APPLICATION FOR COUNTERFEIT-PROOF PRESCRIPTION PAD VENDOR

Effective July 1, 2011, counterfeit-proof prescription pads or blanks must be used by licensed healthcare practitioners who prescribe controlled substances listed in Chapter 893, Florida Statutes. Section 456.42(2), Florida Statutes, was amended requiring licensed healthcare practitioners who prescribe controlled substances purchase counterfeit-proof prescription pads or blanks from vendors approved by the Department of Health (Department).

INSTRUCTIONS: A prospective vendor must submit a complete and legible Counterfeit-Proof Prescription Pad Vendor application to the Department and be approved before the vendor will be added to the Department's approved vendor list located online at http://www.doh.state.fl.us/mqa/counterfeit-proof.html. To complete the application process, sign and date the enclosed application and submit a sample counterfeit-proof prescription blank that meets the specifications required by the Department in Rule 64B-3.005, F.A.C. which is included in this application packet.

MAIL TO: Department of Health
Division of Medical Quality Assurance
Bureau of Operations
4052 Bald Cypress Way, Bin BCO-01
Tallahassee, Florida 32399-3260

EMAIL TO: MQAOPERATIONS@doh.state.fl.us

If you email your application to the Department, **you are required to mail** a sample counterfeit-proof prescription blank, pad, or a sample of the paper you will use to produce a counterfeit-proof prescription blank or pad to the Department. The sample must meet the specifications required by the Department.

64B-3.005 Counterfeit-Proof Prescription Pads or Blanks for Controlled Substance Prescribing

(1) A practitioner authorized in this state to prescribe prescription drugs (hereinafter referred to as "prescribing practitioner") must use a counterfeit-proof prescription pad or blank produced by a vendor approved by the department when writing prescription(s) for controlled substances listed in Chapter 893, F.S.

(2) Any person or entity desiring to produce counterfeit-proof prescription pads or blanks for use by prescribing practitioners shall apply to the department for approval. The application shall be made on incorporated by reference form DH-MQA 1250 (03/12), Application for Counterfeit-Proof Prescription Pad Vendor, which can be obtained at http://www.flrules.org/Gateway/reference.asp?No=Ref-01268 or from the department at Department of Health, 4052 Bald Cypress Way, Bin BCO-01, Tallahassee, Florida 32399-3260, or online at http://www.doh.state.fl.us/mqa/counterfeit-proof.html. To obtain approval, the counterfeit-proof prescription pad or blank must contain the following security features:

(a) The background color must be blue or green and resist reproduction;

(b) The pad or blank must be printed on artificial watermarked paper;

(c) The pad or blank must resist erasures and alterations and;

(d) The word "void" or "illegal" must appear on any photocopy or other reproduction of the pad or blank. This language shall not obstruct or render illegible any portion of the drug name, quantity or directions for use.

(3) The counterfeit-proof prescription pad or blank must contain the following information:

(a) The preprinted name, address and category of professional licensure of the prescribing practitioner or the name and address of the healthcare facility;

(b) A space for the prescribing practitioner's name if not preprinted and federal Drug Enforcement Administration registration number for controlled substances.

(c) A unique tracking identification number for each order on the front of the counterfeit-proof prescription pad or blank. The 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 prefix used to identify the vendor will be assigned by the department and must appear in upper case. The date of printing must immediately follow the vendors' unique alpha identifier and must be presented in six character numerical field using the format YRMODY. The batch number assigned by the vendor must immediately follow the print date and consist of numerical characters and must not contain spaces or special characters (e.g., dashes, periods, commas, slashes, alpha characters). 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.

(4) Vendors approved to produce counterfeit-proof prescription pads or blanks are responsible for the secure production and distribution of the counterfeit-proof prescription pads or blanks to prescribing practitioners. Approved vendors must:

(a) Receive orders in writing signed by an authorized prescribing practitioner or healthcare facility;

(b) Maintain records and information about the production and distribution of counterfeit-proof prescription pads or blanks. A unique tracking identification number and the name of the authorized prescriber or healthcare facility that purchased the prescription pad or blank must be maintained and made available to the department upon request. The department may request random inspections of the counterfeit-proof prescription pads or blanks produced by the vendor;

(c) Destroy counterfeit-proof prescription pads or blanks unused by the prescriber or healthcare facility for which they were produced and returned to the vendor; and

(d) Submit a monthly report to the department documenting the name of the prescribing practitioner or healthcare facility who purchased counterfeit-proof prescription pads or blanks, the batch number assigned to the counterfeit-proof prescription pad or blank order, and the number of pads or blanks sold. This report must be submitted to the department within 15 business days after the end of the reporting month.

(5) The counterfeit-proof prescription pad or blank is not transferable and shall not be used by any person other than the prescribing practitioner whose name appears on the pad or blank or who is authorized to use the pad or blank by the healthcare facility.

Rulemaking Authority 893.065 FS. Law Implemented 893.065 FS. History–New 6-26-08, Amended 6-18-12.

COUNTERFEIT-PROOF PRESCRIPTION PAD
VENDOR APPLICATION

Vendor/Company Name:	
Primary Business Address:	
Authorized Representative and Title:	
Contact Person and Title:	
Federal Tax ID Number:	
Telephone Number:	
E-Mail Address:	

We are interested in learning more about your company and how it will support the Department by producing and distributing counterfeit-proof prescription pads or blanks to health care practitioners who prescribe controlled substances. Your responses to the questions asked in the Vendor History and Vendor References sections of this application are optional and for information only, and are not used to determine whether the application is approved.

VENDOR HISTORY: Provide a response to the following questions on a separate document prepared on your letterhead. Restate the question exactly as listed below followed by your response. You should sign and date your prepared response and attach it to the application packet.

1. Provide a brief history of your company, what products it provides, and the clientele your company serves.

2. Provide a brief description of your company's experience, including the number of years it has been in business, the extent of its experience, and the number of years in producing and distributing fraud-resistant secure documents, and specifics about its experience in producing and distributing counterfeit-proof prescription blanks or pads.

3. Describe in detail your company's operational processes and safeguards for manufacturing a counterfeit-proof prescription blank or pad and describe the security features of your facility. Include, but do not necessarily limit the description to:

    a. Receiving a prescription blank or pad order;
    b. Verifying the prescription blank or pad order is from an authorized licensed healthcare practitioner;
    c. Accurately producing the prescription blank order including meeting program specifications;
    d. Maintaining the security of the produced prescription blank order prior to shipment;
    e. Verifying and shipping the prescription blank order to the licensed healthcare practitioner or healthcare facility's approved address;
    f. Tracking and verifying receipt of the prescription blank or pad order by an approved healthcare practitioner;
    g. Recalling and/or voiding a prescription blank order;
    h. Destroying unused blanks and other destruction procedures.

4. Describe the methodology your company will use to comply with the record keeping requirements for tracking orders, production data, delivery and receipt, recalls, producing reports, and storage of records.

VENDOR REFERENCES: Provide at least three references for your company's experience with production of fraud-resistant secure documents and/or counterfeit-proof prescription blanks or pads. For each reference, provide the name and address of the company, the name and title of the contact person, and that person's telephone number.

Company's Name	Company's Address	Contact Name/Title	Contact's Telephone Number

VENDOR/COMPANY SIGNATURE:

I state that I am the person representing the company referred to in the application to become an approved counterfeit-proof prescription vendor for the Florida Department of Health.

I state that these statements are true and correct. I recognize that providing false information may result in the Department rescinding the approval of the company to produce counterfeit-proof prescription pads or blanks as described in Sections 893.065 and 456.42(2), Florida Statutes.

_____
VENDOR /COMPANY NAME

_____ _____
VENDOR/AUTHORIZED REPRESENTATIVE SIGNATURE DATE