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.

8:83C–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 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.

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.

8:83C–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. 8:83C–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.

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.

8:83C–1.14 Covered pharmaceutical services

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

(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.
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.

8:83C–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 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–1.22);

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–1.23);

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–1.7, 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–1.20(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–1.28);

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; and

8. Cosmetic drugs including drugs used in the treatment of baldness, age spots and weight loss unless medically necessary. The MEP specified at N.J.A.C. 8:83C–1.29 shall be followed to confirm medical necessity.

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.

8:83C–1.16 Quantity of medication

(a) Public Law 1998, c.124 establishes different days supply requirements for pharmacy claims based on the drug use history of a PAAD beneficiary. Days supply limitations for an Initial Prescription Claim for PAAD beneficiaries shall be different from days supply limitations for a Refill Prescription Claim.

1. The following days supply limitations shall apply to PAAD claims:

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.

(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.

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.

(e) The quantity of medication dispensed shall not be affected by a claim's eligibility for submission to Medicare for reimbursement, except where Medicare dispensing guidelines allow a greater than 34–day supply for an initial prescription and the item being dispensed is packaged from the manufacturer in quantities consistent with Medicare dispensing guidelines. In such cases, PAAD will waive the 34–day limit and follow Medicare dispensing guidelines (see N.J.A.C. 8:83C–1.4, Medicare recovery initiative).

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.

8:83C–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.

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.

8:83C–1.18 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.

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.

8:83C–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 phar-

macist. 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.

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.

8:83C–1.20 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.

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. A telephone authorized refill for a prescription with no refill remaining must be assigned a new prescription number.

5. Prescription refills shall not be dispensed until a reasonable quantity (approximately 75 percent) of the medication originally dispensed or refilled could have been consumed in accordance with the prescriber's written directions for use.

i. Exception: When a prescription is lost or destroyed, requiring a replacement prescription to be dispensed before the original prescription could have been consumed in accordance with the prescriber's written directions for use, an original pharmacy claim with written justification must be submitted to the fiscal agent for payment consideration.

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.

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.

8:83C–1.21 Prescription Drug Price and Quality Stabilization Act

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

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription for a drug product listed in the DURC (reference here to where it is defined) Formulary, 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 in the DURC Formulary as interchangeable with the brand name prescribed.

3. When the prescriber orders by generic name, the formulary does not apply. The pharmacist shall dispense the least expensive, therapeutically effective product available to him/her at the time of dispensing. The product is not required to be from the list of interchangeable products.

4. Whenever the prescriber does not specify that substitution is not permitted and an interchangeable drug product that is listed in the latest issue of the formulary 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. In this case, the PAAD beneficiary can choose to either:

5. For non-MAC drugs (see N.J.A.C. 8:83C–1.7), when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC), as defined in N.J.A.C. 8:83C–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).