SUBCHAPTER I. ACCESSRX PROGRAM
PART A. GENERAL

§ 48-831.01. 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.

§ 48-831.02. Definitions.

For the purposes of this chapter, the term:

(1) "AccessRx" means the District of Columbia AccessRx program established by 48-831.03.

(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 48-831.03.

(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 subchapter.

(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.

§ 48-831.03. 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 subchapter, 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.

§ 48-831.04. 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 48-831.10.

§ 48-831.05. 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.

§ 48-831.06. 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 subchapter.

(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), 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 48-831.33(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.

§ 48-831.07. 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 § 48-831.33; and

(2) Prescription drugs dispensed to low-income elderly pursuant to § 48-831.23.

(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.

§ 48-831.08. 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.

§ 48-831.09. 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 subchapter 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.).

§ 48-831.10. 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 subchapter 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 § 48-831.33;

(2) Pay benefits described in § 48-831.23; 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.

§ 48-831.11. 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.

§ 48-831.12. 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.

§ 48-831.13. 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.

§ 48-831.14. Waivers.

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

§ 48-831.15. 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.

§ 48-831.16. 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.

§ 48-831.17. Rulemaking.

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

SUBCHAPTER I. ACCESSRX PROGRAM
PART. B ACCESSRX FOR THE ELDERLY

§ 48-831.21. 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.

§ 48-831.22. 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.

§ 48-831.23. 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.

SUBCHAPTER I. ACCESSRX PROGRAM
PART. C ACCESS FOR UNIINSURED RESIDENTS OF THE DISTRICT OF COLUMBIA

§ 48-831.31. 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.

§ 48-831.32. 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.

§ 48-831.33. Discounted prices for uninsured qualified residents.

(a) Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to § 48-831.05 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.

SUBCHAPTER I. ACCESSRX PROGRAM
PART. D. ACCESSRX PHARMACEUTICAL RESOURCE CENTER

§ 48-831.41. Establishment of AccessRx Pharmaceutical Resource Center.

The Department shall conduct a program to provide life saving prescription and nonprescription medications and medical supplies by enrolling eligible individuals into

pharmaceutical assistance programs. Of the funds appropriated for the Department of Health for fiscal year 2006, the Director shall enter into a contract with the Archdiocesan HealthCare Network, Catholic Charities in the amount of $1.956 million to operate and administer the program and provide sufficient personnel to ensure appropriate oversight of the program.

§ 48-831.42. Eligibility.

(a) To be eligible, an individual shall:

(1) Be a resident of the District;

(2) Have a household income not exceeding 300% of the federal poverty level; and

(3) Lack prescription coverage.

(b) Eligibility shall be determined by the contract organization administering the program.

(c) Eligibility for District Medicaid, DC Healthcare Alliance, and other public programs shall be screened at the time an individual seeks to enroll in the program, and appropriate referrals shall be made to the Income Maintenance Administration in the Department of Human Services.