

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

ARTICLE VI PRACTICE OF PHARMACY PERMITS

Every business or location in this state where prescription drugs are maintained and/or pharmacy services are provided shall obtain a permit from the Mississippi Board of Pharmacy. Every location issued a permit by the Board shall renew this permit biennially. The Board shall identify written criteria and issue permits accordingly in one of the following general classifications:

- A. Community Pharmacy; or
- B. Institutional Pharmacy; or
- C. Limited Closed-Door Pharmacy; or
- D. Nonresident Pharmacy; or
- E. Pharmacy Advisory Services.
- F. Outsourcing Pharmacy

1. For purposes of this ARTICLE, definitions are as follows:

- A. A Community Pharmacy shall mean any place, other than an Institutional Pharmacy or a Limited Closed-Door Pharmacy, which is accessible to the general public and where pharmacy services are offered. These pharmacies may include but are not limited to independent retail or chain retail pharmacies.
- B. A Specialty Community Pharmacy shall mean any place other than an Institutional Pharmacy, Limited Closed-Door Pharmacy or a Community Pharmacy where the practice of pharmacy occurs and pharmacy services are provided to patients. These services may include, but are not limited to the following: dispensing sterile pharmaceuticals for home infusion, nuclear pharmacy services, compounding, consulting pharmacist services, disease state management, respiratory services and dispensing of nursing home medications. These pharmacies may be open on a full or part-time basis.
- C. An Institutional Pharmacy shall mean that portion of an institutional facility where the practice of pharmacy occurs and where medications, devices and other materials are dispensed to their patients.
 - (1) An Institutional I Pharmacy:
 - (a) Institutional I Pharmacy shall mean that portion of an institutional facility where the practice of pharmacy occurs and which is engaged in the compounding, production, and dispensing of drugs, medications, devices and other materials which are used in the diagnosis and treatment of injury, illness and disease. For purposes of these regulations a hospital shall mean any institution for the care and treatment of the sick and injured which is licensed and approved by the Mississippi State Department of Health, Health Facilities, Licensure and Certification.
 - (b) An Institutional I Pharmacy shall also include Out-Patient surgery facilities which maintain, dispense and administer medications, devices and other materials in treatment and diagnosis of injury, illness and disease.
 - (2) An Institutional II Pharmacy shall mean that portion of an institution, other than a hospital, where the practice of pharmacy occurs and which is engaged in the compounding, production and dispensing of drugs, medications, devices and other

materials used in the diagnosis and treatment of injury, illness and disease.

(3) Various categories of Institutional Pharmacies are recognized as follows:
"Institutional Facility" or "Organized Health Care Setting" is a:

- (1) Hospital;
- (2) Convalescent Home;
- (3) Nursing Home;
- (4) Extended Care Facility;
- (5) Mental Institution;
- (6) Rehabilitation Center;
- (7) Retardation Center;
- (8) Correctional Facility;
- (9) Hospice;
- (10) Out-patient surgery facilities;
- (11) Any other such organization whose primary purpose is to provide a residential environment for patients to obtain health care services, and shall not include those places where physicians, dentists, veterinarians or other practitioners of the healing arts, who are duly licensed, engage in private practice.

D. Limited Closed-Door Pharmacy shall mean any place where pharmacy services are provided and where preferentially priced prescription drugs are purchased for the pharmacy's own use to dispense only to their own patients. These pharmacies are not accessible to the general public and may or may not provide full-time pharmacy services. A Limited Closed-Door Pharmacy may include, but is not limited to, pharmacies owned by any city, county or state government and federally, state or privately funded non-profit community health clinics.

E. A Nonresident Pharmacy shall mean any pharmacy other than an outsourcing pharmacy that is located outside the State of Mississippi which ships, mails or delivers prescription or legend drugs or devices to patients residing in this state.

F. Pharmacy Advisory Services shall include locations where a pharmacist engages in certain professional advisory services as authorized under the definition of the Practice of Pharmacy. Various types of Advisory Services Permits may be recognized as follows:

(1) Professional Services 1

- (a) Pharmacists advise and provide pharmacotherapeutic consultations concerning therapeutic values, content, hazards and uses of drugs and devices.
- (b) Initiate or modify drug therapy in accordance with written guidelines or protocols previously established and approved by the Board.
- (c) Order lab work in accordance with written guidelines or protocols as defined by Section 73-21-73, Mississippi Code of 1972.
- (d) Such services do not apply to Medication Therapy Management (MTM) conducted under a Pharmacy Permit at the permitted location.
- (e) The permit must be obtained for the location in compliance with zoning requirements of the city or municipality and may not be located in a residence.
- (f) A stock of drugs or devices may not be maintained or distributed from this location.

(2) Professional Services 2

- (a) Pharmacists advise and provide pharmacotherapeutic consultations concerning therapeutic values, content, hazards and uses of drugs and devices.

- (b) Initiate or modify drug therapy in accordance with written guidelines or protocols previously established and approved by the Board.
 - (c) Order lab work in accordance with written guidelines or protocols as defined by Section 73-21-73, Mississippi Code of 1972.
 - (d) Such services do not apply to medication therapy management conducted under a Pharmacy Permit at the permitted location.
 - (e) The permit must be obtained for the location in compliance with zoning requirements of the city or municipality and may not be located in a residence.
 - (f) A pharmacist may assist in maintaining and distribution of medications provided to the patients from a manufacturer patient assistance program that assists medically indigent persons to obtain their prescription medications only.
- (3) Professional Services Outpatient Surgery Center
 - (a) A pharmacist supervises appropriate documentation of administration, wastage and disposal of medications in accordance with documented policies and procedures of the facility.
 - (b) The Medical Director of the facility is responsible for obtaining the Drug Enforcement Administration (DEA) registration number for the facility and compliance with applicable DEA regulations.
- G. Outsourcing Pharmacy – a pharmacy at one geographic location or address that:
 - (1) Is engaged in the compounding of drugs for human or animal use;
 - (2) Is registered as an outsourcing facility with the FDA; and
 - (3) Complies with all of the requirements of Section 503B of the Federal FD&C Act and state laws and regulations.
 - (4) May not hold multiple pharmacy permits at the same location.
- 2. To obtain a pharmacy permit or outsourcing pharmacy permit or renew a permit, the applicant shall have:
 - A. Submitted a written application on a form(s) prescribed by the Board;
 - B. Submitted the required fees as follows: Three hundred dollars (\$300.00) for the registration period January 1, 2011 through December 31, 2012, and each biennial registration period thereafter.
 - C. Any permit renewal application postmarked after December 31 of the renewal period shall be returned and a fifty (\$50.00) late renewal fee shall be assessed prior to renewal.
- 3. To obtain a Pharmacy Advisory Services permit or renew a permit, the applicant shall have:
 - A. Submitted a written application on a form(s) prescribed by the Board;
 - B. Submitted the required fees as follows: One hundred dollars (\$100.00) for the registration period January 1, 2014 through December 31, 2015, and each biennial registration period thereafter.
 - C. Any permit renewal application postmarked after December 31 of the renewal period shall be returned and a fifty (\$50.00) late renewal fee shall be assessed prior to renewal.
- 4. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period. If the permit is issued in the second half of the

registration period, it must be renewed at the end of the next registration period.

5. Permits issued to any type of facility become null and void sixty (60) days from the date of issuance if inspection reveals a lack of legitimate business activity.
6. A permit for a location shall not be issued or renewed on the application of any person unless such person be a pharmacist licensed in this state.
7. Original permits, once issued for a new facility, may be returned to the Board and a new permit issued without being assessed an additional permit fee provided:
 - A. The change is on a one-time basis and is within sixty (60) days of original issuance; and
 - B. Controlled substance inventory requirements are met; and
 - C. A twenty-five dollar (\$25.00) processing fee is paid to the Board.
8. A pharmacy permit shall not be required for the sale or delivery of dialysate solutions or devices necessary to perform home peritoneal renal dialysis to patients with end stage renal disease, provided the following criteria are met:
 - A. The dialysate solutions or devices are approved or cleared by the Food and Drug Administration (FDA), as required by federal law;
 - B. The dialysate solutions or devices are lawfully held by a manufacturer or a manufacturer's agent that is properly registered with the Mississippi Board of Pharmacy as a manufacturer, wholesale drug distributor (WDD) or third-party logistics provider (3PL) under Mississippi Code Section 73-21-105;
 - C. The dialysate solutions or devices are held and delivered in their original, sealed packaging from the manufacturing facility;
 - D. The dialysate solutions or devices are delivered only upon receipt of a valid prescription by a pharmacy permitted by the Mississippi Board of Pharmacy and the transmittal of an order from the pharmacy to the manufacturer or the manufacturer's agent;
 - E. The manufacturer or the manufacturer's agent delivers the dialysate solutions or devices directly to:
 - (1) A patient with chronic kidney failure, or his/her designee, for the patient's self-administration or the dialysis therapy, or
 - (2) A health care provider or institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

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

ARTICLE VI PRACTICE OF PHARMACY PERMITS

1. Every business or location in this state where prescription drugs are maintained and/or pharmacy services are provided shall obtain a permit from the Mississippi Board of Pharmacy. ~~Effective January 1, 2016,~~ Every location issued a permit by the Board shall renew this permit biennially. The Board shall identify written criteria and issue permits accordingly in one of the following general classifications:
 - A. Community Pharmacy; or
 - B. Institutional Pharmacy; or
 - C. Limited Closed Door Pharmacy; or
 - D. Nonresident Pharmacy; or
 - E. Pharmacy Advisory Services.
 - F. ~~Sterile Product~~ Outsourcing Pharmacy
2. For purposes of this ARTICLE, definitions are as follows:
 - A. A Community Pharmacy shall mean any place, other than an Institutional Pharmacy or a Limited Closed Door Pharmacy, which is accessible to the general public and where pharmacy services are offered. These pharmacies may include but are not limited to independent retail or chain retail pharmacies.
 - B. A Specialty Community Pharmacy shall mean any place other than an Institutional Pharmacy, Limited Closed Door Pharmacy or a Community Pharmacy where the practice of pharmacy occurs and pharmacy services are provided to patients. These services may include, but are not limited to the following: dispensing sterile pharmaceuticals for home infusion, nuclear pharmacy services, compounding, consulting pharmacist services, disease state management, respiratory services and dispensing of nursing home medications. These pharmacies may be open on a full or part-time basis.
 - C. ~~B.~~ An Institutional Pharmacy shall mean that portion of an institutional facility where the practice of pharmacy occurs and where medications, devices and other materials are dispensed to their patients.
 - (1) Institutional I Pharmacy
 - (a) An Institutional I Pharmacy shall mean that portion of an institutional facility where the practice of pharmacy occurs and which is engaged in the compounding, production, and dispensing of drugs, medications, devices and other materials which are used in the diagnosis and treatment of injury, illness and disease. For purposes of these regulations a hospital shall mean any institution for the care and treatment of the sick and injured which is licensed and approved by the Mississippi State Department of Health, Health Facilities, Licensure and Certification.
 - (b) An Institutional I Pharmacy shall also include Out-Patient surgery facilities which maintain, dispense and administer medications, devices and other

materials in treatment and diagnosis of injury, illness and disease.

(2) An Institutional II Pharmacy shall mean that portion of an institution, other than a hospital, where the practice of pharmacy occurs and which is engaged in the compounding, production and dispensing of drugs, medications, devices and other materials used in the diagnosis and treatment of injury, illness and disease.

(3) Various categories of Institutional Pharmacies are recognized as follows: "Institutional Facility" or "Organized Health Care Setting" is a:

- (1) Hospital;
- (2) Convalescent Home;
- (3) Nursing Home;
- (4) Extended Care Facility;
- (5) Mental Institution;
- (6) Rehabilitation Center;
- (7) Retardation Center;
- (8) Correctional Facility;
- (9) Hospice;
- (10) Out-patient surgery facilities;
- (11) Any other such organization whose primary purpose is to provide a residential environment for patients to obtain health care services, and shall not include those places where physicians, dentists, veterinarians or other practitioners of the healing arts, who are duly licensed, engage in private practice.

D. Limited Closed Door Pharmacy shall mean any place where pharmacy services are provided and where preferentially priced prescription drugs are purchased for the pharmacy's own use to dispense only to their own patients. These pharmacies are not accessible to the general public and may or may not provide full-time pharmacy services. A Limited Closed Door Pharmacy may include, but is not limited to, pharmacies owned by any city, county or state government and federally, state or privately funded non-profit community health clinics.

E. A Nonresident Pharmacy shall mean any pharmacy other than an outsourcing pharmacy that is located outside the State of Mississippi which ships, mails or delivers prescription or legend drugs or devices to patients residing in this state.

F. Pharmacy Advisory Services shall include locations where a pharmacist engages in certain professional advisory services as authorized under the definition of the Practice of Pharmacy. Various types of Advisory Services Permits may be recognized as follows:

(1) Professional Services 1

(a) Pharmacists advise and provide pharmacotherapeutic consultations concerning therapeutic values, content, hazards and uses of drugs and devices.

(b) Initiate or modify drug therapy in accordance with written guidelines or protocols previously established and approved by the Board.

(c) Order lab work in accordance with written guidelines or protocols as defined

by Section 73-21-73, ~~paragraph (jj)~~, Mississippi Code of 1972.

(d) Such services do not apply to Medication Therapy Management (MTM) conducted under a Pharmacy Permit at the permitted location.

(e) The permit must be obtained for the location in compliance with zoning requirements of the city or municipality and may not be located in a residence.

(f) A stock of drugs or devices may not be maintained or distributed from this location.

(2) Professional Services 2

(a) Pharmacists advise and provide pharmacotherapeutic consultations concerning therapeutic values, content, hazards and uses of drugs and devices.

(b) Initiate or modify drug therapy in accordance with written guidelines or protocols previously established and approved by the Board.

(c) Order lab work in accordance with written guidelines or protocols as defined by Section 73-21-73, ~~paragraph (jj)~~, Mississippi Code of 1972.

(d) Such services do not apply to medication therapy management conducted under a Pharmacy Permit at the permitted location.

(e) The permit must be obtained for the location in compliance with zoning requirements of the city or municipality and may not be located in a residence.

(f) A pharmacist may assist in maintaining and distribution of medications provided to the patients from a manufacturer patient assistance program that assists medically indigent persons to obtain their prescription medications only.

(3) Professional Services Outpatient Surgery Center

(a) A pharmacist supervises appropriate documentation of administration, wastage and disposal of medications in accordance with documented policies and procedures of the facility.

(b) The Medical Director of the facility is responsible for obtaining the Drug Enforcement Administration (DEA) registration number for the facility and compliance with applicable DEA regulations.

~~F. Sterile Product Outsourcing shall mean the compounding and distribution of sterile medications both in-state and out-of-state in accordance with FDA guidelines. The facility must apply for a Human Drug Compounding Outsourcing Registration from the U. S. Food and Drug Administration (FDA) and must comply with applicable FDA Current Good Manufacturing Practice requirements and other applicable guidelines. Facilities are subject to inspection by FDA on a risk based schedule. Facilities must be in compliance with applicable U. S. Drug Enforcement Administration (DEA) regulations. On the application for Sterile Product Outsourcing, the Pharmacist In-Charge must certify that the facility is in full compliance all applicable FDA and DEA regulations and guidelines. The facility may not hold a pharmacy permit within the same location as an Outsourcer.~~

G. Outsourcing Pharmacy – a pharmacy at one geographic location or address that:

(1) Is engaged in the compounding of drugs for human or animal use;

(2) Is registered as an outsourcing facility with the FDA; and

- (3) Complies with all of the requirements of Section 503B of the Federal FD&C Act and state laws and regulations.
 - (4) May not hold multiple pharmacy permits at the same location.
- 3. To obtain a pharmacy permit or ~~sterile product~~ outsourcing pharmacy permit or renew a permit, the applicant shall have:
 - A. Submitted a written application on a form(s) prescribed by the Board;
 - B. Submitted the required fees as follows:
Three hundred dollars (\$300.00) for the registration period January 1, 2011 through December 31, 2012, and each biennial registration period thereafter.
 - C. Any permit renewal application postmarked after December 31 of the renewal period shall be returned and a fifty (\$50.00) late renewal fee shall be assessed prior to renewal.
- 4. To obtain a Pharmacy Advisory Services permit or renew a permit, the applicant shall have:
 - A. Submitted a written application on a form(s) prescribed by the Board;
 - B. Submitted the required fees as follows:
One hundred dollars (\$100.00) for the registration period January 1, 2014 through December 31, 2015, and each biennial registration period thereafter.
 - C. Any permit renewal application postmarked after December 31 of the renewal period shall be returned and a fifty (\$50.00) late renewal fee shall be assessed prior to renewal.
- 5. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period. If the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.
- 6. Permits issued to any type of facility become null and void sixty (60) days from the date of issuance if inspection reveals a lack of legitimate business activity.
- 7. A permit for a location shall not be issued or renewed on the application of any person unless such person be a pharmacist licensed in this state.
- 8. Original permits, once issued for a new facility, may be returned to the Board and a new permit issued without being assessed an additional permit fee provided:
 - A. The change is on a one-time basis and is within sixty (60) days of original issuance; and
 - B. Controlled substance inventory requirements are met; and
 - C. A twenty-five dollar (\$25.00) processing fee is paid to the Board.
- 9. A pharmacy permit shall not be required for the sale or delivery of dialysate solutions or devices necessary to perform home peritoneal renal dialysis to patients with end stage

renal disease, provided the following criteria are met:

- A. The dialysate solutions or devices are approved or cleared by the Food and Drug Administration (FDA), as required by federal law;
- B. The dialysate solutions or devices are lawfully held by a manufacturer or a manufacturer's agent that is properly registered with the Mississippi Board of Pharmacy as a manufacturer, wholesale drug distributor (WDD) or third-party logistics provider (3PL) under Mississippi Code Section 73-21-105;
- C. The dialysate solutions or devices are held and delivered in their original, sealed packaging from the manufacturing facility;
- D. The dialysate solutions or devices are delivered only upon receipt of a valid prescription by a pharmacy permitted by the Mississippi Board of Pharmacy and the transmittal of an order from the pharmacy to the manufacturer or the manufacturer's agent;
- E. The manufacturer or the manufacturer's agent delivers the dialysate solutions or devices directly to:
 - (1) ~~(i)~~ A patient with chronic kidney failure, or his/her designee, for the patient's self-administration or the dialysis therapy, or
 - (2) ~~(ii)~~ A health care provider or institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.