

# The Dos and Don'ts of Controlled Substance Prescribing in Michigan

*Robert S. Iwrey*  
*The Health Law Partners PC*  
*Southfield*

*Neda Mirafzali*  
*The Health Law Partners PC*  
*Southfield*

I. The Current Landscape: Enforcement Is on the Rise . . . . .	11-1
II. HHS's New Focus: Prescription Drug Fraud. . . . .	11-4
III. The Gatekeepers Role of Physicians and Pharmacists . . . . .	11-5
IV. The Interplay Between State and Federal Law. . . . .	11-7
V. The Standard of Care in Michigan . . . . .	11-16
VI. Electronic Prescribing ("ePrescribing"). . . . .	11-20
VII. Narcotics/Opioid Agreements . . . . .	11-24
VIII. Conclusion . . . . .	11-24
IX. Additional Helpful Resources . . . . .	11-24
Appendixes	
Appendix A Schedule I-V Drugs . . . . .	11-27
Appendix B Summary of Controlled Substance Act Requirements. . . . .	11-29
Appendix C Sample Narcotics Agreement. . . . .	11-31
Appendix D Sample Patient Termination Letter. . . . .	11-33

## **I. The Current Landscape: Enforcement Is on the Rise**

According to the Federal Drug Enforcement Administration ("DEA"), in 2006, more than 6 million Americans were abusing prescription drugs—exceeding the number of American abusing cocaine, heroin, hallucinogens and inhalants, combined.<sup>1</sup> Michigan is no exception to this alarming statistic.<sup>2</sup> According to a Detroit Free Press article,

---

1. *Practitioner's Manual: An Informational Outline of the Controlled Substances Act*, a DEA publication found at: [http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf).

2. <http://www.nabp.net/news/michigan-officials-note-alarming-prescription-drug-abuse-trends-in-the-state/>; <http://www.annarbor.com/news/deaths-from-prescription-drug-abuse-on-the-rise-statewide/>

In Michigan, more residents now die from prescription drug abuse than from heroin and cocaine combined... Nearly one in four seeking emergency care in Michigan for the abuse was younger than 25, particularly alarming because prescription drugs are a gateway to heroin and are being mixed by teens and young adults in potentially lethal combinations to get a more intense high, substance abuse experts say.<sup>3</sup>

As such, it is with great fervor that both State and Federal agencies have turned their attention to preventing diversion and abuse of controlled substances.<sup>4</sup>

### **A. Regulatory and Enforcement Teams**

Both State and Federal governments have empowered a number of enforcement bodies to combat the increasing problems relating to controlled substance abuse, including, State and local law enforcement, State medical and pharmacy boards, the Federal Health Care Fraud Prevention and Enforcement Action Team (“HEAT”), the DEA, the Department of Health and Human Services Office of Inspector General (“OIG”), the Department of Justice (“DOJ”) and the Federal Bureau of Investigations (“FBI”).

### **B. Examples of Recent Enforcement Activity in Michigan<sup>5</sup>**

The crack down on practitioners (*e.g.*, MDs and Dos) prescribing controlled substances is at an all time high and Michigan practitioners are not exempt from the increased scrutiny. In fact, Michigan practitioners are, arguably, under even more scrutiny in light of the presence of a HEAT taskforce established in Detroit. Newspaper headlines are replete with prescription drug abuse and issues related to prescription drug abuse on a regular basis. The following are examples of recent enforcement activity in Michigan:

#### **1. Gwendolyn Washington, M.D.**

In 2011, Dr. Washington plead guilty to a laundry list of charges, including conspiring to defraud and defrauding Medicare, drug trafficking, healthcare fraud, public corruption and conspiring to illegally distribute prescription drugs.<sup>6</sup> According to a DOJ press release:

Dr. Washington also admitted to committing two counts of controlled substances offenses. In February 2010, when Medicare suspended payments to Washington, resulting in a drastic reduction in her income, she began writing prescriptions for tens of thousands of doses of OxyContin, Opana ER, and Roxicodone, highly addictive pain medications that have a significant “street value” on the illicit market. Washington sometimes wrote prescriptions for individuals who were not her patients, without an examination or determination of medical necessity, and without an appropriate diagnosis or entry in a patient chart. Washington then provided these illegal prescriptions to Virginia Dillard, her niece and co-defendant. Dillard filled the prescriptions at various

3. “Prescription Drug Deaths Soar in State,” Patricia Anstett, Detroit Free Press (Jul. 11, 2011).

4. A list of controlled substances may be found at 21 CFR Part 1308.

5. The DEA issues a document entitled *Criminal Cases Against Doctors* wherein it summarizes cases from across the country involving physicians and drug diversion. Moreover, the DEA compiles a list, organized by year, of the administrative actions against doctors. Both the document and the lists may be found online at: [http://www.deadiversion.usdoj.gov/crim\\_admin\\_actions/index.html](http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html).

6. [http://www.justice.gov/usao/mie/news/2011/2011\\_11\\_28\\_gwashington.html](http://www.justice.gov/usao/mie/news/2011/2011_11_28_gwashington.html)

pharmacies in Highland Park, Warren, and Detroit. After filling the illegal prescriptions, Virginia Dillard delivered the controlled substances to prescription drug dealers in exchange for money. Dillard sold each filled prescription in amounts ranging from \$1,000 to \$2,200, and shared the proceeds with Washington. Dillard was sentenced, on October 20, 2011, to 112 months' imprisonment.<sup>7</sup>

In November 2011, Dr. Washington was sentenced to 120 months in prison and her niece was sentenced to 112 months.<sup>8</sup>

## 2. **26 Indicted including Pharmacists and Doctors**<sup>9</sup>

A 34-count indictment was unsealed in August 2011 charging 26 individuals, including physicians and pharmacists, of conspiracy to commit healthcare fraud, aiding and abetting healthcare fraud, conspiracy to distribute controlled substances and criminal forfeiture. According to the press release, a pharmacist-owner of over 25 pharmacies across Michigan ("Pharmacist") allegedly paid kickbacks, bribes and inducements to physicians to induce them to write prescriptions and direct that those prescriptions be filled at one or more of Pharmacist's pharmacies. The indictment alleges that Pharmacist billed insurers for dispensing medications that were not medically necessary or ever provided. Such medically unnecessary medications were allegedly dispensed to patients in exchange for the permission to unlawfully bill the patients' insurances. Allegedly, this practice cost Medicare at least \$37.7 million and \$20.8 million to Medicaid. According to the press release, since January 2009, Pharmacist's pharmacies dispensed at least 250,000 doses of OxyContin, 4.6 million doses of Vicodin, 1.5 million doses of Xanax and 6,100 pints of codeine cough syrup.

## 3. **John Doe, M.D.**<sup>10</sup>

In May 2011, a southeast Michigan doctor was charged with unlawful distribution of prescription drug controlled substances, including OxyContin. Between April 2008 and March 2010, Dr. Doe allegedly prescribed more than 3 million doses of Schedule II and III narcotics. Between June and October 2010, alone, Dr. Doe allegedly prescribed 2 million doses of Schedule II narcotics. Moreover, Dr. Doe is alleged to have: (1) prescribed controlled substances for as many as 250 patients per day, paying bonuses to employees when the number of patients in a single day exceeded 200; (2) prescribed narcotics prior to any legitimate examination or doctor-patient relationship; and (3) refused to act when learning

---

7. *Id.*

8. *Id.*

9. The authors of this outline have chosen not to include the names of those parties charged and/or indicted out of fairness to such parties since the matter has not yet been resolved.

10. The authors of this outline have chosen not to include the name of the involved physician charged out of fairness to the physician since the matter has not yet been resolved.

that patients were selling prescriptions in the parking lot. Dr. Doe's charges carry a maximum penalty of 20 years in prison and/or a \$1 million fine.

4. **Paul H. Emerson, D.O.**

Dr. Emerson, of Taylor, Michigan, plead guilty in 2009 for conspiracy to distribute controlled substances and distribution of controlled substances resulting in death. Emerson operated the "Emerson Medical Clinic" wherein, according to DEA documents, he

[W]ould falsify, and direct and instruct others to falsify, patient files; prescribe controlled pharmaceuticals in such combinations as were likely to cause death or injury; prescribe or approve the prescription of controlled substances without performing an appropriate physical examination and without determining medical necessity; prescribe controlled substances at such strength, frequencies, and amounts as were likely to cause and did cause patients to become dependent on the medications; and prescribe controlled substances and prescription drugs to persons that Emerson knew were addicted to controlled substances, abused controlled substances and/or illegally distributed controlled substances. Emerson also provided various controlled substance prescriptions in exchange for sexual favors.

Dr. Emerson unlawfully provided a number of Schedule II (*e.g.*, oxycodone, methadone, hydrochloride, hydromorphone, etc.), Schedule III (*e.g.*, hydrocodone bitartrate, buprenorphine, etc.) and Schedule IV (*e.g.*, alprazolam, diazepam, propoxyphene, etc.) drugs which resulted in 3 patient deaths. Dr. Emerson, facing up to 30 years in prison, was sentenced to 12 years for his assistance in prosecuting co-defendants.

## II. HHS's New Focus: Prescription Drug Fraud

### A. HHS: Insurance Companies Should Take *Every Step Possible* to Prevent Prescription Fraud

Recently, HHS has elevated its enforcement activities by reaching out to drug insurance companies to solicit their assistance in combating prescription drug fraud. Specifically, HHS has directed insurance companies to "take every step possible" to prevent prescription drug fraud, including withholding payment on suspicious claims (*e.g.*, when an enrollee doctor-shops for painkillers and narcotics).<sup>11</sup> In fact, insurance companies are permitted to delay prompt payment of claims if the "plan sees signs of suspicious activity" and should withhold the payment until the claim is validated. Moreover, the Federal government specifically cited OxyContin and Percocet as red flag drugs for the insurance companies to scrutinize.

### B. Pharmacies Taking the Fraud Battle into Their Own Hands

In January, it was reported<sup>12</sup> that CVS sent unsigned letters to a number of Florida physicians indicating that CVS pharmacists would no longer fill prescriptions for painkillers and other addictive drugs written by those physicians. Such action by CVS has been

11. <http://www.hhs.gov/news/press/2011pres/12/20111213a.html>

12. [http://articles.orlandosentinel.com/2012-01-21/health/os-cvs-blacklisted-doctors-20120114\\_1\\_cvs-oxycodone-purchasing-doctors-pharmacy-chain](http://articles.orlandosentinel.com/2012-01-21/health/os-cvs-blacklisted-doctors-20120114_1_cvs-oxycodone-purchasing-doctors-pharmacy-chain)

met with both criticism and praise. Supporters commend the pharmacy for taking responsibility and action in the fight against prescription fraud, while others question whether CVS's position goes too far—presuming these “blacklisted” physicians are guilty as a result of allegations and charges that have not yet been proven, admitted or adjudicated and, potentially, tarnishing their reputations thereby affecting their livelihoods.

### **III. The Gatekeepers Role of Physicians and Pharmacists**

Both Federal and State authorities have imposed a gatekeeper's role upon physicians and pharmacists to aid in the deterrence, mitigation and prevention of prescribed controlled substance diversion, fraud and abuse. As such, physicians and pharmacists are the gatekeepers of a closed system of prescription drug distribution designed to protect the health, safety and welfare of our citizens through limited access to drugs that can have serious and lethal adverse consequences if misused. The first step in limiting public access to controlled substances is the requirement that the substances be prescribed by a licensed provider<sup>13</sup>. In Michigan, a medical doctor and a doctor of osteopathy must be licensed in accordance with the applicable Michigan statutory laws and administrative rules governed by the Bureau of Health Professions within the Department of Licensing and Regulatory Affairs and the Board of Medicine and Board of Osteopathic Medicine and Surgery, respectively. Importantly, while being licensed to practice medicine or osteopathic medicine in the State of Michigan does confer the right to prescribe or dispense non-controlled substances (e.g., antibiotics), a physician who wishes to prescribe and/or dispense controlled substances must also obtain the appropriate license from the Michigan Board of Pharmacy. A physician prescribing controlled substances requires a **Michigan Controlled Substance License**<sup>14</sup> from the Board of Pharmacy. A physician who prescribes controlled substances at more than one location only needs one such license. However, a separate Michigan Controlled Substance License is required for each business location at which a physician or a pharmacist dispenses controlled substances. Each pharmacy location must also have a separate Michigan Controlled Substance License. In addition to a Michigan Controlled Substance License, a physician who routinely dispenses drugs (controlled and/or non-controlled) other than the issuance of complimentary starter dose drugs, must also obtain a **Michigan Drug Control License**<sup>15</sup> from the Board of Pharmacy for each location where the physician dispenses such drugs.<sup>16</sup> It should also be noted that a physician who prescribes/dispenses narcotics to treat substance abuse (e.g., Suboxone) must obtain a **Michigan Substance Abuse License**.<sup>17</sup>

In addition to the aforementioned Michigan licenses, physicians, pharmacists and pharmacies who handle controlled substances must also obtain the appropriate Federal registrations from the DEA.<sup>18</sup> Generally, a separate DEA registration is required for each

---

13. Please note that the scope of this outline is limited to the role of physicians and pharmacists in prescribing and dispensing controlled substances. The authors acknowledge that there are other licensed providers in Michigan such as nurse practitioners, physician assistants and dentists who have authority to prescribe controlled substances. Moreover, there are statutes, regulations and administrative rules pertaining to the manufacture and wholesale distribution of controlled substances that are also beyond the scope of this outline.

14. [http://www.michigan.gov/documents/mdch\\_phar\\_cs\\_app\\_97886\\_7.pdf](http://www.michigan.gov/documents/mdch_phar_cs_app_97886_7.pdf).

15. [http://www.michigan.gov/documents/mdch\\_drug\\_control\\_app\\_123209\\_7.pdf](http://www.michigan.gov/documents/mdch_drug_control_app_123209_7.pdf).

16. MCLA §333.17745

17. [http://www.michigan.gov/documents/lara/Appendix\\_D\\_App\\_for\\_SA\\_Lic\\_for\\_Use\\_of\\_Meth\\_Other\\_CS\\_in\\_Treatment\\_of\\_Narc\\_Addict\\_SUB-023\\_370545\\_7.pdf](http://www.michigan.gov/documents/lara/Appendix_D_App_for_SA_Lic_for_Use_of_Meth_Other_CS_in_Treatment_of_Narc_Addict_SUB-023_370545_7.pdf)

location where controlled substances are dispensed (e.g., each pharmacy location must have a separate DEA registration). Furthermore, physicians who dispense narcotics to treat substance abuse (e.g., Suboxone) must also obtain a separate **DEA Registration for Narcotic Treatment Programs**.<sup>19</sup> Please see the below table for a summary of these requirements.

Type of License	Required for...	Issued by...	Statutory/ Regulatory Authority
M.D. or D.O.	The practice of medicine or osteopathic medicine & surgery including the prescribing of non-controlled substances	Michigan Board of Medicine or Michigan Board of Osteopathic Medicine & Surgery	MCLA 333.17708
Michigan Controlled Substance License	Prescribing and otherwise handling controlled substances	Michigan Board of Pharmacy	MCLA §333.7303; Mich. Admin. Code R. 338.3132
Michigan Drug Control License	Routine dispensing of controlled substances	Michigan Board of Pharmacy	MCLA §333.17745
Michigan Substance Abuse License	Prescribing or dispensing controlled substances to treat narcotic addiction	Michigan Substance Abuse Program	Mich. Admin. Code R. 325.14101– 325.14928
DEA Registration	Prescribing, dispensing or otherwise handling controlled substances	DEA	21 CFR §1301.11
DEA Registration for Narcotic Treatment Programs	Dispensing narcotics to individuals for substance abuse treatment	DEA	21 USCA §823 21 CFR §1306.07

18. [http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/pdf\\_apps.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm); 21 CFR §1301.11

19. [http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/363/363\\_instruct.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/363/363_instruct.htm); 21 USCA §823. Please note that the DEA Registration for Narcotic Treatment Program is not required for physicians administering narcotics to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's referral for treatment so long as not more than one day's medication is administered or given to a patient at one time, the treatment is not carried on for more than 72-hours and the 72-hour period is not renewed or extended. 21 CFR 1306.07.

#### **IV. The Interplay Between State and Federal Law**

The DEA, in its *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*,<sup>20</sup> characterizes the relationship between State and Federal laws as follows:

Federal controlled substance laws are designed to function in tandem with state controlled substance laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to make certain that pharmaceutical controlled substances are prescribed, administered, and dispensed for a legitimate medical purpose in the usual course of professional practice. Within this framework, the majority of investigations into possible violations of controlled substance laws are carried out by state authorities. DEA focuses its investigations on cases involving violators of the highest level or most significant impact.

In the event a state board revokes the license of a pharmacy, DEA will request a voluntary surrender of the pharmacy's DEA registration. If the pharmacy refuses to surrender its registration, DEA will seek administrative action to revoke its DEA registration based on lack of state authorization. Additional administrative remedies that may be utilized to correct a lack of compliance include a letter of admonition or an administrative hearing. DEA may also pursue civil or criminal sanctions if there is sufficient evidence to justify a prosecution. All such actions are designed to protect the public health and safety.<sup>21</sup>

Because of this "interplay," review of *both* State and Federal laws, regulations and guidance is essential to an evaluation of permissible prescribing practices of controlled substances. **Since there are times when the Federal and State laws and regulations conflict or differ, a vital rule of thumb to employ is: *follow the stricter laws/regulations.***

##### **A. Michigan State Laws and Administrative Rules**

Michigan laws and administrative rules, similar to the Federal rules, impose a joint responsibility upon physicians and pharmacists to act as gatekeepers to ensure the proper distribution of controlled substances.

##### **1. Controlled Substances Must be Prescribed and Dispensed in "Good Faith"**

Michigan requires that a controlled substance be prescribed or dispensed by a practitioner with a Michigan Controlled Substance License in good faith.<sup>22</sup> *Good faith*, with respect to a physician who prescribes or dispenses, means the controlled substance was prescribed or dispensed "in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance."<sup>23</sup> With respect to pharmacists, *good faith* means "dispensing of a controlled substance pursuant to a prescriber's order which, in the professional judgment of the pharmacist, is lawful."<sup>24</sup> Under Michigan statutory law, a pharmacist's "professional judgment"

---

20. [http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm\\_manual.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf).

21. *Id.* pg. 3.

22. MCLA 333.7333.

23. *Id.*

should take into consideration the following “nationally accepted professional standards” when dispensing controlled substances:

- Lack of consistency in the doctor-patient relationship;
- Frequency of prescriptions for the same drug by 1 prescriber for larger numbers of patients;
- Quantities beyond those normally prescribed for the same drug;
- Unusual dosages;
- Unusual geographic distances between patient, pharmacist, and prescriber.<sup>25</sup>

## 2. **Prescriptions for Controlled Substances Must be Issued and Dispensed for a “Legitimate and Professionally Recognized Purpose”**

In addition to the requirement that prescriptions be issued and dispensed in good faith, there is a requirement that a prescription for controlled substances be issued for a “legitimate and professionally recognized” purpose.<sup>26</sup>

Moreover, having a Michigan Controlled Substance License “does not authorize a licensee to dispense, manufacture, distribute, or prescribe a controlled substance if the dispensing, manufacture, distribution, or prescribing is not for a legitimate and professionally recognized therapeutic, scientific, or industrial purpose or is not in the scope of practice of a practitioner-licensee.”<sup>27</sup> This requirement is iterated and reiterated throughout the Michigan Public Health Code and, as set forth below in Section IV of this manuscript, the Federal laws and regulations as well.<sup>28</sup>

While there is no codified definition of “legitimate and professionally recognized purpose,” in an unpublished opinion, *People v. Nirajian Lai, M.D.*, the Court of Appeals broadly defined the phrase:

---

24. *Id.*

25. *Id.* **Please note:** Pharmacists have a heightened responsibility when dispensing controlled versus non-controlled substances. MCLA 333.17751 provides, in pertinent part, that when dispensing prescription drugs in general, pharmacists must exercise professional judgment to determine all of the following:

- (a) That the prescription was issued pursuant to an existing physician-patient or dentist-patient relationship.
- (b) That the prescription is authentic.
- (c) That the prescribed drug is appropriate and necessary for the treatment of an acute, chronic, or recurrent condition.
- (d) A pharmacist or prescriber shall dispense a prescription only if the prescription falls within the scope of practice of the prescriber.
- (e) A pharmacist shall not knowingly dispense a prescription after the death of the prescriber or patient.”

However, the aforementioned additional nationally accepted professional standards are required for pharmacists to consider when dispensing controlled substances in addition to the factors listed set forth in MCLA 333.17751.

26. The requirement that prescriptions for controlled substances be issued pursuant to a legitimate medical purpose is also a Federal requirement. A greater discussion of the Federal requirement is found in Section IV.B. of this manuscript.

27. *Id.*

28. *See e.g.*, MCLA §§333.7311, 7401 & 17766.



In determining if a practitioner failed to act for a legitimate and professional purpose or acted outside the scope of his practice, **the question of fact turns on whether the physician made an “honest” or “good faith effort” to treat and prescribe in compliance with an accepted standard of medical practice.**<sup>29</sup>

In this case, the physician-defendant prescribed Vicodin to an undercover police officer. The court determined that the physician-defendant did *not* prescribe for a legitimate and professionally recognized purpose. The court took into consideration the following:

Defendant's statements to the officer during one visit provide strong evidence of defendant's intent to prescribe the Vicodin for non-medical purposes. First, defendant himself acknowledged that the officer was experiencing neither elbow nor back pain. Second, after being pressured by defendant to reveal how he was using the Vicodin, the officer told defendant he was giving it to a girl. Defendant asked the officer whether Vicodin can be sold for a profit. The officer said yes. After discussing the street value of a pill, defendant stated “I admit it, at least you're honest, you know.” Defendant told the officer, “make sure that the person you're selling it to doesn't get hooked on it.” The officer assured defendant that would not happen, indicating that he gave the pills to different people. Defendant then told the officer that the officer was going to get him in trouble. Finally, defendant said “I don't know why I do it for you but...ah since you're so honest I think, I feel guilty not to.”<sup>30</sup>

These statements indicate that defendant believed the officer was using the Vicodin for a purpose other than to eliminate his own pain. In particular, defendant's statement “I don't know why I do it,” and his assertions that he was going to get in trouble indicate that his act of prescribing Vicodin was not for any particular medical purpose. Furthermore, because defendant apparently believed the officer was being honest when he told defendant he was giving away the Vicodin, defendant clearly intended to prescribe Vicodin for a reason other than treatment.

As is evident from the court's definition and its analysis, there is no one-size-fits-all formula to apply to every situation to determine whether the physician (or even the pharmacist) acted with a legitimate and professionally recognized purpose. Such determination must be made by looking at the totality of the circumstances.

As set forth above, the determination of whether a prescription for controlled substances has a legitimate medical purpose does not rest solely with the prescribing physician. Rather, a pharmacist also has an independent duty to scrutinize the prescription presented to him/her by the patient. In fact, a pharmacist is prohibited from filling a prescription if, in the pharmacist's professional judgment, “the pharmacist has reason to believe that the prescription will be used for other than legitimate medical purpose.”<sup>31</sup> Interestingly, the Michigan Adminis-

---

29. (emphasis added). *People v. Niranjan Lai, M.D.*, 220064, 2000 WL 33400229 (Mich. Ct. App. Nov. 21, 2000).

30. *Id.*

trative Code provides for 3 legitimate purposes for which controlled substances may be dispensed for a drug-dependent person.<sup>32</sup>

### 3. Prescriptions for Controlled Substances Must Include Certain Elements

Prescriptions for controlled substances must be dated and signed when issued and contain all of the following information:

- The full name and address of the patient for whom the substance is being prescribed;
- The prescriber's DEA registration number, printed name, address, and professional designation;
- The drug name, strength and dosage form;
- The quantity prescribed;<sup>33</sup>
- The directions for use.<sup>34</sup>

Moreover, a prescriber may “not prescribe a controlled and noncontrolled substance on the same prescription form.”<sup>35</sup> Michigan's Administrative Code provides that “[a] pharmacist who dispenses a controlled substance pursuant to a prescription not prepared in the form required by these rules is liable pursuant to the act.”<sup>36</sup> While these elements are required for all controlled substance prescriptions in Michigan, there are additional requirements for drugs classified as Schedule II (as opposed to Schedules III through V). Importantly, both Michigan and Federal authorities distinguish between Schedule II controlled substances and the remaining Schedules III through V with regard to prescribing and dispensing. These schedules are based upon the potential for addiction and abuse.<sup>37</sup> For instance, a prescription for a Schedule II controlled substance may *not* include refills (i.e., a new prescription must be obtained each time).<sup>38</sup> However, a prescription for a Schedule III or IV controlled substance may be refilled up to five times within the six months after the prescription's date of issuance as appropriately determined by the prescribing physician. A Schedule V controlled substance has no cap on the number of refills authorized by the prescriber on the prescription.<sup>39</sup> Moreover, a pharmacist may partially fill a Schedule III through V controlled substance so long as each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the

---

31. Mich. Admin. Code R. 338.490. *See*, Mich. Admin. Code R. 338.3162, which provides “[o]nly an order that is issued in the usual course of professional treatment or in the course of legitimate and authorized research is a prescription.” It is interesting to note that under Mich. Admin. Code R. 338.3167 a pharmacist can dispense a Schedule V controlled substances without a prescription so long as *all* of the following elements are met:

- (a) ***The dispensing pharmacist has determined it is to be used for a medical purpose.***
- (b) Not more than 240 cc (8 ounces) or 48 solid doses of a substance containing opium or more than 120 cc (4 ounces) or 24 solid doses of any other substance listed in schedule 5 are distributed at retail to the same purchaser in any single 48-hour period.
- (c) The purchaser is at least 18 years of age.
- (d) The pharmacist requires a purchaser not known to the pharmacist to furnish suitable identification, including proof of age where appropriate.

(emphasis added).

total quantity prescribed, and no Schedule III or IV controlled substances are dispensed more than six months after the date on which the prescription was issued.<sup>40</sup>

Unless there is an emergency situation (as is described in Mich. Admin. Code R338.3165), a practitioner may dispense a Schedule II controlled substance upon receipt of a *written* prescription from a physician with a Controlled Substances License.<sup>41</sup> To dispense a Schedule III-V controlled substance, the practitioner must have a *written, oral or electronically transmitted* prescription from a practitioner.<sup>42</sup> This distinction between Schedule II and Schedules III-V whereby a Schedule II generally cannot be dispensed via a verbal prescription whereas such verbal orders are allowed for Schedules III-V illustrates the gatekeeper role imposed upon physicians and pharmacists to limit access to those drugs that have the highest potential for abuse and/or addiction. Notably, if an order for a Controlled Substance listed in Schedule III through V is issued by the prescriber's agent under delegation, the pharmacist must record on the prescription it generates all of the aforementioned required elements, the transmitting agent's identity and the individual who received the prescription at the pharmacy.<sup>43</sup>

A pharmacist's failure to scrutinize prescriptions to ensure they contain all of the required elements can result in dispensing of a prescription for other than a legitimate medical purpose, exposing the pharmacist to liability. Finally, a pharmacist has a duty to require a positive identification of individuals to whom s/he is dispensing controlled substances when the pharmacist or the pharmacy employees do not know the person.<sup>44</sup>

---

32. Mich. Admin. Code R. 338.3163. The rule provides the following as legitimate purposes for which controlled substances may be dispensed for a drug-dependent person:

- (1) A prescription shall not be issued for a controlled substance nor shall a controlled substance be dispensed or administered to a drug dependent person for the purpose of continuing his or her drug dependency, except as follows:
  - (a) A prescriber, licensed in accordance with federal and state law to conduct the drug treatment of a drug dependent person in a program may prescribe a controlled substance for the purpose of legitimate treatment of the drug-dependent person.
  - (b) A controlled substance may be administered or dispensed, or both, by a dispenser, directly to a drug-dependent person for the purpose of continuing his or her dependence who is enrolled in a drug treatment and rehabilitation program.
- (2) A controlled substance may be prescribed and dispensed in an acute care hospital to continue maintenance treatment for drug dependency for a patient whose hospitalization is for treatment of a medical condition other than addiction. The enrollment of the patient in an approved maintenance treatment program shall be verified.

33. Mich. Admin. Code R. 338.3161 provides that written prescriptions contain the quantity in both written *and* numerical terms. It provides that a "written prescription is in compliance if it contains preprinted numbers representative of the quantity next to which is a box or line the prescriber may check."

34. *Id.*

35. Mich. Admin. Code R. 338.3161.

36. *Id.*

## B. Federal Laws and Regulations

### 1. Ensuring a Valid Prescription for Controlled Substances is a Shared Responsibility

The Federal Controlled Substances Act (“CSA”)<sup>45</sup> and the regulations promulgated thereunder set forth the requirements for prescribing controlled substances. A valid prescription for controlled substances must contain the following elements:

- Dated as of, and signed on, the day when the prescription was issued;
- The full name and address of the patient;
- The name of the drug;
- The strength of the drug;
- The dosage form of the drug;
- The quantity prescribed;
- The directions for use; and
- The name, address and registration number of the practitioner.<sup>46</sup>

Prescriptions must be written in ink or indelible pencil, written with a typewriter or printed on a computer printer, and manually signed by the practitioner on the date it was issued.<sup>47</sup>

---

37. In Michigan, for instance, the factors that must be taken into consideration when placing a drug into a schedule are the following:

- (a) The actual or relative potential for abuse.
- (b) The scientific evidence of its pharmacological effect, if known.
- (c) The state of current scientific knowledge regarding the substance.
- (d) The history and current pattern of abuse.
- (e) The scope, duration, and significance of abuse.
- (f) The risk to the public health.
- (g) The potential of the substance to produce psychic or physiological dependence liability.
- (h) Whether the substance is an immediate precursor of a substance already controlled under this article.

MCLA §333.7202. Please see **Appendix A** for a table summarizing each of the Michigan controlled substance schedules, the elements that must be satisfied for a drug to be in each schedule, and some examples of drugs in each schedule. It should be noted that, although not included in a controlled substance schedule, drugs used to make methamphetamine, including ephedrine, pseudoephedrine or pseudopod, are governed by specific statutes that apply to retailers of such products regulating their sale and storage (MCLA §333.1776e–f).

38. Mich. Admin. Code R. 338.3168.

39. *Id.*

40. *Id.*

41. MCLA §333.7333.

42. *Id.*; Mich. Admin. Code R. 338.3162.

43. Mich. Admin. Code R. 338.3162.

44. Mich. Admin. Code R. 338.3162.

The Federal regulations, mirrored by the State regulations, require that pharmacists scrutinize prescriptions for controlled substances and ensure their compliance with the regulations:

A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. **A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.**<sup>48</sup>

As such, both State and Federal regulations place the responsibility of proper prescribing and dispensing of controlled substances in the hands of both the prescriber and the pharmacist.

The DEA provides a number of safeguards for prescribers to ensure the issuance of proper prescriptions:<sup>49</sup>

- Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.
- Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
- Use prescription blanks only for writing a prescription order and not for notes.
- Never sign prescription blanks in advance.
- Assist the pharmacist when they telephone to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription.
- Contact the nearest DEA field office to obtain or to furnish information regarding suspicious prescription activities.<sup>50</sup>
- Use tamper-resistant prescription pads.

---

45. 21 USCA §801 *et seq.*

46. 21 CFR §1306.05.

47. *Id.*

48. *Id. See*, 21 U.S.C.A. §829.

49. *DEA Practitioner's Manual*, Pg. 15.

50. The nearest DEA field office for Michigan is located in Detroit with the following contact information:

**Diversion Program Manager:** James Geldhof

**Address:**

211 W. Fort Street

Suite 610

Detroit, Michigan 48226

**Diversion Phone:** (313) 226-7523

**Diversion Fax:** (313) 226-7542

**Diversion Program Manager Fax:** (313) 226-7541

**Registration Number for MI, OH, KY:** (800) 230-6844

## 2. The Legitimate Medical Purpose Test

The CSA requires that DEA registrants have an obligation to take reasonable measures to prevent diversion.<sup>51</sup> As such, the Federal regulations provide that when physicians prescribe controlled substances, they should be guided by the following principles:

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.**<sup>52</sup>

The DEA, in a 2006 notice regarding dispensing controlled substances for the treatment of pain,<sup>53</sup> interpreted “legitimate medical purpose” broadly stating, “[t]his requirement has been construed to mean that the prescription must be ‘in accordance with a standard of medical practice generally recognized and accepted in the United States.’” The DEA continued, quoting the Supreme Court in the landmark case of *U.S. v. Moore*,<sup>54</sup> and confirmed that the determination of whether a prescription was written for a legitimate purpose takes into account the totality of the circumstances:

There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts.

\* \* \*

The foregoing quotation makes a particularly important point: that **the types of cases in which physicians have been found to have dispensed controlled substances improperly under Federal law generally involve facts where the physician’s conduct is not merely of questionable legality, but instead is a glaring example of illegal activity.**<sup>55</sup>

As reflected above, there is no one-size-fits-all test for legitimate medical purpose. However, the DEA has provided a number of factors regarding a patient that a physician may consider (i.e., the factors the DEA takes into consideration when making a determination of legitimacy of purpose) prior to issuing a prescription for controlled substances<sup>56</sup>:

- Whether the patient is demanding to be seen immediately;
- Whether the patient is stating that s/he is visiting the area and is in need of a prescription to hold him/her over until returning to a local physician;
- Whether the patient is appearing to feign symptoms in an effort to obtain narcotics;

---

51. 21 U.S.C.A. §823.

52. 21 CFR §1306.04.

53. 71 Fed. Reg. 52716 (Sept. 6, 2006).

54. *U.S. v. Moore*, 423 U.S. 122 (1975).

55. 71 Fed. Reg. 52716, 52717 quoting *Moore* at 139.

56. *Id.* at 52722.

- Whether the patient is indicating that non-narcotic analgesics do not work for him/her;
- Whether the patient is requesting a particular narcotic drug;
- Whether the patient is complaining that a prescription has been lost or stolen and needs replacing;
- Whether the patient is requesting more refills than originally prescribed;
- Whether the patient is using pressure tactics or threatening behavior to obtain prescriptions; and
- Whether the patient is showing visible signs of drug abuse, such as track marks.

To be valid, a prescription must also be issued in the usual course of professional treatment, a determination, according to 21 CFR §1306.04, that needs to be made by the pharmacist in addition to the physician:

**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.** An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829)<sup>57</sup> and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.<sup>58</sup>

Therefore, a prescription filled by a pharmacist that was not issued by a practitioner in the “usual course of business,” as determined by a pharmacist, would constitute filling an invalid prescription. While recognizing that this requirement

---

57. 21 USCA §829 “valid prescription” as the following:

- (A) The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—
  - (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or
  - (ii) a covering practitioner.
- (B)
  - (i) The term “in-person medical evaluation” means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.
  - (ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.
- (C) The term “covering practitioner” means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—
  - (i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and
  - (ii) is temporarily unavailable to conduct the evaluation of the patient.

58. *Id.*

may not be received well by the physician who can be offended by the pharmacist questioning his/her medical judgment or by the pharmacist who can be offended by a pharmacy inspector questioning why he/she filled a non-fraudulent prescription that was written and validated by a fully licensed physician, a cooperative effort by physicians and pharmacists is necessary in order to fulfill the goal of preventing prescription drug diversion and abuse. For a summary of the CSA requirements as they pertain to each Schedule, please see **Appendix B**.

## V. The Standard of Care in Michigan

Under Michigan law, a physician, pharmacist and pharmacy are subject to disciplinary action against their respective licenses for (1) a “violation of general duty, consisting of negligence or failure to exercise due care...whether or not injury results...”<sup>59</sup> or (2) “incompetence.”<sup>60</sup> Both of these bases essentially allow State action against the physician, pharmacist and/or pharmacy for not following the applicable standards of care. The applicable standards of care, while not delineated by statute, have been developed by the Boards of Medicine, Osteopathic Medicine & Surgery and Pharmacy to include a consideration of the following:

- Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain developed by the Michigan Board of Medicine and the Michigan Board of Osteopathic Medicine and Surgery;
- Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain;
- *Responsible Opioid Prescribing: A Guide for Michigan Physicians*—a book endorsed by the Michigan Department of Community Health as representing the standard of care in Michigan; and
- Use of the Michigan Automated Prescription System (“MAPS”).

### A. Michigan’s Policy for the Use of Controlled Substances for the Treatment of Pain

The Michigan Boards of Medicine and Osteopathic Medicine & Surgery, in conjunction with staff members of the Michigan Department of Community Health, issued the *Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain* (the “Medical Guidelines”).<sup>61</sup> The Medical Guidelines, recognizing that treating pain is an essential aspect of the practice of medicine, aid in the establishment of the standard of care to be used when prescribing controlled substances to treat pain. The Medical Guidelines delineate the following steps to be taken when determining the need for prescribing controlled substances:

1. **Evaluation of Patient**—A medical history and physical examination must be obtained, evaluated and documented in the medical record, including the nature and intensity of pain, current and past treatments for pain, underlying or coexist-

59. MCLA §333.16221.

60. *Id.*

61. [http://www.michigan.gov/documents/mdch\\_article\\_MI\\_guidelines\\_91793\\_7.pdf](http://www.michigan.gov/documents/mdch_article_MI_guidelines_91793_7.pdf) and [http://www.michigan.gov/documents/mdch\\_article\\_MI\\_guidelines\\_91793\\_7.pdf](http://www.michigan.gov/documents/mdch_article_MI_guidelines_91793_7.pdf)



ing diseases or conditions, the effect of the pain on physical and psychological function, history of substance abuse, and the presence of one or more recognized medical indications for the use of a controlled substance.

2. **Treatment Plan**—The physician should state the objectives that will be used to determine treatment success and any further diagnostic evaluations or treatments that are planned. The treatment plan should be flexible to meet the evolving needs of the patient.
3. **Informed Consent and Agreement for Treatment**—The physician should discuss the risks and benefits of the use of controlled substances with the patient (or patient's parent, guardian or surrogate). If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider using a written agreement between physician and patient outlining the patient's responsibilities (this is often referred to as a "narcotics agreement" and is discussed further below in Section VII of this manuscript).
4. **Periodic Review**—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health and adjust the pain treatment accordingly.
5. **Consultation**—The physician should be willing to refer the patient, as necessary, for additional evaluation and treatment in order to achieve treatment objectives.
6. **Medical Records**—Keeping complete, current and accurate medical records to include:
  - The medical history and physical examination;
  - Diagnostic, therapeutic and laboratory results;
  - Evaluations and consultations;
  - Treatment objectives;
  - Discussion of risks and benefits;
  - Treatments;
  - Medications (including date, type, dosage and quantity prescribed); and
  - Periodic reviews.
7. **Compliance with Controlled Substances Laws and Regulations**

## **B. Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain<sup>62</sup>**

The Board of Pharmacy, recognizing that the use of controlled substances to be essential to treating pain, provided the following guidelines when dispensing controlled substances to treat pain:

1. **Review the Prescription**—Exercise due diligence in verifying that a prescription for controlled substances must be issued for a legitimate medical purpose. This

---

<sup>62</sup>[http://www.michigan.gov/documents/mdch\\_pharmacyguidelinesusecpain\\_139447\\_7.pdf](http://www.michigan.gov/documents/mdch_pharmacyguidelinesusecpain_139447_7.pdf)

verification should include (but not be limited to) a review of the prescription for evidence of:

- Forgery;
  - Alteration;
  - Discussion with the patient regarding the signs and symptoms of the disorder or disease and the diagnosis;
  - Review of the patient's prescription records;
  - A discussion with the prescriber; and
  - A query to MAPS, if fraud is suspected.
2. **Fictitious or Possibly Fictitious Prescriptions**—In instances in which the pharmacist is reasonably certain that a prescription is fictitious, s/he should contact law enforcement. If the pharmacist is not certain (but suspects) that a prescription is fictitious, s/he should ensure the patient's symptoms are managed during the time it takes for him/her to verify the validity of the prescription. The pharmacist may also determine that a query to MAPS is appropriate.
  3. **Prescription Refills**—Each time a patient returns to the pharmacist for refills, the pharmacist should evaluate the patient to ensure positive results are achieved and the patient is not experiencing inappropriate effects. This evaluation includes, but is not limited to, the following:
    - A discussion with the patient regarding signs and symptoms of the condition being treated;
    - A review of signs and symptoms of untoward effects;
    - A review of the patient's prescription records;
    - A discussion with the prescriber regarding the need for continuing or modifying the prescription therapy; and/or
    - When applicable, special attention should be given to monitoring patient at risk for misusing medications.
  4. **Patient Referrals**—If the pharmacy is not stocked with the controlled substance requested by the patient (pursuant to a valid order), the pharmacist should refer the patient to another source to help ensure the patient finds access to the medication s/he requires for symptom relief.

### C. Responsible Opioid Prescribing: A Guide for Michigan Physicians

In 2009, the Michigan Department of Community Health ("MDCH") distributed a booklet to Michigan-licensed physicians, residents, dentists, physician assistants, advanced practice nurses and pharmacists entitled: "*Responsible Opioid Prescribing: A Guide for Michigan Physicians*."<sup>63</sup> In a press release, MDCH stated the following:

The purpose of the booklet is to offer physicians (and other health professionals) concise and effective strategies for improving patient care around pain while at the same time reducing the risk of addiction, abuse, and diversion.

Dr. Greg Holzman, chief medical executive of the Michigan Department of Community Health, acknowledges that medical conditions involving pain impact many citizens within our state's population, and believes the booklet will give clear guidance to physicians and other health professionals on how to improve the medical practice of pain management and opioid prescribing in Michigan.<sup>64</sup>

The booklet, comprised of seven chapters, evaluates issues such as effectively evaluating the patient, creating a treatment plan, informed consent and agreements, periodic review, referral and patient management, documentation, and compliance with relevant law. The expectation is that practitioners have a copy of and have read this booklet and, as such, are held to the standards contained therein.

#### **D. MAPS<sup>65</sup>**

MAPS is the prescription monitoring system for Michigan. "Prescription monitoring programs are used to identify and prevent drug diversion at the prescriber, pharmacy and patient levels by collecting Schedule II-V controlled substances prescriptions dispensed by pharmacies and practitioners."<sup>66</sup> Over the years, there has been a nationwide push to incorporate prescription drug monitoring programs in each state. As of February 1, 2012, 39 states have operational monitoring systems; nine states have enacted legislation to implement the program although the program is not yet operational; and two states have pending legislation.<sup>67</sup> In Michigan, *dispensing* pharmacies and physicians are required to register with MAPS<sup>68</sup> and report certain information regarding dispensing certain controlled substances.

The Michigan Administrative Code requires pharmacists or dispensing prescribers to report, on the 1st and 15th day of every month,<sup>69</sup> the following information when dispensing Schedule II through Schedule V controlled substances:

- The patient identifier;
- The name of the controlled substance dispensed;
- The metric quantity of the controlled substance dispensed;
- The national drug code number (NDC) of the controlled substance dispensed;
- The date of issue of the prescription;

---

63. This booklet expressly provides that it is effective only until March 1, 2012. Waterford Life Sciences, the publishing company of the booklet, has recently advised the authors if this manuscript that a new version of the booklet would be released in April 2012 with updated information. The publisher advised that Michigan has placed an order for 12,000 copies of the new issue and would be one of the first states to receive the new edition. To obtain a copy of the current edition or the new edition (when released), please see the contact information contained in the Additional Helpful Resources section located at the end of this manuscript.

64. <http://www.michigan.gov/mdch/0,4612,7-132-8347-223099--,00.html>

65. [http://www.michigan.gov/lara/0,1607,7-154-27417\\_55478---,00.html](http://www.michigan.gov/lara/0,1607,7-154-27417_55478---,00.html)

66. *Id.*

67. From Alliance of States with Prescription Monitoring Programs (<http://www.pmpalliance.org/pdf/pmpstatusmap2012.pdf>).

68. [http://www.michigan.gov/lara/0,4601,7-154-27417\\_55478\\_55480---,00.html](http://www.michigan.gov/lara/0,4601,7-154-27417_55478_55480---,00.html)

69. There is an initiative to amend the Administrative Code to increase reporting by dispensing pharmacies and physicians from bi-monthly to weekly. Though this initiative was supposed to be implemented in mid-to-late 2011, it still has not been implemented. The expectation is that, at some point, reporting to MAPS will be a weekly requirement.

- The date of dispensing;
- The estimated days of supply of the controlled substance dispensed;
- The prescription number assigned by the dispenser;
- The DEA registration number of the prescriber and the dispensing pharmacy; and
- The Michigan license number of the dispensing pharmacy.<sup>70</sup>

While not statutorily required or required by an administrative rule, prescribing practitioners are “encouraged to register to MAPS Online to request prescription data on patients...Using MAPS Online before and during treatment...can alert you to any past ‘doctor shopping’ or questionable behavior.”<sup>71</sup> Practitioners should not take this “encouragement” lightly. The Michigan Department of Licensing and Regulatory Affairs (“LARA”) and law enforcement have taken the position that the applicable standards of care *require* physicians to perform MAPS queries regularly on patients for whom they prescribe controlled substances and that failure to do so is a breach of the standard of care.

## VI. Electronic Prescribing (“ePrescribing”)

Electronic prescribing or “ePrescribing” is defined by CMS as “a prescriber’s ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care.”<sup>72</sup> ePrescribing has afforded practitioners, pharmacists and patients with numerous benefits, including increased accuracy, efficiency and coordination of care. In addition, practitioners have a financial benefit to employ ePrescribing. There are incentive payments by the Federal government for meaningfully using electronic health record (“EHR”) technologies under the Health Information Technology for Economic and Clinical Health Act (HITECH”) as well as the incentive payments authorized under the Medicare Improvements for Patients and Providers Act of 2008 (“MIPPA”) both of which require the use of ePrescribing.

While ePrescribing is gaining popularity nationwide, the requirements for prescribing controlled substances tend to vary from state-to-state. Some states completely prohibit ePrescribing of controlled substances while other states, like Michigan, have enacted statutes and regulations to facilitate the increased use of ePrescribing.

### A. Michigan Guidance

ePrescribing is permissible under Michigan law so long as it is not prohibited under Federal law.<sup>73</sup> “Electronically transmitted prescription” is defined as follows:

[T]he communication of an original prescription or refill authorization by electronic means including computer to computer, computer to facsimile machine, or electronic mail transmission that contains the same information it contained when the prescriber or authorized agent transmitted the prescription. Electronically transmitted prescription does not include a prescription or refill authorization transmitted by telephone or facsimile machine.<sup>74</sup>

70. Mich. Admin. Code R. 338.3162b; MCLA §333.733a.

71. [http://www.michigan.gov/lara/0,4601,7-154-27417\\_55478\\_55485---,00.html](http://www.michigan.gov/lara/0,4601,7-154-27417_55478_55485---,00.html)

72. <https://www.cms.gov/EPrescribing/>

73. MCLA §333.7333.

74. MCLA §333.17703.

Michigan law requires the following in issuing ePrescriptions:

- (1) \* \* \*
  - (a) The name, address, and telephone number of the prescriber;
  - (b) The full name of the patient for whom the prescription is issued;
  - (c) An electronic signature or other identifier that specifically identifies and authenticates the prescriber or the prescriber's authorized agent;
  - (d) The time and date of the transmission;
  - (e) The identity of the pharmacy intended to receive the transmission; and
  - (f) Any other information required by the federal act or state law.
- (2) The electronic equipment or system utilized in the transmission and communication of prescriptions shall provide adequate confidentiality safeguards and be maintained to protect patient confidentiality as required under any applicable federal and state law and to ensure against unauthorized access. The electronic transmission of a prescription shall be communicated in a retrievable, recognizable form acceptable to the intended recipient. The electronic form utilized in the transmission of a prescription shall not include "dispense as written" or "d.a.w." as the default setting.<sup>75</sup>

A physician choosing to issue a prescription electronically must do so with the patient's consent. According to Michigan statute, "[i]f, with the patient's consent, a prescription is electronically transmitted, it shall be transmitted directly to a pharmacy of the patient's choice by the prescriber or the prescriber's authorized agent, and the data shall not be altered, modified, or extracted in the transmission process."<sup>76</sup>

As it relates to ePrescribing controlled substances, and as is described in more detail in Section VI of this manuscript, Schedule II controlled substances may **not** be ePrescribed; however, Schedule III through V controlled substances *may* be ePrescribed.<sup>77</sup> Dispensing controlled substances pursuant to an ePrescription is permissible provided that the prescribing practitioner is located in or licensed in Michigan or the prescribing practitioner is licensed in the state in which the practitioner is practicing.<sup>78</sup> In addition to a pharmacist's duty to ensure that a prescription contains all of the required elements to be a valid prescription, as set forth above,<sup>79</sup> for an ePrescription pharmacists must also "exercise professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription."<sup>80</sup>

---

75. MCLA 333.17754; Mich. Admin. Code R. 338.3162a.

76. MCLA §333.7333.

77. *Id.* **Please note:** Although Michigan law prohibits Schedule II ePrescribing, Federal law permits such ePrescribing. However, as mentioned earlier in this manuscript, from a practical perspective practitioners must follow the stricter law in order to be fully compliant—which in this case is Michigan law.

78. MCLA §§333.17751, 17763 & 7405. In 2009, this became the new, more flexible requirement. "Prior legislation required that pharmacists could only dispense controlled substance prescriptions (Schedules 2–5) prescribed by physicians who resided adjacent to the land border between Michigan and the adjoining states or who resided in Illinois and Minnesota" ([http://www.michigan.gov/lara/0,4601,7-154-27417\\_55478\\_55483---,00.html](http://www.michigan.gov/lara/0,4601,7-154-27417_55478_55483---,00.html)).

79. MCLA §333.17751.

80. MCLA §333.17754; Mich. Admin. Code R. 338.3162a.

## B. Federal Guidance<sup>81</sup>

On March 31, 2010, the DEA issued an interim final rule regarding the ePrescribing of controlled substances (“Interim Final Rule”).<sup>82</sup> The Interim Final Rule “provide[s] practitioners with the option of writing prescriptions for controlled substances electronically...[and] also permit[s] pharmacies to receive, dispense, and archive these electronic prescriptions.”<sup>83</sup> ePrescribing of controlled substances is permissible so long as the practitioner has a valid DEA registration, the practitioner uses an electronic prescription application meeting all of the applicable requirements of 21 CFR §1311.120, and the prescription otherwise meets the requirements of the CSA and the regulations promulgated thereunder.<sup>84</sup> A prescription for controlled substances created using an ePrescribing application failing to meet these requirements is not a valid prescription.<sup>85</sup>

Some key provisions of the Interim Final Rule include the following:

1. Physicians must use an e-Prescribing application that is certified for e-prescribing controlled substances;
2. Identity Proofing<sup>86</sup>—Physicians must apply for certification from certain federally approved credential service providers (CSPs) or certification authorities (CAs) that will conduct an identity proofing process that verifies that the prescriber’s identity;
3. Authentication Protocols<sup>87</sup>—Each time an e-Prescription is issued for a controlled substance, physicians must prove their identity through a two-factor authentication process to approve access controls and sign prescriptions. The two-factors include **two** of the following:
  - Something you **know** (e.g., password, pin, etc.);
  - Something you **have** (e.g., hard token separate from computer being accessed); or
  - Something you **are** (e.g., any biometric that meets the DEA’s requirements)
4. Signature Requirements<sup>88</sup>—For a physician to sign an e-Prescription for controlled substances, the physician must review a list of the controlled substance prescriptions for that patient and complete the two-factor authentication protocol. e-Prescriptions may also be digitally signed using the physician’s private key that is associated with the digital certificate. Digitally signing the e-Prescription still requires the physician to complete the two-factor authentication to use the private key.

---

81. 21 CFR §1311.01 *et seq.*

82. 75 Fed. Reg. 16236 (Mar. 31, 2010).

83. *Id.*

84. 21 CFR §1311.100.

85. *Id.*

86. 75 Fed. Reg. at 16224; 21 CFR §1311.105.

87. 75 Fed. Reg. at 16249; 21 CFR §1311.115.

88. 75 Fed. Reg. at 16254, 21 CFR §1311.140.

5. Internal Audits<sup>89</sup>—The application providers must establish and implement a list of auditable events to include, at a minimum, the following:
- Attempted unauthorized access to the e-Prescription application, or successful unauthorized access (where the determination of such is feasible);
  - Attempted unauthorized modification or destruction of any information or records, or successful unauthorized modification or destruction of any information or records (where the determination of such is feasible);
  - Interference with the operations of the prescription application;
  - Any setting of, or change to, logical access controls related to issuing controlled substance prescriptions;
  - Attempted, or successful, interference with audit trail functions; and
  - Any attempted, or successful, creation, modification, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by an agent or employee of the application service provider.

The e-Prescription application must analyze the audit trail at least once per day and generate an incident report that identifies each of the aforementioned auditable events.

6. Transmission Requirements<sup>90</sup>—The e-Prescription application must transmit the e-Prescription as soon as possible after the physician signs the prescription and must be transmitted from the physician to the pharmacy in its electronic form. During transmission, the contents of the prescription, as required by 21 CFR Part 1306, may not be altered; however, the prescription may be converted from one software version to another between the physician's prescription application and the pharmacist's application.
7. Pharmacy's Application and Access to the Application<sup>91</sup>—Prior to dispensing prescriptions for controlled substances, the pharmacy must ensure that a third-party auditor or a certification organization has found that the pharmacy application meets certain requirements prescribed in 21 CFR §§1311.200 and 205. Moreover, the pharmacy must determine which of its employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of those prescriptions. The pharmacy must ensure that logical access controls in the pharmacy application are set so that only such employees are granted access to perform these functions.
8. Receiving ePrescriptions<sup>92</sup>—When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist must check its records to ensure the electronic version was not received and the prescription dispensed. If both of the prescriptions were received, the pharmacist must mark one as void. If a pharmacist receives a paper or oral prescription that indicates it was originally transmitted electronically to

---

89. 75 Fed. Reg. at 16261; 21 CFR §1311.150.

90. 75 Fed. Reg. at 16263; 21 CFR §1311.170.

91. 75 Fed. Reg. at 16265; 21 CFR §1311.200.

92. 21 CFR §1311.200.

another pharmacy, the pharmacist has a duty to check with the other pharmacy to determine if the prescription was received and dispensed. If the other pharmacy that received the original e-Prescription had not dispensed it, that pharmacy must mark the electronic version as void or cancelled. If the pharmacy that received the original e-Prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void. At all times, the pharmacist must continue to only dispense controlled substances pursuant to a prescription issued for a legitimate medical purpose by a physician acting in the usual course of professional practice.

In addition to a pharmacist's responsibility to scrutinize the prescription to ensure a legitimate purpose, prior to filling digitally signed orders, pharmacists are required to do the following:

- Verify the integrity of the signature and the order by having the system validate the order;
- Verify the certificate holder's Controlled Substance Ordering System ("CSOS") digital certificate has not expired or has not been revoked; and
- Confirm that the sender has the authority to order the controlled substance.<sup>93</sup>

## VII. Narcotics/Opioid Agreements

Narcotics or opioid agreements ("Agreements") are among some of the measures that prescribing physicians may take to help prevent patients from abusing the controlled substances prescribed to them for a legitimate medical purpose. While there is no statutory or regulatory requirement to have patients enter into such Agreements, such Agreements are routinely used by pain management and other physicians who treat chronic pain patients. In *Responsible Opioid Prescribing: A Guide for Michigan Physicians*, there is a chapter entitled: "Informed Consent and Agreements" wherein the author sets forth suggested components to include in such Agreements. Please see **Appendix C** for a sample Agreement and **Appendix D** for a sample termination letter for a patient that fails to abide by such Agreement.

## VIII. Conclusion

As set forth above, both physicians and pharmacists have a coordinated obligation to ensure the proper prescribing of controlled substances to prevent the abuse and diversion of prescription drugs. In fact, failure of either to perform his/her duties under State and/or Federal law could result in investigation and/or prosecution. With increased enforcement, especially in Michigan, it is imperative that physicians and pharmacists (as well as their legal counsel) are educated on the statutory and regulatory requirements of controlled substance prescribing and dispensing in addition to the applicable standards of care as they relate to each profession.

## IX. Additional Helpful Resources

1. *Responsible Opioid Prescribing: A Guide for Michigan Physicians*, Scott M. Fishman, M.D., Michigan Department of Community Health, 2007. A copy may

---

93. 21 CFR §1311.50



be obtained by calling the Michigan Bureau of Health Professions Professional Practice Section Office at (517) 335-6557.

2. Michigan Department of Community Health DVD regarding MAPS and pain management. A copy may be obtained by calling the Michigan Bureau of Health Professions Professional Practice Section Office at (517) 335-6557.
3. **DEA**—<http://www.justice.gov/dea/>
  - **DEA Diversion Control**—<http://www.deadiversion.usdoj.gov/>
  - **DEA Audits**—Pursuant to the DEA's regulations (21 CFR §1316.01 *et seq.*), the “Administrator, through his inspectors, is authorized in accordance with sections 510 and 1015 of the Act (21 U.S.C. 880 and 965) to enter controlled premises and conduct administrative inspections thereof.” An article discussing DEA audits may be found here: [http://www.americanbar.org/newsletter/publications/aba\\_health\\_resource\\_home/aba\\_health\\_law\\_resource\\_1110\\_friedman.html](http://www.americanbar.org/newsletter/publications/aba_health_resource_home/aba_health_law_resource_1110_friedman.html)
4. **Federal Controlled Substances Act**—21 USCA §801 *et seq.* (<http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html>); 21 CFR §1300.01 *et seq.* (<http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>)
  - **Theft or Significant Loss**—Instances of theft or significant loss must be reported to the DEA on a Form 106 within 1 business day of discovery ([http://www.deadiversion.usdoj.gov/21cfr\\_reports/theft/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html)) (21 CFR §1301.76). Michigan requires reporting to the Board of Pharmacy within 10 days of discovery by submitting the DEA Form 106 (or copy or equivalent) (Mich. Admin. Code R. 338.3141).
5. **Michigan's Controlled Substances Act**—MCLA §333.7101 *et seq.* (<http://www.legislature.mi.gov/%28S%28pudhrrfd33sf2g45kgn5ss45%29%29/mileg.aspx?page=getObject&objectName=mcl-368-1978-7>)
  - **Manufacture, Distribution and Dispensing**—MCLA §333.7301 *et seq.*

In addition to the requirements for issuing and dispensing prescriptions, there are certain labeling, manufacturing and distributing requirements set forth in the statutes.
  - A prescriber may write more than one Schedule II controlled substance prescription on a single prescription form pursuant to MCLA §333.7333.
6. **Michigan Controlled Substances Benchbook**—<http://courts.michigan.gov/mji/resources/csbb/Controlled-Substances.pdf>
7. **Michigan Board of Medicine**—[http://www.michigan.gov/lara/0,1607,7-154-27417\\_27529\\_27541-58914--,00.html](http://www.michigan.gov/lara/0,1607,7-154-27417_27529_27541-58914--,00.html)
  - **Board of Medicine General Rules**—Mich. Admin. Code R. 338.2301 *et seq.* ([http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin\\_Num=33802301&Dpt=LG&RngHigh=](http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33802301&Dpt=LG&RngHigh=))

8. **Michigan Board of Osteopathic Medicine & Surgery**—[http://www.michigan.gov/lara/0,4601,7-154-27417\\_27529\\_27547---,00.html](http://www.michigan.gov/lara/0,4601,7-154-27417_27529_27547---,00.html)
  - **Board of Osteopathic Medicine & Surgery General Rules**—Mich. Admin. Code R. 338.101 *et seq.* ([http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin\\_Num=33800101&Dpt=LG&RngHigh=](http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33800101&Dpt=LG&RngHigh=))
9. **Michigan Board of Pharmacy**—[http://www.michigan.gov/lara/0,4601,7-154-27417\\_27529\\_27548---,00.html](http://www.michigan.gov/lara/0,4601,7-154-27417_27529_27548---,00.html)
  - **Board of Pharmacy General Rules**—Mich. Admin. Code R. 338.471 *et seq.* ([http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin\\_Num=33800471&Dpt=LG&RngHigh=](http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33800471&Dpt=LG&RngHigh=))
  - **Board of Pharmacy Rules Pertaining to Controlled Substances**—Mich. Admin. Code R. 338.3101 *et seq.* ([http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin\\_Num=33803101&Dpt=LG&RngHigh=](http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33803101&Dpt=LG&RngHigh=))
10. *Clinician's Guide to ePrescribing*, the American Medical Association (“AMA”) *et al.* (<http://www.ama-assn.org/resources/doc/hit/clinicians-guide-erx.PDF>)
11. **Prescription Writing Do's and Don'ts**—<http://www.apppharma.com/patient-safety/health-care-professionals/preventing-medical-errors/prescription-writing-dos-and-donts.html>
12. **State Prescription Drug Monitoring Programs and HIPAA**—<http://www.ncsl.org/print/cj/hippa.pdf>
13. **National Alliance for Model State Drug Laws**—<http://www.namsdl.org/home.htm>
14. **AMA Policy on Termination of the Physician-Patient Relationship**—<http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/ending-patient-physician-relationship.page>

**Appendix A**  
**Schedule I-V Drugs**

Schedule	Qualifications	Examples	Citation
I	Have a high potential for abuse and have no accepted medical use in treatment in the United States or lack accepted safety for use in treatment under medical supervision.	Marijuana, Peyote, Ecstasy	MCLA §333.7211 & §333.7212
II	(a) The substance has high potential for abuse; (b) The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and (c) The abuse of the substance may lead to severe psychic or physical dependence.	Oxycodone, Morphine, Codeine, Opium, Fentanyl	MCLA §333.7213 – §333.7214
III	(a) The substance has a potential for abuse less than the substances listed in schedules 1 and 2; (b) The substance has currently accepted medical use in treatment in the United States; and (c) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.	Vicodin ES, Suboxone	MCLA §333.7215 – §333.7216
IV	(a) The substance has a low potential for abuse relative to substances in schedule 3; (b) The substance has currently accepted medical use in treatment in the United States; and (c) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in schedule 3.	Xanax, Valium, Soma, Ambien	MCLA §333.7217 – §333.7218
V	(a) The substance has low potential for abuse relative to the controlled substances listed in schedule 4; (b) The substance has currently accepted medical use in treatment in the United States; and (c) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in schedule 4 or the incidence of abuse is such that the substance should be dispensed by a practitioner.	Loperamide, Certain compounds or mixtures of narcotic drugs as prescribed by MCLA §333.7220.	MCLA §333.7219 – §333.7220



## Appendix B Summary of Controlled Substance Act Requirements<sup>94</sup>

	Schedule II	Schedules III & IV	Schedule V
<i>Registration</i>	Required	Required	Required
<i>Receiving Records</i>	DEA Form 222	Invoices, readily retrievable	Invoices, readily retrievable
<i>Prescriptions</i>	Written <sup>1</sup> prescriptions <sup>2</sup>	Written, oral, or fax	Written, oral, or fax
<i>Refills</i>	No	No more than 5 within 6 months	As authorized when prescription is issued or if renewed by a practitioner
<i>Maintenance of Prescriptions</i>	Separate file	Separate file or readily retrievable	Separate file or readily retrievable <sup>3</sup>
<i>Distribution Between Registrants</i>	DEA Form 222	Invoices	Invoices
<i>Security</i>	Locked cabinet or dispersed among non-controlled pharmaceuticals	Locked cabinet or dispersed among non-controlled pharmaceuticals	Locked cabinet or dispersed among non-controlled pharmaceuticals
<i>Theft or Significant Loss</i>	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106

Note: *All records* must be maintained for 2 years, unless state law requires a longer period.

<sup>1</sup> Written prescriptions include paper prescriptions and electronic prescriptions that meet DEA's requirements for such prescriptions.

<sup>2</sup> Emergency prescriptions require a signed follow-up prescription within seven days.  
*Exceptions:* A facsimile prescription serves as the original prescription when issued to residents of Long Term Care Facilities, hospice patients, or patients with a diagnosed terminal illness, or for immediate administration (21 C.F.R. § 1306.11(e), (f) and (g)).

<sup>3</sup> The record of dispensing can also be a schedule V logbook, if state law allows.

<sup>94</sup>DEA Pharmacy Manual, Pg. 61.



**Appendix C**  
**Sample Narcotics Agreement**

**INFORMED CONSENT AGREEMENT FOR TREATMENT  
OF INTRACTABLE PAIN WITH NARCOTICS**

I have been diagnosed with \_\_\_\_\_ which is the cause of my intractable pain. This diagnosis has been confirmed in consultation with Dr. \_\_\_\_\_.

The medication that I have been prescribed for treatment of my condition is \_\_\_\_\_.

I understand that there are alternative treatments which include \_\_\_\_\_.

The goal of my therapy is to reduce my pain to a level that is tolerable and will allow me to improve my day to day functioning.

I understand that daily use of a narcotic increases certain risks, which include but are not limited to:

- Addiction
- Nausea, vomiting and constipation
- Impaired judgment, sleepiness, and confusion
- Allergic reactions, overdose and fatal complications
- Breathing problems
- Dizziness
- Impaired ability to operate machines or drive motor vehicles
- Development of tolerance

In consideration for treatment of my pain by Dr. \_\_\_\_\_, I agree to the following guidelines:

1. I will take this medication as prescribed by Dr. \_\_\_\_\_. I will not vary the dosage or interval without authorization from Dr. \_\_\_\_\_.
2. I will submit to random urine or blood tests if requested by Dr. \_\_\_\_\_, to assess my compliance.
3. I will obtain all my prescriptions through Dr. \_\_\_\_\_ and will fill all prescriptions at \_\_\_\_\_. In an acute emergency another  
[name of pharmacy]  
provider may prescribe medications for me. If this occurs I will notify Dr. \_\_\_\_\_ as soon as possible.

4. Due to the potential for misuse, I know that I will be unable to obtain early refills or replacement of lost or stolen medication. I understand that there will be no refills of my prescriptions over the telephone and that I must appear in person for an assessment by Dr.\_\_\_\_\_.
5. I agree to see Dr.\_\_\_\_\_ for on-going case management and will schedule regular appointments as long as I am taking this (these) narcotic medication(s).
6. I will provide Dr.\_\_\_\_\_ with a list of all of my current treating physicians and I hereby grant Dr.\_\_\_\_\_ permission to speak with any of my current treating physicians regarding my medical condition and treatment for it.
7. If I do not follow these guidelines, I understand that Dr.\_\_\_\_\_’s treatment of my pain may be terminated.

I have discussed the risks, benefits and alternatives to narcotic treatment with Dr.\_\_\_\_\_. I have had an opportunity to ask questions and receive answers to those questions to my satisfaction.

\_\_\_\_\_  
Patient Signature                      Date

\_\_\_\_\_  
Dr.\_\_\_\_\_                                      Date



**Appendix D**  
**Sample Patient Termination Letter**

***Sent Via Certified Mail, Return Receipt Requested***

[insert date]

[insert patient name]

[insert patient address]

RE: Notice of Discharge from our Practice

Dear Patient:

It is with regret that I must inform you that we are no longer able to provide for your health care needs at this office. As part of our commitment to high quality care, our office participates with the Michigan Automated Prescription System (MAPS) to assure that patients who receive controlled substances as part of their treatment with us are not obtaining similar substances elsewhere. Recently, a MAPS report was obtained by this office indicating that, despite our clear instructions to you to the contrary, you have sought and obtained such controlled substances elsewhere. As such, we are notifying you that you are hereby discharged from the care and treatment by Dr. \_\_\_\_\_, his practice, \_\_\_\_\_, and all of its employees. Upon receipt of a properly executed authorization, we will be happy to provide you with a copy of your medical records.

If you believe that you have a substance abuse problem, please contact:

**OAKLAND COUNTY HEALTH DIVISION**

PACE Unit (SARF)

250 Elizabeth Lake Rd., Ste. 1570

Pontiac, MI 48341

248-858-5200 / toll free 1-888-350-0900 ext. 85200

and ask for a referral to a local substance abuse facility.

If you are in need of immediate medical attention, please go to the nearest hospital's emergency room.

We wish you well in the future.

Sincerely,

Dr. \_\_\_\_\_

