

HUMAN SERVICES

DIVISION OF AGING SERVICES

**OFFICE OF STATE HEALTH INSURANCE FOR THE AGED AND DISABLED AND
FACILITIES MANAGEMENT**

Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual

Proposed Readoption with Amendments: N.J.A.C. 10:167

Authorized By: Elizabeth Connolly, Acting Commissioner, Department of Human Services.

Authority: N.J.S.A. 30:4D-24 and P.L. 2012, c. 17.

Calendar Reference: See Summary below for explanation of exception to calendar requirements.

Proposal Number: PRN 2016-011.

Submit written comments by March 19, 2016, electronically to DoAS.Legal@dhs.state.nj.us, or by regular mail to:

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The agency proposal follows:

Summary

N.J.A.C. 10:167 governs the Pharmaceutical Assistance to the Aged and Disabled (PAAD) Eligibility Manual. Pursuant to N.J.S.A. 52:14B-5.1, N.J.A.C. 10:167 is scheduled to expire on December 9, 2015. Pursuant to N.J.S.A. 52:14B-5.1.c(2), the filing of this notice of proposal with the Office of Administrative Law prior to the expiration date extends the expiration date of

this chapter by 180 days to June 6, 2016. The Department has met with stakeholders, has reviewed N.J.A.C. 10:167, and has determined that, with the proposed amendments, the rules are necessary, adequate, reasonable, efficient, understandable, and responsive to the purposes for which they were originally promulgated. The Department, therefore, proposes to readopt the chapter and proposes certain amendments.

The PAAD Eligibility Manual was adopted, effective April 5 1976, and originally codified as N.J.A.C. 10:69A. See 7 N.J.R. 505(c); 8 N.J.R. 232(b). The chapter was readopted, pursuant to Executive Order No. 66 (1978) (EO66), effective April 20, 1988. See 20 N.J.R. 369(a); 1106(a). Again, the chapter was readopted pursuant to EO66, effective March 26, 1993. See 24 N.J.R. 4479(a); 25 N.J.R. 1764(a). Pursuant to Reorganization Plan No. 001-1996, the chapter was recodified as N.J.A.C. 8:83, effective October 15, 1997. See 29 N.J.R. 4679(a). The chapter was readopted, pursuant to EO66, effective March 13, 1998. See 29 N.J.R. 5280(a); 30 N.J.R. 1314(b). The Department readopted the chapter, effective September 9, 2003. See 35 N.J.R. 1335(a); 4721(a). The Department readopted the chapter, effective December 9, 2008. See 40 N.J.R. 4479(a); 41 N.J.R. 221(a).

Effective July 1, 2012, the functions, powers, and duties of the Division of Senior Benefits and Utilization Management in the Department of Health (formerly Department of Health and Senior Services) were transferred to the newly established Division of Aging Services in the Department of Human Services (Department). See P.L. 2012, c. 17. Consequently, the authority for PAAD was transferred to the Department and, as a result thereof, the rules for the PAAD Eligibility Manual were recodified from N.J.A.C. 8:83 to 10:167 administratively, effective June 16, 2014. See 46 N.J.R. 1643(a).

The PAAD Eligibility Manual is promulgated to set forth the basic policies and procedures relating to assistance to persons who are financially disqualified from medical assistance under the New Jersey Medical Assistance and Health Services Act, P.L. 1968, c. 413 (N.J.S.A. 30:4D-1 et seq.), and who have significant needs for prescribed drugs and/or insulin needles, insulin syringes, and/or needles and syringes used for medications that can be injected for the treatment of multiple sclerosis, but are unable to fully meet the cost of such items. The PAAD Program is a State-funded program that was created as, and remains, a payer of last resort.

The PAAD Eligibility Manual refers to and relies upon a list of interchangeable drug products approved and published pursuant to N.J.A.C. 8:71. Specifically, N.J.A.C. 10:167-4.3 provides the reimbursement standards for brand name drugs that are deemed medically necessary by the prescriber and for those drugs where a substitution is permitted by the prescriber.

N.J.A.C. 8:71, Interchangeable Drug Products, established a list of interchangeable drug products that is necessary to the routine pharmaceutical dispensing of interchangeable drug products in the State and to the ability of pharmacists to comply with the Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq. The list of interchangeable drug products consisted of drug products that were determined to be acceptable substitutes for prescribed brand name drug products. See 36 N.J.R. 3051(a).

Pursuant to the Federal Food, Drug, and Cosmetic Act, at 21 U.S.C. § 355(j)(7), the Secretary of the United States Department of Health and Human Services, through the Office of Generic Drugs in the Office of Pharmaceutical Science of the Center for Drug Evaluation and Research of the United States Food and Drug Administration (FDA), produces a list of “Approved Drug Products with Therapeutic Equivalence Evaluations” commonly known as the “Orange Book.” Effective November 13, 2004, N.J.A.C. 8:71 was amended to incorporate those

drug products with therapeutic equivalence ratings of “A” identified in the Orange Book, as amended and supplemented, and those drug products approved by the FDA with therapeutic equivalence ratings of “A” that appear on the FDA’s “Drugs@FDA” website, as amended and supplemented. The Orange Book functioned as the Federal equivalent of the list of interchangeable drug products provided at N.J.A.C. 8:71 (also referred to as the “State formulary”). As amended, N.J.A.C. 8:71 provided for the concurrent operation of two lists of interchangeable drug products, specifically the Orange Book and the State formulary. The Department of Health, however, intended to eventually repeal the State formulary and to designate the Orange Book as the exclusive list of interchangeable drug products required by the Prescription Drug Price and Quality Stabilization Act. See 36 N.J.R. 3051(a).

N.J.A.C. 8:71 expired on November 13, 2009.

The PAAD Program and the PAAD Eligibility Manual have relied upon the Orange Book and the FDA’s “Drugs@ FDA” website for the list of interchangeable drug products. The Orange Book can be obtained by contacting the United States Government Printing Office at PO Box 979050, St. Louis, MO 63197, or at (866) 512-1800, and it is available on-line at <http://www.accessdata.fda.gov/scripts/cder/ob/>. The formal internet address for the FDA’s “Drugs@FDA” website is <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

N.J.A.C. 10:167 contains seven subchapters. The following is a summary of those subchapters and the proposed amendments:

Subchapter 1 contains the introduction, setting forth the purpose and intent of the chapter and the legal authority.

Subchapter 2 provides the definitions of terms used in the chapter.

The Department proposes to amend the definition of “applicant” to clarify that an applicant includes an individual who reapplies for PAAD.

The Department proposes to amend the definition of “business income” to correct a technical error.

The Department proposes to add the definition of “Division” to reflect the organizational change within the Department.

The Department proposes to change the term “Food Stamp Program” to the term “Supplemental Nutrition Assistance Program,” to address the change in the name of the program.

The Department proposes to add the definition of “interchangeable drug product” to address the expiration of N.J.A.C. 8:71, which will incorporate the Orange Book by reference, as amended and supplemented.

The Department proposes to amend the definition of “PAAD Co-pay” from \$6.00 for generic drugs to \$5.00 for generic drugs as mandated by Fiscal Year 2016 Appropriations Act, P.L. 2015, c. 63, as amended and supplemented by subsequent appropriations acts. The Department also proposes to amend the definition to include payment made by a primary payer on behalf of a beneficiary.

The Department proposes to amend the definition of “pharmaceutical assistance” to remove the form in which payment is made to pharmacies.

The Department proposes to amend the definition of “prescription drugs” to address the expiration of N.J.A.C. 8:71.

The Department proposes to amend the definition of “resident” to update a cross-reference.

The Department proposes to amend N.J.A.C. 10:167-2.2(a)8 and 12 to reflect the organizational change involving PAAD (and to use the newly defined term).

Subchapter 3 addresses the administrative organization.

Subchapter 4 establishes the scope of service.

The Department proposes to amend N.J.A.C. 10:167-4.3 to address the expiration of N.J.A.C. 8:71 and to reference the current Appropriations Act.

The Department proposes to amend N.J.A.C. 10:167-4.4 to update a cross-reference.

The Department proposes to amend N.J.A.C. 10:167-4.5 to reference the current Appropriations Act.

Subchapter 5 addresses the application process.

The Department proposes to amend N.J.A.C. 10:167-5.3 to reflect the change in the renewal application process from required annual renewal for each beneficiary to automatic renewal annually for those beneficiaries who appear to have no change in circumstances affecting eligibility based on information obtained by PAAD and the submission of renewal applications by those beneficiaries when specifically requested by PAAD upon the appearance of a change in circumstances affecting eligibility based on information obtained by PAAD. The Department also proposes to amend N.J.A.C. 10:167-5.3 to reflect the continuity of PAAD benefits during the renewal process and to clarify that the continuity of PAAD benefits applies only to those individuals eligible for the program.

The Department proposes to amend N.J.A.C. 10:167-5.4 to correct a technical error and to remove reference to a temporary eligibility card.

The Department proposes to amend N.J.A.C. 10:167-5.6 to correct a technical error and to delete the specific reference to microfilming and scanning so that the Department may implement new methods for the maintenance of records as technology changes over time. The Department also proposes to amend N.J.A.C. 10:167-5.6 to accurately reflect the change in the

renewal application process, which is automatic annually unless specifically requested by PAAD to submit a renewal application.

The Department proposes to amend N.J.A.C. 10:167-5.7 to remove the identification numbers for the application forms.

Subchapter 6 addresses eligibility.

The Department proposes to amend N.J.A.C. 10:167-6.2 to correct the income example for an institutionalized spouse and to correct a technical error.

The Department proposes to amend N.J.A.C. 10:167-6.6 to address the current website where application forms may be found, to remove identification numbers for the application forms, and to require the use of application forms approved by PAAD.

The Department proposes to amend N.J.A.C. 10:167-6.10 to accurately reflect the change in the renewal process, which is to automatically renew benefits annually unless a beneficiary is specifically requested by PAAD to submit a renewal application.

The Department proposes to amend N.J.A.C. 10:167-6.11 to correct a technical error (changing the “Department” to the “Department of Health”) and to reflect the current name of the food assistance program.

Subchapter 7 addresses recoveries and liens.

As the Department is providing a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The PAAD Program is a State-funded prescription drug program that provides prescription discounts to lower income elderly and disabled New Jersey residents who do not qualify for Medicaid, but need help in meeting the costs of prescription drugs and certain prescribed

supplies. Approximately 124,000 individuals currently receive PAAD benefits. The rules proposed for readoption with amendments would assure that those eligible individuals continue to receive assistance through the PAAD Program without interruption.

The amendments proposed at N.J.A.C. 10:167-5.3, 5.6, 6.6, and 6.10 address the automatic renewal of benefits for some beneficiaries and the submission of renewal applications by other beneficiaries. These changes reflect the current renewal process, which occurs when the Department internally reevaluates a beneficiary's eligibility for PAAD. If information indicates that a beneficiary's income may have increased, the Department will require the beneficiary to complete and submit a renewal application form to verify continued eligibility for PAAD. Otherwise, each beneficiary is automatically renewed annually and a renewal application is not necessary. This process eliminates the burden of re-applying for PAAD each year.

Economic Impact

The rules proposed for readoption with amendments would continue to have a beneficial economic impact because the current rules provide economic assistance to PAAD beneficiaries. Readoption of the rules would continue to allow eligible individuals to obtain prescription drugs from any participating pharmacy and assure subsidies to participating pharmacies for the prescription drugs dispensed. The availability of subsidies has allowed and would continue to allow eligible individuals to afford the medications necessary to improve or maintain their health. In addition, Fiscal Year 2016 Appropriations Act, P.L. 2015, c. 63, has mandated the reduction of co-payments for generic drugs from \$6.00 to \$5.00. This change provides further financial relief to eligible individuals without any added costs to participating pharmacies. Participating pharmacies have incurred and would continue to incur varying administrative costs directly related to their participation in PAAD. Therefore, the Department does not anticipate

that the rules proposed for readoption with amendments would have an added economic impact on participating pharmacies or eligible individuals.

With the adoption of prescription coverage through the Medicare Prescription Drug Program established pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. 108-173, effective December 8, 2003, and the regulations promulgated thereunder at 42 CFR 423.1 et seq., PAAD benefit costs have decreased because PAAD benefits are secondary to benefits provided through the Medicare Prescription Drug Program. The Department remains of the opinion that coverage available under the Medicare Prescription Drug Program to PAAD beneficiaries has resulted in a savings to New Jersey taxpayers. The Federal Medicare program is the primary payer of prescription drug costs for approximately 93 percent of PAAD beneficiaries. Therefore, the Department does not anticipate that the rules proposed for readoption with amendments would have an added economic impact on the taxpayers of New Jersey.

Federal Standards Statement

The PAAD Eligibility Manual establishes polices and requirements for the PAAD Program. The PAAD Program is completely State-funded after payment by primary payers, such as Medicare Part D. Therefore, there are no Federal standards governing eligibility or services under PAAD since these are established by State law. However, there are Federal requirements to be followed in other sections of the rules. In such cases, the Department imposes the same requirements as are imposed by the Federal government.

Section 101 of the Federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub.L. 108-173 (2003)), added sections 1860 D-1 through 1860 D-24 to the Federal Social Security Act and established a new Part D program for voluntary prescription drug

coverage. Section 1860 D-14 provides for premium and cost sharing subsidies of prescription drug coverage for certain individuals with low income and resources (42 U.S.C. § 1395w-114). As a condition of eligibility for the subsidy, a beneficiary is required to apply for the subsidy with the Federal Social Security Administration or with a state office that accepts Medicaid applications. (42 U.S.C. § 1395w-114(a)(3)).

The Health Insurance Portability and Accountability Act of 1996, Pub.L. 104-191, and the regulations promulgated thereunder by the United States Secretary of Health and Human Services at 45 CFR Parts 160 and 164, known as the "Standards for Privacy of Individually Identifiable Health Information" (collectively referred to as "HIPAA") apply to health information created or maintained by health care providers who engage in certain electronic transactions, health plans and health care clearinghouses. The Department is a covered entity within the meaning of HIPAA.

Pursuant to 45 CFR 164.512(d), a covered entity may disclose protected health information to a health oversight agency (such as the Centers for Medicare & Medicaid Services (CMS)) for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of the health care system, government benefit programs for which health information is relevant to beneficiary eligibility, entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards, or entities subject to civil rights laws for which health information is necessary for determining compliance. Moreover, pursuant to 45 CFR 164.514(d)(3)(iii)(A), when making disclosure permitted under 45 CFR 164.512, a covered entity may reasonably rely on the representation of a public official that the information

requested is the minimum necessary for the stated purpose. Therefore, for example, the disclosure of PAAD applicant, reapplicant, or beneficiary information protected under HIPAA to CMS and its endorsed agents, for the purpose of coordination of benefits between the Medicare Prescription Drug Program and the PAAD Program, would not constitute a violation of HIPAA. To the extent the PAAD Program may be subject to HIPAA, the rules proposed for readoption with amendments would meet but not exceed the requirements of HIPAA.

Except as described above, there are no Federal standards applicable to the subject matter of the rules proposed for readoption with amendments. Since any Federal requirements applicable to the rules are met, but not exceeded, no Federal standards analysis is required.

Jobs Impact

The Department does not anticipate that the rules proposed for readoption with amendments would have an impact on employment in New Jersey. The rules proposed for readoption with amendments would continue the current requirements imposed upon pharmacies participating in the PAAD Program.

Agriculture Industry Impact

The rules proposed for readoption with amendments are not expected to have an impact on the agriculture industry.

Regulatory Flexibility Analysis

Although this chapter is concerned primarily with the eligibility requirements for PAAD beneficiaries, the rules proposed for readoption with amendments would continue to impose requirements for pharmacies or prescribers, some of which may be considered small businesses that employ fewer than 100 full-time employees pursuant to the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The rules proposed for readoption with amendments do not impose

new reporting, recordkeeping, or compliance requirements on participating pharmacies, regardless of size.

In general, the requirements for pharmacies that want to participate in PAAD are set forth in N.J.A.C. 10:167A. Pharmacies would continue to be required to operate under a valid retail and/or institutional permit issued by the State Board of Pharmacy, file an application with the Department, and execute an agreement of participation. Out-of-State pharmacies would continue to be prohibited from participating in PAAD with the exception of mail order pharmacies that are part of an approved Medicare Part D plan's network of pharmacies or a mail order pharmacy required by the PAAD beneficiary's primary payer. The PAAD program requires all drugs to be prescribed by licensed practitioners within the scope of their practice and to be dispensed by licensed pharmacists pursuant to rules promulgated by the New Jersey State Board of Pharmacy at N.J.A.C. 13:39. (See N.J.A.C. 10:167A-1.5). Pharmacies are required to maintain records, including, but not limited to, identification of the patient, date of service, drug name, quantity dispensed, and price.

The rules would continue to require PAAD beneficiaries to join, where possible, a Medicare Part D prescription drug plan (PDP). Coordination of benefits with Medicare Part D and PAAD would continue to require electronic recordkeeping by pharmacies with the Centers for Medicare and Medicaid Services, PAAD, and the PDP. All PAAD pharmacies are equipped with the necessary software and recordkeeping systems to process claims and there would be no capital costs for PAAD pharmacies associated with the rules proposed for readoption with amendments.

The computer hardware and software costs for a pharmacy seeking to participate in PAAD would be the same for start-up pharmacies generally. The systems and equipment required to process a PAAD claim would continue to be the same as those required to process any claim

other than a claim paid in full by the customer. Since PAAD would continue to be the payer of last resort, pharmacies would continue with the process of split-billing, which bills the primary payer first and then bills the remainder to PAAD. Pharmacies should not need to retain any additional services to comply with the rules proposed for reoption with amendments.

Pharmacies have been and would continue to be the types of businesses affected by this chapter. As the reporting, recordkeeping, and compliance requirements are necessary for participation by pharmacies in PAAD, and are intended to ensure public health and the public's access to affordable prescription drugs, no lesser requirements or exemptions can be provided for small businesses.

Housing Affordability Impact Analysis

The rules proposed for reoption with amendments would have no impact on the affordability of housing or the average costs associated with housing in New Jersey because the rules pertain to the Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual and the provision of prescription discounts for those elderly and disabled residents eligible for the PAAD Program.

Smart Growth Development Impact Analysis

The rules proposed for reoption with amendments would have no impact on smart growth or housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the rules pertain to the Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual and the provision of prescription discounts for those elderly and disabled residents eligible for the PAAD Program.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 10:167.

Full text of the proposed amendments follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 2. DEFINITIONS

10:167-2.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

...

"Applicant" means an individual who applies **or reapplies** for PAAD, either personally or through an authorized agent.

...

"Business income" means net income derived from a business, trade, or profession or from the rental of property after deductions of the ordinary and necessary expenses attributable to the business, trade, profession, or to the rental [or] **of** property, which are allowed under the Federal Internal Revenue Code and regulations issued thereunder.

...

"Division" means the Division of Aging Services within the Department of Human Services.

...

["Food Stamp Program" means the Federal nutrition program established by 42 U.S.C. §1786 within the U.S. Department of Agriculture/Food and Nutrition Services which provides assistance with the purchase of food for low income households. This program is administered

by the county welfare agencies under supervision by the New Jersey Department of Human Services, Division of Family Development.]

...

“Interchangeable drug product” means those drug products, with therapeutic equivalence ratings of “A,” identified in the publication of the Office of Generic Drugs in the Office of Pharmaceutical Science of the Center for Drug Evaluation and Research of the Food and Drug Administration (FDA) of the United States Department of Health and Human Services, “Approved Drug Products with Therapeutic Equivalence Evaluations,” 34th Edition, incorporated herein by reference, as amended and supplemented (commonly known as the “Orange Book”) promulgated pursuant to the Federal Food, Drug, and Cosmetic Act, at 21 U.S.C. § 355(j)(7); and those drug products approved by the FDA with therapeutic equivalence ratings of “A” that appear on the FDA’s “Drugs@FDA” website, bearing formal internet address <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>, which is incorporated herein by reference, as amended and supplemented. The Orange Book can be obtained by contacting the United States Government Printing Office at PO Box 979050, St. Louis, MO 63197, or at (866) 512-1800, or it is available on-line at <http://www.accessdata.fda.gov/scripts/cder/ob/>.

...

"PAAD Co-pay" means a maximum amount of \$[6.00]**5.00** for generic drugs and \$7.00 for brand name drugs, which must be paid by each PAAD beneficiary, **or by the primary payer(s) on behalf of the beneficiary**, to the pharmacy toward the cost for each prescription for a legend drug and/or insulin, insulin syringes, and insulin needles. If the prescription is paid first by payers other than PAAD and the remaining cost of the prescription is less than \$[6.00]**5.00** for

generic drugs and \$7.00 for brand name drugs, then that remaining cost becomes the PAAD co-pay. The co-pay is not reimbursable by the PAAD. The co-payment shall be paid in full by each eligible person, **or by the primary payer(s) on behalf of the eligible person**, to the pharmacist at the time of each purchase of prescription drugs, and shall not be waived, discounted, or rebated in whole or in part. **PAAD co-payment amounts shall be determined in accordance with the Fiscal Year 2016 Appropriations Act, P.L. 2015, c. 63, approved June 26, 2015, as amended and supplemented by subsequent State appropriations acts.**

"Pharmaceutical assistance" means the payments authorized by the Department [in the form of a check] to a participating pharmacy on behalf of a PAAD beneficiary.

...

"Prescription drugs" means all approved legend drugs, including any interchangeable drug products [contained in the latest list approved and published pursuant to N.J.A.C. 8:71] and in conformance with the provisions of the "Prescription Drug Price and Quality Stabilization Act," and insulin, insulin syringes, and insulin needles when prescribed.

1.-2. (No change.)

...

"Resident" means "one legally domiciled within the State (of [N.J.] **New Jersey**) for a period of 30 days immediately preceding the date of application for inclusion in the PAAD Program. Mere seasonal or temporary residence within the State, of whatever duration, does not constitute domicile." (See N.J.A.C. [10:69A-6.4] **10:167-6.4** for residence requirements.)

...

"Supplemental Nutrition Assistance Program" (SNAP) means the Federal nutrition program established by 42 U.S.C. § 1786 within the U.S. Department of Agriculture/Food

and Nutrition Services, which provides assistance with the purchase of food for low income households. This program is administered by the county welfare agencies under supervision by the New Jersey Department of Human Services, Division of Family Development.

...

10:167-2.2 Special needs trusts

(a) To be considered a special needs trust, the trust shall include the following provisions:

1.-7. (No change.)

8. The trustee shall be specifically identified by name and address. The trust shall state that the original trust beneficiary cannot be the trustee. The trust shall make provisions for naming a successor trustee in the event that any trustee is unable or unwilling to serve. The [Office of Support Services for the Aged] **Division**, as well as the trust beneficiary and/or guardian, shall be given prior notice if there is a change in the trustee;

9.-11. (No change.)

12. The State shall be given advance notice of any expenditure in excess of \$5,000, and of any amount which would substantially deplete the principal of the trust. Notice shall be given to the [Office of Support Services for the Aged] **Division**, PO Box 715, Trenton, NJ 08625-0715, or any successor agency, 45 days prior to the expenditures;

13. (No change.)

SUBCHAPTER 4. SCOPE OF SERVICE

10:167-4.3 Interchangeable drug products

(a) Whenever PAAD is the primary payer and any interchangeable drug product [contained in the latest list approved and published pursuant to N.J.A.C. 8:71] is available for the prescription written, the PAAD Program shall reimburse for multisource generic drugs without prior authorization, but not for multisource brand name drugs without prior authorization.

(b) (No change.)

(c) If the prescriber specifies on the prescription that substitution is not permitted, and that the brand name drug is medically necessary, when required, the PAAD Program shall reimburse for the reasonable cost of the prescribed product, less the PAAD co-pay pursuant to the requirements respecting prior authorization set forth in the Fiscal Year [2008] **2016** Appropriations Act, [P.L. 2007, c. 111, approved June 28, 2007] **P.L. 2015, c. 63, approved June 26, 2015**, as amended and supplemented by subsequent State appropriations acts.

10:167-4.4 Beneficiary co-payment

(a) (No change.)

(b) In the event that a PAAD beneficiary receives [his/her] **his or her** eligibility identification card later than 30 days from the date that [his/her] **his or her** complete and valid Eligibility Application was received by the PAAD program, [he/she] **he or she** may be eligible to receive direct reimbursement for prescription drugs purchased. See N.J.A.C. [10:69A-5.4] **10:167-5.4** for details.

10:167-4.5 Medicare Part D Prescription Drug Plan premium payments

(a) The Department shall pay Medicare Part D premiums to the PDP on behalf of PAAD beneficiaries in accordance with the Fiscal Year [2008] **2016** Appropriations Act, [P.L. 2007, c.

111] P.L. 2015, c. 63, approved June 26, 2015, as amended and supplemented by subsequent State appropriations acts.

1.-2. (No change.)

SUBCHAPTER 5. APPLICATION PROCESS

10:167-5.3 Eligibility effective date

(a) (No change.)

(b) The PAAD program shall conduct periodic redeterminations of the eligibility of PAAD beneficiaries.

1. (No change.)

2. PAAD shall request and review renewal applications to verify continued eligibility of certain beneficiaries on a case-by-case basis. Those beneficiaries required to renew [annually or biennially must submit a valid renewal application 45 days prior to their expiration date to insure that their PAAD benefits continue uninterrupted; however,] **shall be notified in writing and shall receive a renewal application from PAAD. At least 45 days prior to the expiration of PAAD benefits, the beneficiary shall submit a fully and accurately completed renewal application form, along with the required signature(s) and supporting documentation. However,** if beneficiaries are late in submitting their renewal applications, but apply within 90 days after the expiration date, [their PAAD benefits will continue uninterrupted] **those beneficiaries who meet the PAAD eligibility criteria shall receive continuous PAAD benefits.** If the renewal application is submitted more than 90 days after the expiration date, the eligibility effective date **for eligible beneficiaries** will be the date when a valid and completed renewal application is processed by the PAAD program. If the PAAD beneficiary is late in filing

his or her renewal application by more than 90 days after the expiration date, the PAAD program shall not make reimbursement until the new eligibility period has been established.

3. For those beneficiaries submitting renewal applications, PAAD shall reassess eligibility. If PAAD determines that a beneficiary is eligible for the program, then PAAD shall mail a new eligibility card to the beneficiary. If PAAD determines that a beneficiary is ineligible for the program, then PAAD shall notify such person, in writing, and he or she shall be disenrolled from PAAD. The PAAD program shall not reimburse a beneficiary for the cost of prescription drugs purchased after he or she has been disenrolled from the program.

10:167-5.4 Exceptions from normal standards

(a) (No change.)

(b) A PAAD applicant, who meets all the PAAD eligibility criteria, can reasonably expect to receive [his/her] **his or her** PAAD [temporary] eligibility card within 30 days from the date that a complete and valid Eligibility Application is received by PAAD.

(c) In the event that mailing of the eligibility card is delayed, the PAAD program shall reimburse the PAAD beneficiary directly for the cost (minus a PAAD co-payment per prescription) of all prescription drugs purchased by the person on or after the 30th day after his or her properly completed application was received by the PAAD program, subject to the following conditions:

1. The eligibility application **or** renewal application must have been fully and properly completed.

2.-3. (No change.)

10:167-5.6 Responsibilities in the application **and** renewal process

(a) (No change.)

(b) The Pharmaceutical Assistance to the Aged and Disabled Program has responsibility in the application process to:

1.-3. (No change.)

4. [Automatically mail] **Mail** reapplication forms [approximately four months] prior to the eligibility expiration date **when current information is necessary to verify continued eligibility;**

5. [Microfilm or electronically scan] **Maintain** the eligibility application and supporting documents [and retain the microfilm or electronic copy] for audit purposes; and

6. (No change.)

(c) The applicant or beneficiary has the responsibility to:

1.-4. (No change.)

5. Reapply for eligibility, **when requested to do so**, on forms mailed by the Department, at least 45 days prior to [his/her] **his or her** eligibility expiration date, if [he/she] **he or she** wishes to renew PAAD eligibility.

6.-9. (No change.)

(d) (No change.)

10:167-5.7 Combined application for PAAD/Lifeline

(a) There shall be only one application for those beneficiaries who apply for both PAAD and Lifeline.

1. (No change.)

2. If an applicant wishes to apply only for Lifeline, he or she shall [still] use the [AP-2] **PAAD eligibility application** form. (See N.J.A.C. 10:167D-4.8)

3. On reapplication for Lifeline, the applicant shall complete [an AP-12] **the PAAD** renewal form.

(b)-(c) (No change.)

SUBCHAPTER 6. ELIGIBILITY REQUIREMENTS

10:167-6.2 Income standards

(a) (No change.)

(b) Any married permanent resident of New Jersey who is 65 years of age or over or who is under 65 and over 18 years of age and is receiving Social Security Title II disability benefits must have a combined (applicant and spouse) annual income of less than \$32,582 to be eligible for PAAD.

1. (No change.)

2. An applicant and spouse may be considered separated when the spouse has been institutionalized in a long-term facility, either skilled or intermediate, or in a State or county psychiatric hospital at least 30 consecutive days prior to application.

i. PAAD shall consider the applicant and spouse separated only when doing so is more favorable to the applicant for PAAD (for example, when the income of an applicant and his **or her** institutionalized spouse is combined at [\$25,060] **\$32,582**, the applicant is ineligible for PAAD, but if the applicant and spouse are considered separated, the applicant could be eligible for PAAD under the single income standard. If the institutionalized spouse was not covered by Medicaid, the spouse could become eligible under the single income standard).

(c) All income, from whatever source derived, is considered in determining eligibility for the purpose of PAAD. Jointly owned income sources, will be allocated according to degree of ownership.

1. (No change.)

2. Sources of income, which are excluded in considering eligibility for PAAD are as follows:

i.-iv. (No change.)

v. Stipends from the Volunteers [to] **in** Service [in] **to** America (VISTA), Foster Grandparents programs, Workforce 55+ program, and programs under Title V of the Older Americans Act of 1965;

vi.-xiv. (No change.)

(d)-(n) (No change.)

10:167-6.6 PAAD eligibility application and renewal application forms

(a) [The Pharmaceutical Assistance to the Aged and Disabled Eligibility Application (AP-2) is the only acceptance form to be utilized in determining the applicant's initial eligibility for PAAD.

These] **The eligibility application** forms are available to applicants in central and local offices

and other convenient locations throughout the State, on the Department's website at

[www.state.nj.us/health/seniorbenefits/forms.shtml]

www.state.nj.us/humanservices/doas/home/ap2.html, and by writing to the New Jersey

Department of Human Services, Pharmaceutical Assistance to the Aged and Disabled (PAAD),

PO Box 715, Trenton, NJ 08625-0715.

[(b) The only acceptable form to be utilized in determining the beneficiary's continuation of eligibility will be the PAAD Eligibility Renewal Application Form (AP-12). This form is automatically mailed to the beneficiary approximately four months prior to the eligibility expiration date.]

(b) Applicants shall apply, or renew their application, for PAAD and/or for Lifeline on forms approved by PAAD.

(c) (No change.)

10:167-6.10 Eligibility period

(a) A PAAD eligibility card is effective for the dates indicated on the card. **PAAD shall automatically renew each beneficiary's eligibility card annually unless PAAD determines, in its sole discretion, that a beneficiary must submit current information by completing a renewal application.** The PAAD beneficiary shall renew his or her eligibility in accordance with the provisions of N.J.A.C. 10:167-5.3(b). [In that case, he or she would receive an updated eligibility card automatically for the second year, and would complete a renewal application every two years. Beneficiaries who are subject to the two year renewal provision will have their eligibility card renewed automatically for one additional year.]

(b) [Approximately four months prior to his or her expiration date,] PAAD will notify the beneficiary if he or she must complete a renewal form. Renewal applications must be returned to the PAAD Program by the beneficiary at least 45 days prior to the expiration date to ensure continuous coverage.

10:167-6.11 Confidentiality and disclosure of information

(a)-(b) (No change.)

(c) The prohibition of (a) above against unauthorized disclosure shall not be construed to prevent:

1.-5. (No change.)

6. The release of information to the Department **of Health** and participating licensed veterinarians for the purpose of verifying eligibility for benefits under the Animal Population Control Program.

7. The release of information or files to county welfare agencies for the purpose of determining eligibility for Medicaid or [Food Stamp] **Supplemental Nutrition Assistance** Program benefits or for subsequent verification of Medicaid eligibility.

8.-11. (No change.)