

Questions for the District of Columbia Board of Pharmacy for the drafting of SafeRx Frequently Asked Questions Document

- Is there a threshold, such as a percentage of time working in the District as a “detailer”, to require submitting an application?
- By way of example: A physician, licensed to practice medicine in the District, attends a convention in the District (e.g. at the DC Convention Center) and attends a session where a pharmaceutical company employee, likely an MD or PhD, speaks about a company product, e.g., presenting new scientific or medical information. Would that pharmaceutical company employee, even though clearly not a pharmaceutical detailer, be required to register as a pharmaceutical detailer in the District?
- What types of activities qualify as “pharmaceutical detailing” versus general scientific exchange? Examples of occupations that inadvertently may fall under the definition of “providing information” (Section 8399.1):
 - Medical Science Liaison: Medical science liaisons (MSLs) are integral in assisting practicing physicians in their treatment of patients, by providing up-to-date scientific /medical information, as well as assisting in the implementation of the Risk Evaluation and Mitigation Strategies (REMS) that FDA requires in order for physicians to be permitted to use or prescribe certain drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by Congress in 2007. The role of the MSL is to educate medical professionals with respect to the clinical science underlying appropriate use of a particular product, including contraindications, risk factors, and symptoms to be monitored when prescribing or considering use of a product. MSLs are designated by companies to respond to highly technical questions raised by prescribers. Would such pharmaceutical company employees be required to obtain a license as a pharmaceutical detailer before they meet or have discussions with a physician in the District, even though they are not sales representatives or pharmaceutical detailers for the company?
 - Clinical Trial Professional: Individuals within manufacturers’ medical affairs and clinical departments are integral in developing and assisting with clinical trials and clinical research protocols involving investigational drugs and biologics, as well as studies and new research on approved drugs and biologics. In this capacity, clinical trial professionals may be involved in communicating regarding such research to a DC health care provider, often in response to an unsolicited request from the provider. Would a discussion such as this warrant the licensing as a detailer of a clinical trial professional?
- What steps should a company take to get important product information to doctors that may affect patient safety if they do not have a licensed pharmaceutical detailer in the District? What if FDA requires the dissemination of such information?
- Will a list of approved continuing education programs be listed by the Board (section 8037.4)? If, so where?
- What steps should a company take to have a continuing education program approved by the Board (section 8037.2)?
- Will all disciplines involved with “detailing” be required to complete CE as part of ongoing licensure, even if their professional degree does not require them to do so (e.g. PhD’s)?

- If a health care provider licensed in the District participates in a company training program (in which new hires practice “detailing” health care providers in a non-selling environment), and where the health care providers are compensated as consultants. Would these new hires need to be licensed?
- What is the estimated approval time of a new license application for pharmaceutical detailers?
- When a pharmaceutical detailed renews their license in 2 years, does the application process still take 60 days? Or is this process length shortened?
- As stated on the application a decision to license the applicant “will be made within sixty (60) days from the receipt of the COMPLETED application and all supporting documents” by the Board. Is this period for sixty (60) calendar or business days?
- During the sixty (60) day application approval period will the applicant need to refrain from interactions with physicians until the license application is approved?
- What steps will be taken to ensure that the detailers’ personal information on the application (applicants are required to provide social security number, drivers license number, and answer several questions about termination/resignation from previous employment, criminal record, and medical history) will remain confidential to prevent identity theft and protect privacy?
- What qualifies as an “official certification of graduation”?
- Because licenses “will expire at 12:00 Midnight, the last day of February or each even numbered year” if an individual becomes licensed (for example) in December of an odd number year will that individual need to complete “fifteen (15) hours of approved continuing education credit” (Section 8306) during that 2-3 month period to renew their license for the next two years?
- What constitutes “willfully harass, intimidate, or coerce” by a pharmaceutical detailer (section 8305.4)?
- Will the names of the Medication Advisory Committee Members be listed or made public, in light of the prohibition on giving them gifts (Section 8305.7)? If so, where will they be posted?
- Do the legislation and regulations apply to over the counter products and/or animal products?
- Do the legislation and regulations apply to meetings between a detailer and prescriber taking place outside of the District (such as in Maryland or Virginia) or over the phone?
- Regarding the statute’s provision stating that “the Board of Pharmacy and an agent acting on its behalf is authorized to collect information from licensed pharmaceutical detailers relating to their communication with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District”(Section 8309.1), does this encompass ALL communications with health care professionals? For example, Regional Medical Liaisons and sales representatives track their communications / interactions with physicians but that is generally not the case for the broader organization.