

CHAPTER 83C

PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)

Authority

N.J.S.A. 30:4D-20 et seq., Reorganization Plan No. 001-1996, and the New Jersey Appropriations Act, P.L. 1998, c.45.

Source and Effective Date

R.1998 d.464, effective August 14, 1998.
See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

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Chapter 83C, Provision of Pharmaceutical Services Under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD), expires on August 14, 2003.

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). See, also, section annotations.

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SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

8:83C-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 diabetic testing materials 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. 8:83.

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.

8:83C-1.2 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 and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey. A pharmacy operating under an out-of-State retail or institutional pharmacy permit may not participate as an approved provider in the PAAD program.

2. File an application and sign an agreement with the Department of Human Services (DHS), Division of Medical Assistance and Health Services (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 of Medical Assistance and Health Services, Department of Human Services, by contacting the Medicaid Provider Enrollment Unit (see N.J.A.C. 10:49, Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit.

3. To enroll as a Medicaid provider of pharmaceutical services, a pharmacy shall contact the Fiscal Agent Provider Enrollment Unit (see N.J.A.C. 10:51, Appendix D, Fiscal Agent Billing Supplement).

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.

8:83C-1.3 Conditions for participation as a provider of pharmaceutical service

(a) All participating pharmacies shall provide complete prescription services, including injectables and injectable anti-neoplastic agents, compounding, and prescription refill services, when allowable. Prescriptions must be dispensed in compliance with all current existing Federal and State laws.

(b) All drugs must be prescribed.

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

i. Prescribed by a practitioner licensed or authorized by the state of New Jersey, or the state in which he or she practices, to prescribe drugs and medicine within the scope of his or her license and practice;

ii. 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 information in accordance with P.L. 1994, c.67, as revised by P.L. 1995, c.5 (see N.J.A.C. 8:83C-1.13(b)); and

iii. Dispensed by licensed pharmacists on the basis of a written prescription that is recorded and maintained in the pharmacist's records.

(c) Participating pharmacies shall permit properly identified representatives of the Division of Medical Assistance and Health Services or Department of Health and Senior Services (DHSS) 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;
- (3) Price;
- (4) Prescription number (for reference purposes only); and
- (5) Date dispensed.

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 records of purchases of covered drugs for which claims have been made for reimbursement.

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.

8:83C-1.4 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 the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 8:83C-1.12 and 13, respectively;
2. Quantity of medication (see N.J.A.C. 8:83C-1.14);
3. Pharmaceutical services requiring pharmacist intervention as part of the PAAD Prospective Drug Utilization Review (PDUR) program (see N.J.A.C. 8:83C-1.26);
4. Dosage and directions (see N.J.A.C. 8:83C-1.15);
5. Telephone rendered original prescriptions (see N.J.A.C. 8:83C-1.16);
6. Changes or additions to the original prescription (see N.J.A.C. 8:83C-1.17);
7. Prescription refill (see N.J.A.C. 8:83C-1.18);
8. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 8:83C-1.19);

i. Products listed in the current New Jersey Drug Utilization Review Council (DURC) Formulary (hereafter referred to as "the Formulary"), and all subsequent revisions, distributed to all prescribers and pharmacists; and

ii. Non-proprietary or generic dispensing (see N.J.A.C. 8:83C-1.10);

9. Federal regulations (42 CFR 447.301, 331-333) 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 costs" (MAC) drugs (see N.J.A.C. 8:83C-1.5, Basis of payment); and

10. 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. 8:83C-1.20 and listing of DESI drugs in N.J.A.C. 10:51, Appendix 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.

8:83C-1.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation 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. 8:83C-1.4;

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 contractor; 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 meets the criteria specified in N.J.A.C. 8:83C-1.12 (Covered pharmaceutical services).

3. Federal regulations (42 CFR 447.301, 331-333) 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, insulin needles and syringes, or diabetic testing materials.

(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, incorporated herein by reference, 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 Health Care Financing Administration (HCFA) 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 current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. For information about the "regression categories and discounts," see N.J.A.C. 8:83C-1.6 and for usual and customary charge, see N.J.A.C. 8:83C-1.11.

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.

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

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

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

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

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

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".

8:83C-1.6 Regression categories and discounts

(a) For pharmaceutical services provided prior to July 15, 1996, the maximum cost for each eligible prescription claim not covered by the maximum allowable cost price (see N.J.A.C. 8:83C-1.5 Basis of payment) shall be subject to the following fiscal conditions based upon six categories. The category, as determined by the New Jersey Medicaid program, is based on the previous year's total prescription volume for each participating pharmacy. The categories shall be reviewed annually and adjusted as appropriate.

1. Those pharmacy providers who have been in business for less than one calendar year shall have their prescription volume projected for the entire year, to determine the appropriate category.

(b) For pharmaceutical services provided prior to July 15, 1996, the pharmacy provider shall submit, in writing, an annual report on form FD-70 (See N.J.A.C. 10:51, Appendix C, incorporated herein by reference, Pharmacy Provider Certification Statement) certifying its prescription volume. The Division of Medical Assistance (Medicaid) shall determine a provider's total prescription volume, which includes all prescriptions filled (both new and refills), including nursing facility prescriptions, for private patients, Medicaid, PAAD, and other third party recipients for the previous calendar year. Failure to submit this report annually shall result in the provider being placed in the maximum discount category (category VI) for the year of non-compliance, or until the required report is received.

1. Category I: Pharmacies whose total prescription volume in the preceding calendar year was not more than 14,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5—basis of payment, as the maximum.

2. Category II: Pharmacies whose total prescription volume in the preceding calendar year was at least 15,000 but not greater than 19,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5, less two percent, as the maximum.

3. Category III: Pharmacies whose total prescription volume in the preceding calendar year was at least 20,000 but not greater than 29,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5, less three percent, as the maximum.

4. Category IV: Pharmacies whose total prescription volume in the preceding calendar year was at least 30,000 but not greater than 39,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5, less four percent, as the maximum.

5. Category V: Pharmacies whose total prescription volume in the preceding calendar year was at least 40,000 but not greater than 49,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5, less five percent, as the maximum.

6. Category VI: Pharmacies whose total prescription volume in the preceding calendar year was 50,000 prescriptions or more.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5, less six percent, as the maximum.

ii. For pharmacies with a total prescription volume, in the preceding calendar year of 50,000 prescriptions or greater, completion of the portion of the FD-70 Certification Statement is optional. For these pharmacies a maximum regression shall be automatically applied.

7. The appropriate calculated discount shall be automatically deducted, regardless of prescription cost, by the fiscal agent, from the cost of each covered drug or device during claim processing by the New Jersey Medicaid Management Information System (NJMMIS).

(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.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: