Pharmaceutical Representative License
Draft Rules, March 2017

Section 1. Definitions.

Definitions for terms used in these Rules can be found in Section 4-6-310 of the Municipal Code of Chicago. The following terms are further defined for the purposes of these Rules.

"BACP" means the Chicago Department of Business Affairs and Consumer Protection.

"CDPH" means the Chicago Department of Public Health.

"Health care professional" shall mean any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical or biologic products. However, health care professional shall not be interpreted to include health care practitioners who work exclusively with animals.

"Medical Science Liaison" means a person with an advanced science or medical degree who provides technical assistance to healthcare professionals and does not carry out a marketing or sales function. Medical Science Liaisons may also be known by other titles including but not limited to Medical Liaison, Medical Manager, Regional Scientific Manager, Clinical Liaison, and Scientific Affairs Manager.

"Ordinance" means Section 4-6-310 of the Municipal Code of Chicago.

"Pharmaceutical representative" means a person who markets or promotes pharmaceuticals to health care professionals and excludes Medical Science Liaisons.

Section 2. License Required.

Per Section 4-6-310(b) of the Municipal Code of Chicago, a license is required to conduct business as a pharmaceutical representative in the City of Chicago for fifteen or more days per calendar year. A person conducting business as a pharmaceutical representative must show the license or an exact copy thereof when contacting a health care professional in person if the health care professional asks to see it.

As defined in the Code, a "pharmaceutical representative" means a person who markets or promotes pharmaceuticals to health care professionals.

These regulations shall not apply to individuals who provide information about a pharmaceutical product solely for the purpose of clinical trials, investigational drugs, or a Risk Evaluation and Mitigation Strategy pursuant to the Federal Food, Drug and Cosmetic Act.

Section 3. Education Requirements.

In order to satisfy the professional education requirement for an initial pharmaceutical representative license, applicants must complete an online course that will be available at www.cityofchicago.org/health. This course will provide an introduction to the pharmaceutical

representative license, an overview of the Ordinance's ethical standards and disclosure requirements, and other topics appropriate to the license. Proof of completion of the online course must accompany the application for the pharmaceutical representative license.

In order to renew a pharmaceutical representative license, applicants must complete five hours of continuing professional education. By applying for renewal, the applicant is affirming that he has completed five hours of continuing education during the previous year. The continuing education must be provided by an institution approved by CDPH to provide such education. The continuing education coursework must be in one or more of the following subject areas:

1) General medical and pharmaceutical terminology and abbreviations
2) Food and Drug Administration laws and regulations pertaining to drug marketing, labeling, and clinical trials
3) The cost effectiveness of pharmacological treatments
4) Therapeutic drug classes and categories
5) Professional ethics
6) Properties and actions of drugs and drug delivery mechanisms
7) Etiologies, characteristics, and therapeutics of disease states
8) Pharmacology
9) The anatomical and physiological effect of pharmaceuticals
10) The comparative effectiveness of pharmacological treatments
11) How to read and analyze peer-reviewed literature on pharmacological treatments
12) Safe prescribing practices to prevent abuse

CDPH will audit renewal applications to confirm that applicants completed the continuing education requirements. Upon request, applicants must provide information on courses completed, including the title and date of the course(s), number of credit hours completed, name of the education provider(s), and signed certificate(s) of completion. CDPH may confirm this information with the continuing education provider(s). If a licensed pharmaceutical representative's continuing education requirements have not been met and/or were fraudulently affirmed, the pharmaceutical representative in violation may face suspension or revocation of the license, inclusion in a public list of pharmaceutical representatives whose licenses have been revoked, and a fine of no less than $1,000.00 and no more than $3,000.00 per day of violation.

A list of approved course providers will be posted at www.cityofchicago.org/health. Courses offered by an approved provider satisfy the continuing education requirements as long as the course is primarily focused on one of the approved subjects listed in this Section.

Institutions or organizations seeking to provide continuing education courses in the subjects referenced above can find an application for approval by CDPH at www.cityofchicago.org/health. To qualify for approval, a continuing education program shall be an educational program given at a conference, lecture, seminar, course of instruction, workshop, or on the Internet and must be provided by: 1) a nationally or locally accredited program provider; 2) a governmental unit; 3) a health care facility; or 4) an institution of higher learning recognized by an accrediting body approved by the Secretary of the United States Department of Education. A pharmaceutical company that employs or in any way provides compensation to any pharmaceutical representative shall not be an approved education provider. Approved education providers must submit course titles, course descriptions, and course curricula to CDPH through the process indicated at www/cityofchicago.org/health.

It is the responsibility of the continuing education provider to provide participants with a certificate of course completion containing the name and address of the provider; the name and address of the participant; the course name; the number of course hours completed; the date and location of the course; and the signature of the provider. Providers and pharmaceutical representatives must maintain records of this information for at least five years.

Each annual renewal will also require review, through the online application process, of the ethical standards set out in Section 5 of these rules.

Section 4. Disclosure.

Pharmaceutical representatives shall provide the information required by the Ordinance annually upon the end of each license period. Pharmaceutical representatives shall also provide the information upon request by the Commissioner of Public Health. The information shall be compiled and submitted in a format that will be described on the CDPH website at www.cityofchicago.org/health.

The time periods covered in the information shall be as follows:

A) After a pharmaceutical representative receives his initial license, the information will be due in one year and cover the 11-month time period starting from the day of initial licensure and lasting until one month before license expiration.

B) After a pharmaceutical representative receives a license renewal, the information will cover the 12-month time period starting one month before the license renewal and lasting until one month before license expiration.

If the Commissioner of Public Health requests the information at other times, the information will be due within 30 days of the request and shall cover a time period designated by the Commissioner, provided that the time period ends no later than 30 days before the request was made.

Section 5. Ethical Standards.

Licensed pharmaceutical representatives shall adhere to the following ethical standards:

1) A pharmaceutical representative shall not engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact.

2) A pharmaceutical representative shall not use a title or designation that could reasonably lead a licensed health professional, or an employee or representative of a licensed health professional, to believe that the pharmaceutical representative is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or any other similar health occupation, unless the pharmaceutical representative holds an active license to practice that health occupation.

3) A pharmaceutical representative shall not attend patient examinations or have any direct contact with patients without the express, written consent of the patient. The representatives also shall not enter an area meant primarily for healthcare providers and patients, other than a designated waiting area, unless invited in by a healthcare provider working on site.

4) A pharmaceutical representative shall not harass, intimidate, or coerce a licensed health professional, or an employee or representative of a licensed health professional, through any form of communication, including expressing disappointment for the failure to prescribe certain medications.

5) A pharmaceutical representative shall cease making sales calls to a health professional, or an employee or representative of a health professional, if the health professional requests it in writing or verbally to the pharmaceutical representative or the representative's employer.

6) A pharmaceutical representative shall not make any misleading statements to gain access to a healthcare professional.

7) A pharmaceutical representative shall provide healthcare professionals with information that is accurate and compliant with FDA-approved labeling.

8) A pharmaceutical representative shall comply with the standards of ethical and professional conduct established by the Pharmaceutical Research and Manufacturers of America (PhRMA) in its publication entitled "PhRMA Code on Interactions with Healthcare Professionals" as it may be amended or republished from time to time. Where there is a conflict between the PhRMA publication, the Ordinance and/or these Rules, the Ordinance and the Rules shall control.

Section 6. Complaints.

If a health care professional or patient wishes to file a complaint about a pharmaceutical representative for failure to comply with any of the requirements detailed in the Ordinance or these Rules, he may call 311 or submit a complaint through the 311 online complaint system. The complaint shall include the name of the pharmaceutical representative, if known; the pharmaceutical company being represented, if known; the nature of the violation; the date, approximate time, and location of the violation; and any other pertinent information to support the complaint.

The City will review all complaints and, when warranted, investigate them. Pharmaceutical representatives who violate the Ordinance or these Rules are subject to suspension or revocation of the license and/or a fine of no less than $1,000 and no more than $3,000 per day of violation.