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

ARTICLE XLVII PHYSICIAN DISPENSING FACILITY PERMITS

For the purposes of this Article, a "dispensing physician" means any physician who dispenses to a patient for the patient's use any controlled substance, legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made.

Section 1: Application for Permit

Pursuant to Part 2640, Chapter 1, Rule 1.9 of the Mississippi Board of Medical Licensure Regulations, every dispensing physician in this State shall obtain a dispensing physician facility permit from the Mississippi Board of Pharmacy for every location where controlled substances or legend drugs are dispensed. The dispensing physician must obtain a certificate to dispense medications from the Mississippi Board of Medical Licensure prior to applying for a dispensing physician facility permit from the Mississippi Board of Pharmacy. Such permit shall be obtained by applying for a permit on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee of Three Hundred Dollars ($300.00). All physician dispensing facility permits expire on December 31 of each year and shall be renewed annually by submitting a renewal application and a renewal fee of Three Hundred Dollars ($300.00). Any renewal application postmarked after December 31st of the renewal period shall be returned and assessed a Fifty Dollar ($50.00) late fee prior to renewal. Dispensing physician facility permits are not transferable or assignable.

Any physician that utilizes an automated dispensary must obtain a separate Automated Physician Dispensing Facility Permit. Each automated dispensary shall be required to have a separate permit. An automated physician dispensing facility permit shall be obtained by applying on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee of Three Hundred Dollars ($300.00). All automated physician dispensing facility permits expire on December 31 of each year and shall be renewed annually by submitting a renewal application and a renewal fee of Three Hundred Dollars ($300.00). Any renewal application postmarked after December 31st of the renewal period shall be returned and assessed a Fifty Dollar ($50.00) late fee prior to renewal. Automated dispensing physician facility permits are not transferable or assignable.

Section 2: Record Keeping

1. Every Physician Dispensing Facility Permit issued by the Board of Pharmacy shall keep complete and accurate records of the acquisition and disposition of all controlled substances. An annual inventory shall be conducted on all controlled substances. These records shall include:

    a. A current dated and signed inventory of all controlled substances on hand on the inventory date;
    b. Complete and accurate records of receipt of all controlled substances;
    c. Complete and accurate records of disposition of all controlled substances.

Records of acquisition must be maintained for a period of two (2) years. Records of disposition must be maintained for a period of six (6) 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 the controlled substances on hand and the record of disposition of controlled substances.

2. 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. A dispensing physician may use a data processing system or a manual record keeping system for the storage and retrieval of all drug order and dispensing information. All records of controlled substances in Schedule II shall be maintained separately from all other records. All records of controlled substances in Schedule III, IV and V, whether maintained manually or in a data processing system, shall be maintained separately or in such a manner that they are readily retrievable from the other business records. Invoices for controlled substances shall be dated and initialed by the person receiving the order.

3. If a dispensing physician utilizes a data processing system, it must provide immediate retrieval of drug dispensing information. The data processing system must have the capability of producing a hard copy printout of all dispensing information including an audit trail for any specified strength and dosage form of any controlled substance either by brand name or generic name or both for any time period in the prior two (2) years. The audit trail specified by this Article must be produced on verbal or written request of any Compliance Agent of the Board. Failure to produce and provide this audit trail within twenty-four (24) hours constitutes prima facie evidence of failure to keep and maintain records as required by this Article.

4. The records of controlled substances in Schedules II, III, IV and V, which are maintained in a data processing system shall be maintained with the following information pertaining to the initial dispensing of the drug shall be entered into the data processing system:

    a. Date of initial dispensing;
    b. Name and address of patient;
    c. Dispensing physician's name and DEA registration number; and
    d. The name, strength, dosage form and quantity of the controlled substance ordered and dispensed.

5. A record of all controlled substance dispensing information shall be transmitted to the Prescription Monitoring Program every twenty-four (24) hours or within the next business day by all dispensing physicians for all controlled substances dispensed which amounts to greater than a forty-eight (48) hour supply. Dispensers will be required to collect and transmit the following information:
    a. The recipient’s name;
    b. The recipient’s or the recipient representative’s identification number;
    c. The recipient’s date of birth;
    d. The national drug code (NDC) number of the controlled substance dispensed;

e. The date the controlled substance is dispensed;
f. The quantity of the controlled substance dispensed;
g. The number of days supply dispensed;
h. The dispenser's NCPDP registration number;
i. The dispenser's DEA registration number, and
j. The method of payment of the prescription purchase.

6. A single physician dispenser may not share or otherwise allow other practitioners to utilize medications or inventory ordered under their authority. Proper transference of medications may take place pursuant to an accurate record of acquisition and disposition of the medications being transferred. Additionally, for the transference of controlled substances, all Federal Drug Enforcement Agency (DEA) regulations must be followed.

Section 3: Storage and Dispensing Conditions

1. All drug products which are stored or maintained in a facility permitted by the Board of Pharmacy shall remain in the manufacturer's or repackager's original container. The label of any container in which drugs are maintained must bear the drug name, strength, the manufacturer's control lot number and the expiration date. Drugs which are precounted and prepackaged, or placed in automatic tablet counting machines, for purposes of dispensing shall be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained shall not be labeled in any false or misleading manner. The labeling requirements of this ARTICLE are in addition to, and not in lieu of, other labeling requirements of the laws of the state of Mississippi and laws of the United States or federal regulations.

2. No physician may delegate dispensing authority to another person. Except as allowed pursuant to an automated dispensing physician facility permit, a physician must personally dispense the medication. For the purpose of this regulation, "personally dispense" means the physician must actually obtain the medication, prepare, count, place the medication into the appropriate container and affix the appropriate label to the container.

3. A physician shall not dispense out-of-date drugs and shall not maintain out-of-date drugs intermixed with the stock of current drugs. Out-of-date drugs shall be promptly removed from current stock and stored separately until proper disposal shall be made.

4. The Board of Pharmacy or its representative may seize, embargo, quarantine or place under seal any drug or controlled substance which may constitute an imminent danger to the public health or safety.

5. A physician shall not accept the return for subsequent resale or exchange any drug after such drug has been taken from the premises where sold, distributed or dispensed and from the control of the physician.

6. All drug products shall be maintained, stored and dispensed in such a manner as to maintain the integrity of the product.

7. Unless requested not to do so, all medication dispensed in a liquid or solid dosage form shall be dispensed in child resistant packaging.

8. Disasters, accidents or emergencies which may affect the strength, purity or labeling of drugs shall be immediately reported to the Board of Pharmacy.

9. Customized Patient Medication Packages: In lieu of dispensing two or more prescribed drug products in separate containers, a physician may, with the consent of the patient or a patient's care giver, provide a customized package, known as a patient med-pak provided:
    a. Patient med-paks shall bear a label (or labels) including all information required on a traditional prescription label. In addition, the med-pak shall bear an identification number unique to that patient med-pak, the date of preparation and the beyond-use date of the patient med-pak (not to exceed ninety (90) days from the date of preparation). If the patient med-pak allows for the removal or separation of individual cells within the med-pak, each cell shall bear a label identifying each of the drug products contained.
    b. It is the responsibility of the dispensing physician when preparing the med-pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each cell of the med-pak, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.
    c. A record of each patient med-pak shall be made and filed. Each record shall contain at a minimum:
        i. The name and address of the patient;
        ii. The unique identification number of the patient med-pak;
        iii. The drug name, manufacturer or distributor name and lot number of each drug product contained;
        iv. Any special labeling instructions;
        v. Information identifying or describing the design, characteristics, or specifications of the med-pak, sufficient to allow subsequent preparation of the med-pak for the patient;
        vi. The date of preparation of the patient med-pak and the beyond-use date that was assigned; and
        vii. The name or initials of the physician responsible for preparing the med-pak.

Section 4: Labeling

The label on the dispensing container shall include:

1. The name and address of the patient to whom the medication was dispensed;
2. The date that the medication was dispensed;
3. The drug name, manufacturer or distributor name and lot number of the drug product dispensed;
4. The strength and quantity of the medication;
5. Directions for taking or administering the medication;
6. The name and address of the physician dispensing the medication, and
7. Any other information which is necessary or required.

The label shall be affixed to the outside of the container of the dispensed medication by means of adhesive or tape or any other means which will assure that the label remains attached to the container.

Section 5: Security

In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. Storage of controlled substances in any schedule may be made in a securely locked, substantially constructed container or area; or they may be dispersed throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances; or they may be stored by a combination of these methods. Only the dispensing physician or person authorized by the dispensing physician shall have access to this storage area.

Section 6: Inventory

1. 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 dispensing physician conducting the inventory. Any loss or suspected loss of controlled substances shall be reported directly to the Mississippi Board of Pharmacy immediately upon discovery and a written report made to the Mississippi Board of Pharmacy within fifteen (15) days; this written report shall include a copy of the inventory required by this ARTICLE.

2. When a facility has a change in ownership, 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 dispensing physician shall notify the Board in writing within fifteen (15) days by what means and as to whom controlled substances were transferred or disposed of.

3. Every dispensing physician 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 so 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.

Section 7: Disposal of Controlled Substances

1. Any dispensing physician authorized to possess controlled substances in the course of their professional practice or the course of their business may dispose of any expired, excess or unwanted controlled substances by contacting and utilizing the services of a reverse distributor as defined by the Federal Drug Enforcement Administration. Any such reverse distributor must hold a valid Certificate of Registration Number issued by the Federal Drug Enforcement Administration and the Mississippi Board of Pharmacy. All records of the disposal of controlled substances shall be maintained for a period of two (2) years.

2. A dispensing physician facility permitted by the Mississippi Board of Pharmacy in which controlled substances are administered to patients, may make on-premises destruction of controlled substances provided:

    a. The controlled substance is the remainder of a prepackaged single dosage unit or unit of use.
    b. At least part of the unit dose or unit of use was administered.
    c. The destruction is recorded showing:
        i. The name of the drug;
        ii. The amount of the drug which was administered and the amount of the drug which was destroyed;
        iii. The time and the date of destruction;
        iv. The name of the patient;
        v. The name of the person administering the drug;
        vi. The signature of the person (physician or nurse) making the destruction;
        vii. The signature of a second person who witnessed the destruction.
    d. The record of the destruction is maintained by the facility.
    e. A single dosage unit or any unit of use of a controlled substance which (1) is broken, (2) becomes contaminated, (3) or for any reason cannot be used, may be destroyed on premise provided the destruction is documented.

3. Except as provided for in this ARTICLE, no controlled substance may be destroyed or disposed of by a permitee without written permission of the Regional Director of the Federal Drug Enforcement Administration.

Section 8: Automated Dispensaries

1. Any physician utilizing an automated dispensary will be responsible for developing and implementing written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality and maintenance of the quality, potency and purity of the medications dispensed by the automated dispensary.

2. Any physician utilizing an automated dispensary will be responsible for the proper maintenance and inventory/accountability requirements as if the physician were personally dispensing the medications to the patients from his or her medication stock/inventory in their personal practice.

3. An automated dispensary may only be stocked by the inventory/stock from a single physician and may not dispense controlled substances.

4. The stocking of an automated dispensary shall be performed only by the responsible physician. This task may not be delegated.

5. All medications dispensed from the automated dispensary shall comply with the labeling requirements of Section 4 of this regulation.

6. No medication may be dispensed from an automated dispensary unless the patient has first had an initial or follow-up visit with the physician. Any refills dispensed from an automated dispensary must be accompanied by its own preceding physician visit.

7. Any automated dispensing system shall maintain an electronic record of all information related to each and every medication dispensed including, but not limited to, all label information and date and time of dispensing.

Section 9: Dispensing Compounded Products

A. Prior to engaging in compounding pharmaceuticals for dispensing, a physician dispensing facility shall obtain a compounding certificate from the Mississippi Board of Pharmacy.

   i. To obtain a compounding certificate, an applicant must complete a compounding certificate application. A compounding certificate is required for each physician dispenser. The physician dispenser shall not delegate any part of the compounding process to another person.

   ii. A compounding certificate will expire when the physician dispensing permit expires and can be renewed at the time the physician dispensing permit is renewed.

   iii. Compounding for dispensing, without obtaining the compounding certificate, shall be grounds for disciplinary action.

   iv. Every physician dispenser that engages in compounding for dispensing shall keep records of all compounded products that are dispensed to patients. Such records shall be readily available for authorized inspection for 6 years from the date of dispensing.

   v. Any dispensing physician with an active compounding certificate for dispensing is subject to a compounding inspection by the Board.

B. Every dispensing physician that is engaged in compounding pharmaceuticals for dispensing shall comply with USP 795, USP 797, and USP 800 when compounding in the scope of those chapters.

C. For the purposes of this Section, flavoring is not considered compounding. In addition, the combining of commercially manufactured, ready-to-use products shall be exempt from USP 795 compounding standards under the following conditions:

   i. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;

   ii. Compounding is not done in anticipation of orders;

   iii. Must follow USP 795 beyond use dates (BUDs);

   iv. The prescription label complies with all related USP chapter requirements as well as the labeling requirements set forth in this regulation.

D. A physician dispenser may compound for dispensing to an individual patient, medications that are not commercially available in the marketplace in compliance with Compounding Using

Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act. This includes compounding a copy of a commercial product when that commercial product is not available as evidenced by either of the following:

i. Products that appear as unresolved status on the FDA drug shortage list in effect under section 506E of the FD&C Act; or

ii. Products discontinued and no longer marketed by the manufacturer.

E. A physician dispenser shall not compound for dispensing products that appear on the FDA List of Drugs withdrawn or removed from the market for safety reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.

F. A physician dispenser shall not offer compounded human drug products to other practitioners or to pharmacies for resale or dispensing. A physician dispenser may not dispense compounded product from another practitioner or that was compounded by a 503A or 503B pharmacy.

G. Nothing in this section prohibits a physician from compounding for immediate administration or requires a physician dispenser to obtain a compounding certificate from the MS Board of Pharmacy for compounding for administration.

ARTICLE XLVII PHYSICIAN DISPENSING FACILITY PERMITS

For the purposes of this Article, a "dispensing physician" means any physician who dispenses to a patient for the patient's use any controlled substance, legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made.

Section 1: Application for Permit

Pursuant to Part 2640, Chapter 1, Rule 1.9 of the Mississippi Board of Medical Licensure Regulations, every dispensing physician in this State shall obtain a dispensing physician facility permit from the Mississippi Board of Pharmacy for every location where controlled substances or legend drugs are dispensed. The dispensing physician must obtain a certificate to dispense medications from the Mississippi Board of Medical Licensure prior to applying for a dispensing physician facility permit from the Mississippi Board of Pharmacy. Such permit shall be obtained by applying for a permit on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee of Three Hundred Dollars ($300.00). All physician dispensing facility permits expire on December 31 of each year and shall be renewed annually by submitting a renewal application and a renewal fee of Three Hundred Dollars ($300.00). Any renewal application postmarked after December 31st of the renewal period shall be returned and assessed a Fifty Dollar ($50.00) late fee prior to renewal. Dispensing physician facility permits are not transferable or assignable.

Any physician that utilizes an automated dispensary must obtain a separate Automated Physician Dispensing Facility Permit. Each automated dispensary shall be required to have a separate permit. An automated physician dispensing facility permit shall be obtained by applying on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee of Three Hundred Dollars ($300.00). All automated physician dispensing facility permits expire on December 31 of each year and shall be renewed annually by submitting a renewal application and a renewal fee of Three Hundred Dollars ($300.00). Any renewal application postmarked after December 31st of the renewal period shall be returned and assessed a Fifty Dollar ($50.00) late fee prior to renewal. Automated dispensing physician facility permits are not transferable or assignable.

Section 2: Record Keeping

1. Every Physician Dispensing Facility Permit issued by the Board of Pharmacy shall keep complete and accurate records of the acquisition and disposition of all controlled substances. An annual inventory shall be conducted on all controlled substances. These records shall include:

    a. A current dated and signed inventory of all controlled substances on hand on the inventory date;

b. Complete and accurate records of receipt of all controlled substances;

c. Complete and accurate records of disposition of all controlled substances. Records of acquisition must be maintained for a period of two (2) years. Records of disposition must be maintained for a period of six (6) 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 the controlled substances on hand and the record of disposition of controlled substances.

2. 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. A dispensing physician may use a data processing system or a manual record keeping system for the storage and retrieval of all drug order and dispensing information. All records of controlled substances in Schedule II shall be maintained separately from all other records. All records of controlled substances in Schedule III, IV and V, whether maintained manually or in a data processing system, shall be maintained separately or in such a manner that they are readily retrievable from the other business records. Invoices for controlled substances shall be dated and initialed by the person receiving the order.

3. If a dispensing physician utilizes a data processing system, it must provide immediate retrieval of drug dispensing information. The data processing system must have the capability of producing a hard copy printout of all dispensing information including an audit trail for any specified strength and dosage form of any controlled substance either by brand name or generic name or both for any time period in the prior two (2) years. The audit trail specified by this Article must be produced on verbal or written request of any Compliance Agent of the Board. Failure to produce and provide this audit trail within twenty-four (24) hours constitutes prima facie evidence of failure to keep and maintain records as required by this Article.

4. The records of controlled substances in Schedules II, III, IV and V, which are maintained in a data processing system shall be maintained with the following information pertaining to the initial dispensing of the drug shall be entered into the data processing system:

    a. Date of initial dispensing;
    b. Name and address of patient;
    c. Dispensing physician's name and DEA registration number; and
    d. The name, strength, dosage form and quantity of the controlled substance ordered and dispensed.

5. A record of all controlled substance dispensing information shall be transmitted to the Prescription Monitoring Program every twenty-four (24) hours or within the next business day by all dispensing physicians for all controlled substances dispensed which amounts to greater than a forty-eight (48) hour supply. Dispensers will be required to collect and transmit the following information:
    a. The recipient’s name;
    b. The recipient’s or the recipient representative’s identification number;

c. The recipient's date of birth;
d. The national drug code (NDC) number of the controlled substance dispensed;
e. The date the controlled substance is dispensed;
f. The quantity of the controlled substance dispensed;
g. The number of days supply dispensed;
h. The dispenser's NCPDP registration number;
i. The dispenser's DEA registration number, and
j. The method of payment of the prescription purchase.

6. A single physician dispenser may not share or otherwise allow other practitioners to utilize medications or inventory ordered under their authority. Proper transference of medications may take place pursuant to an accurate record of acquisition and disposition of the medications being transferred. Additionally, for the transference of controlled substances, all Federal Drug Enforcement Agency (DEA) regulations must be followed.

Section 3: Storage and Dispensing Conditions

1. All drug products which are stored or maintained in a facility permitted by the Board of Pharmacy shall remain in the manufacturer's or repackager's original container. The label of any container in which drugs are maintained must bear the drug name, strength, the manufacturer's control lot number and the expiration date. Drugs which are precounted and prepackaged, or placed in automatic tablet counting machines, for purposes of dispensing shall be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained shall not be labeled in any false or misleading manner. The labeling requirements of this ARTICLE are in addition to, and not in lieu of, other labeling requirements of the laws of the state of Mississippi and laws of the United States or federal regulations.

2. No physician may delegate dispensing authority to another person. Except as allowed pursuant to an automated dispensing physician facility permit, a physician must personally dispense the medication. For the purpose of this regulation, "personally dispense" means the physician must actually obtain the medication, prepare, count, place the medication into the appropriate container and affix the appropriate label to the container.

3. A physician shall not dispense out-of-date drugs and shall not maintain out-of-date drugs intermixed with the stock of current drugs. Out-of-date drugs shall be promptly removed from current stock and stored separately until proper disposal shall be made.

4. The Board of Pharmacy or its representative may seize, embargo, quarantine or place under seal any drug or controlled substance which may constitute an imminent danger to the public health or safety.

5. A physician shall not accept the return for subsequent resale or exchange any drug after such drug has been taken from the premises where sold, distributed or dispensed and from the control of the physician.

6. All drug products shall be maintained, stored and dispensed in such a manner as to maintain the integrity of the product.

7. Unless requested not to do so, all medication dispensed in a liquid or solid dosage form shall be dispensed in child resistant packaging.

8. Disasters, accidents or emergencies which may affect the strength, purity or labeling of drugs shall be immediately reported to the Board of Pharmacy.

9. Customized Patient Medication Packages: In lieu of dispensing two or more prescribed drug products in separate containers, a physician may, with the consent of the patient or a patient's care giver, provide a customized package, known as a patient med-pak provided:
    a. Patient med-paks shall bear a label (or labels) including all information required on a traditional prescription label. In addition, the med-pak shall bear an identification number unique to that patient med-pak, the date of preparation and the beyond-use date of the patient med-pak (not to exceed ninety (90) days from the date of preparation). If the patient med-pak allows for the removal or separation of individual cells within the med-pak, each cell shall bear a label identifying each of the drug products contained.
    b. It is the responsibility of the dispensing physician when preparing the med-pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each cell of the med-pak, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.
    c. A record of each patient med-pak shall be made and filed. Each record shall contain at a minimum:
        i. The name and address of the patient;
        ii. The unique identification number of the patient med-pak;
        iii. The drug name, manufacturer or distributor name and lot number of each drug product contained;
        iv. Any special labeling instructions;
        v. Information identifying or describing the design, characteristics, or specifications of the med-pak, sufficient to allow subsequent preparation of the med-pak for the patient;
        vi. The date of preparation of the patient med-pak and the beyond-use date that was assigned; and
        vii. The name or initials of the physician responsible for preparing the med-pak.

Section 4: Labeling

The label on the dispensing container shall include:

1. The name and address of the patient to whom the medication was dispensed;
2. The date that the medication was dispensed;
3. The drug name, manufacturer or distributor name and lot number of the drug product dispensed;
4. The strength and quantity of the medication;
5. Directions for taking or administering the medication;
6. The name and address of the physician dispensing the medication, and
7. Any other information which is necessary or required.

The label shall be affixed to the outside of the container of the dispensed medication by means of adhesive or tape or any other means which will assure that the label remains attached to the container.

Section 5: Security

In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. Storage of controlled substances in any schedule may be made in a securely locked, substantially constructed container or area; or they may be dispersed throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances; or they may be stored by a combination of these methods. Only the dispensing physician or person authorized by the dispensing physician shall have access to this storage area.

Section 6: Inventory

1. 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 dispensing physician conducting the inventory. Any loss or suspected loss of controlled substances shall be reported directly to the Mississippi Board of Pharmacy immediately upon discovery and a written report made to the Mississippi Board of Pharmacy within fifteen (15) days; this written report shall include a copy of the inventory required by this ARTICLE.

2. When a facility has a change in ownership, 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 dispensing physician shall notify the Board in writing within fifteen (15) days by what means and as to whom controlled substances were transferred or disposed of.

3. Every dispensing physician 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 so 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.

Section 7: Disposal of Controlled Substances

1. Any dispensing physician authorized to possess controlled substances in the course of their professional practice or the course of their business may dispose of any expired, excess or unwanted controlled substances by contacting and utilizing the services of a reverse distributor as defined by the Federal Drug Enforcement Administration. Any such reverse distributor must hold a valid Certificate of Registration Number issued by the Federal Drug Enforcement Administration and the Mississippi Board of Pharmacy. All records of the disposal of controlled substances shall be maintained for a period of two (2) years.

2.A dispensing physician facility permitted by the Mississippi Board of Pharmacy in which controlled substances are administered to patients, may make on-premises destruction of controlled substances provided:

a. The controlled substance is the remainder of a prepackaged single dosage unit or unit of use.
b. At least part of the unit dose or unit of use was administered.
c. The destruction is recorded showing:
    i. The name of the drug;
    ii. The amount of the drug which was administered and the amount of the drug which was destroyed;
    iii. The time and the date of destruction;
    iv. The name of the patient;
    v. The name of the person administering the drug;
    vi. The signature of the person (physician or nurse) making the destruction;
    vii. The signature of a second person who witnessed the destruction.
d. The record of the destruction is maintained by the facility.
e. A single dosage unit or any unit of use of a controlled substance which (1) is broken, (2) becomes contaminated, (3) or for any reason cannot be used, may be destroyed on premise provided the destruction is documented.

3. Except as provided for in this ARTICLE, no controlled substance may be destroyed or disposed of by a permitee without written permission of the Regional Director of the Federal Drug Enforcement Administration.

Section 8: Automated Dispensaries

1. Any physician utilizing an automated dispensary will be responsible for developing and implementing written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality and maintenance of the quality, potency and purity of the medications dispensed by the automated dispensary.

2. Any physician utilizing an automated dispensary will be responsible for the proper maintenance and inventory/accountability requirements as if the physician were personally dispensing the medications to the patients from his or her medication stock/inventory in their personal practice.

3. An automated dispensary may only be stocked by the inventory/stock from a single physician and may not dispense controlled substances.

4. The stocking of an automated dispensary shall be performed only by the responsible physician. This task may not be delegated.

5. All medications dispensed from the automated dispensary shall comply with the labeling requirements of Section 4 of this regulation.

6. No medication may be dispensed from an automated dispensary unless the patient has first had an initial or follow-up visit with the physician. Any refills dispensed from an automated dispensary must be accompanied by its own preceding physician visit.

7. Any automated dispensing system shall maintain an electronic record of all information related to each and every medication dispensed including, but not limited to, all label information and date and time of dispensing.

Section 9: Dispensing Compounded Products

A. Prior to engaging in compounding pharmaceuticals for dispensing, a physician dispensing facility shall obtain a compounding certificate from the Mississippi Board of Pharmacy.

   i. To obtain a compounding certificate, an applicant must complete a compounding certificate application. A compounding certificate is required for each physician dispenser. The physician dispenser shall not delegate any part of the compounding process to another person.

   ii. A compounding certificate will expire when the physician dispensing permit expires and can be renewed at the time the physician dispensing permit is renewed.

   iii. Compounding for dispensing, without obtaining the compounding certificate, shall be grounds for disciplinary action.

   iv. Every physician dispenser that engages in compounding for dispensing shall keep records of all compounded products that are dispensed to patients. Such records shall be readily available for authorized inspection for 6 years from the date of dispensing.

   v. Any dispensing physician with an active compounding certificate for dispensing is subject to a compounding inspection by the Board.

B. Every dispensing physician that is engaged in compounding pharmaceuticals for dispensing shall comply with USP 795, USP 797, and USP 800 when compounding in the scope of those chapters.

C. For the purposes of this Section, flavoring is not considered compounding. In addition, the combining of commercially manufactured, ready-to-use products shall be exempt from USP 795 compounding standards under the following conditions:

   a. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;

   b. Compounding is not done in anticipation of orders;

   c. Must follow USP 795 beyond use dates (BUDs);

   d. The prescription label complies with all related USP chapter requirements as well as the labeling requirements set forth in this regulation.

D. A physician dispenser may compound for dispensing to an individual patient, medications that are not commercially available in the marketplace in compliance with Compounding Using

Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act. This includes compounding a copy of a commercial product when that commercial product is not available as evidenced by either of the following:

a. Products that appear as unresolved status on the FDA drug shortage list in effect under section 506E of the FD&C Act; or

b. Products discontinued and no longer marketed by the manufacturer.

E. A physician dispenser shall not compound for dispensing products that appear on the FDA List of Drugs withdrawn or removed from the market for safety reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.

F. A physician dispenser shall not offer compounded human drug products to other practitioners or to pharmacies for resale or dispensing. A physician dispenser may not dispense compounded product from another practitioner or that was compounded by a 503A or 503B pharmacy.

G. Nothing in this section prohibits a physician from compounding for immediate administration or requires a physician dispenser to obtain a compounding certificate from the MS Board of Pharmacy for compounding for administration.