

FREQUENTLY ASKED QUESTIONS

Licensure and Regulation of Pharmaceutical Detailers in the District of Columbia

1. What is the timing for implementation of the SafeRX legislation?

Implementation of the Act will begin on October 1, 2008. Beginning October 1, 2008, the Board of Pharmacy will begin issuing pharmaceutical detailer licenses. However, the requirement to have a license to practice pharmaceutical detailing will not be imposed until April 1, 2009 to ensure everyone has sufficient notice and opportunity to obtain licensure.

2. Will there be a phase-in period?

Yes, although the Board will begin issuing licenses on October 1, 2008, there will be a six months phase-in period for pharmaceutical detailers to apply for and obtain a license. However, the requirement to have a license to practice pharmaceutical detailing will not be imposed until April 1, 2009 to ensure everyone has sufficient notice and opportunity to obtain licensure.

3. What is the application fee?

The application fee for a pharmaceutical detailer license is \$175.00. Application fees must be paid by either check or money order made payable to "DC Treasurer."

4. Can I pay the application fee by credit card? If not to who should I make the check payable?

Presently the Department does not have the ability to accept credit card payments for new license applications. Application fees must be paid by either check or money order made payable to "DC Treasurer." All checks that are not made payable to DC Treasurer will be returned with the applicant's application materials.

5. How long does the application process take?

In most cases a license will typically be approved for issuance within 3-5 business days after the Board has received and reviewed a complete application package containing all required materials, information, and supporting documents and in which there are no issues regarding the applicant's qualifications or fitness to be licensed. If an application is incomplete or otherwise deficient, this will significantly delay the process and can result in the return of your application materials to you. Please carefully read the application forms and submit all required materials and information to ensure timely processing of your application.

For those applications where there are issues regarding the applicant's qualifications or fitness to be licensed, the process may take longer. However, in all cases the Board shall make a decision whether to approve or to initiate the process to deny an application for licensure within sixty (60) days after receipt of a complete application package containing all required materials, information, and supporting documents.

If the Board intends to deny an application, the Applicant will receive notice of the Board's intent within sixty (60) days. However, the formal denial process under the District's Administrative Procedures Act shall not be included within the sixty (60) day requirement.

6. Can I practice as a pharmaceutical detailer while my application is pending?

Until close of business March 30, 2009 you may continue to engage in the practice of pharmaceutical detailing. However, beginning April 1, 2009 you will no longer be able to engage in the practice of pharmaceutical detailing in the District of Columbia until you have been issued a pharmaceutical detailer license.

7. How will I be notified if my license application is denied and the reasons for denial?

If your application is not being approved because you do not meet the requirements for licensure, you will be notified by letter which will state which requirement you do not meet. However, if your license is being denied for any other reason, you will receive a Notice of Intent to Deny licensure document in the mail which will state the basis for the proposed denial and advise you of your right to request a hearing and the procedures for doing so.

8. What are the "relevant documents" that I need to provide as part of my application package?

In section 7 of the application form, you are instructed to provide full information and complete details, including copies of any relevant documents, for any of the questions to which you answer "yes." The types of documents will depend upon the question to which you have answered yes and your explanation. The goal is to provide the Board with all applicable information to assist in evaluating your application. For example, if you answered yes that you have been convicted of a crime; relevant documents would include copies of your court papers. If you answered yes to a termination, a relevant document would be a copy of the termination letter.

9. How long is the license good for once it has been issued?

The term of a license, certificate, or registration issued or renewed shall be two (2) years or for the balance of the license period, whichever is shorter. However, If the date that a license is issued or renewed is less than (120) days prior to the expiration date for the current licensure period, the expiration of that license will automatically be extended to the subsequent licensure period. For example, if the license is issued on January 1, 2010 and the current licensure period will expire on February 28, 2010, then the license will be issued with an expiration date of February 28, 2012.

10. Does the requirement for licensure apply to representatives who sell, market, or promote veterinarian drug products? No.

11. Does the requirement for licensure apply to representatives who sell, market, or promote over-the-counter drug products? Yes.

12. Do I need a license to work in the District on a temporary or emergency basis?
Yes, after April 1, 2009 a license will be required to engage in the practice of pharmaceutical detailing in the District of Columbia.

13. How many continuing education credits will be required for renewal of licensure?

An applicant for renewal of licensure must complete a minimum of fifteen (15) credit hours of approved continuing education during the two year period preceding the date the license expires. A minimum of fifty (50) minutes constitutes one credit hour.

14. How will I know if a continuing education programs will be acceptable for use toward meeting the continuing education requirements?

17 DCMR 8307.2 sets forth the approved subjects for which applicants can obtain continuing education. Likewise, 17 DCMR 8307.3 sets forth the acceptable programs and providers that can be used for obtaining the required continuing education credits. As long as the continuing education course provides instruction in one of the areas set forth in 17 DCMR 8301.2 and is provided by a provider type set forth in 17 DCMR 8307.3 the continuing education program will be accepted. Additionally, licensees may contact the Board at 202-724-8938 to confirm that a program will be acceptable before attending the course.

15. How will the Board track compliance with continuing education requirements?

At the conclusion of each renewal period the Board will conduct a random audit. Those licensees selected in the random audit will be required to submit proof of having completed the required fifteen hours of continuing education. 17 DCMR 8306.6 sets forth the information that must be provided on continuing education certificates and documentation of course completion.

16. Will internal training, as provided by a representative's company, be acceptable for use toward meeting the continuing education requirements?

Yes, if it provides instruction in one of the approved subjects and was completed during the two years preceding renewal of the license.

17. What is the process for submitting a continuing education program for approval by the Board of Pharmacy?

If you are a program provider who wants to receive board approval to provide, sponsor or administer a continuing education course, you will need to complete the “**Application for Approval to Provide Continuing Education Course**” form located on the Board’s website in the Pharmaceutical Detailer’s application package materials and submit it to the Board as indicated in the application instructions.

If you are licensee who wants to confirm that a course will be acceptable for continuing education credit prior to taking the course, simply send in a copy of the course description and syllabus materials to the Board at: Karin Barron 717 14th Street, NW, 6th Floor Washington, DC 20005 or via facsimile at 202-727-8471. Include your name and contact information.

18. Why is my social security number required on my license application?

Pursuant to the Child Support and Welfare Reform Compliance Amendment Act of 2000 (D.C. Law 13-269, D.C. Official Code § 3-1205.05(b)(2001)) it is required that the social security number of each applicant for a license issued under the Health Occupations Revision Act be recorded on the application. However, this information is not available to the public. This information is kept on file in an internal database. In the unlikely event of a security breach, all affected or potentially affected persons would be notified by mail at their address on file with the Department and provided further information and instructions. An additional notification would also be placed on the Department’s website.

19. Why does my license have to expire on the last day of February of each even-numbered year instead of exactly two years from the date I receive it?

For administrative efficiency, all pharmaceutical detailer licenses will expire on the same date biennially. This allows the Department's staff to prepare for the renewal cycle, issue renewal notices to all licensees, and process renewal applications in an efficient and streamlined process.

20. Am I required to present my license to a health care professional before communicating with the licensed health professional or his or her employee or representative?

No, however the Representative should carry the wallet-sized license with him or her and have it available for presentation upon request of a licensed health care professional or his or her employee or representative.

21. Does the Code of Ethics prohibition against deceptive or misleading marketing practices have the same meaning as set forth in the FDA guidelines?

Yes.

22. Does the requirement to provide information to healthcare professionals that is accurate and fairly balanced in compliance with FDA policy and practices on the provision of information to health care professionals mean that I have to provide a healthcare professional with information regarding another company's product?

This regulation has the same meaning and intent as set forth in the federal law and FDA guidelines on this issue, it does not create a new requirement to discuss or promote your competitor's product.

23. What type of documents and information is a pharmaceutical detailer required to maintain relating to his or her communications with health care professionals and their representatives?

The documentation to be maintained should include, who the detailer visited, the date and time of the visit, the products discussed, whether samples were provided, and the type of materials provided to the health care professional.

24. If a representative moves to another territory or state, but stays with the same company, is he or she required to notify the board of the move?

Yes, D.C. Official Code § 3-1205.13(b) requires a licensee to notify the board of any change of residence or business address within thirty (30) days after the change.

25. Can the documents and information that the pharmaceutical detailer is required to maintain be stored by his or her employer?

Yes. Upon receipt of a request by the Board or its agent for the documents, the detailer will have ten (10) business days to notify his employer of the request and arrange for the documents to be provided to the Board.

26. Who is responsible for ensuring that a company's corporate offices are made aware of a health care providers request not to receive any more sales calls?

The person to who the written notice is given is responsible for forwarding the notice to the corporate office. However, unless the person continuing to make the sales calls has actual knowledge of the request, a pharmaceutical manufacturer or labeler's employees and representatives will not be deemed to have knowledge of a health care provider's request until thirty (30) days after the health care provider submits the written request to the pharmaceutical detailer or his or her employer.

27. How can I identify the members of the Medication Advisory Committee?

The District of Columbia's Medical Assistance Administration's Medicaid Community Advisory Committee, Pharmacy and Therapeutics Committee, and Drug Utilization Review (DUR) Board fall under the ambits of this prohibition. The District's newly established Health Care Finance Agency has oversight of these committees. To obtain a listing of the members of these committees you may contact:

The Department of Health Care Finance
Suite 4179
825 North Capitol Street, NE
Washington, DC 20002

- **Medicaid Community Advisory Committee**
Contact: Dr. Julie Hudman, Director MAA
Asst. Adrian Cooper – (202) 442-9050

- **Pharmacy and Therapeutics Committee (P&T Committee) and**

- **Drug Utilization Review (DUR)**

Contact: Charlene Fairfax – (202) 442-9076

28. What information on the application form can be shared with the public?

Information from an application form that may be shared with the public, pursuant to a Freedom of Information Request, is governed by the District's Freedom of Information Act (D.C. Official Code Title 2 § 2-531 et. seq.)

Requests made pursuant to the Freedom Information Act are reviewed by the Department's FOIA officer where a determination is made as to what information is subject to disclosure under the Act and which information falls under one of the exemptions from disclosure.

29. Will the number of required continuing education credits for the February 2010 renewal be prorated?

For the February 2010 renewal only, the Board has voted to prorate the continuing education requirement for renewal of pharmaceutical detailer licenses to 7.5 CEUs. For all subsequent renewals, pharmaceutical detailers will be required to complete all 15 CEUs whether or not it is the licensee's first renewal and regardless of how long they have held the license. Further as is indicated in section 8306.7, beginning with the 2010 renewal period, the Board shall conduct a random audit of continuing education credits at the completion of each renewal period.