ENROLLED ORIGINAL

AN ACT

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IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To establish the AccessRx program, to require drug manufacturers and labelers that sell prescription drugs in the District through a publicly funded pharmaceutical assistance program to enter into rebate agreements with the District, to require the Director of the Department of Health to negotiate the amount of the rebate, to provide for reimbursement to participating retail pharmacies for the amount of the discount, to provide for the calculation of the rebate amount and any discrepancies between the Department and the manufacturer or labeler, to publicize the names of manufacturers and labelers who do and do not enter into rebate agreements, to impose prior authorization requirements as permitted by law to encourage participation in AccessRx, to establish the AccessRx Fund as a nonlapsing fund to receive rebate payments from manufacturers and labelers and any appropriations and to reimburse pharmacies for discounts, to provide the method of prescribing or ordering drugs, to establish the basic and supplemental components of AccessRx, to allow the Department of Health to contract with a third party for the administration of AccessRx and to seek any waivers of federal law necessary to implement AccessRx, to require the Department of Health to submit an annual report to the Council on the enrollment and financial status of AccessRx, to permit the District to negotiate and enter into purchasing alliances with other jurisdictions and public and private entities, to require the Department of Health to conduct an AccessRx program for low-income elderly District residents, to establish eligibility for low-income elderly, to establish the amount of payment to be made by low-income elderly for the basic and supplemental components of AccessRx, to require the Department of Health to conduct an AccessRx program for uninsured District residents, to establish eligibility for uninsured District residents, to provide that the Department of Health establish discounted prices for uninsured qualified residents for drugs covered by rebate agreements, to establish transparent business practice requirements for pharmacy benefits managers with regard to conflicts of interest, the dispensation of substitute prescription drugs, and their relationships with a covered entity, to require manufacturers and labelers who dispense drugs in the District to disclose and report all of their marketing costs, with some exceptions, to the Department of Health, to require the Department of Health to provide an annual report to the Council and the Corporation

Counsel on prescription drug marketing expenses, to provide that the information submitted by manufacturers and labelers is confidential, and to provide for civil enforcement for noncompliance by manufacturers and labelers with the marketing expense report requirement.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "AccessRx Act of 2004".

TITLE I. ACCESSRx.

SUBTITLE A. AccessRx - In General.

Sec. 101. Findings and declaration of intent.

The Council finds that:

(1) Affordability is critical in providing access to prescription drugs for District of Columbia residents.

(2) AccessRx enables the District to take steps to make prescription drugs more affordable for qualified District residents, thereby increasing the overall health of District residents, promoting healthy communities, and protecting the public health and welfare.

(3) AccessRx can be integrated with any District-wide program for the uninsured.

(4) The intent of AccessRx is not to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified District residents under AccessRx.

Sec. 102. Definitions.

For the purposes of this act, the term:

(1) "AccessRx" means the District of Columbia AccessRx program established by section 103.

(2) "Average wholesale price" means the wholesale price charged for a specific commodity that is assigned by the drug wholesaler and is listed in a nationally recognized drug pricing registry that is updated daily and charged to the retail pharmacy.

(3) "Basic component of AccessRx" includes the provision of drugs and medications for cardiac conditions and high blood pressure, diabetes, arthritis, anticoagulation, hyperlipidemia, osteoporosis, chronic obstructive pulmonary disease and asthma, incontinence, thyroid diseases, glaucoma, Parkinson's disease, multiple sclerosis, amyotrophic lateral sclerosis, and other conditions approved by the Department. The term "basic component of AccessRx" shall also include the provision of over-the-counter medications that are prescribed by a health care provider and approved as cost-effective by the Department.

(4)(A) "Covered entity" means:

(i) Any hospital or medical service organization, insurer, health coverage plan, or health maintenance organization licensed in the District that contracts with another entity to provide prescription drug benefits for its customers or clients;

(ii) Any health program administered by the Department or the District in its capacity as provider of health coverage; or

(iii) Any employer, labor union, or other group of persons organized in the District that contracts with another entity to provide prescription drug benefits for its employees or members.

(B) The term “covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care, or other limited benefit health insurance policies and contracts.

(5) "Covered individual" means a member, participant, enrollee, contract holder, policy holder, or beneficiary of a covered entity who is provided a prescription drug benefit by the covered entity. The term "covered individual" includes a dependent or other person provided a prescription drug benefit through a policy, contract, or plan for a covered individual.

(6) “Department” means the Department of Health.

(7) “Director” means the Director of the Department of Health.

(8) “District” means the District of Columbia.

(9) "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

(10) “Initial discounted price" for a drug means the price the Department pays D.C. Medicaid participating retail pharmacies for that drug for District of Columbia Medicaid recipients.

(11) "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 under 21 C.F.R.§ 207.20.

(12) "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

(13) "Marketing" means advertising and promotional activities, including, but not limited to, the activities described in section 303.

(14) “National Drug Code registration number” means the number registered for a drug pursuant to the listing system established by the United States Food and Drug Administration under section 510 of the Federal Food, Drug, and Cosmetic Act, approved October 10, 1962 (76 Stat. 794; 21 U.S.C. § 360).

(15) "Participating retail pharmacy" or "retail pharmacy" means a retail pharmacy located in the District, or another business licensed to dispense prescription drugs in the District, that participates in the program.

(16) "Pharmacy benefits management" means a service provided to covered

entities to facilitate the provision of prescription drug benefits to covered individuals, including negotiating pricing and other terms with drug manufacturers and retails pharmacies. "Pharmacy benefits management" may include any or all of the following:

(A) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(B) Clinical formulary development and management services;

(C) Rebate contracting and administration;

(D) Certain patient compliance, therapeutic intervention, and generic substitution programs; and

(E) Disease management programs.

(17) "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. The term "pharmacy benefits manager" includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity.

(18) "Qualified resident" means a resident of the District who is eligible for the AccessRx program pursuant to this title.

(19) "Secondary discounted price" means the initial discounted price minus any further discounts paid for out of the AccessRx Fund.

(20) "Supplemental component of AccessRx" includes all prescription drugs and medications provided under the D.C. Medicaid program excluding those provided pursuant to the basic component of AccessRx.

Sec. 103. Establishment of AccessRx.

(a) AccessRx is hereby established. AccessRx shall be administered by the Department, which shall utilize, among other things, manufacturer rebates, pharmacy discounts, and aggregate purchasing to reduce prescription drug prices. In addition, the Department shall investigate the purchase of prescription drugs from outside of the United States.

(b) The Department shall administer AccessRx and other medical and pharmaceutical assistance programs in a manner that is advantageous to the programs and to the enrollees in those programs. In implementing this title, the Department may coordinate the other programs and AccessRx and may take actions to enhance efficiency, reduce the cost of prescription drugs, and maximize the benefits to the programs and enrollees, including providing the benefits of AccessRx to enrollees in other programs.

Sec. 104. Cost containment and savings with respect to existing publicly funded pharmaceutical programs.

The Department shall make every effort to reduce and contain the cost of prescription drugs purchased for publicly funded pharmaceutical assistance programs, including D.C. Medicaid, the D.C. Health Care Alliance, and the Department of Mental Health. These efforts

shall include manufacturer rebates, pharmacy discounts, and reductions through aggregate purchases, and may include importation of pharmaceuticals from outside of the United States. These savings shall be deposited in the AccessRx Fund established in section 110.

Sec. 105. Rebate agreement.

A drug manufacturer or labeler that sells prescription drugs in the District through any publicly funded pharmaceutical assistance program shall enter into a rebate agreement with the Department under AccessRx. The rebate agreement shall require the manufacturer or labeler to make rebate payments to the District for deposit in the AccessRx Fund each calendar quarter or according to a schedule established by the Department.

Sec. 106. Rebate amount.

(a) The Director of the Department shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this title.

(b) The Director shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to section 1927 of the Social Security Act, approved November 5, 1990 (104 Stat. 1388-143; 42 U.S.C. § 1396r-8)("42 U.S.C. § 1396r-8"), the average wholesale price of prescription drugs, and any other information on prescription drug prices and price discounts.

(c) The Director shall use the Director's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 U.S.C. § 1396r-8.

(d) With respect to the rebate that takes effect on October 1, 2005 pursuant to section 133(d), the Director shall use the Director's best efforts to obtain an amount equal to or greater than the amount of any discount, rebate, or price reduction for prescription drugs provided to the federal government. If the Department is not able to achieve the rebate amount described by this subsection, the Department shall report that fact to the standing committee of the Council having jurisdiction over the Department.

Sec. 107. Operation of program.

(a) Participating retail pharmacies shall submit claims to the Department to verify the amount charged to qualified residents and to receive reimbursement.

(b) The Department shall not impose transaction charges on participating retail pharmacies that submit claims or receive payments under AccessRx.

(c) On a periodic basis, to be established by the Department, the Department shall reimburse a participating retail pharmacy for:

(1) The discounted price provided to uninsured qualified residents pursuant to section 133; and

(2) Prescription drugs dispensed to low-income elderly pursuant to section 123.

(d) The Department shall conduct ongoing quality assurance activities similar to those used in the D.C. Medicaid program.

(e) The Department shall collect utilization data from participating retail pharmacies submitting claims necessary to calculate the amount of the rebate from the manufacturer or labeler. The Department shall protect the confidentiality of all information subject to confidentiality protection under District or federal law, rule or regulation.

Sec. 108. Discrepancies in rebate amounts.

(a) (1) Upon receipt of the data from the Department, the manufacturer or labeler shall calculate the quarterly payment. If a discrepancy is discovered, the Department may, at its expense, hire a mutually agreed-upon independent auditor to verify the manufacturer's calculation. If a discrepancy is still found, the manufacturer or labeler shall justify its calculation or make payments to the Department for any additional amount due. The manufacturer or labeler
may, at its expense, hire a mutually agreed-upon independent auditor to verify the accuracy of the utilization data provided by the Department. If a discrepancy is discovered, the Department shall justify its data or refund any excess payment to the manufacturer or labeler.

(2) If the dispute over the rebate amount is not resolved, a request for a hearing with supporting documentation shall be submitted to the Office of Administrative Hearings. Failure to resolve the dispute may be cause for terminating the drug rebate agreement and denying payment to the manufacturer or labeler for any drugs.

(b) All prescription drugs of a manufacturer or labeler that enters into a rebate agreement that appear on the list of approved drugs shall be immediately available and the cost of the drugs shall be reimbursed, except as provided in this section.

Sec. 109. Action with regard to nonparticipating manufacturers and labelers.

(a) The names of manufacturers and labelers who do and do not enter into rebate agreements pursuant to this title are public information. The Department shall release this information to health care providers and the public on a regular basis. The Department also shall publicize participation by manufacturers and labelers that is of particular benefit to the public.

(b) The Department shall impose prior authorization requirements, as permitted by law, in all publicly funded pharmaceutical assistance programs to the extent the Department determines it is appropriate to do so in order to encourage manufacturer and labeler participation in AccessRx, as long as the additional prior authorization requirements remain consistent with the goals of the D.C. Medicaid program and Title 19 of the Social Security Act, approved July 30, 1965 (79 Stat. 343; 42 U.S.C. § 1396 *et seq.*).

Sec. 110. AccessRx Fund.

(a) The AccessRx Fund is established as a nonlapsing, dedicated fund, into which shall

be deposited revenue from manufacturers and labelers that pay rebates pursuant to this title and any appropriations or allocations designated for the AccessRx Fund, along with accruing interest, to be used for the purposes specified in subsection (b) of this section.

(b) All funds in the AccessRx Fund, including any surplus or interest, shall be used to:

(1) Reimburse retail pharmacies for discounted prices provided to uninsured qualified residents pursuant to 133;

(2) Pay benefits described in section 123; and

(3) Reimburse the Department for contracted services, including pharmacy claims processing fees, administrative and associated computer costs, and other reasonable program costs.

(c) The funds deposited in the AccessRx Fund shall not revert to the General Fund but shall continually be available for the uses designated in subsection (b) of this section, subject to authorization by Congress in an appropriations act.

Sec. 111. Eligibility procedures.

The Department shall:

(1) Establish simplified procedures for determining eligibility and issuing AccessRx enrollment cards to qualified residents;

(2) Undertake outreach efforts to build public awareness of AccessRx and maximize enrollment of qualified residents; and

(3) Adjust the requirements and terms of AccessRx to accommodate any new federally funded prescription drug program.

Sec. 112. Method of prescribing or ordering drugs.

The method of prescribing or ordering drugs may include, but is not limited to, the use of standard or larger prescription refill sizes in order to minimize operational costs and maximize economy. Unless the prescribing physician indicates otherwise, the use of the lowest cost generic or chemically equivalent drugs is required; provided, that these drugs are of the same quality and have the same mode of delivery as is provided to the general public, consistent with good pharmaceutical practice.

Sec. 113. Third-party administration.

The Department may contract with one or more third parties to administer any or all components of AccessRx, including outreach, eligibility, claims, administration, and rebate recovery and redistribution.

Sec. 114. Waivers.

The Department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this act.

Sec. 115. Annual summary report.

The Department shall submit a written report on the enrollment and financial status of AccessRx to the Council by the 2nd week of January each year.

Sec. 116. Agreements with governments of other jurisdictions and other entities.

The District may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions, and with other public and private entities, for the purpose of reducing prescription drug prices for residents of the District.

Sec. 117. Rulemaking.

The Mayor is authorized to issue any rules necessary to implement the provisions of this title.

SUBTITLE B. ACCESSRx FOR THE ELDERLY.

Sec. 121. Establishment of AccessRx for the low-income elderly.

(a) The Department shall conduct a program to provide low-cost prescription and nonprescription drugs, medications, and medical supplies to low-income elderly individuals ("AccessRx for low-income elderly").

(b) The Director shall provide sufficient personnel to ensure efficient administration of the program. The extent and magnitude of the program shall be determined by the Director on the basis of the calculated need of the recipient population and the available funds.

(c) The Department may not spend more on this program than is available through appropriations from the General Fund, dedicated revenue, federal or other grants, and other established and committed funding sources. The Director may accept, for the purpose of carrying out this program:

(1) Federal funds appropriated under any federal law relating to the furnishing of free or low-cost drugs to elderly individuals, and may take such action as is necessary for the purposes of carrying out that federal law; and

(2) Funds that may be available from any other agency of government, individual, group, or corporation.

Sec. 122. Eligibility for low-income elderly.

To be eligible, an individual shall:

(1) Be a resident of the District;

(2) Be at least 62 years of age; and

(3) Have a household income that is not more than 200% of the federal poverty level.

Sec. 123. Payment for drugs by low-income elderly.

(a) The Director shall establish the amount of payment to be made by eligible low-income elderly individuals toward the cost of prescription or nonprescription drugs, medications, and medical supplies furnished under AccessRx for low-income elderly; provided, that:

(1) The total cost paid by the low-income elderly individual for any covered purchase of a prescription or nonprescription drug or medication provided under the basic component of AccessRx does not exceed 20% of the price allowed for that prescription under AccessRx rules, or $2, whichever is greater; and

(2) For the supplemental component of AccessRx, except as otherwise provided in this section, the total cost paid by the low-income elderly individual for any covered purchase of a prescription drug or medication shall not exceed 50% of the price allowed for that prescription under AccessRx.

(b) Prior to January 1, 2006, the Director shall establish annual limits on the costs incurred by eligible household members for prescription or nonprescription drugs or medications covered under AccessRx for low-income elderly. After the annual limits have been established, beginning on January 1, 2007, AccessRx for low-income elderly shall pay 80% of the cost of all prescription or nonprescription drugs or medications covered by the supplemental component of AccessRx. The limits shall be set by the Director by regulation as necessary to operate the program within the AccessRx for low-income elderly budget.

SUBTITLE C. ACCESSRx FOR UNINSURED RESIDENTS OF THE DISTRICT OF COLUMBIA.

Sec. 131. Establishment of AccessRx for uninsured District residents.

The Department shall conduct a program to negotiate low-cost prescription and nonprescription drugs, medications, and medical supplies for uninsured District residents ("AccessRx for uninsured"). The Director shall provide sufficient personnel to ensure efficient administration of the program. The extent and magnitude of the program shall be determined by the Director on the basis of the calculated need of the recipient population and available funds.

Sec. 132. Eligibility of the uninsured.

To be eligible, an individual shall:

(1) Be a resident of the District;

(2) Have a household income that is not more than 350% of the federal poverty level; and

(3) Not be enrolled in any public or private medical insurance program.

Sec. 133. Discounted prices for uninsured qualified residents.

(a) Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to section 105 of this title shall discount the retail price of those drugs sold to uninsured qualified residents.

(b) The Department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead, and incentive payments.

(c) Beginning January 1, 2005, a participating retail pharmacy shall offer the initial discounted price.

(d) Beginning no later than October 1, 2005, a participating retail pharmacy shall offer the secondary discounted price, if available.

TITLE II. TRANSPARENT BUSINESS PRACTICES AMONG PHARMACY BENEFITS MANAGERS.

Sec. 201. Fiduciary duty.

(a) A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with all applicable laws. In performance of that duty, a pharmacy benefits manager shall adhere to the practices set forth in this section.

(b) (1) A pharmacy benefits manager shall:

(A) Perform its duties with care, skill, prudence, and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims;

(B) Discharge its duties with respect to the covered entity for the primary purpose of providing benefits to covered individuals and defraying reasonable expenses incurred; and

(C) Notify the covered entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest with the duties imposed by this title; and

(2) A pharmacy benefits manager that receives from any drug manufacturer or labeler any payment or benefit of any kind in connection with the utilization of prescription drugs by covered individuals, including payments or benefits based on volume of sales or market share, shall pass that payment or benefit on in full to the covered entity. This provision does not prohibit the covered entity from agreeing by contract to compensate the pharmacy benefits manager by returning a portion of the benefit or payment to the pharmacy benefits manager.

(c)(1) Upon request by a covered entity, a pharmacy benefits manager retained by that covered entity shall:

(A) Provide information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs. This information shall include all rebates, discounts, and other similar payments. If requested by the covered entity, the

pharmacy benefits manager shall provide such quantity and net cost information on a drug-by-drug basis by National Drug Code registration number rather than on an aggregated basis; and

(B) Disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-substitution programs, educational support, claims processing, and data sales fees.

(2) A pharmacy benefits manager providing information to a covered entity under this section may designate that information as confidential. Information designated as confidential may not be disclosed by the covered entity to any other person or entity without the consent of the pharmacy benefits manager, unless ordered by a court of the District for good cause shown.

(d) The following provisions apply to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual:

(1) The pharmacy benefits manager may substitute a lower-priced therapeutically equivalent drug for a higher-priced prescribed drug.

(2) If the substitute drug costs more than the prescribed drug, the substitution shall be made for medical reasons that benefit the covered individual. If a substitution is being made under this paragraph, the pharmacy benefits manager shall obtain the approval of the prescribing health professional or that person's authorized representative after disclosing to the covered individual and the covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution.

(3) The pharmacy benefits manager shall transfer in full to the covered entity any benefit or payment received in any form by the pharmacy benefits manager as a result of a prescription drug substitution under paragraphs (1) or (2) of this subsection.

Sec. 202. Compliance.

Compliance with the requirements of this title is required in all contracts between a pharmacy benefits manager and a covered entity executed after the effective date of this act.

Sec. 203. Enforcement.

A violation of this title is a violation of the District of Columbia Consumer Protection Procedures Act, effective July 22, 1976 (D.C. Law 1-76; D.C. Official Code § 28-3901 *et seq*.), for which a fine of not more than $10,000 may be adjudged.

TITLE III. FULL DISCLOSURE OF PRESCRIPTION DRUG MARKETING COSTS.

Sec. 301. Requirement to disclose prescription drug marketing costs.

A manufacturer or labeler of prescription drugs dispensed in the District that employs,

directs, or utilizes marketing representatives in the District shall report marketing costs for prescription drugs in the District. These marketing costs shall be reported to the Department for the purposes of assisting the District in its role as a purchaser of prescription drugs and as an administrator of prescription drug programs, enabling the District to determine the scope of prescription drug marketing costs and their effect on the cost, utilization, and delivery of health care services, and furthering the role of the District as guardian of the public interest.

Sec. 302. Manner of reporting.

By July 1st of each year, a manufacturer or labeler of prescription drugs that directly or indirectly distributes prescription drugs for dispensation to residents of the District shall file a report with the Department in the form and manner provided by the Department. The report shall be accompanied by payment of a fee, as set by the Department in rule, to support the work of the Department under this title.

Sec. 303. Content of annual report by manufacturer or labeler.

(a) Except as provided in subsection (b) of this section, the annual report filed pursuant to section 302 shall include the following information as it pertains to marketing activities conducted within the District in a form that provides the value, nature, purpose, and recipient of the expense:

(1) All expenses associated with advertising, marketing, and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail, and telephone communications as they pertain to District residents;

(2) With regard to all persons and entities licensed to provide health care in the District, including health care professionals and persons employed by them in the District, carriers licensed under Title 31, health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide health care in the District, the following information:

(A) All expenses associated with educational or informational programs, materials, and seminars, and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials;

(B) All expenses associated with food, entertainment, gifts valued at more than $25, and anything provided to a health care professional for less than market value;

(C) All expenses associated with trips and travel; and

(D) All expenses associated with product samples, except for samples that will be distributed free of charge to patients; and

(3) The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs (1) and (2) of this subsection, including all forms of payment to those employees.

The cost reported under this paragraph shall reflect only that portion of payment to employees or contractors that pertains to activities within the District or to recipients of the advertising or promotional activities who are residents of or are employed in the District.

(b) The following marketing expenses are not subject to the requirements of this title:

(1) Expenses of $25 or less;

(2) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, or treatment; and

(3) Scholarships and reimbursement of expenses for attending a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

Sec. 304. Department reports.

By November 30th of each year, the Department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses to the Council and the Corporation Counsel. By January 1, 2005, and every 2 years thereafter, the Department shall provide a report to the Council and the Corporation Counsel, providing information in aggregate form, containing an analysis of the data submitted to the Department, including the scope of prescription drug marketing activities and expenses and their effect on the cost, utilization, and delivery of health care services, and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

Sec. 305. Confidentiality; public information.

Notwithstanding any provision of law to the contrary, information submitted to the Department pursuant to this title is confidential and is not a public record. Data compiled in aggregate form by the Department for the purposes of reporting required by this title is a public record as long as it does not reveal trade information that is protected by District, state, or federal law.

Sec. 306. Penalty.

This title may be enforced in a civil action brought by the Corporation Counsel. A manufacturer or labeler that fails to provide a report as required by this title commits a civil violation for which a fine of $1,000 plus costs and attorney's fees may be adjudged.

Sec. 307. Rulemaking.

The Mayor is authorized to issue any rules necessary to implement the provisions of this title.

Sec. 308. Report.

The Department shall report to the committee of the Council having jurisdiction over health and human services matters on or before January 1, 2005 and on or before July 1, 2005 on the assessment of fees on manufacturers and labelers of prescription drugs.

Sec. 309 Applicability date.

This title shall apply as of July 1, 2004.

TITLE IV. FISCAL IMPACT STATEMENT; EFFECTIVE DATE.

Sec. 401. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)).

Sec. 402. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of Congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.

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Chairman
Council of the District of Columbia

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Mayor
District of Columbia