48 NJR 10(1)
October 3, 2016
Filed September 13, 2016

HUMAN SERVICES

DIVISION OF AGING SERVICES

Provision of Pharmaceutical Services Under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD)

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

Proposed Repeal: N.J.A.C. 10:167A-1.4

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

Authority: N.J.S.A. 30:4D-24.

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

Proposal Number: PRN 2016-167.

Submit written comments by December 2, 2016, to:

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A copy of the notice of proposal is available for review at all offices of the Area Agencies on Aging, which are situated in all 21 counties.

The agency proposal follows:

Summary

The requirements of N.J.A.C. 10:167A pertain to the specific arrangements between licensed pharmacies and the Pharmaceutical Assistance to the Aged and Disabled (PAAD) program administration and beneficiaries. The PAAD program provides assistance to certain persons whose level of income disqualifies them for medical assistance under the Medical Assistance and Health Services Act, but who have medical needs for prescribed drugs and/or insulin, insulin needles, insulin syringes, and syringes and needles for injectable medicines, and are unable to fully meet the cost of such items.

The PAAD program was transferred from the Department of Human Services (Department) to the Department of Health and Senior Services (DHSS) pursuant to Executive Reorganization Plan No. 001-1996. Pursuant to that Plan, the PAAD Program Pharmacy Manual was proposed for recodification from Title 10 of the New Jersey Administrative Code, N.J.A.C. 10:51-4, to Title 8, N.J.A.C. 8:83C. 30 N.J.R. 2197(a), June 15, 1998. N.J.A.C. 8:83C was adopted, effective September 8, 1998. 30 N.J.R. 3309(a). N.J.A.C. 8:83C expired on February 10, 2004, and was adopted as new rules, effective April 19, 2004. 35 N.J.R. 4416(a); 36 N.J.R. 2053(a). N.J.A.C. 8:83C was readopted, effective September 2, 2009. 41 N.J.R. 1637(a); 3804(a).

In 2012, N.J.S.A. 30:1A-14 transferred to the Division of Aging Services (DoAS), the powers and duties of the Department of Health and Senior Services that relate to the provision of programs or services for senior citizens, the New Jersey State Commission on Aging, the Division on Aging and Community Services, and any other

division relating to senior benefits. P.L. 2012, c. 17 reestablished the Department of Health and Senior Services as the Department of Health and established the DoAS within the Department.

N.J.A.C. 8:83C, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), was recodified as N.J.A.C. 10:167A by administrative change, effective June 16, 2014. As part of the recodification, administrative changes were made throughout concerning cross-references, agency names and addresses, and the elimination of text rendered redundant or moot by the transfer of authority. 46 N.J.R. 1643(a)

Pursuant to N.J.S.A. 52:14B-5.1, N.J.A.C. 10:167A was scheduled to expire on September 2, 2016. The DoAS has reviewed the rules and determined them to be necessary, adequate, reasonable, proper, and responsive for the purpose for which they were originally promulgated. The rules proposed for readoption with amendments are intended to continue the rules beyond September 2, 2016, without interruption. As DoAS has filed this notice of readoption with the Office of Administrative Law prior to September 2, 2016, the expiration date is extended 180 days to March 1, 2017, pursuant to N.J.S.A. 52:14B-5.1.c(2). Grammatical changes are proposed throughout the chapter, where appropriate.

N.J.A.C. 10:167A-1.1 provides an introduction and summary of the PAAD program.

N.J.A.C. 10:167A-1.2 defines words and terms used in the chapter. The Department proposes to amend the definition of “applicant” to mean someone who applies “or re-applies” for PAAD. The Department proposes to amend the definition of

"prescription drugs" to delete the reference to interchangeable drug products contained in the latest list and published in N.J.A.C. 8:71, which expired on November 13, 2009. A reference to the definition of legend drug is proposed for deletion. Prescription drugs is proposed to include syringes and needles for injectable medicines, not only syringes and needles for multiple sclerosis. The Department proposes a new definition of interchangeable drug products, which would incorporate by reference the Federal Orange Book.

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). 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 online 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/.

The definitions of durable medical equipment, electronic data interchange (EDI) enrollment form, Medicare Part B supplier, National Supplier Clearinghouse (NSC), and NSC supplier number are proposed for deletion. The PAAD program no longer pays for diabetic testing supplies or other durable medical equipment; therefore, these definitions are no longer needed. The PAAD program no longer needs to check whether a Part B supplier has a number issued by the NSC and the EDI enrollment forms for these suppliers are no longer necessary.

The Department proposes new definitions of “active pharmaceutical ingredient,” “bulk drug substance,” “electronic media claim” or “EMC,” “excipient,” “national drug code,” and “national provider identifier” or “NPI.”

N.J.A.C. 10:167A-1.3 details the requirements that providers must satisfy and maintain in order to qualify as a PAAD provider. The requirements for a pharmacy to maintain enrollment as a Medicare Part B durable medical goods supplier and proof of an NSC number are proposed for deletion. The section would be amended to require a provider of pharmaceutical services to be assigned a national provider identifier and to state that a provider may obtain a copy of the provider application online at njmmis.com. The Division of Medical Assistance and Health Services is proposed to be referred to as the Division.

N.J.A.C. 10:167A-1.4, Medicare recovery initiative, is proposed for repeal. This section details the procedure used to recover the cost of prescription drug benefits paid by PAAD that were payable under Medicare Part B. This section is no longer needed because PAAD does not pay for supplies covered by Medicare Part B.

N.J.A.C. 10:167A-1.5 details the conditions necessary for pharmacy participation in PAAD. The section is amended to provide that participating pharmacies shall provide services within the scope of their permits issued by the Board of Pharmacy in place of requiring them to provide complete prescription services. A proposed amendment would provide that drugs may also be dispensed on the basis of telephonic or electronic prescriptions. The proposed amendments would add the following to the list of items a pharmacy must allow the Department to review: refills, the date dispensed and date written, NDC, brand-drug dispensing authorizations, other insurance payments, patient

payment liability amounts, days supply, usual and customary charge, drug acquisition cost, and customer certifications. The Department would also be allowed to review acquisition records for the purchase of covered drugs based on NDC numbers.

N.J.A.C. 10:167A-1.6 details the restrictions that affect payment for prescribed drugs under PAAD. This section is amended to reference the new Federal regulations that set upper limits of payment for prescription drugs and to delete the reference to N.J.A.C. 8:71, which expired on November 13, 2009. The section would also be amended to reference the requirements for faxed or electronically submitted original prescriptions. The section would also be amended to provide that reimbursement would be denied if any of the requirements of the chapter are not met, and reference to specific sections of the chapter are deleted.

N.J.A.C. 10:167A-1.7 sets forth the basis of payment for legend or certain non-legend drugs. This section is amended to provide that basis of payment is subject to the requirements of the State appropriations acts. See P.L. 2015, c. 63, p. 112. Subsections (d) through (g), which establish limits on PAAD payments prior to and after July 15, 1996, and after July 1, 2008, are no longer needed and would be deleted. Subsection (h) is proposed for deletion because it is no longer needed. In 2009, N.J.A.C. 10:167A-1.7 was amended to add subsection (h), which provided that, for claims after October 1, 2009, where PAAD is the primary payer, reimbursement for the cost of multisource generic drugs shall be in accordance with 42 CFR 447.512 and 514, and the listings established and issued by the Federal Centers for Medicare and Medicaid Services (CMS) pursuant to 42 CFR 447.514. 42 CFR 447.512 and 514 are already referenced in N.J.A.C. 10:167A-1.6. 42 CFR 447.512 and 514 are the

regulations adopted by CMS, pursuant to the Federal "Deficit Reduction Act of 2005," Pub. L. 109-171 (42 U.S.C. § 1396r-8(a) through (d)), which set the upper limits of payment for multiple source drugs. See 42 CFR 447.500 and 72 FR 39142, 39239.

Pursuant to 42 CFR 447.514, CMS has established and issued listings that identify and set upper limits for multiple source drugs that meet certain requirements. 42 CFR 447.512(a) requires that agency payment for multiple source drugs not exceed the limits established in accordance with 42 CFR 447.514. 42 CFR 447.512(c) establishes a different upper limit of payment for drugs not listed pursuant to 42 CFR 447.514 and for brand name drugs certified as medically necessary by a physician. The amendments to the Social Security Act regarding the regular update by CMS of the prescription drug pricing standard was delayed until plan years beginning on or after January 1, 2009. See 42 U.S.C. § 1395w-27(f)(2)(C), note and 42 U.S.C. § 1395w-112(b)(6). Therefore, N.J.A.C. 10:167A-1.7(h)1 provided that, for claims after July 1, 2008, and until October 1, 2009, where PAAD is the primary payer, reimbursement for the cost of multisource generic drugs shall be in accordance with the listings established and issued by CMS pursuant to 42 CFR 447.332 (effective December 31, 2006). 42 CFR 447.332 was replaced by 42 CFR 447.514. See 72 FR 39142, 39154. Paragraph (h)1 is no longer needed and is proposed for deletion.

N.J.A.C. 10:167A-1.9 details the dispensing fee paid to providers under the PAAD program. Subsection (a) is amended to reflect that the current dispensing fee when PAAD is the primary payer is $3.73 "to $3.99," which includes the emergency services and area impact fees, and which is required by the State fiscal year 2016

appropriations act, P.L. 2015, c. 63, p. 112. Subsection (d) is amended to specify the report in subsection (c).

N.J.A.C. 10:167A-1.10 details the beneficiary copayment responsibility under PAAD. The pharmacy is responsible for the collection of the copayment at the point-of-sale (POS). Subsection (c) is deleted because the Medicare recovery initiative requirements at N.J.A.C. 10:167A-1.4 are proposed for repeal.

N.J.A.C. 10:167A-1.11 defines compounded prescriptions and the conditions under which they may be reimbursed by PAAD. Subsection (a) is amended to provide that pharmaceutical excipients by themselves are not covered compounded prescriptions. The delineation of acceptable pharmaceutical excipients would be deleted. Subsection (b) is amended to provide that manual claims for compounded prescriptions are no longer accepted, and that electronic claims shall (rather than may) be submitted. Paragraph (c)1 and subsections (d) and (e) are amended and deleted, respectively, to delete the method for reimbursing for compound prescriptions and to require that compound prescriptions be reimbursed in accordance with N.J.A.C. 10:167A-1.7 and 1.9. Recodified subsections (d) and (e) are amended to provide that legend ingredients in compounded prescriptions are covered by PAAD in accordance with N.J.A.C. 10:167A-1.14 and 1.15, and the reference to the Drug Efficacy Study Implementation would be deleted.

N.J.A.C. 10:167A-1.12 details the dispensing procedures for non-proprietary or generic prescription drugs under the PAAD program. The reference to generic drugs listed in N.J.A.C. 8:71 is deleted and replaced with the list of interchangeable drug products. The section is amended to provide that the drug package size code must be

reported on the claim form and the provision that allowed the package size code to differ from the stock package size is deleted.

N.J.A.C. 10:167A-1.13 details how the provider's usual and customary charge is considered in reimbursement by PAAD.

N.J.A.C. 10:167A-1.14 details the pharmaceutical services covered under PAAD. This section is amended to provide that claims shall be billed to the fiscal agent using the NCPDP format. Covered syringes and needles for injectable medicines would not be limited to the treatment of multiple sclerosis. The definition of legend drugs in paragraph (b)1 is deleted.

N.J.A.C. 10:167A-1.15 details the non-covered pharmaceutical services under PAAD. The section is amended to correct a reference to the Department of Health. This section is amended to add the following drugs, ingredients, and conditions as not covered by PAAD: diabetic testing materials; vitamins; cough and/or cold medications; drugs used for the treatment of erectile dysfunction; drugs used for alopecia, hair removal or hair restoration, eyelash growth, weight loss, and skin conditions; and active pharmaceutical ingredients, bulk drug substances, and excipients that are not covered outpatient drugs. Therefore, paragraph (b)6 is proposed for deletion because it allowed coverage of cosmetic drugs when medically necessary. Subsection (b) is proposed for amendment to provide that otherwise reimbursable products shall also be excluded under the following conditions: drugs prescribed by practitioners not assigned a national provider identifier; drugs provided by excluded practitioners as defined by the Patient Protection and Affordable Care Act regulations; drugs not dispensed within 14 calendar days; brand name drugs requested by a PAAD beneficiary when a generic is required;

drugs subject to the medical exception process that do not receive authorization; and legend drugs distributed by a manufacturer that has not entered into a rebate agreement with the Department.

N.J.A.C. 10:167A-1.16 details the quantity of medication covered under PAAD for both an initial prescription claim and a refill prescription claim. Subsection (a) is amended to delete the reference to claims with service dates after November 1998.

N.J.A.C. 10:167A-1.17 details how the dosage and directions should be indicated on all PAAD eligible prescriptions. In addition, it directs the provider to indicate the number of days supply reported for the days supply in the appropriate field of the claim or a reasonable estimation of the drug's intended duration of use.

N.J.A.C. 10:167A-1.18 details how providers handle telephone-rendered, faxed, or electronically transmitted original prescriptions.

N.J.A.C. 10:167A-1.19 details how the providers handle changes or additions to an original prescription.

N.J.A.C. 10:167A-1.20 details how a provider's claim would be submitted for prescription refills. The section is amended to require refill instructions be indicated on a facsimile of the prescription and in the electronic prescription. All authorized refills, not only those by telephone, would be assigned a new prescription number. Prescription refills would not be dispensed until 85 percent of the original prescription is used: no refills would issue if a lesser quantity is used. The exception to the 85 percent requirement for prescriptions lost or destroyed would be eliminated.

N.J.A.C. 10:167A-1.21 explains the Prescription Drug Price and Quality Stabilization Act and how it applies to PAAD covered claims. This section is amended

to delete references to N.J.A.C. 8:71 and to add references to the list of interchangeable drug products. The references to the claim format or similar field is deleted and the section is amended to provide that reimbursement for MAC drugs and non-MAC drugs would not equal the estimated acquisition cost, but would be in accordance with N.J.A.C. 10:167A-1.7. References to service dates on or after July 15, 1996, are no longer necessary and are deleted.

N.J.A.C. 10:167A-1.22 explains the drug efficacy study implementation (DESI) and the conditions under which DESI drugs would not be eligible for reimbursement by PAAD. A reference to notice of opportunity for hearing is replaced with the acronym NOOH.

N.J.A.C. 10:167A-1.23 explains bundled drug services and the conditions for reimbursement of the bundled drug services. Paragraph (b)1 is deleted because product information from manufacturers or distributors of bundled drug services is no longer necessary for reimbursement.

N.J.A.C. 10:167A-1.24 explains how providers must submit prescription drug claims for reimbursement under PAAD. This section is amended to delete the claim filing requirements and to require approved providers enter into an agreement with a point-of-sale (POS) intermediary in accordance with N.J.A.C. 10:167A-1.27. The reference to the specific version of the NCPDP is proposed for deletion and the new version D.0 is proposed to be incorporated by reference, as amended and supplemented, in the proposed new definition of electronic media claim. Subsection (b) is deleted.

N.J.A.C. 10:167A-1.25 requires that PAAD applicants shall be determined to be eligible only if physically present in New Jersey at the time of application and utilization in accordance with the provisions of N.J.A.C. 10:167A. In addition, N.J.A.C. 10:167A-1.25 requires that benefits shall not be paid when recipients are in nursing facilities, hospitals, or special hospitals and are covered by other insurance benefits or if the prescriptions are covered in the daily rate of the facility.

N.J.A.C. 10:167A-1.26 requires pharmacies to verify that the beneficiary is covered by PAAD by requesting the beneficiary to produce a PAAD identification card. A technical amendment is proposed to this section to correct the reference to Validation Identification Card.

N.J.A.C. 10:167A-1.27 details the POS claims adjudication system, and what is required by PAAD to process and approve these claims, including hardware, software, format, and data. The references to POS as an alternative to other methods of claim submission is proposed for deletion and to require use of the POS. The reference to the Health Care Financing Administration is proposed to be replaced with CMS. The provisions of subsection (e), which provides that pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose delivery systems are precluded from the POS system is proposed to be relocated to subsection (a).

N.J.A.C. 10:167A-1.28 details the prospective drug utilization review (PDUR) program and the requirements on pharmacies regarding the system. The program was established by the Department of Human Services and the Department of Health to assist pharmacy providers in monitoring drug utilization by beneficiaries. It is a

component of the POS claims adjudication system and helps to identify problems including, but not limited to, drug interactions, dosage alerts, and duplications.

N.J.A.C. 10:167A-1.29 provides the medical exception process (MEP) that permits the override of a claim denial, when medically necessary. The section states that PAAD will deny payment for claims subject to the MEP for which an authorization number has not been issued by the MEP contractor. The section also provides an appeal process for the beneficiary, pharmacy, or prescriber. Subsection (a) is proposed for amendment to replace the reference to institutionalized beneficiaries with long-term care facility providers.

N.J.A.C. 10:167A-1.30 provides that reimbursement for legend drugs shall be limited to manufacturers who have entered into a PAAD rebate agreement with the Department of Human Services through the Division of Medical Assistance and Health Services. The section is proposed for amendment to reference the requirement that manufacturers also enter into an agreement to pay rebates on drugs for which PAAD is a secondary payer.

As the Department of Human Services has provided a 60-day comment period for 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 rules proposed for readoption with amendments and a repeal impact New Jersey residents who are 65 years of age or older, or who are under 65 and over 18 years of age and are receiving Social Security disability benefits, and meet the income

eligibility requirements. Approximately 124,000 individuals currently receive PAAD benefits. The income eligibility limits for the calendar year 2016 are $26,575 for a single person and $32,582 for a married couple. The income limits are adjusted annually by the maximum Social Security benefit cost-of-living increase for single and married persons, respectively, in accordance with 42 U.S.C. § 415(i)(2)(D). See N.J.A.C. 10:167A-6.2(m).

The rules proposed for readoption with amendments and a repeal should have a positive effect on beneficiaries since the rules will assure the continued coverage of pharmaceutical services to the approximately 124,000 participating beneficiaries. The continued coverage of pharmaceutical services provided to individuals who might otherwise not be able to afford the medications should have a positive social impact because access to medications may alleviate or prevent the need for medical care for more acute symptoms of a medical disorder.

The rules proposed for readoption with amendments and a repeal impact pharmacy providers that participate in the program. Currently, approximately 2,000 pharmacies participate in the PAAD network. These providers are subject to the program requirements described in this chapter. However, while the compliance requirements impose a burden on the providers, the business acquired by accepting PAAD beneficiaries should outweigh this burden. In addition, participation in PAAD is voluntary. No pharmacy is required to participate. The technical amendments to the chapter, the amendments to delete references to expired N.J.A.C. 8:71, and the addition of a definition of interchangeable drug products are not expected to have a negative social impact.

For all these reasons, the Department expects a beneficial social impact and a primarily positive reaction to the rules proposed for readoption with amendments and a repeal.

Economic Impact

The Department believes that, because the existing rules proposed for readoption with amendments and a repeal regarding the PAAD Program provide economic assistance to eligible individuals for the purchase of their needed medications, the rules would continue to have a positive economic impact. The technical amendments to the chapter, amendments to delete references to expired N.J.A.C. 8:71, and the addition of a definition of interchangeable drug products are not expected to have an economic impact. The vast majority of PAAD claims are now made through Part D providers at the Part D provider's pricing rate. Over 90 percent of PAAD beneficiaries are enrolled in Medicare Part D plans, which are their primary payers. PAAD is the primary payer on only a very small percentage of claims and the basis of payment required by the State fiscal year appropriations act (P.L. 2015, c. 63, p. 118), only applies to claims where PAAD is the primary payer. The electronic POS format version that would be required by N.J.A.C. 8:83C-1.24 can be purchased for an annual cost of $650.00. This electronic format is necessary for filing electronic claims with most insurance companies, and through any Federal or State programs like Medicaid, Medicare, and PAAD. Medicare Part D requires that participating pharmacies use POS format. Therefore, usage of these standards for the electronic submission of claims is a

general cost of doing business for a pharmacy and most pharmacies should already be using POS.

Federal Standards Statement

N.J.A.C. 10:167A establishes policies and requirements, with regard to the PAAD Program, which is completely State-funded after payment by primary payers, such as Part D. Therefore, there are no Federal standards governing eligibility or services under PAAD, as these are established by State law. However, there are Federal requirements followed by PAAD in several other sections of the rules. In these cases, the Department imposes the same requirements as are imposed by the Federal government. Federal regulations at 42 CFR 440.120 define what may be covered as prescribed drugs. See also 42 U.S.C. § 1396r-8(d). Rebate requirements are contained in 42 U.S.C. §§ 1396r-8(b) through (c) and (k). Federal restrictions regarding payment for less than effective drugs (known as DESI) are included in Section 1927(k) of the Act (42 U.S.C. § 1396r-8(k)(2)(A) and 21 CFR 310.6).

Payment for drugs is subject to Federal upper payment limits (42 CFR 447.500 through 447.520) and Section 1927(e) and (k) of the Act (42 U.S.C. §§ 1396r-8(e) and 8(k), respectively).

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,” hereinafter collectively referred to as “HIPAA,” apply to health information created or maintained by health plans and

health care clearinghouses. The Department's PAAD Program complies with the requirements of HIPAA.

Pursuant to 45 CFR 164.512(d), a covered entity may disclose protected information to a health oversight agency (such as 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 disclosures 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 and a repeal 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 and a repeal. Since any Federal requirements applicable to the rules are met, but not exceeded, no Federal standards analysis is required.

Jobs Impact

The Department anticipates that no jobs will be gained or lost as a result of the rules proposed for readoption with amendments and a repeal. However, as the PAAD program spends approximately $100,000,000 annually on drug claims for its beneficiaries, the Department believes that the program undoubtedly has a positive impact on maintaining jobs within the pharmaceutical sector. The Department has budgeted money for administrative costs. Therefore, State employees, and employees of the fiscal agent, will continue to process applications and process claims for payment, respectively.

Agriculture Industry Impact

The rules proposed for readoption with amendments and a repeal will have no impact on the agriculture industry in the State of New Jersey.

Regulatory Flexibility Analysis

The rules proposed for readoption with amendments and a repeal apply equally to all providers regardless of size. Currently, there are approximately 2,000 New Jersey pharmacies in the PAAD network, some of which might be considered small businesses under the terms of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16. All pharmacy

providers must operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey (N.J.A.C. 10:167A-1.2(b)1). Pharmacy providers are required to be staffed by a registered pharmacist to provide pharmaceutical services pursuant to N.J.A.C. 13:39-1.2. Pharmacy providers may choose to retain other professional staff to submit claims, but they are not required to do so. There are no capital costs associated with the rules proposed for readoption with amendments and a repeal.

Pharmacies would still be required to file an application and agreement of participation with the Division of Medical Assistance and Health Services of the Department of Human Services. (See N.J.A.C. 8:83-4.2 and 10:167A-13). The PAAD program requires that all drugs be prescribed by licensed practitioners within the scope of their practice and 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). Providers are currently required to keep sufficient records to fully disclose the name of the recipient (beneficiary) to whom the service was rendered, the date of the service, nature and extent of the service, and any additional information as may be required by statute, N.J.S.A. 30:4D-12(d). The rules proposed for readoption with amendments and a repeal do not create any additional recordkeeping requirements.

Pharmacies are not required to participate in PAAD and it is a business decision on their part to increase their business by participating in PAAD and incurring the costs necessary for participation.

Therefore, pharmacies should not need to obtain any additional professional services to comply with the rules proposed for readoption with amendments and a

repeal, unless they are new pharmacies that wish to participate and may need to hire professionals at varying fees to assist with the installation and operation of the necessary software and computer systems to process claims with CMS, PAAD, PDPs, and other private insurers.

The proposed elimination of the requirement that pharmacies provide PAAD with proof of enrollment as a Medicare Part B durable goods provider would eliminate this regulatory burden on all participating pharmacies.

As the application, recordkeeping, and infrastructure requirements are necessary for participation by pharmacies in PAAD and Medicare Part D, 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 readoption with amendments and a repeal will have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing because the rules proposed for readoption with amendments and a repeal concern PAAD program requirements.

Smart Growth Development Impact Analysis

The rules proposed for readoption with amendments will have an insignificant impact on smart growth and there is an extreme unlikelihood that the rules would evoke a change in 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 proposed for readoption with amendments and a repeal concern PAAD program requirements.

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

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

SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

10:167A-1.2 Definitions

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

"Active pharmaceutical ingredient" means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient of the drug product.

…

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

…

"Bulk drug substance" means a bulk drug substance as defined in 21 CFR 207.3(a)(4), that includes any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug,

becomes an active ingredient or finished dosage form of the drug. "Bulk drug substance" does not include intermediates used in the synthesis of such substances.

…

["Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)" means a type of Medicare Part B coverage that applies to certain types of medical equipment and supplies. Pharmacies enrolling as Medicare Part B suppliers for the purpose of PAAD's Medicare Recovery initiative must enroll under DMEPOS.

"Electronic Data Interchange (EDI) Enrollment Form" means an agreement signed by a Medicare Part B Supplier authorizing PAAD to bill Medicare electronically on its behalf for claims that are eligible under both PAAD and Medicare.]

"Electronic Media Claim" or "EMC" means an electronic media claim processed by the State's fiscal agent, including claims submitted as real-time claims via modem or electronic bulletin board through the World Wide Web (www), in an electronic format that complies with the standards of the National Council on Prescription Drug Plans (NCPDP), DCPDP D.0/1.2 Payer Sheet, version D.0, which is incorporated herein by reference, as amended and supplemented. The NCPDP standards can be obtained from the NCPDP at 9240 East Raintree Drive, Scottsdale, Arizona 85260-7516, or by accessing the Pharmacy NCPDP-HIPAA Payer Sheet at https://www.njmmis.com/downloadDocuments/NJ_D-0_NCPDP_Payer_Sheet.pdf.

"Excipient" means an ingredient that does not contribute therapeutically to a compound, including, but not limited to, fillers, diluents, wetting agents,

solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

…

"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/, 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/.

…

["Medicare Part B Supplier" means a supplier of Medicare Part B (Medical Insurance) services to Medicare beneficiaries including Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).]

…

["National Supplier Clearinghouse (NSC)" means the entity that issues Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) supplier authorization numbers nationwide to Medicare Part B Suppliers for the Centers for Medicare and Medicaid Services (CMS). The National Supplier Clearinghouse is located at P.O. Box 100142, Columbia, SC 29202-3142.

"NSC Supplier Number" means the authorization number issued by the National Supplier Clearinghouse (NSC) to a Medicare Part B Supplier of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for the Centers for Medicare and Medicaid Services (CMS).]

“National drug code” or “NDC” means the three-segment identification number for a specific drug product issued by the U.S. Food and Drug Administration pursuant to 21 U.S.C. § 360 of the Federal Food, Drug and Cosmetic Act.

“National Provider Identifier” or “NPI” means a national identifier issued to a healthcare provider by the National Plan and Provider Enumeration System (NPPES) established pursuant to 45 CFR Part 162, Subpart D.

…

"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. The term “prescription drugs” includes:

i. (No change.)

ii. Every product considered to be a legend prescription drug [which is required by the Federal Food, Drug and Cosmetic Act to have the following statement on the manufacturer’s original packaging label: “Caution: Federal law prohibits dispensing without a prescription”];

iii. (No change.)

iv. Syringes and needles for injectable medicines [for the treatment of multiple sclerosis].

2. (No change.)

…

10:167A-1.3 Participation of eligible providers

(a) (No change.)

(b) To be approved as a provider of pharmaceutical services, the pharmacy shall:

1. Operate under a valid retail [and/or] **or** institutional permit issued by the Board of Pharmacy of the State of New Jersey **and be assigned a national provider identifier**. A pharmacy operating under an out-of-State retail or institutional pharmacy permit may not participate as an approved provider in the PAAD program, except for a voluntary prescription drug mail-order program or specialty pharmacy in a Medicare Part D Plan or a mail order prescription drug program required by a PAAD beneficiary's primary payer and, which maintain a permit from the Board of Pharmacy of the State of New Jersey.

2. File an application and sign an agreement with the Department of Human Services (DHS), Division of Medical Assistance and Health Services (DMAHS) and [shall] maintain a Medicaid provider number issued by DMAHS.

[i. All new PAAD/Medicaid provider applications from a prospective PAAD pharmacy provider (Form FD-29) shall list the pharmacy's NSC Supplier Number or include a statement that the pharmacy has applied for a NSC Supplier Number. Proof of the assigned NSC Supplier Number or of application for a NSC Supplier Number as listed in (c) below shall be provided with the application.]

[ii.] **i.** Upon sale or other change of ownership of an approved pharmacy, the agreement is automatically terminated. To execute a new agreement to participate in the PAAD program, the new owner(s) shall apply to the Division [of Medical Assistance and Health Services, Department of Human Services], by contacting the Medicaid Provider Enrollment Unit (see N.J.A.C. 10:49, Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit.

3. To enroll as a Medicaid provider of pharmaceutical services, a pharmacy shall **obtain a copy of the provider application on-line at www.njmmis.com or** contact the Fiscal Agent Provider Enrollment Unit (see N.J.A.C. 10:51, Appendix D, Fiscal Agent Billing Supplement).

[4. Establish and maintain active enrollment as a Medicare Part B DMEPOS Supplier, provide proof of such enrollment to PAAD, an authorized PAAD to bill eligible claims electronically on the pharmacy's behalf as a billing agent for those claims that are dually eligible for both PAAD and Medicare (see N.J.A.C. 10:167A-1.4, Medicare recovery initiative).

(c) To ensure continued enrollment as a PAAD-participating pharmacy, a pharmacy shall:

1. Establish and maintain active enrollment as a Medicare Part B DMEPOS Supplier by obtaining a NSC Supplier Number from the National Supplier Clearinghouse (NSC) or other appropriate agent of the Centers for Medicare and Medicaid Services (CMS);

2. Provide proof of such enrollment to PAAD in the form of either:

i. A copy of a recent Medicare Part B remittance letter, with the NSC Supplier Number clearly indicated;

ii. A copy of a recently submitted original CMS 1500 claim form, with the NSC Supplier Number clearly indicated;

iii. A copy of the approval letter from NSC containing the assigned NSC Supplier Number; or

iv. If an approval letter has not yet been received from NSC, a copy of the completed application form CMS 855s can be submitted to show that a good faith effort is being made to obtain a NSC Supplier Number;

3. Complete and return an EDI Enrollment Form, included with the provider enrollment packet, authorizing PAAD to bill Medicare electronically for eligible claims; and

4. Comply with Medicare dispensing and documentation requirements as described in Medicare's Supplier Manual.]

10:167A-1.4 [Medicare recovery initiative] **(Reserved)**

[(a) PAAD beneficiaries are required to authorize assignment of benefits to the State of New Jersey for any plan of assistance or insurance that covers the cost of prescription drugs at least in part. (See N.J.A.C. 10:167-6.9, Authorization.) The Medicare Recovery initiative was established to allow PAAD to recoup the cost of prescription drug benefits payable under Medicare Part B.

(b) All New Jersey pharmacies that participate in the PAAD program are mandated to comply with the requirements of the Medicare recovery initiative as a condition of continued participation.

1. Pharmacies shall enroll as Medicare Part B DMEPOS suppliers and maintain active status. Proof of Medicare enrollment shall be supplied to PAAD as described in N.J.A.C. 10:167A-1.3(c)2.

2. Pharmacies shall comply with all Medicare documentation requirements as described in the Medicare Supplier Manual, including ensuring that the patient's diagnosis code is recorded by the doctor on every Medicare-eligible written order, and retaining records for the specified period of time.

(c) Recoupment of PAAD's expenditures for Medicare-eligible drugs and supplies is made using the following procedures:

1. When pharmacies submit claims to PAAD, the point-of-sale system identifies those claims that are potentially eligible for reimbursement by Medicare. The pharmacy is notified to maintain Medicare documentation requirements for these claims via an edit code returned by the system.

2. PAAD, acting as a billing agent for the pharmacies under 42 C.F.R. § 424.73, submits eligible claims to Medicare.

3. Medicare pays its allowable amount for eligible claims directly to the pharmacies.

4. PAAD collects the reimbursement by withholding the amount of the Medicare payments from future PAAD remittances.]

10:167A-1.5 Conditions for participation as a provider of pharmaceutical service

(a) All participating pharmacies shall provide [complete prescription] services[, including injectables and injectable anti-neoplastic agents, compounding, and prescription refill services, when allowable] **within the scope of the permit issued by the Board of Pharmacy of the State of New Jersey**. Prescriptions must be dispensed in compliance with all current existing Federal and State laws.

(b) All drugs must be prescribed.

1. "Prescribed drugs" means simple or compounded substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are:

[ii.] **i.** (No change in text.)

[iii.] **ii.** Dispensed by licensed pharmacists on the basis of a written**, telephonic, or electronic** prescription that is recorded and maintained in the pharmacist's records.

(c) Participating pharmacies shall permit properly identified representatives of the Department to:

1.-2. (No change.)

3. Inspect private sector records, where deemed necessary to determine a pharmacy's usual and customary charges to the public[;]**.**

i. Information pertaining to the patient's name, address, and prescriber will remain confidential within the limits of the law. Only the following items may be reviewed:

(1) (No change.)

(2) Quantity dispensed **(including refills)**;

(3) (No change.)

(4) Prescription number (for reference purposes only); [and]

(5) Date **written and date** dispensed[.]**;**

(6) National Drug Code;

(7) Brand-drug dispensing authorizations;

(8) Other insurance payments;

(9) Patient payment liability amounts;

(10) Days supply;

(11) Usual and customary charge;

(12) Drug acquisition cost; and

(13) Customer certifications, such as manual or electronic signature log entries.

ii. (No change.)

[4. Inspect records of purchases of covered drugs for which claims have been made for reimbursement.]

4. Inspect acquisition records for the purchase of covered drugs based on the NDC numbers.

10:167A-1.6 Program restrictions affecting payment for prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescriber within the limits of applicable laws. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if **any of the following, or any of** the requirements of [the following rules] **this chapter** are not met:

[1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 10:167A-1.14 and 1.15, respectively;

2. Quantity of medication (see N.J.A.C. 10:167A-1.16);

3. Pharmaceutical services requiring pharmacist intervention as part of the PAAD Prospective Drug Utilization Review (PDUR) program (see N.J.A.C. 10:167A-1.28);

4. Dosage and directions (see N.J.A.C. 10:167A-1.17);

5. Telephone-rendered original prescriptions (see N.J.A.C. 10:167A-1.18);

6. Changes or additions to the original prescription (see N.J.A.C. 10:167A-1.19);

7. Prescription refill (see N.J.A.C. 10:167A-1.20);]

[8.] **1.** Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 10:167A-1.21)[;] **and**

[i. Products pursuant to N.J.A.C. 8:71; and]

[ii.] Non-Proprietary or generic dispensing (see N.J.A.C. 10:167A-1.12);

[9.] **2.** Federal regulations (42 [C.F.R.] **CFR** 447.[301,331-333]**500, 512-516**) that set the aggregate upper limits on payment for certain multi-source drugs if Federal Financial Participation (FFP) is to be made available. The limit applies to all "maximum allowable cost" drugs (see N.J.A.C. 10:167A-1.7, Basis of payment); and

[10.] **3.** (No change in text.)

10:167A-1.7 Basis of payment

(a) [This] **Subject to the requirements of the annual State appropriations act, this** section provides a summary of the elements involved in the calculations of the payment of legend or certain non-legend drugs. The elements include the following:

1. – 4. (No change.)

(b) –(c) (No change.)

[(d) The maximum allowance for the non-legend drugs, devices, or supplies under the PAAD program, for claims with service dates prior to July 15, 1996, shall be:

1. The product's AWP plus 50 percent; or

2. The usual over-the-counter (OTC) retail price charged to the other persons in the community, whichever is less.

(e) For claims with service dates on or after July 15, 1996, the maximum allowance for non-legend drugs, devices, or supplies under the New Jersey Medicaid program shall be calculated in accordance with (b)1ii above.

(f) For claims with service dates on or after July 15, 1996, the maximum cost for each eligible prescription claim not covered by the Maximum Allowable Cost price, as defined in (b)1i above, shall be based on the Average Wholesale Price (AWP) of a drug, as defined in (b)1ii above, less a discount of 10 percent.

(g) For claims with service dates on or after July 1, 2008, where PAAD is the primary payer, reimbursement for the cost of single source brand name legend drugs and non-legend drugs shall be on the basis of average wholesale price (AWP) less a 15 percent discount.

(h) For claims with service dates on or after October 1, 2009, where PAAD is the primary payer, reimbursement for the cost of multisource generic drugs shall be in accordance with 42 CFR 447.512 and 514, as amended and supplemented, which are incorporated herein by reference and the listings established and issued by CMS pursuant to 42 CFR 447.514.

1. For claims with service dates on or after July 1, 2008 and until October 1, 2009, where PAAD is the primary payer, reimbursement for the cost of multisource generic drugs shall be in accordance with the listings established and issued by CMS pursuant to 42 CFR 447.332 (effective December 31, 2006).]

10:167A-1.9 Prescription drug dispensing fee

(a) The dispensing fee for each prescription dispensed to recipients by providers having retail permits**,** and where PAAD is the primary payer is $3.73 **to $3.99**. Additional dispensing fees (add-ons) per prescription shall be given, when PAAD is the primary payer, to pharmacy providers who provide the following:

1. (No change.)

2. Impact area location: $0.15. The provider shall have a combined Medicaid and PAAD **primary** prescription volume, as calculated by DMAHS, equal to or greater than 50 percent of the provider's total prescription volume.

i. (No change.)

(b) (No change.)

(c) In order to receive any or all of the above increments, the provider shall certify annually to the Division on Form FD-70, that the services[(s)]**,** as defined in (a) above,

are being provided and/or that the provider is entitled to the impact increment as defined in (a) above.

1. (No change.)

(d) Failure to submit [this] **the** report **required by (c) above** annually shall result in retail pharmacy provider payments based on the basic dispensing fee of $3.73.

10:167A-1.10 PAAD program copayment

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

[(c) The beneficiary co-payment amount shall not be affected by a claim's eligibility for submission to Medicare for reimbursement (see N.J.A.C. 10:167A-1.4, Medicare recovery initiative).]

10:167A-1.11 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the PAAD program. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients [and/or a pharmaceutical excipient or excipients] and are dispensed by approved providers.

[1. Acceptable pharmaceutical excipients which do not contribute therapeutically to a compound, include, but are not limited to hydrophilic ointment, petrolatum, aquifer, eucerin cream, phenol, menthol, resorcinol, caffeine, talc, simple syrup, aromatic elixir, distilled water, and glycerin.]

(b) Claims for compounded prescriptions [may] **shall** be [manually or] electronically submitted to the fiscal agent through a point-of-sale (POS) claim adjudication system approved by the PAAD program. (See N.J.A.C. 10:167A-1.27).

1. A compounded prescription is indicated by the provider by the use of the "compound drug" indicator field [on a manual claim or in a similar field] in the EMC claim format.

(c) Reimbursement for compound prescriptions shall [not exceed the lower of] **be**:

1. [The cumulative cost of the active ingredient(s), as described in] **In accordance with** N.J.A.C. 10:167A-1.7[, and/or pharmaceutical excipient(s),] plus a dispensing fee, as described in N.J.A.C. 10:167A-1.9; or

2. (No change.)

[(d) For compounded prescriptions without an active ingredient(s), reimbursement is based on the cumulative cost of the pharmaceutical excipient(s).

1. For pharmaceutical excipients costing less than $0.25, the provider may charge PAAD $0.25 for each ingredient.

2. Reimbursement for compounded prescriptions without an active ingredient(s) shall be provided under a common drug code assigned by DMAHS.

(e) Reimbursement for compounded prescriptions submitted manually or as an EMC claim is calculated based on the ingredient cost, as described in N.J.A.C. 10:167A-1.7, of the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 10:167A-1.9.

1. For compounded prescriptions without an active ingredient(s), reimbursement is based on (d) above, plus a dispensing fee, as described in N.J.A.C. 10:167A-1.9.]

[(f)] **(d)** (No change in text.)

[(g)] **(e)** Restrictions on payments for compounded prescriptions are as follows:

1. All legend ingredients [which] **that** are contained in compounded prescriptions [must] **shall** be covered by the PAAD program **in accordance with N.J.A.C. 10:167A-1.14 and 1.15**. [If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 10:167A-1.22) drug, the compounded prescriptions are not covered.]

2. (No change.)

10:167A-1.12 Non-proprietary or generic dispensing

When medication is prescribed by its non-proprietary or generic name, the pharmacist shall dispense the least expensive, therapeutically effective equivalent product available, preferably one listed [pursuant to N.J.A.C. 8:71] **in the list of interchangeable drug products**. The labeler code**,** [and] drug product code**, and package size code** of the actual product dispensed must be reported on the claim form. [The package size code reported may differ from the stock package size used to fill the prescription.]

10:167A-1.14 Covered pharmaceutical services

(a) All covered pharmaceutical services shall be provided within the scope of the Medicaid or PAAD programs, and billed to the fiscal agent [on the claim form or other approved billing method (see N.J.A.C. 10:51, Appendix D, incorporated herein by

reference, Fiscal Agent Billing Supplement)] **using the NCPDP claim format available at https://www.njmmis.com/downloadDocuments/NJ_D-0_NCPDP_Payer_Sheet.pdf**.

(b) Covered pharmaceutical services include:

1. Prescribed legend drugs (for their medically accepted indication) as defined in Section 1927(k)(6) of the Social Security Act. ["Legend drugs" mean those drugs whose labels include the legend statement "Caution: Federal Law Prohibits Dispensing Without a Prescription."]

2. Non-legend drugs, as follow:

i. – ii. (No change.)

iii. Syringes and needles for injectable medicines [for the treatment of multiple sclerosis].

10:167A-1.15 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the PAAD program:

1.- 13. (No change.)

14. Preventive vaccines, biologicals**,** and therapeutic drugs distributed to hospital clinics and/or community health centers by the New Jersey Department of Health [and Senior Services]; [and]

15. If the provider has a delivery service, he or she may waive or discount delivery charges to the recipient but is prohibited from charging more than his or her usual and customary charge to the general public for delivery[.]**;**

16. Diabetic testing materials;

17. Vitamins;

18. Cough and/or cold medications;

19. Drugs used for the treatment of erectile dysfunction;

20. Drugs used for alopecia, hair removal or hair restoration, eyelash growth, weight loss, and skin conditions; and

21. Active pharmaceutical ingredients, bulk drug substances, and excipients that are not a covered outpatient drug as defined in the Social Security Act at 42 U.S.C. § 1396r-8(k)(2).

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1.- 4. (No change.)

5. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the PAAD program. (See N.J.A.C. 10:167A-1.28); [and]

[6. Cosmetic drugs including drugs used in the treatment of baldness, age spots and weight loss unless medically necessary. The MEP specified at N.J.A.C. 10:167A-1.29 shall be followed to confirm medical necessity.]

6. Drugs prescribed by practitioners not assigned a National Provider Identifier;

7. Drugs prescribed by excluded practitioners, as defined under the Patient Protection and Affordable Care Act regulations at 42 CFR Part 455;

8. Adjudicated claims for drugs not dispensed within 14 calendar days;

9. Brand-name drug dispensing at the request of a PAAD beneficiary when the substitution and reimbursement requirements of N.J.A.C. 10:167A-1.21 apply;

10. Drug products subject to the medical exception process that do not receive authorization in accordance with N.J.A.C. 10:167A-1.29; and

11. Legend drugs distributed by a manufacturer that has not entered into a rebate agreement with the Department as required by N.J.A.C. 10:167A-1.30.

10:167A-1.16 Quantity of medication

(a) Days supply limitations for an Initial Prescription Claim for PAAD beneficiaries shall be different from days supply limitations for a Refill Prescription Claim.

1. - 2. (No change.)

3. For PAAD claims [with service dates on or after November 1998, and] where PAAD is the primary payer, the following days supply limitations shall apply:

i.-ii. (No change.)

4. (No change.)

(b) – (d) (No change.)

10:167A-1.19 Changes or additions to the original prescription

Changes or additions to the original prescription, when approved by the prescriber, shall be clearly indicated (including date and time) and signed by the dispensing pharmacist. No changes (for example, dosage, quantity, number [or] **of** refills, days supply, etc.) are permitted on the original prescription order after the claim is submitted for payment.

10:167A-1.20 Prescription refill

(a) The provider shall submit [a properly completed claim form or] **an** electronic claim in the proper EMC claim format to the fiscal agent for reimbursement of an allowable refill. An allowable refill shall comply with the following instructions in order to be reimbursed as such:

1. Refill instructions [must] **shall** be indicated in writing by the prescriber on the original prescription**, on a facsimile of the prescription, in the electronic prescription,** or verbally when telephoning the original prescription to the pharmacist. Verbal instructions shall be reduced to writing by the pharmacist.

2. – 3. (No change.)

4. [A telephone] **An** authorized refill for a prescription with no refill remaining must be assigned a new prescription number.

5. Prescription refills shall not be dispensed until [a reasonable quantity (approximately] 85 percent[)] of the medication originally dispensed or refilled could have been consumed in accordance with the prescriber's written directions for use.

[i. Exception: When a prescription is lost or destroyed, requiring a replacement prescription to be dispensed before the original prescription could have been consumed

in accordance with the prescriber's written directions for use, an original pharmacy claim with written justification must be submitted to the fiscal agent for payment consideration.]

10:167A-1.21 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall apply to the PAAD program. This law requires that every prescription blank contain the statements “Substitution Permissible” and “Do Not Substitute.” The prescriber shall initial one of the statements in addition to signing the prescription blank.

1. When the prescriber does not initial “Substitution Permissible” or the “Do Not Substitute” statement on a prescription for a drug product [listed pursuant to N.J.A.C. 8:71], the pharmacist shall substitute from the list of interchangeable products and bill PAAD accordingly.

2. When the prescriber initials “Substitution Permissible,” the pharmacist shall dispense and bill PAAD for one of the less expensive products listed [pursuant to N.J.A.C. 8:71] as **an** interchangeable **drug product** with the brand name prescribed.

3. When the prescriber orders by generic name, the [listing pursuant to N.J.A.C. 8:71 does not apply. The] pharmacist shall dispense the least expensive, therapeutically effective product available to him or her at the time of dispensing. The product is not required to be from the list of interchangeable products.

4. Whenever the prescriber does not specify that substitution is not permitted and an interchangeable drug product [that is listed pursuant to N.J.A.C. 8:71] is available for the prescription written, the PAAD program shall reimburse the

pharmacy only for the maximum allowable cost of the interchangeable product, less the PAAD program co-payment.

i. For non-MAC drugs (see N.J.A.C. 10:167A-1.7), when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" [on the claim form or the similar field] in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be [the estimated acquisition cost (EAC), as defined] in **accordance with** N.J.A.C. 10:167A-1.7 (see N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions about the claim form or N.J.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format); or

ii. [Claims for] **For** MAC drugs [with service dates on or after July 15, 1996,] and in those situations in which a prescriber authorizes, in accordance with (b) below, the dispensing of a brand drug, the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" [on the claim form, or similar field] in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be [the estimated acquisition cost (EAC), (see N.J.A.C. 10:167A-1.7) plus applicable dispensing fee or the usual and customary charge, whichever is less for the product] **in accordance with N.J.A.C. 10:167A-1.7** (see N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions about the claim form or N.J.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format).

(b) (No change.)

(c) [For claims with service dates on or after July15, 1996, a] **A** blanket authorization denying substitutions shall not be permitted. Each prescription order shall state “Brand Medically Necessary” in the prescriber’s own handwriting. For non-MAC drugs, each prescription order shall follow the requirements of N.J.S.A. 24:6E-1 et seq. (see (a) above).

(d) (No change.)

10:167A-1.22 Drug Efficacy Study Implementation (DESI)

(a) “Less than effective drugs” are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:

i.-ii. (No change.)

iii. The drug product is the subject of a [notice of opportunity for hearing] **NOOH** issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of **the** FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and

iv. (No change.)

2. (No change.)

3. The initial list of drugs and related drug products classified as “less than effective” by the FDA pending outcome of the NOOH appears at 21 CFR 310.6.

Subsequent revisions to this list [which] **that** are adopted, shall appear in the Federal Register.

(b) (No change.)

10:167A-1.23 Bundled drug service

(a) (No change.)

(b) Bundled drug service shall not be eligible for reimbursement by the PAAD program. The cost of the drug product which is a component of a bundled drug service (see N.J.A.C. 10:167A-1.14, Covered Pharmaceutical Services) shall be covered by the PAAD program.

[1. In order to determine eligibility for reimbursement, manufacturers or distributors of a bundled drug service shall submit complete product information, including the cost to the PAAD program of the drug product component of the bundled drug service, and other information as requested by the Department, to the Commissioner, Department of Human Services, PO Box 700, Trenton, New Jersey 08625-0700.]

10:167A-1.24 Claim submission

[(a) An approved pharmacy provider may choose to:

1. Submit a properly completed hard copy pharmacy claim form approved by the New Jersey Division of Medical Assistance and Health Services (DMAHS).

2. Submit an electronic media claim (EMC) by modem, diskette or magnetic tape in an electronic format approved by DMAHS.

i. In order for a pharmacy provider to be eligible to submit an EMC claim to the Medicaid and/or PAAD programs, a pharmacy provider or vendor of EMC services shall complete the "New Jersey Medicaid Provider Electronic Billing Agreement."

ii. The completed agreement shall be submitted to the fiscal agent and approved by the Division of Medical Assistance and Health Services.

iii. The pharmacy provider or vendor of EMC services shall submit electronic media claims under an approved submitter identification number and comply with EMC requirements contained in the EMC Manual, Appendix E, incorporated herein by reference.

iv. For the purposes of this subchapter, all electronically submitted claims, including POS claims, shall commonly be referred to as EMC claims; or]

[3.] **(a)** [Enter] **An approved pharmacy provider shall enter** into an agreement with a point-of-sale (POS) intermediary **in accordance with the requirements of N.J.A.C. 10:167A-1.27** or directly provide a similar telecommunication network approved by DMAHS to submit claims to the fiscal agent for adjudication. POS claims require an electronic format, which complies with the **EMC** National Council Prescription Drug Program standards[, Version 5.1, as amended and supplemented, incorporated herein by reference. The Council's address is 9240 East Raintree Drive, Scottsdale, Arizona 85260-7518, or http://www.ncpdp.org].

[i.] **1.** (No change in text.)

[(b) A properly completed claim form or a properly formatted electronic media claim (EMC) may be submitted to the fiscal agent, or transmitted by an approved POS

intermediary or provider established telecommunication network to the fiscal agent for claims adjudication.

1. A single claim form shall be completed manually or by computer or an EMC claim shall be transmitted in the approved EMC format for each PAAD prescription dispensed. See N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions concerning the completion and submission of the specified claim form, and N.J.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format;

2. All claim forms and EMC claims must contain the National Drug Code (NDC) of the actual drug dispensed. The 11-digit NDC has three components. The first five digits are the manufacturer's labeler code, the next four digits are the product code, and the final two digits are the package size code. For claim submission, leading zeros shall be included in all fields. For example, 00003-0234-01.

i. The dispenser shall always report the actual labeler code and drug product code of the drug dispensed. The package size code reported on the claim.

3. All PAAD pharmacy claims submitted to the fiscal agent for payment consideration shall be adjudicated based on the outcome of established POS and PDUR edits, regardless of the mode of claim submission.]

10:167A-1.26 PAAD beneficiary identification

(a) (No change.)

(b) The PAAD program shall issue to all PAAD eligibles a Validation Identification [Care] **Card**. The document shall contain the patient's name, PAAD identification number, effective date**,** and expiration date.

(c) (No change.)

10:167A-1.27 Point of sale (POS) claims adjudication system

(a) PAAD pharmacy claims [may] **shall** be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real-time. [The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette and paper claims.] The pharmacist [would] **shall** be required to enter pharmacy claim detail data into a computer or POS device and transmit this data to the fiscal agent over a dedicated telephone line. Regardless of the method of claim submission, all claims will go through all New Jersey Medicaid Management Information System (NJMMIS) claims processing edits and the claims will be processed to determine their payment disposition (for example, paid or denied).

1. Pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose delivery systems are precluded from the POS system.

(b) In order for a PAAD-approved pharmacy provider, in accordance with N.J.A.C. 10:167A-1.5, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly provide a similar telecommunications network approved by the [New Jersey] Division [of Medical Assistance and Health Services].

1. - 2. (No change.)

3 The Division shall consider the following in evaluating an application:

i. – iv. (No change.)

v. The applicant's adherence to the requirements of [the Health Care Financing Administration] **CMS**.

(c) A POS participating pharmacy or intermediary [must] **shall** supply the computer hardware or POS device and required software to generate electronic media claims (EMC) in a format consistent with POS standards adopted by the PAAD program.

(d) (No change.)

(e) All PAAD pharmacy providers [choosing to submit claims through the POS system,] shall submit claims in the [approved electronic] **EMC** format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.

[1. Pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose drug delivery systems are precluded from the POS system.]

(f) Claim data requirements for [electronic media claims (]EMC**s**[)] generated by POS participating pharmacies include:

1.-12. (No change.)

(g)- (j) (No change.)

(k) Pharmacies are required to interact with prescribers [and/or] **and** beneficiaries at POS to resolve matters related to on-line messages resulting [form] **from** claim adjudication by the fiscal agent.

10:167A-1.29 Medical exception process (MEP)

(a) For pharmacy claims with service dates on or after May 3, 1999**,** that exceed DUR Board standards, the PAAD program shall utilize the medical exception process (MEP) to allow the override of a claim denial, when medically necessary.

1. (No change.)

2. All pharmacy claims shall be subject to the MEP regardless of claims media, except that claims from [institutionalized beneficiaries] **long-term care facility providers** shall be exempt from the PDUR and MEP until notice is issued otherwise.

(b) – (d) (No change.)

10:167A-1.30 Drug rebate program

Reimbursement for legend drugs shall be limited to manufacturers who have entered into a PAAD rebate agreement**, including an agreement to pay rebates on claims for which PAAD is a secondary payer,** with the Department of Human Services through the Division of Medical Assistance and Health Services pursuant to N.J.A.C. 10:51-1.22.