STATE OF MICHIGAN
JOCELYN BENSON, SECRETARY OF STATE
DEPARTMENT OF STATE
LANSING

May 19, 2023

NOTICE OF FILING

ADMINISTRATIVE RULES

To: Secretary of the Senate
Clerk of the House of Representatives
Joint Committee on Administrative Rules
Michigan Office of Administrative Hearings and Rules (Administrative Rule #21-093-LR)
Legislative Service Bureau (Secretary of State Filing #23-05-07)
Department of Licensing and Regulatory Affairs

In accordance with the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6, this is to advise you that the Michigan Office of Administrative Hearings and Rules filed Administrative Rule #2021-093-LR (Secretary of State Filing #23-05-07) on this date at 10:14 A.M. for the Department of Licensing and Regulatory Affairs entitled, "Central Fill Pharmacies".

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(9) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

Sincerely,

Jocelyn Benson
Secretary of State

Lashana Threlkeld, Departmental Supervisor
Office of the Great Seal

Enclosure

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING
MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
SUZANNE SONNEBORN
EXECUTIVE DIRECTOR

ORLENE HAWKS
DIRECTOR

May 19, 2023

The Honorable Jocelyn Benson
Secretary of State
Office of the Great Seal
Richard H. Austin Building – 1st Floor
430 W. Allegan
Lansing, MI 48909

Dear Secretary Benson:

Re: Administrative Rules – Michigan Office of Administrative Hearings and Rules
Administrative Rules #: 2021-93 LR

The Michigan Office of Administrative Hearings and Rules received administrative rules, dated February 16, 2023 for the Department of Licensing & Regulatory Affairs **"Central Fill Pharmacies".** We are transmitting these rules to you pursuant to the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6.

Sincerely,

Michigan Office of Administrative Hearings and Rules

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

CERTIFICATE OF ADOPTION

By authority conferred on the Director of the Department of Licensing and Regulatory Affairs by Sections 16145, 17753, and 17767 of the Public Health Code, 1978 PA 368, MCL 333.16145, 333.17753, and 333.17767, and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030.

R 338.3051, R 338.3052, R 338.3053, R 338.3054, R 338.3055, and R 338.3056 of the Michigan Administrative Code are amended.

Date: 03/22/2023

Adopted by: Marlon I. Brown

Marlon I. Brown
Chief Administrative Officer
Department of Licensing and Regulatory Affairs

STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

ORLENE HAWKS
DIRECTOR

LEGAL CERTIFICATION OF RULES

I certify that I have examined the attached administrative rules, dated February 16, 2023, in which the Department of Licensing and Regulatory Affairs proposes to modify a portion of the Michigan Administrative Code entitled "**Central Fill and Shared Pharmacy Services**" by:

- Amending R 338.3051, R 338.3052, R 338.3053, R 338.3054, R 338.3055, and R 338.3056.

The Legislative Service Bureau has approved the proposed rules as to form, classification, and arrangement.

I approve the rules as to legality pursuant to the Administrative Procedures Act, MCL 24.201 *et seq.* and Executive Order No. 2019-6. In certifying the rules as to legality, I have determined that they are within the scope of the authority of the agency, do not violate constitutional rights, and are in conformity with the requirements of the Administrative Procedures Act.

Dated: April 3, 2023

Michigan Office of Administrative Hearings and Rules

By: Emily Leik

Emily Leik,
Attorney

LEGISLATIVE SERVICE BUREAU
Since 1941

Legal Division

Kevin H. Studebaker, Director

CERTIFICATE OF APPROVAL

On behalf of the Legislative Service Bureau, and as required by section 45 of the Administrative Procedures Act of 1969, 1969 PA 306, MCL 24.245, I have examined the proposed rules of the Department of Licensing and Regulatory Affairs dated February 16, 2023, amending R 338.3051, R 338.3052, R 338.3053, R 338.3054, R 338.3055, and R 338.3056 of the Department's rules entitled "Central Fill and Shared Pharmacy Services." I approve the rules as to form, classification, and arrangement.

Dated: April 3, 2023

LEGISLATIVE SERVICE BUREAU

By _____
Rachel M. Hughart,
Legal Counsel

Michigan Legislature
124 W. Allegan Street, 3rd Floor • P.O. Box 30036 • Lansing, MI 48909-7536 • (517) 373-9425 • Fax: (517) 373-5642

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

CENTRAL FILL AND SHARED PHARMACY SERVICES

Filed with the secretary of state on May 19, 2023

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(9) of the administrative procedures act of 1969,1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 16145, 17753, and 17767 of the public health code, 1978 PA 368, MCL 333.16145, 333.17753, and 333.17767, and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.3051, R 338.3052, R 338.3053, R 338.3054, R 338.3055, and R 338.3056 of the Michigan Administrative Code are amended, as follows:

PART 1. GENERAL PROVISIONS

R 338.3051 Definitions.

Rule 1. (1) As used in these rules:

(a) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.

(b) "Central fill pharmacy" means a pharmacy that engages in dispensing functions of centralized prescription processing at the request of an originating pharmacy.

(c) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

(d) "Deliver," as used in this part, means the actual, constructive, or attempted transfer of a prescription drug, including a controlled substance, directly to a patient or a patient's agent by the lawful order of a practitioner. Deliver does not include a central fill pharmacy that provides a prescription product to another pharmacy for subsequent issuance to a patient or a patient's agent.

(e) "Delivering pharmacist" means a pharmacist who is responsible for delivering a prescription directly to a patient or a patient's agent.

(f) "Delivering pharmacy" means the pharmacy that delivers the filled or refilled prescription to the patient or the patient's agent. The delivering pharmacy must be either the originating pharmacy or the central fill pharmacy.

(g) "Department" means the department of licensing and regulatory affairs (LARA).

(h) "Originating pharmacy" means a pharmacy that initially receives a patient's or a prescribing practitioner's request to fill or refill a prescription.

(2) Unless otherwise defined in these rules, a term defined in the code has the same meaning if used in these rules.

R 338.3052 Central fill and shared pharmacy services rules; prevail over other pharmacy rules.

Rule 2. (1) In addition to these rules, pharmacies must follow all applicable board rules. However, to the extent that these rules conflict with other board rules, the provisions in these rules must prevail.

(2) Shared pharmacy services for processing functions of centralized pharmacy processing that do not involve the dispensing process, such as completing claims adjudication or remote data entry, may be performed under the general supervision of a pharmacist. For this subrule, dispensing process means the physical preparing, compounding, packaging, or labeling of a drug product intended for delivery to the patient.

R 338.3053 Centralized prescription processing; dispensing requirements.

Rule 3. (1) In addition to complying with the requirements of section 17753 of the code, MCL 333.17753, a pharmacy must meet all of the following requirements before it either performs centralized prescription processing or outsources centralized prescription processing to another pharmacy:

(a) Hold a pharmacy license in this state.

(b) Share sufficient patient and drug information to minimize the possibility of an adverse drug event.

(c) Maintain records required in R 338.3054, for 5 years from the date of dispensing. The pharmacy shall ensure that the records are readily retrievable within 48 hours after the department makes a request for the records. If the records are maintained in a digital format, a printed copy must be made available to the department or other authorized individual upon request.

(2) The originating pharmacy shall maintain the original prescription for a period of 5 years after the date the prescription was filled.

(3) Two years after the prescription was filled, the originating pharmacy may make an electronic duplicate of the original paper prescription, which becomes the original prescription. The originating pharmacy shall present a printed copy of the electronic duplicate of the prescription to the department or board upon request.

(4) A pharmacy engaging in centralized prescription processing is responsible for each function of the prescription's processing performed by that pharmacy.

(5) A delivering pharmacist is responsible for complying with R 338.589(4) regarding patient counseling.

(6) The prescription label for a prescription that was filled by a central fill pharmacy must identify each pharmacy that was involved in dispensing and delivering the prescription. A central fill pharmacy may be identified on a prescription label by use of a unique identifier that is recognized by the delivering pharmacist. A central fill pharmacy shall create and maintain a unique identifier and communicate the unique identifier to all pharmacies that use its services. As used in this subrule, "unique identifier" means a unique combination of letters, numbers, or symbols that allows the delivering pharmacy to identify the specific central fill pharmacy involved in the processing of the prescription.

(7) A prescription that was not delivered to a patient may be transferred back to the pharmacy that filled the prescription, if the transfer records are maintained. A central fill

pharmacy and an originating pharmacy shall establish procedures for the disposition of prescription medication that was not delivered to patients. This medication may be returned to stock and may be re-dispensed without constituting a violation of R 338.503(1).

(8) A pharmacy that performs or contracts for centralized prescription processing shall comply with the procedures described in its policies and procedures manual, pursuant to section 17753(2) of the code, MCL 333.17753.

R 338.3054 Records maintenance; requirements for central fill pharmacies.

Rule 4. (1) An originating pharmacy shall maintain records that indicate all of the following:

(a) The date the request for centralized prescription processing was transmitted to a central fill pharmacy.

(b) The method of transmittal.

(c) The identification of the pharmacist responsible for the transmission.

(d) The name and address of the central fill pharmacy where the request for centralized prescription processing was transmitted.

(e) The date the delivering pharmacy received the filled prescription from the central fill pharmacy.

(f) The name of the pharmacy employee who accepted the transfer of a filled prescription from a central fill pharmacy.

(g) The identification of the pharmacist who was responsible for delivering the prescription to the patient or the patient's agent.

(2) A central fill pharmacy that receives the transmitted prescription shall maintain records that indicate all of the following, as applicable to its function:

(a) The date the request for centralized prescription processing was received from the originating pharmacy.

(b) The name and address of the originating pharmacy where the request for centralized prescription processing was received.

(c) The date the prescription was processed, verified, or filled.

(d) The identification of the pharmacists who were responsible for processing the prescription and shipping ~~a~~the filled prescription to an originating pharmacy or delivering the filled prescription to a patient or a patient's agent.

(e) The date the filled prescription was shipped to the originating pharmacy or was shipped or delivered to the patient or the patient's agent.

(f) The name and address of the patient to whom the filled prescription was shipped, if shipped.

(g) The method of delivery, such as private, common, or contract carrier, if shipped.

(3) If a prescription was not delivered to a patient and was transferred back to the pharmacy that filled the prescription, that pharmacy shall maintain the transfer records.

PART 2. CONTROLLED SUBSTANCES PRESCRIPTIONS

R 338.3055 Schedule 2, 3, 4, or 5 controlled substances prescriptions; requirements for central fill pharmacies.

Rule 5. (1) In addition to complying with the requirements of part 1 of these rules, a pharmacy that performs or contracts for centralized prescription processing shall comply with this rule if processing a prescription for a schedule 2, 3, 4, or 5 controlled substance.

(2) Prescriptions for controlled substances may be transmitted electronically, including by facsimile, from an originating pharmacy to a central fill pharmacy.

(3) An originating pharmacy that transmits prescription information for a controlled substance to a central fill pharmacy shall comply with all of the following:

(a) Ensure that the words "CENTRAL FILL" are on the face of the original prescription and the originating pharmacy shall record all of the following information:

(i) The name, address, and the Federal Drug Enforcement Administration (DEA) registration number of the central fill pharmacy where the prescription was transmitted.

(ii) The name of the pharmacist at the originating pharmacy who transmitted the prescription.

(iii) The date of transmittal.

(b) Ensure that the information that is required on a prescription under 21 CFR-1306.05 and R 338.3161 is transmitted to the central fill pharmacy, either on the face of the original prescription or in the electronic transmission of the prescription.

(c) Include all of the following in the prescription:

(i) The number of refills already dispensed.

(ii) The number of refills remaining.

(d) Maintain the original prescription for a period of 5 years from the date the prescription was filled.

(4) Two years after the prescription was filled, the originating pharmacy may make an electronic duplicate of the original printed prescription, which becomes the original prescription. A pharmacy shall present a printed copy of the electronic duplicate of the prescription to the department or board upon request.

(5) In addition to complying with the requirements in R 338.3054(2)(a), (b), (c), (d), (e), (f) and (g), a central fill pharmacy that receives the transmitted prescription shall comply with all of the following:

(a) Maintain records for 5 years after the date of transmittal.

(b) Maintain a copy of the prescription if it was sent via facsimile or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and DEA registration number of the originating pharmacy that transmitted the prescription.

(c) Maintain a record of the date the filled prescription was dispensed and the method of dispensing.

R 338.3056 Reporting to the electronic system for monitoring controlled substances.

Rule 6. As used in this part, the pharmacy that uses its stock to fill a prescription for a controlled substance is the pharmacy responsible to report to the department or the department's contractor the information required in R 338.3162b for each controlled substance prescription.

FILED WITH SECRETARY OF STATE

ON 5/19/2023 AT 10:14 AM