

Dispensing Practitioners:

Information you should know

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[General Information]

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[Overview]

- Definitions
- Registration
- Compliance
- Inspection
- Laws & Rules
- Disciplinary Action

[Definitions]

- A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section. s. 456.0276, F.S.

[Definitions continued]

- Dispensing – selling medicinal drugs to patients in the office
 - A practitioner who writes prescriptions or provides complimentary professional samples is not a dispensing practitioner and does not have to register

[Registration]

- Application
- \$100 fee for initial registration – there is no limit on the number of facilities that can be registered
- \$100 at renewal in addition to renewal fees
- Registration Statistics:

[Registration continued]

- Where do I go to obtain the application?
 - Go to the web site below
 - Click on Current Licensees
 - Click on the Dispensing Practitioner Application from the list of frequently requested forms

www.doh.state.fl.us/mqa/medical

[Registration Statistics]

- Currently licensed physicians = 61,513
 - Statistics from Division of Medical Quality Assurance Annual Report 2006-2007
- Currently registered dispensing practitioners = 3,710
 - Statistics from database report pulled March 25, 2008

[Compliance]

- Must comply with Chapters 458, 465, 499 & 893, F.S.
- Must consent to inspection
- Must provide patient with written prescription and verbally advise patient he/she may fill the prescription in the practitioner's office or any pharmacy

[Compliance continued]

- Must notify Board Office of address changes within 30 days
- Must comply with requirements for labeling
 - Practitioner's name
 - Patient's name
 - Name and strength of drug
 - Directions for use

[Inspection]

- S. 456.069, F.S. states agents of the Department of Health will inspect any establishment at which the services of a licensee authorized to prescribe controlled substances specified in Chapter 893 are offered
- Purpose: to ensure the practitioner is in compliance with the provisions of the applicable statutes and rules

What happens during an inspection?

- By registering to dispense, you have agreed to unannounced inspections of your facility and dispensing practices.
- An inspector will tour your facility to ensure you are in compliance with various statutes and rules related to dispensing.
- Non-compliance results in a failed inspection and possible disciplinary action.

[Inspection form]

- 1. Practitioner properly registered with the Board
- 2. Dispensing area clean and safe
- 3. Generic drug sign displayed
- 4. Stock medications appropriately labeled for dispensing from a licensed manufacturer
- 5. Medications purchased from a Florida licensed wholesaler/distributor
- 6. Outdated medications removed from stock
- 7. Medications requiring refrigeration appropriately stored
- 8. Medications dispensed being placed in childproof container
- 9. Medication labels properly completed for dispensing
- 10. Practitioner providing written prescription for medication to be dispensed.

Inspection form continued

- 11. Practitioner advising prescription may be filled on premise or at any pharmacy
- 12. Expiration/Discard date on prescription label or provided in written form
- 13. Practitioner is present when dispensing occurs
- 14. Practitioner is personally certifying filled prescriptions for accuracy prior to patient receiving
- 15. Offer made to counsel patients regarding prescription made verbally and in writing
- 16. Patient record contains medical history required for counseling
- 17. Controlled substances securely maintained and stored in a locked cabinet
- 18. Controlled substance prescriptions initialed and dated by practitioner
- 19. Controlled substance prescriptions provide patient's name and address
- 20. Controlled substance prescriptions provide practitioner's name, address and DEA number

[Inspection form continued]

- 21. Controlled substance prescription refills initialed and dated by practitioner
- 22. Controlled substance prescriptions properly maintained
- 23. Controlled substance purchase records properly maintained
- 24. Controlled substance records readily retrievable
- 25. Controlled substance biennial inventory conducted
- 26. DEA 222 forms properly completed
- 27. Daily hard copy printout or log of all prescriptions is dated/signed by each practitioner if computer system utilized
- 28. Practitioner's computer information readily retrievable

[Common deficiencies found during inspections]

- Failing to place appropriate information on prescription labels [s. 893.04(1)(e), F.S.]
- Failing to certify prescription [Rule 64B16-27.400(1)(g), (3), FAC]
- Failing to be present when controlled substances are dispensed [Rule 64B16-27.400(4), FAC]
- Allowing an unlicensed person to dispense medications [458.331(1)(w), F.S.]
- Failing to maintain daily dispensing log and signing off on the log each day [s. 893.07(1)(a)&(b), F.S.]

[Common deficiencies found during inspections continued]

- Failing to meet the requirements for dispensing controlled substances [multiple statutes/rules]
- Failing to provide documentation in the patient's medical record regarding controlled substances [893.07(1)(a)&(b), F.S.]
- Failing to maintain controlled substances in a locked cabinet/drawer [21CFR 1301.75 – Federal law]
- Pre-signing prescriptions [s. 458.331(1)(aa), F.S.]

[Common deficiencies found during inspections continued]

- Purchasing medications from an unlicensed supplier [s. 499.005(14), F.S.]
- Conducting controlled substance inventory only once or twice a month and/or failing to maintain an adequate count of controlled substances [s. 893.07(1)(a), F.S.]
- Outdated medications [Rule 64B16-28.402(1)(h), FAC]

Laws: Where do I find them and which ones should I review?

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

- Chapter 458, F.S. – Medicine
- Chapter 465, F.S. – Pharmacy
- Chapter 456, F.S. – Health Professions, General Provisions
- Chapter 893, F.S. – Drug Abuse Prevention and Control
- Chapter 499, F.S. – Drug, Cosmetic, and Household Products
- Chapter 120, F.S. – Administrative Procedures Act

[Rules: Where do I find them?]

<https://www.flrules.org/Default.asp>

[Laws & Rules: Here are just a few]

- S. 499.005, F.S. – Prohibited Acts (29 prohibited acts)
- S. 499.007, F.S. – Misbranded drug or device
- S. 499.028, F.S. – Drugs samples or complimentary drugs; start packs; permits to distribute
- 499.0054, F.S. – Advertising and labeling of drugs, devices and cosmetics
- S. 893.04, F.S. – Pharmacist and Practitioner
- S. 893.07, F.S. – Records

[Laws & Rules continued]

- Rule 64B8-9.012, FAC – Standards for the Prescription of Obesity Drugs
- Rule 64B8-9.013, FAC – Standards for the Use of Controlled Substances for the Treatment of Pain
- Rule 64B8-9.014, FAC – Standards for Telemedicine Prescribing Practice

[Disciplinary action]

Disciplinary action may be taken against a practitioner's license for any of the following reasons as they are related to dispensing:

- S. 458.331(1)(g) Failing to perform any statutory or legal obligation placed upon a licensed physician
- S. 456.072(1)(k) Failing to perform any statutory or legal obligation placed upon a licensed physician
- S. 458.331(1)(w) Delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified by training, experience, or licensure to perform them
- S. 458.331(1)(m) Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations

[Other disciplinary action]

- s. 458.331(1)(f) Aiding, assisting, procuring, or advising any unlicensed person to practice medicine contrary to this chapter or to a rule of the department or the board
- S. 458.331(1)(q) Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.
- S. 458.331(1)(nn) Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto

Penalties for violations: Depends on severity of offense and potential for patient harm

- S. 458.331(1)(g) – from letter of concern to revocation and \$1,000 - \$10,000 fine
- S. 456.072(1)(k) – from letter of concern to revocation and \$1,000 - \$10,000 fine
- S. 458.331(1)(w) – from one year probation or five years suspension followed by probation and \$1,000 - \$10,000 fine
- S. 458.331(1)(m) – from reprimand or two years suspension followed by probation and \$1,000 - \$10,000 fine
- S. 458.331(1)(f) – from probation to revocation and \$1,000 - \$10,000 fine
- S. 458.331(1)(q) – from one year probation to revocation and \$1,000 - \$10,000 fine
- S. 458.331(1)(nn) - from letter of concern to revocation and \$1,000 - \$10,000 fine

[New legislation and rules]

- To view bills and monitor progress, go to:
<http://www.leg.state.fl.us/Welcome/index.cfm?CFID=32044477&CFTOKEN=99229904>
- To view rules and changes, go to
<https://www.flrules.org/Default.asp> or go to
www.doh.state.fl.us/mqa/medical and view the
agendas and minutes for the Rules/Legislative
Committee of the Board of Medicine

[New Legislation and Rules]

- The 2007 Legislature passed a law that allows Physician Assistant's (PA's) to dispense [s. 458.347, F.S.]
 - PA's may dispense any medication used in the supervising physician's practice unless such medication is listed on the Formulary
 - PA's may not dispense controlled substances
 - PA's are not required to register as a dispensing practitioner, but his/her supervising physician must be registered