

AMENDMENTS TO BILL NO. 180888

(Matter added by these amendments shown in ***bold***;
Matter deleted by these amendments shown by ~~strike through~~)

Amending Title 6 of The Philadelphia Code, entitled “Health Code,” by adding a new Chapter 6-1200, entitled “Pharmaceutical Sales and Marketing Practices,” to provide for registration of pharmaceutical manufacturer agents and certain other requirements; and to prohibit gifts by pharmaceutical manufacturers and their agents to health care practitioners; all under certain terms and conditions.

WHEREAS, the opioid crisis has reached epidemic proportions in Philadelphia, such that over 1,200 people are believed to have died from drug overdoses in 2017, over 80% of which involve prescription opioid painkillers, heroin, or fentanyl; and where tens of thousands of people are believed to be addicted to opioids; and

WHEREAS, four out of five new heroin users nationally started with prescription opioids; and

WHEREAS, rates of sales of prescription opioids more than doubled between 2001 and 2011 in Philadelphia and currently remain well above the sales levels of 2001; and

WHEREAS, this increase in sales has been driven to a significant extent by aggressive and misleading marketing by pharmaceutical companies and their representatives, who—as stated in detail in the complaint that the City has filed against multiple opioid manufacturers in *City of Philadelphia v. Allergan, et al*--encouraged health care providers to overprescribe these medications; and

WHEREAS, there is significant evidence that in-person sales visits by pharmaceutical representatives, accompanied by gifts such as free meals and office supplies, influence providers’ prescribing behavior; and

WHEREAS, there is evidence that pharmaceutical companies have made misleading claims about medications other than opioids, such as Zyprexa, Effexor and Pamine; and

WHEREAS, prohibiting gifts of any value from pharmaceutical representatives to health care providers will reduce inappropriate influence and restore trust among patients in their providers; and

WHEREAS, collection of pharmaceutical manufacturers’ and their agents’ materials related to pharmaceutical products will allow the Health Department to respond to new products, and provide education and training to providers as needed;

THE COUNCIL OF THE CITY OF PHILADELPHIA HEREBY ORDAINS:

SECTION 1. Title 6 of The Philadelphia Code is hereby amended to read as follows:

TITLE 6. HEALTH CODE

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CHAPTER 6-1200. PHARMACEUTICAL SALES AND MARKETING PRACTICES

§ 6-1201. Definitions.

“Biologic.” A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, immunoglobulin product, or analogous product, as defined by Section 351 of the Public Health Service Act applicable to the prevention, treatment, or cure of a disease or condition of human beings and regulated as a drug under the Federal Food, Drug, and Cosmetic Act.

“Controlled substance.” A drug, substance, or immediate precursor included in Schedules I through V of The Act of April 14, 1972 (P.L. 233, No. 64), known as the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-101 et seq.).

“Gift.” A payment, subscription, advance, forbearance, rendering or deposit of money, services, entertainment, food, drink, travel or lodging, or anything of value given to, or for the benefit of, another individual, unless consideration of equal or greater value is received.

“Health Care Practitioner.” An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.

“Health Care Provider.” An individual, partnership, corporation or other association that operates a health care facility for treatment of patients.

“Opioid.” A prescription drug containing a preparation or derivative of opium; a synthetic narcotic that has opiate-like effects but is not derived from opium; or a group of naturally occurring peptides that bind at or otherwise influence opiate receptors, including opioid agonist.

“Patient.” A natural person receiving health care from a health care practitioner.

“Pharmaceutical Manufacturer.” An entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs or biologics, or is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs or biologics.

“Pharmaceutical Manufacturer Agent.” A person who, while employed by or under contract with a pharmaceutical manufacturer, engages in sales, promotional activities or other marketing of prescription drugs or biologics to any health care practitioner.

“PHLCVB.” The Philadelphia Convention and Visitors Bureau, or any successor organization that serves as the sales and marketing agency for the Pennsylvania Convention Center.

“Prescription Drug.” Any drug, and any biologic, which is required by federal law to be dispensed only pursuant to a prescription from an authorized health care practitioner.

§ 6-1202. *Registration required; fee assessed.*

(1) Every pharmaceutical manufacturer that employs or contracts with a pharmaceutical manufacturer agent to engage in sales, promotional activity or other marketing of prescription drugs directed to health care practitioners in Philadelphia shall:

(a) Require that each such agent register with the Department, providing such information as the Department may require;

(b) Ensure that each such agent is provided with an identification badge, identifying the agent and the pharmaceutical manufacturer by name, and that the agent displays the badge at all times when engaging in the sale, promotion or marketing of prescription drugs in the City.

(2) Every pharmaceutical manufacturer agent, prior to engaging in any sales, promotional activity or other marketing of prescription drugs directed to health care practitioners in Philadelphia shall:

(a) Register with the Department, providing such information as the Department may require;

(b) Display an identification badge, providing the name of the agent and the pharmaceutical manufacturer for whom the agent is performing sales or marketing activity, at all times when engaging in the sale, promotion or marketing of prescription drugs in the City; and

*(c) Provide to the Department, in a manner to be specified by the Department, copies of all written materials describing or concerning such drugs, ~~prior to~~ **within 60 days of first** distributing any such materials to health care practitioners. The Department shall **treat such written materials as confidential and shall** review ~~them~~ **such written materials** only for purposes of determining what further education and*

training may be beneficial to pharmaceutical manufacturer agents or health care practitioners regarding such drugs.

(d) The requirements of this § 6-1202 shall not apply to pharmaceutical manufacturer agents whose activities are conducted exclusively within the location of a health care or life sciences convention organized through PHLCVB.

(3) The Department is authorized to assess a reasonable registration fee, as determined by the Board of Health but not to exceed \$250, payable annually, from each pharmaceutical manufacturing agent it registers, to cover its costs in administering the registry and related provisions of this Chapter.

§ 6-1203. Gifts prohibited.

(1) No pharmaceutical manufacturer shall, directly or indirectly, provide a gift of any value to any health care practitioner who is not a salaried employee of the pharmaceutical manufacturer.

(2) No pharmaceutical manufacturer or pharmaceutical manufacturer's agent shall provide gifts of any kind, including items such as coffee mugs or pens, to any health care practitioner or health care provider, or to the employees or office staff of health care practitioners or health care providers.

(3) No health care practitioner shall solicit or accept gifts of any kind from a pharmaceutical manufacturer or its employees or agents.

(4) The prohibitions of this Section 6-1203 shall not include:

(a) Reasonable compensation and expense reimbursement to a health care practitioner who serves as a speaker or on the faculty at a professional or educational conference or meeting;

(b) Reasonable compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project (as "research" is defined in federal law, 42 CFR 50.603 (Public Health Service Act)); or

*(c) The provision of samples of a prescription drug to a health care practitioner or health care provider for the sole purpose of its distribution to patients without cost. This exemption shall not include the provision of coupons for the purchase of any Controlled substance, **unless it is indicated for the treatment of substance use disorder**, at no cost or reduced cost, to health care practitioners for distribution to patients. Such coupons are prohibited gifts under this § 6-1203.*

(d) Funding for Continuing Medical Education that is consistent with the standards of the Accreditation Council for Continuing Medical Education.

(e) Gifts provided to health care practitioners during a health care or life sciences convention organized through the PHLCVB, while such practitioners and pharmaceutical manufacturer's agents are physically located at the convention.

§ 6-1204. Regulations authorized.

The Board of Health is authorized to promulgate such regulations as the Board deems necessary for the implementation and administration of this Chapter, including the fixing of a reasonable annual registration fee, not to exceed \$250, for the costs of administering § 6-1202 and any related requirements of this Chapter.

§ 6-1205. Enforcement and Penalties.

A violation of this Section shall be punishable by a fine of up to five hundred dollars (\$500). Each day a violation continues shall be a separate offense. For the purpose of enforcing the provisions of this Section, notices of violation shall be issued by authorized Health Department inspectors or any other persons authorized to enforce ordinances. Such notices of violation shall be issued under the procedures set forth in § 1-112, except that the amount required to be remitted in response to a notice of violation shall be two hundred fifty dollars (\$250).

SECTION 2. Effective Date. This Ordinance shall take effect ~~90~~ **180** days after it is signed into law.