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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 593 Session of 2021

INTRODUCED BY ZABEL, HANBIDGE, GALLOWAY, McNEILL, FREEMAN, T. DAVIS, DeLUCA, FRANKEL, O'MARA, WEBSTER, GUENST, PISCIOTTANO, KINKEAD, SHUSTERMAN, MADDEN, KENYATTA AND HOWARD, FEBRUARY 24, 2021

REFERRED TO COMMITTEE ON HEALTH, FEBRUARY 24, 2021

AN ACT

Providing for Pharmaceutical Manufacturing Prohibited Gifts Act.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Pharmaceutical Manufacturer Prohibited Gifts Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Allowable expenditures." The term includes:

(1) Payment to the sponsor of a significant educational, medical, scientific or policymaking conference or seminar, provided:

(i) the payment is not made directly to a health care professional or pharmacist;

(ii) funding is used solely for bona fide educational purposes, except that the sponsor may, in the sponsor's discretion, apply some or all of the funding to provide meals and other food for all conference participants; and

(iii) all program content is objective, free from industry control and does not promote specific products.

(2) Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific or policymaking conference or seminar, provided:

(i) there is an explicit contract with specific deliverables that are restricted to medical issues, not marketing activities; and

(ii) consistent with Federal law, the content of the presentation, including slides and written materials, is determined by the health care professional.

(3) For a bona fide clinical trial:

(i) gross compensation for the location or locations involved;

(ii) direct salary support per principal investigator and other health care professionals per year; and

(iii) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.

(4) A research project or bona fide marketing research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge and reasonably can be considered to be of significant interest or

value to scientists or health care professionals working in the particular field of inquiry, including:

(i) gross compensation;

(ii) direct salary support per health care professional; and

(iii) expenses paid on behalf of each health care professional.

(5) Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a device if the commitment to provide the expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.

(6) Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.

(7) The payment of the reasonable expenses of an individual related to the interview of the individual by a manufacturer of prescribed products in connection with a bona fide employment opportunity or for health care services on behalf of an employee of the manufacturer.

(8) Sponsorship of an educational program offered by a device manufacturer at a national or regional professional society meeting at which programs accredited by the Accreditation Council for Continuing Medical Education, or a comparable professional accrediting entity, are also offered, provided:

(i) no payment is made directly to a health care professional or pharmacist; and

(ii) the funding is used solely for bona fide educational purposes, except that the manufacturer may provide meals and other food for program participants.

(9) Items with a total combined retail value, in any calendar year, of not more than $50.

(10) Payment to a practitioner for participation in bona fide marketing research conducted by a third party, if the payments are made by the third party and the sponsoring manufacturer is not informed of the identity of the participating practitioner.

(11) Other reasonable fees, payments, subsidies or other economic benefits provided by a manufacturer of prescribed products at fair market value.

"Bona fide clinical trial." An FDA-reviewed clinical trial that constitutes research, as that term is defined in 45 CFR § 46.102 (relating to definitions for purposes of this policy), and reasonably can be considered to be of interest to scientists or health care professionals working in the particular field of inquiry.

"Bona fide marketing research." The collection and analysis of data regarding opinions, needs, awareness, knowledge, views, experiences and behaviors of a population, through the development and administration of surveys, interviews, focus groups, polls, observation or other research methodologies, in which no sales, promotional or marketing efforts are involved and through which there is no attempt to influence a participant's attitudes or behavior.

"Clinical trial." Any study assessing the safety or efficacy

of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed products in comparison with other prescribed products or other therapies.

"Device." As defined in section 201 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.).

"Free clinic." A health care facility operated by a nonprofit private entity that:

(1) in providing health care, does not accept reimbursement from any third-party payor, including reimbursement from any insurance policy, health plan or Federal or State health benefits program that is individually determined;

(2) in providing health care, either:

(i) does not impose charges on patients to whom service is provided; or

(ii) imposes charges on patients according to the patient's ability to pay;

(3) may accept patients' voluntary donations for health care service provision; and

(4) is licensed or certified to provide health care services in accordance with the laws of this Commonwealth.

"Gift." Means:

(1) anything of value provided for free to a health care provider; or

(2) except as provided for allowable expenditures, any payment, food, entertainment, travel, subscription, advance, service or anything else of value provided to a health care provider, unless:

(i) it is an allowable expenditure; or

(ii) the health care provider reimburses the cost at fair market value.

"Health benefit plan administrator." The person or entity who sets formularies on behalf of an employer or health insurer.

"Health care professional." The following:

(1) A person who is authorized by law to prescribe or to recommend prescribed products, who regularly practices in this Commonwealth, and who either is licensed by the Commonwealth to provide or is otherwise lawfully providing health care in this Commonwealth.

(2) A partnership or corporation made up of the persons described in paragraph (1).

(3) An officer, employee, agent or contractor of a person described in paragraph (1) who is acting in the course and scope of employment, of an agency or of a contract related to or supportive of the provision of health care to individuals.

(4) The term shall not include a person described in paragraph (1) who is employed solely by a manufacturer.

"Health care provider." A health care professional, hospital, nursing home, pharmacist, health benefit plan administrator or any other person authorized to dispense or purchase for distribution prescribed products in this Commonwealth. The term does not include a hospital foundation that is organized as a nonprofit entity separate from a hospital.

"Manufacturer." A pharmaceutical, biological product or device manufacturer or any other person who is engaged in the production, preparation, propagation, compounding, processing, marketing, packaging, repacking, distributing or labeling of

prescribed products. The term does not include:

(1) a wholesale distributor of biological products or a retailer or a pharmacist licensed under the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act; or

(2) a manufacturer whose only prescribed products are classified as Class I by the United States Food and Drug Administration, are exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act and are sold over-the-counter without a prescription.

"Marketing." Includes promotion, detailing or any activity that is intended to be used or is used to influence sales or market share or to evaluate the effectiveness of a professional sales force.

"Pharmaceutical manufacturer." Any entity that is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs. The term does not include a wholesale distributor of prescription drugs, a retailer or a pharmacist licensed under the Pharmacy Act.

"Prescribed product." A drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, a compound drug or drugs, a device as defined in this section, a biological product as defined in section 351 of the Public Health Service Act (58 Stat. 682, 42 U.S.C. § 201 et seq.) for human use or a combination product as defined in 21 CFR § 3.2(e) (relating to definitions). The term does not include prescription eyeglasses,

prescription sunglasses or other prescription eyewear.

"Regularly practices." To practice at least periodically under contract with, as an employee of or as the owner of a medical practice, health care facility, nursing home, hospital or university located in this Commonwealth.

"Sample." A unit of a prescription drug, biological product or device that is not intended to be sold and is intended to promote the sale of the drug, product or device. The term includes starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price. The term does not include prescribed products distributed free of charge or at a discounted price under a manufacturer-sponsored or manufacturer-funded patient assistance program.

"Significant educational, scientific or policymaking conference or seminar." An educational, scientific or policymaking conference or seminar that:

(1) is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization or is presented by an approved sponsor of continuing education, provided that the sponsor is not a manufacturer of prescribed products; and

(2) offers continuing education credit, features multiple presenters on scientific research or is authorized by the sponsor to recommend or make policy.

Section 3. Expenditures by manufacturers of prescribed products.

(a) Prohibition.--A manufacturer of a prescribed product or any wholesale distributor of devices, or any agent thereof, may not offer or give any gift to a health care provider.

(b) Exception.--The prohibition under subsection (a) shall not apply to any of the following:

(1) Samples of a prescribed product or reasonable quantities of an over-the-counter drug, a nonprescription device, an item of nonprescription durable medical equipment, an item of medical food as defined in section 360ee(b)(3) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.) or infant formula as defined in section 201(z) of the Federal Food, Drug, and Cosmetic Act, provided to a health care provider for free distribution to patients.

(2) The loan of a device for a short-term trial period, not to exceed 120 days, to permit evaluation of a device by a health care provider or patient.

(3) The provision of reasonable quantities of device demonstration or evaluation units to a health care provider to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future.

(4) The provision, distribution, dissemination or receipt of peer-reviewed academic, scientific or clinical articles or journals and other items that serve a genuine educational function provided to a health care provider for the benefit of patients.

(5) Scholarship or other support for medical students, residents or fellows to attend a significant educational, scientific or policymaking conference or seminar of a national, regional or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(6) Rebates and discounts for prescribed products

provided in the normal course of business.

(7) Labels approved by the Food and Drug Administration for prescribed products.

(8) The provision to a free clinic of financial donations or of free:

(i) prescription drugs;

(ii) over-the-counter drugs;

(iii) devices;

(iv) biological products;

(v) combination products;

(vi) medical food;

(vii) infant formula; or

(viii) medical equipment or supplies.

(9) Prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.

(10) Fellowship salary support provided to fellows through grants from manufacturers of prescribed products, provided:

(i) the grants are applied for by an academic institution or hospital;

(ii) the institution or hospital selects the recipient fellows;

(iii) the manufacturer imposes no further demands or limits on the institution's, hospital's or fellow's use of the funds; and

(iv) fellowships are not named for a manufacturer and no individual recipient's fellowship is attributed to a particular manufacturer of prescribed products.

(11) The provision of coffee or other snacks or

refreshments at a booth at a conference or seminar.

(c) Fee, payment, subsidy or other economic benefit prohibited.--Except for allowable expenditures, no manufacturer or other entity on behalf of a manufacturer shall provide any fee, payment, subsidy or other economic benefit to a health care provider in connection with the provider's participation in research.

(d) Penalties.--The Attorney General or appropriate legal authority may bring legal action for a violation of this act and may impose on a manufacturer that violates the provisions of this act a civil penalty of not more than $10,000 per violation. Each unlawful gift shall constitute a separate violation. In any action brought under this act, the Attorney General or appropriate legal authority shall have the same authority to investigate and to obtain remedies as if the action were brought under the act of December 17, 1968 (P.L.1224, No.387), known as the Unfair Trade Practices and Consumer Protection Law.

Section 4. Effective date.

This act shall take effect in 60 days.