EPIC Statute and Regulations

Table of Contents

EPIC Statute

New York Elder Law

Article II. Programs for the Elderly

Title 3. Program for the Elderly Pharmaceutical Insurance Coverage

§ 240 Short title

This title shall be known and may be cited as the "program for elderly pharmaceutical insurance coverage".

§ 241 Definitions

For purposes of this title, the terms:

1. [Expires and repealed June 15, 2012, as amended, L 2005, ch 58, § 14 (Part C), L 2005, ch 645, § 3, L 2006, ch 57, § 11 (Part B), L 2008, ch 58, § 29 (Part A)] "Covered drug" shall mean a drug dispensed subject to a legally authorized prescription pursuant to section sixty-eight hundred ten of the education law, and insulin, an insulin syringe, or an insulin needle. Such term shall not include: (a) any drug determined by the commissioner of the federal food and drug administration to be ineffective or unsafe; (b) any drug dispensed in a package, or form of dosage or administration, as to which the commissioner of health finally determines in accordance with the provisions of section two hundred fifty-two of this title that a less expensive package, or form of dosage or administration, is available that is pharmaceutically equivalent and equivalent in its therapeutic effect for the general health characteristics of the eligible program participant population; (c) any device for the aid or correction of vision; (d) any drug, including vitamins, which is generally available without a physician's prescription; and (e) drugs for the treatment of sexual or erectile dysfunction, unless such drugs are used to treat a condition, other than sexual or erectile dysfunction, for which the drugs have been approved by the federal food and drug administration; and (f) a brand name drug for which a multi-source therapeutically and generically equivalent drug, as determined by the federal food and drug administration, is available, unless previously authorized by the elderly pharmaceutical insurance coverage program, provided, however, that the elderly pharmaceutical insurance coverage panel is authorized to exempt, for good

cause shown, any brand name drug from such restriction, and provided further that such restriction shall not apply to any drug that is included on the preferred drug list under section two hundred seventy-two of the public health law or is in the clinical drug review program under section two hundred seventy-four of the public health law to the extent that the preferred drug program and the clinical drug review program are applied to the elderly pharmaceutical insurance coverage program pursuant to section two hundred seventy-five of the public health law, or to any drug covered under a program participant's Medicare part D or other primary insurance plan. Any of the drugs enumerated in the preceding sentence shall be considered a covered drug or a prescription drug for purposes of this article if it is added to the preferred drug list under article two-A of the public health law. For the purpose of this title, except as otherwise provided in this section, a covered drug shall be dispensed in quantities no greater than a thirty day supply or one hundred units, whichever is greater. In the case of a drug dispensed in a form of administration other than a tablet or capsule, the maximum allowed quantity shall be a thirty day supply; the panel is authorized to approve exceptions to these limits for specific products following consideration of recommendations from pharmaceutical or medical experts regarding commonly packaged quantities, unusual forms of administration, length of treatment or cost effectiveness. In the case of a drug prescribed pursuant to section thirty-three hundred thirty-two of the public health law to treat one of the conditions that have been enumerated by the commissioner of health pursuant to regulation as warranting the prescribing of greater than a thirty day supply, such drug shall be dispensed in quantities not to exceed a three month supply.

1. [Eff June 15, 2012, as amended, L 2005, ch 645, § 4, L 2006, ch 57, § 12 (Part B)] "Covered drug" shall mean a drug dispensed subject to a legally authorized prescription pursuant to section sixty-eight hundred ten of the education law, and insulin, an insulin syringe, or an insulin needle. Such term shall not include: (a) any drug determined by the commissioner of the federal food and drug administration to be ineffective or unsafe; (b) any drug dispensed in a package, or form of dosage or administration, as to which the commissioner of health finally determines in accordance with the provisions of section two hundred [fig 1] fifty-two of this title that a less expensive package, or form of dosage or administration, is available that is pharmaceutically equivalent and equivalent in its therapeutic effect for the general health characteristics of the eligible program participant population; (c) any device for the aid or correction of vision, or any drug, including vitamins, which is generally available without a physician's prescription; and (d) drugs for the treatment of [fig 2] sexual or erectile dysfunction, unless such drugs are used to treat a condition, other than sexual or erectile dysfunction, for which the drugs have been approved by the federal food and drug administration. For the purpose of this title, except as otherwise provided in this section, a covered drug shall be dispensed in quantities no greater than a thirty day supply or one hundred units, whichever is greater. In the case of a drug dispensed in a form of administration other than a tablet or capsule, the maximum allowed quantity shall be a thirty day supply; the panel is authorized to approve exceptions to these limits for specific products following consideration of recommendations from pharmaceutical or medical

experts regarding commonly packaged quantities, unusual forms of administration, length of treatment or cost effectiveness. In the case of a drug prescribed pursuant to section thirty-three hundred thirty-two of the public health law to treat one of the conditions that have been enumerated by the commissioner of health pursuant to regulation as warranting the prescribing of greater than a thirty day supply, such drug shall be dispensed in quantities not to exceed a three month supply.

2. "Provider pharmacy" shall mean a pharmacy registered in the state of New York pursuant to section sixty-eight hundred eight of the education law, a non-resident establishment registered pursuant to section sixty-eight hundred eight-b of the education law, or a pharmacy registered in a state bordering the state of New York when certified as necessary by the executive director pursuant to section two hundred fifty-three of this title, for which an agreement to provide pharmacy services for purposes of this program pursuant to section two hundred forty-nine of this title is in effect.

3. "Income" shall mean "household gross income" as defined in the real property tax circuit breaker credit program, pursuant to subparagraph (C) of paragraph one of subsection (e) of section six hundred six of the tax law, but only shall include the income of program applicants and spouses and shall exclude the income of other members of the household.

4. "Contractor" shall mean a private not-for-profit or proprietary corporation which has entered into a contractual arrangement with the state to carry out the provisions of section two hundred forty-three of this title.

5. "Resident" shall mean an individual legally domiciled within the state.

6. "Annual coverage period" shall mean the period of twelve consecutive calendar months for which an eligible program participant has met the application fee or deductible requirements, as the case may be, of sections two hundred forty-seven and two hundred forty-eight of this title.

7. "Program year" shall mean a year beginning on October first and ending the following September thirtieth.

§ 242 Program eligibility

1. Persons eligible for comprehensive coverage under section two hundred forty-seven of this title shall include:

   (a) any unmarried resident who is at least sixty-five years of age and whose income for the calendar year immediately preceding the effective date of the annual coverage period beginning on or after January first, two thousand five, is less than or equal to twenty thousand dollars. After the initial determination of eligibility, each eligible individual must be redetermined eligible at least every twenty-four months; and

(b) any married resident who is at least sixty-five years of age and whose income for the calendar year immediately preceding the effective date of the annual coverage period when combined with the income in the same calendar year of such married person's spouse beginning on or after January first, two thousand [fig 1] one, is less than or equal to twenty-six thousand dollars. After the initial determination of eligibility, each eligible individual must be redetermined eligible at least every twenty-four months.

2. Persons eligible for catastrophic coverage under section two hundred forty-eight of this title shall include:

(a) any unmarried resident who is at least sixty-five years of age and whose income for the calendar year immediately preceding the effective date of the annual coverage period beginning on or after January first, two thousand [fig 1] one, is more than twenty thousand and less than or equal to thirty-five thousand dollars. After the initial determination of eligibility, each eligible individual must be redetermined eligible at least every twenty-four months; and

(b) any married resident who is at least sixty-five years of age and whose income for the calendar year immediately preceding the effective date of the annual coverage period when combined with the income in the same calendar year of such married person's spouse beginning on or after January first, two thousand [fig 1] one, is more than twenty-six thousand dollars and less than or equal to fifty thousand dollars. After the initial determination of eligibility, each eligible individual must be redetermined eligible at least every twenty-four months.

3. (a) Eligibility for assistance under this title shall not be granted to any person who at the time an application is made is receiving medical assistance under section three hundred sixty-six of the social services law, or to any person receiving equivalent or better coverage from any other public or private third party payment source or insurance plan than those benefits provided for under this title.

(b) An individual who is determined eligible for assistance under this title whose prescription costs are covered in part by any public or private plan may receive reduced assistance under this title. In such cases, benefits provided through this title shall be considered payments of last resort.

(c) The fact that some of an individual's prescription drug expenses are paid or reimbursable under the provisions of the medicare program shall not disqualify an individual, if he or she is otherwise eligible, from receiving assistance under this title. In such cases, the state shall pay the portion of the cost of those prescriptions for qualified drugs for which no payment or reimbursement is made by the medicare program or any federally funded prescription drug benefit, less the participant's co-payment required on the amount not paid by the medicare program. In addition, the participant registration fee charged to eligible program participants for comprehensive coverage pursuant to section two hundred forty-seven of this title shall be waived for the portion of the

annual coverage period that the participant is also enrolled as a transitional assistance beneficiary in the medicare prescription drug discount card program, authorized pursuant to title XVIII of the federal social security act, provided that: (i) any sponsor of such drug discount card program has signed an agreement to complete coordination of benefit functions with EPIC, and has been endorsed by the EPIC panel; or (ii) any exclusive sponsor of such drug discount card program authorized pursuant to title XVIII of the federal social security act that limits the participants to the medicare prescription drug discount card program sponsored by such exclusive sponsor, shall coordinate benefits available under such discount card program with EPIC. The participant registration fee charged to eligible program participants for comprehensive coverage pursuant to section two hundred forty-seven of this title shall be waived for the portion of the annual coverage period that the participant is also enrolled as a full subsidy individual in a prescription drug or MA-PD plan under Part D of title XVIII of the federal social security act.

(d) The elderly pharmaceutical insurance coverage program is authorized to apply for transitional assistance under the [fig 1] medicare prescription drug discount program with a specific drug discount card under title XVIII of the federal social security act on behalf of applicants and eligible program participants under this [fig 2] title. The elderly pharmaceutical insurance coverage program shall provide applicants and eligible program participants with prior written notice of, and the opportunity to decline, such automatic enrollment.

(e) As a condition of continued eligibility for benefits under this title, if a program participant's income indicates that the participant could be eligible for an income-related subsidy under section 1860D-14 of the federal social security act by either applying for such subsidy or by enrolling in a medicare savings program as a qualified medicare beneficiary (QMB), a specified low-income medicare beneficiary (SLMB), or a qualifying individual (QI), a program participant is required to provide, and to authorize the elderly pharmaceutical insurance coverage program to obtain, any information or documentation required to establish the participant's eligibility for such subsidy, and to authorize the elderly pharmaceutical insurance coverage program to apply on behalf of the participant for the subsidy or the medicare savings program. The elderly pharmaceutical insurance coverage program shall make a reasonable effort to notify the program participant of his or her need to provide any of the above required information. After a reasonable effort has been made to contact the participant, a participant shall be notified in writing that he or she has sixty days to provide such required information. If such information is not provided within the sixty day period, the participant's coverage may be terminated.

(f) As a condition of continued eligibility for benefits under this title, if a program participant is eligible for Medicare part D drug coverage under section 1860D of the federal social security act, the participant is required to enroll in Medicare part D at the first available enrollment period and to maintain such enrollment. This requirement

shall be waived if such enrollment would result in significant additional financial liability by the participant, including, but not limited to, individuals in a Medicare advantage plan whose cost sharing would be increased, or if such enrollment would result in the loss of any health coverage through a union or employer plan for the participant, the participant's spouse or other dependent. The elderly pharmaceutical insurance coverage program shall provide premium assistance for all participants enrolled in Medicare part D as follows:

(i) for participants with comprehensive coverage under section two hundred forty-seven of this title, the elderly pharmaceutical insurance coverage program shall pay for the portion of the part D monthly premium that is the responsibility of the participant. Such payment shall be limited to the low-income benchmark premium amount established by the federal centers for Medicare and Medicaid services and any other amount which such agency establishes under its de minimus premium policy, except that such payments made on behalf of participants enrolled in a Medicare advantage plan may exceed the low-income benchmark premium amount if determined to be cost effective to the program.

(ii) for participants with catastrophic coverage under section two hundred forty-eight of this title, the elderly pharmaceutical insurance coverage program shall credit the participant's annual personal covered drug expenditure amount required under this title by an amount equal to the annual low-income benchmark premium amount established by the centers for Medicare and Medicaid services, prorated for the remaining portion of the participant's elderly pharmaceutical insurance coverage program coverage period. The elderly pharmaceutical insurance coverage program shall, at appropriate times, notify participants with catastrophic coverage under section two hundred forty-seven of this title of their right to coordinate the annual coverage period with that of Medicare part D, along with the possible advantages and disadvantages of doing so.

(g) The elderly pharmaceutical insurance coverage program is authorized and directed to conduct an enrollment program to facilitate, in as prompt and streamlined a fashion as possible, the enrollment into Medicare part D of program participants who are required by the provisions of this section to enroll in part D. Provided, however, that a participant shall not be prevented from receiving his or her drugs immediately at the pharmacy under the elderly pharmaceutical insurance coverage program as a result of such participant's enrollment in Medicare part D.

(h) In order to maximize prescription drug coverage under Medicare part D, the elderly pharmaceutical insurance coverage program is authorized to represent program participants under this title in the pursuit of such coverage. Such representation shall not result in any additional financial liability on behalf of such program participants and shall include, but not be limited to, the following actions:

(i) application for the premium and cost-sharing subsidies on behalf of eligible program participants;

(ii) enrollment in a prescription drug plan or MA-PD plan; the elderly pharmaceutical insurance coverage program shall provide program participants with prior written notice of, and the opportunity to decline such facilitated enrollment subject, however, to the provisions of paragraph (f) of this subdivision;

(iii) pursuit of appeals, grievances, or coverage determinations.

§ 243 Pharmaceutical insurance contract

1. The elderly pharmaceutical insurance coverage panel, established pursuant to section two hundred forty-four of this title shall, subject to the approval of the director of the budget, enter into a contract with one or more contractors to assist in carrying out the provisions of this title. Such contractual arrangements shall be made subject to a competitive process pursuant to the state finance law and shall ensure that state payments for the contractor's necessary and legitimate expenses for the administration of this program are limited to the amount specified in advance, and that such payments shall not exceed the amount appropriated therefor in any fiscal year. The panel shall, at each of its regularly scheduled meetings, review the contract pricing provisions to assure that the level of contract payments are in the best interest of the state, giving consideration to the total level of participant enrollment achieved, the volume of claims processed, and such other factors as may be relevant in order to contain state expenditures. In the event that the panel determines that the contract payment provisions do not protect the interest of the state, the executive director shall initiate contract negotiations for the purpose of modifying contract payments and/or scope requirements.

2. The responsibilities of the contractor or contractors shall include, but need not be limited to:

(a) providing for a method of determining, on an annual basis and upon their application therefor, the eligibility of persons pursuant to section two hundred forty-two of this title within a reasonable period of time, including alternative methods for such determination of eligibility, such as through the mail or home visits, where reasonable and/or necessary, and for notifying applicants of such eligibility determinations;

(b) notifying each eligible program participant in writing upon the commencement of the annual coverage period of such participant's cost-sharing responsibilities pursuant to sections two hundred forty-seven and two hundred forty-eight of this title. The contractor shall also notify each eligible program participant of any adjustment of the co-payment schedule by mail no less than thirty days prior to the effective date of such adjustments and shall inform such eligible program participants of the date such adjustments shall take effect;

(c) issuing an identification card to each program participant who is eligible to purchase prescribed covered drugs for an amount specified pursuant to subdivision three of

section two hundred forty-seven or subdivision three of section two hundred forty-eight of this title. The dates of the annual coverage period shall be imprinted on the card. When an eligible program participant meets the annual limits on point of sale co-payments set forth in subdivision four of section two hundred forty-seven or subdivision four of section two hundred forty-eight of this title, either new identification cards shall be issued to such participant indicating waiver of such co-payment requirements for the remainder of the annual coverage period or the contractor shall develop and implement an alternative method to permit the purchase of covered drugs without a co-payment requirement;

(d) developing and implementing the system for those individuals electing the deductible option to record their personal covered drug expenditures in accordance with subdivision three of section two hundred forty-eight of this title. Such recordkeeping system shall be provided to each such participant at a nominal charge which shall be subject to the approval of the panel. The contractor shall also reimburse participants for personal covered drug expenditures made in excess of their deductible requirements, less the co-payments required by subdivision four of section two hundred forty-eight of this title, made prior to their receipt of an identification card issued in accordance with paragraph (c) of this subdivision;

(e) processing of claims for reimbursement to participating provider pharmacies pursuant to section two hundred fifty of this title;

(f) performing or causing to be performed utilization reviews for such purposes as may be required by the elderly pharmaceutical insurance coverage panel;

(g) conducting audits and surveys of participating provider pharmacies as specified pursuant to the terms and conditions of the contract; and

(h) coordinating coverage with insurance companies and other public and private organizations offering such coverage for those eligible program participants having partial coverage for covered drugs through third-party sources, and providing for recoupment of any duplicate reimbursement paid by the state on behalf of such eligible program participants.

3. The contractor or contractors shall be required to provide such reports as may be deemed necessary by the elderly pharmaceutical insurance coverage panel and shall maintain files in a manner and format approved by the executive director.

4. The contractor or contractors may contract with private not-for-profit or proprietary corporations, or with entities of local government within the state of New York, to perform such obligations of the contractor or contractors as the elderly pharmaceutical insurance coverage panel shall permit.

§ 244 Elderly pharmaceutical insurance coverage panel

1. There is hereby established within the executive department, a panel to be known as the elderly pharmaceutical insurance coverage panel hereinbefore or hereinafter referred to as the panel.

2. The panel shall consist of the commissioners of the departments of education and health, the superintendent of insurance, and the directors of the office for the aging and the division of the budget. Each panel member may designate an officer of his or her respective department, office, or division to represent and exercise all the powers of such panel member as the case may be at all meetings of the panel from which such panel member may be absent.

3. The director and the commissioner of health shall serve as co-chairs of the panel.

4. The panel shall meet at such times as may be requested by the co-chairs, provided that the panel shall meet at least four times a year.

5. The panel shall:

   (a) subject to the approval of the director of the budget, promulgate program regulations pursuant to section two hundred forty-six of this title;

   (b) determine the annual schedule of cost-sharing responsibilities of eligible program participants pursuant to sections two hundred forty-seven and two hundred forty-eight of this title;

   (c) enter into contracts pursuant to section two hundred forty-three of this title;

   (d) recommend and implement alternative program improvements for the efficient and effective operation of the program in accordance with the provisions of this title;

   (e) establish or contract for a therapeutic drug monitoring program. Such program shall monitor therapeutic drug use of eligible program participants in an effort to prevent the incorrect or unnecessary consumption of such therapeutic drugs;

   (f) develop and implement, in cooperation with area offices for the aging, an outreach program to inform the elderly of benefits they may be entitled to pursuant to this title, and to make available information concerning the program for elderly pharmaceutical insurance coverage and benefits to which they may be entitled through a prescription drug coverage program funded by the federal government;

   (g) prepare an annual report and submit such report to the governor and the legislature no later than the first day of January of each year. The panel should include in the report a summary of the administrative cost containment initiatives completed during the year. Such report shall, at a minimum, contain annual statistical information regarding the number of persons enrolled in the program by marital status and income level, the total

and per capita number of prescriptions filled and total state reimbursement and participant co-payment expenditures, by income levels, the total numbers of prescriptions filled with generic drugs, brand name drugs and sole source drugs, the authorization and substitution rate for the total numbers of prescriptions filled with generic, brand name and sole source drugs, the distribution of the top three hundred most commonly used drugs by volume and cost, a distribution of all prescriptions by volume and price, the annual percentage increase in the cost of these drugs, numbers of participating provider pharmacies, recipients and payments by county, the amount of cost recoveries for the period covered in the report, projections of program costs for the following two years, and an evaluation of the performance of the program contractor or contractors and of the cost effectiveness of all outreach efforts;

(h) prepare an evaluation report on the experience of the program for the governor and the legislature no later than November first, [fig 1] nineteen hundred ninety-five. Such report should include the recommendations of the panel concerning the continuation of the program beyond its expiration;

(i) establish policies and procedures to allow individuals who participate in the catastrophic deductible plan on December thirty-first, two thousand [fig 1] to continue to receive benefits under the provisions of section two hundred forty-eight of this title in effect on December thirty-first, two thousand [fig 2] , if and for as long as the enrollee so chooses; and

(j) facilitate implementation of an expanded elderly pharmaceutical insurance coverage program on January first, two thousand [fig 1] one, by commencing no later than October first, two thousand [fig 2] , outreach activities, including but not limited to the dissemination of information to local governments and senior citizen provider advocacy groups regarding such expanded program. The panel shall make applications available for the expanded elderly pharmaceutical insurance coverage program on October first, two thousand [fig 3] .

(k) enter into an agreement with one or more sponsors of a drug discount card program or a prescription drug plan authorized under title XVIII of the federal social security act, to serve as an endorsed EPIC drug discount card program or prescription drug plan for the purposes of effective coordination of benefits.

(l) [Expires and repealed May 15, 2012] implement a preferred drug program and clinical drug review program in accordance with the provisions of article two-A of the public health law, including taking necessary actions consistent with this article to apply prior authorization under article two-A of the public health law to EPIC.

6. The panel members shall receive no compensation for their services as panel members.

7. There shall be an advisory committee to the panel comprised of twelve persons. Four members shall be appointed by the governor, three members shall be appointed by the

temporary president of the senate, one member shall be appointed by the minority leader of the senate, three members shall be appointed by the speaker of the assembly and one member shall be appointed by the minority leader of the assembly. The committee members shall be representatives of consumers, pharmacists, pharmaceutical drug manufacturers and pharmaceutical wholesalers. No less than fifty percent of the committee membership shall represent the consumers. The executive director shall consult the advisory committee and consider its recommendations concerning the implementation of this program and the policies governing the continued operation of this program. Committee members shall receive no compensation for their services but shall be allowed their actual and necessary expenses incurred in the performance of their duties.

§ 245 Executive director

Upon the recommendation of the co-chairs, the governor shall appoint an executive director of the elderly pharmaceutical insurance coverage panel hereinafter referred to as the executive director. The executive director shall receive an annual salary fixed by the governor within the amount available therefor by appropriation and shall be entitled to reimbursement for reasonable expenses incurred in connection with the performance of his or her duties. The executive director shall:

1. Monitor the provision of services pursuant to contractual arrangements entered into pursuant to section two hundred forty-three of this title and examine and review all documents and other information to assure compliance with all provisions of this article whether such documents or other information are under the control of a contractor or a participating provider pharmacy;

2. Appoint staff and request the assistance of any department or other agency of the state in performing such functions as may be necessary to carry out the provisions of this title;

3. Perform such other functions as may be specifically required by this title, as assigned by the panel, or necessary to ensure the efficient operation of the program; and

4. Establish procedures to prorate registration fees for any participant's annual coverage period which began after January first, two thousand [fig 1] and before January first, two thousand [fig 2] one. Such proration shall be calculated on a daily basis and ensure that program participants are afforded an equitable transition from the program established pursuant to this title to the revised program to go into effect on January first, two thousand [fig 3] one.

§ 246 Regulations

Program regulations shall:

1. Provide for a process of determining and redetermining eligibility for participation in this program including provisions for submission of proof of income, age, and residency and

information on existing complete or partial coverage of prescription drug expenses under a third party assistance or insurance plan;

2. Provide for a fair hearing process pursuant to an agreement with the department of health for individuals and participating provider pharmacies to appeal determinations or actions of the contractors;

3. Establish procedures for the state to recover the value of benefits or payments made under this title, if any, that were based on applications or claims submitted in violation of any provision of this title; and

4. Establish procedures to ensure that all information obtained on persons pursuant to paragraph (a) of subdivision two of section two hundred forty-three of this title shall remain confidential and shall not be disclosed to persons or agencies other than those entitled to such information because such disclosure is necessary for the proper administration of the program established pursuant to this title.

§ 247 Cost-sharing responsibilities of eligible program participants for comprehensive coverage

1. Registration fee. Eligible individuals meeting the registration fee requirements of this section may purchase prescribed covered drugs for an amount specified by subdivision three of this section, subject to the limits on point of sale co-payments specified by subdivision four of this section.

2. Registration fee schedule. Eligible individuals electing to meet the requirements of this subdivision shall pay a quarterly registration fee in a manner and form determined by the executive director; at the option of the participant, the registration fee may be paid annually in a lump sum upon the beginning of the annual coverage period. No eligible individual electing to meet the requirements of this subdivision shall have his participation in the program lapse by virtue of non-payment of the applicable registration fee unless the contractor has provided notification of the amount and due date thereof, and more than thirty days have elapsed since the due date of the individual's registration fee. The registration fee to be charged to eligible program participants for comprehensive coverage under this option shall be in accordance with the following schedule:

   (a) Quarterly registration fees for unmarried individual program participants:

   individual income of $ 5,000 or less . . . . . $ 2.00
   individual income of $ 5,001 to $ 6,000 . . . . . $ 2.00
   individual income of $ 6,001 to $ 7,000 . . . . . $ 4.00
   individual income of $ 7,001 to $ 8,000 . . . . . $ 5.50
   individual income of $ 8,001 to $ 9,000 . . . . . $ 7.00
   individual income of $ 9,001 to $ 10,000 . . . . . $ 9.00
   individual income of $ 10,001 to $ 11,000 . . . . . $ 10.00
   individual income of $ 11,001 to $ 12,000 . . . . . $ 11.50

individual income of $ 12,001 to $ 13,000 . . . . . $ 13.50
individual income of $ 13,001 to $ 14,000 . . . . . $ 15.00
individual income of $ 14,001 to $ 15,000 . . . . . $ 20.00
individual income of $ 15,001 to $ 16,000 . . . . . $ 27.50
individual income of $ 16,001 to $ 17,000 . . . . . $ 35.00
individual income of $ 17,001 to $ 18,000 . . . . . $ 42.50
individual income of $ 18,001 to $ 19,000 . . . . . $ 50.00
individual income of $ 19,001 to $ 20,000 . . . . . $ 57.50

(b) Quarterly registration fees for each married individual program participant:

joint income of $ 5,000 or less . . . . . $ 2.00
joint income of $ 5,001 to $ 6,000 . . . . . $ 2.00
joint income of $ 6,001 to $ 7,000 . . . . . $ 3.00
joint income of $ 7,001 to $ 8,000 . . . . . $ 4.00
joint income of $ 8,001 to $ 9,000 . . . . . $ 5.00
joint income of $ 9,001 to $ 10,000 . . . . . $ 6.00
joint income of $ 10,001 to $ 11,000 . . . . . $ 7.00
joint income of $ 11,001 to $ 12,000 . . . . . $ 8.00
joint income of $ 12,001 to $ 13,000 . . . . . $ 9.00
joint income of $ 13,001 to $ 14,000 . . . . . $ 10.00
joint income of $ 14,001 to $ 15,000 . . . . . $ 10.00
joint income of $ 15,001 to $ 16,000 . . . . . $ 21.00
joint income of $ 16,001 to $ 17,000 . . . . . $ 26.50
joint income of $ 17,001 to $ 18,000 . . . . . $ 31.50
joint income of $ 18,001 to $ 19,000 . . . . . $ 37.50
joint income of $ 19,001 to $ 20,000 . . . . . $ 43.00
joint income of $ 20,001 to $ 21,000 . . . . . $ 48.50
joint income of $ 21,001 to $ 22,000 . . . . . $ 54.00
joint income of $ 22,001 to $ 23,000 . . . . . $ 59.50
joint income of $ 23,001 to $ 24,000 . . . . . $ 65.00
joint income of $ 24,001 to $ 25,000 . . . . . $ 68.75
joint income of $ 25,001 to $ 26,000 . . . . . $ 75.00

(c) In the event that the state expenditures per participant meeting the registration fee requirements of this subdivision, exclusive of expenditures for program administration, in the program year commencing October first, [fig 1] nineteen hundred eighty-eight, and in each program year thereafter, exceed such expenditures in the previous program year by a minimum of ten percent, the annual registration fees set forth in this subdivision may, unless otherwise provided by law, be increased, pro-rata, for the subsequent program year, provided that such increase shall not exceed 7.5 percent of the prior year registration fees as may have been adjusted in accordance with this paragraph.

(d) In the event that the state expenditures per such participant, incurred pursuant to this subdivision, exclusive of expenditures for program administration, in the program year commencing October first, [fig 1] nineteen hundred eighty-eight, and in each program year thereafter, are less than such expenditures in the previous program year by a minimum of ten percent, the annual registration fees set forth in this subdivision may, unless otherwise provided by law, be decreased, pro-rata, for the subsequent program year, provided that such decrease shall not exceed 7.5 percent of the prior year registration fees as may have been adjusted in accordance with this paragraph.

(e) The determination to adjust annual registration fees set forth in this subdivision shall follow a review of such factors as the relative financial capacity of the state and such eligible program participants to support such adjustments and changes in the consumer price index. The frequency of such adjustments shall not exceed once in any program year and such adjustments shall not become effective for individual program participants prior to the first day of the next annual coverage period for each participant.

3. Point of sale co-payment.

(a) Upon satisfaction of the registration fee pursuant to this section an eligible program participant must pay a point of sale co-payment as set forth in paragraph (b) of this subdivision at the time of each purchase of a covered drug prescribed for such individual. Such co-payment shall not be waived or reduced in whole or in part, subject to the limits provided by subdivision four of this section.

(b) The point of sale co-payment amounts which are to be charged eligible program participants shall be in accordance with the following schedule:

For each prescription of covered drugs costing $ 15.00 or less . . . . . $ 3.00
For each prescription of covered drugs costing $ 15.01 to $ 35.00 . . . . . $ 7.00
For each prescription of covered drugs costing $ 35.01 to $ 55.00 . . . . . $ 15.00
For each prescription of covered drugs costing $ 55.01 or more . . . . . $ 20.00

(c) For the purposes of the foregoing schedule of point of sale co-payments, "costing" shall mean the amount of reimbursement which shall be paid by the state to a participating provider pharmacy in accordance with section two hundred fifty of this title plus the point of sale co-payment, calculated as of the date of sale.

4. Limits on point of sale co-payments. During each annual coverage period no point of sale co-payment as set forth in subdivision three of this section shall be required to be made for the remainder of such period by any eligible program participant who has already incurred co-payments in excess of the limits set forth in the following schedule:

(a) Limits on co-payments by unmarried individual eligible program participants:

individual income of $ 5,000 or less . . . . . no more than $ 340

individual income of $ 5,001 to $ 6,000 . . . . . no more than $ 408
individual income of $ 6,001 to $ 7,000 . . . . . no more than $ 476
individual income of $ 7,001 to $ 8,000 . . . . . no more than $ 544
individual income of $ 8,001 to $ 9,000 . . . . . no more than $ 612
individual income of $ 9,001 to $ 10,000 . . . . . no more than $ 700
individual income of $ 10,001 to $ 11,000 . . . . . no more than $ 720
individual income of $ 11,001 to $ 12,000 . . . . . no more than $ 827
individual income of $ 12,001 to $ 13,000 . . . . . no more than $ 896
individual income of $ 13,001 to $ 14,000 . . . . . no more than $ 964
individual income of $ 14,001 to $ 15,000 . . . . . no more than $ 1,016
individual income of $ 15,001 to $ 16,000 . . . . . no more than $ 1,034
individual income of $ 16,001 to $ 17,000 . . . . . no more than $ 1,052
individual income of $ 17,001 to $ 18,000 . . . . . no more than $ 1,070
individual income of $ 18,001 to $ 19,000 . . . . . no more than $ 1,088
individual income of $ 19,001 to $ 20,000 . . . . . no more than $ 1,160

(b) Limits on co-payments by each married individual eligible program participant:

joint income of $ 5,000 or less . . . . . no more than $ 291
joint income of $ 5,001 to $ 6,000 . . . . . no more than $ 342
joint income of $ 6,001 to $ 7,000 . . . . . no more than $ 399
joint income of $ 7,001 to $ 8,000 . . . . . no more than $ 456
joint income of $ 8,001 to $ 9,000 . . . . . no more than $ 513
joint income of $ 9,001 to $ 10,000 . . . . . no more than $ 570
joint income of $ 10,001 to $ 11,000 . . . . . no more than $ 622
joint income of $ 11,001 to 12,000 . . . . . no more than $ 641
joint income of $ 12,001 to $ 13,000 . . . . . no more than $ 660
joint income of $ 13,001 to $ 14,000 . . . . . no more than $ 684
joint income of $ 14,001 to $ 15,000 . . . . . no more than $ 710
joint income of $ 15,001 to $ 16,000 . . . . . no more than $ 826
joint income of $ 16,001 to $ 17,000 . . . . . no more than $ 877
joint income of $ 17,001 to $ 18,000 . . . . . no more than $ 928
joint income of $ 18,001 to $ 19,000 . . . . . no more than $ 980
joint income of $ 19,001 to $ 20,000 . . . . . no more than $ 990
joint income of $ 20,001 to $ 21,000 . . . . . no more than $ 1,008
joint income of $ 21,001 to $ 22,000 . . . . . no more than $ 1,026
joint income of $ 22,001 to $ 23,000 . . . . . no more than $ 1,044
joint income of $ 23,001 to $ 24,000 . . . . . no more than $ 1,062
joint income of $ 24,001 to $ 25,000 . . . . . no more than $ 1,080
joint income of $ 25,001 to $ 26,000 . . . . . no more than $ 1,150

(c) Effective October first, [fig 1] nineteen hundred eighty-eight, the limits on point of sale co-payments as set forth in this subdivision may be adjusted by the panel on the anniversary date of each program participant's annual coverage period, and such adjustment shall be in

effect for the duration of that annual coverage period. Any such annual adjustment shall be made using a percentage adjustment factor which shall not exceed one-half of the difference between the year-to-year percentage increase in the consumer price index for all urban consumers, as published by the United States Department of Labor, and, if larger, the year-to-year percentage increase in the aggregate average cost of covered drugs purchased under this title, which year-to-year percentage increase in such cost shall be determined by comparison of such cost in the same month of each of the appropriate successive years; provided, however, that for any such adjustment based wholly on experience in the program year commencing October first, [fig 3] nineteen hundred eighty-seven, the year-to-year percentage increase in such cost shall be determined by comparison of such cost in each of two months no less than five months apart and within such program year, which comparison shall be annualized. Such percentage adjustment factor shall be the same as that used to determine any similar annual adjustment for the same annual coverage periods pursuant to the provisions of subdivision [fig 3] four of section two hundred forty-eight of this title.

(d) Such annual adjustments shall be calculated by multiplying the percentage adjustment factor by (1) ten percent and applying the resulting percentage to the upper income limitation of each income level for unmarried individuals contained in this subdivision, and by (2) seven and one-half percent and applying the resulting percentage to the upper income limitation of each income level for married individuals contained in this subdivision; each result of such calculations, minus any applicable registration fee increases made pursuant to subdivision two of this section and plus the result of applying the percentage adjustment factor to the sum of any such annual adjustments applicable thereto for any prior annual coverage period, shall be the amount by which the limit on co-payments for each such income level may be adjusted, and such amount shall be in addition to any such amount or amounts applicable to prior annual coverage periods.

(e) The determination to adjust the limits on point of sale co-payments set forth in this subdivision shall follow a review of such factors as the relative financial capacity of the state and such eligible program participants to support such adjustments.

§ 248 Cost-sharing responsibilities of eligible program participants for catastrophic coverage

1. Deductible. Eligible individuals meeting the deductible requirements of this section may purchase prescribed covered drugs for an amount specified by subdivision three of this section, subject to the limits on point of sale co-payments specified by subdivision four of this section.

2. Deductible schedule. Eligible individuals electing to meet the requirements of this subdivision shall incur an amount of personal covered drug expenditures during any annual coverage period which are not reimbursed by any other public or private third party payment source or insurance plan, and shall be deemed to have met their deductible requirements for the remainder of such annual coverage period. The amount of personal

covered drug expenditures to be incurred by eligible program participants for catastrophic coverage under this option shall be in accordance with the following schedule:

(a) Annual personal covered drug expenditures for unmarried individual eligible program participants:

individual income of $ 20,001 to $ 21,000 . . . . . $ 530
individual income of $ 21,001 to $ 22,000 . . . . . $ 550
individual income of $ 22,001 to $ 23,000 . . . . . $ 580
individual income of $ 23,001 to $ 24,000 . . . . . $ 720
individual income of $ 24,001 to $ 25,000 . . . . . $ 750
individual income of $ 25,001 to $ 26,000 . . . . . $ 780
individual income of $ 26,001 to $ 27,000 . . . . . $ 810
individual income of $ 27,001 to $ 28,000 . . . . . $ 840
individual income of $ 28,001 to $ 29,000 . . . . . $ 870
individual income of $ 29,001 to $ 30,000 . . . . . $ 900
individual income of $ 30,001 to $ 31,000 . . . . . $ 930
individual income of $ 31,001 to $ 32,000 . . . . . $ 960
individual income of $ 32,001 to $ 33,000 . . . . . $ 1,160
individual income of $ 33,001 to $ 34,000 . . . . . $ 1,190
individual income of $ 34,001 to $ 35,000 . . . . . $ 1,230

(b) Annual personal covered drug expenditures for each married individual eligible program participant:

joint income of $ 26,001 to $ 27,000 . . . . . $ 650
joint income of $ 27,001 to $ 28,000 . . . . . $ 675
joint income of $ 28,001 to $ 29,000 . . . . . $ 700
joint income of $ 29,001 to $ 30,000 . . . . . $ 725
joint income of $ 30,001 to $ 31,000 . . . . . $ 900
joint income of $ 31,001 to $ 32,000 . . . . . $ 930
joint income of $ 32,001 to $ 33,000 . . . . . $ 960
joint income of $ 33,001 to $ 34,000 . . . . . $ 990
joint income of $ 34,001 to $ 35,000 . . . . . $ 1,020
joint income of $ 35,001 to $ 36,000 . . . . . $ 1,050
joint income of $ 36,001 to $ 37,000 . . . . . $ 1,080
joint income of $ 37,001 to $ 38,000 . . . . . $ 1,110
joint income of $ 38,001 to $ 39,000 . . . . . $ 1,140
joint income of $ 39,001 to $ 40,000 . . . . . $ 1,170
joint income of $ 40,001 to $ 41,000 . . . . . $ 1,200
joint income of $ 41,001 to $ 42,000 . . . . . $ 1,230
joint income of $ 42,001 to $ 43,000 . . . . . $ 1,260
joint income of $ 43,001 to $ 44,000 . . . . . $ 1,290
joint income of $ 44,001 to $ 45,000 . . . . . $ 1,320

joint income of $ 45,001 to $ 46,000 . . . . . $ 1,575
joint income of $ 46,001 to $ 47,000 . . . . . $ 1,610
joint income of $ 47,001 to $ 48,000 . . . . . $ 1,645
joint income of $ 48,001 to $ 49,000 . . . . . $ 1,680
joint income of $ 49,001 to $ 50,000 . . . . . $ 1,715

(c) In the event that the state expenditures per participant electing to meet the deductible requirements of this subdivision, exclusive of expenditures for program administration, in the program year commencing October first, [fig 1] nineteen hundred eighty-eight, and in each program year thereafter, exceed such expenditures in the previous program year by a minimum of ten percent, the annual personal covered drug expenditures set forth in this subdivision may, unless otherwise provided by law, be increased, pro-rata, for the subsequent program year, provided that such increase shall not exceed eight percent of the prior year personal covered drug expenditures as may have been adjusted in accordance with this paragraph.

(d) In the event that the state expenditures per such participant, incurred pursuant to this subdivision, exclusive of expenditures for program administration, in the program year commencing October first [fig 1] nineteen hundred eighty-eight, and in each program year thereafter, are less than such expenditures in the previous program year by a minimum of ten percent, the annual personal covered drug expenditures set forth in this subdivision may, unless otherwise provided by law, be decreased, pro-rata, for the subsequent program year, provided that such decrease shall not exceed eight percent of the prior year personal covered drug expenditures as may have been adjusted in accordance with this paragraph.

(e) The determination to adjust annual personal covered drug expenditures set forth in this subdivision, shall follow a review of such factors as the relative financial capacity of the state and such eligible program participants to support such adjustments and changes in the consumer price index. The frequency of such adjustments shall not exceed once in any twelve month period and such adjustments shall not become effective for individual program participants prior to the first day of the next annual coverage period for each participant.

3. Point of sale co-payment.

(a) Upon satisfaction of the deductible requirements pursuant to subdivision two of this section, an eligible program participant shall pay a point of sale co-payment as set forth in paragraph (b) of this subdivision at the time of each purchase of a covered drug prescribed for such individual. Such co-payment shall not be waived or reduced in whole or in part, subject to the limits provided by subdivision four of this section.

(b) The point of sale co-payment amounts which are to be charged eligible program participants shall be in accordance with the following schedule:

For each prescription of covered drugs costing $ 15.00 or less . . . . . $ 3.00
For each prescription of covered drugs costing $ 15.01 to $ 35.00 . . . . . $ 7.00
For each prescription of covered drugs costing $ 35.01 to $ 55.00 . . . . . $ 15.00
For each prescription of covered drugs costing $ 55.01 or more . . . . . $ 20.00

(c) For the purposes of the foregoing schedule of point of sale co-payments, "costing" shall mean the amount of reimbursement which shall be paid by the state to a participating provider pharmacy in accordance with section two hundred fifty of this title plus the point of sale co-payment, calculated as of the date of sale.

4. Annual limits on point of sale co-payments. During each annual coverage period, no point of sale co-payments as set forth in subdivision three of this section shall be required to be made for the remainder of such period by any eligible program participant meeting the personal covered drug expenditure requirements of subdivision two of this section in excess of the limits set forth in the following schedule:

(a) Limits on co-payments by unmarried individual eligible program participants:

individual income of $ 20,001 to $ 21,000 . . . . . no more than $ 1,050
individual income of $ 21,001 to $ 22,000 . . . . . no more than $ 1,100
individual income of $ 22,001 to $ 23,000 . . . . . no more than $ 1,150
individual income of $ 23,001 to $ 24,000 . . . . . no more than $ 1,200
individual income of $ 24,001 to $ 25,000 . . . . . no more than $ 1,250
individual income of $ 25,001 to $ 26,000 . . . . . no more than $ 1,300
individual income of $ 26,001 to $ 27,000 . . . . . no more than $ 1,350
individual income of $ 27,001 to $ 28,000 . . . . . no more than $ 1,400
individual income of $ 28,001 to $ 29,000 . . . . . no more than $ 1,450
individual income of $ 29,001 to $ 30,000 . . . . . no more than $ 1,500
individual income of $ 30,001 to $ 31,000 . . . . . no more than $ 1,550
individual income of $ 31,001 to $ 32,000 . . . . . no more than $ 1,600
individual income of $ 32,001 to $ 33,000 . . . . . no more than $ 1,650
individual income of $ 33,001 to $ 34,000 . . . . . no more than $ 1,700
individual income of $ 34,001 to $ 35,000 . . . . . no more than $ 1,750

(b) Limits on co-payments by each married individual eligible program participant:

joint income of $ 26,001 to $ 27,000 . . . . . no more than $ 1,080
joint income of $ 27,001 to $ 28,000 . . . . . no more than $ 1,120
joint income of $ 28,001 to $ 29,000 . . . . . no more than $ 1,160
joint income of $ 29,001 to $ 30,000 . . . . . no more than $ 1,200
joint income of $ 30,001 to $ 31,000 . . . . . no more than $ 1,240
joint income of $ 31,001 to $ 32,000 . . . . . no more than $ 1,280
joint income of $ 32,001 to $ 33,000 . . . . . no more than $ 1,320
joint income of $ 33,001 to $ 34,000 . . . . . no more than $ 1,360
joint income of $ 34,001 to $ 35,000 . . . . . no more than $ 1,400

joint income of $ 35,001 to $ 36,000 . . . . . no more than $ 1,440
joint income of $ 36,001 to $ 37,000 . . . . . no more than $ 1,480
joint income of $ 37,001 to $ 38,000 . . . . . no more than $ 1,520
joint income of $ 38,001 to $ 39,000 . . . . . no more than $ 1,560
joint income of $ 39,001 to $ 40,000 . . . . . no more than $ 1,600
joint income of $ 40,001 to $ 41,000 . . . . . no more than $ 1,640
joint income of $ 41,001 to $ 42,000 . . . . . no more than $ 1,680
joint income of $ 42,001 to $ 43,000 . . . . . no more than $ 1,720
joint income of $ 43,001 to $ 44,000 . . . . . no more than $ 1,760
joint income of $ 44,001 to $ 45,000 . . . . . no more than $ 1,800
joint income of $ 45,001 to $ 46,000 . . . . . no more than $ 1,840
joint income of $ 46,001 to $ 47,000 . . . . . no more than $ 1,880
joint income of $ 47,001 to $ 48,000 . . . . . no more than $ 1,920
joint income of $ 48,001 to $ 49,000 . . . . . no more than $ 1,960
joint income of $ 49,001 to $ 50,000 . . . . . no more than $ 2,000

(c) Effective October first, [fig 1] nineteen hundred eighty-eight, the limits on point of sale co-payments as set forth in this subdivision may be adjusted by the panel on the anniversary date of each program participant's annual coverage period, and such adjustment shall be in effect for the duration of that annual coverage period. Any such annual adjustment shall be made using a percentage adjustment factor which shall not exceed one-half of the difference between the year-to-year percentage increase in the consumer price index for all urban consumers, as published by the United States Department of Labor, and, if larger, the year-to-year percentage increase in the aggregate average cost of covered drugs purchased under this title, which year-to-year percentage increase in such cost shall be determined by comparison of such cost in the same month of each of the appropriate successive years; provided, however, that for any such adjustment based wholly on experience in the program year commencing October first, [fig 2] nineteen hundred eighty-seven, the year-to-year percentage increase in such cost shall be determined by comparison of such cost in each of two months no less than five months apart and within such program year, which comparison shall be annualized. Such percentage adjustment factor shall be the same as that used to determine any similar annual adjustment for the same annual coverage periods pursuant to the provisions of subdivision four of section two hundred forty-seven of this title. Such annual adjustments shall be calculated by multiplying the percentage adjustment factor by (1) ten percent and applying the resulting percentage to the upper income limitation of each income level for unmarried individuals contained in this subdivision, and by (2) seven and one-half percent and applying the resulting percentage to the upper income limitation of each income level for married individuals contained in this subdivision; each result of such calculations, minus any applicable deductible increases made pursuant to subdivision two of this section and plus the result of applying the percentage adjustment factor to the sum of any such annual adjustments applicable thereto for any prior annual coverage period, shall be the

amount by which the limit on co-payments for each such income level may be adjusted, and such amount shall be in addition to any such amount or amounts applicable to prior annual coverage periods.

(d) The determination to adjust the limits on point of sale co-payments set forth in this subdivision shall follow a review of such factors as the relative financial capacity of the state and such eligible program participant to support such adjustments.

§ 249 Participating provider pharmacies

1. The state shall offer an opportunity to participate in this program to all provider pharmacies as defined in section two hundred forty-one of this title, provided, however, that the participation of pharmacies registered in the state pursuant to section sixty-eight hundred eight-b of the education law shall be limited to state assistance provided under this title for prescription drugs covered by a program participant's medicare or other drug plan.

2. To participate in this program, a pharmacy shall be required to enter into a provider agreement and shall abide by such terms and conditions as shall be prescribed in the agreement, including the release of financial information for the purpose of program audits and surveys.

§ 250 Reimbursement to participating provider pharmacies

1. The amount of reimbursement which shall be paid by the state to a participating provider pharmacy for any covered drug filled or refilled for any eligible program participant shall be equal to the allowed amount defined as follows, minus the point of sale co-payment as required by sections two hundred forty-seven and two hundred forty-eight of this title:

   (a) Multiple source covered drugs. Except for brand name drugs that are required by the prescriber to be dispensed as written, the allowed amount for a multiple source covered drug shall equal the lower of:

      (1) The pharmacy's usual and customary charge to the general public, taking into consideration any quantity and promotional discounts to the general public at the time of purchase, or

      (2) The [fig 1] upper limit, if any, set by the centers for medicare and medicaid services for such multiple source drug, or [fig 2]

      (3) Average wholesale price discounted by twenty-five percent [fig 1] , or

      (4) The maximum allowable cost, if any, established by the commissioner of health pursuant to paragraph (e) of subdivision nine of section three hundred sixty-seven-a of the social services law.

Plus a dispensing fee for drugs reimbursed pursuant to subparagraphs two, three, and four of this paragraph, as defined in paragraph (c) of this subdivision.

(b) Other covered drugs. The allowed amount for brand name drugs required by the prescriber to be dispensed as written and for covered drugs other than multiple source drugs shall be determined by applying the lower of:

(1) Average wholesale price discounted by [fig 1] sixteen and twenty-five one hundredths percent, plus a dispensing fee as defined in paragraph (c) of this subdivision, or

(2) The pharmacy's usual and customary charge to the general public, taking into consideration any quantity and promotional discounts to the general public at the time of purchase.

(c) As required by paragraphs (a) and (b) of this subdivision, a dispensing fee of four dollars fifty cents will apply to generic drugs and a dispensing fee of three dollars fifty cents will apply to brand name drugs.

2. For purposes of determining the amount of reimbursement which shall be paid to a participating provider pharmacy, the panel shall determine or cause to be determined, through a statistically valid survey, the quantities of each covered drug that participating provider pharmacies buy most frequently. Using the result of this survey, the contractor shall update every thirty days the list of average wholesale prices upon which such reimbursement is determined using nationally recognized and most recently revised sources. Such price revisions shall be made available to all participating provider pharmacies. The pharmacist shall be reimbursed based on the price in effect at the time the covered drug is dispensed.

3. (a) Notwithstanding any inconsistent provision of law, the program for elderly pharmaceutical insurance coverage shall reimburse for covered drugs which are dispensed under the program by a provider pharmacy only pursuant to the terms of a rebate agreement between the program and the manufacturer (as defined under section 1927 of the federal social security act) of such covered drugs; provided, however, that:

(1) any agreement between the program and a manufacturer entered into before August first, [fig 1] nineteen hundred ninety-one, shall be deemed to have been entered into on April first, [fig 2] nineteen hundred ninety-one; and provided further, that if a manufacturer has not entered into an agreement with the department before August first, [fig 3] nineteen hundred ninety-one, such agreement shall not be effective until April first, [fig 4] nineteen hundred ninety-two, unless such agreement provides that rebates will be retroactively calculated as if the agreement had been in effect on April first, [fig 5] nineteen hundred ninety-one; and

(2) the program may reimburse for any covered drugs pursuant to subdivisions one and two of this section, for which a rebate agreement does not exist and which are determined by the elderly pharmaceutical insurance coverage panel to be essential to the health of persons participating in the program; and likely to provide effective therapy or diagnosis for a disease not adequately treated or diagnosed by any other covered drug; and which are recommended for reimbursement by the panel and approved by the commissioner of health.

(b) The rebate agreement between such manufacturer and the program for elderly pharmaceutical insurance coverage shall utilize for covered drugs the identical formula used to determine the rebate for federal financial participation for drugs, pursuant to section 1927(c) of the federal social security act, to determine the amount of the rebate pursuant to this subdivision.

(c) The amount of rebate pursuant to paragraph (b) of this subdivision shall be calculated by multiplying the required rebate formulas by the total number of units of each dosage form and strength dispensed. The rebate agreement shall also provide for periodic payment of the rebate, provision of information to the program, audits, verification of data, damages to the program for any delay or non-production of necessary data by the manufacturer and for the confidentiality of information.

(d) The program in providing utilization data to a manufacturer (as provided for under section 1927 (b) of the federal social security act) shall provide such data by zip code, if requested, for the top three hundred most commonly used drugs by volume covered under a rebate agreement.

(e) Any funds collected pursuant to any rebate agreements entered into with a manufacturer pursuant to this subdivision, shall be deposited into the elderly pharmaceutical insurance coverage program premium account.

4. Notwithstanding any other provision of law, entities which offer insurance coverage for provision of and/or reimbursement for pharmaceutical expenses, including but not limited to, entities licensed/certified pursuant to article thirty-two, forty-two, forty-three or forty-four of the insurance law (employees welfare funds) or article forty-four of the public health law, shall participate in a benefit recovery program with the elderly pharmaceutical insurance coverage (EPIC) program which includes, but is not limited to, a semi-annual match of EPIC's file of enrollees against the entity's file of insured to identify individuals enrolled in both plans with claims paid within the twenty-four months preceding the date the entity receives the match request information from EPIC. Such entity shall indicate if pharmaceutical coverage is available from the entity for the insured persons, list the copayment or other payment obligations of the insured persons applicable to the pharmaceutical coverage, and (after receiving necessary claim information from EPIC) list the amounts which the entity would have paid for the pharmaceutical claims for those identified individuals and the entity shall reimburse EPIC for pharmaceutical expenses paid

by EPIC that are covered under the contract between the entity and its insured in only those instances where the entity has not already made payment of the claim. Reimbursement of the net amount payable (after rebates and discounts) that would have been paid under the coverage issued by the entity will be made by the entity to EPIC within sixty days of receipt from EPIC of the standard data in electronic format necessary for the entity to adjudicate the claim and if the standard data is provided to the entity by EPIC in paper format payment by the entity shall be made within one hundred eighty days. After completing at least one match process with EPIC in electronic format, an entity shall be entitled to elect a monthly or bi-monthly match process rather than a semi-annual match process.

5. Notwithstanding any other provision of law, the [fig 1] panel shall maximize the coordination of benefits for persons enrolled under Title XVIII of the federal social security act (medicare) and enrolled under this title in order to facilitate medicare payment of claims. The [fig 2] panel may select an independent contractor, through a request-for-proposal process, to implement a centralized coordination of benefits system under this subdivision for individuals qualified in both the [fig 3] elderly pharmaceutical insurance coverage (EPIC) program and medicare programs who receive [fig 4] medications [fig 5] or other covered products from a pharmacy provider currently enrolled in the [fig 6] elderly pharmaceutical insurance coverage (EPIC) program.

6. (a) The EPIC program shall be the payor of last resort for individuals qualified in both the EPIC program and title XVIII of the federal social security act (Medicare). For such individuals, no reimbursement shall be available under EPIC for covered drug expenses except:

   (i) where a prescription drug plan authorized by Part D of the federal social security act (referred to in this subdivision as a Medicare Part D plan) has approved coverage and EPIC has an obligation under this title to pay a portion of the participant's cost-sharing responsibility under Medicare Part D; or

   (ii) where the provider pharmacy has certified that: (1) a Medicare Part D plan has denied coverage, and (2) either, after consultation with the prescriber, the prescriber has declined to revise the prescription to a drug that would be covered by the Medicare Part D plan, or the provider pharmacy has been unable to contact the prescriber.

   (b) If the provider pharmacy certifies as set forth in subparagraph (ii) of paragraph (a) of this subdivision, the EPIC program shall pay for the drug as the primary payor. If determined by the EPIC program to be practical and cost-effective, the program, or its contractor, shall attempt to obtain Medicare Part D coverage of the drug by initiating a Medicare Part D appeal. If the initial appeal is denied by the Medicare Part D plan, the EPIC program shall pursue additional levels of Medicare Part D appeals when practical and cost-effective.

§ 251 Penalties for fraud and abuse

1. Any person who knowingly makes a false statement or representation, or who by deliberate concealment of any material fact, or by impersonation or other fraudulent device, obtains or attempts to obtain or aids or abets any person to obtain any benefit under this title to which he or she is not entitled, shall be guilty of a class A misdemeanor.

2. Any person who, having made application to receive any benefit under this title for the use and benefit of another and having received it, knowingly and willfully converts such benefit or any part thereof to a use other than for the use and benefit of such other person, shall be guilty of a class A misdemeanor.

3. Any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining greater compensation than that to which he or she is legally entitled for furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining authorization for furnishing services or merchandise under this title, shall be guilty of a class A misdemeanor.

§ 252 Procedures for determinations relating to package, or form of dosage or administration, of certain drugs

1. If the department of health makes an initial determination that a particular package, or form of dosage or administration, of a drug shall be excluded in accordance with the provisions of paragraph (b) of subdivision one of section two hundred forty-one of this title, the executive department shall notify the manufacturer of such drug product that the executive department intends to seek the exclusion of such package, or form of dosage or administration, from the program and shall provide such manufacturer with the reasons therefor together with the facts which the department relies upon to support its initial determination. The manufacturer shall have fifteen days after receiving such exclusion notice to notify the executive department of an intent to appeal the decision. If the manufacturer fails to notify the executive department of an intent to appeal within the time specified in this section, the commissioner of health shall forthwith determine whether the package, or form of dosage or administration, shall be excluded from the program. If the manufacturer notifies the executive department of an intent to appeal, the manufacturer shall submit to the executive department within forty-five days of receiving such exclusion notice, the basis of the manufacturer's appeal. Within fifteen days of receiving such submission from the manufacturer, the executive department shall provide to the manufacturer any additional facts concerning the drug product that the department relies upon to support its initial determination. Within ten days of receiving such facts, the manufacturer may submit additional facts concerning the drug package, or form of dosage or administration. Based on the facts submitted pursuant to this section, the commissioner of health shall make a final determination, in accordance with the standard set forth in paragraph (b) of subdivision one of section two hundred forty-one of this title, as to whether the package, or form of dosage or administration, of the drug product shall constitute a

covered drug for the purposes of this article. A determination to exclude the drug package, or form of dosage or administration, shall be subject to judicial review pursuant to article seventy-eight of the civil practice law and rules.

2. The commissioner of health shall establish by regulation an appropriate process allowing drug packages, or forms of dosage or administration, finally determined under this section not to be covered drugs for the purposes of this title to be dispensed to program participants for whom such drug packages, or forms of dosage or administration, are medically indicated as certified to by a physician treating such participant. Any such drug package, or form of dosage or administration, so certified as medically indicated for a specific participant in accordance with such regulations shall be a covered drug for the purpose of this title.

§ 253 Utilization of out-of-state provider pharmacies; necessity and convenience

1. In counties having a population of seventy-five thousand or less that are in proximity to the state boundary and which are determined by the executive director to be not adequately served by provider pharmacies registered in New York, and in Fishers Island in the town of Southold, Suffolk county, the executive director may approve as provider pharmacies, pharmacies located in New Jersey, Connecticut, Vermont, Pennsylvania or Massachusetts. Such approvals shall be made after (a) consideration of the convenience and necessity of New York residents in the rural areas served by such pharmacies, (b) consideration of the quality of service of such pharmacies and the standing of such pharmacies with the governmental board or agency of the state in which such pharmacy is located, (c) the executive director shall give all licensed pharmacies within the county notice of his or her intention to approve such out-of-state provider pharmacies, and (d) the executive director has held a public hearing at which he or she has determined factually that the licensed pharmacies within such county are not adequately serving as provider pharmacies.

2. The executive director shall investigate and determine whether certification shall be granted within ninety days of the filing of an application for certification by the governing body of any city, town or village, within a county determined by the executive director to be not adequately served by provider pharmacies registered in New York pursuant to subdivision one of this section, claiming to be lacking adequate pharmaceutical service.

3. Every certification granted pursuant to this section shall expire not more than five years after the date of issuance.

§ 254 Cost of living adjustment

1. Within amounts appropriated, the panel shall adjust the program eligibility standards set forth in subdivision two of section two hundred forty-two of this title to account for increases in the cost of living.

2. The panel shall further adjust individual and joint income categories set forth in subdivisions two and four of section two hundred forty-eight of this title to conform to the adjustments made pursuant to subdivision one of this section.

EPIC Regulations

Title 9. Executive Department

Subtitle KK. Program for Elderly Pharmaceutical Insurance Coverage

§ 9600.1 Scope

These regulations govern the application and eligibility determination process under the Program for Elderly Pharmaceutical Insurance Coverage and establish the rights and responsibilities of applicants, participants and the contractor in that process.

§ 9600.2 Definitions

The following definitions shall apply to this Part:

(a) An applicant is a person who has, directly or by a representative, expressed, in writing on the State-approved form a desire to receive coverage or to have his/her eligibility considered.

(b) An application is the process by which a person indicates, in writing on the State-approved form, his/her desire either to receive assistance or to have his/her eligibility considered. Such action shall be considered an application even though the applicant subsequently withdraws the application or proves, upon investigation, to be ineligible. Application may also mean the State-approved form which must be filed to complete the process.

(c) An eligible person is one who has applied for participation in the program using the State-approved form; and who, based upon that form, has been determined to have satisfied the statutory and regulatory requirements for eligibility.

(d) Income means household gross income of the applicant and his/her spouse, pursuant to subdivision 3 of section 547-a of the State Executive Law.

(e) Resident means a person legally domiciled within the State. A person is domiciled within the State if it is his/her permanent home, as contrasted to a temporary home, or summer or winter home. Domicile is evidence by a person's physical presence within the State on a regular and ongoing basis and by its use in official or legal documents.

(f) Authorized representative means any person duly authorized by an applicant or participant to act on his/her be-half, except a provider or physician who does not have a familial relationship to the applicant or participants. Institutions may not act as authorized representatives.

(g) Cost-sharing responsibilities include the required registration fees, premiums and copayment obligations of the participant.

(h) Program means the Program for Elderly Pharmaceutical Insurance Coverage provided for under article 19-K of the Executive Law.

(i) Annual Coverage period means a consecutive 12-month period for which an eligible person has met the required registration fee, premium or deductible requirements.

(j) Fraud shall mean an intentional deception or misrepresentation made with the knowledge that the deception could result in some unauthorized benefit to the person or another person and includes the acts prohibited by section 547-k of the Executive Law.

(k) Abuse shall mean participant practices that are inconsistent with sound consumer practices or that result in un-necessary costs to the program.

(l) The executive director is the person appointed by the Governor to monitor the provision of services under the program and to perform any other functions necessary to the efficient operation of the program, or his/her duly authorized designee.

(m) Contractor means the private not-for-profit or proprietary corporation which has entered into a contract with the pharmaceutical insurance coverage panel to assist in carrying out the provisions of the program.

(n) Panel means the pharmaceutical insurance coverage panel established by the Legislature and consisting of the commissioners of the departments of Education, Health and Social Services, the Superintendent of Insurance and the directors of the State Office for the Aging and the Division of the Budget.

(o) Timely means that the notice is mailed at least 10 days before the date the action is to be effective.

(p) Adequate means that the notice is in writing and contains the details of the reasons for the action, an explanation of the person's right to a reconsideration and the circumstances under which benefits may be continued if a reconsideration is requested.

(q) Mass change in the program means changes initiated by the panel or Legislature which affect all or a significant portion of all participants.

§ 9600.3 Information concerning application/coverage

Any person shall be entitled to receive information concerning:

(a) the eligibility requirements of the program under which he/she is applying;

(b) his/her responsibility for reporting all facts material to a proper determination of eligibility;

(c) the applicant's responsibility for securing, wherever possible, records or documents to support his/her statements concerning eligibility;

(d) the kinds of verification needed;

(e) the fact that an investigation to determine eligibility may be undertaken; and

(f) the cost-sharing responsibilities of the program.

§ 9600.4 Confidentiality

(a) All applicants and participants have the right to confidentiality concerning any information provided to determine their eligibility for coverage and any information discovered in the course of an investigation of eligibility.

(b) Information received by the contractor, his agents, employees or any other person or agency concerning applicants for or participants in the program may be disclosed or used only for purposes directly related to and necessary for the proper administration of the program.

*(c) For the purpose of assisting participants to receive an appropriate amount of federal Food Stamp benefits, the Program for Elderly Pharmaceutical Insurance Coverage (EPIC) shall provide to the Office of Temporary and Disability Assistance (OTDA) information identifying EPIC participants who are also enrolled in the Medicare prescription drug discount card program authorized by Title XVIII of the Social Security Act. Information provided shall be limited to eligibility and enrollment data available to EPIC and sufficient to enable OTDA to identify those participants who are also Food Stamp recipients. OTDA's use of this information shall be limited to the purpose of identifying EPIC partici-pants who are also Food Stamp recipients and are eligible for additional Food Stamp benefits by virtue of their enrollment in the Medicare prescription drug discount card program. * NB Effective until December 6, 2006

§ 9600.5 Statistical reports

(a) The contractor shall maintain a record of every application or request for coverage and the disposition thereof.

(b) Additionally, the contractor shall maintain statistical reports as required by the executive director and provide the executive director with a periodic report of all applications denied, actions affecting coverage and reconsiderations made.

§ 9610.1 Application for coverage

(a) Any person who believes that he/she is eligible for coverage has the right to make application for coverage. The applicant himself/herself or an authorized representative shall have the right to make application on his/her behalf.

(b) Applications may be submitted by mail or by other means authorized by the contractor and approved by the State.

(c) Home visits shall be available where the physical or mental inability of the applicant makes it impracticable for him/her to submit a written application by mail.

(d) Applications and program information may be obtained from the contractor by calling the designated toll-free telephone number, by writing the contractor or contacting a designated outreach agency.

(e) Local in-person assistance shall be available for assisting applicants to apply and to answer questions.

§ 9610.2 Use of the application form

(a) The State-approved form must be completed:

(1) for each applicant upon initial application and recertification;

(2) when there is a change in status affecting eligibility; and

(3) in the event of a reapplication more than 30 days following the end of any eligibility period.

(b) Signatures on State-approved forms are required, as follows:

(1) For married applicants, both the husband and wife shall sign.

(2) Where the case involves a single individual, such individual shall sign.

(3) In any case where the applicant or spouse, whose signature is required, is incapable of signing the application because of physical incapability, mental incompetency or not residing in the household, the application shall be signed on behalf of such person by his authorized representative.

(c) The State-approved form shall contain the following information in addition to any other information which the contractor may require for the proper administration of the program:

(1) full name(s) of the applicant(s);

(2) date(s) of birth of the applicant(s);

(3) income amount and source(s) of the applicant(s);

(4) permanent address of the applicant(s);

(5) marital status of the applicant(s) and spouse's full name;

(6) county of residence of the applicant(s);

(7) other public or private insurance coverage(s), including medical assistance; and

(8) legal status of New York State residency.

§ 9610.3 Eligibility for coverage

(a) Residents of the State who are at least 65 years of age, who have incomes within the limitations prescribed by the statute and who are not in receipt of medical assistance shall be eligible for coverage upon meeting the required registration fee, premium or deductible requirements of the program.

(b) Each applicant and participant shall furnish evidence, and when requested provide verification of, those factors which affect eligibility and the amount of registration fee, premium or deductible, including:

(1) Age. The applicant or participant shall furnish evidence that he/she is at least 65 years of age.

(2) Receiving medical assistance. The applicant or participant shall furnish current and accurate information concerning the availability of his/her receipt of medical assistance.

(3) Residence. Information shall be provided sufficient to establish that the applicant or participant is residing within the State.

(4) Spouse. For each married applicant the following information shall be furnished concerning his/her spouse: full name and date of birth.

(5) (Reserved)

(6) Income. The applicant or participant shall furnish sufficient information in order to permit calculation of his/her income.

(7) Insurance coverage. The applicant or participant shall furnish current and accurate information concerning the availability of coverage of prescription drug expenses under a third-party assistance or insurance plan.

(c) An applicant or participant is not eligible to receive coverage if he/she has equivalent or better coverage from any other public or private third-party payment source or plan or program of insurance.

§ 9610.4 Decision on eligibility

(a) Decision on eligibility is the conclusion or determination reached in the application process. Such decision shall constitute the decision of the contractor. The decision shall be one of the following:

(1) Accepted for coverage. This means that eligibility has been established through review and verification to the satisfaction of the contractor.

(2) Not accepted for coverage. Applications are denied when:

(i) in the course of the application process the information given by the applicant establishes, without the need for further review and verification, that he/she is ineligible;

(ii) ineligibility is determined in the course of or upon completion of a review and verification, or if the applicant refuses to comply with any requirement essential to the determination of eligibility; or

(iii) the application is incomplete.

(3) No decision is required when:

(i) an application is withdrawn by the applicant; or

(ii) the contractor documents that the applicant has died, cannot be located, or has left the State prior to the completion of the review and verification.

(b) The applicant shall be notified in writing of the decision in accordance with these regulations.

§ 9610.5 Responsibility for prompt determination of eligibility

(a) Upon receipt of an application for coverage, the contractor shall conduct an appropriate review and verification and secure, record and evaluate its findings in order to promptly determine eligibility or ineligibility.

(b) The decision to accept or deny the application shall be made as soon as the facts to support it have been established, but not later than 30 days from the date of application, except where the applicant requests additional time or where difficulties in verification lead to unusual delay.

§ 9610.6 Notification

(a) Applicants have the right to adequate notice of their determination of eligibility.

(1) Notification shall be given within three days of the decision to accept or deny an application (except during the 120-day period beginning July 1, 1987, when notification of denial shall be given within 10 days of a decision to deny.)

(2) Notification of denial shall clearly set forth the decision of the contractor and the specific reason why the application was denied. Notification of acceptance shall clearly set forth the decision and the cost-sharing responsibilities of the applicant.

(b) Participants are entitled to timely and adequate notice of any change affecting their coverage, except for mass changes.

(c) Participants are entitled to adequate notice of any adjustment to the copayment schedule 30 days prior to the effective date of the change.

(d) Participants also have the right to adequate notice 30 days prior to the due date of any quarterly or annual registration fee or premium. The notice shall state the amount due, the date on which payment is to be received and that his/her coverage shall expire 30 days after the due date if payment is not received.

§ 9610.7 Issuance of identification cards

(a) The contractor shall issue an identification card to each person determined eligible for benefits within three days of the applicant's meeting his/her registration fee or premium or deductible requirements.

(b) The card shall include on its face the following information:

(1) participant's full name;

(2) participant's identification number;

(3) participant's annual coverage period; and

(4) any restriction on use.

(c) Upon a participant's meeting the annual limits on point-of-sale copayments, a new card shall be issued or an adjustment made to the eligibility file to reflect the waiver of the copayment requirement.

(d) Upon receipt of notification from a participant that his/her card has been lost or stolen, the contractor shall take necessary action to invalidate the original card and issue a replacement within three working days.

§ 9620.1 Investigation

(a) The contractor is responsible for reviewing all aspects of eligibility and obtaining verification of information received. Appropriate inquiry shall be made of the applicant and secondary sources of information as the efficient administration of the program may require taking into account the administrative costs of full review and verification of each application and the need to maintain the fiscal integrity of the program. In this respect the contractor may defer full re-view and verification or fully review and verify only a statistically valid random sample of the applications filed with the approval of the executive director.

(b) Any review and verification of eligibility shall be conducted in a manner that will not result in practices that violate an applicant's or participant's constitutional rights. An applicant or participant shall be permitted to appear with an attorney or other representative at any interview, conference or redetermination with a representative of the contractor, whenever such interview, conference or redetermination relates the questions of eligibility for assistance, or the amount of the registration fee, premium or deductible which the person interviewed is or was required to pay.

§ 9620.2 Aspects of investigation of eligibility

(a) Documents, personal observation, personal and collateral interviews and contacts, reports, correspondence and conferences are means of verification of information supplied.

(b) When information is sought from collateral sources other than public records because the applicant or participant cannot provide verification, there shall be a clear interpretation to the applicant, participant or his/her representative of what information is desired, why it is needed and how it will be used.

§ 9630.1 Required procedures for reconsiderations

(a) The contractor shall use reconsiderations to explain actions taken or to be taken and to settle disputes with applicants and participants.

(b) When an applicant or participant makes any oral or written request of a contractor's employee which indicates a desire to have any action of the contractor reviewed, and the matter cannot be resolved by that employee, the applicant or participant shall be informed of the right to reconsideration by the contractor.

(c) If the applicant or participant indicates that he/she wants a reconsideration one shall be arranged.

(d) An employee of the contractor, who has authority to reverse the action, or failure to act, and who did not participate in the determination to take the action complained of, shall conduct the reconsideration. The reconsideration shall be made at such a time and in a manner as to afford a meaningful opportunity to resolve the dispute. Provisions shall be made for reconsiderations by mail, telephone and in person.

(e) A determination on the reconsideration shall be made within 30 days of the request and a notice of determination after reconsideration shall be mailed to the applicant or participant at his/her designated address. Where a reconsideration is favorable to the applicant, this determination notice will include a statement that the applicants will be reimbursed for program-eligible costs incurred from the date on which the annual coverage period would have commenced if the application was approved initially.

§ 9640.1 Personal expenditures reporting system

The contractor shall establish the system whereby each participant in the catastrophic coverage portion of the program who elects the deductible option shall have his/her personal covered drug expenditures recorded upon payment of a nominal charge.

§ 9650.1 Responsibility for repayment of overpayments

Participants are responsible for repaying the value of any benefits or payments made under the program that were based on applications or claims submitted in violation of the eligibility requirements of the program.

§ 9650.2 Recovery of overpayments

(a) The contractor shall establish a procedure to ensure that the value of any benefits received by any person in violation of the eligibility requirements of article 19-K of the Executive Law and these regulations is recovered from the person prior to his/her recertification for entitlement to benefits for any period beyond the initial annual eligibility period.

(b) Where after authorization of benefits to an applicant it is discovered that the applicant was not entitled to benefits or that a participant has received benefits in excess of those to which he/she was entitled, the contractor shall promptly notify the applicant or participant of the overpayment and request that the value thereof be refunded.

(c) Where repayment is not forthcoming from the applicant or participant, the contractor shall attempt collection in a manner consistent with the State debt collection procedures law. Where the contractor is unsuccessful in its collection efforts, the matter shall be referred to the executive director for collection proceedings consistent with the economies of effective administration.

(d) Notwithstanding any provision in this section to the contrary, no person shall be deemed eligible to receive benefits under the program until he/she has repaid the full value of any benefits previously furnished to or on behalf of that person in violation of article 19-K of the Executive Law and these regulations, or has entered into a plan for repayment and remains current with such plan.

§ 9650.3 Right to reimbursement of covered drug expenses

Participants have the right to be reimbursed for excess copayments and for personal covered drug expenses, less required copayments, made in excess of their required deductible payments, made prior to receipt of their new identification card or appropriate adjustment to the eligibility file.

§ 9660.1 Referral of suspected fraud and abuse

Whenever, in the conduct of a review and verification into the eligibility of an applicant or the recertification of a participant, the evaluation of utilization review reports or participant profiles, there is evidence of program fraud or abuse by an applicant or participant, the contractor shall promptly refer the matter to the executive director for review.

§ 9660.2 Fraud and abuse

(a) The executive director shall maintain a statewide program for investigation and referral for prosecution of violations of State laws pertaining to fraud or abuse in the program.

(b) Where initial review of a contractor referral indicates substantial potential for criminal prosecution, the executive director shall refer the matter to the Attorney General or local prosecutive authority. Where initial review does not indicate substantial potential for criminal prosecution, the executive director shall conduct further review to determine

whether or not a participant's participation in the program should be restricted or terminated.

(c) Where review indicates substantial evidence of abusive practices, the participant may be removed from the program or restricted to a single provider.

§ 9700.1 General

(a) These regulations govern the fair hearing process for applicants for coverage under and participation in the Pro-gram for Elderly Pharmaceutical Insurance Coverage and establish the rights and obligations of those applicants, participants and the contractor.

(b) The State Department of Health will consider all appeals from the contractor's written decisions after reconsideration on the basis of the eligibility requirements of the program and the reasonable application of discretionary judgments properly exercised by the contractor.

§ 9700.2 Applicants/participants

For applicants and participants, these regulations govern the following:

(a) Notice. These regulations set forth what information applicants and participants are entitled to receive with the notice of determination after reconsideration, if coverage has been refused or if there is to be a change in the coverage which the participant has been receiving.

(b) Timing. These regulations set forth the time periods within which applicants and participants are obligated to request a fair hearing after a written determination after reconsideration by the contractor.

(c) Procedures. These regulations set forth what applicants and participants are required to do to have a determination after reconsideration reviewed when you are refused coverage or there is a change in the coverage which you are receiving; how to request another hearing date if you are unable to go to the fair hearing on the day it is to be held; how to get an interpreter if you do not speak English or if you are deaf; and who may come with you to a fair hearing.

(d) Decision. These regulations set forth what you should do if the contractor refuses to comply with the fair hearing decision.

§ 9700.3 Contractor

For the contractor, these regulations govern the following:

(a) notices to be sent to applicants and participants under the program;

(b) information and documents to be provided to applicants/participants, or their representatives, who have re-quested a fair hearing;

(c) the fair hearing process; and

(d) compliance with fair hearing decisions.

§ 9710.1 Definitions

The definitions set forth in Part 9600 of this Title shall also apply here and, in addition, the following terms shall have the following meanings:

(a) Appellant. An applicant or participant who requests a fair hearing shall be termed an appellant.

(b) A reconsideration is the procedure by which an applicant or participant has an action, or the failure to act, of the contractor reviewed by a contractor employee with authority to reverse the action, or failure to act.

(c) Department means the State Department of Health.

(d) Fair hearing is the procedure by which an applicant or participant may appeal from certain reconsiderations of the contractor and have a hearing thereon.

(e) Hearing officer means the person who is employed by the department exclusively to conduct fair hearings.

(f) The parties to a fair hearing shall be the appellant and the contractor whose decision after reconsideration is being reviewed.

(g) Notice of determination after reconsideration means a notice from the contractor advising an applicant or participant that the contractor has reconsidered its action, or failure to act, and the contractor intends to take, or has taken, action to discontinue, suspend, or reduce coverage.

(h) Witness means a person who presents testimony and/or documentary evidence at a fair hearing, other than the applicant, participant or his/her representative or the representative of the contractor.

§ 9720.1 Introduction

The rights and obligations of applicants and participants with respect to the fair hearing process are governed by this Part.

§ 9720.2 Right to a fair hearing

(a) Applicants and participants shall be entitled to a fair hearing to have a contractor's determination after reconsideration reviewed on the following grounds:

(1) denial of benefits;

(2) failure to determine the applicant's eligibility or, if found eligible, failure to issue a card or authorize services within three days from the date the applicant met his/her registration fee, premium or deductible requirement;

(3) discontinuance or suspension of coverage, in whole or in part;

(4) computation of his/her cost-sharing responsibilities;

(5) any other grounds affecting the applicant or participant's coverage, including a determination of the receipt of medical assistance or equivalent or better public or private insurance benefits.

(b) Notwithstanding the above, participants have no right to a hearing when the contractor discontinues payment to a provider or the panel authorizes a mass change.

§ 9720.3 Information concerning the right to a fair hearing

Every applicant and participant has the right to receive certain information in writing when the contractor issues a written determination after reconsideration which affects the applicant's/participant's coverage. Each applicant and participant has the right to a notice which advises:

(a) of his/her right to a State fair hearing;

(b) of the method by which he/she may obtain a hearing;

(c) that he/she may be represented by legal counsel, or by a relative, friend or other spokesman, or he/she may rep-resent himself/herself;

(d) of the community legal services and senior citizen services available to assist him/her in the reconsideration or fair hearing; and

(e) of the types of information he/she may submit at the hearing.

§ 9720.4 Notice of determination after reconsideration

(a) After having reviewed an action, or failure to act, which denied, discontinued, suspended or reduced coverage pursuant to the mandatory reconsideration process provided for in Part 9630 of this Title, the contractor shall issue a writ-ten notice of determination after reconsideration to the applicant or participant requesting the reconsideration.

(b) The notice shall be issued within three days of the determination and mailed to the applicant's/participant's designated address.

(c) The notice shall clearly state the determination made, the basis and specific reasons for the determination, the action to be taken and the effective date of the action, and shall include information concerning the right to a fair hearing.

§ 9720.5 Rights in fair hearing process

When an applicant or participant requests a fair hearing, he/she becomes the appellant and has the right to:

(a) examine his/her file and receive copies of documents in the file needed to prepare for the fair hearing;

(b) examine and receive copies of all documents and records which will be submitted into evidence at the fair hear-ing by the contractor;

(c) reschedule the hearing (adjournment);

(d) be represented by an attorney or other representative or to represent himself/herself;

(e) have an interpreter, at no charge, if he/she does not speak English or is deaf (the appellant must advise the department prior to the hearing if an interpreter will be needed); and

(f) have witnesses present written and oral evidence to explain why action taken was wrong.

§ 9720.6 Request for a fair hearing

(a) Any clear communication to the department by or on behalf of an applicant or participant requesting review of a contractor's determination after a reconsideration shall constitute a request for a fair hearing if made within 60 days of the written determination after reconsideration.

(b) A fair hearing may be requested in writing, by telephone or in person.

(1) Telephone requests should be made to the toll-free telephone number specified by the contractor in the notice of determination after reconsideration.

(2 Written requests should be made to the department by writing: Fair Hearing Section EPIC P.O. Box 1930 Albany, NY 12201

§ 9720.7 Examination of file prior to hearing

(a) If copies of the documentary evidence which the contractor plans to use at the hearing have not already been pro-vided to the appellant or his/her representative, an opportunity to examine such documents, if requested, shall be afforded the appellant or his/her representative at a reasonable time before the date of the hearing.

(b) The appellant or the representative shall be afforded an opportunity to examine the entire case file at a reason-able time before the hearing and to make copies of any documents contained in the file without charge.

§ 9720.8 Authorization of representative

An individual or organization, other than an attorney, representing an appellant must have a written authorization, unless the condition of the appellant makes it impracticable for him to execute one.

§ 9730.1 Introduction

The rights and obligations of the contractor are governed by this Part.

§ 9730.2 Proposed actions

When the contractor proposes to deny, discontinue, suspend or reduce coverage, it shall:

(a) review, or cause to be reviewed, the proposed action to determine its correctness on the basis of the available evidence in support of such action which shall be included in the case file;

(b) if, after the review, it is decided that the proposed action would be correct, send a timely and adequate notice of the proposed action to the applicant/participant at least 10 days before the date the action is to be taken on forms approved by the State;

(c) upon request of the applicant or participant, promptly reconsider its determination and send written notice of its determination after reconsideration to the applicant/participant together with the information concerning the applicant's/participant's right to a fair hearing as required by sections 9720.2 and 9720.3 of this Title.

§ 9730.3 Prehearing responsibilities

When the contractor is notified that a request for a fair hearing has been received, it shall:

(a) send the appellant or his/her representative copies of all documents to be submitted into evidence at the hearing in support of the contractor's action;

(b) provide copies of any document or information in the file if requested by appellant or his/her representative, without charge;

(c) take such action as is necessary to assure that an appropriate representative will appear at the hearing with the case file and a brief written summary including:

(1) the names, addresses, relationships and ages of persons affected;

(2) the decision or action which prompted the request for the fair hearing;

(3) a brief description of the facts, evidence and reasons allegedly supporting such decision or action, including identification of the specific provisions of law or regulations which allegedly support the action;

(4) the income determination prepared for the appellant; and

(5) a copy of its determination upon reconsideration.

§ 9730.4 Responsibilities and rights at the fair hearing

(a) The contractor must provide complete copies of its documentary evidence to the hearing officer at the fair hearing and to the appellant or his/her representative, if such documents were not already provided. Such documents must be provided without a charge.

(b) The contractor must provide a representative at the hearing along with the file and a written summary of the case.

(c) Such representative must have the authority to make binding decisions at the hearing on behalf of the contractor, including the authority to withdraw the action.

§ 9730.5 Compliance with fair hearing decision and mediation order

The contractor must promptly comply with all fair hearing decisions and initiate directives without delay, in accordance with this Part.

§ 9740.1 Introduction

The fair hearing process for persons applying for or receiving coverage under the Program for Elderly Pharmaceutical Insurance Coverage is governed by this Part.

§ 9740.2 Notice of hearing

At least 10 calendar days prior to the date of the hearing, written notice shall be sent to the parties and their representatives. The notice shall inform them:

(a) of the date and place of the hearing and the appellant's right to a change in the date and place of the hearing where necessary;

(b) of the manner and means by which adjournments may be requested and granted;

(c) of the issues which are to be the subject of the hearing;

(d) of the manner in which the hearing will be conducted; and

(e) of the right of each party to be represented, to testify, to produce witnesses, to present documentary evidence and to examine opposing witnesses and evidence.

§ 9740.3 Scheduling and adjourning the hearing

(a) The hearing shall be held at a time and place convenient to the appellant as far as practicable, taking into account circumstances such as the physical inability of the applicant to travel to the regular hearing location.

(b) Upon request, an appellant or the contractor may have the fair hearing rescheduled to another date upon a showing of good cause.

(c) The hearing officer may adjourn the hearing when he/she believes that due process rights of an appellant would best be served by adjourning the fair hearing or if there are special circumstances which make proceeding with the case fundamentally unfair.

(d) Requests to adjourn a fair hearing made prior to the date of the fair hearing must be made to the department in accordance with the instructions in the notice of fair hearing. Requests for adjournments made on the day of the fair hearing must be made on the record to the hearing officer.

§ 9740.4 Withdrawal or abandonment of a request for hearing

(a) A request for a hearing is considered abandoned if neither the appellant nor his/her representative appears at the time and place agreed upon for the hearing or neither the appellant or his/her representative has contacted the department to reschedule the hearing.

(b) The department will consider a hearing request to be withdrawn only under the following circumstances:

(1) the department has received a written statement from the appellant or his/her representative stating that the re-quest for a fair hearing is withdrawn; or

(2) the appellant or his/her representative has made a statement to the hearing officer withdrawing the request on the record at the hearing.

§ 9740.5 Hearing officer

(a) The hearing officer shall have all the powers conferred by law to require attendance of witnesses and the production of books and records, and to administer oaths and to take testimony.

(b) The hearing officer shall preside over the hearing.

(c) The contractor shall make an opening statement describing the nature of the proceeding, the issues and the manner in which the hearing shall be conducted.

(d) The hearing officer shall elicit testimony, review the evidence submitted by the parties, determine the credibility of the witnesses, examine the parties if necessary, and shall make findings of fact relevant to the issues of the hearing.

(e) The hearing officer shall also prepare an official report containing the substance of what transpired at the hearing.

§ 9740.6 Who may be present at hearing

The appellant, his/her representative (who may be an attorney or other persons representing him), counsel or other representative of the contractor, the executive director, members of the panel or their agents, witnesses of both parties or who may be called by the hearing officer, and

such other persons as the hearing officer in his/her discretion may admit, with the consent of the appellant.

§ 9740.7 Fair hearing procedures

(a) Technical rules of evidence followed in a court of law shall not be followed, but evidence must be relevant and material.

(b) Irrelevant and unduly repetitious testimony and cross-examination may be excluded at the discretion of the hearing officer.

(c) The appellant shall have the burden of showing that its determination after reconsideration was incorrect.

(d) Records and documents in the possession of the contractor may be admitted as complete photocopies; however, the originals shall be available to the appellant or his/her representative for inspection at the direction of the hearing officer.

(e) The decision must be supported by and in accordance with substantial evidence.

§ 9740.8 Hearing record

(a) A verbatim record of the hearing shall be made.

(b) The fair hearing testimony, the fair hearing exhibits, the written determination after reconsideration, the hearing officer's official report containing the substance of what happened at the fair hearing, all papers and requests filed in the proceeding prior to the close of the fair hearing, the findings of the hearing officer and the fair hearing decision constitute the complete and exclusive record of the fair hearing.

§ 9740.9 Examination of the record after hearing

The record of the hearing shall be confidential, but it may be examined by either party or their representatives, the executive director, members of the panel or their agents at a place accessible to them and at a reasonable time.

§ 9750.1 Introduction

All decisions issued after a request for a fair hearing are governed by this Part.

§ 9750.2 Decision after hearing

(a) The hearing decision shall be made and issued in accordance with the agreement between the Department of Health and the panel, and shall be based exclusively on the record and testimony introduced at the hearing.

(b) The decision shall be issued as promptly as feasible and within 60 days from the date the request for a fair hearing is received by the department. The decision shall describe the issues, recite the relevant facts, the pertinent provisions of law, regulation and State-

approved policy, make appropriate findings, determine the issues, state reasons for the determinations and, when appropriate, direct specific action.

(c) Where the issue at hearing involves the mere calculation of income or determination of the amount of any required fee, premium or deductible paid or to be paid, the hearing officer may issue a directive on the record, directing specific action by the contractor. Where such immediate directive is issued, a written memorandum decision shall be made setting forth the directive.

(d) The decision shall be binding on the parties.

(e) A copy of the decision or the memorandum of an immediate directive issued on the record, as appropriate, shall be sent to each of the parties and their representatives, if any.

(f) In the letter transmitting the decision, clear reference shall be made to availability of judicial review.

§ 9750.3 Decision without hearing

(a) The appellant shall have the option to request that his/her appeal from a contractor's determination after reconsideration be decided without a hearing. Such request will be granted when it is determined that no unresolved material issue of fact is involved in the case and that the only questions presented are questions of law. A request for a decision without a hearing must be accompanied by sufficient information to ascertain whether any unresolved material issue of fact exists, and should contain a full and clear statement of the issue and the appellant's position on the issue.

(b) Upon receipt of a request for a decision without a hearing which presents, on its face, no factual dispute, a copy of the request and any supporting documents will be sent to the contractor. Within 10 working days of its receipt of the documents submitted by the appellant, the contractor shall forward, to the hearing officer, the appellant and the appellant's representative, its response containing sufficient information to ensure resolution of the dispute.

(c) The hearing officer shall make any further inquiries of the appellant, the appellant's representative and the con-tractor which are necessary to resolve the issues involved.

(d) If at any point after a request for a decision without a hearing is received, it appears that there is a material and unresolved issue of fact relating to the issue or issues upon which the hearing has been requested, the hearing officer shall inform the parties that a full hearing in accordance with the provisions of this Part must be scheduled to resolve the dispute, and the appellant shall then have the option of proceeding with such hearing or withdrawing the request for review.

§ 9750.4 Correction of error

When a fair hearing decision has ordered the correction of a discontinuance, the correction of a denial of an application for benefits or the correction of the amount of cost-sharing responsibilities, a payment shall be made to the appellant to cover the full amount to which he/she was entitled in accordance with the decision for the entire period from the date the incorrect action was taken.

§ 9750.5 Compliance with decision

(a) When a decision directs the contractor to perform specific actions, the contractor shall comply within 10 calendar days with such direction.

(b) The appellant for whose benefit such direction was given shall address any inquiry concerning contractor compliance to the panel's executive director who shall ascertain compliance with such direction by such means as the executive director may deem necessary and appropriate under the circumstances of the case.

§ 9800.1 Policy and scope

(a) The policy of the State is to assist elderly persons with low income to meet the cost of their prescription drug expenditures. In pursuit of this goal, the State will contract with only those pharmacies which can demonstrate that they are qualified to provide prescription drugs and which can provide reasonable assurance that public funds will be properly utilized. Only qualified and responsible pharmacies may be enrolled as providers under the Program for Elderly Pharmaceutical Insurance Coverage.

(b) The following definitions shall apply to this Part unless the context requires otherwise:

(1) Affiliate or affiliated person means any person having an overt, covert or conspiratorial relationship with an-other, such that either of them may directly or indirectly control the other or such that they are under a common control. For example: persons with an ownership or control interest in a provider; agents and managing employees of a provider; subcontractors; and wholly owned suppliers of a provider with whom the provider has significant business transactions are considered affiliated with each other. Similarly, providers sharing a common ownership or control interest are affiliated with each other.

(2) Fraud shall mean an intentional deception or misrepresentation made with the knowledge that the deception could result in same unauthorized benefit to the person or another person, and includes the acts prohibited by section 547-k of the Executive Law.

(3) Abuse shall mean practices that are inconsistent with sound fiscal business or generally accepted pharmacy practice and result in unnecessary costs to the program.

(4) Agent means a person who has actual or apparent authority to obligate or to act for another.

(5) Pharmacy-applicant is any pharmacy which has submitted an application for enrollment.

(6) Application for enrollment or application means any document submitted by a person for the purpose of enrolling in the program.

(7) Conviction or convicted means that a plea of guilty or no contest or a verdict of guilty has been entered in a Federal, State or local court, regardless of whether an appeal from the judgment is pending or whether a certificate of relief from civil disabilities has been granted.

(8) Contractor means the State fiscal intermediary responsible for enrollment of providers and making payments under the program.

(9) Enrollment or enrolling is the process by which a pharmacy-applicant contracts to participate in the program as a provider of prescription drugs.

(10) Furnishes means the provision of prescription drugs either directly or indirectly by supervising the provision thereof.

(11) Indirect ownership interest means an ownership interest in an entity that has an ownership interest in a provider. This term includes an ownership interest in any entity that has an indirect ownership interest in a provider.

(12) Indictment means an indictment has been handed down by a grand jury, or an accusatory instrument charging a crime which would be a felony under New York State law has been filed.

(13) Managing employee means a general manager, business manager, administrator, director, or other person who exercises operational or managerial control of a provider, or who directly or indirectly conducts the day-to-day operation of a provider.

(14) Medicaid is the program of State-administered medical assistance established by title XIX of the Social Security Act.

(15) Medical assistance program means the program of medical assistance for needy persons provided for in title 11 of article 5 of the Social Services Law.

(16) Medicare is the program of hospital and medical insurance established under title XVIII of the Social Security Act.

(17) Ownership interest means possession of equity in the capital, the stock or the profits of a provider.

(18) Participation is the ability and authority to furnish prescription drugs to eligible participants and to receive payment from the program.

(19) Person includes natural persons, corporations, partnerships, associations, clinics, groups and other entities.

(20) Person with an ownership or control interest means a person who:

(i) has an ownership interest totalling five percent or more in a provider;

(ii) has an indirect ownership interest equal to five percent or more in a provider;

(iii) has a combined direct and indirect ownership interest equal to five percent or more in a provider;

(iv) owns an interest of five percent or more in any mortgage, deed of trust, note or other obligation secured by the provider if that interest equals at least five percent of the value of the property or assets of the provider;

(v) is an officer or director of a provider that is organized as a corporation; and

(vi) is a partner in a provider that is organized as a partnership.

(21) Covered drug means a drug dispensed subject to a legally authorized prescription pursuant to section 6810 of the Education Law, and insulin, an insulin syringe or an insulin needle, as more fully defined in Part 9960 of this Title.

(22) Program means the Program for Elderly Pharmaceutical Insurance Coverage as provided for by article 19-K of the Executive Law.

(23) Provider is any person who has enrolled as a provider of prescription drugs under the program.

(24) Significant business transaction means any business transaction or series of transactions that, during any one fiscal year, exceed the lesser of $ 25,000 or five percent of a provider's total operating expenses.

(25) Subcontractor means any person to which a provider has contracted or delegated some of its management functions or responsibilities for providing covered drugs.

(26) Supplier means a person from whom a provider purchases goods and services used in carrying out its responsibilities under the program.

(27) Wholly owned supplier means a supplier whose total ownership interest is held by a provider or a person with an ownership or control interest in a provider.

(28) Common ownership means:

(i) ownership by a person or group of persons who have a combined direct or indirect ownership interest of 50 per-cent or more in two or more providers; or

(ii) two or more providers with any common ownership where common purchasing is practiced.

(29) 24-hour emergency prescription services means a service in which a pharmacist is available to fill or refill a prescription at any time of the day or night, to treat the existence of any condition requiring the alleviation of severe pain or which threatens to cause disability or take life if not promptly treated.

(30) Emergency delivery service at no cost to the consumer means a participant is able to obtain free emergency de-livery service, within a five-mile radius of the pharmacy, during operating hours, to treat the existence of any condition requiring the alleviation of severe pain or which threatens to cause disability or take life if not promptly treated.

(31) "Maintain a patient profile means each pharmacist shall maintain a patient medication profile. Such medication profile shall include, but not be limited to, the patient's name, address, telephone number, gender, date of birth or age, known allergies and drug reactions, chronic diseases, a comprehensive list of medications and relevant devices and other information reported to the pharmacist which is appropriate for counseling an individual regarding use of prescription and over-the-counter drugs. Pharmacists shall conduct a prospective drug review before each prescription is dispensed or delivered to a patient or person acting on behalf of the patient. Such review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-drug interactions, including serious interactions with over-the-counter drugs, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse.

(32) Direct patient consulation with each prescription shall mean pharmacists providing prescription services shall offer to discuss with each patient, recipient or caregiver of such patient, (in person, whenever practicable, or by telephone, or for pharmacies engaged primarily in the mail order delivery of prescriptions, through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in exercise of the pharmacist's professional judgment, the pharmacist deems significant, including the following:

(i) the name and description of the medication;

(ii) dosage form, dosage, route of administration and duration of drug therapy;

(iii) special directions and precautions for preparation, administration and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self-monitoring drug therapy;

(vi) proper storage;

(vii) prescription refill information; and

(viii) action to be taken in the event of a missed dose. If the offer to counsel is accepted, the pharmacist, or registered pharmacy intern shall counsel the person presenting the prescription to the extent the pharmacist deems appropriate in the pharmacist's professional judgment. Such counseling may include subparagraphs (i) - (viii) of this paragraph. In the event a patient chooses not to supply information necessary for maintenance of a medication profile, or not to accept counseling, a pharmacist may fill a prescription as presented, without having violated this regulation, provided the refusal to provide such information or accept counseling is documented in the records of the pharmacy. Patient medication profiles shall be maintained in a retrievable form for five years following the date of the most recent entry.

§ 9800.2 Application for enrollment

(a) Information regarding application for enrollment may be obtained by writing to the provider enrollment unit of the contractor.

(b) Any person who furnishes covered drugs and who wishes to receive payments under the program must enroll as a provider of services prior to being eligible to receive such payments.

(c) A pharmacy-applicant must hold a proper and currently valid New York State pharmacy license and registration to be eligible to furnish the care, services or supplies under the program.

(d) To apply for enrollment as a provider of covered drugs, a pharmacy-applicant must submit a complete, original, signed and sworn application in the form and manner as may be required by the contractor. The ownership and disclosure form required by the contractor is part of the application.

(e) The contractor may require the provision of information relative to the pharmacy-applicant's ability to provide high-quality services and to be financially responsible.

§ 9800.3 Duties of the provider

By enrolling, the provider agrees:

(a) to prepare and to maintain contemporaneous records demonstrating its right to receive payment under the program and to keep, for a period of three years from the date care, services or supplies were furnished, all records necessary to disclose the nature and extent of services furnished and all information regarding claims for payment submitted by, or on behalf of, the provider, and to furnish such records and information, upon request, to the contractor, the panel, executive director, or agents and designees;

(b) to comply with the disclosure requirements with respect to ownership and control interests, significant business transactions and involvement with convicted persons;

(c) to accept payment from the program as payment in full for all covered drugs billed under the program, except where specifically provided in law to the contrary with respect to required copayments;

(d) not to illegally discriminate on the basis of handicap, race, color, religion, national origin, sex or age;

(e) to submit claims for payment only for covered drugs actually furnished and which were provided to eligible persons;

(f) to submit claims on officially authorized claim forms in the manner specified by the contractor in accordance with the standards and procedures for claims submission;

(g) to permit audits, by the persons and agencies denominated in subdivision (a) of this section, of all books and records or, in the discretion of the auditing agency, a sample thereof, relating to services furnished and payments received under the program;

(h) that the information provided in relation to any claim for payment shall be true, accurate and complete; and

(i) to comply with the rules, regulations of the program and official directives of the contractor and the executive director.

§ 9800.4 Duties of the contractor

(a) Upon receipt of a complete, original and signed application, an appropriate review, at the direction of the executive director, shall be conducted to verify or supplement the information contained in the application. Incomplete applications shall be returned to the pharmacy-applicant within three working days with deficiencies noted.

(b) The contractor may request further information from a pharmacy-applicant. In such a case, it shall make a clear and precise request to the pharmacy-applicant for the information and inform the pharmacy-applicant whether or not action on the application will be postponed pending receipt of the requested information. Delay occasioned by the pharmacy-applicant's failure to timely reply shall not be counted in calculating the time within which the contractor shall make its determination on the application.

(c) The contractor shall complete its review and determine whether or not to enroll the pharmacy-applicant within 30 calendar days after receipt of an application.

(d) If a pharmacy-applicant cannot be fully reviewed within the required time, the contractor may extend the time for acting on an application for up to one additional 30-day period from the date of receipt of the application. Written notice of this extension will be mailed to the pharmacy-applicant within 30 calendar days from the time the application was received.

(e) Upon completion of its consideration of an application, the contractor shall either:

(1) enroll the pharmacy-applicant as a provider; or

(2) deny the application, if it is in the best interests of the program to do so, specifying the reasons for denial.

§ 9800.5 Denial of an application

(a) In determining whether to enter into a contract with a pharmacy-applicant, the following factors shall be grounds for denial of an application:

(1) any false representation or omission of any material fact in making the application;

(2) any previous or current suspension, exclusion or involuntary withdrawal from participation in the medical assistance program or the Medicaid program of any other state of the United States or from participation in any other governmental or private medical insurance program, including but not limited to Medicare, workers' compensation, physically handicapped children's program and rehabilitation services;

(3) the receipt of, but not having made restitution for, a Medicaid or Medicare overpayment, as determined to have been made pursuant to a final decision or determination of an agency having the powers to conduct the proceeding and after an adjudicatory proceeding in which no appeal is pending or after resolution of the proceeding by stipulation or agreement; however, if a pharmacy-applicant has entered into a plan of restitution of such overpayment, an application may not be denied based solely on this factor unless the pharmacy-applicant has defaulted in repayment;

(4) any false representation or omission of a material fact in making application in any state of the United States for any license, permit, certificate or registration related to a profession or business;

(5) any previous failure to correct deficiencies in the operation of a business or enterprise after having received written notice of the deficiencies from a State or Federal licensing or auditing agency;

(6) any failure to supply further information concerning the application after receiving a written request for such further information;

(7) the submission of an application which conceals an ownership or control interest of any person who would otherwise be ineligible to participate;

(8) an outstanding indictment for, or prior conviction of, any crime relating to the furnishing of, or billing for, medical care, services or supplies, or which is considered an offense involving theft or fraud or an offense against public administration or against public health and morals;

(9) a prior finding by a licensing, certifying or professional standards board or agency of the violation of the standards or conditions relating to licensing or certification or as to the quality of services provided;

(10) the pharmacy-applicant's prior pattern or practices in furnishing medical care, services or supplies under any private or publicly funded program or policy of insurance; and

(11) any other factor having a direct bearing on the pharmacy-applicant's ability to provide high-quality pharmaceutical services to participants in the program, or to be fiscally responsible under the program, including actions by per-sons affiliated with the pharmacy-applicant.

(b) If any application is denied, the pharmacy-applicant shall be given a written notice of the denial, stating the reason or reasons for the denial, within three days of the determination to deny the application. The written notice of denial will be effective upon the date it is mailed to the pharmacy-applicant.

(c) The pharmacy-applicant may request a reconsideration of a denial by submitting a written request for a reconsideration to the executive director within 30 days of the date of the denial. The request shall include all arguments and documentation which the pharmacy-applicant wishes to be considered in its behalf. A written determination of acceptance or denial of the application shall be issued by the executive director within 60 days of receipt of the request for reconsideration, stating the basis for the determination and the reasons for affirming or reversing the initial determination.

(d) If an application has been denied, the pharmacy-applicant may reapply only upon correction of the factors leading to its denial, or after one year if the factors relate to prior conduct of the pharmacy-applicant or an affiliated person.

(e) Denial of an application shall preclude the pharmacy-applicant from submitting claims for payment under the program either directly, or indirectly through any other person. Any claims submitted by such pharmacy-applicant or such other person and paid by the contractor shall constitute overpayments.

§ 9800.6 Acceptance of an application

(a) Upon acceptance of an application, the contractor shall issue to the provider a provider agreement, identification number and instructions on participation in the program and

filing of claims for payment. Upon receipt of a complete, signed provider agreement, the contractor shall enroll the provider within 15 working days.

(b) Enrollment, including the use of the identifying number, is not assignable or transferable but is strictly limited to the provider to which it was issued, unless authorized in writing by the contractor prior to the assignment or transfer.

(c) A provider's participation may begin only on or after the date specified in the notification of acceptance. A provider may participate in the program for the period specified in the notice of acceptance, unless participation has been otherwise terminated or suspended.

(d) A provider may submit claims only for services provided by the provider or another person under his supervision and in compliance with this Subtitle.

§ 9800.7 Continued enrollment/termination

(a) A provider's participation in the program may be terminated by the provider upon 30 days' written notice to the contractor without cause.

(b) A provider's participation in the program may be terminated, suspended or restricted for a reasonable period of time if the provider has abused the program, and shall be terminated if the provider has engaged in fraud.

(c) A provider's participation shall be terminated or suspended as of the date of the provider's suspension or termination from Medicare or the medical assistance program.

(d) A provider's participation shall be terminated or suspended as of the date of any termination, revocation or suspension of its registration.

(e) A provider must maintain an up-to-date "Disclosure of Ownership and Control Interest Statement" on file with the contractor, amending it at least biennially or sooner when necessary to assure that the information contained in the statement is true, accurate and complete. Failure to maintain an up-to-date disclosure form on file, or to submit one within 35 days of a request by the contractor, will result in the termination of the provider's participation.

(f) A provider's participation may be terminated and a new application for enrollment required where the ownership or control of the provider has substantially changed since acceptance of its enrollment application, whether by the sale or exchange of the capital stock in a provider organized as a corporation, the addition or elimination of one or more partners in a provider organized as a partnership, or the sale of the business or assets of any provider entity.

(g) A provider's participation will be terminated where the provider furnished incorrect, inaccurate or incomplete information in connection with an application and where provision of correct, accurate and complete information would have resulted in the denial of

the application based upon one or more of the factors set forth in section 9800.5(a) of this Part.

(h) Where a provider's participation is to be terminated, suspended or restricted, it is entitled to notice and an opportunity to be heard in accordance with the provisions of sections 9850.7 through 9850.13 of this Title. The provider must be given written notice of the action at least 15 days prior to its effective date, stating: the reasons for the action, the effective date, the effect of the action upon the provider's participation in the program, the earliest date on which participation may be reinstated, and the requirements for requesting a hearing.

§ 9800.8 Audit and claim review

(a) Providers shall be subject to audit by the panel, the executive director, their agents or the contractor. With respect to such audits the provider may be required:

(1) to reimburse the contractor for overpayments discovered by audits; and

(2) to pay restitution for any direct or indirect monetary damage to the program resulting from their improperly or inappropriately furnishing covered drugs.

(b) The panel, the executive director, their agents or the contractor may conduct or have conducted audits and claims reviews which may be limited to reviews of costs of operation or validity of claims submitted, and adherence to accepted pharmacy practices and established contractor policy and procedures, conduct therapeutic drug monitoring reviews applying generally accepted pharmaceutical practice standards or conduct investigations as to the provider's conduct relative to fraud and abuse.

(c) The contractor upon prepayment review, or therapeutic drug monitoring review, may deny claims, adjust claims to eliminate noncompensable items or to reflect established rates or fees, pend claims for review, or approve the claim for payment, subject to post-payment audit and verification.

(1) For claims denied as a result of therapeutic drug monitoring reviews, as a condition for payment, the provider must submit information indicating that the pharmacist has either reviewed the questioned prescription(s), consulted with the participant or interacted with the prescribing physician. Information submitted must describe any actions taken as a result of such review, consultation or interaction to deter or prevent the incorrect or unnecessary consumption of a therapeutic agent.

(2) For claims denied as a result of suspected excessive quantities, providers must submit, as a condition for payment, additional dispensing information, such as the dose prescribed, which justifies the quantities billed.

(d) Where the contractor's analysis of claims or initial onsite audit findings indicate that a provider has claimed or is claiming for covered drugs which may be inconsistent with regulations governing the program or with established standards for quality, or which are

otherwise inappropriate, payment of all claims submitted and of all future claims may be delayed or suspended, upon the written approval of the executive director, pending completion of an investigation upon approval of the executive director. A notice of the withholding of payment shall be sent to the provider contemporaneous with withholding of payments.

§ 9850.1 Scope

(a) This Part establishes the procedures for the recovery of overpayments paid under the Program for Elderly Pharmaceutical Insurance Coverage, as determined by an audit of the provider's books, records, reports or other available documentation.

(b) Recovery of overpayments shall be made only upon a determination by the executive director that such over-payments have been made, and recovery shall be made of all money paid to the provider to which it has no lawful right or entitlement.

(c) Recovery of overpayments pursuant to this Part shall not preclude the executive director or any other authorized governmental body or agency from taking any other action with respect to the provider, including auditing or reviewing of other payments or claims for payment for the same or similar periods, imposing program sanctions, or taking any other action authorized by law.

(d) The existence of procedures for the recovery of overpayments pursuant to this Part shall not preclude the executive director from utilizing other lawful means to recover overpayments, including civil lawsuit, participation in a proceeding in bankruptcy, common law setoff, or such other actions or proceedings authorized or recognized by law.

§ 9850.2 Definitions

The definitions employed in Part 9800 of this Title shall apply equally in this Part, and as used in this Part the following terms shall have the following meanings:

(a) Contractor shall mean the State fiscal intermediary making payments under the program, or any person or per-sons acting on behalf of the contractor.

(b) Executive director shall mean the executive director of the program.

(c) Office of Administrative Hearings shall mean that office within the Division of Legal Affairs of the State Department of Health which conducts hearings under contract with the panel.

§ 9850.3 Audit and record retention

(a) All fiscal and statistical records and reports of providers and prescriptions filled or refilled which are used for the purpose of establishing the provider's right to payment under the program, and any underlying books, logs, records and documentation which formed the basis for such fiscal and statistical records and reports, shall be subject to audit. Providers must maintain a contemporaneous signature log which shall contain at a minimum the

following elements of in-formation for all prescriptions, except those prescriptions which are delivered to the participant by courier or mail: the prescription number, the date the prescription was dispensed and the signature of the participant or the participant's authorized representative. All underlying books, logs, records and documentation, including all prescriptions filled or re-filled, shall be kept and maintained by the provider for a period of not less than three years from the date of completion of such reports or the date upon which the fiscal and statistical records were required to be filed, whichever is later, or the date the prescription was filled or refilled. Failure to maintain accurate records in accordance with this section may result in the disallowance of any claims for which such documentation is lacking.

(b) All claims made under the program shall be subject to audit by the executive director or contractor for a period of three years from the date of their filing. This limitation shall not apply to situations in which fraud may be involved or where the provider or an agent thereof prevents or obstructs the contractor from performing an audit pursuant to this Part.

(c) Notification to the provider of the intent to audit shall toll the period for record retention and audit. The audit shall commence within 60 days of the notification. However, this period may be extended for 60 days upon written notice to the provider. There shall be no more than one extension of a notification of intent to audit.

(d) If an audit has not been commenced within 60 days of a notification of intent to audit or within 120 days of an extended notification, the effectiveness of the notification shall lapse. However, subsequent notifications of intent to audit may be issued within the period described in subdivision (b) of this section. The passage of this period shall preclude the conduct of an audit unless there is in existence an unexpired notification of intent to audit or an extended notification. The passage of this period shall not prohibit the conclusion of an audit already begun.

(e) Notwithstanding the provisions of subdivisions (c) and (d) of this section, the period within which to commence an audit may be indefinitely extended on account of delays in the commencement of the audit caused or requested by the provider or a representative of the provider.

(f) The audit shall begin with an entrance conference at which the nature and extent of the audit shall be discussed. The time, manner and place of an audit shall be determined by the executive director or the contractor.

(g) In their discretion, the executive director or the contractor may terminate an audit at any time in the audit process. The provider shall be notified in writing of such termination. This written notification shall serve in the place of a closing conference, draft audit report or final audit report, as appropriate. If an audit is terminated, the executive director or the contractor is precluded from recommencing an audit of those items which were the subject of the terminated audit.

§ 9850.5 Draft audit report

(a) If, after affording the provider the opportunity for a closing conference and after consideration of any additional documentation and information presented in connection therewith, the executive director or the contractor believes that overpayments have been made to the provider, a draft audit report shall be issued.

(b) The draft audit report shall contain a clear statement of the action to be taken. The items disallowed and the amount of the overpayments shall afford the provider the opportunity to object to the proposed action within 30 days and shall advise the provider that failure to object within the time provided may result in the adoption of the proposed action as the final action.

(c) The report shall be accompanied by a document identifying the person to whom objections to the report should be mailed. The provider's objections to the draft audit report must be mailed by the provider to that person within 30 days of the report. It shall include a statement detailing the specific items of the draft report to which the provider ob-jects, and provide any additional material or documentation which the provider wishes to be considered in support of the objections.

§ 9850.6 Final audit report

(a) After receipt of the provider's objections to the draft audit report, or at any time after the expiration of 40 days after mailing of the draft audit report without objections having been received, a final report shall be issued by the executive director. In preparing the final audit report for the executive director, the contractor shall consider the objections, any supporting documents and materials submitted therewith, the draft audit report, and any additional material which may become available.

(b) Upon receipt of a final report from the contractor, the executive director shall conduct a review of the report for conformance with program policy, law and regulations. The report may be modified by the executive director prior to issuance in light of his/her review.

(c) The final audit report and/or the cover letter accompanying it shall clearly advise the provider:

(1) of the nature and amount of the audit findings, the basis for the action and the statutory, regulatory or other legal basis therefor;

(2) of the action which will be taken;

(3) that the effective date of the intended action shall be not less than 15 days from the date of the final audit report;

(4) of the right to appeal the administrative action by requesting a hearing, and the name, title, address and telephone number of the appropriate official of the Office of Administrative Hearings the provider must contact to request a hearing;

(5) that a request for a hearing must be made in writing and postmarked or delivered within 60 days of receipt of the final audit report which shall be presumed to be five days from date of mailing; and

(6) that the request may not address issues regarding the methodology used to determine the rate of payment under the program or the dispensing fee, but shall be limited to those issues relating to determinations contained in the final audit report.

§ 9850.7 Request for hearing

(a) A provider has the right to an administrative hearing to challenge the final audit report and may request such a hearing within 60 days of receipt of the final audit report which shall be presumed to be five days from date of mailing.

(b) The request for hearing shall be in writing and shall be delivered or mailed to the appropriate official of the Office of Administrative Hearings. It shall specify by number and date the final audit report which is to be the subject of the hearing and shall include the following additional information:

(1) the specific item or items to which objections are made;

(2) the factual basis for the objections; and

(3) any legal authority for the objections.

(c) When a timely request for a hearing has been made, a hearing shall be held, except when the request has been withdrawn or abandoned by the provider.

(1) A request for a hearing shall be considered withdrawn only upon receipt of a written statement or by the making of a statement on the record at the hearing by the provider or by the provider's attorney or representative.

(2) A request for a hearing shall be considered abandoned if, without good cause, neither the provider nor the provider's attorney or representative appears at the time and place designated for the hearing.

(d) Upon receipt of a request for a hearing, the Office of Administrative Hearings shall forward a copy of the re-quest to the executive director, and:

(1) designate a hearing officer to hear the matter;

(2) establish a time and place for such hearing;

(3) notify the provider, contractor and executive director of the time and place of such hearing at least 15 days be-fore the commencement of the hearing; and

(4) include in a notice of hearing a statement:

(i) of those issues which are controverted and to be determined at the hearing;

(ii) of the provider's rights to be represented by an attorney or other representative, to cross-examination, to present evidence and produce witnesses on the provider's own behalf; and

(iii) that the burden of proof at the hearing shall be on the provider as the appellant.

§ 9850.8 The hearing officer

The hearing shall be conducted by an impartial hearing officer employed for that purpose. The hearing officer shall have all the powers conferred by law and the regulations of the executive director to administer oaths, issue subpoenas, require the attendance of witnesses and production of records, rule upon requests for adjournment, rule upon evidentiary matters, and to otherwise regulate the hearing, observe requirements of due process and effectuate the purposes and provisions of applicable law.

§ 9850.9 Who may be present at hearing; authorization of representative

(a) The hearing shall be open to the public. However, upon the hearing officer's motion, or upon the motion of either party, potential witnesses may be excluded from the hearing during the testimony of other witnesses.

(b) An individual, other than an attorney, representing the provider shall have written authorization signed by the provider if the operator thereof is a natural person, or by an officer, member or director of an operating entity which is not a natural person.

§ 9850.10 Conduct of hearings; rights of provider

(a) The hearing officer shall preside over the hearing, make all procedural rulings, and make a statement on the record describing the nature of the proceedings, the issues, and the manner in which the hearing will be conducted.

(b) The issues and documentation presented at the hearing shall be limited to issues relating to determinations made in the final audit report. A provider may not raise issues regarding the methodology used to determine the rate of payment or dispensing fee.

(c) The rules of evidence observed by a court of law need not apply.

(d) Computer-generated documents prepared by the contractor or its agent to show the nature and amount of payments made under the program shall be presumed, in the absence of evidence to the contrary, to constitute an accurate reflection of the contractor's records as to the amount and type of payment made to a provider as well as the basis for such payment.

(e) An extrapolation based upon a contractor audit utilizing a valid statistical sampling method shall be presumed, in the absence of evidence to the contrary, to be accurate.

(f) An audit report of the contractor shall be presumed to be correct and the burden of proof shall be on the provider to show by substantial evidence that any item of such report is incorrect.

(g) All testimony shall be given under oath or affirmation administered by the hearing officer.

(h) The provider shall be entitled to be represented, to have witnesses give testimony and to otherwise present relevant and material evidence on the provider's behalf, to cross-examine witnesses and to examine any document or other item offered into evidence.

(i) A verbatim record of the hearing will be maintained.

(j) In the discretion of the hearing officer, the hearing may be adjourned for good cause upon the request of either party or upon the hearing officer's own motion.

(k) The hearing shall be conducted in conformity with procedural requirements of section 12-a of the Public Health Law and the State Administrative Procedure Act.

(l) At the conclusion of the hearing, the hearing officer may direct the provider and the contractor to submit memoranda on any legal issues relevant to the proceeding within time frames established by the hearing officer. The hearing officer may also direct the parties to submit proposed findings of fact.

§ 9850.11 The record

(a) The record shall include those matters required to be included by section 302 of the State Administrative Procedure Act, as amended from time to time, and the transcript of the proceedings.

(b) Findings of fact shall be based on the evidence at the hearing and on matters administratively noticed.

§ 9850.12 Examination of record after hearing

The record and transcript of the hearing and the memoranda of law or other post-hearing submissions of the parties may be examined by any party to the hearing at the Office of Administrative Hearings during regular business hours.

§ 9850.13 Decision after hearing

(a) The hearing decision shall be made and issued in accordance with the agreement between the Department of Health and the panel and shall be based exclusively on the record and transcript of the hearing. In reaching a decision, memoranda of law of the parties, if any, may be reviewed and noted. The decision shall be in writing and shall describe the issues, recite the relevant facts, the pertinent provisions of law and regulations, make appropriate findings, deter-mine the issues, state reasons for the determinations and, when appropriate, direct specific action.

(b) A copy of such decision shall be mailed to the provider and the provider's attorney or representative, if any, and to the contractor and executive director.

(c) In the event that a decision is adverse to the provider, in whole or in part, the provider shall be given notice of the right to judicial review in accordance with the provisions of article 78 of the Civil Practice Law and Rules.

§ 9850.14 Adjustments after audit

Adjustments which result in revisions to the amount of reimbursement made shall be satisfied pursuant to section 9850.15 or 9850.16 of this Part.

§ 9850.15 Recoupment of overpayments

(a) Overpayments determined to have been made pursuant to this Part shall be recovered by withholding the provider's current or future payments on claims submitted or a percentage of payments otherwise payable on such claims, at the option of the contractor, unless the provider and contractor agree otherwise. Such withholding may be made at any time after the issuance of a decision after hearing or, if a hearing has not been requested in accordance with this Part, at any time after expiration of the time period allowed in section 9850.7 of this Part for the making of such request.

(b) Any money due to the provider from the contractor shall be used as an offset against an overpayment deter-mined to have been made by the audit made pursuant to this Part.

§ 9850.16 Recovery of overpayments pending hearing

(a) Notwithstanding the provisions of subdivision (a) of section 9850.15 of this Part, the executive director may re-quest the contractor commence recoupment of overpayments by withholding all or part of payments otherwise due the provider, upon notice to the provider and not sooner than 15 days after issuance of the final audit report.

(b) If a request for hearing shall have been timely made and the Office of Administrative Hearings is unable to schedule the hearing so that it is commenced within 90 days of receipt of such request or if the contractor is unable to proceed within 90 days, any recovery begun under this section shall be stayed pending the commencement of the hear-ing. If a hearing shall have been scheduled to commence within 90 days of receipt of a hearing request, any delays or adjournments to the commencement of the hearing occasioned by or attributable to the contractor shall forestall the commencement of continuation of recoupment.

§ 9850.17 Fraud and abuse

(a) The executive director shall maintain a statewide program for investigation and referral for prosecution of violations of State laws pertaining to fraud or abuse in the program.

(b) Whenever, in the conduct of an audit of the books and records of a provider or in the evaluation of utilization review reports or provider profiles, there is sufficient evidence of

program fraud or abuse to warrant investigation of the provider, the contractor shall promptly refer the matter to the executive director for investigation.

(c) Where initial review of a contractor referral indicates substantial potential for criminal prosecution, the executive director shall refer the matter to the Attorney General or local prosecutive authority. Where initial review does not indicate substantial potential for criminal prosecution, the executive director shall conduct further investigation to determine whether or not the subject provider should be discontinued from participation in the program.

(d) Where investigation indicates substantial evidence of abusive practices on behalf of a provider or his affiliates, the provider may be terminated, suspended or restricted in accordance with the provisions of section 9800.7(b) of this Title.

§ 9950.1 Statement of purpose

The purpose of this Part is to set forth the methods and procedures governing the availability, location and nature of those records of the Elderly Pharmaceutical Insurance Coverage Panel subject to the provisions of article 6 of the Public Officers Law, known as the Freedom of Information Law, and the rules of the Committee on Open Government.

§ 9950.2 Definitions

As used in this Part, the following words and terms shall have the indicated meanings:

(a) Statistical tabulation means a collection or orderly presentation of numerical data logically arranged in columns, rows or graphic representation. Opinions, policy options and recommendations do not constitute statistical tabulations.

(b) Factual tabulation means a collection of statements of objective information logically arranged and reflecting objective reality, actual existence or an actual occurrence. Opinions, policy options and recommendations do not constitute factual tabulations.

(c) Records access officer means the person designated as responsible for ensuring that the panel complies with provisions of the Freedom of Information Law and the regulations herein and coordinates the panel's response to requests for access to or copies of records.

(d) Records access appeals officer means the Executive Director, Elderly Pharmaceutical Insurance Coverage Panel, whose business address is: Empire State Plaza, Corning Tower, Albany, NY 12237.

(e) Record means any information kept, held, filed, produced or reproduced by, with or for the panel, in any physical form whatsoever, including but not limited to reports, statements, examinations, memoranda, opinions, folders, files, books, manuals, pamphlets, forms, papers, designs, drawings, maps, photos, letters, microfilms, computer tapes or discs, rules, regulations or codes.

(f) Trade secret means information which, if disclosed, would cause substantial injury to the competitive position of the subject enterprise.

(g) Panel means the Elderly Pharmaceutical Insurance Coverage Panel established by article 19-K of the Executive Law.

§ 9950.3 Times and places for inspecting records

(a) Records shall be available for inspection and copying by members of the public and members of the news media on every day that the offices of the panel are open for the transaction of business between the hours of 8:30 a.m. and 4:45 p.m.

(b) Records may be inspected at locations designated by the records access officer, whose title and business address are as set forth in section 9950.4 of this Part.

§ 9950.4 Persons from whom records may be obtained

All requests from the public, or members of the news media, to inspect and/or copy records subject to public disclosure as provided by this Part are to be made to the records access officer whose business address is: Empire State Plaza, Corning Tower, Albany, NY 12237.

§ 9950.5 Fees for copying records

(a) Fees for certification of copies and supplying transcripts of all documents and records under the seal of the panel shall be the fees as prescribed by applicable regulations of the panel.

(b) Fees for photocopies or data printouts of records available pursuant to this Part shall be 25 cents per page and $ 60 for transfer of computer files to a requestor's computer tape.

(c) Except where fees are established by law, rule or regulation, no fee shall be charged for:

(1) inspection of a record;

(2) record searches;

(3) certification pursuant to this Part; and

(4) publications of the panel provided free to residents of the State of New York.

(d) Fees shall be paid in full or a valid offer made to pay established fees prior to issuance of copies, transcripts or certification of records.

(e) Payment shall be made in the form of a check, bank draft or money order payable to the panel, or, if personally delivered, may be made in cash, for which a receipt shall be given.

§ 9950.6 Availability of panel records

(a) All records of the panel are available for public inspection and copying, except that access may be denied to re-cords or portions thereof that:

(1) are specifically exempted from disclosure by State or Federal statute;

(2) if disclosed would constitute an unwarranted invasion of personal privacy;

(i) an unwarranted invasion of personal privacy includes, but is not limited to:

(a) disclosure of employment, medical or credit histories or personal references of applicants for employment;

(b) disclosure of items involving the medical or personal records of an Elderly Pharmaceutical Insurance Coverage program participant;

(c) sale or release of lists, names and addresses if such lists would be used for commercial or fund-raising purposes;

(d) disclosure of information of a personal nature when disclosure would result in economic or personal hardship to the subject party and such information is not relevant to the work of the panel or the agency requesting it; or

(e) disclosure of information of a personal nature reported in confidence to the panel and not relevant to the ordi-nary work of the panel;

(ii) disclosure is not construed to constitute an unwarranted invasion of personal privacy when:

(a) identifying details are deleted;

(b) the person to whom a record pertains consents in writing to disclosure;

(c) upon presenting reasonable proof of identity, a person seeks access to records pertaining to him/her;

(3) if disclosed would impair present or imminent contract awards or collective bargaining negotiations;

(4) are trade secrets or are maintained for the regulation of commercial enterprise which, if disclosed, would cause substantial injury to the competitive position of the subject enterprise;

(5) are compiled for law enforcement purposes and which, if disclosed, would:

(i) interfere with law enforcement investigations or judicial proceedings;

(ii) deprive a person of a right to a fair trial or impartial adjudication;

(iii) identify a confidential source or disclose confidential information relating to a criminal investigation; or

(iv) reveal criminal investigative techniques or procedures, except routine techniques or procedures;

(6) if disclosed would endanger life or safety of any person;

(7) are inter-agency or intra-agency material which are not:

(i) statistical or factual tabulations or data;

(ii) instructions to staff that affect the public; or

(iii) final agency policy or determination; or

(8) are examination questions or answers which are requested prior to the final administration of such questions.

(b) Nothing in this Part shall permit disclosure which constitutes an unwarranted invasion of personal privacy, if such disclosure is prohibited under article 6-A (Personal Privacy Protection Law) of the Public Officers Law.

§ 9950.7 Procedures governing inspection and copying of records

Inspection and copying of records shall be made in the following manner:

(a) Records access requests must be reasonably described and in writing.

(b) The records access officer shall, within five business days after receipt of a request:

(1) make requested records available;

(2) deny the request in writing. Such denial should:

(i) explain the reason for the denial;

(ii) set forth the right of appeal to the records access appeals officer; and

(iii) provide the name, title, business address and telephone number of the records access appeals officer; or

(3) furnish written acknowledgment of the request and the approximate date when the request will be granted or denied.

(c) If access to records is neither granted nor denied within 10 business days after the date of acknowledgment of receipt of request, the request may be construed as a denial of access that may be appealed.

(d) If access is approved, the records access officer shall cause a search for the records requested.

(e) If the record cannot be found after diligent search, the records access officer shall so notify the requestor.

(f) Upon request, the records access officer will certify that the record is a true copy.

(g) Where applicable, nondisclosable information will be deleted from a record as authorized by the Freedom of In-formation Law.

(h) The original or file copies of records will not be released from panel files.

(i) Persons requesting records in the possession of the panel, but which records originated in any other State or Federal agency, shall be referred to the originating agency when there is a question concerning confidentiality requirements.

(j) Persons inspecting a record shall be allowed to copy it by any means which will not damage the record.

(k) A reasonably detailed current list of any records subject to the Freedom of Information Law, shall be maintained by the panel and updated semiannually.

(l) The locations where public records are available for inspection or copying pursuant to this Part shall be posted in conspicuous places.

§ 9950.8 Trade secrets

Documents which contain trade secrets or are maintained for the regulation of commercial enterprise which, if disclosed, would cause substantial injury to the competitive position of an enterprise may be withheld from public disclosure.

(a) Requests of exceptions from disclosure shall:

(1) be in writing to the records access officer;

(2) be submitted at the time the trade secret information is submitted;

(3) include the name, address and telephone number of the manufacturer, producer, formulator, employer or person desiring to register a trade secret;

(4) include the name and title of an individual who may be contacted concerning the request;

(5) include the name or other identification of the trade secret; and

(6) state reasons why the information should be excepted from disclosure.

(b) Information submitted as a trade secret is excepted from disclosure until 15 days after a determination regarding entitlement status has been finally determined or, when entitlement to an exception from disclosure has been granted, until such entitlement has expired, or until such further time as ordered by a court of competent jurisdiction.

(c) Documents pending or granted trade secret status will be assigned a control number by the records access officer.

(d) Panel units responsible for collecting trade secret information are responsible for determining trade secret entitlement and safeguarding the information during the review process and until trade secret entitlement no longer exists.

(e) Documents granted trade secret status or pending a trade secret status determination will be filed in envelopes with flaps, or other containers which will effectively maintain the integrity of the documents and which can be marked so as to clearly limit access to the contents. The container is to be marked with the following:

(1) "contains trade secrets";

(2) the trade secret control number;

(3) bureau identification; and

(4) "access to or use of contents only with bureau director authorization."

(f) Trade secrets are to be maintained apart from other documents in a locked file cabinet, locked desk drawer or other place secure from general access. Bureau directors assigned custody are responsible for establishing control of trade secret documents and establishing a system of limited access which identifies persons within the panel for whose inspection and study the record will be made available so as to prevent intentional or unintentional disclosure of the information.

(g) On the initiative of the panel at any time, or upon the request of any person for a record excepted from disclosure, the panel will:

(1) inform the person who requested the exception of the panel's intention to determine whether such exception should be granted or continued;

(2) permit the person who requested the exception, within 10 business days of receipt of notification from the panel, to submit a written statement of the need for continuation of such exception;

(3) within seven business days of receipt of such written statement, or within seven business days of the expiration of the period prescribed for submission of such statement, issue a written determination granting, continuing or terminating such exception and stating the reasons therefor; copies of such determination shall be served upon the person, if any, requesting the record, the person who requested the exception, and the Committee on Open Government.

(h) A denial of exception from disclosure or a denial of access to excepted information may, within seven business days of receipt of written notice of the denial, be appealed to the records access appeals officer. The appeal determination shall be made within 10 business days of the receipt of the appeal. A written notice of the determination shall be served upon the person, if any, requesting access, the person who requested exception and the Committee on Open Government. The notice shall contain a statement of the reasons for the determination.

§ 9950.9 Appeals of denial of access to records

(a) Except as provided for in section 9950.8 of this Part, any person who has been denied access to records by the re-cords access officer may appeal such denial in writing within 30 days to the records access appeals officer.

(b) The time for deciding on an appeal by the records access appeals officer shall commence upon receipt of the written appeal, which shall identify:

(1) the date and location of request for records;

(2) the records to which the requestor was denied access; and

(3) the name and return address of the requestor.

(c) The records access appeals officer shall, on receipt, forward a copy of the appeal to the Committee on Open Government and within 10 business days review the matter and affirm, modify or reverse the denial.

(d) If the records access appeals officer determines that the denial of access was erroneous, he/she shall instruct the records access officer to allow prompt inspection or copying of the record as requested.

(e) If the records access appeals officer affirms or modifies the denial, he/she shall communicate the determination and reasons in writing to the person making the appeal and inform such person of the right of judicial appeal with a copy to the Committee on Open Government.

§ 9951.1 Statement of purpose

The purpose of this Part is to set forth the methods and procedures governing the availability, location and nature of those records of the Elderly Pharmaceutical Insurance Coverage Panel

subject to the provisions of article 6-A of the Public Officers Law, known as the Personal Privacy Protection Law, and the rules of the Committee on Open Govern-ment.

§ 9951.2 Definitions

As used in this Part, the following words and terms shall have the indicated meanings:

(a) Data subject means any natural person about whom personal information has been collected by an agency.

(b) Personal information means any data concerning a data subject which, because of name, number, symbol, mark or other identifier, can be used to identify that data subject.

(c) Records access officer means the records access officer or his/her authorized representative and shall be the per-son from whom records may be obtained, as listed in section 9950.4 of this Subtitle.

(d) Records access appeals officer means the Executive Director, of the panel, whose business address is: Empire State Plaza, Corning Tower, Albany, NY 12237.

(e) Records means any item, collection or grouping of personal information about a data subject which is maintained and is retrievable by use of name or other identifier of the data subject. The term record shall not include personal information not used to make a determination about a data subject, such as:

(1) a telephone book or directory;

(2) a card catalog, book or other resource material in any library;

(3) a compilation of information containing names and addresses used exclusively for mailing agency information;

(4) personal information required by law to be maintained, and required by law to be used only for statistical re-search or reporting purposes;

(5) correspondence files; or

(6) information requested by the panel which is necessary to answer unsolicited requests by the data subject for in-formation.

(f) System of records means any group of records under the actual or constructive control of the panel pertaining to one or more data subject from which personal information is retrievable by use of the name or other identifier of a data subject.

(g) Panel means the Elderly Pharmaceutical Insurance Coverage Panel established by article 19-K of the Executive Law.

§ 9951.3 Times, places for inspecting records and means for verifying the identity of a data subject

(a) Records shall be available for inspection and copying by data subjects/authorized representatives on every day that the offices of the panel are open for the transaction of business between the hours of 8:30 a.m. and 4:45 p.m.

(b) Records may be inspected at locations designated by the appropriate records access officer, whose title and business address is as set forth in section 9950.4 of this Subtitle.

(c) The identity of a data subject who requests access to his/her record may require verification as follows:

(1) Prior to being given access to personal information, an individual may be required to provide reasonable verification of his/her identity. No verification of identity, however, shall be required of an individual seeking access to re-cords which are otherwise available to any member of the public under the Freedom of Information Law.

(2) In the case of an individual who seeks access or amendment in person, verification of identity will normally be made from those documents that an individual is likely to have readily available, such as an employee identification card, driver license, etc.

(3) When access or amendment is requested by mail, verification of identity may be obtained by requiring the individual to provide certain minimum identifying data, such as date of birth and some item of information in the record that only the concerned individual would likely know. If the sensitivity of the information in the record warrants, a signed and notarized statement of identity may be required.

§ 9951.4 Persons from whom records may be obtained

All requests to inspect and/or copy records subject to disclosure as provided by this Part are to be made to the records access officer.

§ 9951.5 Fees for copying records

(a) Fees for certification of copies and supplying transcripts of all documents and records under the seal of the panel shall be the fees as prescribed by the applicable regulations of the panel.

(b) Fees for photocopies or data printouts of records available pursuant to this Part shall be 25 cents per page or $ 60 for transfer of a computer file to a requestor's computer tape.

(c) Except where fees are established by law, rule or regulation, no fee shall be charged for:

(1) inspection of a record;

(2) record searches;

(3) certification pursuant to this Part; and

(4) amendment or correction of an agency record found to be in error.

(d) Fees shall be paid in full or a valid offer made to pay established fees prior to issuance of copies, transcripts or certification of records.

(e) Payment shall be made in the form of a check, bank draft, or money order payable to the panel, or if personally delivered, may be made in cash for which a receipt shall be given.

(f) Notwithstanding the above subdivisions of this section, when a data subject requests a copy of his/her record(s), the records access officer may, in his discretion, waive all or any part of the fees authorized by this section for any re-cord or class of records after considering the fiscal capability of the data subject to make payment for the fees required by this section.

§ 9951.6 Procedures governing inspection and copying of records

Inspection and copying of records shall be made in the following manner:

(a) Records access requests must be reasonably described and in writing.

(b) The records access officer shall, within five business days after receipt of a request:

(1) make requested records available;

(2) deny the request in writing. Such denial should:

(i) explain the reason for the denial;

(ii) set forth the right of appeal to the records access appeals officer; and

(iii) provide the name, title, business address and telephone number of the records access appeals officer;

(3) furnish written acknowledgment of the request and the approximate date when the request will be granted or denied, which date shall not exceed 30 days from the date of acknowledgment.

(c) If access is approved, the records access officer shall cause a search for the records requested.

(d) If the record cannot be found after diligent search, the records access officer shall so notify the requestor.

(e) Upon request, the records access officer will certify that the record is a true copy.

(f) The original or file copies will not be released from panel files.

(g) Persons requesting records in the possession of the panel but which records originated in any other State or Federal agency shall be referred to the originating agency when there is a question concerning confidentiality requirements.

(h) Persons inspecting a record shall be allowed to copy it by any means which will not damage the record.

(i) The locations where records are available for inspection or copying pursuant to this Part shall be posted in conspicuous places.

§ 9951.7 Appeals of denial of access to records

(a) Any person who has been denied access to records by the records access officer may appeal such denial in writing within 30 business days to the records access appeals officer.

(b) The time for deciding on an appeal by the records access appeals officer shall commence upon receipt of the written appeal, which shall identify:

(1) the date and location of request for records;

(2) the records to which the requestor was denied access; and

(3) the name and return address of the requestor.

(c) The records access appeals officer shall, within seven business days of the receipt of a written appeal, review the matter and affirm, modify or reverse the denial.

(d) If the records access appeals officer determines that the denial of access was erroneous, he/she shall instruct the records access officer to allow prompt inspection or copying of the record as requested.

(e) If the records access appeals officer affirms or modifies the denial, he/she shall communicate the reasons in writing by either first class mail or certified mail, return receipt requested, to the person making the appeal and inform such person of the right of judicial appeal.

(f) The records access appeals officer shall immediately forward to the Committee on Open Government a copy of such appeal and the determination thereon.

§ 9951.8 Procedures governing the correction or amendment of records

The correction or amendment of records shall be made in the following manner:

(a) Records to be corrected or amended shall be reasonably described and must be made in writing.

(b) The records access officer shall, within 30 business days after receipt of a request:

(1) make requested correction or amendment in whole or part and advise the individual that, upon request, parties to which such data has been disclosed will be advised if such data was disclosed in accordance with section 94(3)(c) of the Public Officers Law;

(2) deny the request in writing. Such denial should:

(i) explain the reason for the denial;

(ii) set forth the right of appeal to the records access appeals officer; and

(iii) provide the name, title, business address and telephone number of the records access appeals officer.

§ 9951.9 Appeals of denial of correction or amendment of records

(a) Any person who has been denied correction or amendment of records by the records access officer may appeal such denial in writing within 30 business days to the records access appeals officer.

(b) The time for deciding on an appeal by the records access appeals officer shall commence upon receipt of the written appeal, which shall identify:

(1) the date and location of request for records;

(2) the records to which the requestor was denied correction or amendment to and the requestor's justification for correction; and

(3) the name and return address of the requestor.

(c) The records access appeals officer shall, within 30 business days of the receipt of a written appeal, review the matter and affirm, modify or reverse the denial.

(d) If the records access appeals officer determines that the denial was erroneous, he/she shall instruct the records access officer to allow correction or amendment of the record as requested and notify appropriate parties, if requested, by the requestor.

(e) If the records access appeals officer affirms or modifies the denial, he/she shall communicate the reasons in writing by either first class mail or certified mail, return receipt requested, to the person making the appeal and inform such person of the right of judicial appeal. In addition, the records access appeals officer will notify the requestor of his/her right to file with the agency a statement of reasons for disagreement with the agency's determination. This agency will note any portions of the record which are disputed and attach requestor's statement as part of the record. Upon an individual's request, such statement will be provided to parties to which such data have been disclosed in accordance with section 94(3)(c) of the Public Officers Law together, if appropriate, with a concise statement of the agency's reasons for not making the requested amendment.

(f) The records access appeals officer shall immediately forward to the Committee on Open Government a copy of such appeal and the determination thereon.

§ 9960.1 Covered drug

(a) Definitions. For purposes of this Part, the following terms shall have the following meanings:

(1) Department means the New York State Department of Health.

(2) Commissioner means the New York State Commissioner of Health.

(3) EPIC means the Elderly Pharmaceutical Insurance Coverage Program established pursuant to section 19K* of the Executive Law.

(4) Eligible participant means a person deemed eligible to receive benefits coverage under EPIC.

(5) Licensed physician means a legally authorized prescriber of drugs.

(6) Excluded drug means any drug package, dosage form or administration deemed to be excluded as a covered benefit under EPIC pursuant to section 9960.3 of this Part.

(7) Drug Application Information form means a form developed by the department for the purpose of collecting in-formation from licensed physicians and used by the department in determining coverage of excluded drugs under EPIC.

(8) Contractor means the private, not-for-profit, or proprietary corporation which has entered into a contract with EPIC to assist in carrying out the provisions of EPIC.

(b) To be eligible for an insurance benefit, a prescription drug shall be dispensed subject to a legally authorized prescription from a registered pharmacy.

(c) Insulin, insulin syringes and insulin needles shall qualify as a covered drug benefit.

(d) Dispensing of a covered drug shall be in quantities ordered by the prescriber not to exceed a 30-day supply or 100 doses, whichever is greater.

(e) A covered drug shall not include any drug product:

(1) (i) where the Federal Food and Drug Administration (FDA) of the Federal Department of Health and Human Services (HHS) has issued any notice of a proposed order indicating that there is a lack of substantial evidence that such drug product will have the effect it purports or is represented to have under the conditions of use

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* So in original. "section 19K" s.b. "article 19-K"

prescribed, recommended or suggested in its labeling until the secretary of HHS withdraws such order; or

(ii) which the FDA determines to be identical, related, or similar to the drug product identified in subparagraph (i) of this paragraph until such time as the secretary of HHS withdraws the order identified in subparagraph (i) of this paragraph.

(2) marketed by a company without FDA approval where the FDA finds its approval is required;

(3) which is generally available without a physician's prescription, including vitamins, except for insulin;

(4) properly administered only by a physician, dentist or podiatrist as indicated in the official labeling of such drug product;

(5) generally available free of charge to eligible participants;

(6) marketed as a therapeutic agent with official labeling which states that the product is contraindicated by virtue of age or therapeutic condition for program participants;

(7) any device for the aid or correction of vision; or

(8) for which a pharmaceutically and therapeutically equivalent drug is available in a less expensive package, or form of dosage or administration as identified and determined according to specified procedures delineated in section 9960.3 of this Part. .SO EFF 01/05 T14B

§ 9960.2 Process for allowing coverage of excluded drugs

(a) Request for coverage.

(1) Any drug package, or form of dosage or administration excluded from coverage as a benefit under EPIC pursuant to section 9960.3 of this Part may be allowed to be dispensed to a specific eligible participant based upon a written request for coverage by a licensed physician and a legal prescription.

(2) Each request for coverage shall be supported by a written certification and specific reasons why an excluded drug package or form of dosage or administration is considered by a licensed physician to be medically indicated for treatment of a specific patient.

(3) Requests for coverage pursuant to paragraph (1) of this subdivision shall be made only by a licensed physician treating an eligible participant for whom such excluded drug benefit is considered to be medically indicated.

(4) All requests for coverage of an excluded drug benefit shall be supported by information submitted by a physician on a Drug Application Information form and submitted to the department. Telephone requests may be made to the department; however, all such telephone requests for information shall be followed by submission of the required information on a completed Drug Application Information form to facilitate proper review and disposition of each re-quest.

(b) Drug Application Information form.

(1) Information to support a certification by a licensed physician as to the medical indication for treating an eligible participant with a drug considered to be an excluded drug shall be contained on a Drug Application Information form. Such information shall include the following:

(i) name of drug, dosage form, strength and name of marketer;

(ii) name and identification number of participant;

(iii) length of time physician has treated the participant;

(iv) name of illness/disease/condition being treated;

(v) length of time participant has been taking the drug requested;

(vi) list of other medications used to treat the participant;

(vii) specific reasons why requested drug is medically indicated;

(viii) medical consequences if excluded drug is not provided as a covered drug benefit;

(ix) identification and signature of the licensed physician treating the participant.

(2) Copies of the Drug Application Information form shall be made available by the department, or from local county offices for the aging or health departments, or the EPIC executive director or EPIC contractor.

(c) Decisions on coverage.

(1) Upon receipt of a completed Drug Application Information form submitted by a licensed physician, the department shall review the request and render a decision within three working days. Failure to render a decision within this time period shall not constitute approval by the department.

(2) Written notice of the decision shall be sent by the department to the licensed physician who requested coverage of an excluded drug for a particular eligible participant within seven working days following such decision. Similar written notice shall also be provided to the EPIC contractor by the EPIC executive director and to the participant to

in-form such person of his individual rights to be reimbursed for an excluded drug which is determined to be included as a covered benefit.

§ 9960.3 Procedures for determinations relating to package, dosage form or form of administration

For purposes of designating a given package, dosage form or form of administration as excluded from coverage, the following shall apply:

(a) An initial determination based upon information and facts available, shall be made by the department utilizing such considerations as:

(1) the availability of low-cost alternative packaging, dosage form or forms of administration;

(2) any particular health needs of the EPIC population;

(3) the degree to which the packaging, dosage form or form of administration offers comfort, convenience or ease of administration at added cost;

(4) availability of pharmaceutically equivalent and therapeutically equivalent products for the covered population;

(5) any drug marketed as a therapeutic agent with official labeling which states that the product is contraindicated by virtue of age or therapeutic condition for program participants; or

(6) recommendations of the Technical Pharmacy Advisory Committee of the department, where appropriate, as to current pharmacy practice and drug marketing principles.

(b) The department shall notify the manufacturer(s) in writing of its intent to exclude a specific drug's packaging, dosage form or form of administration giving the reasons for the intended exclusion, together with the facts upon which the initial determination is based.

(c) The manufacturer(s) shall then have 15 days following receipt of notice of initial determination to notify the department in writing of intent to appeal the initial determination.

(1) Failure on the part of the manufacturer(s) to so notify the department of its intent to appeal within the 15 days, allows for immediate final determination to be made by the commissioner.

(2) If the manufacturer notifies the department of an intent to appeal, the manufacturer shall submit to the department, within 45 days of receiving the initial determination, all the information and documentation which forms the basis of the manufacturer's appeal.

(d) (1) The department, within 15 days of receiving the manufacturer's basis for appeal, shall provide to the manufacturer any additional facts concerning the intent to exclude a drug product to support the initial determination.

(2) Within 10 days of receiving such additional facts, the manufacturer may submit to the department additional facts relevant to the drug package, or form of dosage or administration.

(3) Based upon all of the facts and information gathered and submitted, the commissioner shall make a final determination as to whether to designate a package, dosage form or form of administration, and exclude drug from program benefits coverage.

(4) As final determinations of excluded drugs relating to package, dosage form or form of administration are made by the commissioner pursuant to this subdivision, written notice of such determinations shall be made to the EPIC con-tractor by the EPIC executive director and to the drug manufacturer of such drug product.