Advisory

APRIL 2017

If you have any questions about this Advisory, please contact:

ALAN G. SCHWARTZ
203.498.4332
aschwartz@wiggin.com

Chicago's Pharmaceutical Representative Licensing Requirements Just around the Corner

Chicago has rolled up the welcome mat for pharmaceutical companies and their field representatives. Come July 1, 2017, the Second City essentially will ban pharmaceutical representatives from marketing or promoting any prescription drug within Chicago's city limits. Passed in November, 2016, Chicago municipal code § 4-6-310 imposes licensing and other requirements on pharmaceutical representatives who wish to call on health care providers in Chicago on 15 or more occasions per year. Chicago substitutes its own judgment for national standards of conduct found in FDA regulations and the industry's self-imposed PhRMA code, and burdens pharmaceutical representatives with onerous, arbitrary, and costly additional requirements. A likely result is that pharmaceutical companies will think twice before sending their representatives to call on Chicago-based health care providers because it may be too expensive and risky to do business in Chicago.

Mayor Emanuel bills this municipal legislation as one of several measures taken by the City to combat Chicago's drug "epidemic." Indeed, according to Mayor Emanuel, "marketing from pharmaceutical drug representatives to medical professionals has played a key role in the overprescribing of opioids, helping to fuel a nationwide epidemic of addiction and overdose." Notwithstanding the Mayor's specific concern with opioids, the licensing requirements apply to the promotion of all prescription drugs, including, for example, statins and birth control pills.

In March of 2017, the Chicago Departments of Public Health, and Business Affairs and Consumer Protection, promulgated Draft Rules implementing Section 4-6-310, with a public comment period ending April 2, 2017. As described below, the Draft Rules require representatives to obtain annual licenses and pay substantial fees, and comply with continuing education, record-keeping and disclosure requirements that exist nowhere else in the country.[1] The violation of any of these requirements results in punishment ranging from license revocation to financial penalties up to $3,000 per day of violation.

Notably, the Chicago Draft Rules vaguely define covered individuals and activities, forcing pharmaceutical companies and their representatives to work in Chicago at their peril. For example, the rules define pharmaceutical representative as a person "who markets or promotes pharmaceuticals to health care professionals." Equally broad, "Health care professional" is defined as "any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical or biologic products." Chicago casts a wide net, ensnaring virtually any pharmaceutical company employee, who markets any prescription drug, to any health care service provider, within the city limits. Under these rules, a company marketing manager who shares a

CONTINUED

Connecticut Appellate Court Upholds the Preclusion of Plaintiff's Nursing Standard of Care Expert

cab from O'Hare International Airport to the Loop with an endocrinologist, and discusses the company's latest diabetes drug while within the city limits, is deemed to have conducted business in Chicago. If that same marketing manager "conduct[s] business" in Chicago on 14 additional occasions, he is in violation of the Chicago rules if he did not previously obtain an annual license and pay a fee of $750. If the discussion took place at O'Hare, outside the city limits, the company marketing manager would be exempt from the license registration requirements.

Regardless of the months of company-sponsored training, testing, and refresher courses that a pharmaceutical representative must take and pass in order to become and remain a representative, the Draft Rules require more and different education. Specifically, each year representatives must take an online course addressing a myriad of topics, including "an overview of the Ordinance's ethical standards and disclosure requirements." To renew a license, a representative must complete five hours of continuing professional education from a provider that the Department of Public Health must approve (pharmaceutical companies cannot be approved providers) in one or more of 12 subject areas mandated by the Department. The annual renewal fee is $750.

The Department of Public Health has broad audit authority. It can audit renewal applications and examine continuing education courses, the credit hours completed, the provider, and certificates of completion. If the continuing education requirements have not been met, the pharmaceutical representative faces suspension or revocation of his license, "public flogging" by being on a public list of pharmaceutical representatives whose licenses have been revoked, and a fine of no less than $1,000 and as high as $3,000 per day of violations.[2]

Each annual renewal requires the pharmaceutical representative to provide a list of all health care professionals that they "contacted" during the prior license period. This list must also disclose (1) the location and duration of the contact, (2) the promoted pharmaceuticals, (3) samples, materials or gifts to the health care professional, and the value of these items, and (4) whether and how the health care provider was compensated in exchange for the contact with the pharmaceutical representative.

Health care professionals and patients can register complaints about a pharmaceutical representative by simply calling 311 or using an on-line complaint system.

Pharmaceutical representatives found to have violated the Draft Rules face severe penalties, including license revocation and fines. Finally, pharmaceutical representatives must adhere to the PhRMA Code on interactions with Health care professionals, and the Chicago Department of Health Ethical Standards. However, in circumstances where the PhRMA Code conflicts with Chicago's requirements, the Chicago requirements control.

As a matter of public policy, singling out the pharmaceutical industry for such harsh treatment is unfair, misguided, and harmful to public health. The Chicago license requirements may increase mayoral approval ratings, but are likely to have no effect on a vexing problem deeply rooted in so many factors.[3] Rather, the Chicago Draft Rules likely will impede the delivery of educational materials regarding new pharmaceuticals to Chicago-based practitioners. Finally, though outside the scope of this article, it is questionable that the Chicago Ordinance and Draft Rules will stand-up to constitutional scrutiny.

[1] Washington D.C.'s Safe Rx Amendment Act of 2008 also requires a license to practice pharmaceutical detailing in the District. The D.C. Act differs from the Chicago code in certain ways: (1) it provides for a two-year license for $150, (2) the continuing education requirement may be satisfied by completing programs given by a pharmaceutical company, and (3) the D.C. Act does not apply to activities taking place at a conference involving health-related issues or a scientific or medical education meeting.

[2] The Draft Rules do not specify whether the $3,000 per day penalty applies to each rule violation.

[3] The District of Columbia's drug overdose death rate in 2008 was 9.4 per 100,000, and in 2010 the rate increased to 13.0 per 100,000. See CDC Prevention Status Report 2013, District of Columbia Prescription Drug Overdose; CDC Morbidity and Mortality Weekly Report, Nov. 4, 2001.