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

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;
      - Insulin; and iii.
    - 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

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;
    - 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 theraputic 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-1.3 and amended by R.2003 d. 248, effective June 16, 2003.

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

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.