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TITLE 218 – DEPARTMENT OF HUMAN SERVICES

CHAPTER 40 – DIVISION OF ELDERLY AFFAIRS

SUBCHAPTER 00 – N/A

PART 02 – RULES, REGULATIONS, AND STANDARDS GOVERNING THE PHARMACEUTICAL ASSISTANCE TO THE ELDERLY PROGRAM

2.1 Overview and General Requirements

- A. 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. Gen. Laws § 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
- B. The intent of the Program is to be the payer of last resort and is limited to eligible persons and eligible drugs
- C. Pursuant to the provisions of the Administrative Procedures Act, R.I. Gen. Laws § 42-35-3, the following were given consideration in arriving at the regulations:
 - 1. alternative approaches to the regulations;
 - 2. duplication or overlap with other state regulations; and significant economic impact.
 - a. No alternative approach was identified;
 - b. nor any duplication or overlap.

2.1.1 Program Authority

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

2.1.2 Non-discrimination and Civil Rights Policy

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. Gen. laws § 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 those on the basis of disability by R.I. Gen. Laws § 28-5; and the Rhode Island Fair Employment Practices Act.

2.1.3 Compliance with All Laws, Codes, Rules and Regulations

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.

2.1.4 Compliance with Pharmacy Laws, Codes, Rules and Regulations

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.

2.1.5 Division's Duties under the Program

- A. The Director shall enter into a contract with a contractor for the effective administrative support of this program.
- B. The contractor shall serve as the link between RIPAE and participating pharmacies. All payments to pharmacies shall be made by the contractor. The contractor and all participating pharmacies shall be in compliance with all applicable sections of R.I. Gen. Laws § 42-66.2, as amended, and these rules and regulations.

2.2 Definitions

2.2.1 Definitions

- A. For the purpose of these rules and regulations, the following terms shall be construed as follows:
 - 1. "The Act" means R.I. Gen. Laws § 42-66.2, as amended.
 - 2. "Additional drugs" means those drugs as defined in R.I. Gen. Laws § 42-66.2-3, as amended.

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.
4. "Consumer" means any full-time resident of the State of Rhode Island who fulfills the eligibility requirements set forth in the R.I. Gen. Laws §44-66.2-3 and § 2.3.3 herein.
5. "Contractor" means a third party or private vendor as defined in R.I. Gen. Laws § 42-66.2-3, as amended.
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 §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 §1860D2(b)(4)(B) of the Patient Protection and Affordable Care Act for the year.
7. "Delegate agency" means any local community-based agency with which the Division negotiates a contract for assistance with the implementation of the RIPAE Program.
8. "Department" means the Department of Human Services.
9. "Director" means the Director of the Division of Elderly Affairs
10. "Division" means the Department of Human Services, Division of Elderly Affairs.
11. "Eligible Drugs" is defined in R.I. Gen. Laws § 42-66.2-3, as amended.
12. "Full-time Resident" shall be determined consistent with the residency requirements set forth in R.I. Gen. Laws § 17-1-3.1, as amended, entitled, "Residence for Voting Purposes".
13. "Income" means the sum of federal adjusted gross income as defined in the R.I. Gen. Laws § 42-66.2-3, as amended.
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.
15. "Pharmaceutical manufacturer" means any entity as defined in R.I. Gen. Laws § 42-66.2-3, as amended.

2.3 Program Components

2.3.1 Allowances and Restrictions of the Program

- A. The RIPAE Program shall include the following criteria:
1. Experimental drugs are excluded from the program.
 2. A system of mail order delivery for prescriptions is allowed under the program.
 3. Eligible and additional drugs must be dispensed within one (1) year of the original prescription order.
 4. Expenditures for multiple sclerosis drugs shall not exceed thirty thousand dollars (\$30,000 per fiscal year).
 5. Senior citizens participating in the program are required to maintain records of each transaction, as specified by the Director in accordance with R.I. Gen. Laws § 42-66.2-4(c) and this Part.
 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 100-day supply or 200 doses, whichever is less; and/or a 100-day supply or one quart of liquid, whichever is less; provided, however, that disposable insulin syringes are dispensed in a quantity of 100.
 7. Generic drug substitution is mandatory when there is an available generic drug equivalent.

2.3.2 Program Prohibitions

Violation of any of the above criteria in § 2.3.1(A) of this Part shall constitute fraud and shall be handled in accordance with § 2.4 of this Part.

2.3.3 Consumer Eligibility

- A. Eligibility shall be determined by the Division and its delegate agencies. In order to be eligible to participate in RIPAE, consumers shall meet all of the following criteria:
1. Participants shall be 65 years of age or older at the time of application or between the ages of 55-64 and receiving Social Security Disability benefits.

2. Participants shall be full time residents of the State of Rhode Island at the time of application. Full time residence shall be determined consistent with R.I. Gen. Laws § 17-1-3.1 entitled, "Residence for Voting Purposes."
3. Participants shall be determined by the 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 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 90 days prior to application for benefits and projecting that income on an annual basis.
 - d. Except that, on January first of each year 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.
- B. 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 60% of the cost, the state shall make no payment.
- C. Medicare Part D - All consumers shall demonstrate and maintain proof of enrollment in a Medicare prescription drug program ("Medicare Part D") in order to receive benefits under RIPAE.

2.3.4 Program Benefits

- A. The RIPAE Program shall pay the appropriate percentage of the cost of eligible drugs for eligible consumers, 55 years or older, that are dispensed within one (1) year of the original prescription order.
- B. The percentage of cost RIPAE pays shall be based on the annual income of the eligible, consumer as stipulated in § 2.3.4(C) of this Part, 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.

- C. State and consumer co-payment shares for consumers shall be determined on an annual basis. The Division will formally update co-payment shares from the direction of the U.S. Social Security Administration. Information regarding income and cost-share requirements are reflected in a Division fact sheet and is available upon request.

2.3.5 Financial Participation by Consumer

- A. RIPAE participants, 65 years in age or older, shall pay up to 40%, 70% or 85%, as determined by their income, of the cost of eligible drugs after applicable senior citizen discounts, 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.
- B. RIPAE consumers 65 years in age or older shall pay 100% of the RIPAE discount price for additional drugs as referred to in § 2.2.1(B) of this Part.
- C. RIPAE consumers between 55-64 years of age and receiving Social Security Disability benefits (SSDI) shall pay 100% of the RIPAE discount price for both eligible and additional drugs, as referred to in § 2.2.1(B) of this Part.

2.3.6 Program Benefit in the Coverage Gap

- A. The state shall reimburse the consumer up to the percentage rate of the maximum allowable amount per prescription as set forth in § 2.3.4(C) in this Part as of the date of the purchase of the drug, in accordance with the income eligibility and co-payment shares set forth in R.I. Gen. Laws § 42-66.2-5 and this Part.
- B. The rebates generated pursuant to R.I. Gen. Laws § 42-66.2-10 shall be used to offset the state's payment under this section.
- C. Reimbursement payments shall be made to consumers no less than annually.
- D. 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.
- E. The Division shall verify the expenses, determine the reimbursement payment amount, and authorize payment(s) to the eligible consumer, as applicable.
 - 1. Delegate agencies, as referred to in §2.2.1(G) of this Part, shall not be authorized to determine the reimbursement payment amount for the eligible consumer.
 - 2. Claims for reimbursement for the purchase of eligible drugs shall be submitted for the calendar year immediately preceding the annual reimbursement period.

- F. Reimbursement payments can be made to the consumer's properly designated legal representative, or upon death, the state's executor/executrix, or administrator, and in the absence of probate, next of kin.

2.3.7 Application Form and Required Documentation

- A. The 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:
 - 1. Pertinent demographic information;
 - 2. Residence;
 - 3. Date of birth;
 - 4. Annual income for the previous calendar year, including amount and source of income (such income documentation shall be supplied for applicant and spouse when applicant is married);
 - 5. Social Security number;
 - 6. All other data essential for the determination of eligibility and maintenance of client statistics;
 - 7. Certification through signature of the applicant that permission is granted to the 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 Division upon request, written documentation of all information included on the application form.
- B. Required documentation includes:
 - 1. Verification of Medicare ID number;
 - 2. Verification of Medicare Part D ID number.
- C. Such application form shall be made available at the Division and its delegate agencies.
- D. The Division may verify eligibility information in one or more of the following ways:
 - 1. Review and certification of eligibility by trained staff for each application file with the Division or its delegate agencies;
 - 2. Perform computer cross checks with available data banks to verify eligibility;

3. Conduct personal interviews to review documentation for age, residence and previous year's annual income or income for 90 days prior to application.
- E. Notification shall be made to each applicant of eligibility/ineligibility within 30 days of receipt of application by the Division or its delegate agencies
 - F. 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 § 2.7 of this Part).
 - G. Names and pertinent information for each eligible consumer shall be supplied to the contractor.
 - H. Benefits shall be paid only to those persons determined eligible by the Division as provided herein.
 - I. The following documentation shall be accepted as verification of age/residence/income under RIPAE:
 1. Any one of the following documents shall be acceptable to document age:
 - a. RI Driver's License, OR RI Identification Card;
 - b. Birth Certificate;
 - c. Pharmacy printout with date-of-birth imprint.
 2. Any one of the following documents shall be acceptable to document residency:
 - a. Address furnished to the Registry of Motor Vehicles for the applicant's license, OR identification card;
 - b. Address at which the applicant's motor vehicle is registered;
 - c. Any other official document which indicates applicants' permanent residence.
 3. A combination of the following documents shall be sufficient to document all income:
 - a. For previous calendar year: federal income tax return and Social Security income document, otherwise known as an award letter;
 - 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.) a current or previous year's award letter or, a copy of most recent check, written verification from income source, current statement from bank showing pension or Social Security income direct deposit;
- g. 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.

J. Income Disregards

- 1. The following shall be excluded for purposes of income determination as provided in § 2.3.3 of this Part:
 - a. Gifts from non-governmental sources;
 - b. 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 Home 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 90 days income data is used for eligibility purposes, three percent (3%) of applicant's preceding 90 day income computed on annual basis.

- K. 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.

2.3.8 Duration of Eligibility

- A. Consumers whose eligibility has been established as described in § 2.3.3 of this Part shall remain eligible for a period determined by the Division or until the following, whichever occurs first:
 1. The consumer moves out of Rhode Island and is no longer a full-time resident;
 2. The Division conducts a recertification of consumer eligibility and determines the consumer to be ineligible.
 3. The consumer becomes eligible for Medical Assistance (Medicaid).
 4. The consumer discontinues participation in a Medicare Part D plan.

2.3.9 Eligible Drugs

- A. The contractor shall supply to all participating pharmacies and to the Division a periodically updated list of formulary eligible drugs.
- B. The contractor shall supply to all participating pharmacies and to the Division a periodically updated list of additional drugs, and discontinued formulary drugs.

2.3.10 Reporting Requirements

The Director and Contractor shall submit an annual report to the Governor, the Budget Officer, the Chairperson of the House Finance Committee, the Chairperson of the Senate Finance Committee, and the Chairperson of the Board of Pharmacy as established by R.I. Gen. Laws § 5-19.1-4 in accordance with and pursuant to RI Gen. Law § 42-66.2-9.

2.4 Fraud and Abuse

2.4.1 Fraud and Abuse

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

- B. Delegate agencies and participating pharmacies shall report to the Division any suspected incident of fraud or abuse. Such reports shall be made to the Director or designee.
- C. Fraud and 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. Falsification of information by a participating pharmacy;
 - 4. Consumer or provider claims for duplicative benefits;
 - 5. Any violation or attempt to violate the provisions of R.I. Gen. Laws § 42-66.2, as amended or this Part.
- D. Individuals attempting fraud or abuse and individuals who aid or abet another in attempting fraud or abuse shall be subject to R.I. Gen. Laws § 42-66.2-8, as amended.
- E. Any provider or consumer found guilty of intentionally violating the provisions of these rules and regulations shall be subject to R.I. Gen. Laws § 42-66.2-8, as amended.
- F. Any provider or consumer who is found guilty under the Act and these regulations shall be subject to R.I. Gen. Laws § 42-66.2-8, as amended.

2.5 Pharmaceutical Manufacturer Rebates

2.5.1 Rebates

Matters regarding rebates from pharmaceutical manufacturers must be in accordance with R.I. Gen. Laws § 42-66.2-10.

2.6 Severability

2.6.1 Severability

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.

2.7 Appeals Procedure

2.7.1 Appeals Procedure

Any person whose application for assistance under the RIPAE Program is denied shall have the right to appeal such a decision. Such appeals shall follow the procedures described under the Executive Office of Health and Human Services, as outlined under Chapter 30, Appeals and Hearings.