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§5A-3C-13. Advertising costs; reporting of same.

(a) Advertising costs for prescription drugs, based on aggregate national data, must be reported to the state council by all manufacturers and labelers of prescription drugs dispensed in this state that employs, directs or utilizes marketing representatives. The reporting shall assist this state in its role as a purchaser of prescription drugs and an administrator of prescription drug programs, enabling this state to determine the scope of prescription drug advertising costs and their effect on the cost, utilization and delivery of health care services and furthering the role of this state as guardian of the public interest.

(b) The council shall establish, by legislative rule, the reporting requirements of information by labelers and manufacturers which shall include all national aggregate expenses associated with advertising and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this state.

(c) The following shall be exempt from disclosure requirements:

(1) All free samples of prescription drugs intended to be distributed to patients;

(2) All payments of reasonable compensation and reimbursement of expenses in connection with a bona fide clinical trial. As used in this subdivision, "clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies or new ways of using known treatments; or

(3) All scholarship or other support for medical students, residents and fellows to attend significant educational, scientific or policy-making conference of national, regional or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(d) The council is further authorized to establish time lines, the documentation, form and manner of reporting required as the council determines necessary to effectuate the purpose of this article. The council shall report to the joint committee on government and finance, in an aggregate form, the information provided in the required reporting.

(e) Notwithstanding any provision of law to the contrary, information submitted to the council pursuant to this section is confidential and is not a public record and is not available for release pursuant to the West Virginia freedom of information act. Data compiled in aggregate form by the council for the purposes of reporting required by this section is a public record as defined in the West Virginia freedom of information act, as long as it does not reveal trade information that is protected by state or federal law.

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§5A-3C-3. Definitions.

In this article:

(1) "Advertising or marketing" means any manner of communication of information, either directly or indirectly, that is paid for and usually persuasive in nature about products, services or ideas related to pharmaceuticals by identified sponsors through various media, persons or other forms as further defined by legislative rule.

(2) "AWP" or "average wholesale price" means the amount determined from the latest publication of the blue book, a universally subscribed pharmacist reference guide annually published by the Hearst Corporation. "AWP" or "average wholesale price" may also be derived electronically from the drug pricing database synonymous with the latest publication of the blue book and furnished in the national drug data file (NDDF) by first data bank (FDB), a service of the Hearst Corporation.

(3) "Dispensing fee" means the fee charged by a pharmacy to dispense pharmaceuticals.

(4) "Drug manufacturer" or "pharmaceutical manufacturer" means any entity which is engaged in: (A) The production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (B) in the packaging, repackaging, labeling, relabeling or distribution of prescription drug products. "Drug manufacturer" or "pharmaceutical manufacturer" does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law.

(5) "Federal supply schedule" or "FSS" means the price available to all federal agencies for the purchase of pharmaceuticals authorized in the Veterans Health Care Act of 1992, PL 102-585. FSS prices are intended to equal or better the prices manufacturers charge their "most-favored" non-federal customers under comparable terms and conditions.

(6) "Multiple-source drug", "innovator drug" and "noninnovator drug" mean the following:

(A) The term "multiple-source drug" means, for which there are two or more drug products which are: Rated as therapeutically equivalent (under the food and drug administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"), except as provided in paragraph (B) of this subdivision, are pharmaceutically equivalent and bioequivalent, as determined by the food and drug administration, and the term "innovator drug" shall hereinafter be referred to as "brand". The term "innovator drug" means a drug which is produced or distributed under an original new drug application approved by the food

and drug administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application and any multiple-source drug that was originally marketed under an original new drug application approved by the food and drug administration. The term "noninnovator drug" shall hereinafter be referred to as "generic". The term "noninnovator drug" means a multiple-source drug that is not an "innovator drug".

(B) Paragraph (A) of this subdivision shall not apply if the food and drug administration changes by regulation the requirement that, for purposes of the publication described in paragraph (A) of this subdivision, in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent.

(7) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal food and drug administration pursuant to 21 C.F.R. §207.20 (1999).

(8) "Person" means any natural person or persons or any corporation, partnership, company, trust or association of persons.

(9) "Pharmaceutical drug detailing" or "detailing" means the function performed by a sales representative who is employed by a pharmaceutical manufacturer for the purpose of: Promotion of pharmaceutical drugs or related products; education about pharmaceutical drugs or related products; or to provide samples of pharmaceutical drugs, related products or related materials, gifts, food or meals.

(10) "Savings" means the difference between the previous price of a prescription drug including any discounts, rebates or price containments and the current price after the effective date of this article for the public employees insurance agency, children's health insurance program, medicaid and workers' compensation programs or other programs which are payors for prescription drugs.

(11) "Sole source" means a pharmaceutical that provides a unique and powerful advantage available in the market to a broad group of patients established under federal law.

(12) "West Virginia Pharmaceutical Cost Management Council" or "council" means the council created pursuant to section eight of this article.