

PROGRAM GUIDELINES FOR THE MICHIGAN CANCER DRUG REPOSITORY PROGRAM

The Public Health Code (P.A. 368 of 1978, as amended and referred to as the “Code”) requires the Department of Licensing and Regulatory Affairs (formerly the Department of Community Health) to establish and maintain a Cancer Drug Repository Program that allows an individual to donate a cancer drug or supplies to be used by another individual who meets the eligibility criteria specified in the Code. As part of the establishment of this program, the Board of Pharmacy is required under MCL 333.17780(1) of the Code to establish program guidelines, policies and procedures that address the Cancer Drug Repository Program. In accordance with this requirement, the Board of Pharmacy is requiring a health facility or pharmacy that participates in the program to establish written policies and procedures that pertain to the implementation of the program.

Participation

A health facility or pharmacy that participates in the Michigan Cancer Drug Repository Program is required to comply with the requirements of the Public Health Code, as specified in MCL 333.17780. Participation in the repository program is voluntary. A health facility or pharmacy may choose to participate fully in the program by accepting, storing and dispensing or administering drugs or supplies, or may choose to limit its participation by only accepting and storing donated drugs and supplies. In accordance with these guidelines, a health facility or pharmacy that participates in the program is required to specify in its policies the level of its participation in the program. If a health facility or pharmacy chooses to limit its participation, it must specify procedures that will be used to distribute any donated drugs to a fully participating pharmacy or health facility, as required under the Code.

Notice of Participation or Withdrawal Form

A health facility or pharmacy that intends to participate in the Michigan Cancer Drug Repository Program must complete this form and submit it to the address listed. The application will be reviewed and the status of the facility will be verified by the Department. The facility will be notified of its approval or rejection. If the program is approved, the name and address of the facility or program will be added to the list of participants that will be available upon request or on the website at www.michigan.gov/healthlicense.

If the facility or pharmacy decides to discontinue its participation, this form must be submitted to the Department with the date of the termination of the Cancer Drug Repository Program. The termination of the program will cause the facility or pharmacy to be removed from the Registry of active participants.

Donations

Under MCL 333.17780(3), an individual who is at least 18 years of age may donate legally obtained cancer drugs or supplies to the Michigan Cancer Drug Repository Program. The Code also permits a pharmacy, health facility, manufacturer, or wholesale distributor to donate cancer drugs or supplies to a cancer drug repository, if the donated drugs have not been dispensed previously. The policies must specify the procedures that a participating health facility or pharmacy will use to ensure that donations of cancer drugs and supplies meet all of the requirements specified in the Code, including identifying the type of documentation that donors will have to provide to prove that special storage or handling procedures have been met.

If a health facility, manufacturer, or wholesaler donates drugs, the policies and procedures must establish methods to demonstrate that the drugs had not been donated previously and that the drugs and supplies will not be resold. A participating pharmacy or health facility will have to indicate in its policies that the drugs used in the cancer drug repository program will be stored separately from the rest of a pharmacy's or practitioner's stock.

The policies must state that controlled substances are not eligible for the cancer drug repository program, as provided in MCL 333.17780 (4).

The policies must prohibit the donation of cancer drugs that can only be dispensed to a patient registered with the drug manufacturer because donation could prevent manufacturers from maintaining patient registration data.

The policies must prohibit the donation of a cancer drug that requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature because the effectiveness and safety of the cancer drug can no longer be ensured.

The policies shall not require a pharmacist or practitioner to accept or utilize a cancer drug donated to a cancer drug repository program when, in the professional judgment of the pharmacist or practitioner, the drug should not be accepted or utilized.

The policies must also specify the manner in which a Michigan licensed pharmacist, who is employed by or under contract with a cancer drug repository, will determine that the donated drugs or supplies meet all of the following requirements of the statute:

- that the drug's expiration date is at least six months later than the date the drug was donated;
- that the drug is in the original manufacturer's unopened, tamper-evident, unit dose packaging that includes a lot number and expiration date;

- that the drug has not been adulterated or misbranded; and,
- that the person making the donation or the person's authorized representative affirms, with a signature on the cancer drug repository form, which is required under MCL 333.17780(3), that the donated drugs and supplies were properly stored, never opened, never used, never tampered with, and not adulterated or misbranded.

Donation, Transfer and Destruction Record Form

The donor of drugs or supplies to the Cancer Drug Repository for distribution, transfer to a participating repository or destruction must complete the Donation, Transfer and Destruction Record Form. The donor must specify their name, relationship to the patient who had the drugs or supplies, the name, strength and quantity of the medication or supplies being donated and the name of the receiving facility. The donor must also sign a statement that the drug or supplies were not opened, used, tampered with, adulterated or misbranded and that they were stored as recommended by the manufacturer. The participating repository must also sign the form indicating their acceptance of the donation.

If the donated drugs or supplies are transferred to another participating repository or if the drugs or supplies must be destroyed or disposed of, the repository must indicate the status of the donation on this form.

Dispensing

According to MCL 333.17780(5), donated cancer drugs and supplies must be dispensed by a pharmacist pursuant to a prescription written by a prescriber or may be dispensed or administered by a dispensing practitioner.

The policies must specify the procedures that pharmacists and prescribers will use to address the Code's dispensing requirements, as specified in MCL 333.17780(6), as well as the prescription labeling and patient counseling requirements specified in the Code and the Michigan Board of Pharmacy administrative rules.

Under the Michigan Cancer Drug Repository Program, any resident of the State of Michigan who is diagnosed with cancer is eligible to receive drugs or supplies. The Code requires that before a cancer drug or supply is dispensed or administered to an individual, the individual must provide verification that he or she has a current diagnosis of cancer. The policies must indicate the manner in which the Code's eligibility requirements will be met, including verification that an individual is a Michigan resident who has a current diagnosis of cancer. The policies should also indicate the order of priority as described in MCL 333.17780(7) for individuals who are eligible to receive the cancer drug or supply.

In addition, the policies must specify the method by which all cancer drug repository program drugs will be verified and a drug utilization review will be performed. Furthermore, procedures must be established to ensure that these drugs will be dispensed by a pharmacist or a dispensing practitioner when it is within the prescriber's scope of practice, according to the provisions of MCL 333.17745.

Recipient Record Form

Before a cancer drug or supply may be dispensed or administered to an individual, MCL 333.17780(6) of the Code requires the individual to comply with certain requirements, including that a recipient of the cancer drug or supplies sign a cancer drug recipient record form. In addition to meeting these requirements, the procedures must require the recipient form to state clearly that the recipient of the cancer drug or supply is making an informed consent decision about his or her treatment and is not merely signing a form.

The policies must include a procedure that provides for the entry on a patient profile of all cancer drug repository program drugs dispensed to a patient, including information that the drugs were obtained through the cancer drug repository program.

Storage and Distribution

The policies and procedures must provide for a monthly inspection of all drugs donated to the cancer drug repository program. In addition to meeting the requirements in MCL 333.17780(6), the inspection must include a check of the expiration date of the drug and the security of the storage area, as well as a reconciliation of all cancer drug repository program drugs and supplies.

MCL 333.17780(8) permits cancer drug repositories to distribute drugs and supplies donated under the program to other repositories when requested by a participating repository. If a repository distributes drugs and supplies to another repository, the policies must specify that the repository will have to comply with the requirements in this section of the Code, including requiring the completion of a cancer drug repository donor form.

Records

The policies must specify procedures to ensure that cancer drug repository program prescriptions will be filed separately, or that a pharmacy will have an auditable record system that identifies all necessary information for the cancer drug repository program.

The policies must include procedures so that all drugs used in the cancer drug repository program will be auditable with an accounting of every dose. The policies must require that a perpetual inventory logbook be maintained and include the following entries:

- a. Name of the drug.
- b. Quantity of the drug.
- c. Expiration date of the drug.
- d. Lot number of the drug.
- e. Name of the person who accepted the drug from the donor.
- f. Name of the person who donated the drug.
- g. Name of the person to whom the drug was originally prescribed.
- h. Name of the person to whom the drug was dispensed.
- i. Date the drug was dispensed.
- j. Name of the prescribing practitioner who wrote the prescription for the drug to be dispensed under the cancer drug repository program.
- k. Name of the medical facility or pharmacy to which the drug was distributed.
- l. Date the drug was distributed to another cancer drug repository.
- m. Date of destruction or disposal of the drug.
- n. Whether a handling fee was charged and the amount of any such fee.

**STATE OF MICHIGAN
MICHIGAN BOARD OF PHARMACY**

P.O. Box 30670
Lansing, MI 48909

**CANCER DRUG REPOSITORY PROGRAM
DONATION, TRANSFER AND DESTRUCTION RECORD**

Completion of this form meets the notification requirements under the Michigan Public Health Code 1978 PA 368 as amended (MCL 333.17780) for donating cancer drugs or supplies, for distribution of cancer drugs or supplies to a participating repository and for destruction of cancer drugs or supplies under the Cancer Drug Repository Program. A copy of this form must be retained for at least five years by the dispensing repository. Questions about completing this form may be directed to 517-335-0918.

DONATION INFORMATION

PLEASE PRINT CLEARLY

Name of Donor		Name of Patient, If Not Donor		Relationship to Patient	
Name of Pharmacy or Health Facility Receiving Donation				Michigan Pharmacy I.D./License Number	
Name of Medication or Medical Supply				Date Donated	
Medication Strength		Expiration Date	Lot Number, If Available		Quantity Donated
I certify that to the best of my knowledge, the above named cancer drug or supply was stored as recommended by the manufacturer and that the cancer drug or supply has never been opened, used, tampered with, adulterated, or misbranded.					
SIGNATURE of Donor (must be 18 years of age)				Date Signed	
Name of Pharmacist Accepting Donation		Signature of Pharmacist Accepting Donation		MI License Number of Pharmacist	

DISTRIBUTION OF DONATED CANCER DRUG OR MEDICAL SUPPLY TO A PARTICIPATING REPOSITORY

A **COPY** of the original donation form must accompany this form for all distributions between participating repositories.

Name of Pharmacy or Health Facility Receiving Cancer Drug or Medical Supply		Date Distributed
Quantity of Medication or Description of Medical Supply Distributed		

DESTRUCTION OR DISPOSAL INFORMATION

Name, Strength and Quantity of Cancer Drug or Medical Supply		Date of Destruction
Source of Cancer Drug or Medical Supply		
Name of Person or Firm Destroying or Disposing of Cancer Drug or Medical Supply		
Signature of Person or Firm Representative Destroying or Disposing Cancer Drug or Medical Supply		Date of Destruction

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**CANCER DRUG REPOSITORY PROGRAM
RECIPIENT RECORD**

Completion of this form meets the notification requirements under the Michigan Public Health Code 1978 PA 368 as amended (MCL 333.17780) for dispensing or administering cancer drugs and medical supplies to recipients who meet the eligibility requirements of the Cancer Drug Repository Program. Complete and submit this form to the address listed above. A copy of this form must be retained for at least five years by the dispensing repository. Questions about completing this form may be directed to 517-335-0918.

RECIPIENT INFORMATION

PLEASE PRINT CLEARLY

Name of Recipient			
Name of Medication or Medical Supply			Date Received
Medication Strength	Expiration Date	Lot Number, If Available	Quantity Received
<p>I certify that I am a Michigan resident and that I understand that the above named cancer drug or medical supply I am receiving has been donated, may have been previously dispensed, and has potentially been stored in a non-controlled environment. I understand that a visual inspection has been conducted by the pharmacist or practitioner to ensure that the cancer drug has not expired, does not appear adulterated or misbranded and is in its original manufacturer's unopened packaging. I understand that the dispensing pharmacist, the administering practitioner, the cancer drug repository, the Board of Pharmacy, and any other participant of the cancer drug repository program cannot guarantee the safety of the cancer drug or medical supply being dispensed or administered and that the pharmacist or practitioner has determined that the cancer drug or medical supply is safe to dispense or administer based on the accuracy of the donor's form submitted with the donated cancer drug or medical supply.</p>			
SIGNATURE of Recipient or Authorized Representative			Date Signed
List the name of prescribing practitioner who authorized the above prescription for cancer drug to be dispensed under the Cancer Drug Repository Program.			
<p>Handling Fee: \$ _____</p> <p>(The dispensing practitioner may charge a handling fee of not more than 250% of the Medicaid dispensing fee or \$5.00, whichever is less.)</p>			

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**CANCER DRUG REPOSITORY PROGRAM
NOTICE OF PARTICIPATION OR WITHDRAWAL**

Completion of this form meets the notification requirement for participation in, or withdrawal from, the Cancer Drug Repository Program under the Michigan Public Health Code 1978 PA 368 as amended (MCL 333.17780). Complete and submit this form to the address listed below. Questions about completing this form may be directed to 517-335-0918. A copy of this form must be retained for at least five years by the dispensing repository.

Michigan Board of Pharmacy
Cancer Drug Repository Program
P.O. Box 30670
Lansing, Michigan 48909

A pharmacy or health facility may fully participate in the cancer drug repository program by accepting, storing and dispensing donated cancer drugs and supplies or may limit its participation to only accepting and storing donated cancer drugs and medical supplies. Check one of the following:

- Full Participation
(WILL dispense cancer drugs and supplies)
- Partial Participation
(WILL NOT dispense cancer drugs and supplies)

PLEASE PRINT CLEARLY

Name of Pharmacy or Health Facility		
Michigan Pharmacy I.D./License Number	Telephone Number with Area Code	
Street Address		
City	State	Zip Code
Name of Pharmacist or Authorized Individual	Michigan Health Professional I.D./License Number	
I certify that the above names facility is licensed in the State of Michigan and is in compliance with all State and Federal laws and administrative rules.		
SIGNATURE – Pharmacist or Authorized Individual		Date Signed

**NOTICE OF WITHDRAWAL
PHARMACY OR HEALTH FACILITY**

Name of Pharmacy or Health Facility		
Michigan Pharmacy I.D./License Number	Telephone Number with Area Code	
Street Address		
City	State	Zip Code
As of _____ the pharmacy or health facility identified above, will no longer be participating in (enter withdrawal date) The Cancer Drug Repository Program.		
SIGNATURE – Pharmacist or Authorized Individual		Date Signed