

Prescribing in Florida (Guidance Provided by the Florida Department of Health)

(Note: This information was contained in a handout for the public at a Florida Board of Medicine meeting held in October 2010.)

Introduction:

This documentation contains information regarding prescribing in Florida and is an effort to highlight Florida laws and rules related to prescribing in one document. These rules and statutes are taken directly from the Board of Medicine and Pharmacy Practice Acts but are not all inclusive. It is important to understand that the Federal government, DEA, hospital bylaws, HIPAA, as well as other entities also have laws, rules and policies concerning prescribing and you should be familiar with those as well as the ones provided below. This document is to aid in research regarding prescribing requirements in Florida and should not preclude practitioners from reading and becoming familiar with the actual laws and rules themselves. This document should not be used as a substitute for legal advice.

Prescriptive Authority:

There are several professions in Florida that have prescriptive authority of various levels, including: physicians, osteopathic physicians, physician assistants, advanced registered nurse practitioners, optometrists, podiatrists and dentists.

The Prescription:

There are several Florida laws and rules that outline specifics related to the prescription and the electronic transfer of the prescription. These rules are:

- § 456.42, Florida Statutes - Written prescriptions for medicinal drugs (commonly referred to as the legible prescription law)
- Rule 64B-3.005, Florida Administrative Code - Counterfeit-resistant Prescription Blanks for Controlled Substance Prescribing
- § 456.43, Florida Statutes - Electronic prescribing for medicinal drugs
- § 668, Florida Statutes - Electronic signatures

The legible prescription law requires that the prescription be legibly written or typed; that the quantity of the drug must be written in numerical and textual format; that the date of the prescription must be written in textual letters (e.g. July 1, 2003); and that the practitioner must sign the prescription on the day it is issued. This law does not preclude a practitioner from using standard abbreviations such as "p.o. or t.i.d." This law does not apply to written orders; it applies to written prescriptions. If a practitioner has preprinted prescription blanks that does not contain

information required by this law, the information must be hand written on the prescription. Do not pre-sign prescription forms.

Practitioners may use counterfeit-resistant prescription blanks when prescribing controlled substances in Schedule II, Schedule III, or Schedule IV. If a practitioner elects to use counterfeit-resistant prescription blanks, the following features must be present on the prescription blank: background color must be blue or green and resist reproduction; blank must be printed on watermarked paper; blank must resist erasures and alterations; and the word "void" or "illegal" must appear on any photocopy or other reproduction of the blank, but should not obstruct or render illegible any portion of the drug name, quantity or directions for use. The counterfeit-resistant prescription blank must contain the following information: preprinted name, address and category of professional licensure of the prescribing practitioner; space for the prescribing practitioner's federal DEA registration number for controlled substances. The counterfeit-resistant prescription blank is not transferable and shall not be used by any person other than the prescribing practitioner.

Section 456.43, Florida Statutes, outlines requirements for electronic prescribing software. Electronic signatures is the usage of any letters, characters, or symbols manifested by electronic or similar means, executed or adopted by a party with an intent to authenticate a writing. A "writing" is electronically signed if an electronic signature is logically associated with such writing and shall have the same force and effect as a written signature.

Dispensing & Prescribing Practitioners:

Pertinent laws and rules that apply to dispensing practitioners include: § 465.0276, Florida Statutes - Dispensing Practitioner

- § 458.347, Florida Statutes - Physician Assistants
- § 499, Florida Statutes - Drug, Cosmetics and Household Products
- § 893, Florida Statutes - Drug Abuse Prevention and Control
- Rule 64B8-30.006, Florida Administrative Code - Dispensing Drugs
- Rules 64B8-30.007, Florida Administrative Code - Requirements and Limitations of Prescribing Privileges

Dispensing practitioners are practitioners authorized by law to prescribe drugs and therefore, may dispense such drugs to his or her patients in the regular course of his or her practice. The first requirement to becoming a dispensing practitioner in Florida is to register and pay a \$100 fee. The fee is charged initially and again at renewal. Dispensing practitioners must comply with all laws and rules applicable to pharmacists and pharmacies including undergoing inspections.

It is important to understand that the practitioner is still required to give the patient a written prescription and the option to fill that prescription in the practitioner's office or at a pharmacy of the patient's choice.

If the practitioner is dispensing complimentary packages of medicinal drugs, the practitioner is not required to register. However, there are requirements for dispensing complimentary packages. These requirements include dispensing the medicinal drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed. If complimentary medicinal drugs are not in the manufacturer's packaging, they must be dispensed in a container which bears the following information: practitioner's name, patient's name, date dispensed, name and strength of drug and directions for use. See appendix F.

Last year, the Legislature passed into law HB 989 which amended §458.347, Florida Statutes and allows supervising physicians to delegate dispensing authority to his or her Physician Assistant (PA). No registration is required for PA's to dispense. PA's may prescribe under his or her supervising physician; however, PA's cannot prescribe controlled substances. To be a prescribing PA, registration is required along with a \$400 fee initially. At renewal, the fee is \$150. Each PA and supervising physician must enter into and keep on file a written agreement outlining which medicinal drugs, not prohibited by the PA Formulary (discussed in the next section), the supervising physician has specifically authorized the PA to prescribe. Before commencing to prescribe or dispense, PA's must complete at least three (3) hours of continuing education in prescriptive practices. The PA must also, at renewal, provide documentation of completion of ten (10) hours continuing education in the specialty area in which the PA has prescriptive privileges. The prescription signed by a PA must contain the following information in addition to those items required by the legible prescription law: the supervising physician's name, address, telephone number and the PA's prescribing number (assigned during the registration process).

During the 2007 Legislative Session, HB 543 passed which allows pharmacists to give the flu shot to patients under the supervision of a physician.

Formulary:

Many practitioners may not be aware that pharmacists may prescribe certain medications and that pharmacists may order medicinal drugs.

- Rule 64B8-36.00I, Florida Administrative Code - Prescription of Certain Medicinal Drugs by Pharmacists
- § 465.186, Florida Statutes - Pharmacy
- Rule 64B8-36.002, Florida Administrative Code - General Terms and Conditions to be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products
- Rule 64B8-36.003, Florida Administrative Code - Medicinal Drugs Which May Be Ordered by Pharmacists
- Rule 64BI6-27.500, Florida Administrative Code - Negative Drug Formulary
- Rule 64B8-30.008, Florida Administrative Code - Formulary

Rules 64B8-36.001-.003, Florida Administrative Code, were created to implement §465.186,

Florida Statutes. These rules set forth which medicinal drug products may be ordered and dispensed by pharmacists and the terms and conditions under which said drugs may be ordered and dispensed.

Rule 64B16-27.500, Florida Administrative Code, is a negative drug formulary composed of medicinal drugs which have been determined to have a clinically significant biological or Therapeutic inequivalence and which, if substituted, could produce adverse clinical effects or could otherwise pose a threat to the health and safety of patients receiving such prescription medications. If the practitioner is prescribing a medication which is not on the list, but does not want the pharmacist to change the medication, the practitioner should write "medically necessary" on the prescription.

The PA Formulary lists all the medicinal drugs in which a PA may not prescribe. The rule is subject to change, and in fact, a change is in the rulemaking process now, so it is important to periodically review the rule for updates.

Prescribing Standards:

In addition to the laws and rules directly related to the prescription and prescribing, there are other standards which should be followed as well.

- § 458.336, Florida Statutes - Drugs to treat obesity; rules establishing guidelines
- Rule 64B8-9.012, Florida Administrative Code - Standards for the Prescription of Obesity Drugs
- Rule 64B8-9.013, Florida Administrative Code - Standards for the Use of Controlled Substances for the Treatment of Pain
- Rule 64B8-9.014, Florida Administrative Code - Standards for Telemedicine Prescribing Practice

Both the law and the rule for treating obesity outline practice guidelines for the safe use of phentermine, fenfluramine, and other drugs used to treat obesity. All physicians should become knowledgeable about effective methods for the treatment of pain and the requirements for prescribing controlled substances which are outlined in the rule. The rule on telemedicine makes it explicitly clear that practitioners may not prescribe based solely on electronic medical questionnaires and that a history and physical must be taken prior to prescribing medications to a patient.

Miscellaneous Information:

The Board of Medicine is often asked if physicians may prescribe to themselves. Although there is no law prohibiting the prescribing of medications by physicians to themselves, it is not recommended. Furthermore, physicians cannot prescribe controlled substances to themselves at all.

We are also often asked if a physician may prescribe for family members, friends or employees. The answer is yes, but all other standards apply including performance of a history and physical and the maintenance of medical records.

DEA issued a policy regarding controlled substance prescriptions in 2005. Although this document is not an outline that policy, it does offer the following advice:

- Pain management is an integral part of patient care and should be handled in a compassionate and comprehensive manner.
- DEA had initially interpreted regulations regarding the writing of refills, postdating or writing instructions to fill Schedule II controlled substances prescriptions at a later date is the equivalent to unauthorized refills. However, starting December 19, 2007, DEA has allowed the issuance of separate prescriptions for Schedule II controlled substances, dated on the same day they were written, for up to 3 months with a notation on them designating the earliest date they may be filled.
- There is no DEA requirement to see patients on a monthly basis.
- Patients on stable regimens may have their Schedule II prescriptions mailed to their home or the patient's pharmacy.
- There is no specific time limit on the number of days worth that a physician may write per prescription.
- Physicians have a duty to ensure that their prescribing of controlled substances occur in a manner consistent with effective controls against diversion and misuse.

Where are the Laws & Rules:

Florida Statutes: <http://www.leg.state.fl.us/statutes/index.cfm>

Florida Administrative Code: <https://www.flrules.org/Default.asp>

Board of Medicine Web Site: <http://www.doh.state.fl.us/mga/medical/>

Board of Medicine email address: MQAMedicine@doh.state.fl.us

Division of Medical Quality Assurance:

http://ww2.doh.state.fl.us/mgaservices/flhealth_index.asp

Board of Pharmacy

Drug Enforcement Agency Web Site: <http://www.usdoj.gov/dea/index.htm>

Conclusion:

Good physicians get in the disciplinary process because they don't know the rules. Take the time to learn the rules. Section 458.331, Florida Statutes outlines grounds for disciplinary action for

physicians. There are two (2) pertinent sections directly related to prescribing. It is important to note that physicians could also be charged with violation of the standards of care for inappropriate prescribing as well.

- § 458.331(1)(q), Florida Statutes - Grounds for disciplinary action
- § 458.331(1)(r), Florida Statutes - Grounds for disciplinary action

We recommend you read this document and the appendices to become knowledgeable regarding Florida prescribing laws and rules. If you still have questions or questions specifically related to your particular practice or practice type, you may wish to obtain private counsel for assistance.

Any additional questions can be emailed to: MQAMedicine@doh.state.fl.us

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