

PHARMACY LAW IN A STATE OF TRANSITION

Objectives

- Understand the recent change to the public health code related to the new requirements for reporting the sale of pseudoephedrine products.
- Understand the recent change to the scope of practice for Physician's Assistants and how it differs for that of Advanced Practice Nurses.
- Understand the change in both the Controlled Substance Section and the Pharmacy and Drug Control Section related to dispensing prescriptions for out-of-state practitioners.

DEA News Flash

Carisoprodol (Soma) schedule IV
Effective January 11, 2012

PA 84, 85 & 86 of 2011

- Jan. 1, 2012
- NPLEx
- Sales limitations
 - 3.6gms/day; 9 gms/30 days
- Software provided by National Association of Drug Diversion Investigators

Dear Pharmacy Manager/Business Owner:

The Michigan Pharmacists Association (MPA) in cooperation with the Michigan State Police (MSP) is sending this letter to notify you of HB 4749. This bill requires all pharmacies and retailers in the state of Michigan that sell **over the counter** cold and allergy medications containing ephedrine and/or

pseudoephedrine (PSE) to participate in a statewide, real-time electronic PSE monitoring program for the purpose of tracking illegal PSE purchases.

In compliance with HB 4749, the state of Michigan has joined the National Precursor Log Exchange (NPLEx). As part of our project launching September 1st, 2011, the technology provider, Appriss, will provide a web-accessed database at no charge to pharmacies and retailers in the state. Pursuant to the Combat Methamphetamine Act of 2005, pharmacies and retailers are currently required to capture data regarding PSE sales. The NPLEx system enables pharmacies and retailers to easily enter the same PSE sales data currently being gathered online rather than recording the information into a manual log or in-store computer system. Data will be stored in a secure, central repository that treats the data collected as if it were HIPAA data. Furthermore, the collected data will be viewable by law enforcement in keeping with CMEA and HB 4749.

To secure your sales information, only your pharmacy will be able to inquire and view your sales data. As part of the project, pharmacies will be provided access licenses and system training at no cost to the pharmacy. NPLEx will assist pharmacies by speeding up the logging and maintenance of purchase/sales information. For law enforcement, NPLEx will provide real-time access to view PSE purchases and will computerize tracking and investigative reporting information. Michigan Pharmacy Association and MSP encourage all pharmacies and retailers in the state to begin using this system by **December 1st, 2011** (or sooner) to ensure compliance with the new electronic reporting requirements by **January 1st, 2012**, at which time participation will be mandatory. Appriss will provide training sessions for all pharmacies and retailers located throughout the state during the launching of this project. Members from the MPA, the MSP, or Appriss will be contacting you within the next few weeks to provide you with access to NPLEx and to discuss integration, training and any other related questions. **If your pharmacy does not sell PSE products or your pharmacy only administers PSE products by prescription, please notify Appriss by email at MINPLEx@appriss.com.** Be sure to include your pharmacy contact information and state license number. We look forward to partnering with you on this important effort.

PA 155

- Sec. 7405. (1) A person:
- (e) Who is a practitioner shall not dispense a prescription for a controlled substance written and signed or transmitted by facsimile, electronic transmission, or other means of communication by a physician prescriber or

dentist prescriber licensed to practice in a state other than Michigan, unless the prescription is issued by a physician prescriber or dentist prescriber who is authorized under the laws of that state to **practice dentistry**, medicine, or osteopathic medicine and surgery and to prescribe controlled substances.

PA 155

Sec. 17708. (3)

- “Prescription”
- (2), (e) In addition to the prohibition contained in section 7405(1)(e), dispensing a prescription for a controlled substance as defined in section 7104 that is written and signed or transmitted by facsimile, electronic transmission, or other means of communication by a physician prescriber or dentist prescriber in a state other than Michigan, unless the prescription is issued by a physician prescriber or dentist prescriber who is authorized under the laws of that state to **practice dentistry, medicine, or osteopathic medicine and surgery and to prescribe controlled substances.**

A patient presents to you a prescription for oxycodone 10mg #20 (twenty) Sig: i tab q 12 hours written by Dr. I M Inpain DMD, Marinette, WI. Can this prescription be dispensed by a Michigan pharmacist?

- a. Can only dispense out of state controlled substance prescriptions written by a MD or DO.
- b. Can dispense out of state controlled substance prescriptions written by a MD, OD or DDS.
- c. Can dispense out of state controlled substance prescriptions written by a MD, DO, DDS or DMD
- d. Can dispense out of state controlled substance prescriptions written by a MD, DO or DVM.

SB 384

- PAs prescribe CII substances
 - eliminate restrictions related to qty, location
 - require name of delegator and delegatee on prescription
 - require DEA registration number of delegator and delegatee on prescription

- require name of prescribing individual on Rx label
Labeling

Name of the prescriber or the delegated prescriber to appear on the label.

SB 481 & HB 4774

- Nurse Practitioners
 - Independent practice
 - No longer prescribing under delegation
 - No restrictions
 - Issues
 - Drug Control License
 - Scope of Practice

Transitional Legislation

- SB 591 Sen. Green
License Pharmacy Technicians
- SB 735 Sen. Whitmer
Dispense Rxs w/o bias
- SB 789 Sen. Jones
Powers to BOP to temporarily schedule drugs

Transitional Legislation

- HB 5056 Rep. Brown
Schedule Soma as C-IV
- HB 5089 Rep. Johnson
Creates a drug repository
- HB 5090 Rep. Ananich

Mandates pharmacists dispose of medications

- HB 5131 Rep. Liss
Transition of care – medication orders

Controlled Substance Act

- The CSA unique among criminal law in that it stipulates acts pertaining to controlled substances that are permissible.
- If the CSA does not explicitly permit an action pertaining to a controlled substance, then by its lack of explicit permissibility the act is prohibited.

Federal Register/Vol. 75, No. 61/ Wednesday, March 31, 2010 P. 16237

State vs. Federal Regulations

- In many cases state law is more stringent than federal law, and must be complied with in addition to federal law. Pharmacists should make sure they understand their state and DEA controlled substance regulations.

Corresponding Responsibility

Section 1306.04 Purpose of issue of prescription.

- (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

Prescription Requirements

- **A prescription for a controlled substance must be dated and signed on the date when issued.** The prescription must include the patient's full name and address, and the practitioner's name, address, and registration number. The prescription must also include the drug name, strength, dosage form, quantity prescribed, directions for use, and number of refills. Where an oral prescription is not permitted, a prescription must be written in ink or indelible pencil or typewritten and must be **manually signed** by the practitioner.

PUBLIC HEALTH CODE (EXCERPT) Act 368 of 1978
Valid Signature?

- Lisinopril 20mg
#30
Sig: i tab daily.

6 refills
Dr. Karen Jonas/gjb

What Type of Signature is required?

Schedule	Paper Patient Presents	Fax to Fax	Computer to Fax	Computer to Computer
II	Manual	Manual Only 3 situations	NO	DEA Electronic Signature
III	Manual	Manual	NO	DEA Electronic Signature
IV	Manual	Manual	NO	DEA Electronic Signature
V	Manual	Manual	NO	DEA Electronic Signature
Non C.S.	Manual	Manual	MI Electronic Signature	MI or DEA Electronic Signature

Facsimile Transmission of Prescriptions by Intermediaries

- A faxed prescription is a paper prescription and, therefore, must be manually signed by the prescribing practitioner registered with DEA to

prescribe controlled substances. If an intermediary cannot complete a transmission of a controlled substance prescription, it must notify the practitioner in the manner discussed above.

- *It is not permissible to electronically generate and fax a controlled substance prescription without the practitioner manually signing it.*

Can Subutex® or Suboxone® be prescribed for other than opioid addiction?

❖ Off-label

❖ “Physicians and other practitioners who are authorized to prescribe Schedule III controlled narcotic medications under Federal and State laws are eligible and the unique identifier under the Drug Addiction Treatment Act is not required.”

- <http://www.buprenorphine.samhsa.gov/bwns/faq.html#A21>

Institute for Patient Medication Safety and Pharmacist Peer Review

- Reduce risk of disciplinary action
 - Voluntary error reporting
- Joint Venture - MPA, BOP & MDCH
- Benefits of reporting
 - Help to educate others
 - Minimize risk of disciplinary sanctionsInstitute for Patient Medication Safety and Pharmacist Peer Review
- Information is confidential
 - Patient or pharmacist info not retained
 - Not public record
 - Not discoverable
- Nothing reported to BOP

- Nothing shared with employer
- Aggregated data shared with profession

Institute for Patient Medication Safety and Pharmacist Peer-Review

Medication Error or Accident Reporting Form

Note:

- The Institute is a "review entity" as defined under MCL 333.531. Under the provisions of this statute, a pharmacist may provide the Institute with information or data relating to the condition of a patient and/or the necessity, appropriateness or quality of health care rendered to that patient. The Institute operates in compliance with all provisions of the Health Insurance Portability and Accountability Act (HIPAA).
- The information provided in this document will be used exclusively to improve patient safety and the quality of health care delivery, specifically as these relate to safe and effective medication use.
- Systems in use by the Institute have been designed to preserve confidentiality of and provide appropriate security for patient safety data, reports and records as well as the identity of those practitioners who may have been involved in an error or accident.
- Identity information requested at the bottom of this form is not recorded or saved in any way by the Institute. It only serves as a means to provide the reporting individual with proof that a report was voluntarily filed in a timely fashion. This section of the document will be detached from the report, stamped as having been received by the Institute, and returned via US Mail to the individual filing the report. The Michigan Board of Pharmacy considers voluntary reporting a mitigating factor if and when it investigates patient reports of medication errors. Consequently, the stamped receipt (proof that you voluntarily filed a report) should be kept for your records.

Briefly describe the error or accident and how you believe it happened – Do not include anything that will identify you or any of the parties or facilities involved:

General information regarding type of practice. Please place a check mark next to the term that best describes the practice where the error or accident occurred:

<input type="checkbox"/>	Hospital inpatient pharmacy	
<input type="checkbox"/>	Medical center or hospital ambulatory care pharmacy	
<input type="checkbox"/>	Community pharmacy (independent)	
<input type="checkbox"/>	Community pharmacy (local/regional chain)	
<input type="checkbox"/>	Community pharmacy (national chain)	
<input type="checkbox"/>	Long-term care pharmacy	
<input type="checkbox"/>	Prescription compounding center	
<input type="checkbox"/>	Other (please describe):	

Exclusion Lists

- U.S. Department of Health and Human Services, Office of Inspector General
 - Bases for exclusion include convictions for program-related fraud and patient abuse, licensing board actions and default on Health Education Assistance Loans.

- <http://www.oig.hhs.gov/fraud/exclusions.asp>

- General Services Administration

- Parties excluding from receiving federal contracts, certain subcontracts, etc.

- <https://www.epls.gov/>

DEA

- <http://www.dea diversion.usdoj.gov/>

- DEA Office of Diversion – Publications

- Code of Federal Regulations
Practitioner's Manual
Title 21 Regulations & Codified CSA

Michigan

- www.michigan.gov/healthlicense

- License application information

- Michigan Public Health Code
How to look up a particular section

- Boards of Medicine, Osteopathic Medicine & Surgery Rules

- Board of Pharmacy Rules
Click on Pharmacy
- 517-335-0918 <http://www.michigan.gov>

Michigan Association of Health Plans Pharmacy Audit Statement of Best Practices

The Michigan Association of Health Plans (MAHP) promotes principles and guidelines of best-practices in the administration of health care goods and services. In recent years, the federal government has placed increased scrutiny upon health plans to conduct extensive audits of contracting pharmacies and pharmacy benefit managers, particularly as those activities affect federal health programs such as Medicare and Medicaid. This increased federal oversight has made the terms, "Fraud, Waste, Abuse (FWA)" commonplace within the realm of federally sponsored health programs. The federal government's emphasis on detecting and eliminating FWA within health programs promotes the integrity of the programs and decreases overall costs.

As a result of the heightened importance of compliance with federal laws and regulations, health plans must establish effective protocols to detect FWA. Part of any effective compliance program is assuring thorough and rigorous auditing of pharmacy activities. It is MAHP's intent, therefore, to promote effective health plan compliance programs that include thorough pharmacy auditing procedures, while at the same time assuring that the procedures are equitable to all contracting pharmacists and are not unduly burdensome to their businesses. This Best-Practices Statement seeks a reasonable balance between effective health plan compliance and equity in the pharmacy auditing process.

Pharmacy Auditing Guidelines

The rights and responsibilities between MAHP member plans and their participating pharmacies are specified in network pharmacy agreements. These agreements should set forth the rights of MAHP member plans to perform pharmacy audits and should describe the responsibilities of network pharmacies to consent to such audits and to assure that pharmacy activities comply with state and federal laws and regulations. This Best-Practices Statement will describe the MAHP suggestions for handling pharmacy audits.

A. Conduct of audit.

When conducting an audit, a pharmacy benefits manager should:

- (1) if the audit is onsite, provide written notice to the pharmacy or pharmacist at least 2 weeks before conducting the initial onsite audit for each audit cycle; and to the greatest degree possible, the audit should not be scheduled during the first five calendar days of a month unless requested by the pharmacy or pharmacist.
- (2) identification of prescriptions for desk audits should be done using algorithms that have a high likelihood of identifying a true auditable finding.
- (3) employ the services of a pharmacist if the audit requires the clinical or professional judgment of a pharmacist;
- (4) For purposes of validating the pharmacy record with respect to orders or refills, allow the pharmacy or pharmacist to use hospital or physician records that are:
 - (i) written; or
 - (ii) transmitted or stored electronically, including file annotations, document images, and other supporting documentation; that are date/time stamped.
- (5) only audit claims submitted or adjudicated within the 2-year period immediately preceding the audit, unless a longer period is permitted under federal or State law or a longer period is warranted by special circumstances;
- (6) deliver the preliminary audit report to the pharmacy or pharmacist within 120 calendar days after the completion of the audit, with reasonable extensions allowed;
- (7) in accordance with section (B), allow a pharmacy or pharmacist to produce documentation to address any discrepancy found during the audit; and
- (8) deliver the final audit report to the pharmacy or pharmacist:
 - (i) within 6 months after delivery of the preliminary audit report if the pharmacy or pharmacist does not request an internal appeal under section (B) of this section; or
 - (ii) within 30 days after the conclusion of the internal appeals process under section (B) if the pharmacy or pharmacist requests an internal appeal.

- 9 A pharmacy benefits manager should not use the accounting practice of extrapolation to calculate overpayments or underpayments.
- (10) The recoupment of a claims payment from a pharmacy or pharmacist by a pharmacy benefits manager should be based on an actual overpayment or denial of an audited claim unless the projected overpayment or denial is part of a settlement agreed to by the pharmacy or pharmacist.
- (11) Notwithstanding paragraphs (9) and (10) of this section, calculation of overpayments and underpayments should be reasonable and proportional in relation to the type of errors detected. For example, a simple clerical error that has no financial effect should not be recouped and such errors should not affect the dispensing fees associated with those prescriptions

B. Internal appeals process.

(1) A pharmacy benefits manager should establish an internal appeals process under which a pharmacy or pharmacist may appeal any disputed claim in a preliminary audit report.

(2) Under the internal appeals process, a pharmacy benefits manager should allow a pharmacy or pharmacist to request an internal appeal within 30 business days after receipt of the preliminary audit report, with reasonable extensions allowed.

(3) The pharmacy benefits manager should include in its preliminary audit report a written explanation of the internal appeals process, including the name, address, and telephone number of the person to whom an internal appeal should be addressed.

(4) The decision of the pharmacy benefits manager on an appeal of a disputed claim in a preliminary audit report by a pharmacy or pharmacist should be reflected in the final audit report.

(5) The pharmacy benefits manager should deliver the final audit report to the pharmacy or pharmacist within 30 calendar days after conclusion of the internal appeals process.

C. Timing for setoff for overpayment or remittance of underpayment.

(1) A pharmacy benefits manager should not recoup by setoff any moneys for an overpayment or denial of a claim until 30 working days after the date the final audit report has been delivered to the pharmacy or pharmacist.

(2) A pharmacy benefits manager should remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 30 working days after the final audit report has been delivered to the pharmacy or pharmacist.

(3) Notwithstanding the provisions of paragraph (1) of this section, a pharmacy benefits manager may withhold future payments before the date the final audit report has been delivered to the pharmacy or pharmacist if the identified discrepancy for all disputed claims in a preliminary audit report for an individual audit exceeds \$20,000.

D. Exception for fraud, waste, abuse, or illegal activity.

(1) Sections A, B, and C do not apply to audits involving probable or potential fraud, waste, abuse, illegal activity, or willful misrepresentation by a pharmacy or pharmacist.

CSA Requirements	Schedule II	Schedule III & IV	Schedule V
Registration	Required	Required	Required
Receiving Records	DEA Form 222	Invoices, readily retrievable	Invoices, readily retrievable
Prescriptions	Written Prescriptions	Written, oral or fax	Written, oral or fax
Refills	No refills	No more than 5 within 6 months	As authorized when prescription is issued or if renewed by a practitioner
Maintenance of Prescriptions	Separate file	Separate file or readily retrievable	Separate file or readily retrievable
Distribution Between Registrants	DEA For 222	Invoices	Invoices
Security	Locked Cabinet or dispersed among non-controlled pharmaceuticals	Locked Cabinet or dispersed among non-controlled pharmaceuticals	Locked Cabinet or dispersed among non-controlled pharmaceuticals
Theft of Significant Loss	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106

WHAT TO DO WHEN AN INSPECTOR/INVESTIGATOR ARRIVES

1. **Ask for their credentials**
 - Inspectors and investigators must show you their credentials.
 - Individuals should also tell you why they are at the pharmacy.
 - If a reason is not provided, ask why they are there.
2. **Obtain a business card from the inspector/investigator.**
 - The inspector or investigator may be there with other agencies (Federal Bureau of Investigations, State Police, etc.)
 - Anyone who arrives should show you their credentials or identification of who they are.
 - Get a business card from all of the agents so you know who was there.
3. **If it is not disclosed, ask why they are at the pharmacy.**
 - Is it an inspection, an investigation or both?
 - Are they there to obtain more information?
4. **Inform your district manager, main office or owner (if applicable) before they start.**
5. **Be a good host.**
6. **Remember, you do not have to incriminate yourself. Ask for an administrative warrant.**
 - An administrative warrant is useful in protecting yourself against claims of breaching confidentiality by patients or physicians when you disclose otherwise confidential or privacy-covered material. You can then always claim you were acting pursuant to a legal order for documents. Inspectors usually hate it when pharmacists ask for this piece of paper because the inspector has to go back to the office, get the paperwork and then return. It is too bad if they don't like it. It's your right to demand it and it will protect you down the line.
7. **The inspector, investigator or police do not necessarily have to be truthful.**
8. **If it's an inspection:**
 - They are entitled to look at documents and records required to be maintained by pharmacy regulations.
 - You should retrieve documents for the inspector (don't let the inspector retrieve them). These documents could include:
 - Licenses, registration
 - Annual controlled substances inventory
 - Prescriptions
 - Controlled substance invoices
 - DEA 222 forms
 - Technician policies and procedures
 - Will call prescriptions

- If they are asking to take documents or copy of documents you may want to release them through your privacy officer (HIPAA tracking) and ask for a self addressed stamped envelope to send them.
- Should go over the inspection report with the pharmacist and leave a copy with you.

9. If it's an investigation:

- They will usually ask you for specific documents.
- If they request to take original documents, they should give you a receipt for the documents – this is for an evidence trail.
- If they are asking to take documents or copies of documents, you should release them through your privacy officer (HIPAA tracking) and ask for a self-addressed, stamped envelope to send them.
- They should also give you a receipt for the copies of records taken if you give them to the agent, as this establishes an evidence trail for them. If they don't, don't make a fuss about it.
- There is no requirement for you to answer their questions. You don't have to incriminate yourself; you can simply answer "I will need to check with my attorney first."

10. If you receive an official complaint in writing from the Department of Community Health, Bureau of Health Professionals, you must respond to it. It is advisable to obtain the services of an attorney because any action on your license is permanent, public and published. There are attorneys that specialize in this area. Contact Michigan Pharmacists Association for a referral list of these attorneys.

IMPORTANT DEFINITIONS

Inspector: Is a pharmacist who has been trained by the Department of Community Health to conduct pharmacy investigations and inspections.

Investigator: Is NOT a pharmacist, usually has other degree (i.e., criminal justice, some are former police officers) and have been trained by the Department of Community Health to conduct investigations of health professionals.

Pharmacy Inspection: A review of the pharmacy records for compliance with pharmacy laws and regulations.

Investigation: Could be conducted by either an inspector or investigator as a result, most commonly, of an allegation (a patient has complained that a health professional has committed a violation of the Public Health Code) and is conducting interviews and collecting information regarding the allegation.

Credentials: Picture identification issued by the agency who the person works for (for the inspectors/investigators it would be the Department of Community Health, Bureau of Health Professionals).



This resource is provided as a benefit to members of:
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