1 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A (2017)

Title 10, Chapter 167A -- Chapter Notes

CHAPTER AUTHORITY:

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

CHAPTER SOURCE AND EFFECTIVE DATE:

R.2017 d.035, effective January 31, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

CHAPTER EXPIRATION DATE:

Chapter 167A, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), expires on January 31, 2024.

CHAPTER HISTORICAL NOTE:

Chapter 83C, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), was recodified from N.J.A.C. 10:51-4 by R.1998 d.464, effective September 8, 1998. See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a). Chapter 83C, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), expired on February 10, 2004.

Chapter 83C, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), was adopted as new rules by R.2004 d.163, effective April 19, 2004. See: 35 N.J.R. 4416(a), 36 N.J.R. 2053(a).

Chapter 83C, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), was readopted as R.2009 d.293, effective September 2, 2009. See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Chapter 83C of Title 8, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), was recodified as Chapter 167A of Title 10 by administrative change, effective June 16, 2014. As a 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. See: 46 N.J.R. 1643(a).

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 167A, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), was scheduled to expire on September 2, 2016. See: 43 N.J.R. 1203(a).

Chapter 167A, Provision of Pharmaceutical Services under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), was readopted as R.2017 d.035, effective January 31, 2017. See: Source and Effective Date. See, also, section annotations.

**NOTES:**
Chapter Notes

2 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.1 (2017)

§ 10:167A-1.1 Introduction

This subchapter provides information about the provision of pharmaceutical services under the PAAD program, which shall extend 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 used in the treatment of multiple sclerosis and are unable to fully meet the cost of such items. For additional information regarding PAAD eligibility, see N.J.A.C. 10:167.

HISTORY:

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Inserted "and syringes and needles for injectable medicines used in the treatment of multiple sclerosis," in the first sentence, and changed N.J.A.C. reference in the second sentence.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Inserted a comma following "program", and deleted "diabetic testing materials and" preceding the second occurrence of "syringes", and a comma following "sclerosis".

**NOTES:**
Chapter Notes

3 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.2 (2017)

§ 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.

"Annual income" means all income from whatever source derived, actually received or anticipated.

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

"Beneficiary" means an individual who has been found eligible for PAAD benefits.

"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.

"Calendar year" means a year beginning January 1 and ending on December 31. It is the base period utilized to determine annual income and PAAD eligibility.

"Centers for Medicare and Medicaid Services (CMS)" means the agency of the Federal Department of Health and Human Services which is responsible for the administration of the Medicare program in the United States. CMS was formerly known as the Health Care Financing Administration (HCFA).

"Commissioner" means the Commissioner of the Department of Human Services.

"Current year" means the calendar year in which a person applies or reapplies for PAAD.

"Department" means the Department of Human Services.

"Division" or "DMAHS" means the Division of Medical Assistance and Health Services in the New Jersey Department of Human Services.

"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.

"Expiration date" means the date when a beneficiary's PAAD eligibility ends.

"Initial Prescription Claim" means a PAAD claim for a drug not previously paid by the State during the 200-day calendar period immediately preceding the service date of a claim being considered for payment; or a PAAD claim that exceeds a time period based on the service date of the previously paid PAAD claim.

"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/.

"Legend drug" means any approved drug product which by Federal law cannot be dispensed without a prescription and bears the statement on the label: "Caution: Federal law prohibits dispensing without a prescription."

"Medicare" means medical assistance provided to certain aged and disabled persons as authorized under Title XVIII (Medicare) of the Social Security Act.

"Medicare Prescription Drug Program" or "Medicare Part D" means the prescription drug coverage program established under the Federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173 (42 U.S.C. § 1395w-101 et seq.)

"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.

"Pharmacy" means any pharmacy located in New Jersey, operating under a valid permit from the Board of Pharmacy of the State of New Jersey, which has filed an application and agreement of participation, which has been approved by the New Jersey Medicaid Program. The term "pharmacy" also includes any volunteer prescription drug mail-order program or specialty pharmacy in a Medicare Part D plan provider network or a mail order prescription drug program required by a PAAD beneficiary's primary payer.

"Prescription drugs" means all approved legend drugs, including any interchangeable drug products 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. Any drug product which by Federal law cannot be dispensed unless ordered by a physician, dentist or podiatrist;

ii. Every product considered to be a legend prescription drug;

iii. Insulin, insulin syringes and insulin needles. While not legend drugs, these items are covered by this program when prescribed; and

iv. Syringes and needles for injectable medicines.

2. The term "prescription drugs" excludes cosmetic drugs as indicated at N.J.A.C. 10:167A-1.15 unless medically necessary.

"Previous year" means the calendar year preceding the year in which the person is applying or reapplying for PAAD. For example, 1995 is the "previous year" when referring to an application which is dated between January 1, 1996 through December 31, 1996, inclusive.

1. If a person, who is required to submit a Federal, State and/or City Income Tax return, applies for PAAD at the beginning of a calendar year but has not yet filed an income tax return for the previous year, the last year for which the person filed a tax return is considered to be the "previous year" when completing the PAAD application.

"Provider" means any individual, partnership, association, corporation, institution, or any other public or private entity, agency, or business concern, meeting applicable requirements and standards for participation in the New Jersey Medicaid Program, and the Pharmaceutical Assistance to the Aged and Disabled Program, and where applicable, holding a current valid license, and lawfully providing medical care, services, goods and supplies authorized under N.J.S.A. 30:4D-1 et seq. and amendments thereto.

"Refill Prescription Claim" means a PAAD claim for a previously paid prescription in which the time period between claims is less than or equal to two times the days supply reported by the previously paid PAAD claim for the same prescription. A refill prescription claim may have the same or different prescription number.

"Resident" means "one legally domiciled within the State (of NJ) 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. 10:167-6.4 for residence requirements.)

HISTORY:

New Rule, R.2003 d.248, effective June 16, 2003.

See: 34 N.J.R. 3458(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.2, Participation of eligible providers, recodified to N.J.A.C. 8:83C-1.3.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

In the introductory paragraph, substituted a colon for a period at the end; added definitions "Division" and "Medicare Prescription Drug Program"; in definition "Pharmacy", inserted a comma following "participation", and inserted the last sentence; in the introductory paragraph of definition "Prescription drugs", substituted "pursuant to N.J.A.C. 8:71 and" for "by the Drug Utilization Review Council" and "syringes and" for "syringes,", and deleted "and certain diabetic testing materials" following "needles"; in paragraph 1iii of definition "Prescription drugs", inserted "and" at the end; in definition "Prescription drugs", deleted former paragraph 1iv and recodified paragraph 1v as new paragraph 1iv.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Added definitions "Active pharmaceutical ingredient", "Bulk drug substance", " 'Electronic Media Claim' or 'EMC' ", "Excipient", "Interchangeable drug product", " 'National drug code' or 'NDC' ", and " 'National Provider Identifier' or 'NPI' "; in definition "Applicant", inserted "or reapplies"; in definition "Prescription drugs", in the introductory paragraph, deleted "contained in the latest list approved and published pursuant to N.J.A.C. 8:71" following "products", rewrote paragraph 1ii, and in paragraph 1iv, deleted "for the treatment of multiple sclerosis" following "medicines"; and deleted definitions "Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)", "Electronic Data Interchange (EDI) Enrollment Form", "Medicare Part B Supplier", "National Supplier Clearinghouse (NSC)", and "NSC Supplier Number".

**NOTES:**
Chapter Notes

4 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.3 (2017)

§ 10:167A-1.3 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the PAAD program as a provider of pharmaceutical services.

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

1. Operate under a valid retail 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 maintain a Medicaid provider number issued by DMAHS.

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, 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).

HISTORY:

Amended by R.1997 d.252, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2678(a).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (b), changed a reference to the Division of Medical Assistance and Health Services in 2, and changed N.J.A.C. reference in 3.

Recodified from N.J.A.C. 8:83C-1.2 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

In (b)2, added i, recodified existing i as ii, added 4; added (c). Former N.J.A.C. 8:83C-1.3, Conditions for participation as a provider of pharmaceutical service, recodified to N.J.A.C. 8:83C-1.5.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Rewrote (b)1; and in the introductory paragraph of (b)2, inserted "and shall maintain a Medicaid provider number issued by DMAHS".

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote (b); and deleted (c).

**NOTES:**
Chapter Notes

5 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.4 (2017)

§ 10:167A-1.4 (Reserved)

HISTORY:

New Rule, R.2003 d.248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.4, Program restrictions affecting payment for prescribed drugs, recodified to N.J.A.C. 8:83C-1.6.

Repealed by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Section was "Medicare recovery initiative".

**NOTES:**
Chapter Notes

6 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.5 (2017)

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

(a) All participating pharmacies shall provide services 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:

i. Dispensed by licensed pharmacists in accordance with regulations promulgated by the New Jersey State Board of Pharmacy, N.J.A.C. 13:39; and additional prescription pricing in accordance with P.L. 1994, c.67, as revised by P.L. 1995, c.5 (see N.J.A.C. 10:167A-1.15(b)); and

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. Inspect written prescriptions on file;

2. Audit records pertaining to covered persons;

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) Drug name;

(2) Quantity dispensed (including refills);

(3) Price;

(4) Prescription number (for reference purposes only);

(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. The pharmacy shall provide sufficient information with regard to its contractual agreement(s) and payment history with other private third party prescription plans to identify and verify number of claims, amount paid, and dispensing fee paid by group contracts within the plan. Records and contracts shall be available on-site at the time of audit; or available within 10 working days of an on-site audit. Records shall include, but not be limited to:

(1) Payment vouchers;

(2) Contracts; and

(3) Agreements; and

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

HISTORY:

Amended by R.1996 d.313, effective July 15, 1996.

See: 27 N.J.R. 3666(a), 28 N.J.R. 3573(a).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (b)1, changed N.J.A.C. reference in ii; and in (c), inserted a reference to the Department of Health and Senior Services in the introductory paragraph.

Recodified from N.J.A.C. 8:83C-1.3 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

In (b)1ii, amended the N.J.A.C. reference. Former N.J.A.C. 8:83C-1.5, Basis of payment, recodified to N.J.A.C. 8:83C-1.7.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote the section.

**NOTES:**
Chapter Notes

7 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.6 (2017)

§ 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 this chapter are not met:

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

2. Federal regulations (42 CFR 447.500, 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

3. Drug Efficacy Study Implementation (DESI): "Less than effective drugs" subject to a Notice of Opportunity for Hearing (NOOH) by the Federal Food and Drug Administration (see N.J.A.C. 10:167A-1.22) and listing of DESI drugs in (N.J.A.C. 10:51, Appendix A).

HISTORY:

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (a), changed N.J.A.C. references throughout.

Recodified from N.J.A.C. 8:83C-1.4 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Amended N.J.A.C. references throughout. Former N.J.A.C. 8:83C-1.6, Regression categories and discounts, recodified to N.J.A.C. 8:83C-1.8.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

In the introductory paragraph of (a), substituted "prescriber" for "prescribed"; and rewrote (a)8i.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote the section.

CASE NOTES:

Pharmacy not entitled to reimbursement. Park Plaza Pharmacy v. Division of Medical Assistance and Health Services, 94 N.J.A.R.2d (DMA) 53.

**NOTES:**
Chapter Notes

8 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.7 (2017)

§ 10:167A-1.7 Basis of payment

(a) 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. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 10:167A-1.6;

2. Price information as supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division of Medical Assistance (Medicaid) as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The drug price shall not exceed the lower of the average wholesale price minus 10 percent as supplied by the reference drug file contractors; the provider's usual and customary charge; or the drug's maximum allowable cost, if applicable (see (b) below);

i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meet the criteria specified in N.J.A.C. 10:167A-1.14, Covered pharmaceutical services.

3. Federal regulations (42 CFR 447.512 through 514) that set the aggregate upper limits on payment for certain covered drugs in the pharmaceutical program. The New Jersey Medicaid program refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. Provider's usual and customary charge for legend drugs (see (c) below), insulin or insulin needles and syringes.

(b) Payment for legend drugs is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). See N.J.A.C. 10:51, Appendix B, for the listing of MAC drugs.

1. Maximum allowable cost is defined as:

i. The MAC price for listed multi-source drugs published periodically by the CMS of the United States Department of Health and Human Services; or

ii. For legend drugs not included in (b)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid program), in the current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus discount.

2. For information about the usual and customary charge, see N.J.A.C. 10:167A-1.13.

3. If the published MAC price as defined in (b)1i above is higher than the maximum allowable cost which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

(c) The maximum charge to the PAAD program for drugs, including the charge for the cost of medication and the dispensing fee, shall not exceed the provider's usual and customary and/or posted or advertised charge.

HISTORY:

Amended by R.1997 d.252, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2678(a).

In (b)1ii; inserted "For legend drugs not included in (b)1i above" and ", minus regression category or discount"; deleted the first sentence of former (b)1ii(1) and recodified the remaining text as (b)2; recodified former (b)2 as (b)3; in (b)3, substituted "maximum allowable cost" for "average wholesale price"; in (c), substituted "for drugs" for "for a legend drug" and deleted provision that the maximum charge not exceed the MAC price determined in (b)1 plus a dispensing fee if lower than the usual and customary/advertised or posted charge; in (d), substituted ", for claims with service dates prior to July 15, 1996, shall be:" for "is:"; and added (e) and (f).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Changed N.J.A.C. references throughout; in (a)2, changed a reference to the Division of Medical Assistance, and inserted "minus 10 percent" following "wholesale price" in the introductory paragraph; and in (b), inserted ", incorporated herein by reference," following "Appendix B".

Recodified from N.J.A.C. 8:83C-1.5 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Amended N.J.A.C. references throughout. Former N.J.A.C. 8:83C-1.7, Prescription drug dispensing fee, recodified to N.J.A.C. 8:83C-1.9.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

In (a)3, substituted "447.512 through 514" for "447.301, 331-333"; in (a)4, substituted "insulin or" for "insulin,", and deleted ", or diabetic testing materials" from the end; in (b)1i, substituted "CMS" for "Health Care Financing Administration (HCFA)"; in (b)1ii, inserted "the" preceding "current", and deleted "regression category or" preceding "discount"; in (b)2, deleted " 'regression categories and discounts,' see N.J.A.C. 8:83C-1.8 and for" preceding "usual"; and added (g) and (h).

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote the introductory paragraph of (a); and deleted (d) through (h).

**NOTES:**
Chapter Notes

9 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.8 (2017)

§ 10:167A-1.8 (Reserved)

HISTORY:

Amended by R.1995 d.104, effective February 21, 1995.

See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).

Amended by R.1997 d.252, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2678(a).

In (a) and (b), inserted "For pharmaceutical services provided prior to July 15, 1996,"; and added (c).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Changed N.J.A.C. references throughout; and in (b), inserted "incorporated herein by reference," following "Appendix C," and changed a reference to the Division of Medical Assistance in the introductory paragraph.

Recodified from N.J.A.C. 8:83C-1.6 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Amended N.J.A.C. references throughout. Former N.J.A.C. 8:83C-1.8, PAAD program copayment, recodified to N.J.A.C. 8:83C-1.10.

Repealed by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Section was "Regression categories and discounts".

**NOTES:**
Chapter Notes

10 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.9 (2017)

§ 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. Twenty-four hour emergency service: $ 0.11. The provider shall have a 24-hour per day, 365 days per year prescription service available and shall have provided PAAD beneficiaries opportunities to utilize this service.

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. The nursing facility prescription volume shall be included for the determination of total prescription volume in determining entitlement to the impact allowance.

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

(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, 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. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the PAAD program determines that the provider was not entitled to reimbursement for them.

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

HISTORY:

Amended by R.1997 d.252, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2678(a).

In (a), substituted "each prescription" for "legend drug"; and added (d).

Recodified from N.J.A.C. 8:83C-1.7 by R.2003 d. 248, effective June 16, 2002.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.9, Compounded prescriptions, recodified to N.J.A.C. 8:83C-1.11.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Rewrote the introductory paragraph of (a); deleted former (a)2; recodified former (a)3 as (a)2; and in the introductory paragraph of (a)2, inserted ", as calculated by DMAHS,".

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

In the introductory paragraph of (a), inserted "to $ 3.99"; in the introductory paragraph of (a)2, inserted "primary"; in the introductory paragraph of (c), substituted "services," for "services(s)"; and in (d), substituted "the report required by (c) above" for "this report".

**NOTES:**
Chapter Notes



NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.10 (2017)

§ 10:167A-1.10 PAAD program copayment

(a) Beneficiaries in the PAAD program are responsible for a part of the cost of drugs and devices covered by the PAAD program. At the point of sale, a PAAD beneficiary shall render to a pharmacy provider a fixed or adjustable copayment of an amount determined appropriate by the Legislature (see N.J.A.C. 10:167A-1.21(a)4).

(b) A copayment shall be rendered to a pharmacy provider for each original or refill prescription dispensed. The provider's usual and customary charge billed to the PAAD program shall be inclusive of the copayment amount which will be deducted by the New Jersey Medicaid Management Information System (NJMMIS).

1. Under no circumstances is the required rendered copayment amount to be waived for reasons of promotion, advertisement and/or competitive considerations. Failure to comply with PAAD program copayment requirements may result in a suspension of a provider's approval to participate in the PAAD program.

HISTORY:

Amended by R.1997 d.252, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2678(a).

In (a), added N.J.A.C. reference.

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (a), changed N.J.A.C. reference.

Recodified from N.J.A.C. 8:83C-1.8 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

In (a), amended the N.J.A.C. reference and added (c). Former N.J.A.C. 8:83C-1.10, Non-proprietary or generic dispensing, recodified to N.J.A.C. 8:83C-1.12.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Deleted (c).

**NOTES:**
Chapter Notes

12 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.11 (2017)

§ 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 are dispensed by approved providers.

(b) Claims for compounded prescriptions shall be 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 in the EMC claim format.

(c) Reimbursement for compound prescriptions shall be:

1. In accordance with N.J.A.C. 10:167A-1.7 plus a dispensing fee, as described in N.J.A.C. 10:167A-1.9; or

2. A provider's usual and customary charge.

(d) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 10:167A-1.16.

(e) Restrictions on payments for compounded prescriptions are as follows:

1. All legend ingredients that are contained in compounded prescriptions shall be covered by the PAAD program in accordance with N.J.A.C. 10:167A-1.14 and 1.15.

2. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:167A-1.15 are not covered.

HISTORY:

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Changed N.J.A.C. references throughout; and in (a) and (d), substituted references to PAAD for references to Medicaid.

Recodified from N.J.A.C. 8:83C-1.9 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Amended N.J.A.C. references throughout. Former N.J.A.C. 8:83C-1.11, Provider's usual and customary charge or advertised charge, recodified to N.J.A.C. 8:83C-1.13.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote the section.

**NOTES:**
Chapter Notes

13 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.12 (2017)

§ 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 in the list of interchangeable drug products. The labeler code, drug product code, and package size code of the actual product dispensed must be reported on the claim form.

HISTORY:

Recodified from N.J.A.C. 8:83C-1.10 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.12, Covered pharmaceutical services, recodified to N.J.A.C. 8:83C-1.14.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Substituted "pursuant to N.J.A.C. 8:71" for "in the DURC Formulary".

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote the section.

**NOTES:**
Chapter Notes

14 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.13 (2017)

§ 10:167A-1.13 Provider's usual and customary charge or advertised charge

(a) The provider's usual and customary charge or advertised charge is an element considered in the calculation of the basis of payment for legend drugs (see N.J.A.C. 10:167A-1.7, Basis of payment).

(b) The usual and customary charge to the PAAD program is defined as the amount a provider charges the general public for a prescription for the same drug product (same NDC number) in the same quantity as the prescription being dispensed to a PAAD beneficiary. "Usual and customary charge" means the actual charge made to the majority (51 percent) of the total patient population served by the individual pharmacy.

1. The provider shall not charge the Program more than would be charged to a cash customer when the general public, including private third party plans, accounts for more than 50 percent of a provider's total prescription volume.

i. In the event Medicaid and/or PAAD represent more than 50 percent of a provider's total prescription volume, then, for reimbursement purposes, the provider's usual and customary charge may be considered the amount the Program would reimburse for the same services.

HISTORY:

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (a), changed N.J.A.C. reference.

Recodified from N.J.A.C. 8:83C-1.11 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

In (a), amended N.J.A.C. the reference. Former N.J.A.C. 8:83C-1.13, Non-covered pharmaceutical services, recodified to N.J.A.C. 8:83C-1.15.

**NOTES:**

Chapter Notes

15 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.14 (2017)

§ 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 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.

2. Non-legend drugs, as follow:

i. Insulin needles and/or syringes;

ii. Insulin; and

iii. Syringes and needles for injectable medicines.

HISTORY:

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (a), substituted references to the Medicaid and PAAD programs for references to N.J.A.C. 10:49 and this chapter, and substituted "N.J.A.C. 10:51, Appendix D, incorporated herein by reference," for "Appendix"; and in (b)2, added iv.

Recodified from N.J.A.C. 8:83C-1.12 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.14, Quantity of medication, recodified to N.J.A.C. 8:83C-1.16.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Deleted (b)2i; and recodified (b)2ii through (b)2iv as (b)2i through (b)2iii.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote (a); in (b)1, deleted the second sentence; and in (b)2iii, deleted "for the treatment of multiple sclerosis" following "medicines".

**NOTES:**
Chapter Notes

16 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.15 (2017)

§ 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. Prescriptions which are not for medically accepted indications as defined in Section 1927(k)(6) of the Social Security Act;

2. Drug products for which adequate and accurate information is not readily available, such as, but not limited to, product literature, package inserts and price catalogues;

3. Experimental drugs;

4. Medication furnished by a prescriber or an employee of a prescriber;

5. Medication prescribed for hospital inpatients;

6. Non-legend drugs other than insulin; insulin needles and/or syringes; and syringes and needles for injectable medicines for the treatment of multiple sclerosis;

7. Prescriptions written and/or dispensed with nonspecific directions;

8. Food supplements, milk modifiers, infant formulas, therapeutic diets, special liquid or powered diets used in the treatment of obesity;

9. Drug products for which final orders have been published by the Food and Drug Administration, withdrawing the approval of their new drug application (NDA);

10. Drugs or drug products not approved by the Food and Drug Administration, when such approval is required by Federal law and/or regulation;

11. Radiopaque contrast materials (for example, Telepaque);

12. Drugs for which Federal Financial Participation (FFP) is not available, including:

i. Drug Efficacy Study Implementation (DESI) drugs and identical, similar and related drugs (see N.J.A.C. 10:167A-1.22);

13. Any bundled drug service, except drug product cost which is a component of a bundled drug service (see N.J.A.C. 10:167A-1.23);

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

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. Products whose costs are found to be in excess of defined costs outlined in N.J.A.C. 10:167A-1.7, Basis of payment;

2. Manufacturers and distributors may request the review of a denial of reimbursement for products under this subsection by providing supportive information not previously submitted, within 30 days of the date of the denial. Agency decision after review of support material is final;

3. Drug products available in unit-dose packaging and dispensed to residents in a boarding home or residential care setting or other community-type setting. Other community-type setting shall not include certain assisted living settings, including assisted living residency (ALRs), comprehensive personal care homes (CPCHs) and alternative family care (AFC) homes licensed by the Department of Health.

4. A prescription refilled too soon as described in N.J.A.C. 10:167A-1.20(a)5;

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);

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.

HISTORY:

Amended by R.1995 d.359, effective July 3, 1995.

See: 26 N.J.R. 3349(a), 27 N.J.R. 2615(a).

Added (b)4.

Amended by R.1996 d.144, effective March 18, 1996.

See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Amended by R.1996 d.313, effective July 15, 1996.

See: 27 N.J.R. 3666(a), 28 N.J.R. 3573(a).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Changed N.J.A.C. references throughout; and in (a)14, changed a reference to the Department of Health and Senior Services.

Amended by R.2000 d.286, effective July 3, 2000.

See: 32 N.J.R. 428(a), 32 N.J.R. 2441(b).

Added (b)8.

Recodified from N.J.A.C. 8:83C-1.13 and amended by R.2003 d.248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Amended N.J.A.C. references throughout. Former N.J.A.C. 8:83C-1.15, Dosage and directions, recodified to N.J.A.C. 8:83C-1.17.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Rewrote (a)6; deleted (b)2 and (b)7; recodified (b)3 through (b)6 as (b)2 through (b)5 and (b)8 as (b)6; and in (b)5, inserted "and" at the end.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

In (a)14, substituted a semicolon for "and Senior Services; and"; in (a)15, substituted a semicolon for a period; added (a)16 through (a)21 and (b)7 through (b)11; in (b)5, deleted "and" from the end; and rewrote (b)6.

**NOTES:**
Chapter Notes

17 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.16 (2017)

§ 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. As used in this section, "Initial Prescription Claim" shall mean a PAAD claim for a drug not previously paid by the State during the 200-day calendar period immediately preceding the service date of a claim being considered for payment; or a PAAD claim with a service date that has exceeded two times the day's supply reported by the previously paid PAAD claim for the same prescription.

2. As used in this section, "Refill Prescription Claim" shall mean a PAAD claim for a previously paid prescription in which the time period between claims is less than or equal to two times the days supply reported by the previously paid PAAD claim for the same prescription. A Refill Prescription Claim may have the same or different prescription number.

3. For PAAD claims where PAAD is the primary payer, the following days supply limitations shall apply:

i. The days supply limitation for an Initial Prescription Claim shall be limited to a 34-day supply; and

ii. The days supply limitation for a Refill Prescription Claim shall be limited to a 34-day supply or 100 dosage units, whichever is greater.

4. PAAD shall accept the days supply limitations of other primary payers, including, but not limited to Medicare.

(b) Any medication continuously prescribed regardless of the frequency of administration, for a period of 14 days or more shall be considered a maintenance medication.

(c) The pharmacist shall dispense the full quantity of medication prescribed within the limitations described in (a) above.

(d) Prescriptions shall not be split or reduced in quantity, unless the quantity prescribed exceeds Program limits, in which case the quantity shall be reduced to Program limits described in (a) above.

1. Exception: When the full quantity prescribed (within Program limits) is not available when a prescription is ready to be dispensed, the pharmacist shall retain the claim form or submit an Electronic Media Claim after the balance

of the medication is dispensed. The pharmacist may dispense the quantity available and shall notify the beneficiary accordingly.

2. When the item prescribed is packaged from the manufacturer in quantities higher than PAAD limits, PAAD will waive the 34-day requirement limit for the reimbursement and allow the prepackaged quantity.

HISTORY:

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Amended by R.1997 d.252, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2678(a).

In (a), inserted "For claims with service dates on or after July 15, 1996," and changed allowable supply to 34 days from 69 days; and recodified (a)1 through 3 as (b) through (d).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Former (a) not readopted.

Recodified from N.J.A.C. 8:83C-1.14 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Rewrote (a); in (d), added 2; added (e). Former N.J.A.C. 8:83C-1.16, Telephone-rendered original prescriptions, recodified to N.J.A.C. 8:83C-1.18.

Amended by R.2004 d.350, effective September 20, 2004.

See: 36 N.J.R. 2417(a), 36 N.J.R. 4313(a).

Rewrote (a); in (d), substituted "Electronic Media Claim" for "EMC claim" in 1.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

In the introductory paragraph of (a), deleted the first sentence; in the introductory paragraph of (a)3, inserted "and where PAAD is the primary payer,"; added (a)4; and deleted (e).

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

In the introductory paragraph of (a)3, deleted "with service dates on or after November 1998, and" following "claims".

**NOTES:**
Chapter Notes

18 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.17 (2017)

§ 10:167A-1.17 Dosage and directions

(a) Dosage and directions for use shall be indicated on all prescriptions. Prescriptions written and dispensed with no specific directions, such as "prn," "as directed" or "ad lib," etc. are not eligible for reimbursement. Specific directions such as "1 tablet 4 times a day PRN" are required.

1. Exceptions:

i. Topical preparations including ophthalmic and otic drops and ointments;

ii. Aerosol inhalers; and

iii. Nitroglycerin.

2. For all oral medication and injectables, the number of days the medication should last, based on the prescriber's directions of use, shall be entered in the "Days Supply" field on the pharmacy claim form or similar field in the EMC claim format.

(b) The number of days reported for the days supply dispensed on the pharmacy claim or in the appropriate field on the EMC claim must accurately reflect the intended duration of drug utilization, or a reasonable estimation by the dispensing pharmacist of a drug's intended duration of use when a drug's dosage is unrelated to a specific days supply.

HISTORY:

Amended by R.1996 d.144, effective March 18, 1996.

See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Recodified from N.J.A.C. 8:83C-1.15 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.17, Changes or additions to the original prescription, recodified to N.J.A.C. 8:83C-1.19.

**NOTES:**
Chapter Notes

19 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.18 (2017)

§ 10:167A-1.18 Telephone-rendered, faxed or electronically transmitted original prescriptions

(a) Telephone, facsimile or electronically transmitted orders from prescribers for original prescriptions shall be permitted in accordance with all applicable Federal and State laws and regulations.

(b) For purposes of reimbursement, telephone-rendered or faxed authorization to refill an original prescription with no refill remaining is considered a new order and requires a new written prescription with a new prescription number. Stamping or writing a new number on the original prescription order does not constitute a new prescription under the PAAD program.

(c) When a prescriber chooses not to allow product interchange on a telephone-rendered or faxed order, the statement "Substitution not permitted by prescriber-telephoned Rx" plus the pharmacist's full signature next to or below the statement, shall appear on the prescription order. A rubber stamp bearing the statement is acceptable.

(d) Electronically transmitted prescriptions shall be in compliance with the State Board of Pharmacy requirements at N.J.A.C. 13:39-7.11.

HISTORY:

Recodified from N.J.A.C. 8:83C-1.16 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.18, Prescription refill, recodified to N.J.A.C. 8:83C-1.20.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

Section was "Telephone-rendered original prescriptions". In (a), inserted ", facsimile or electronically transmitted"; in (b) and (c), inserted "-rendered or faxed"; and added (d).

**NOTES:**

Chapter Notes

20 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.19 (2017)

§ 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 of refills, days supply, etc.) are permitted on the original prescription order after the claim is submitted for payment.

HISTORY:

Recodified from N.J.A.C. 8:83C-1.17 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.19, Prescription drug price and quality stabilization act, recodified to N.J.A.C. 8:83C-1.21.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Substituted "of" for the second occurrence of "or".

**NOTES:**
Chapter Notes

21 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.20 (2017)

§ 10:167A-1.20 Prescription refill

(a) The provider shall submit 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 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. The original prescription is valid for the 12 month period beginning with the date of the original prescription. There is no limit to the number of refills dispensed during the 12 month period.

i. Exception: Oral contraceptives originally prescribed for three ovulatory cycles may be refilled up to three times within one year if so indicated by the prescriber on the original prescription.

3. Refill instructions indicating "refill prn" or indicating more than five refills, shall be subject to the limits imposed in (a)2 above, and shall be reimbursed up to these limits only.

4. 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 85 percent of the medication originally dispensed or refilled could have been consumed in accordance with the prescriber's written directions for use.

HISTORY:

Amended by R.1996 d.144, effective March 18, 1996.

See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Recodified from N.J.A.C. 8:83C-1.18 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.20, Drug efficacy study implementation (DESI), recodified to N.J.A.C. 8:83C-1.22.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

In (a)1, deleted ", in accordance with N.J.S.A. 45:14-14" from the end; and in the introductory paragraph of (a)5, substituted "85" for "75".

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote the section.

CASE NOTES:

Denial of reimbursement for prescription refills was appropriate. Crestview Pharmacy v. Division of Medical Assistance and Health Services, 94 N.J.A.R.2d (DMA) 40.

**NOTES:**
Chapter Notes

22 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.21 (2017)

§ 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, 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 as an interchangeable drug product with the brand name prescribed.

3. When the prescriber orders by generic name, 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 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" in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be 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. For MAC drugs 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" in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be 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) Federal regulations at 42 CFR 447.512 prescribe the aggregate upper limit, or maximum allowable cost (MAC) for certain legend drugs, which are applied to Medicaid-covered pharmacy services (see (d) below). For claims with service dates on or after July 15, 1996, these limits shall apply to all MAC drugs (see N.J.A.C. 10:51, Appendix B, incorporated herein by reference) covered by PAAD unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone-rendered prescription (see N.J.A.C. 10:167A-1.7) the phrase "Brand Medically Necessary." The Federal regulation at 42 CFR 447.512 requires a written statement and does not permit the use of alternatives, such as a check-off box initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a handwritten statement "Do Not Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E-1 does not apply to drugs, which have a Federal MAC limit.

(c) 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) The dispenser must always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the stock package size used to fill the prescription.

HISTORY:

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Amended by R.1997 d.252, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2678(a).

In (a)5, substituted "as defined in" for "see" and deleted reference to adding applicable dispensing fees or usual and customary charges to reimbursement amount; added (a)6; inserted new (b); recodified former (b) as (d); and added (c).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Changed N.J.A.C. references and inserted "incorporated herein by reference" following Appendix references throughout.

Recodified from N.J.A.C. 8:83C-1.19 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Amended N.J.A.C. reference in (a)5, 6, (b). Former N.J.A.C. 8:83C-1.21, Bundled drug service, recodified to N.J.A.C. 8:83C-1.23.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

In (a)1, substituted "pursuant to N.J.A.C. 8:71," for "in the DURC (reference here to where it is defined) Formulary,"; in (a)2, substituted "pursuant to N.J.A.C. 8:71" for "in the DURC Formulary"; in (a)3, substituted "listing pursuant to N.J.A.C. 8:71" for "formulary" and "him or her" for "him/her"; in (a)4, substituted "pursuant to N.J.A.C. 8:71" for "in the latest issue of the formulary" and deleted the last sentence; recodified (a)5 and (a)6 as (a)4i and (a)4ii; in (a)4i, substituted "; or" for a period at the end; and in (b), substituted "CFR 447.512" for "C.F.R. 447.331" twice and "maximum allowable cost" for "Maximum Allowable Cost", and inserted a comma following "legend drugs", "alternatives", and "drugs" in the last sentence.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote (a); and in (c), substituted "A" for "For claims with service dates on or after July 15, 1996, a".

**NOTES:**
Chapter Notes

23 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.22 (2017)

§ 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. The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962;

ii. The drug product is available only through prescription;

iii. The drug product is the subject of a 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. The drug product is presently the subject of an efficacy review study performed by FDA (see 21 CFR 310.6 including all subsequent amendments and supplements). The FDA efficacy review potentially can determine justification for a drug product's medical need. If a drug product fails this review, the product is classified as a DESI drug.

2. Reimbursement is not available for the purchase or administration of any drug product that is identical, related or similar, as defined in 21 CFR 310.6 (including all subsequent amendments and supplements), to a drug product that meets the conditions of (a) above.

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 that are adopted, shall appear in the Federal Register.

(b) To obtain a list of DESI drugs, see N.J.A.C. 10:51, Appendix A.

HISTORY:

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Added (b).

Recodified from N.J.A.C. 8:83C-1.20 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.22, Claim submission, recodified to N.J.A.C. 8:83C-1.24.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

In (a)1iii, substituted "NOOH" for "notice of opportunity for hearing", and inserted the fourth occurrence of "the"; and in (a)3, substituted "that" for "which".

**NOTES:**
Chapter Notes

24 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.23 (2017)

§ 10:167A-1.23 Bundled drug service

(a) "Bundled drug service" means a drug or service that is marketed or distributed by the manufacturer or distributor as a combined package which includes in the cost the drug product and ancillary services such as, but not limited to, case management services and laboratory testing.

(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.

HISTORY:

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (b), changed N.J.A.C. reference in the introductory paragraph, and changed a reference to the PAAD program and changed the mailing address in 1.

Recodified from N.J.A.C. 8:83C-1.21 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

In (b), amended N.J.A.C. reference. Former N.J.A.C. 8:83C-1.23, Eligible PADD beneficiary, recodified to N.J.A.C. 8:83C-1.25.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Deleted (b)1.

**NOTES:**
Chapter Notes

25 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.24 (2017)

§ 10:167A-1.24 Claim submission

(a) 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.

1. The approved POS intermediary or provider established network shall enter into an agreement with the State of New Jersey to provide on-line telecommunication services, including transmission of pharmacy claim detail data, access to the fiscal agent's POS computer and return of adjudicated claim data to the provider.

HISTORY:

Repeal and New Rule, R.1995 d.104, effective February 21, 1995.

See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).

Formerly "EMC Incentive Program".

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (b), substituted references to PAAD for references to Medicaid throughout, and changed Appendix references and inserted ", incorporated herein by reference," following Appendix references in 1.

Recodified from N.J.A.C. 8:83C-1.22 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.24, PAAD beneficiary identification, recodified to N.J.A.C. 8:83C-1.26.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

In the introductory paragraph of (a)3, inserted a comma following "format", and substituted "5.1" for "3.2" and "9240 East Raintree Drive, Scottsdale, Arizona 85260-7518 or http://www.ncpdp.org" for "4201 North 24th Street, Suite 365, Phoenix, Arizona 85016".

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote the section.

**NOTES:**
Chapter Notes

26 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.25 (2017)

§ 10:167A-1.25 Eligible PAAD beneficiary

(a) An applicant shall be determined to be eligible for Pharmaceutical Assistance to the Aged and Disabled only if physically present in New Jersey at the time of application and utilization, in accordance with the provisions of N.J.A.C. 10:167.

1. Benefits shall not be payable for patients in nursing facilities, hospitals or special hospitals by the PAAD program during any period recipients are covered for drug benefits by Medicaid, Medicare, Blue Cross and Blue Shield of New Jersey, Inc., or other insurance benefits or if such benefits are covered in the daily rate of the facility.

HISTORY:

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Rewrote the section.

Recodified from N.J.A.C. 8:83C-1.23 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.25, Point-of-sale (POS) claims adjudication system, recodified to N.J.A.C. 8:83C-1.27.

**NOTES:**
Chapter Notes

27 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.26 (2017)

§ 10:167A-1.26 PAAD beneficiary identification

(a) Pharmacies should verify that the beneficiary is a PAAD covered person. This is done by checking the beneficiary's PAAD identification card.

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

(c) The beneficiary is eligible only for the period of time indicated on the identification card.

HISTORY:

Amended by R.1997 d.252, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2678(a).

In (a), deleted "plastic" preceding "PAAD identification card" and deleted reference to checking a Temporary Validation Identification Letter"; and in (b), substituted "The PAAD program" for "The Division".

Recodified from N.J.A.C. 8:83C-1.24 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.26, Prospective drug utilization review (PDUR) program, recodified to N.J.A.C. 8:83C-1.28.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

In (b), substituted "Card" for "Care", and inserted a comma following "effective date".

**NOTES:**
Chapter Notes

28 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.27 (2017)

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

(a) PAAD pharmacy claims shall be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real-time. The pharmacist 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 Division.

1. In order to become an approved POS intermediary or provider established network, a firm shall notify the Division at the following address:

Division of Medical Assistance and Health Services
Office of Information Systems
PO Box 712
Trenton, New Jersey 08625-0712
Telephone: (609) 588-2802

2. The Division shall send the interested party a summary of the program and instructions on how to submit an application.

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

i. The applicant's general approach and plans to meet the requirements of the POS project;

ii. The applicant's detailed approach and plans to meet the requirements of the POS project;

iii. The applicant's documented qualifications, expertise, and experience on similar projects;

iv. The applicant's proposed staff's documented qualifications, expertise, and experience on similar projects; and

v. The applicant's adherence to the requirements of CMS.

(c) A POS participating pharmacy or intermediary 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) A POS participating pharmacy or intermediary shall supply modem capability required to properly transmit claim detail data to the approved POS intermediary or to participate in the provider established telecommunication network.

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

(f) Claim data requirements for EMCs generated by POS participating pharmacies include:

1. The first five alpha characters of the last name and the first three alpha characters of the PAAD beneficiary's first name;

2. The 12 digit PAAD identification number;

3. The date of birth, if applicable;

4. The date of service or dispense date;

5. The pharmacy prescription number;

6. The actual 11 digit National Drug Code (NDC) of the drug dispensed;

7. The metric quantity dispensed;

8. The days supply;

9. The prescriber's Medicaid provider service number;

10. The third party payment, if applicable;

11. The provider's usual and customary charge; and

12. The pharmacy provider number.

(g) Additional supplementary data requirements, which are claim specific, include:

1. The medical certification indicator;

2. The nursing facility residency indicator;

3. The compound drug indicator;

4. The other insurance indicator, if applicable; and

5. The carrier code(s), if applicable.

(h) A POS participating pharmacy or intermediary shall be required to implement software changes requested by the Division within 60 days of notification of such a request to ensure the generation of electronic claims acceptable to the PAAD program.

(i) Pharmacy software must have the capability to display on-line adjudicated claim data returned to the pharmacy by the fiscal agent, including:

1. Payment disposition;

2. Error code messages; and

3. Claim pricing data, including drug cost reimbursement, dispensing fee and applicable copayment amounts.

(j) Pharmacy software must provide the pharmacy with the capability of claim reversal and resubmission, if required by Federal or State laws or regulations, or as follows:

1. A pharmacy may initiate a claim reversal of a previously submitted pharmacy claim for a period of 12 months from the initial date of claim service.

2. Pharmacies are required to initiate claim reversals for those services in which a claim was generated and adjudicated to payment by the fiscal agent's POS computer and the service was not subsequently provided to a PAAD beneficiary.

3. Upon notification by PAAD, the pharmacy shall reverse and reprocess a claim where the primary payer is Medicare Part D, the claim was denied for payment by the Medicare Part D provider and where the claim is successfully appealed through the Medicare Part D appeal process.

4. All prescriptions adjudicated to payment by the fiscal agent's computer shall be subsequently dispensed and their receipt by PAAD beneficiaries properly documented on a PAAD approved certification statement/signature log. (See N.J.A.C. 10:49-9.6)

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

HISTORY:

New Rule, R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (b), changed N.J.A.C. reference in the introductory paragraph; and in (f)2, substituted a reference to PAAD for a reference to Medicaid.

Recodified from N.J.A.C. 8:83C-1.25 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

In (b), amended the N.J.A.C. reference in the introductory paragraph. Former N.J.A.C. 8:83C-1.27, Medical exception process (MEP), recodified to N.J.A.C. 8:83C-1.29.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3804(a).

In the introductory paragraph of (b), substituted "PAAD-approved" for "PAAD approved"; in the address in (b)1, deleted "--Mail Code #4" following "PO Box 712"; in the introductory paragraph of (j), inserted a comma following "resubmission", and substituted "by Federal or State laws or regulations, or as follows:" for a period at the end; added new (j)3; and recodified former (j)3 as (j)4.

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Rewrote (a) and (e); in the introductory paragraph of (b), substituted "Division" for "New Jersey Division of Medical Assistance and Health Services"; in (b)3v, substituted "CMS" for "the Health Care Financing Administration"; in (c), substituted "shall" for "must"; in (f), substituted "EMCs" for "electronic media claims (EMCs)"; and in (k), substituted "and" for "and/or" and "from" for "form".

**NOTES:**

Chapter Notes

29 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.28 (2017)

§ 10:167A-1.28 Prospective drug utilization review (PDUR) program

(a) The Division of Medical Assistance and Health Services of the Department of Human Services and the Department of Health have established a prospective drug utilization review (PDUR) program to assist pharmacy providers in monitoring drug utilization by PAAD beneficiaries. As a component of the PAAD point-of-sale (POS) claims adjudication system, the State's fiscal agent will review drug utilization based on claims submitted on-line and provide pharmacists with responses in real-time regarding utilization within PDUR standards as recommended by the Drug Utilization Review (DUR) Board and approved by the Department. Similar responses related to electronic media claims (EMC) or paper claims processed by the New Jersey Medicaid Management Information System (NJMMIS) shall be received by pharmacies on the Remittance Advice statement.

1. PDUR standards developed by the DUR Board shall be based on official compendia and accepted medical literature and shall include, but not be limited to, those standards established by First Data Bank (FDB) as part of the FDB DUR information system. The FDB standards are incorporated herein by reference and may be obtained from First Data Bank, The Hearst Corp., 1111 Bayhill Drive, San Bruno, CA 94066.

2. PDUR standards shall be applied to all PAAD pharmacy claims, regardless of the mode of claim submission.

(b) POS participating pharmacy providers shall be required to meet the conditions described in N.J.A.C. 10:167A-1.27.

(c) In addition to POS responses related to adjudication of PAAD pharmacy claims returned to the pharmacy, pharmacists shall be notified regarding drug utilization inconsistent with adopted PDUR standards which may include, but not be limited to:

1. Drug interactions;

2. Maximum/minimum daily dosage alerts;

3. Therapeutic duplication;

4. Drug age conflicts;

5. Duration of therapy;

6. Drug-disease precautions; and

7. Drug-pregnancy precautions.

(d) The PDUR program may apply adopted standards based on a severity index approved by the Department or DUR Board to determine appropriate pharmacist intervention and/or claim disposition (for example, payment or denial) of PAAD pharmacy claims.

(e) Based on the severity of a potential PDUR conflict or interaction, pharmacists shall be required to consult with the beneficiary and/or prescriber to resolve matters indicated by PDUR messages returned by the POS system.

(f) The pharmacist intervention requirements related to the PDUR program are in addition to beneficiary interactions related to New Jersey State Board of Pharmacy requirements regarding the "offer to consult," as described in N.J.A.C. 13:39-7.14, Patient profile record system.

HISTORY:

New Rule, R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Amended by R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

In (a) and (d), inserted references to the Department of Health and Senior Services throughout; in (b), changed N.J.A.C. reference; and in (c), substituted a reference to PAAD for a reference to Medicaid in the introductory paragraph.

Amended by R.1999 d.148, effective May 3, 1999.

See: 30 N.J.R. 4109(a), 31 N.J.R. 1197(b).

In (a), substituted "as recommended by the Drug Utilization Review (DUR) Board and approved by DHSS" for "approved by the Medicaid Drug Utilization Review (DUR) Board" at the end of the second sentence of the introductory paragraph, rewrote the first sentence of 1, and deleted "adopted by the Medicaid Drug Utilization Review Board or DHSS" following "standards" in 2; rewrote (c)5; and in (d), deleted "Medicaid" following "DHSS or".

Recodified from N.J.A.C. 8:83C-1.26 and amended by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Former N.J.A.C. 8:83C-1.28, Drug rebate program, recodified to N.J.A.C. 8:83C-1.30.

**NOTES:**
Chapter Notes

30 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.29 (2017)

§ 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. The MEP may be administered by a vendor on behalf of the Department.

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

(b) The MEP shall be as follows:

1. Upon the occurrence of a PDUR edit indicating that a claim is denied unless a medical exception override is applied, the pharmacist shall contact the MEP contractor.

2. The MEP contractor shall approve the claim for payment for the full prescription specified, or a 30-day supply of the prescription, whichever amount is less, unless it is clear that consumption of the prescribed medication poses a threat to the patient's life or may result in a potentially serious illness based on the information available to the pharmacist and the MEP contractor.

3. If the prescription exceeds a 30-day supply, the MEP contractor shall send the prescriber an MEP Prescriber Notification Letter form, along with the PAAD beneficiary's name and PAAD identification number, the dispense date, drug quantity and drug description, and the toll-free telephone number of the MEP contractor.

4. In order to request the medical exception override, the prescriber shall submit the completed MEP Prescriber Notification Letter to the MEP contractor with a justification for the medical exception override, and the anticipated length of time the medical exception override for the PAAD beneficiary will be necessary to satisfy the length of therapy required.

5. The MEP contractor shall render a decision on the request for the medical exception override documented in the completed MEP Prescriber Notification Letter, basing the decision whether to grant or deny the request upon drug standards and protocols established by the DUR Board, and shall notify the PAAD beneficiary, the prescriber and the pharmacist of the decision.

6. If the request is approved, the MEP contractor shall issue an authorization number recognized by the NJMMIS for the medical exception override to facilitate claim payment.

(c) Except as (b)2 above applies, the PAAD program shall deny payment for claims subject to the MEP process for which an authorization number has not been issued by the MEP contractor.

(d) PAAD beneficiaries, or prescribers acting with the consent of the PAAD beneficiary, and pharmacies (following receipt of a Remittance Advice Statement) may request a fair hearing to appeal a decision by the MEP contractor not to approve a claim pursuant to (b)2 or 5 above within 30 calendar days following the date of the claim denial, in accordance with N.J.A.C. 10:167-6.12.

1. The request for a fair hearing shall be made in writing, and shall specify the reasons the PAAD beneficiary, pharmacy or prescriber believes that the MEP's decision was incorrect.

2. The request for a fair hearing shall be submitted to:

PAAD MEP
PO Box 715
Trenton, NJ 08625-0715

HISTORY:

New Rule, R.1999 d.148, effective May 3, 1999.

See: 30 N.J.R. 4109(a), 31 N.J.R. 1197(b).

Former N.J.A.C. 8:83C-1.27, Drug rebate program, recodified to N.J.A.C. 8:83C-1.28.

Recodified from N.J.A.C. 8:83C-1.27 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

In the introductory paragraph of (a), inserted a comma after "1999", and in (a)2, substituted "long-term care facility providers" for "institutionalized beneficiaries".

**NOTES:**
Chapter Notes

31 of 31 DOCUMENTS

NEW JERSEY ADMINISTRATIVE CODE


*** This file includes all Regulations adopted and published through the ***
*** New Jersey Register, Vol. 49 No. 11, June 5, 2017 ***

TITLE 10. HUMAN SERVICES
CHAPTER 167A. PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)
SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

**Go to the New Jersey Administrative Code Archive Directory**

N.J.A.C. 10:167A-1.30 (2017)

§ 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.

HISTORY:

New Rule, R.1998 d.464, effective September 8, 1998.

See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Recodified from N.J.A.C. 8:83C-1.27 by R.1999 d.148, effective May 3, 1999.

See: 30 N.J.R. 4109(a), 31 N.J.R. 1197(b).

Recodified from N.J.A.C. 8:83C-1.28 by R.2003 d. 248, effective June 16, 2003.

See: 34 N.J.R. 3456(a), 35 N.J.R. 2642(a).

Amended by R.2017 d.035, effective March 6, 2017.

See: 48 N.J.R. 2005(a), 49 N.J.R. 446(a).

Inserted ", including an agreement to pay rebates on claims for which PAAD is a secondary payer,".

**NOTES:**
Chapter Notes