CHAPTER 83

PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED ELIGIBILITY MANUAL

Authority

N.J.S.A. 30:4D–20 through 24.

Source and Effective Date

R.1998 d.176, effective March 13, 1998.
See: 29 N.J.R. 5280(a), 30 N.J.R. 1314(b).

Executive Order No. 66(1978) Expiration Date

Chapter 83, Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual, expires on March 13, 2003.

Chapter Historical Note

Chapter 83, Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual, was originally codified in Title 10 as Chapter 69A, Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual. Chapter 69A, Pharmaceutical Assistance to the Aged Program, was adopted as R.1976 d.102, effective April 5, 1976. See: 7 N.J.R. 505(c), 8 N.J.R. 232(b).

Pursuant to Executive Order No. 66(1978), Chapter 69A was readopted as R.1988 d.211, effective April 20, 1988. See: 20 N.J.R. 369(a), 20 N.J.R. 1106(a).

Pursuant to Executive Order No. 66(1978), Chapter 69A, Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual, was readopted as R.1993 d.175, effective March 26, 1993 See: 24 N.J.R. 4479(a), 25 N.J.R. 1764(a).

Pursuant to Reorganization Plan No. 001–1996, Chapter 69A, Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual, was recodified to Title 8, Chapter 83, effective October 15, 1997. See: 29 N.J.R. 4679(a).

Pursuant to Executive Order No. 66(1978), Chapter 83, Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual, was readopted as R.1998 d.176, effective March 13, 1998. See: Source and Effective Date. See, also, section annotations.

Cross References

See N.J.A.C. 10:51–4.1 et seq., Pharmaceutical assistance to the aged and disabled program.

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SUBCHAPTER 1. INTRODUCTION

8:83–1.1 Purpose and intent

(a) It is intended that Pharmaceutical Assistance to the Aged and Disabled (PAAD) shall extend assistance to certain persons whose level of income disqualifies them for medical assistance under the New Jersey Medical Assistance and Health Services Act, but who have significant needs for prescribed drugs and/or insulin, insulin needles, insulin syringes, and/or certain diabetic materials and are unable to fully meet the cost of such items.

(b) This manual has been developed as a statement of policy and procedures and is applicable only to eligibility for the PAAD Program.

Amended by R.1985 d.690, effective January 21, 1986.
See: 17 N.J.R. 2332(a), 18 N.J.R. 190(a).
Added text in (a) "and/or certain diabetic materials".
Amended by R.1998 d.176, effective April 6, 1998.
See: 29 N.J.R. 5280(a), 30 N.J.R. 1314(b).

8:83–1.2 Legal authority

(a) The New Jersey Program of Pharmaceutical Assistance to the Aged and Disabled (PAAD) was established by Chapter 194, Laws of 1975, as amended by:

1. Chapter 194, Laws of 1975, effective August 21, 1975. Amended by Chapter 312, Laws of 1975, effective February 19, 1976;

2. Chapter 268, Laws of 1977, effective January 1, 1978;

3. Chapter 171, Laws of 1978, effective December 22, 1978;

4. Chapter 27, Laws of 1979, effective March 1, 1979;

5. Chapter 499, Laws of 1981, effective March 1, 1982;

6. Chapter 209, Laws of 1985, effective August 1, 1985;

7. Chapter 221, Laws of 1987, effective July 29, 1987 and retroactive to December 31, 1986;

8. Chapter 16, Laws of 1989, effective February 1, 1989; and

9. Chapter 84, Laws of 1991, effective April 3, 1991 and retroactive to January 1, 1991; and

10. Chapter 30, Laws of 1992, effective June 29, 1992.

11. Chapter 3, Laws of 1993, effective January 13, 1993 and retroactive to January 1, 1993;

12. Chapter 27, Laws of 1995, effective February 15, 1995, retroactive to January 1, 1995;

13. Chapter 323, Laws of 1995, effective April 4, 1996; and

14. Reorganization Plan No. 001–1996.

(b) These Statutes supplement the New Jersey Medical Assistance and Health Services Act (P.L. 1968, c.413).

Amended by R.1985 d.259, effective May 20, 1985.
See: 17 N.J.R. 367(a), 17 N.J.R. 1318(b).
Deleted (a)1, and substituted new text; added (a)5.
Amended by R.1985 d.690, effective January 21, 1986.
See: 17 N.J.R. 2332(a), 18 N.J.R. 190(a).
Added (a)6.
Amended by R.1988 d.174, effective April 18, 1988.
See: 19 N.J.R. 2375(a), 20 N.J.R. 902(a).
Added (a)7.
Amended by R.1990 d.182, effective March 19, 1990.
See: 21 N.J.R. 3047(a), 22 N.J.R. 953(a).
Added (a)8.
Amended by R.1991 d.563, effective November 18, 1991.
See: 23 N.J.R. 2623(a), 23 N.J.R. 3514(a).
New (a)9. added; reference to Chapter 84, Laws of 1991.
Amended by R.1993 d.608, effective December 6, 1993.
See: 25 N.J.R. 3407(a), 25 N.J.R. 5528(b).
Amended by R.1994 d.191, effective April 18, 1994.
See: 25 N.J.R. 5750(a), 26 N.J.R. 1657(a).
Amended by R.1996 d.7, effective January 2, 1996.
See: 27 N.J.R. 3541(a), 28 N.J.R. 184(c).
Amended by R.1998 d.176, effective April 6, 1998.
See: 29 N.J.R. 5280(a), 30 N.J.R. 1314(b).
In (a), added 13 and 14.

SUBCHAPTER 2. DEFINITIONS

8:83–2.1 Definitions

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

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

"Anticipated income" means the amounts of income the applicant can reasonably be expected to receive during the calendar year.

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

"Authorized agent" means a person who initiates the PAAD application for a person who is incompetent or incapable of filing the PAAD application on his/her behalf.

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

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

"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.

"Commissioner" means the Commissioner of the Department of Health and Senior Services.

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

"Department" means the Department of Health and Senior Services.

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

"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".

"Lifeline Credit Program" means the utility assistance program that offers a benefit in the form of a credit to the utility account during the heating season to eligible New Jersey residents.

"PAAD Co-pay" means the amount of $5.00 which must be paid by each PAAD beneficiary to the pharmacy toward the cost for each prescription for a legend drug and/or insulin, insulin syringes, insulin needles, and certain diabetic testing materials. The co-pay is not reimbursable by the PAAD. The $5.00 co-payment shall be paid in full by each eligible person to the pharmacist at the time of each purchase of prescription drugs, and shall not be waived, discounted or rebated in whole or in part.

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

"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.

"Prescription drugs" means all approved legend drugs, including any interchangeable drug products contained in the latest list approved and published by the Drug Utilization Review Council in conformance with the provisions of the "Prescription Drug Price and Quality Stabilization Act," and insulin, insulin syringes, insulin needles and certain diabetic testing materials 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 which is required by the Federal Food, Drug and Cosmetic Act to have the following statement on the manufacturer's original packaging label: "Caution: Federal law prohibits dispensing without a prescription";

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

iv. Diabetic testing materials including blood glucose reagent strips which can be visually read, urine monitoring strips, tapes and tablets and bloodletting devices and lancets (electronically monitored devices are not included); and

v. Syringes and needles for injectable medicines for the treatment of multiple sclerosis.

"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.

"Reasonable cost" means the maximum allowable cost of prescription drugs plus a dispensing fee as determined by the Commissioner.

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

"Tenants Lifeline Assistance Program" means a utility assistance program that offers a benefit in the form of a check issued to tenants whose utilities are included in their rent and do not have a separate utility bill.

As amended, R.1989 d.375, eff. September 25, 1979.
See: 11 N.J.R. 558(c). As amended, R.1982 d.198, eff. June 21, 1982.
See: 14 N.J.R. 321(b), 14 N.J.R. 659(a).
Section substantially amended.
As amended, R.1985 d.259, effective May 20, 1985.
See: 17 N.J.R. 367(a), 17 N.J.R. 1318(b).
Added definition "reasonable cost".
Amended by R.1985 d.690, effective January 21, 1986.
See: 17 N.J.R. 2332(a), 18 N.J.R. 190(a).
Amended "PAAD Co-pay" and "prescription drugs".
Amended by R.1993 d.155, effective April 5, 1993.
See: 24 N.J.R. 4328(a), 25 N.J.R. 1514(a).
Revised copayment to $5.00.
Amended by R.1998 d.176, effective April 6, 1998.
See: 29 N.J.R. 5280(a), 30 N.J.R. 1314(b).
In "Prescription drugs" added 1v; in "Previous year", inserted "for which the person filed a tax return" following "last year" in 1; and inserted "Provider".

Case Notes

"Income" defined. Atty.Gen.F.O.1978, No. 3.

SUBCHAPTER 3. ADMINISTRATIVE ORGANIZATION

8:83–3.1 Department of Health and Senior Services

The Department of Health and Senior Services is the administrative unit of the State government which has con-

trol over the administration of PAAD. Under the terms of the PAAD law, this Department is responsible for the general policies governing administration of PAAD, and for effecting the issuance of rules, regulations and procedures in accordance with the Administrative Procedure Act for implementing the statutory provisions.

8:83–3.2 Division of Medical Assistance and Health Services

The Division of Medical Assistance and Health Services is the administrative unit of the Department of Human Services that performs certain administrative functions for, or in conjunction with, the Department.

8:83–3.3 Pharmaceutical Assistance to the Aged and Disabled Program

The Pharmaceutical Assistance to the Aged and Disabled is the program in the Department which has the direct responsibility for the processing of eligibility applications from applicants.

SUBCHAPTER 4. SCOPE OF SERVICE

8:83–4.1 Statutory limitations

By statute, the Pharmaceutical Assistance to the Aged and Disabled Program is limited to payment or reimbursement to pharmacies for the reasonable cost of prescription drugs for eligible persons which exceeds the PAAD co-pay.

Amended by R.1985 d.690, effective January 21, 1986.
See: 17 N.J.R. 2332(a), 18 N.J.R. 190(a).
Added text "insulin, insulin syringes . . . diabetic testing materials".
Amended by R.1993 d.155, effective April 5, 1993.
See: 24 N.J.R. 4328(a), 25 N.J.R. 1514(a).
Revised copayment to $5.00.
Amended by R.1998 d.176, effective April 6, 1998.
See: 29 N.J.R. 5280(a), 30 N.J.R. 1314(b).
Rewrote the section.

8:83–4.2 Principles of reimbursement to participating pharmacies

(a) Reimbursement for PAAD prescriptions will be made only to pharmacies located in New Jersey and operating under a valid permit from the Board of Pharmacy of the State of New Jersey. In order to become an approved provider, such a pharmacy must file an application and agreement of participation which must be approved by the Division of Medical Assistance and Health Services of the Department of Human Services.

(b) No reimbursement will be made to an unlicensed pharmacy or to a pharmacy located in another state or country.

(c) Reimbursement on behalf of PAAD beneficiaries will be made directly to the participating pharmacies and will be for the reasonable cost of prescription drugs of beneficiaries as determined by the Commissioner, Department of Human Services, which exceeds the $5.00 co-payment per prescription.

Amended by R.1993 d.155, effective April 5, 1993.
See: 24 N.J.R. 4328(a), 25 N.J.R. 1514(a).
Revised copayment to $5.00.

8:83–4.3 Interchangeable drug products

(a) Whenever any interchangeable drug product contained in the latest list approved and published by the Drug Utilization Review Council is available for the prescription written, the PAAD Program shall reimburse only for the reasonable cost of the interchangeable product, less the PAAD co-pay, unless:

1. The prescriber specifies that substitution is not permitted; or

2. For certain brand name products as specified at N.J.A.C. 10:51–4.19(b), the prescriber handwrites the statement "Brand Medically Necessary" on the prescription form.

(b) If the prescriber does not specify to the contrary, the PAAD beneficiary has two options:

1. To purchase an interchangeable drug product which is equal to or less than the maximum allowable cost, at the PAAD co-pay; or

2. To purchase the prescribed drug product which is higher in cost than the maximum allowable cost and pay the difference between the two, in addition to the PAAD co-pay.

(c) If the prescriber specifies on the prescription that substitution is not permitted, and that the brand name drug is medically necessary, when required, the PAAD Program will reimburse for the reasonable cost of the prescribed product, less the PAAD co-pay. In this instance, the beneficiary may purchase the prescribed product at the PAAD co-payment.

Amended by R.1993 d.155, effective April 5, 1993.
See: 24 N.J.R. 4328(a), 25 N.J.R. 1514(a).
Revised copayment to $5.00.
Amended by R.1998 d.176, effective April 6, 1998.
See: 29 N.J.R. 5280(a), 30 N.J.R. 1314(b).
Substituted references to the PAAD co-pay for references to the $5.00 co-pay throughout; in (a), designated 1, and added 2; and in (c), inserted "and that the brand name drug is medically necessary, when required," following "permitted,".

Case Notes

Regulation of the division of medical assistance and health services which excludes senior citizens who are inpatients in nursing homes or hospitals from the benefits provided by the pharmaceutical assistance for the aged program for the coverage of prescribed drugs, insulin, insulin syringes or insulin needles is inconsistent with the governing statutory provisions on eligibility relating to income of the recipient and is invalid. Atty.Gen.F.O.1978, No. 3.

(c) For claims with service dates on or after July 15, 1996, the discount is 10 percent for each eligible prescription claim not covered by the Maximum Allowable Cost price.

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.

8:83C–1.7 Prescription drug dispensing fee

(a) The dispensing fee for each prescription, dispensed by providers having retail permits to recipients other than those in nursing facilities, is $3.73. Additional dispensing fees (add-ons) per prescription shall be given 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. Patient consultation: $0.08. In addition to routinely monitoring recipient profiles for drug interactions, contra-indications, allergies, etc., the provider shall, where appropriate, discuss the course of drug therapy with the recipient. This discussion must include emphasis on compliance with the prescriber's orders; proper drug utilization; cautions about possible side effects; foods to avoid; proper drug storage conditions; and any other information that will prove beneficial to the recipient while on drug therapy.

3. Impact area location: $0.15. The provider shall have a combined Medicaid and PAAD prescription volume 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(s) as defined in (a) above, are being provided and/or that the provider is entitled to the impact increment as defined in (a) above.

1. 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 this report annually shall result in retail pharmacy provider payments based on the basic dispensing fee of $3.73.

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).

8:83C–1.8 PAAD program co-payment

(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 co-payment of an amount determined appropriate by the Legislature (see N.J.A.C. 8:83C–1.19(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.

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.

8:83C–1.9 Compounded prescriptions

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

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

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claims adjudication system approved by the PAAD program. (See N.J.A.C. 8:83C–1.25.)

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

(c) Reimbursement for compound prescriptions shall not exceed the lower of:

1. The cumulative cost of the active ingredient(s), as described in N.J.A.C. 8:83C–1.5, and/or pharmaceutical excipient(s), plus a dispensing fee, as described in N.J.A.C. 8:83C–1.7; or

2. A provider's usual and customary charge.

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

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

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

(e) Reimbursement for compounded prescriptions submitted manually or as an EMC claim is calculated based on the ingredient cost, as described in N.J.A.C. 8:83C–1.5, of the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 8:83C–1.7.

1. For compounded prescriptions without an active ingredient(s), reimbursement is based on (d) above, plus a dispensing fee, as described in N.J.A.C. 8:83C–1.7.

(f) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 8:83C–1.14.

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

1. All legend ingredients which are contained in compounded prescriptions must be covered by the PAAD program. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 8:83C–1.20) drug, the compounded prescription is not covered.

2. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 8:83C–1.13 are not covered.

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.

8:83C–1.10 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 DURC Formulary. The labeler code and drug product code of the actual product dispensed must be reported on the claim form. The package size code reported may differ from the stock package size used to fill the prescription.

8:83C–1.11 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. 8:83C–1.5, 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.

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.

8:83C–1.12 Covered pharmaceutical services

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

(b) Covered pharmaceutical services include:

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

2. Non-legend drugs, as follow:

i. Diabetic testing materials;

ii. Insulin needles and/or syringes;

iii. Insulin; and

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

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.

8:83C–1.13 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 diabetic testing materials; insulin; and insulin needles and/or syringes;

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. 8:83C–1.20);

13. Any bundled drug service, except drug product cost which is a component of a bundled drug service (see N.J.A.C. 8:83C–1.21);

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

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

(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. 8:83C–1.5, Basis of payment;

2. Covered diabetic testing materials which do not offer significant price and/or therapeutic advantage. The criteria shall be cost and improvement in accuracy over existing reimbursable products. Therapeutic advantage (in the case of diabetic testing materials, improvement in accuracy) shall be determined by evaluation of literature and/or cost effectiveness data submitted in support of a request for admission of a diabetic testing material for inclusion in the list of reimbursable products;

3. 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;

4. 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.

5. A prescription refilled too soon as described in N.J.A.C. 8:83C–1.18(a)5;

6. 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. 8:83C–1.26);

7. Prescriptions dispensed with service dates on and after July 1, 1995, without the usual price charged by the pharmacy to other persons in the community at the time of purchase prominently displayed on the prescription receipt.

i. This requirement shall not apply to prescriptions dispensed to PAAD beneficiaries residing in nursing facilities or residential care facilities.

ii. The requirements contained in this paragraph (b)7 shall expire on July 1, 1998.

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.

8:83C–1.14 Quantity of medication

(a) (Reserved)

(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 EMC claim after the balance of the medication is dispensed. The pharmacist may dispense the quantity available and shall notify the beneficiary accordingly.

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.

8:83C–1.15 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.

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).

8:83C–1.16 Telephone-rendered original prescriptions

(a) Telephone 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 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 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.

8:83C–1.17 Changes or additions to the original prescription

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

8:83C–1.18 Prescription refill

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

1. Refill instructions must be indicated in writing by the prescriber on the original prescription or verbally when telephoning the original prescription to the pharmacist. Verbal instructions shall be reduced to writing by the pharmacist, in accordance with N.J.S.A. 45:14–14.

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.