From: <u>BPL-BoardSupport</u>
To: <u>Ditschman, Andria (LARA)</u>

Subject: FW: Department of Licensing and Regulatory Affairs - Regulatory Impact Statement was approved. Title: Central Fill Pharmacies

 Date:
 Monday, November 28, 2022 9:00:16 AM

 Attachments:
 Central Fill DraftRule (Public Comment).doc

From: Mollien, Charlie < Charlie. Mollien@meijer.com>

Sent: Friday, November 25, 2022 1:14 PM

**To:** BPL-BoardSupport <BPL-BoardSupport@michigan.gov>

Cc: Mollien, Charlie < Charlie. Mollien@meijer.com>

Subject: FW: Department of Licensing and Regulatory Affairs - Regulatory Impact Statement was approved. Title:

Central Fill Pharmacies

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Attached are public comments for Michigan Board of Pharmacy's proposed ruleset on Central Fill Pharmacies.

Charlie Mollien

From: Michigan Department of Licensing and Regulatory Affairs LARA@govsubscriptions.michigan.gov

**Sent:** Wednesday, November 2, 2022 2:13 PM **To:** Mollien, Charlie <a href="mailto:Charlie.Mollien@meijer.com">Charlie.Mollien@meijer.com</a>

Subject: Department of Licensing and Regulatory Affairs - Regulatory Impact Statement was approved. Title:

Central Fill Pharmacies

The Regulatory Impact Statement was approved by the Administrative Rules Division for the Department of Licensing and Regulatory Affairs - Bureau of Professional Licensing.

MOAHR ID: 2021-93 LR
Title: Central Fill Pharmacies

The Administrative Code for the Department of Licensing and Regulatory Affairs can be viewed by clicking on the following link.

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# DEPARTMENT OF COMMUNITY HEALTHLICENSING AND REGULATORY AFFAIRS

#### DIRECTOR'S OFFICE

# CENTRALIZED PRESCRIPTION PROCESSING CENTRAL FILL AND SHARED PHARMACY SERVICESPHARMACIES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6)(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 community health department of licensing and regulatory affairs by sections 16145, and 1770117753, and 17767 of the public health code, 1978 PA 368, MCL 333.16145, and 333.17701 333.17753, et seq. and 333.17767, and Executive Reorganization Order Numbers Nos. 1996-1 1991-9, 1996-2, and 2003-1, and 2011-4, being MCL 330.3101 338.3501, 445.2001, and 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** parts 1 and 2 of the centralized prescription processing rules, R 338.3051 to R 338.3054:

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

(b)(a) "Centralized prescription Central fill pharmacyprocessing center" means a pharmacy operated under the direction of a pharmacist that processes information related to the practice of pharmacy and engages in dispensing functions of centralized prescription processing at the request of an originating pharmacy.

- (b) "Centralized prescription processing" is the term defined in section 17753(3) of the code.
- (c) "Code" means **the public health code,** 1978 PA 368, MCL 333.1101 et seq. to **333.25211.**
- (d) "Deliver," as used in this part, means **the actual, constructive, or attempted transfer of to issue** a prescription drug, including a controlled substance, directly to a patient or a patient's agent by the lawful order of a practitioner. A centralized prescription **Deliver does not include a central fill** processing center **pharmacy** that provides a prescription product to another pharmacy for subsequent issuance to a patient or a patient's agent. has not met the definition of deliver as defined in this subrule.

Commented [MC1]: These rules appear to regulate both central fill pharmacy and shared pharmacy services. Consider updating the title to "Central Fill and Shared Pharmacy Services".

Commented [MC2]: Defining "central fill pharmacy" as the all encompassing term for any pharmacy engaged in centralized prescription processing incorrectly combines industry terms used to delineate between shared pharmacy services, a pharmacy engaged in non-dispensing centralized prescription processing, and central fill pharmacy, a pharmacy that engages in dispensing functions of centralized prescription processing.

- (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 authorized representativeagent. The delivering pharmacy shallmust be either the originating pharmacy or the centralized prescription processing center central fill pharmacy.
- (g) "Department" means the department of licensing and regulatory affairs (LARA).
- $\frac{g}{h}$  "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 The termsterm defined in the code havehas the same meanings meaning when if used in these rules.

R 338.3052 Centralized prescription processing Central fill and shared pharmacy services pharmacies rules; prevail

over other pharmacy rules.

- Rule 2. To(1) In addition to these rules, central fill—pharmacies must follow all applicable board rules. However, to the extent that any rule in parts 1 and 2 of the centralized prescription processing these rules conflicts conflict with other board of pharmacy rules, the provisions in parts 1 and 2 of the centralized prescription processing these rules shallmust 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 may perform centralized prescription processing services or outsource outsources these services centralized prescription processing to another pharmacy:-Pharmacies that perform or outsource prescription processing services shall meet all of the following requirements:
- (a) Be licensed by the Michigan board of pharmacy 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 prescription information or an equivalent record, as prescribed in section 17752(1) of the code, and the records required in R 338.3054 of this part, for 5 years from the date of dispensing. A centralized prescription processing center and an original pharmacy The pharmacy shall ensure that the information records is are readily retrievable within 48 hours after the board's agent department makes a request for the information records. If the records are maintained in a digital format, a printed copy

Commented [MC3]: Adding this clarification is necessary to reflect contemporary practice of pharmacy with shared pharmacy services and make clear the application of "dispense" as defined by MCL 333.17703(3).

shallmust be made available to the department or other authorized individualimmediately to the board's agent 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.
- (2)(4) A pharmacy engaging in centralized prescription processing shall beis responsible for each function of the prescription's processing performed by that pharmacy.
- (3)(5) A delivering pharmacist shall beis responsible for complying with R 338.490(4) R 338.589(4) regarding patient counseling.
- (4)(6) The prescription label for a prescription that was filled by a eentralized prescription processing center central fill pharmacy shallmust identify each pharmacy that was involved in preparing dispensing and delivering athe prescription. A centralized prescription processing center 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 centralized prescription processing center central fill pharmacy involved in the processing of the prescription. A centralized prescription processing center shall create and maintain a unique identifier and shall communicate the unique identifier to all pharmacies that use its services.
- (5)(7) A prescription that was not delivered to a patient may be transferred back to the pharmacy that filled the prescription, provided thatif the transfer records are maintained. A centralized prescription processing center 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 redelivered re-dispensed without constituting a violation of R 338.472(1)-338.503(1).
- (6)(8) A pharmacy that performs or contracts for centralized prescription **processing** services shall comply with the procedures described in its policies and procedures manual, as provided inpursuant to section 17753(2) of the code, MCL 333.17753.
- R 338.3054 Records maintenance; requirements for <del>centralized prescription processing</del> **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 services was transmitted to a centralized prescription processing center 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 eentralized prescription processing center central fill pharmacy to which where the request for centralized prescription processing services was transmitted.

- (e) The date the delivering pharmacy received the filled prescription from the centralized prescription processing centercentral fill pharmacy.
- (f) The name of the pharmacy employee who accepted the delivery transfer of a filled prescription from a centralized prescription processing center 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 centralized prescription processing centercentral 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 services was received from the originating pharmacy.
- (b) The name and address of the originating pharmacy from whichwhere the request for centralized prescription processing services was received.
  - (c) The date the prescription was processed, verified, or filled.
- (d) The identification of anythe pharmacistpharmacists who waswere responsible for processing the prescription and shipping athe filled prescription to an originating pharmacy or delivering athe 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) If shipped, the 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 centralized prescription processing central fill pharmacies.
- Rule 5. (1) In addition to complying with the requirements of Partpart 1 of these rules, a pharmacy that performs or contracts for centralized prescription processing services shall comply with this rule whenif 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 centralized prescription processing center central fill pharmacy.
- (3) An originating pharmacy that transmits prescription information for a controlled substance to a centralized prescription processing centercentral 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 The name, address, and the federal drug enforcement administration (dea) Federal Drug Enforcement Administration (DEA) registration number of the centralized prescription processing center-central fill pharmacy to which where the prescription had been was transmitted;

- (ii) the The name of the pharmacist at the originating pharmacy who transmitted the prescription.
  - (iii) and, the The date of transmittal.
- (b) Ensure that all the information that is required to be on a prescription pursuant tounder the provisions of 21 CFRC.F.R. § 1306.05 and R 338.3161 is transmitted to the centralized prescription processing centercentral fill pharmacy, either on the face of the original prescription or in the electronic transmission of the prescription information.
- (c) Indicate Include all of the following in the prescription information that is transmitted,:
  - (i) the The number of refills already dispensed.
  - (ii) and the 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.
- (4)(5) In addition to complying with the requirements in R 338.3053338.3054(2)(a), (b), (c), (d), (e), (f) and (g), a centralized prescription processing centercentral fill pharmacy that receives the transmitted prescription shall comply with bothall of the following:
  - (a) Maintain records for 5 years after the date of transmittal.
- (b) KeepMaintain 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 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 shall beis 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 of a controlled substance.

# Central Fill Pharmacies Rules - ORR 2021-093 LR Public Comment Summary Rules Committee's Recommendations to December 14, 2022, Public Comments

# **Testimony/Comments Received:**

Charlie Mollien

### Title

Rule Numbers	Commenter	Comment	
Title	Mollien	The rules appear to regulate both central fill pharmacies and shared pharmacy services. Consider	
		updating the title to "Central Fill and Shared Pharmacy Services".	
<b>Rules Committee</b>	The Rules Committee agrees with the comment to modify the title to include both Central fill and Shared Pharmacy		
Response	Services.		
<b>Board Response</b>	The Board agrees with the comment to modify the title to include both Central fill and Shared Pharmacy		
	Services.		

# CENTRALIZED PRESCRIPTION PROCESSING PHARMACIES CENTRAL FILL AND SHARED PHARMACY SERVICES

## **Rule 338.3051 Definitions.**

Rule Numbers	Commenter	Comment
Section (1)(b)	Mollien	Defining "central fill pharmacy" as the all-encompassing term for any pharmacy engaged in centralized prescription processing incorrectly combines industry terms used to delineate between shared pharmacy services, a pharmacy engaged in non-dispensing centralized prescription processing, and central fill pharmacy, a pharmacy that engages in dispensing functions of centralized prescription processing. Modify to:
		(b)(a) "Centralized prescription Central fill pharmacyprocessing center" means a pharmacy operated under the direction of a pharmacist that processes information related to the practice of pharmacy and engages in dispensing functions of centralized prescription processing at the

	request of an originating pharmacy.		
<b>Rules Committee</b>	The Rules Committee agrees with the comment to clarify that a central fill pharmacy is a pharmacy that is handling		
Response	dispensing functions versus shared pharmacy services that describes a pharmacy engaged in processing functions of		
	centralized pharmacy processing.		
<b>Board Response</b>	The Board agrees with the comment to clarify that a central fill pharmacy is a pharmacy that handles dispensing		
	functions versus shared pharmacy services.		

#### R 338.3051 Definitions.

Rule 1. (1) As used in these rules parts 1 and 2 of the centralized prescription processing rules, R 338.3051 to R 338.3054:

- (a) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.
- (b)(a) "Centralized prescription Central fill pharmacyprocessing center" means a pharmacy operated under the direction of a pharmacist that processes information related to the practice of pharmacy and engages in dispensing functions of centralized prescription processing at the request of an originating pharmacy.
  - (b) "Centralized prescription processing" is the term defined in section 17753(3) of the code.
  - (c) "Code" means the public health code, 1978 PA 368, MCL 333.1101 et seq. to 333.25211.
- (d) "Deliver," as used in this part, means the actual, constructive, or attempted transfer of to issue a prescription drug, including a controlled substance, directly to a patient or a patient's agent by the lawful order of a practitioner. A centralized prescription Deliver does not include a central fill processing center pharmacy that provides a prescription product to another pharmacy for subsequent issuance to a patient or a patient's agent. has not met the definition of deliver as defined in this subrule.
- (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 authorized representative agent. The delivering pharmacy shallmust be either the originating pharmacy or the centralized prescription processing center central fill pharmacy.
  - (g) "Department" means the department of licensing and regulatory affairs (LARA).
- (g)(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 The termsterm defined in the code havehas the same meanings meaning when if used in these rules.

Rule 338.3052 Centralized prescription processing Central fill pharmacies and shared pharmacy services rules; prevail over other pharmacy rules.

Rule Numbers	Commenter	Comment	
Title	Mollien	The rules appear to regulate both central fill pharmacies and shared pharmacy services. Consider	
		updating the title to "Central Fill and Shared Pharmacy Services rules; prevail over other	
		pharmacy rules".	
	Mollien	Divide rule into (1) and (2). Adding this clarification is necessary to reflect contemporary practice	
		of pharmacy with shared pharmacy services and make clear the application of "dispense" as defined	
		by MCL 333.17703(3).	
		Delete "central fill" in first line.	
Modify (1) and	Mollien	(1) Delete central fill from (1)	
Add (2)		(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.	
<b>Rules Committee</b>	<b>Title:</b> The Rules Committee agrees with the comment to modify the title to include both central fill and shared pharmacy		
Response	services.		
	(1) and (2): The Rules Committee agrees with the comment that the rule should be divided into two provisions, a accepts the language recommended in (1) and (2) above, to reflect that central fill involves dispensing versus other		
		processing functions of centralized pharmacy processing that does not involve dispensing.	
<b>Board Response</b>	_	<b>e:</b> The Board agrees with the comment to modify the title to include both central fill and shared pharmacy services.	
	` '	ard agrees with the comment that the rule should be divided into two provisions, and accepts the	
		ded in (1) and (2) above, to reflect that central fill involves dispensing versus other shared services	
	for processing funct	ions of centralized pharmacy processing that does not involve dispensing.	

R 338.3052 Centralized prescription processing Central fill pharmacies rules; prevail over other pharmacy rules.

Rule 2. (1) ToIn addition to these rules, central fill pharmacies must follow all applicable board rules. However, to the extent that any rule in parts 1 and 2 of the centralized prescription processing these rules conflicts conflict with other board of pharmacy rules, the provisions in parts 1 and 2 of the centralized prescription processing these rules shallmust 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.

Rule 338.3053 Centralized prescription processing; requirements.

		6)
Rule Numbers	Commenter	Comment
Title	Mollien	Add "dispensing" to title.
		Centralized prescription processing; <b>dispensing</b> requirements.
<b>Rules Committee</b>	The Rules Committee agrees with the comment to add "dispensing" to the title.	
Response		
<b>Board Response</b>	The Board agrees with the comment to add "dispensing" to the title.	

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 may perform centralized prescription processing services or outsource outsources these services centralized prescription processing to another pharmacy: Pharmacies that perform or outsource prescription processing services shall meet all of the following requirements:
  - (a) Be licensed by the Michigan board of pharmacyHold a pharmacy license in this state.
  - (b) Share sufficient patient and drug information to minimize the possibility of an adverse drug event.
- (c) Maintain prescription information or an equivalent record, as prescribed in section 17752(1) of the code, and the records required in R 338.3054 of this part, for 5 years from the date of dispensing. A centralized prescription processing center and an original pharmacy shall ensure that the information records is are readily retrievable within 48 hours after the board's agent department makes a request for the information records. If the records are maintained in a digital format, a printed copy shallmust be made available to the department or other authorized individual immediately to the board's agent 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.

- (2)(4) A pharmacy engaging in centralized prescription processing shall be is responsible for each function of the prescription's processing performed by that pharmacy.
- (3)(5) A delivering pharmacist shall be is responsible for complying with R 338.490(4) R 338.589(4) regarding patient counseling.
- (4)(6) The prescription label for a prescription that was filled by a centralized prescription processing center central fill pharmacy shallmust identify each pharmacy that was involved in preparing dispensing and delivering athe prescription. A centralized prescription processing center 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 centralized prescription processing center central fill pharmacy involved in the processing of the prescription. A centralized prescription processing center shall create and maintain a unique identifier and shall communicate the unique identifier to all pharmacies that use its services.
- (5)(7) A prescription that was not delivered to a patient may be transferred back to the pharmacy that filled the prescription, provided that if the transfer records are maintained. A centralized prescription processing center 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-delivered re-dispensed without constituting a violation of R 338.472(1) 338.503(1).
- (6)(8) A pharmacy that performs or contracts for centralized prescription **processing** services shall comply with the procedures described in its policies and procedures manual, as provided inpursuant to section 17753(2) of the code, MCL 333.17753.