlled substances shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy.
- D. The ASC/MPC consultant advisory pharmacist shall provide a monthly report outlining any findings from their review. This document shall be signed by the medical director or designee and dated. The facility must maintain these reports for a period of two (2) years, and a copy must be available for inspection upon request.

#### 5. Storage

- A. All drug products shall be maintained and stored in such a manner that maintains the integrity of the product.
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proper disposition of such controlled substances is made. Controlled substances, thus maintained in the drug storage area, shall be kept in a locked cabinet, drawer, or other suitable locked container and only authorized personnel shall have access to the drug storage area.

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- A. A perpetual inventory shall be maintained on all Controlled Substances, Schedule II-V.
- B. The medical director shall develop inventory listings of drugs to be included in specified areas and assure that:
  - (1) Such drugs are available therein, properly stored and labeled
  - (2) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements
  - (3) Each drug stored in these areas shall be assigned a "par value" and each addition or withdrawal by authorized persons shall be properly documented.
- C. If a facility has a loss of controlled substances, a complete inventory of all remaining controlled substances shall be made within forty-eight (48) hours of discovery of the loss of controlled substances. This inventory shall be dated and signed by the ASC/MPC staff conducting the inventory.
- D. The consultant advisory pharmacist shall be notified within twenty-four (24) hours of discovery of any discrepancy in counts or the loss of any controlled substances. The consultant advisory pharmacist shall notify the Board immediately upon his/her notification with a plan to investigate the loss. A written report shall be submitted to the Mississippi Board of Pharmacy within fifteen (15) days; this written report shall include a copy of the inventory required by this ARTICLE.
- E. When a facility has a change in ownership or a change in the consultant advisory pharmacist listed on their permit (pharmacist-in-charge), or is permanently closed, a complete inventory shall be made of all controlled substances at the time of the change. A copy of this inventory shall be kept with other records of controlled substances in the facility and a copy shall be sent to the office of the Board of Pharmacy. When a facility is permanently closed, the consultant advisory pharmacist (pharmacist-in-charge) shall notify the Board in writing within fourteen (14) days by what means and as to whom controlled substances were transferred or disposed of.
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