

Legislation Details (With Text)

File #:	180888-A	Version:	2	Name:	
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File created:	10/11/2018	In control:		Committee on Public Health and Human Services	
On agenda:		Final action:			
Title:	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.				
Sponsors:	Councilmember Greenlee, Councilmember Bass				
Indexes:	HEALTH CODE, PHARMACEUTICAL SALES AND MARKETING PRACTICES				
Code sections:	Title 6 - HEALTH CODE				
Attachments:	1. Bill No. 180888-A02, As Amended on Floor.pdf				

Date	Ver.	Action By	Action	Result	Tally
2/7/2019	1	CITY COUNCIL			
1/31/2019	1	CITY COUNCIL			
1/31/2019	2	CITY COUNCIL			
1/31/2019	2	CITY COUNCIL			
1/31/2019	1	CITY COUNCIL			
12/6/2018	1	CITY COUNCIL	SUSPEND THE RULES OF THE COUNCIL	Pass	
12/6/2018	1	CITY COUNCIL	ORDERED PLACED ON THIS DAY'S FIRST READING CALENDAR	Pass	14:3
12/6/2018	1	CITY COUNCIL	READ AND ORDERED PLACED ON NEXT WEEK'S SECOND READING CALENDAR		
11/30/2018	0	Committee on Public Health and Human Services	HEARING NOTICES SENT		
11/30/2018	0	Committee on Public Health and Human Services	HEARING HELD		
11/30/2018	0	Committee on Public Health and Human Services	AMENDED		
11/30/2018	1	Committee on Public Health and Human Services	REPORTED FAVORABLY, RULE SUSPENSION REQUESTED		
10/11/2018	0	CITY COUNCIL	Introduced and Referred	Pass	

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

* * *

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, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings, as defined by Section 351 of the Public Health Service Act 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 else 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 physically located and regularly practicing in the City and is authorized to provide healthcare services 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 licensed by a Commonwealth licensing agency or board for treatment of patients in the City.

“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 controlled substances or other psychoactive drugs, or is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of controlled substances or other psychoactive drugs.

“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 controlled substances or other psychoactive drugs 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.

“Psychoactive Drug.” Any drug, and any biologic, in the following therapeutic categories as classified by the United States Pharmacopeial Convention Drug Classification: Antidepressants, Antipsychotics, and Anxiolytics Agents.

§ 6-1202. Registration required; fee assessed.

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

(a) Require that each such agent register with the Department within five days of becoming a pharmaceutical manufacturer agent, 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 controlled substances or other psychoactive drugs in the City.

(2) Every pharmaceutical manufacturer agent, prior to engaging in any sales, promotional activity or other marketing of controlled substances or other psychoactive 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 controlled substances or other psychoactive 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, within 60 days of first distributing any such materials to health care practitioners. The Department shall treat such written materials as confidential proprietary information, consistent with Pennsylvania Act 3 of 2008, and shall review them 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 or during a meeting related to health care or life sciences for which a group of at least ten overnight rooms has been occupied at a single hotel, while such practitioners and pharmaceutical manufacturer's agents are physically located at the convention or related meeting.*

(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 or pharmaceutical manufacturer's agent 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, including conferences or meetings organized or sponsored by the pharmaceutical manufacturer;*

(b) *Reasonable compensation and expense reimbursement for the substantial professional or consulting services of a health care practitioner, such as 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; or during a meeting related to health care or life sciences for which a group of at least ten overnight rooms has been occupied at a single hotel, while such practitioners and pharmaceutical manufacturer's agents are physically located at the convention or related meeting.

§ 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 180 days after it becomes law.