

**STATE OF RHODE ISLAND
DEPARTMENT OF HUMAN SERVICES
DIVISION OF ELDERLY AFFAIRS**

PUBLIC NOTICE OF PROPOSED RULE-MAKING

In accordance Rhode Island General Laws (RIGL) 42-35, notice is hereby given that the Department of Human Services Division of Elderly Affairs proposes to amend the following rule:

RULES, REGULATIONS AND STANDARDS GOVERNING THE PHARMACEUTICAL ASSISTANCE TO THE ELDERLY PROGRAM

Proposed rule making to the RIPAE rules are being initiated to support changes made in response to the adoption of the federal Affordable Care Act.

In the development of this rule, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach or duplication or overlap was identified based upon available information.

These proposed rules are accessible on the R.I. Secretary of State website (<http://www.sec.state.ri.us/ProposedRules/>) and the DHS website (www.dhs.ri.gov) or available in hard copy upon request (401 462-2018 or RI Relay, dial 711). **A public hearing will be held to consider the proposed rule adoption on Thursday, November 1, 2012 at 1:00 PM at the Arnold Conference Center located in the Eleanor Slater Hospital, 111 Howard Ave. Cranston, RI 02920.** Persons wishing to testify may do so by signing up at the Hearing or by submitting written testimony by **Friday, November 2, 2012** to Kimberly Merolla-Brito, Office of Policy Development, RI Department of Human Services, Louis Pasteur Building, 57 Howard Avenue Fl # 1, Cranston, RI 02920.

The Hearing will begin at 1:00 P.M. and will conclude when the last speaker finishes testimony or at 3:00 P.M., whichever occurs first. The seating capacity of the Arnold Conference Center will be enforced and therefore the number of persons participating in the Hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.

The Arnold Conference Center is accessible to the handicapped. Individuals with hearing impairments may request an interpreter's presence by calling 711 or Relay RI 1-800-745-6575 (Voice) and 1-800-745-555 (TDD). Requests for this service must be made at least 72 hours in advance of the Hearing date.

The Department of Human Services does not discriminate against individuals based on race, color, national origin, sex, gender identity or expression, sexual orientation, religious belief, political belief or handicap in acceptance for or provision of services or employment in its programs or activities.

**RULES, REGULATIONS AND STANDARDS GOVERNING
THE PHARMACEUTICAL ASSISTANCE TO THE
ELDERLY PROGRAM (RIPAE)**

State of Rhode Island and Providence Plantations

Department of ~~Elderly Affairs~~ Human Services

Division of Elderly Affairs



As Amended:
January 2002 (re-filing in
accordance with the
provisions of section 42-34-
4.1 of the Rhode Island
general laws, as amended)

May 2007

October 2012 (Proposed)

~~Donald L. Carcieri~~

~~Lincoln D. Chafee~~

~~Governor~~

~~Corinne Calise Russo, MSW~~

~~Sandra Powell~~

~~Director~~

COMPILER'S NOTES:

Proposed Additions: Underlined

Proposed Deletions: ~~Strikeouts~~

Statutory language is noted in *italics*.

Table of Contents

Sections	Page(s)
I. Introduction	
<u>Part I: Overview and General Requirements</u>	1
100. Preface	1
200. 1.0 Program Authority	1
300. 2.0 Nondiscrimination and Civil Rights Policy	1
400. 3.0 Compliance with all Laws, Codes, Rules and Regulations	1
500. Compliance with Pharmacy Codes, Rules and Regulations	
II. 4.0 Departmental Divisions Duties under the Program	2
600. 5.0 Severability	2
700. Part II: Definitions	3
<u>Part III: 6.0 Program Components</u>	6
III. 7.0 Allowances and Restrictions of the Program	6
XIII. 8.0 Program Prohibitions	6
IV. 9.0 Consumer Eligibility	7
X. 10.0 Program Benefits	8
XII. 11.0 Financial Participation by Consumer	10
12.0 Program Benefit in the Coverage Gap	10
V. 13.0 Application Form and Required Documentation	11
VI. 14.0 Duration of Eligibility	15
VII. Medicare Part D	
VIII. Eligibility Card	
IX. 15.0 Eligible Drugs	15
XI. Payments to Participating Pharmacies	
XIV. 16.0 Reporting Requirements	16
<u>Part IV: Appeals Procedures and Fraud and Abuse</u>	17
XV. 17.0 Appeal Procedures	17
XVI. 18.0 Fraud and Abuse	18
<u>Part V: Pharmaceutical Manufacturer Rebates</u>	20
XVII. 19.0 Pharmaceutical Manufacturer Drug Rebates	20
<u>References</u>	21

~~SECTION PART I~~ **INTRODUCTION** *Overview and General Requirements*

~~100.~~ ***Preface***

These rules, regulations and standards supersede any and all prior rules, regulations, and standards relating to the creation and provision of pharmaceutical services to the elderly promulgated pursuant to R.I.G.L. § 42-66.2 *et seq.* They have been promulgated to ensure that basic information about the nature of available services and eligibility to receive these services is readily available to qualified service recipients and their families.

The intent of the Program is to be the payer of last resort and is limited to eligible persons and eligible drugs.

Pursuant to the provisions of the Administrative Procedures Act, R.I.G.L. § 42-35-3, the following were given consideration in arriving at the regulations: (a) alternative approaches to the regulations; (b) duplication or overlap with other state regulations; and significant economic impact. No alternative approach was identified; nor any duplication or overlap.

~~200.~~ Section 1.0 ***Program Authority***

1.1 The Rhode Island Pharmaceutical Assistance to the Elderly Program (RIPAE) is authorized by, and these regulations are promulgated under, the authority of R.I.G.L. § 42-66.2 *et seq.*, “Rhode Island Pharmaceutical Assistance to the Elderly Program”, as amended.

~~300.~~ Section 2.0 ***Non-discrimination and Civil Rights Policy***

2.1 Each agency and individual involved in RIPAE shall be responsible for maintaining a policy of nondiscrimination in the provision of services to participants and in the employment of staff without regard to race, color, creed, national origin, sex, sexual orientation, age, handicapping condition or degree of handicap, in accordance with Title VI of the Civil Rights Act of 1964; the Rhode Island Executive Order No. 92-2, dated January 23, 1992 and entitled “Compliance with the Americans with Disabilities Act”; the United States Executive Order No. 11246 entitled “Equal Employment Opportunity”; United States Department of Labor Regulations; Title V of the Rehabilitation Act of 1973, as amended; the 1990 Americans With Disabilities Act; R.I.G.L. § 42-87, which states that “Discrimination” includes those acts prohibited on the basis of race by 42 U.S.C. #1981, 1983 and those on the basis of handicap by 29 U.S.C. #794 and those on the basis of disability by 42 U.S.C. #12100 *et seq.* and U.S.C. #12101 *et seq.*, and those on the basis of ~~handicap~~ disability by R.I.G.L. § 28-5; and the Rhode Island Fair Employment Practices Act.

~~400.~~ Section 3.0 ***Compliance with All Laws, Codes, Rules and Regulations***

3.1 Each agency and individual that delivers RIPAE services shall be responsible for complying with all local, state, and federal laws, codes, rules and regulations that apply to the Program, ~~or facility.~~

~~500.~~ *Compliance with Pharmacy Laws, Codes, Rules and Regulations*

3.2 All pharmacy laws, codes, rules and regulations that apply to prescription medications shall apply to the RIPAE Program. RIPAE enrollees shall be subject to these legal requirements.

Section ~~II.~~ 4.0 *~~Departmental~~ Division's Duties under the Program*

~~1.~~ 4.1 The Director shall enter into a contract with ~~the~~ a contractor for the effective administrative support of this program.

~~2.~~ 4.2 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~~ The contractor ~~shall be responsible for compliance of~~ and all participating pharmacies shall be in compliance with all applicable sections of ~~with RI Law, Chapter 42, section 66.2, Chapter 42-66.2 of the Rhode Island General Laws, as amended, 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.~~

~~600.~~ Section 5.0 *Severability*

5.1 If any provision of the rules and regulations herein or the application thereof to any program or circumstances shall be held invalid, such invalidity shall not affect the provision or application of the rules and regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.

PART II ***Definitions***

700: Section 6.0 ***Definitions***

For the purpose of these rules and regulations, the following ~~words~~ terms shall ~~have the following meaning:~~ be construed as follows:

6.1 ***“The Act”*** means Chapter 42-66.2 of the Rhode Island General Laws, as amended.

6.2 ***“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~~ below. However, ~~this~~ “additional drugs” shall not include prescription drugs used for cosmetic purposes.

6.3 ***“Approved documentation”*** means and includes a current explanation of benefits (EOB) statement from a Medicare prescription drug plan (Part D) and a statement of current year-to-date pharmacy medication expenses from a participating pharmacy.

6.4 ***“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 and Regulations: 9.0 herein.

6.5 ***“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~~ Such vendor ~~to~~ shall be determined through a competitive bid process.

~~“Pilot Program Contractor” means Blue Cross and Blue Shield of Rhode Island.~~

6.6 ***“Coverage gap”*** means the out-of-pocket expenses for medications between the point where an eligible person exceeds the Medicare Part D coverage limit under section 1860D-2(b)(3) (42 U.S.C. 1395w-114a) of the Patient Protection and Affordable Care Act and below the catastrophic amount specified in section 1860D2(b)(4)(B) of the Patient Protection and Affordable Care Act for the year.

6.7 ***“Delegate agency”*** means any local community-based agency with which the ~~Department of Elderly Affairs~~ Division negotiates a contract for assistance ~~in~~ with the implementation of the RIPAE Program.

6.8 ***“Department”*** means the Department of ~~Elderly Affairs~~ Human Services.

6.9 ***“Director”*** means the Director of the ~~Department~~ Division of Elderly Affairs

6.10 ***“Division”*** means the Department of Human Services, Division of Elderly Affairs.

6.11 ***“Eligible Drugs”*** means insulin and non-injectable drugs which:

6.11.1. Require a physician's (or other licensed practitioner authorized by state law to prescribe) prescription according to federal law, and

6.11.2. 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.

6.11.3 “*Classification categories*” means:

1. anticoagulants	11. <u>12.</u> drugs for the treatment of arthritis
2. anti-diabetic agents	12. <u>13.</u> drugs for the treatment of asthma and other <u>chronic respiratory diseases</u>
3. anti-infectives	13. <u>14.</u> drugs for the treatment of glaucoma
4. antilipemic drugs	14. <u>15.</u> drugs for the treatment of multiple sclerosis (including injectables, \$30,000 cap <u>per fiscal year</u>)
5. antidepressants	15. <u>16.</u> drugs for the treatment of osteoporosis
6. cardiac <u>drugs</u>	16. <u>17.</u> drugs for the treatment of Parkinson's disease
7. circulatory insufficiency <u>hypotensive drugs</u>	17. <u>18.</u> drugs for the treatment of urinary incontinence
8. <u>Vasodilators (cardiac indications only)</u>	18. <u>19.</u> hemorrheologic agents 19. <u>drugs for the treatment of hypotension</u>
8. <u>9.</u> drugs approved for the treatment of cancer 9. <u>drugs</u> 10. <u>diuretics</u>	20. insulin and <u>disposable</u> insulin syringes 21. oral antineoplastic drugs
10. <u>11.</u> drugs approved for the treatment of Alzheimer’s disease	22. prescription vitamin and mineral supplements for renal patients. <u>23. neuraminidase inhibiting drugs indicated for the treatment of influenza A and B.</u>

6.12 “*Full-time Resident*” ~~means any resident of the State of Rhode Island who fulfills~~ shall be determined consistent with the residency requirements set forth in section 17-1-3.1 of the General Laws of Rhode Island, as amended, entitled, "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.~~

6.13 **“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:

- ~~1.~~ 6.13.1 The amount of capital gains excluded from adjusted gross income;
- ~~2.~~ 6.13.2 Support money;
- ~~3.~~ 6.13.3 Alimony;
- ~~4.~~ 6.13.4 Non-taxable strike benefits;
- ~~5.~~ 6.13.5 Cash public assistance and relief not including relief granted under ~~this chapter~~ the Act;
- ~~6.~~ 6.13.6 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);
- ~~7.~~ 6.13.7 Non-taxable interest received from the federal government or any of its instrumentalities;
- ~~8.~~ 6.13.8 Workers Compensation;
- ~~9.~~ 6.13.9 The gross amount of "loss of time" insurance.

“Income” shall not ~~mean~~ include:

- ~~1.~~ 6.13.10 Gifts from non-governmental sources;
- ~~2.~~ 6.13.11 Surplus foods;
- ~~3.~~ 6.13.12 Other relief in kind supplied by a public or private agency;
- ~~4.~~ 6.13.13 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.

6.14 **“Participating pharmacy”** means any licensed pharmacy which has a written agreement with the contractor agreeing to the conditions and requirements of participation in the RIPAE Program.

6.15 **“Pharmaceutical manufacturer”** means any entity holding legal title to or possession of a national drug code number issued by the federal Food and Drug Administration.

SECTION PART III *Program Components*

~~1. Rebates for expenses are prohibited. A system of rebates or reimbursements to the consumer for pharmaceutical expenses shall be prohibited. However, this prohibition shall not be interpreted to exclude other consumers not participating in RIPAE from receiving financial offers or redeemable coupons that are available to only those who have paid for the service or product through direct cash payment, insurance premiums, or cost sharing with an employer.~~

Section 7.0 *Allowances and Restrictions of the Program*

7.1 The RIPAE Program shall include the following criteria:

~~2.~~ 7.1.1 Experimental drugs are excluded from the program.

~~3.~~ 7.1.2 A system of mail order delivery for prescriptions is allowed under the program.

~~4.~~ 7.1.3 Eligible and additional drugs must be dispensed within one (1) year of the original prescription order.

~~5.~~ 7.1.4 Expenditures for multiple sclerosis drugs shall not exceed thirty thousand dollars (\$30,000 per fiscal year).

~~6. Collection of the co-payment by pharmacies is mandatory.~~

~~7.~~ 7.1.5 Senior citizens participating in the program are ~~not~~ required to maintain records of each transaction ~~but shall sign a receipt for eligible and additional drugs., as specified by the Director in accordance with subsection 42-66.2-4(c) of the Act and these regulations.~~

~~8.~~ 7.1.6 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, or one (1) quart of liquid, whichever is less; and/or a one hundred (100) day supply or one quart of liquid, whichever is less; provided, however, that disposable insulin syringes are dispensed in a quantity of one hundred (100).

7.1.7 Generic drug substitution is mandatory when there is an available generic drug equivalent.

~~Section XIII~~ 8.0 *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;~~

8.1 Violation of any of the above criteria in section 7.1 herein shall constitute fraud and shall be handled in accordance with ~~section XV of these Rules and Regulations~~ Part IV herein.

Section IV 9.0 *Consumer Eligibility*

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

9.1.1 Participants ~~must~~ shall be 65 years of age or older at the time of application or between the ages of 55-65 and receiving Social Security Disability benefits.

9.1.2 Participants ~~must~~ shall 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 Rhode Island~~ entitled, "Residence for Voting Purposes," (~~refer to definition of full time resident~~).

9.1.3 Participants ~~must~~ shall be determined by the ~~Department~~ Division or its delegate agencies to meet the following income criteria:

a) *Unmarried or married living separate and apart* -Income for the calendar year immediately preceding the year in which assistance is sought. 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.

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.

d) 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.

e) ~~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.~~

5. 9.2 However, the fact that some of a person's prescription drug expenses are paid or reimbursable *either in whole or in part*, under the provisions of Medicare Part D shall not disqualify said person, if he or she is otherwise eligible to receive assistance under the Act,

~~*provided that if the federal share equals or exceeds sixty percent (60%) of the cost, the state shall make no payment.*~~ 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.

Section VII

Medicare Part D

~~1. The fact that some of a person's prescription drug expenses are paid or reimbursable, under the provisions of federal Medicare program shall not disqualify that person, if he or she is otherwise eligible, to receive assistance under RIPAE. In those cases, the state shall pay the eligible percentage of the cost of those prescriptions for qualified drugs for which no payment or reimbursement is made by the federal government.~~

~~2. As of July 1, 2004, all new enrollees in the program whose income qualifies them for Transitional Assistance (135% of poverty) under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1860D-31 [42 U.S.C. § 1395w 141], shall apply annually, for a Medicare prescription drug discount card, to be used in conjunction with benefits offered under this chapter, in order to continue to receive benefits under RIPAE. Enrollees who joined the program prior to July 1, 2004, and who qualify for Transitional Assistance (135% of poverty) under the Medicare Prescription and Drug Improvement, and Modernization Act of 2003, Section 1860D-31 [U.S.C. § 1395w 141], shall by September 30, 2004 and continuously thereafter until such time as Medicare Part D becomes effective;~~

9.3 ~~All consumers shall make application for demonstrate proof of enrollment in a Medicare prescription drug discount card program ("Medicare Part D") to be used in conjunction with benefits offered under RIPAE, in order to continue receiving receive benefits under RIPAE.~~

~~3. To promote coordination of benefits between RIPAE and the Medicare Part D prescription drug program created in the federal Medicare Prescription Drug, Improvement and Modernization Act of 2003, RIPAE enrollees whose income is at or below 150% of the federal poverty limit and whose resources are below the resource eligibility limits determined by the Centers for Medicare and Medicaid Services for low income assistance benefit under Medicare Part D must apply for and enroll in the Medicare Part D prescription drug program.~~

~~4. RIPAE is authorized to apply for transitional assistance with a specific drug card under the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Section 1860D-31 [42 U.S.C. § 1395w 141] on behalf of applicants and eligible members under RI state law. RIPAE shall provide applicants and eligible members with prior written notice of, and the opportunity to decline, such automatic enrollment.~~

Section X 10.0 *Program Benefits*

10.1 The RIPAE Program shall pay the appropriate percentage of the cost of eligible drugs for eligible consumers, 55 years or older, ~~which~~ that are dispensed within one (1) year of the original prescription order.

10.2 The percentage of cost RIPAE pays is shall be based on the annual income of the eligible RIPAE member, ~~55 years old or older consumer as stipulated in section 10.3 below, less the amount of any other health insurance payment and/or federal discounts, including those~~

under the federal Patient Protection and Affordable Care Act (PPACA), that have been paid on the claim at the pharmacy.

10.3 State and consumer co-payment shares for consumers shall be determined as follows:

10.3.1 For unmarried persons or married persons living separate and apart whose income for the calendar year immediately preceding the year in which assistance is sought is:

(i) Less than nineteen thousand three hundred forty-one dollars (\$19,341) the state shall provide reimbursement such that the consumer shall pay no more than forty percent (40%) of the cost of the prescriptions.

(ii) More than nineteen thousand three hundred forty-one dollars (\$19,341) and less than, twenty-four thousand two hundred and eighty dollars (\$24,280) the state shall provide reimbursement such that the consumer shall pay no more than seventy percent (70%) of the cost of the prescriptions; and

(iii) More than twenty-four thousand two hundred and eighty dollars (\$24,280) and less than forty-two thousand four hundred and ninety-three dollars (\$42,493), the state shall provide reimbursement such that the consumer shall pay no more than eighty-five percent (85%) of the cost of prescriptions.

10.3.2 For married persons whose income for the calendar year immediately preceding the year in which assistance is sought hereunder when combined with any income of the person's spouse in the same year is:

(i) Twenty-four thousand one hundred and seventy-nine dollars (\$24,179) or less, the state shall provide reimbursement such that the consumer shall pay no more than forty percent (40%) of the cost of the prescriptions;

(ii) More than twenty-four thousand one hundred and seventy-nine dollars (\$24,179) and less than thirty thousand three hundred and fifty-two dollars (\$30,352), the state shall provide reimbursement such that the consumer shall pay no more than seventy percent (70%) of the cost of prescriptions; and

(iii) More than thirty thousand three hundred and fifty-two dollars (\$30,352) and less than forty-eight thousand five hundred and sixty-three dollars (\$48,563), the state shall provide reimbursement such that the consumer shall pay no more than eighty-five percent (85%) of the cost of prescriptions.

10.3.3 For persons on Social Security Disability benefits who are:

(i) unmarried or married and living separate and apart with income for the calendar year immediately preceding the year in which assistance is sought that is less than forty-two thousand four hundred and ninety-three dollars (\$42,493); or

(ii) married with income that is less than forty-eight thousand five hundred and sixty-three dollars (\$48,563) the state shall provide reimbursement such that the consumer shall pay no more than eighty five percent (85%) of the cost.

~~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 dispensed 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 XII~~ 11.0 Financial Participation by Consumer

11.1 ~~RIPAE Program~~ participants, ~~55~~ 65 years old or older, shall pay ~~either 0%, up to 40%, 70% or 85%, as determined by their income, of the cost of eligible drugs (after applicable senior citizen discounts, and coupons and any other health insurance payment and/or federal discounts, including those provided under the federal Patient Protection and Affordable Care Act (PPACA) have been applied. 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.

11.2 ~~RIPAE participants~~ consumers 65 years old or older shall pay 100% of the RIPAE discount price for additional drugs as defined herein. ~~Additional drugs shall mean only those drugs as defined in these Rules and Regulations (Section II—Definitions) and in R.I.G.L. 42-66.2 §.~~

11.3 ~~RIPAE participants~~ consumers between 55-65 64 years of age and receiving Social Security Disability benefits (SSDI) shall pay ~~85%~~ 100 % of the RIPAE discount price for both eligible and additional drugs, as defined herein. ~~Eligible and Additional drugs shall mean only those drugs as defined in these Rules and Regulations (Section II—Definitions) and in R.I.G.L. 42-66.2 §.~~

Section 12.0 Program Benefit in the Coverage Gap

12.1 The state shall reimburse the consumer up to the percentage rate of the maximum allowable amount per prescription as set forth in section 10.3 herein as of the date of the purchase of the drug, in accordance with the income eligibility and co-payment shares set forth in section 42-66.2-5 of the Act and these regulations.

12.2 The rebates generated pursuant to section 42-66.2-10 of the Act shall be used to offset the state's payment under this section.

12.3 Reimbursement payments shall be made to consumers no less than quarterly.

12.4 After an eligible consumer reaches the coverage gap, he/she shall submit to the Division, or its delegate agencies, a copy of approved documentation for the purchase of eligible drugs.

12.5 The Division shall verify the expenses, determine the reimbursement payment amount, and authorize payment(s) to the eligible consumer, as applicable.

12.5.1 Delegate agencies shall not be authorized to determine the reimbursement payment amount for the eligible consumer.

12.5.2 Claims for reimbursement for the purchase of eligible drugs shall be submitted within one hundred eighty (180) days of the date of purchase of the drug.

Section ~~V~~ 13.0 ***Application Form and Required Documentation***

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

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

13.2 Such application form shall be made available at the ~~Department~~ Division and its delegate agencies.

13.3 The ~~Department~~ Division may verify eligibility information in one or more of the following ways:

- a) Review and certification of eligibility by trained staff for each application file with the ~~Department~~ Division or its delegate agencies;
- b) Perform computer cross checks with available data banks to verify eligibility;
- c) Conduct 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.~~

13.4 Notification shall be made to each applicant of eligibility/ineligibility within thirty (30) days of receipt of application by the ~~Department~~ Division or its delegate agencies. ~~Notification shall be an identification card for those determined eligible.~~

13.5 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~~ 17.0 herein - Appeals Procedures).

13.6 Names and pertinent information for each eligible ~~participant~~ consumer shall be supplied to the contractor.

13.7 Benefits shall be paid only ~~for~~ to those persons determined eligible by the ~~Department~~ Division ~~under these Rules & Regulations.~~ as provided herein.

~~5.~~ 13.8 The following documentation shall be accepted as verification of age/residence/income under ~~the RIPAE Program:~~

~~One of the following:~~ 13.8.1 Any one of the following documents shall be acceptable to document age:

Age:

- a) RI Driver's License;
- b) Birth Certificate;
- c) ~~RIPTA ID~~ Senior bus pass;
- d) ~~Health Insurance Card.~~ Pharmacy printout with date-of-birth imprint.
- ~~DEA ID. Card~~

~~B. One of the following:~~ 13.8.2 Any one of the following documents shall be acceptable to document residency:

Residence:

- a) ~~the~~ Address furnished to the Registry of Motor Vehicles for the applicant's license;
- b) ~~the~~ Address at which the applicant's motor vehicle is registered;
- c) ~~the~~ Address furnished to the companies from which the applicant has obtained retail credit cards;
- d) ~~the~~ Address furnished to the financial institutions where the applicant maintains accounts;

- e) ~~the~~ Address furnished to the tax collector and/or assessor in those communities where the applicant owns taxable real or personal property;
- f) ~~the~~ Address furnished to the insurance companies with which the applicant maintains policies;
- g) ~~the~~ Address furnished to the applicant's employer;
- h) ~~the~~ Address furnished by the applicant to any business, professional, union, or fraternal organizations of which he/she is a member;
- i) ~~the~~ Address furnished to governmental agencies with which the applicant has contact;
- j) ~~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.
- k) ~~the~~ Address at which the applicant filed his last federal and/or state income tax form.

C. 13.8.3 A combination of the following documents shall be sufficient to document all income; ~~included in the definition of such under the RIPAE Program~~

~~Income:~~

- a) For previous calendar year: federal income tax return and Social Security income document;
- b) *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;
- c) *TDI/Worker's Compensation*: an award letter or copies of checks;
- d) *Unemployment benefits*: a stamped unemployment book or copy of check;
- e) *Alimony or support*: a court decree or other documentation;
- f) *Pension benefits*: (Social Security, Veterans Benefits, SSI, etc.) ~~an~~ a current or previous year's award letter or, after determining date of initial award, a copy of most recent check, or written verification from income source, current statement from bank showing pension or Social Security income direct deposit;
- g) ~~AFDC-TANF (Temporary Aid to Needy Families) /GPA (General Public Assistance)~~: a letter from the Department of Human Services detailing income from the previous calendar year or a listing of such supplied by DHS;
- h) *Interest income*: savings statements, passbook, letter from savings institution, W-1099 or W-9 interest form;
- i) *Rental income*: rent receipts, lease agreements;

- j) *Self-employment income*: all receipts, bills, invoices and other documents establishing income and expenses of operations;
- k) any listing or verification from an agency or organization for one of the above shall constitute acceptable documentation of income.

~~D~~ ***Income Disregards***

13.9 The following shall be excluded for purposes of income determination as provided in section 9.0 herein:

- a) Gifts from non-governmental sources;
- b) ~~the~~ Value of surplus foods;
- c) Benefits excluded from income by federal or state law (i.e., stipends received by Senior Companions under the Domestic Volunteer Services Act of 1973, as amended);
- d) Benefits received under the Low Income Energy Assistance Program;
- e) Other relief in-kind supplied by a public or private agency;
- f) Sums of money expended for medical and pharmaceutical expenses 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.

13.10 All income and/or medical expense documentation provided to the Division for purposes of determining income shall have been earned (income) or incurred (expenses) during the current or immediately preceding calendar year.

Section ~~VI~~ 14.0 ***Duration of Eligibility***

14.1 Consumers whose eligibility has been established as described in section ~~IV~~ 9.0 above shall remain eligible for a period determined by the ~~Department~~ Division or until the following, whichever occurs first:

~~1.~~ 14.1.1 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.~~ 14.1.2 The ~~Department~~ Division conducts a recertification of consumer eligibility and determines the consumer to be ineligible.

14.1.3 The consumer becomes eligible for Medical Assistance (Medicaid).

14.1.4 The consumer discontinues participation in a Medicare Part D plan.

SECTION VIII. 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 IX~~ 15.0 *Eligible Drugs*

~~Eligible drugs shall mean only those drugs as defined in these Rules and Regulations (Section II—Definitions) and in R.I.G.L. 42-66.2 §.~~

15.1 The contractor shall supply to all participating pharmacies and to the ~~Department~~ Division a periodically updated list of eligible drugs.

~~Additional drugs shall mean only those drugs as defined in these Rules and Regulations (Section II—Definitions) and in R.I.G.L. 42-66.2 §.~~

15.2 The contractor shall supply to all participating pharmacies and to the ~~Department~~ Division a periodically updated list of additional drugs.

15.3 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.

~~Section XI~~ *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 XIV~~ 16.0 *Reporting Requirements*

16.1 The Director shall submit an annual report to the following:

- a) The Governor;
- b) The Budget Officer;
- c) The Chairperson of the House Finance Committee;
- d) The Chairperson of the Senate Finance Committee;
- e) The Chairperson of the Board of Pharmacy as established by section 5-19-2 of the Rhode Island General Laws, as amended.

- 16.2 This report shall contain at least the following:
- a) Number of consumers eligible for the RIPAE Program;
 - b) ~~The~~ Number of consumers utilizing the program;
 - c) ~~the~~ Number of appeals;
 - d) An outline of problems encountered in the administration of the Program, ~~and~~ suggested solutions to the same, and any recommendations to enhance the program.

16.3 The contractor shall submit an annual report to the following:

- a) ~~the~~ Director ~~DEA~~ of the Division;
- b) ~~the~~ Governor;
- c) ~~the~~ Budget Officer;
- d) ~~the~~ Chairperson of the House Finance Committee;
- e) ~~the~~ Chairperson of the Senate Finance Committee;
- f) ~~the~~ Chairperson of the Board of Pharmacy as established by section 5-19-2 of the Rhode Island General Laws, as amended.

16.4 This report shall contain at least the following:

- a) Financial and utilization statistics as to drug use by therapeutic category, actuarial projections;
- b) 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 XV PART IV Appeals Procedure and Fraud and Abuse~~

~~Part A, Section 17.0~~ *Filing an Appeal*

17.1 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*

17.1.1 Applicants shall receive written notice that ~~the~~ their applications for RIPAE ~~has~~ have been denied.

17.1.2 Such notice shall be provided by the ~~Department~~ Division on a standard denial form developed by ~~DEA~~ the Division. This notice ~~will~~ shall be provided as soon as possible after receipt of the application ~~as possible~~, but not more than thirty (30) days after receipt of the application.

17.1.3 This notice shall include:

- a) The reason (s) for denial; and
- b) The procedure for appeal.

b) Procedure for Appeal

~~1.~~ 17.2 Applicants shall contact the ~~Department Hearing Officer~~ Division to request an appeal.

~~The Department Hearing officer shall be a Department administrative employee who is not responsible for administration of the RIPAE Program.~~

~~2.~~ 17.3 A hearing shall be scheduled to take place as soon as possible but not longer than fourteen (14) days after the request for the hearing.

~~3.~~ 17.4 The applicant ~~must~~ shall contact the ~~Department~~ Division within ninety (90) days of the date of the denial letter from the ~~Department~~ Division. No hearing shall be granted upon a request more than ninety (90) days from the date of the denial letter. However, an applicant may apply or reapply at any time ~~at the appropriate agency.~~

~~4.~~ 17.5 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.

~~e)~~ 17.6 The ~~Department~~ Division Hearing Officer shall conduct the hearing.

~~5.~~ 17.7 The applicant shall have the right to bring with him/her any person or any documentation pertinent to the issues involved. The applicant ~~must~~ shall supply documentation at the time of the hearing for age, residence, and income, as outlined in section ~~13.0~~ 13.0 above.

~~6.~~ 17.8 The ~~Department~~ Division 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 ~~Department~~ Division Hearing Officer; and
- f) All memoranda or data submitted to the ~~Department~~ Division Hearing Officer presiding at the hearing.

~~7.~~ 17.9 A complete record of the proceedings shall be recorded on audiotape or electronic device, or at the discretion of the Hearing Officer, by stenographic record. In the event the Hearing Officer orders a stenographic record, the Hearing Officer shall declare which

party or parties shall bear the cost thereof. Any party to the proceedings may on his, her or its own initiative order a stenographic record made of the proceedings. The requesting party shall incur all costs associated therewith. The Hearing Officer shall be provided, at no cost, with a copy of the stenographic record and the ~~Department's~~ Division's legal counsel shall be provided a copy at no cost. Any party to the proceedings may request a copy of the audiotape record of the proceedings. The requesting party shall bear the cost thereof.

~~§~~17.10 Findings of fact shall be exclusively on the evidence and matters officially noted.

~~Part B~~ *Appeal of Hearing Officer Decision*

17.11 Any ~~elder person~~ or individual acting on behalf of an ~~elder person~~ who elects to appeal an adverse decision of the Hearing Officer shall have thirty (30) days after the mailing of the notice of the final decision to request judicial review. The procedures outlined in R.I.G.L. § 42-35- 15 shall be followed.

17.12 If a party chooses to appeal a final ~~Departmental~~ Division's decision to Superior Court and the Superior Court requires a transcript of the hearing, said party shall be responsible for having the transcript prepared by an independent person or company at his/ her ~~or its~~ expense within twenty (20) days of filing the appeal.

17.13 If any administrative penalty is assessed at the conclusion of an administrative hearing, the administrative penalty shall be final upon the expiration of thirty (30) days if no action for judicial review of the decision is commenced.

Section ~~XVI~~ 18.0 *Fraud and Abuse*

18.1 The ~~Department-Division~~ shall declare ineligible any consumer who abuses or misuses RIPAE. The ~~Department-Division~~ is empowered to investigate cases of suspected provider or consumer fraud.

18.2 Delegate agencies and participating pharmacies shall report to the ~~Department-Division~~ any suspected incident of fraud or abuse. Such reports shall be made to the Director or designee.

18.3 Fraud and abuse shall include but not be limited to:

~~1.~~ 18.3.1 Falsification of information on the application for assistance;

~~2.~~ 18.3.2 Use or attempted use of an eligibility card by an unauthorized individual;

3. ~~rebates or reimbursements to consumers for pharmaceutical expenses;~~

~~4.~~ 18.3.3 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.~~ 18.3.4 Consumer or provider claims for duplicative benefits;

7. 18.3.5 Any violation or attempt to violate the provisions of ~~R.I.G.L. Chapter~~ 42-66.2 § of the Rhode Island General Laws, as amended or these rules and regulations.
- 18.4 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. The ~~Department~~ Division shall investigate all reports of fraud and abuse, and shall refer all pertinent findings to the Office of the Attorney General.
- 18.5 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~~ shall not carry with it the right ~~for~~ to appeal.
- 18.6 Any provider or consumer who is found guilty under ~~this the~~ the Act and these regulations ~~is~~ shall be subject to repay three (3) times the value of the material gain he or she received.

~~SECTION XVII~~ PART V *Pharmaceutical Manufacturer Rebates*

Section 19.0 *Rebates*

- 19.1 ~~On and after March 1, 1992, the~~ The Director shall enter into prescription drug rebate agreements with individual pharmaceutical manufacturers under which the ~~Department~~ Division 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.
- 19.2 Each such agreement shall provide that the pharmaceutical manufactures shall make quarterly rebate payments to the ~~Department~~ Division 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~~ Division 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~~ Division including the number of dosage units reimbursed to providers of prescription drugs during the quarter for which payment is due.
- 19.3 Upon receipt of such data from the ~~Department~~ Division, the pharmaceutical manufacturer shall calculate the quarterly payment. The ~~Department~~ Division 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~~ Division for any additional amount due.
- 19.4 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~~

Division. In the event that a discrepancy is discovered, the ~~Department~~ Division shall justify its data or refund any excess payment to the pharmaceutical manufacturer. The ~~Department~~ Division 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~~ Division shall justify its data or refund any excess payment to the pharmaceutical manufacturer.

19.5 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~~ Division determines the eligible prescription drug is essential to program participants.

19.6 *All rebates collected by the ~~Department~~ Division from the rebate payments made for drugs for persons eligible under the provisions of § 42-66.2-5(a) shall be deposited in a restricted receipt account, hereby created within the agency and known as Pharmaceutical Rebates, to pay costs in accordance with the provisions of § 42-66.2-4 of the Rhode Island General Laws, as amended.*

REFERENCES

1. “Pharmaceutical Assistance to the Elderly Act”, Chapter 42-66.2 of the Rhode Island General Laws, as amended. Available online:
<http://www.rilin.state.ri.us/Statutes/TITLE42/42-66.2/INDEX.HTM>
2. “Administrative Procedures”, Chapter 42-35 of the Rhode Island General Laws, as amended. Available online:
<http://www.rilin.state.ri.us/Statutes/TITLE42/42-35/INDEX.HTM>
3. “Patient Protection and Affordable Care Act”, Public Law 111-148, enacted March 23, 2010. Available online:
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf