

CHAPTER 51

PHARMACEUTICAL SERVICES MANUAL

Authority

N.J.S.A. 30:4D-6a(5)b(6); 30:4D-7, 7a, b, and c; 30:4D-12; 30:4D-20-22, 24; 1927 of the Social Security Act, 42 U.S.C. 1396r-8(a); 42 CFR 440.120.

Source and Effective Date

R.1993 d.434, effective September 7, 1993.  
See: 24 N.J.R. 3053(a), 25 N.J.R. 4082(a).

Executive Order No. 66(1978) Expiration Date

Chapter 51, Pharmaceutical Services Manual, expires on September 7, 1998.

Chapter Historical Note

Chapter 51, Pharmacy Manual, was adopted as R.1971 d.29, effective March 5, 1971. See: 3 N.J.R. 25(a), 3 N.J.R. 62(b).

Pursuant to Executive Order No. 66(1978), Chapter 51 was readopted as R.1985 d.594, effective October 28, 1985. See: 17 N.J.R. 2223(a), 17 N.J.R. 2772(a).

Pursuant to Executive Order No. 66(1978), Chapter 51 was readopted as R.1990 d.530, effective October 9, 1990. See: 22 N.J.R. 2217(a), 22 N.J.R. 3372(a). Chapter 51 was amended by R.1991 d.353, effective July 1, 1991. See: 23 N.J.R. 1310(b), 23 N.J.R. 2035(a); R.1991 d.563, effective November 18, 1991. See: 23 N.J.R. 2623(a), 23 N.J.R. 3514(a); R.1992 d.98, effective March 2, 1992. See: 23 N.J.R. 281(a), 23 N.J.R. 1310(a), 24 N.J.R. 845(a).

Chapter 51, Pharmaceutical Services Manual, was repealed and a new Chapter 51, Pharmaceutical Services Manual, was adopted as R.1993 d.434. See: Source and Effective Date.

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SUBCHAPTER 1. PHARMACEUTICAL SERVICES

**10:51-1.1 Introduction**

(a) This chapter provides information about the provision of pharmaceutical services under the New Jersey Medicaid program and the Pharmaceutical Assistance to the Aged and Disabled (PAAD) program. It is divided into four subchapters:

1. N.J.A.C. 10:51-1 provides a pharmacy operating under a retail permit with the policies and procedures relevant to the provision of services to New Jersey Medicaid recipients, excluding those residing in a nursing facility.
2. N.J.A.C. 10:51-2 pertains to a pharmacy providing pharmaceutical services to Medicaid recipients in a nursing facility.
3. N.J.A.C. 10:51-3 explains the responsibility of a pharmacist acting as a consultant in a nursing facility or other public medical institution.
4. N.J.A.C. 10:51-4 provides information about the provision of pharmaceutical services under the PAAD program.

(b) Incorporated by reference into this chapter as Appendix D is the Fiscal Agent Billing Supplement that provides information about claim processing and related activities.

**10:51-1.2 Participation of eligible providers**

(a) A pharmacy, with a retail or institutional permit, may participate in the Medicaid program as a provider of pharmaceutical services; as a Medical Supplier providing medical supplies and durable medical equipment; and/or as a provider of parenteral nutrition and/or intravenous therapy. The requirements for approval as a provider of these services are listed in (b) through (d) below.

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

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey or by the board of pharmacy of the state in which the pharmacy is located. A pharmacy operating under an out-of-state institutional permit may not participate as an approved provider in the New Jersey Medicaid program; and

2. File an application and sign an agreement with the Division of Medical Assistance and Health Services.

- 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 New Jersey Medicaid 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 (see Appendix, Fiscal Agent Billing Supplement).

3. To enroll as a Medicaid provider of pharmaceutical services, a pharmacy shall contact the fiscal agent Provider Enrollment Unit (see Appendix, Fiscal Agent Billing Supplement).

(c) A pharmacy may also participate as a medical supplier. The Medical Supplier Manual, N.J.A.C. 10:59, available from the Medicaid fiscal agent, provides information concerning the provision of and reimbursement for covered medical supplies and durable medical equipment provided by a medical supplier.

1. A pharmacy may apply to participate as a medical supplier by contacting the Medicaid Provider Enrollment Unit (see N.J.A.C. 10:49—Administrative Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit (see Appendix, Fiscal Agent Billing Supplement).

(d) Requirements for approval as a provider of parenteral nutrition and/or intravenous therapy are as follows:

1. In addition to the requirements for approval as a pharmacy provider listed under (b) above, a pharmacy who supplies parenteral nutrition and/or intravenous therapy must:

- i. Comply with the requirements of the N.J.A.C. 13:39-10, Sterile Admixture Services in Retail and Institutional Pharmacies; or

- ii. Comply with similar applicable requirements of the state in which the applicant is located and submit a copy of the requirements of that state when applying for participation. A copy of the N.J.A.C. 13:39-10, Sterile Admixture Services in Retail and Institutional Pharmacies, is available, subject to copying charges, from OAL Publications, Office of Administrative Law, PO Box 301, Trenton, New Jersey 08625-0301.

**10:51-3.2 Definition of consultant pharmacist**

The term "consultant pharmacist" shall mean a pharmacist licensed by the New Jersey State Board of Pharmacy, and who meets the qualifications in N.J.A.C. 10:51-3.3.

**10:51-3.3 Qualifications**

Qualifications shall include holding a valid license as a registered pharmacist issued by the New Jersey State Board of Pharmacy.

**10:51-3.4 Responsibilities**

(a) The consultant pharmacist shall in cooperation and consultation with the nursing facility staff:

1. Assure that all drugs are dispensed, and in cooperation with the director of nursing, "shall assure all drugs" are administered in compliance with all Federal and State laws;

2. Establish and monitor the implementation of written policies and procedures, through the pharmaceutical services committee (pharmacy and therapeutics committee), to assure the safe use, storage, integrity, administration, control and accountability of drugs;

3. Assure that drug records are in order and an account of all controlled substances is maintained and reconciled;

4. Assure that the recipient's medication records are accurate, up to date, and that these records indicate that medications are administered in accordance with physicians' orders and established stop-order policies;

5. Assure that drugs, biologicals, laboratory tests, special dietary requirements and foods, used or administered concomitantly with other medication to the same beneficiary, are monitored for potential adverse reactions, allergies, rationality, drug evaluation, and laboratory test modifications, and that the physician is advised promptly of any recommended changes;

6. Assure that drugs prescribed for nursing facility beneficiaries are properly administered based on drug utilization standards common to the pharmacy profession, which may include, but not be limited to:

- i. Drug interactions;
- ii. Maximum/minimum daily dosage alerts;
- iii. Therapeutic duplication;
- iv. Drug age conflicts;
- v. Days supply alerts;
- vi. Drug-disease precautions; and
- vii. Drug-pregnancy precautions, if applicable.

7. Review the drug regimen (for example, dosage form, route of administration, time of administration) of each recipient at least monthly and report any irregularities

pertaining to medications to the attending physician, medical director or director of nursing, as appropriate.

i. Irregularities in the administration of medications shall also be reported promptly to the director of nursing.

8. Report in writing at least quarterly to the pharmaceutical services committee (pharmacy and therapeutics committee) on the status of the facility's pharmaceutical services and staff performance as related to pharmaceutical services. This report shall include, but not be limited to, a summary of the review of each recipient's drug regimen and clinical record and the consultant pharmacist's findings and recommendations;

9. Assure there is maintained and available upon request from the Director of the New Jersey Medicaid program or his or her designee, documented records of the disposition, disposal or destruction of unused or discontinued drugs;

10. Serve as an active member of the pharmaceutical services committee (pharmacy and therapeutics committee) and infection control committee of the facility;

11. Provide, and document, in-service programs for the complete nursing staff. This training shall include, but not be limited to, registered nurses, licensed practical nurses, aides, and shall be given at least quarterly; and

12. Devote a sufficient number of hours to carry out these responsibilities, maintain a written record of activities, findings and recommendations.

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).

#### SUBCHAPTER 4. PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)

**10:51-4.1 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 are unable to fully meet the cost of such items. For additional information regarding PAAD eligibility, see N.J.A.C. 10:69A.

**10:51-4.2 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 Division of Medical Assistance and Health Services.

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 Appendix D, Fiscal Agent Billing Supplement).

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).

**10:51-4.3 Conditions for participation as a provider of pharmaceutical services**

(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. 10:51-4.13(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 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.1996 d.313, effective July 15, 1996.  
See: 27 N.J.R. 3666(a), 28 N.J.R. 3573(a).

**10:51-4.4 Program restrictions affecting payment of 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. 10:51-4.12 and 4.13, respectively;

2. Quantity of medication (see N.J.A.C. 10:51-4.14);

3. Pharmaceutical services requiring pharmacist intervention as part of the PAAD Prospective Drug Utilization Review (PDUR) program (see N.J.A.C. 10:51-4.23).
4. Dosage and directions (see N.J.A.C. 10:51-4.15);
5. Telephone-rendered original prescriptions (see N.J.A.C. 10:51-4.16);
6. Changes or additions to the original prescription (see N.J.A.C. 10:51-4.17);
7. Prescription refill (see N.J.A.C. 10:51-4.18);
8. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 10:51-4.19);
  - 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. 10:51-4.9);
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 cost" drugs (see N.J.A.C. 10:51-4.5; 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. 10:51-4.20 and listing of DESI drugs in Appendix 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).

#### 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.

#### 10:51-4.5 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. 10:51-4.4;
2. Price information as 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 drug price shall not exceed the lower of the average wholesale price 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 meet the criteria specified in N.J.A.C. 10:51-4.12 (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 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 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. 10:51-4.6 and for usual and customary charge, see N.J.A.C. 10:51-4.11.

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.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).

#### 10:51-4.6 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. 10:51-4.5 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 Appendix C, Pharmacy Provider Certification Statement) certifying its prescription volume. The Division 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. 10:51-4.5—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. 10:51-4.5, 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. 10:51-4.5, 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. 10:51-4.5, 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. 10:51-4.5, 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. 10:51-4.5, 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.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).

#### 10:51-4.7 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, contraindications, 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).

#### 10:51-4.8 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. 10:51-4.19(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.

#### 10:51-4.9 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the Medicaid 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. 10:51-4.25)

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 compounded prescriptions shall not exceed the lower of:

1. The cumulative cost of the active ingredient(s), as described in N.J.A.C. 10:51-4.5, and/or pharmaceutical excipient(s), plus a dispensing fee, as described in N.J.A.C. 10:51-4.7; 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 Medicaid \$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. 10:51-4.5, of the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 10:51-4.7.

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. 10:51-4.7.

(f) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 10:51-4.14.

(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. 10:51-4.20) drug, the compounded prescription is not covered.

2. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51-4.13 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).

#### 10:51-4.10 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.

#### 10:51-4.11 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. 10:51-4.5, 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.

#### 10:51-4.12 Covered pharmaceutical services

(a) All covered pharmaceutical services shall be provided within the scope of N.J.A.C. 10:49, Administration, and this Chapter, and billed to the fiscal agent on the claim form or other approved billing method (see Appendix, 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 follows:

i. Diabetic testing materials;

- ii. Insulin needles and/or syringes; and
- iii. Insulin.

**10:51-4.13 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. 10:51-4.20);
13. Any bundled drug service, except drug product cost which is a component of a bundled drug service (see N.J.A.C. 10:51-4.21);
14. Preventive vaccines, biologicals and therapeutic drugs distributed to hospital clinics and/or community health centers by the New Jersey Department of Health; and
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. 10:51-4.5, 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.
  - i. Drug products commercially available only as a unit-dose packaged product are not covered when not otherwise marketed as a chemically equivalent product. The potency of individual products may or may not equal the potency of the unit-dose packaged product; and
5. A prescription refilled too soon as described in N.J.A.C. 10:51-4.18(a)5; and.
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. 10:51-4.26)
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).

#### 10:51-4.14 Quantity of medication

(a) For claims with service dates on or after July 15, 1996, the quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness, or if required, an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 34-day supply or 100 unit doses, 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.

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).

#### 10:51-4.15 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).

#### 10:51-4.16 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.

#### 10:51-4.17 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.

#### 10:51-4.18 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.

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).

#### 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.

### 10:51-4.19 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:

i. Purchase the interchangeable drug product which is equal to or less than the maximum allowable cost, at the PAAD program co-payment; or

ii. 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 program co-payment.

5. For non-MAC drugs (see N.J.A.C. 10:51-4.5), 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. 10:51-4.5 (see Appendix D, Fiscal Agent Billing supplement for instructions about the claim form or Appendix E regarding the proper EMC claim format.)

6. Claims for MAC drugs with service dates on or after July 15, 1996, 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" on the claim form, or 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) (see N.J.A.C. 10:51-4.5) plus applicable dispensing fee or the usual and customary charge, whichever is less for that product (see Appendix D Fiscal Agent Billing supplement for instructions about the claim form or Appendix E regarding the proper EMC claim format.)

(b) Federal regulations at 42 C.F.R. 447.331 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 Appendix B) 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. 10:51-4.16) the phrase "Brand Medically Necessary." The Federal regulation at 42 C.F.R. 447.331 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) For claims with service dates on or after July 15, 1996, 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.

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).

#### 10:51-4.20 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 notice of opportunity for hearing issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of 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 which are adopted, shall appear in the Federal Register.

#### 10:51-4.21 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. 10:51-4.12, Covered Pharmaceutical Services) shall be covered by the PAAD program.

1. In order to determine eligibility for reimbursement, manufacturers or distributors of a bundled drug service shall submit complete product information, including the cost to the Program of the drug product component of the bundled drug service, and other information as requested by the Department, to the Chief Pharmaceutical Consultant, Division of Medical Assistance and Health Services, CN 712, Trenton, New Jersey 08625-0712.

#### 10:51-4.22 Claim submission

(a) An approved pharmacy provider may choose to:

1. Submit a properly completed hard copy pharmacy claim form approved by the New Jersey Division of Medical Assistance and Health Services (DMAHS).

2. Submit an electronic media claim (EMC) by modem, diskette or magnetic tape in an electronic format approved by DMAHS.

i. In order for a pharmacy provider to be eligible to submit an EMC claim to the Medicaid and/or PAAD programs, a pharmacy provider or vendor of EMC services shall complete the "New Jersey Medicaid Provider Electronic Billing Agreement."

ii. The completed agreement shall be submitted to the fiscal agent and approved by the Division of Medical Assistance and Health Services.

iii. The pharmacy provider or vendor of EMC services shall submit electronic media claims under an approved submitter identification number and comply with EMC requirements contained in the EMC Manual, Appendix E, incorporated herein by reference.

iv. For the purposes of this subchapter, all electronically submitted claims, including POS claims, shall commonly be referred to as EMC claims; or

3. Enter into an agreement with a point-of-sale (POS) intermediary 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 National Council Prescription Drug Program standards, Version 3.2, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

i. 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.

(b) A properly completed claim form or a properly formatted electronic media claim (EMC) may be submitted to the fiscal agent, or transmitted by an approved POS intermediary or provider established telecommunication network to the fiscal agent for claims adjudication.

1. A single claim form shall be completed manually or by computer or an EMC claim shall be transmitted in the approved EMC format for each Medicaid prescription dispensed. See Appendix D, Fiscal Agent Billing Supplement for instructions concerning the completion and submission of the specified claim form, and Appendix E regarding the proper EMC claim format;

2. All claim forms and EMC claims must contain the National Drug Code (NDC) of the actual drug dispensed. The 11-digit NDC has three components. The first five digits are the manufacturer's labeler code, the next four digits are the product code, and the final two digits are the package size code. For claim submission, leading zeros shall be included in all fields. For example, 00003-0234-01.

i. The dispenser shall always report the actual labeler code and drug product code of the drug dispensed. The package size code reported on the claim.

3. All Medicaid pharmacy claims submitted to the fiscal agent for payment consideration shall be adjudicat-

ed based on the outcome of established POS and PDUR edits, regardless of the mode of claim submission.

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).

#### 10:51-4.23 Eligible PAAD beneficiary

(a) An eligible beneficiary is a permanent resident of the State of New Jersey, 65 years of age or older, or who is under 65 and over 18 years of age and is receiving Social Security Title II disability benefits with an annual income less than \$16,171 for a single person and less than \$19,828 in combined income for a married couple, and who possesses a current valid eligibility identification card.

1. Benefits are not payable 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.

(b) 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.

1. Exception: The PAAD program's determination of the continuing New Jersey residence of a person absent from the State of New Jersey shall be based upon whether the individual intends to return to New Jersey or remain indefinitely in the other jurisdiction. If a beneficiary leaves New Jersey with the intent to establish a place of abode elsewhere, he or she becomes ineligible under the PAAD program and shall notify the Bureau of Pharmaceutical Assistance to the Aged and Disabled of the address and return the PAAD eligibility card.

#### 10:51-4.24 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.

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".

**10:51-4.25 Point-of-sale (POS) claims adjudication system**

(a) PAAD pharmacy claims may be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real-time. The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette and paper claims. The pharmacist would 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).

(b) In order for a PAAD approved pharmacy provider, in accordance with N.J.A.C. 10:51-4.3, 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 New Jersey Division of Medical Assistance and Health Services.

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  
CN 712—Mail Code #4  
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 the Health Care Financing Administration.

(c) A POS participating pharmacy or intermediary must 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 choosing to submit claims through the POS system, shall submit claims in the approved electronic format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.

1. Pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose drug delivery systems are precluded from the POS system.

(f) Claim data requirements for electronic media claims (EMC) 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 Medicaid 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.

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. 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/or beneficiaries at POS to resolve matters related to on-line messages resulting from claim adjudication by the fiscal agent.

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).

#### **10:51-4.26 Prospective Drug Utilization Review (PDUR) program**

(a) The Division of Medical Assistance and Health Services has established a prospective drug utilization review (PDUR) program to assist pharmacy providers with 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 approved by the Medicaid Drug Utilization Review (DUR) Board. Similar responses related to 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 approved by the Medicaid DUR Board shall be based on 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 Dr., San Bruno, CA 94066.

2. PDUR standards adopted by the Medicaid Drug Utilization Review Board 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. 10:51-4.25.

(c) In addition to POS responses related to adjudication of Medicaid 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. Days supply alerts;
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 Medicaid 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.

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).

## **APPENDIX A**

### **DRUG EFFICACY STUDY IMPLEMENTATION (DESI)**

(Update of Drug Products and Known Related Drug Products that Lack Substantial Evidence of Effectiveness)

Appendix A is a list of drugs that the Food and Drug Administration (FDA) has proposed to withdraw from the market which is updated periodically by the Health Care Financing Administration subsequent to published listing changes in the Federal register.

AGENCY NOTE: The Appendix A is filed as a part of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to the Appendix A, replacement pages will be distributed to providers and copies will be filed with the Office of Administrative Law. For a copy of the Appendix A, write to:

Paramax/Unisys  
CN-4801  
Trenton, New Jersey 08650

or contact:

Office of Administrative Law  
Quakerbridge Plaza, Building 9  
CN-049  
Trenton, New Jersey 08625

## APPENDIX B

### UPPER PAYMENT LIMITS FOR MAXIMUM ALLOWABLE COST (MAC) DRUGS

Appendix B is a list of multiple source drugs which meets the criteria set forth in 42 CFR 447.301, 331-333 which is updated periodically by the Health Care Financing Administration subsequent to published listing changes in the Federal register.

AGENCY NOTE: The Appendix B is filed as a part of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to the Appendix B, replacement pages will be distributed to providers and copies will be filed with the Office of Administrative Law. For a copy of the Appendix B, write to:

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Quakerbridge Plaza, Building 9  
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