COUNTERFEIT-PROOF PADS/BLANKS FREQUENTLY ASKED QUESTIONS

These answers do not constitute a legal interpretation of <u>HB 7095</u>. For a legal interpretation on how to conduct your practice, please consult your attorney. You must reference the full text of <u>HB 7095</u> to understand how it impacts your practice.

- General
- Prescribers
- Pharmacists
- Vendors

General

Q: Is there a <u>Department of Health Public Health Emergency Declaration</u>
<u>Supplemental Order #01</u> suspending the requirement for health care practitioners to use counterfeit-proof prescription blanks/pads for 60 days?

A: Under HB 7095, effective July 1, 2011, counterfeit-proof prescription pads/blanks must be used by health care practitioners for prescribing controlled substances listed in Section 893.03, Florida Statutes. To ensure that health care services to patients are not negatively impacted and to allow practitioners time to comply with the new requirement, State Health Officer and Surgeon General, Dr. H. Frank Farmer issued a supplemental order on July 6, 2011 suspending the requirement for health care practitioners to use counterfeit-proof prescription pads/blanks for 60 days. This runs concurrent with the July 1, 2011, Public Health Emergency Declaration, which ends August 29, 2011. View the Department of Health Declaration of Public Health Emergency, Supplemental Order #01 on the Department's website at http://www.doh.state.fl.us.

Q: Where can I get a copy of HB 7095?

A: You can find a copy of http://www.doh.state.fl.us/mqa/Legislation/legis.htm#HB7095. You can also go to the State Archives and Laws of Florida website and look for chapter 2011-141, Laws of Florida.

Q: What prescriptions must be on a counterfeit-proof pad?

A: Prescriptions for controlled substances as listed in Chapter 893, F.S. must be written on a counterfeit-proof pad produced by an <u>approved vendor</u> or electronically prescribed.

Q: What are the requirements for a written prescription?

A: The requirements for a written prescription are outlined in section 456.42, F.S.

Q: What is the definition of dispensing?

A: Per <u>section 893.02(7), F.S.</u>, "dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to

Page 1 Last Updated: 07/27/2011

consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.

Q: What is the definition of prescribing?

A: Per <u>section 893.02(21), F.S.</u>, "prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of <u>s. 893.04.</u> . . . (Please see the statute for the complete definition.)

Q: What is the definition of administering?

A: Per <u>section 893.02(1), F.S.</u>, "administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.

Q: Must veterinarians use counterfeit-proof prescription blanks when writing prescriptions for controlled substances listed in Chapter 893, F.S.?

A: No. Veterinarians are not regulated by section 456.42, F.S.

Prescribers

Q: Do I have a grace period to use my old prescription blanks?

A: <u>HB 7095</u> requires written prescriptions for controlled substances listed in section 893.03, F.S. to be on counterfeit-proof prescription blanks. The <u>Supplemental Order 01#</u> signed by State Health Office and Surgeon General Dr. H. Frank Framer on July 6, 2011 suspends this requirement for health care practitioners to use counterfeit-proof prescription blanks for 60 days. This runs concurrent with the <u>July 1, 2011 Public Health Emergency Declaration</u> which ends August 29, 2011.

Q: Does my prescription have to be handwritten or can it be typed?

A: A prescription may be typed, but must be signed by the prescribing practitioner on the day it is issued.

Q: Can I call in a prescription for a controlled substance? ?

A: Section 893.04(1)(f) and (2)(c), F.S. reflect the following regarding oral prescriptions:

- A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.
- Any controlled substance listed in Schedule III or Schedule IV may be dispensed
 by a pharmacist upon an oral prescription if, before filling the prescription, the
 pharmacist reduces it to writing or records the prescription electronically if
 permitted by federal law. Such prescriptions must contain the date of the oral
 authorization.

Page 2 Last Updated: 07/27/2011

Q: Do I need to have a separate pad to write other prescriptions or can I use the counterfeit-proof prescription pads used for controlled substances?

A: <u>HB 7095</u> does not change the requirements for non-controlled substance prescription pads. See lines 243 – 255 of <u>HB 7095</u>. There is no prohibition from using counterfeit-proof prescription pad/blanks for non-controlled substance prescribing.

Q: What should I do if I already have paper and/or prescription pads that meet AHCA Medicaid standards but the vendor is not on MQA's approval list?

A: Have your vendor contact the Division of Medical Quality Assurance, Bureau of Operations, at (850) 245-4063 or visit our <u>website</u> for information about becoming an approved vendor for the Department of Health.

Q: Can I still send a prescription from my computer to the pharmacy?

A: Please reference <u>section 408.0611, F.S.</u>, which defines an electronic prescription and <u>section 465.035, F.S.</u> for requirements for faxing prescriptions.

Q: Can I print a prescription from my computer to give to the patient?

A: Lines 248 – 250 of HB 7095 outline the requirements for written prescriptions.

Q: Does the requirement to use a counterfeit-proof prescription pad apply to antibiotics?

A: <u>HB 7095</u> requires written prescriptions for controlled substances listed in <u>section</u> 893.03, F.S., to be written on counterfeit-proof prescription pads. Please review <u>section</u> 893.03, F.S. to make your determination.

Q: If I ordered counterfeit-proof pads from an approved vendor prior to July 1st, and they have not been received, am I prohibited from writing any prescriptions until one is sent?

A: Based on discussions with approved vendors, the vendors have indicated that counterfeit-proof prescription pads can be received within 3 to 5 days of the order date. Vendors have also indicated they can expedite orders.

Q: Am I allowed to provide samples to my patients?

A: Lines 1615 – 1620 of <u>HB 7095</u> refer to the dispensing of samples. Please also refer to <u>section 499.028, F.S.</u>, regarding drug samples or complimentary drugs.

Q: Am I still allowed to administer medication in my office?

A: It does not appear that HB 7095 modifies the administration of medication.

Q: Am I required to have my dental license number pre-printed on the counterfeit-proof prescription pads?

A: No, you are not required to pre-print your license number on the counterfeit-proof prescription pad or blank.

Q: Am I required to have my DEA number pre-printed on the counterfeit-proof prescription pads?

A: Approved vendors are required to provide a space on the counterfeit-proof prescription pad for the DEA number.

Page 3 Last Updated: 07/27/2011

Q: May I purchase counterfeit-proof prescriptions pads pre-printed with prescription information or prescription stamps?

A: <u>HB 7095</u> does not appear to address this question. Please consult your attorney and your vendor and use your professional judgment.

Q: Does the physician name, address, etc. need to be preprinted on a counterfeitproof prescription pad/blank when a physician is writing a controlled substance (listed in s. 893.03, F.S.) prescription for a hospital patient?

A: The Department will update its rule to address situations like this one. Until the rule is updated, continue printing the approved counterfeit-proof pad/blank with the information required by the Agency for Health Care Administration (e.g, hospital name/address, space for the physicians DEA number, and the vendor's unique tracking identification number).

Q: Can I use a counterfeit-proof pad/blank produced by an approved vendor?

A: After August 29, 2011, all counterfeit-proof prescription pads/blanks must meet these specifications at http://doh.state.fl.us/mqa/padvendor_specs.html.

Q: May I print controlled substance prescriptions from my computer?

A: The paper used to prescribe controlled substances listed in Chapter 893, Florida Statutes, must be produced by a vendor approved by the Department of Health and must have printed on the front the vendors unique tracking identification number. This number will be used by the Pharmacy to confirm/verify the prescription was written on a pad/blank produced by an approved vendor. For a list of approved vendors, please visit http://www.doh.state.fl.us/mqa/counterfeit-proof.html. If the vendor you currently use to produce the paper for your EMR system is not on our list of approved vendors, please suggest they apply to become an approved vendor. An application can be found online at http://www.doh.state.fl.us/mga/counterfeit-proof.html.

Pharmacists

Q: If a prescription is issued on a date prior to the effective date of the law and it was not written on a counterfeit-proof prescription pad/blank, may I fill the prescription?

A: Yes as long as the date issued is prior to August 29, 2011.

Q: What are the minimum specifications required on the counterfeit-proof prescription blanks/pads?

A: To ensure the quality and security of counterfeit-proof prescription pads provided by the vendor, the vendor must agree to produce a counterfeit-proof prescription pad or blank that meets the minimum specifications listed below:

- A. Resist erasures and reproductions. The blank must be printed on artificial watermarked paper and must be 50# white or other quality approved by the Department.
- B. Contain blue or green background ink that resists reproduction. The color must be consistent on every blank and listed on the blank as a security feature.

Page 4 Last Updated: 07/27/2011

- C. Display the word "VOID" or "ILLEGAL" if the prescription pad is copied. The language used must not obstruct or render illegible any portion of the drug name, quantity or direction for use.
- D. Contain the following information (NOTE: Counterfeit-proof blanks may be sold to licensed healthcare practitioners or facilities who print prescriptions using an Electronic Medical Record System):
 - 1. The preprinted name, address, and category of professional licensure of the prescribing practitioner; and
 - 2. A space for the prescribing practitioner's federal Drug Enforcement Administration registration number for controlled substances.
- E. List security features and descriptions on the prescription blanks, preferably on the reverse side, to assist dispensing pharmacists in detecting forgeries. Examples of such feature listings are: the blank resist erasures and alterations, the background color must appear blue (if blue) or green (if green), the words VOID (if void) or ILLEGAL (if illegal) will appear when copied. Additional security features beyond those required are encouraged, but must be listed on the blank.
- F. List a unique tracking identification number for each order which is printed on the front of the blank and readily visible. A unique tracking identification number and the name of the licensed healthcare practitioner or health-care facility that purchased the prescription blank must be maintained by the vendor and available to the Department upon request. The unique tracking identification number must consist of three subsets: (1) a unique alphabetic prefix that readily identifies the vendor, (2) the date of printing, and (3) a batch number. The alpha characters used to identify the vendor will be assigned by the Department and must appear first in the tracking identification number in upper case. The date the blank was printed must immediately follow the vendor's unique alpha identifier and must be presented in a six character numerical field using the format YRMODY (for example, June 3, 2011, would be coded as 110603). The batch number assigned by the vendor must immediately follow the print date. From left to right, the tracking identification number must appear as alpha prefix, print date, and then batch number, with no blank spaces between subsets. For example, ABC1106030001.
- G. Contain no advertisement on the actual prescription blank. Prescription pads may vary in size and style and contain appropriate advertising on the inside front cover and on alternate sheets within the pad. Advertisements shall be restricted to medically related topics and must be professional in nature.

Q: What does the new law require a pharmacist who receives a fraudulent prescription to do?

Q: Can the pharmacy fill a prescription from an out of state or out of country prescriber?

A: <u>Section 465.003(14), F.S.</u> provides:

Page 5 Last Updated: 07/27/2011

14) "Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

Vendors

Q: Where can I find the requirements to become an approved vendor for counterfeit-proof pads?

A: Contact the Division of Medical Quality Assurance, Bureau of Operations, at (850) 245-4063 or visit our <u>website</u> for information about becoming an approved vendor for the Department of Health.

Q: What are the minimum specifications the vendor must include on the counterfeit-proof prescription pad/blank in order to be approved by the Department?

A: The specifications for counterfeit-proof prescription blanks/pads are published at http://www.doh.state.fl.us/mga/padvendor-specs.html.

Q: What information must be reported to the Department?

A: Section. 456.42, F.S., requires approved vendors submit a monthly report to the Department which, at a minimum, documents the number of prescription pads sold and identifies the purchasers. Such report must be submitted by the approved vendor and received by the Department no later than the 15th day of the following month. The Department is in the process of establishing procedures for vendor reporting. Once procedures are established, we will notify all approved vendors and post information online.

Page 6 Last Updated: 07/27/2011