Are there any statutes or regulations governing the privacy of a customer's personal information used or disclosed by a retail pharmacy?

Yes, in Michigan there are privacy-related statutory and regulatory requirements in the following areas:

- Disclosure
- HIV/AIDS

In addition, there are information-related statutory and regulatory requirements in the following areas:

- Record Maintenance
- Transfer of Prescriptions
- Manual System of Recording Refills
- Uniform System of Recording Refills
- Automated Data Processing Systems

**Disclosure**

A prescription or equivalent record on file in a pharmacy is not a public record. A person having custody of or access to prescriptions may not disclose their contents or provide copies without the patient's authorization, to any person except to:

(a) the patient for whom the prescription was issued, or another pharmacist acting on behalf of the patient;

(b) the authorized prescribed who issued the prescription, or a licensed health professional who is currently treating the patient;

(c) an agency or agent of government responsible for the enforcement of laws relating to drugs and devices;

(d) a person authorized by a court order;

(e) a person engaged in research projects or studies with protocols approved by the board.


**HIV/AIDS**

All reports, records and data pertaining to testing, care, treatment, reporting and research, as well as partner notification information, that are associated with HIV/AIDS are confidential and may be disclosed only in accordance with specified statutory requirements. Information pertaining to
HIV infection or AIDS may be disclosed in response to a court order and subpoena only after the court has made specific findings that other ways of obtaining the information are not available or would not be effective and that the public interest and need for disclosure outweigh the potential for injury to the patient. Should disclosure be ordered, it is further limited to those parts of the patient’s record that are essential and those persons who need to know. Mich. Comp. Laws Ann. § 333.5131 (2002).

Disclosure of information regarding an individual who has HIV or AIDS without a court order is allowed in a number of specified circumstances, including, but not limited to:

(a) to the Department of Health, a local health department, or another health care provider if the disclosure is:

(1) to protect the health of an individual;
(2) to prevent further transmission of HIV;
(3) to diagnose and care for a patient; or

(b) if the disclosure is expressly authorized in writing by the individual. The written authorization must be specific to HIV or AIDS, and if the individual is a minor or incapacitated, the authorization must be executed by the parent or legal guardian.

However, a person who discloses information under (a) above must not include in the disclosure information that identifies the individual to whom the information pertains unless the identifying information is reasonably necessary to prevent a foreseeable risk of transmission of HIV. Mich. Comp. Laws Ann. § 333.5131 (2002).a

Is there any case law governing the privacy of a customer’s personal information used or disclosed by a retail pharmacy?

No.

Are there any Attorney General opinions governing the privacy of a customer’s personal information used or disclosed by a retail pharmacy?

No.
Information-Related Requirements

Record Maintenance

A prescription, or an equivalent record thereof approved by the Board of Pharmacy, must be preserved by a licensee for at least 5 years. A prescription must be numbered, dated, and initialed by the dispensing pharmacist at the time the prescription is first filled. In addition, if the drug that is dispensed is not the brand prescribed or if the prescription was written generically, the name of the manufacturer or supplier of the drug must also be recorded on the prescription. Mich. Comp. Laws Ann. § 333.17552(a) (2002), Mich. Admin. Code r. 338.480(1) (2002).

Transfer of Prescriptions

A pharmacist may refill a copy of a prescription from another pharmacy if the original prescription has remaining authorized refills. The pharmacist issuing a written or oral copy of a prescription must cancel the original prescription and record the cancellation. The record of cancellation must include the date the copy was issued, to whom issued, and the identification of the pharmacist who issued the copy. In addition, the written or oral copy issued must be a duplicate of the original prescription except that it must also include the prescription number, the name of the pharmacy issuing the copy, the date the copy was issued, and the number of authorized refills remaining available to the patient.

The pharmacist receiving a written or oral copy of the prescription must exercise reasonable diligence to determine whether it is a valid copy, and having done so may treat the copy as an original prescription. Except as described above, all other copies of prescriptions furnished must be used for information purposes only and clearly marked “for informational or reference purposes only.” Mich. Comp. Laws Ann. § 333.17752(3) (2002).

Manual System of Recording Refills

A pharmacy may utilize a manual system of recording refills if:

(a) the amount and date dispensed is entered on the prescription in an orderly fashion and the dispensing pharmacist initials the entry. If the pharmacist only initials and dates the prescription, the full face amount of the prescription will be deemed dispensed.

(b) the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed is indicated on the prescription.


Uniform System of Recording Refills

Pharmacies may utilize a uniform system of recording refills. The records must be created and maintained in written form with all original and refill prescription information for a particular
prescription appearing on single documents in an organized format. Each record must contain the following information:

(a) prescription number;
(b) patient’s name and address;
(c) prescriber’s name;
(d) prescriber’s federal drug enforcement administration number, if appropriate;
(e) number of refills authorized;
(f) “dispense as written” instructions, if indicated;
(g) name, strength, dosage form, and quantity of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated;
(h) date of issuance of the prescription; and
(i) date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

This information must be entered on the record for all prescriptions filled at the pharmacy, even if they are not refillable. In addition, prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that the information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and must initial the record each time a prescription is filled or refilled. The pharmacy must preserve the records for 5 years and they are subject to inspection by the Board of Pharmacy or its agents.

MICH. ADMIN. CODE r. 338.480a(3)(b)-(c) (2002).

Automated Data Processing Systems

A pharmacy may utilize a uniform automated data processing system of recording refills if all the information that is pertinent to a prescription is entered on the record, including:

(a) the prescription number;
(b) the patient’s name and address;
(c) the prescriber’s name;
(d) the number of refills authorized;
(e) whether the drug must be dispensed as written;
(f) the name, strength, dosage form, and quantity of the drug prescribed (and the name of the manufacturer or supplier, if dispensed as other than the brand prescribed);
(g) the date of issuance of the prescription;
(h) the prescriber’s DEA number; and

(i) the date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

MIC. ADMIN. CODE r. 338.480a(4)(a) (2002).

Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, even for nonrefillable prescriptions. The format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. The pharmacy must preserve the records on-site for five years, and the records are subject to Board of Pharmacy inspection. MIC. ADMIN. CODE r. 338.480a(4)(b) (2002).

The recording system must provide adequate safeguards against improper manipulation, the alteration of records, and the loss of records. In addition, the recording system must have the capability of producing a printout of all original and refilled prescription data. A printout of an audit trail or other required information shall be made available to an authorized agent of the Board of Pharmacy upon request. MIC. ADMIN. CODE r. 338.480a(4)(d), (e) (2002).

The prescription data must be maintained for 5 years. Prescription data for the most current 16 months must be readily retrievable on site and available for immediate review. Data older than 16 months must be provided within 72 hours of the time the request is first made by the agent. MIC. ADMIN. CODE r. 338.480a(4)(e) (2002).

A pharmacy must assure continuity in the maintenance of records. If the automated data processing system is inoperative for any reason, then the pharmacist must ensure that all refills are authorized and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the pharmacist must enter the information regarding prescriptions filled and refilled during the inoperative period into the automated data processing system within 48 hours. In addition, if the relationship with the supplier terminates for any reason, a pharmacy must have arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records. MIC. ADMIN. CODE r. 338.480a(4)(f), (g) (2002).

The records in an automated data processing system are subject to the same requirements regarding confidentiality and access that apply to original prescriptions. MIC. ADMIN. CODE r. 338.480a(6) (2002).
## ANALYSIS OF MORE STRINGENT LAWS – MICHIGAN

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<tr>
<td>Disclosure</td>
<td>X</td>
<td>X</td>
<td>State law requires patient authorization in order to disclose a prescription or equivalent record on file, except in very limited circumstances, which are narrower than those provided for in HIPAA. However, the pharmacy should follow HIPAA with respect to disclosures for research purposes, as HIPAA provides for greater privacy protection in this context.</td>
<td>Unless authorized by you, we will not disclose your prescription or equivalent record on file, except to the following persons: (a) you, or another pharmacist acting on your behalf; (b) the authorized prescribed who issued the prescription, or a licensed health professional who is currently treating you; (c) an agency or agent of government responsible for the enforcement of laws relating to drugs and devices; or (d) a person authorized by a court order.</td>
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<tr>
<td>HIV/AIDS</td>
<td>X</td>
<td></td>
<td>To the extent applicable, state law is more stringent in that it prohibits the pharmacy from disclosing AIDS-related information without obtaining a specific patient authorization, except in very limited circumstances, which are narrower than those provided for in HIPAA.</td>
<td>We will not disclose AIDS-related information about an individual except in situations where the subject of the information has provided us with a written authorization allowing the release or where we are authorized or required by state or federal law to make the disclosure.</td>
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NACDS FOUNDATION STATE PRIVACY LAW SURVEY

Michigan

STATE LAW SURVEY OF A MINOR’S RIGHT TO CONSENT TO TREATMENT

1. **At what age does a minor become an adult under the law?**

   Eighteen.  

2. **Under what circumstances may an unemancipated minor give effective consent to treatment?**

   a. voluntary inpatient or outpatient mental health services (minor over 14);  

   b. venereal disease or HIV;  

   c. substance abuse;  

   d. pregnancy-related care;  

   e. abortion.  

   A minor who is a parent may give valid consent to the provision of health care for his or her minor child.  

3. **Do the statutes or regulations address a pharmacy’s disclosure of or access to the minor’s prescription records in situations where the minor provided effective consent to treatment?**

   Michigan statutes and regulations do not directly address the disclosure of or access to a minor’s prescription records in circumstances where the minor provided effective consent to the treatment. With the exception of mental health services and abortion, in all of the situations where a minor can provide effective consent to treatment, the treating health professional “may” disclose the treatment information to the minor’s parent, guardian, or spouse, without the minor’s consent, “for medical reasons.”  
   *Mich. Comp. Laws Ann. §§ 333.5127, 333.6121, 333.9132 (West 2002).* However, the parents may not be notified without the minor’s consent when the minor seeks treatment on an outpatient basis, unless there is a substantial probability of harm to the minor or another individual.  

   The Pharmacy Practice Act provides that a “person having custody of or access to prescriptions shall not disclose their contents or provide copies without the patient’s authorization except to...the patient for whom the prescription was issued” and other specified individuals.  

   The term “patient” is not defined in the relevant statutes or regulations. It is therefore unclear whether the term includes minors who have provided effective consent to treatment.

   In a telephone conversation with Mike Whistle, the Pharmacy Specialist with the Board, Mr. Whistle stated that pharmacies are creating their own policies to deal with this issue. He stated that the only real confidentiality provision relating to disclosure of pharmacy records is *Mich. Comp. Laws Ann. § 333.17752,* which only refers to disclosure to the “patient.” He also pointed out a statute that allows for discipline of a pharmacist for unprofessional conduct, including “betrayal of a professional confidence.”  

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NACDS FOUNDATION STATE PRIVACY LAW SURVEY

COMPLAWS ANN. § 333.16221(e) (West 2002). Telephone conference with Mike Whistle, Pharmacy Specialist, on January 7, 2003, (517) 373-9102.

WDC 324524v1

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