

STATE OF RHODE ISLAND

Department of Elderly Affairs
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Rules and Regulations Governing

THE PHARMACEUTICAL ASSISTANCE TO THE ELDERLY PROGRAM



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STATE OF RHODE ISLAND
DEPARTMENT OF ELDERLY AFFAIRS
RULES & REGULATIONS
GOVERNING

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SECTION I

Program Authority

The RI Pharmaceutical Assistance to the Elderly Program (RIPAE) is authorized by, and these regulations are promulgated under, the authority of Title 42 of the General Laws of the State of Rhode Island, Chapter 66.2, "An Act Providing Pharmaceutical Assistance to the Elderly".

SECTION II

Definitions

For the purpose of these Rules & Regulations, the following words shall have the following meaning:

1. Consumer
Means any full time resident of the State of Rhode Island who fulfills the eligibility requirements set forth in Chapter 44-66.2 of the General Laws and Section V of these Rules & Regulations.
2. Contractor
Means a third party or private vendor capable of administering a program of reimbursement for prescription drugs, and drug program eligibility administrative support as required by the director, such vendor to be determined through a competitive bid process in which the director awards a three (3) year contract for services.
3. Pilot Program Contractor
Means Blue Cross and Blue Shield of Rhode Island.
4. Delegate Agency
Means any local community based agency with which the Department of Elderly Affairs negotiates a contract for assistance in the implementation of the RIPAE Program.
5. Department
Means the Department of Elderly Affairs.
6. Director
Means the Director of the Department of Elderly Affairs.
7. Drugs

A. Eligible Drugs

Means insulin and non-injectable drugs which:

- require a physician's prescription according to federal law, and
- are contained in the following American hospital formulary service pharmacologic therapeutic classifications categories that have not been determined by the federal "drug efficacy and safety implementation (DESI) commission" to lack substantial evidence of effectiveness.

Classification Categories:

anticoagulants
anti-diabetic agents
Anti-infectives
antilipemic drugs
cardiac drugs
disposable insulin syringes vasodilators (cardiac indications only)
diuretics
drugs approved for the treatment of Alzheimer's disease
drugs for the treatment of Arthritis
drugs for the treatment of asthma and other respiratory diseases
drugs for the treatment of depression
drugs for the treatment of glaucoma
drugs for the treatment of osteoporosis
drugs for the treatment of Parkinson's disease
drugs for the treatment of urinary incontinence
hemorrhologic agents
hypotensive drugs
insulin
oral antineoplastic drugs
prescription vitamin and mineral supplements for renal patients

B. Additional Drugs

Means non-injectable drugs which require a physician's prescription according to federal law and which are contained in the American Hospital Formulary Service pharmacologic-therapeutic classifications categories that have not been determined by the federal "drug efficacy and safety implementation (DESI) commission" to lack substantial evidence of effectiveness, which are not included in the definition of A. Eligible Drugs listed above. However, this shall not include prescription drugs used for cosmetic purposes.

8. Full-time Resident

Means any resident of the State of Rhode Island who fulfills the residency requirements set forth in 17-1-3 I of the General Laws, "Residence for voting purposes". A person's residence for voting purposes is his/her fixed and established domicile. The determinant of one's domicile is that person's factual physical presence in the voting district on a regular basis incorporating an intention to reside for an indefinite period. The domicile is the place to which, upon temporary absence, he/she has the intention of returning. Once acquired, this domicile continues until another such domicile is established. A person can have only one (1) such domicile.

9. Income

Means the sum of federal adjusted gross income as defined in the internal revenue code of the United States, and all non-taxable income including, but not limited to:

- the amount of capital gains excluded from adjusted gross income;
- support money;
- alimony;
- non-taxable strike benefits;
- cash public assistance and relief not including relief granted under this chapter;
- the gross amount of any pension or annuity (including railroad retirement act benefits, all payments received under the federal social security act, state unemployment insurance laws, and veterans disability pensions);
- non-taxable interest received from the federal government or any of its instrumentalities;
- workers compensation;
- the gross amount of "loss of time" insurance.

Income does not include:

- gifts from non-governmental sources,
- surplus foods,
- other relief in kind supplied by a public or private agency,
- sums of money expended for medical and pharmaceutical that exceed three percent (3%) of applicant's annual income or three percent (3%) of applicant's preceding ninety (90) day income computed on an annual basis.

10. Participating Pharmacy

Means any pharmacy licensed in the State of Rhode Island which has a written agreement with the contractor agreeing to the conditions and requirements of participation in the RIPAE Program.

11. Pharmacy

Means a pharmacy licensed by the State of Rhode Island and whose place of business is physically located within the State of Rhode Island.

12. Pharmaceutical Manufacturer

Means any entity holding legal title to or possession of a national drug code number issued by the federal food & drug administration.

SECTION III

Contract

The director shall enter into a contract with the contractor for the effective administrative support of this program.

The contractor shall serve as the link between the RIPAE Program and participating pharmacies. All payments to pharmacies shall be made by the contractor and the contractor shall be responsible for compliance of participating pharmacies with RI Law, Chapter 42, Section 66.2, and Section XI of these Rules and Regulations. The pilot program contractor shall, under terms agreed to by the director, continue administrative support of the program until a competitive bid process can be

implemented and a three (3) year contract awarded. The director shall initiate said competitive bid process by the issuance and advertisement of specifications and request for proposals, on or before January 1, 1988. The contract resulting from said competitive bid process shall be awarded to become effective for a three (3) year period commencing no later than July 1, 1988. A competitive bid and contract award shall occur every three (3) years thereafter.

SECTION IV

Consumer Eligibility

Eligibility shall be determined by the department and its delegate agencies. In order to be eligible to participate in the RIPAE Program, consumers must meet all of the following criteria:

1. Participants must be 65 years of age or older at the time of application or between the ages of 55-65 receiving Social Security Disability Benefits.
2. Participants must be full time residents of the State of Rhode Island at the time of application. Full time residence shall be determined consistent with Section 17-1-3.1 of the General Laws of the State of RI, " Residence for voting purposes" (refer to definition of full time resident).
3. Participants must be determined by the department or its delegate agencies to meet the following income criteria:
 - a) Unmarried or married living separate & apart -Income for the calendar year immediately preceding the year in which assistance is sought cannot exceed **\$37,167**. Eligibility may also be determined by using income data for the (90) ninety days prior to application for benefits and projecting that income on an annual basis.
 - b) Married - Income for the calendar year immediately preceding the year, in which assistance is sought, when combined with any income of such person's spouse in the same year, cannot exceed **\$42,476**.
 - c) Eligibility may also be determined by using income data for the ninety (90) days prior to application for benefits and projecting that income on an annual basis.
 - c) Except that, on July first of each year commencing in 1991, the maximum amount of allowable income for both unmarried and married residents shall be increased by a percentage equal to the percentage of the cost of living adjustment provided for social security recipients.
 - d) Income levels shall not include those sums of money expended for medical and pharmaceutical expenses that exceed three percent (3%) of applicant's annual income or three percent (3%) of applicant's preceding ninety (90) day income computed on an annual basis.
4. No person whose prescription drug expenses are paid or reimbursable, either in whole or in part, by any other plan of assistance or insurance shall be eligible for assistance under this section until the person's prescription drug coverage is exhausted during a benefit year.

However, the fact that some of a person's prescription drug expenses are paid or reimbursable under the provisions of Medicare, Part B, shall not disqualify said person, if he or she is otherwise eligible to receive assistance. In such cases, the state shall pay either 100%, 60%, 30%,15% or 0% of the cost of those prescriptions for qualified drugs for which no payment or reimbursement is made by the Federal Government.

The Department of Elderly Affairs shall utilize an application form, which shall serve as the primary vehicle for determination of program eligibility. This form may include but not be limited to:

- pertinent demographic information;
- residence;
- date of birth;
- annual income for the previous calendar year, including amount and source of income (such income information must be supplied for applicant and spouse when applicant is married);
- social security number;
- all other data essential for the determination of eligibility and the maintenance client statistics;
- certification through signature of the applicant that permission is granted to DEA to verify any and all information supplied on the application form as well as certification through signature that the applicant will supply to DEA, upon request, written documentation of all information included on the application form.

Such application form shall be made available at the Department of Elderly Affairs and its delegate agencies.

DEA may verify eligibility information in one or more of the following ways:

- review and certification of eligibility by trained staff for each application file with DEA or its delegate agencies;
- computer cross checks with available data banks to verify eligibility;
- personal interviews to review documentation for age, residence and previous year's annual income or income for ninety (90) days prior to application for benefits.

Notification shall be made to each applicant of eligibility/ineligibility within 30 days of receipt of application by DEA or its delegate agencies. Notification shall be an identification card for those determined eligible. Notification of ineligibility shall be in writing and shall detail the reason the application was denied, and the process for appeal of this decision (refer to Section XIV - Appeals Procedures). Names and pertinent information for each eligible participant shall be supplied to the contractor. Benefits shall be paid only for those persons determined eligible by DEA under these Rules & Regulations.

The following documentation shall be accepted as verification of age/residence/income under the RIPAE Program:

One of the following

Age:

- RI Driver's License
- Birth Certificate
- RIPTA I.D.
- Health Insurance Card
- DEA I.D. Card

One of the following

Residence:

- the address furnished to the Registry of Motor Vehicles for the applicant's license;
- the address at which the applicant's motor vehicle is registered;
- the address at which the applicant filed his last federal and/or state income tax form;
- the address furnished to the companies from which the applicant has obtained retail credit cards;
- the address furnished to the financial institutions where the applicant maintains accounts;
- the address furnished to the tax collector and/or assessor in those communities where the applicant owns taxable real or personal property;
- the address furnished to the insurance companies with which the applicant maintains policies;
- the address furnished to the applicant's employer;
- the address furnished by the applicant to any business, professional, union, or fraternal organizations of which he/she is a member;
- the address furnished to governmental agencies with which the applicant has contact;
- the address of a hospital, convalescent home, or like facility at which the applicant has been a patient or resident for the preceding thirty (30) days or longer.

A combination of the following sufficient to document all income included in the definition of such under the RIPAE Program

Income:

- for previous calendar year federal income tax return;
- Employment Income: W-2 Form, pay stubs with year to date total, letter from employer indicating length of employment and wages for previous calendar year;
- TDI/Worker's Compensation: an award letter or copies of checks;
- Unemployment benefits: a stamped unemployment book or copy of check;
- Alimony or Support: a court decree or other documentation;

- Pension Benefits: (Social Security, Veterans Benefits, SSI, etc.) an award letter or, after determining date of initial award, copy of most recent check or written verification from income source;
- AFDC/GPA: a letter from the Department of Human Services detailing income from the previous calendar year or a listing of such supplied by DHS;
- Interest Income: savings statements, passbook, letter from savings institution, W-1099 or W-9 interest form;
- Rental Income: rent receipts, lease agreements ;
- Self Employment income: all receipts, bills, invoices and other documents establishing income and expenses of operations;
- any listing or verification from an agency or organization for one of the above shall constitute acceptable documentation of income.

Income Disregards:

- gifts from non-governmental sources;
- the value of surplus foods;
- benefits excluded from income by federal or state law, i.e. stipends received by Senior Companions under the Domestic Volunteer Service Act of 1973 as amended;
- benefits received under the Low Income Energy Assistance Program;
- other relief in kind supplied by a public or private agency;
- sums of money expended for medical and pharmaceutical that exceed three percent (3%) of applicant's annual income or, if ninety (90) days income data is used for eligibility purposes, three percent (3%) of applicant's preceding ninety (90) day income computed on annual basis.

SECTION V

Duration of Eligibility

Consumers whose eligibility has been established as described in Section IV shall remain eligible for a period determined by DEA, or until the following, whichever occurs first:

1. The consumer moves out of Rhode Island and is no longer a full time resident;
2. If the consumer's prescription drug expenses are paid or reimbursable, either in whole or in part, by any other plan of assistance or insurance, the consumer shall not be eligible for assistance under this section until the consumer's other prescription drug coverage is exhausted during a benefit year.
3. DEA conducts a recertification of consumer eligibility and determines the consumer to be ineligible.

SECTION VI

Eligibility Card

An eligibility card will be issued to each consumer eligible for the RIPAE Program. Each consumer must present this card at a participating pharmacy. Each card will include an individual identification number, group number and an expiration date.

An eligibility card may only be used for the person to whom it was issued. Any deliberate attempt to utilize a RIPAE eligibility card to obtain benefits for an individual other than the individual to whom the card was issued shall constitute fraud (refer to Section XV).

The contractor shall replace lost or destroyed eligibility cards. A replacement card shall be supplied to a consumer as soon as possible. Consumers may be provided with a letter signed by the director verifying eligibility until such time as a lost or destroyed card is replaced.

SECTION VII

Eligible Drugs

Eligible drugs shall mean only those drugs as defined in these Rules & Regulations (Section II - Definitions] and in Chapter 42-66.2 of the General Laws, State of Rhode Island. The contractor shall supply to all participating pharmacies and to DEA a periodically updated list of eligible drugs.

Additional Drugs

Additional drugs shall mean only those drugs as defined in these Rules & Regulations (Section II - Definitions] and in Chapter 42-66.2 of the General Laws, State of Rhode Island. The contractor shall supply to all participating pharmacies and to DEA a periodically updated list of additional drugs.

No payment shall be made under this program to a participating pharmacy for any drug not included on the contractor's list of eligible drugs.

Excluded Drugs

Experimental drugs are to be excluded from this program.

A system of mail order delivery for prescriptions shall be prohibited under this program.

SECTION VIII

Program Benefits

The RIPAE Program shall pay the appropriate percentage of the cost of Eligible drugs for eligible consumers, 65 years or older which are dispensed within one year of the original prescription order. The percentage of cost RIPAE pays is based on the annual income of the eligible RIPAE member, 65 years old or older, as outlined in the following chart.

ANNUAL INCOME		
Single Person	Married Couple	RIPAE Pays
\$0.00 - \$16,919	\$0.00 - \$21,149	60% (100% after \$1,500 in RIPAE member, 65 years or older, co-payments for eligible drugs only)
\$16,920- \$21,238	\$21,150- \$26,548	30%
\$21,239- \$37,167	\$26,549- \$42,476	15%

Effective July 1, 2001, RIPAE members that pay \$1,500 in RIPAE co-payments for Eligible drugs only during a state fiscal year, will be eligible to have RIPAE pay 100% of the cost for RIPAE covered prescriptions for Eligible drugs only for the remainder of that fiscal year. This benefit is only available to RIPAE members 65 or older in the lowest income group.

Prescription benefits for any single prescription may be dispensed in the amounts authorized by the physician, and agreed to by the consumer, up to a maximum of a one hundred (100) day supply or two hundred (200) doses, whichever is less and/or a one hundred (100) day supply or one (1) quart of liquid, whichever is less. Provided, however, that disposable insulin syringes shall be dispersed in a quantity of one hundred (100).

Participants in the RIPAE Program are not required to maintain records of each transaction but shall sign a receipt for eligible drugs.

SECTION IX

Payments to Participating Pharmacies

The RIPAE Program shall pay the appropriate percentage of the maximum allowable amount per prescription as formulated in the contract, as of the date of purchase of the drug, between the contractor and participating pharmacies.

SECTION X

Financial Participation by Consumer

RIPAE Program participants, 65 years old or older, shall pay either 0%, 40%, 70% or ,85%,as determined by their income, of the cost of Eligible drugs (after senior citizen discounts and coupons). This co-payment shall be required at the time the prescription is filled and shall be collected by the participating pharmacy. Effective July 1, 2001, RIPAE members that pay \$1,500 in RIPAE co-payments for Eligible drugs during a state fiscal year, will be eligible to have RIPAE pay 100% of the cost for RIPAE covered Eligible drugs for the remainder of that fiscal year. This benefit is only available to RIPAE members ,65 years old or older, in the lowest income group.

ANNUAL INCOME		
Single Person	Married Couple	RIPAE Member 65+ pays
\$0.00 - \$16,919	\$0.00 - \$21,149	40% (0% after \$1,500 in RIPAE member eligible drug co-payments)
\$16,920- \$21,238	\$21,150- \$26,548	70%
\$21,239- \$37,167	\$26,549- \$42,476	85%

RIPAE participants 65 or older shall pay 100% of the RIPAE discount price for Additional drugs. Additional drugs shall mean only those drugs as defined in these Rules & Regulations (Section II - Definitions] and in Chapter 42-66.2 of the General Laws, State of Rhode Island.

RIPAE participants between 55-65 of age and receiving Social Security Disability benefits (SSDI) shall pay 100% of the RIPAE discount price for both Eligible and Additional Drugs. Eligible and Additional drugs shall mean only those drugs as defined in these Rules & Regulations (Section II - Definitions] and in Chapter 42-66.2 of the General Laws, State of Rhode Island.

SECTION XI

Program Prohibitions

The following shall be prohibited under the RIPAE Program:

1. a system of rebates or reimbursements to the consumer for pharmaceutical expenses is prohibited;
2. experimental drugs are prohibited from this program;
3. a system of mail order delivery for prescriptions is prohibited under this program.

Violation of any of the above shall constitute fraud and shall be handled in accordance with Section XV of these Rules and Regulations.

SECTION XII

Reporting Requirements

The director shall submit an annual report to the following:

- the Governor,
- the Budget Officer,
- the Chairperson of the House Finance Committee,
- the Chairperson of the Senate Finance Committee,
- the Chairperson of the Board of Pharmacy as established by 5-19-2.

This report shall contain at least the following:

- number of consumers eligible for the RIPAE Program,
- the number of consumers utilizing the program,
- an outline of and a report on the educational and outreach program,

- the number of appeals,
- an outline of problems encountered in the administration of the program and suggested solution to the same and any recommendations to enhance the program.

The contractor shall submit an annual report to the following:

- the Governor,
- the Budget Officer,
- the Chairperson of the House Finance Committee,
- the Chairperson of the Senate Finance Committee,
- the Chairperson of the Board of Pharmacy as established by 5-19-2.

This report shall contain at least the following:

- financial and utilization statistics as to drug use by therapeutic category,
- actuarial projections,
- an outline of problems encountered in the administration of the program and suggested solutions to the same and any recommendations to enhance the program.

The first reports by the director and the contractor shall be submitted on or before January 15, 1986.

SECTION XIII

Educational Outreach Program

The Department of Elderly Affairs will institute and conduct an educational outreach program and will provide a mechanism, within the department, to handle all public inquiries concerning the program.

SECTION XIV

Appeals Procedure

Any person whose application for assistance under RIPAE is denied shall have the right to appeal such a decision. Such appeals shall follow the procedures listed below.

a) Notice of Denial

1. Applicants shall receive written notice that the application for RIPAE has been denied. Such notice shall be provided by DEA on a standard denial form developed by DEA. This notice will be provided as soon after receipt of the application as possible, but not more than 30 days after receipt of the application.

This notice shall include:

- the reason (s) for denial and
- the procedure for appeal.

b) Procedure for Appeal

1. Applicants shall contact the DEA Hearing Officer to request an appeal. The DEA Hearing officer shall be a DEA administrative employee who is not responsible for administration of the RIPAE Program.
2. A hearing shall be scheduled to take place as soon as possible but not longer than 14 days after the request for the hearing.
3. The applicant must contact the department within 90 days of the date of the denial letter from DEA. No hearing shall be granted upon a request more than 90 days from the date of the denial letter. However, an applicant may apply or reapply at any time at the appropriate agency.
4. Written notice of the hearing shall be supplied to the applicant and shall include:
 - a) a statement of the time, place, and nature of the hearing;
 - b) a statement of the legal authority and jurisdiction under which the hearing is to be held;
 - c) a reference to the particular sections of the statutes and rules involved; and
 - d) a short and plain statement of the issues involved.
5. The applicant shall have the right to bring with him/her any person or any documentation pertinent to the issues involved. The applicant must supply documentation at the time of the hearing for age, residence, and income.
6. The DEA Hearing Officer shall maintain a record of the hearing including the following:
 - a) evidence received or considered;
 - b) statement of matters officially noted;
 - c) questions and offers of proof and rulings;
 - d) findings and exceptions;
 - e) the decision by the Hearing Officer; and
 - f) all memoranda or data submitted to the Hearing Officer presiding at the hearing.
7. Oral proceedings or any part thereof shall be transcribed on request of any party.
8. Findings of fact shall be exclusively on the evidence and matters officially noted.

SECTION XV

Fraud & Abuse

The department shall declare ineligible any consumer who abuses or misuses the RIPAE Program. The department is empowered to investigate cases of suspected provider or consumer fraud. Delegate agencies and participating pharmacies shall report to DEA any suspected incident of fraud or abuse. Such reports shall be made to the director or his/her designee.

Fraud & Abuse shall include but not be limited to:

1. falsification of information on the application for assistance;
2. use or attempted use of an eligibility card by an unauthorized individual;
3. rebates or reimbursements to consumers for pharmaceutical expenses;

4. falsification of information by a participating pharmacy;
5. consumer attempt to obtain benefits under the RIPAE Program while eligible for another private, state or federal program which pays all or part of prescription drug costs if the consumer knowingly has not exhausted these benefits during a benefit year;
6. consumer or provider claims for duplicative benefits;
7. any violation or attempt to violate the provisions of RI Law, Chapter 42-66.2 or these Rules and Regulations.

Individuals attempting fraud or abuse and individuals who aid or abet another in attempting fraud or abuse shall be subject to imprisonment for a term of not more than one (1) year or a fine of not less than five hundred dollars (\$500) or both. DEA shall investigate all reports of fraud and abuse, and shall refer all pertinent findings to the Office of the Attorney General.

Any provider or consumer found guilty of intentionally violating the provisions of these Rules and Regulations shall be subject to immediate termination from this program for a period of no less than one (1) year. Notice of such termination shall be in writing and will not carry with it the right for appeal. Any provider or consumer who is found guilty under this Act is subject to repay three (3) times the value of the material gain he or she received.

SECTION XVI

Pharmaceutical Manufacturer Drug Rebates

On and after March 1, 1992, the director shall enter into prescription drug rebate agreements with individual pharmaceutical manufacturers under which the department shall receive a rebate from the pharmaceutical manufacturer equal to the basic rebate supplied by the manufacturer under section 1927 of Title XIX of the Social Security Act for every prescription drug dispensed under the program. Each such agreement shall provide that the pharmaceutical manufactures shall make quarterly rebate payments to the department equal to the basic rebate supplied by the manufacturer under section 1927 of Title XIX of the Social Security Act for the total number of dosage units of each form and strength of a prescription drug which the department reports as reimbursed to providers of prescription drugs, provided such payments shall not be due until thirty (30) days following the manufacturer's receipt of utilization data from the department including the number of dosage units reimbursed to providers of prescription drugs during the quarter for which payment is due.

Upon receipt of such data from the department, the pharmaceutical manufacturer shall calculate the quarterly payment. The department may, at its expense, hire a mutually agreed upon independent auditor to verify the calculation and payment. In the event that a discrepancy is discovered between the pharmaceutical manufacturer's calculation and the independent auditor's calculation, the pharmaceutical manufacturer shall justify its calculations or make payment to the department for any additional amount due.

The pharmaceutical manufacturer may, at its expense, hire a mutually agreed upon independent auditor to verify the accuracy of the utilization data provided by the department. In the event that a discrepancy is discovered, the department shall justify its data or refund any excess payment to the

pharmaceutical manufacturer. The department may, at its expense, establish a grievance adjudication procedure which provides for independent review of manufacturer documentation substantiating the basic rebate amount per unit delivered under section 1927 of Title XIX of the Social Security Act. In the event that a discrepancy is discovered, the department shall justify its data or refund any excess payment to the pharmaceutical manufacturer.

All prescription drugs of a pharmaceutical manufacturer that enters into an agreement pursuant to Section XVI of these Rules and Regulations shall be immediately available and the cost of such drugs shall be reimbursed and not subject to any restrictions or prior authorization requirements. Any prescription drug of a manufacturer that does not enter into such an agreement shall not be reimbursable, unless the department determines the eligible prescription drug is essential to program participants.