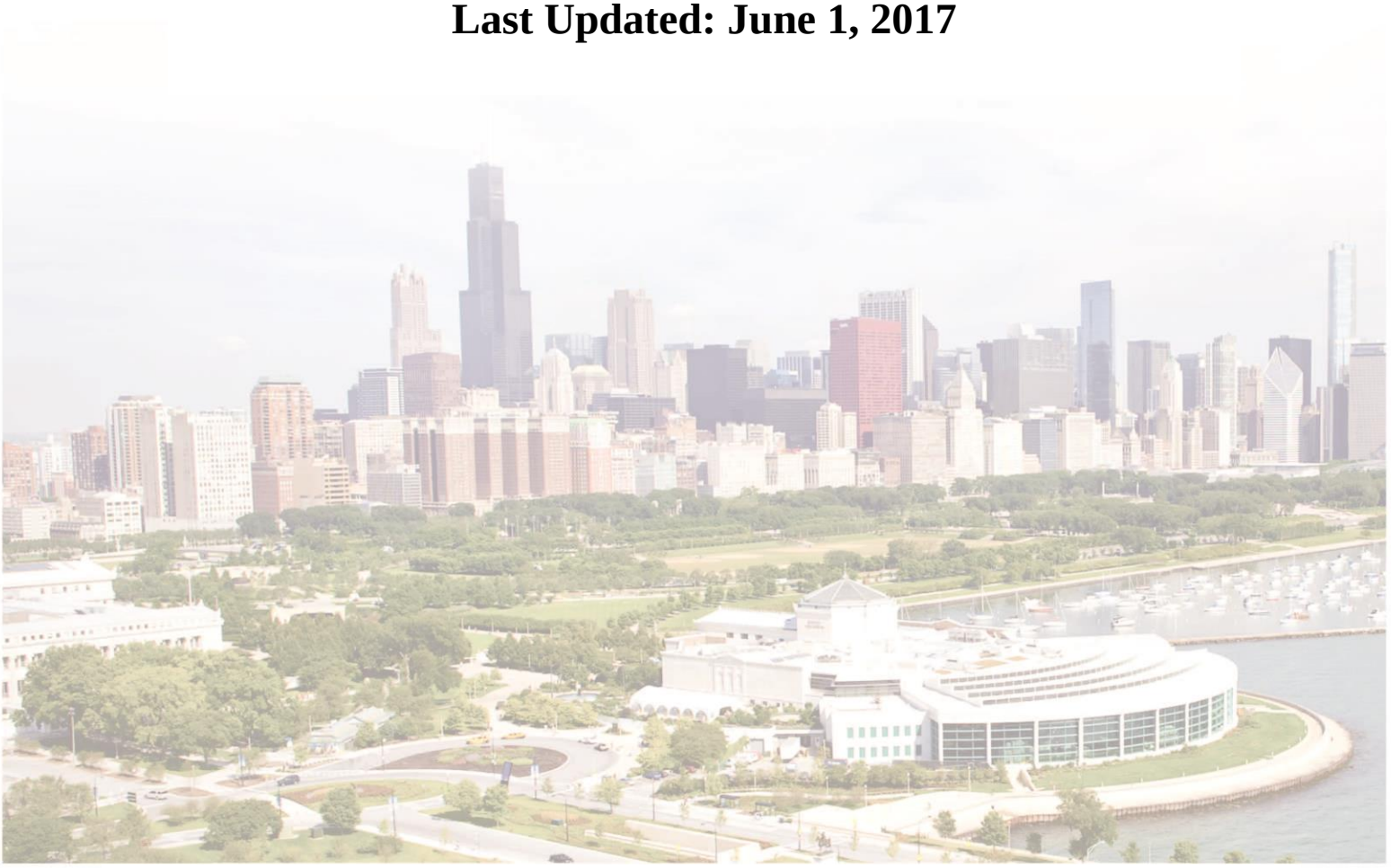
CITY OF CHICAGO

RULES

Pharmaceutical Representative License

Last Updated: June 1, 2017



Mayor Rahm Emanuel – BACP Commissioner Samantha Fields and CDPH Commissioner Julie Morita, M.D.

BY THE AUTHORITY VESTED IN THE COMMISSIONER OF THE DEPARTMENT OF PUBLIC HEALTH AND THE COMMISSIONER OF BUSINESS AFFAIRS AND CONSUMER PROTECTION, PURSUANT TO SECTION 4-6-310 OF THE MUNICIPAL CODE OF CHICAGO, THE FOLLOWING RULES REGARDING PHARMACEUTICAL REPRESENTATIVE LICENSING ARE ADOPTED HEREIN.

By Order of the Commissioners:

Signed: _____ Date: June 1, 2017
JULIE MORITA, M.D.
Commissioner, CDPH

Signed: _____ Date: June 1, 2017
SAMANTHA FIELDS
Commissioner, BACP

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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.

"CDPH" means the Chicago Department of Public Health.

"Health care professional" means 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 a doctoral degree in science or medicine who engages in non-promotional scientific exchange with health care professionals and does not market, sell, or promote pharmaceuticals to health care professionals. 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.

"Wholesale Distributor" means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution.

"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, Wholesale Distributors, and pharmaceutical representative managers or supervisors who do not interact directly with health care professionals while in the City of Chicago.

Section 2. License Required.

A pharmaceutical representative who does business with health care professionals while both are within the City must acquire a license from the Department of Business Affairs and Consumer Protection prior to doing business in the City on fifteen or more days in a calendar year.

A pharmaceutical representative must show his license or an exact copy thereof when a health care professional asks to see it. An exact copy may include a legible reproduction, such as a photocopy or an image saved on an electronic device.

These rules 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 as part of the

licensing process. 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 comparative 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 a selection of 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 apply to be an authorized professional education provider at www.cityofchicago.org/health. To qualify for approval, an authorized professional education provider shall be: 1) a nationally or locally accredited program provider; 2) a governmental unit; 3) a health care facility; 4) an institution of higher learning recognized by an accrediting body approved by the Secretary of the United States Department of Education; or 5) an association of at least three pharmaceutical companies (which shall not be subsidiaries or affiliations of the same company or parent company). A pharmaceutical company that employs or in any way provides compensation to any pharmaceutical representative shall not be an approved professional education provider. However, a pharmaceutical company or other institution, including an association of pharmaceutical companies, may sponsor one or more continuing education courses presented by authorized professional education providers. CDPH reserves the right to reject an application if it determines that the applicant has a conflict of interest, lacks sufficient expertise, or is otherwise unfit to provide quality education. Approved professional education providers must submit course titles, course descriptions, and course curricula to CDPH through the process indicated at www.cityofchicago.org/health.

CDPH may review any professional education provider's course materials to ensure they are accurate in content and germane to the one of the twelve subject areas listed above. CDPH may also rescind a professional education provider's authorization to provide continuing education courses if CDPH determines that the provider's classes fail to provide accurate, sufficient, or germane information, or fail to show good faith with meeting the educational goals of the Ordinance.

It is the responsibility of the professional 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.

After a pharmaceutical representative receives his initial license or becomes eligible for licensure, whichever comes first, he shall provide the information required by the Ordinance upon request by the Commissioner of Public Health. The pharmaceutical representative shall compile and submit the information to CDPH in a format that will be described on the CDPH website (www.cityofchicago.org/health). Only pharmaceutical representatives who market or promote pharmaceuticals, pharmacologic classes, or categories of pharmaceuticals listed at CDPH's website will be obliged to disclose the information required by the Ordinance. As the list may change, a

pharmaceutical representative is responsible for disclosing the information related to the marketing or promotion of the items listed during the month of his license application or renewal for the following year. Only information on activities that take place while both the pharmaceutical representative and the health care professional are in the City must be disclosed.

When the Commissioner of Public Health requests the information, the information will be due within 30 days of the request and shall cover a time period designated by the Commissioner of Public Health, provided that the time period covers no more than one year and ends no later than 30 days before the request was made and does not cover business that the pharmaceutical representative conducted prior to the day of initial licensure or eligibility.

The disclosure obligations shall not apply to activities that take place at large conferences, symposia, conventions, or like gatherings that are expected to be attended by a regional, national, or international audience and where representatives from at least three pharmaceutical companies (which shall not be subsidiaries or affiliations of the same company or parent company) are marketing or promoting products. This exemption shall not apply to activities that take place concurrently with such an event but that are not officially part of the event.

If a pharmaceutical representative claims that any information disclosed is a trade secret, the claim must be accompanied by a description of how the information is proprietary, privileged, or confidential and how disclosure to others beyond the City would inflict substantial competitive harm.

Section 5. Ethical Standards.

Licensed pharmaceutical representatives shall adhere to the following ethical standards:

1) A pharmaceutical representative shall not engage in any illegal, fraudulent, or other deceptive 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 health care professional, or an employee or representative of a health care 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 without the express, written consent of the patient. The representatives also shall not enter an area meant primarily for health care providers and patients, other than a designated waiting area, unless invited in by a health care provider working on site.

4) A pharmaceutical representative shall comply with the applicable policies and procedures of the health care facilities and health care professionals' offices he visits.

5) A pharmaceutical representative shall not harass, intimidate, or coerce a health care professional, or an employee or representative of a health care professional, through any form of communication.

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

7) A pharmaceutical representative shall not make any misleading statements to gain access to a health care professional.

8) A pharmaceutical representative shall provide health care professionals with information that is truthful, accurate, and non-misleading, consistent with Food and Drug Administration laws and regulations.

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 provide pharmaceutical representatives an opportunity to respond to complaints and share relevant information.

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.