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Proposed Rules Pose Challenges For Pharma Reps In Chicago

Law360, New York (March 27, 2017, 3:21 PM EDT) --
On Friday, March 17, 2017, the city of Chicago commissioner of public health published proposed rules to implement the city's highly publicized pharmaceutical representative licensing ordinance enacted in November 2016. The rules specify reporting and record-keeping obligations, explain professional education requirements, articulate minimum ethical standards, and establish monetary and other penalties for violations of the ordinance, the rules and the incorporated ethical standards. The public comment period for the proposed rules runs through Sunday, April 2, 2017. The ordinance and finalized rules take effect on July 1, 2017.


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Pharmaceutical companies and their representatives must prepare to navigate these new regulations in order to market or promote their products to Chicago health care providers. This article explains Chicago's proposed Rules in the context of the ordinance, while analyzing what these changes will mean for pharmaceutical companies and their representatives.

Broad Application to the Entire Pharmaceutical Industry

The rules implement changes to the Chicago Municipal Code enacted by ordinance in November 2016 (the ordinance). Chicago Mayor Rahm Emanuel stated that the purpose of the ordinance was to address Chicago's recent surge in opioid abuse, but the ordinance and proposed rules broadly apply to all pharmaceutical representatives without regard to the specific types of pharmaceuticals they market. Neither the ordinance nor the rules even mention opioid prescription drugs, much less tailor their restrictions to specifically address their misuse and abuse.

Annual License

The ordinance requires any pharmaceutical representative who conducts business within the city of Chicago for 15 or more days per calendar year to obtain a license. A "pharmaceutical representative" is "a person who markets or promotes pharmaceuticals to health care professionals." To obtain a license, the representative must submit an application to the commissioner of business affairs and consumer protection. Any changes to the information submitted in the license application must be

reported in writing within four days of the change. The rules will require a pharmaceutical representative to carry the license or a copy of the license when calling on a health care professional. The license fee will be $750 per year. This fee, in part, prompted a group of pharmaceutical companies and organizations to submit a letter objecting to the city's ordinance.

According to these groups, "The proposed licensure 'fee' would … negatively impact the biopharmaceutical companies that invest billions of dollars to discover medical breakthroughs … [and] make Chicago a less attractive location for medical educational symposia and conferences as biopharmaceutical representatives would likely need to be licensed to participate." As the letter implied, the licensing requirements could be read to apply to any pharmaceutical representative who attends conferences or training within the city, as those activities arguably would constitute "conduct[ing] business."

Exclusion of Medical Science Liaisons and Others

The ordinance and the rules exclude from the licensing requirements any person who "conducts business" as a pharmaceutical representative in the city of Chicago "for fewer than 15 days per calendar year." Neither the ordinance nor the rules define what it means to "conduct business," but at a minimum this would include any time an employee sends "market[ing] or promot[ing] pharmaceuticals to health care professionals." As noted above, attending a conference or training could theoretically count toward a representative's 15 days of "conducting business" in the city.

Also excluded under the rules are medical science liaisons, as defined by rule to include "a person with an advanced science or medical degree who provides technical assistance to health care professionals and does not carry out a marketing or sales function." Similarly, the rules exclude any person who provides pharmaceutical product information "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."

Finally, a person who markets or promotes pharmaceuticals exclusively to veterinarians is not obligated to obtain a pharmaceutical representative license, even if that person is marketing opioids for animals.

Online Course

The ordinance requires all pharmaceutical representatives to complete a professional education course prior to applying for a license. This preapplication course will be available online on the Chicago Department of Public Health (CDPH) website. The 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."

The rules are silent as to how long the preapplication course will take and the format in which it will be presented. An initial license application will require proof that the applicant completed the online course.

Continuing Education Requirements

A pharmaceutical representative must affirm "that he has completed five hours of continuing education during the previous year" by applying for license renewal.

The CDPH will need to approve any institution that provides continuing education, and a list of approved providers will be posted on the CDPH website. While the rules are somewhat unclear, they contemplate approval of only four categories of providers: "(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." The rules will prohibit any "pharmaceutical company that employs or in any way provides compensation to any pharmaceutical representative" from becoming an approved education provider.

The rules enumerate 12 broad subject areas that the continuing education coursework will address (e.g., "professional ethics" and "pharmacology"). The rules offer flexibility in terms of the format of the course by allowing approval of a program "given at a conference, lecture, seminar, course of instruction, workshop or on the internet." While the ordinance and the rules exclude companies who employ pharmaceutical representatives from "providing" these courses, it is unclear whether pharmaceutical companies may sponsor or otherwise financially support these conferences, lectures, seminars, courses and workshops.

The ordinance requires pharmaceutical representatives "upon request" to provide "proof of completion of the continuing professional education requirements." The rules explain that applicants will be required to provide upon request (1) the "title and date of the course(s)" completed; (2) the "number of credit hours completed"; (3) the "name of the education provider(s)"; and (4) the "signed certificate(s) of completion."

The rules provide severe penalties for failure to complete the continuing education requirements and/or for "fraudulently" affirming such completion. These penalties include: (1) suspension or revocation of the license; (2) "inclusion in a public list of pharmaceutical representatives whose licenses have been revoked"; and/or (3) a fine of $1,000 to $3,000 "per day of violation."

By adding the second penalty, "inclusion in a public list of pharmaceutical representatives whose licenses have been revoked," the commissioner of public health seems intent on publicly "shaming" pharmaceutical representatives simply because their "continuing education requirements have not been met." Nothing in the ordinance reflects the City Council's or the mayor's intent to do so.

Record Keeping and Disclosures

The ordinance enumerates specific information pharmaceutical representatives must provide to the CDPH relating to their interactions with health care professionals in Chicago, while the rules specify the timing of those disclosures. The ordinance requires disclosure of the health care professionals' identities; the number, duration and location of the contacts; the pharmaceuticals promoted; whether any "product samples, materials, or gifts of any value" were provided and their value; and "whether and how the health care professional was compensated" for the contact with the pharmaceutical representative. The rules require annual reporting at the end of each license period and specify the time periods covered by each disclosure. They also require a pharmaceutical representative to provide the information within 30 days of a request by the commissioner of public health, which the commissioner will be able to make at any time.

Compliance with Ethical Standards and the PhRMA Code

The rules list eight mandatory ethical standards, which incorporate by reference the Pharmaceutical Research and Manufacturers of America (PhRMA) Code and include, among others, the ethical

standards itemized in the ordinance. The rules require that a pharmaceutical representative in Chicago "shall":

1. "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. "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. "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 health care providers and patients, other than a designated waiting area, unless invited in by a health care provider working on site."

4. "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. "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. "not make any misleading statements to gain access to a health care professional."

7. "provide health care professionals with information that is accurate and compliant with U.S. Food and Drug Administration-approved labeling."

8. "comply with the standards of ethical and professional conduct established by the Pharmaceutical Research and Manufacturers of America in its publication entitled "PhRMA Code on Interactions with Healthcare Professionals" as it may be amended or republished from time to time."

Importantly, the ordinance and the rules prohibit "deceptive or misleading marketing," but fail to define those terms. In light of the penalties discussed in the next section, Chicago's Department of Administrative Hearings, which will presumably be tasked with determining whether a specific presentation is "misleading," will wield enormous authority over pharmaceutical representatives in Chicago.

Penalties for Violations

Pharmaceutical representatives who violate any provision of the ordinance or rules, including the ethical standards, may be fined $1,000 to $3,000 per day for each offense, and may have their license suspended or revoked. The ordinance prohibits reinstatement of a revoked license "for a period of two years from the date of revocation."

Next Steps

If Chicago's proposed pharmaceutical representative licensing rules go into effect without any significant changes, pharmaceutical companies and representatives should focus on the following:

1. **Obtaining Licenses:** Pharmaceutical representatives who market products in Chicago will need a license to operate within the city beginning on July 1, 2017. Given the prerequisites to obtain this license, pharmaceutical representatives should begin working to obtain licensing as soon as the rules are finalized and published, and as soon as the CPDH makes available its online professional education course.

2. **Monitoring Continued Education Requirements:** Pharmaceutical representatives must remain current in their continuing education requirements. If these requirements are not met, a pharmaceutical representative may be subject to fines, license suspension or revocation, and inclusion on a public list. See Rules at § 3.

3. **Ethical Standards Training:** Pharmaceutical companies should incorporate Chicago's ethical standards into pharmaceutical representative training modules, particularly for representatives who conduct business in Chicago.

4. **Timely and Fulsome Record Keeping:** While certain data must currently be disclosed by law, pharmaceutical companies and representatives should become familiar with the additional timing and content demanded under Chicago's ordinance and rules. See Ordinance at § 4-6-310(g)(1); Rules at § 4. Robust record keeping will be essential.

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