

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Chapter 51, Pharmaceutical Services Manual, was repealed and a new Chapter 51, Pharmaceutical Services Manual, was adopted as R.1993 d.434.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, CN 301, Trenton, New Jersey 08625.

2. Parenteral nutrition and/or intravenous therapy may be provided by either a pharmacy/medical supplier or a medical supplier approved to provide these services by the New Jersey Medicaid program; however, billing for the ancillary supplies associated with parenteral nutrition and/or intravenous therapy are subject to the requirements of the Medical Supplier Manual (N.J.A.C. 10:59).

i. "Ancillary supplies" means medical supplies and/or durable medical equipment which are medically necessary to facilitate administration of parenteral or intravenous therapy.

10:51-1.3 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 compound 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

iii. Dispensed by licensed pharmacists on the basis of a written prescription that is 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 comply with the Federal regulations to determine a pharmacy's usual and customary charge 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.

10:51-1.4 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 law. 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. 10:51-1.11 and 10:51-1.12, respectively;

2. Pharmaceutical service requiring prior authorization (see N.J.A.C. 10:51-1.13);

3. Pharmaceutical services requiring pharmacist intervention as part of the Medicaid prospective drug utilization review (PDUR) program (see N.J.A.C. 10:51-1.25).

4. Quantity of medication (see N.J.A.C. 10:51-1.14);

5. Dosage and directions (see N.J.A.C. 10:51-1.15);

6. Telephone-rendered original prescriptions (see N.J.A.C. 10:51-1.16);

7. Changes or additions to the original prescription (see N.J.A.C. 10:51-1.17);

8. Prescription refill (see N.J.A.C. 10:51-1.18);

9. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 10:51-1.19);

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. 10:51-1.9).

10. 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. 10:51-1.5, Basis of payment);

11. 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. 10:51-1.20 and listing of DESI drugs in Appendix A herein incorporated by reference); and

12. Drug Manufacturers' Rebate Agreement with the Health Care Financing Administration of the United States Department of Health and Human Services (see N.J.A.C. 10:51-1.21);

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

Pharmaceutical provider disqualified from participation in programs must be licensed to practice pharmacy by the State Board of Pharmacy before applying for reinstatement. Div. of Medical Assistance and Health Services v. Kares, 8 N.J.A.R. 517 (1983).

10:51-1.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation of the payment of a legend or non-legend drug. The elements include the following:

1. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 10:51-1.4;

2. Price information as supplied from a reference drug file contracted 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 or ingredient cost 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. 10:51-1.11 (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. The provider's usual and customary charge for legend or non-legend drugs (see (c) below), contraceptive diaphragms and legend or non-legend devices.

(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). Appendix B is the listing of MAC drugs, and is hereby incorporated by reference.

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. 10:51-1.6 and for usual and customary charge see N.J.A.C. 10:51-1.10.

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 New Jersey Medicaid 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 (excluding protein replacement supplements, specialized infant formulas and food oils), devices, or supplies under the New Jersey Medicaid 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) The maximum allowance for protein replacement supplements, specialized infant formulas and food oils under the New Jersey Medicaid program is the lesser of:

1. The product AWP less a volume discount (see N.J.A.C. 10:51-1.6) plus dispensing fee (see N.J.A.C. 10:51-1.7); or

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

(f) For claims with service dates on or after July 15, 1996, the maximum allowance for non-legend drugs (including protein replacement supplements, specialized infant formulas and food oils), devices, or supplies under the New Jersey Medicaid program shall be calculated in accordance with (b)1ii above.

(g) 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. 1996 d.59, effective February 5, 1996.
See: 27 N.J.R. 4222(a), 28 N.J.R. 902(a).

In (d) inserted exclusions and added (e).
Amended by R.1997 d.251, effective June 16, 1997.
See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(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 (f) and (g).

Case Notes

Propriety of subpoena duces tecum from grand jury investigating Medicaid irregularities. In re: Grand Jury Subpoena Duces Tecum, 143 N.J.Super. 526, 363 A.2d 936 (Law Div.1976).

10:51-1.6 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. 10:51-1.5, 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 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. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs at average wholesale price (AWP), as defined in N.J.A.C. 10:51-1.5, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less two percent 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. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-1.5, less two percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less four 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. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-1.5, less three percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less five 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. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-1.5, less four percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less six 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. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-1.5, less five percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less seven percent as the maximum.

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

i. For service dates prior to January 2, 1996, pharmacy providers in this category shall receive reimbursement for Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51-1.5, less six percent, as the maximum. For claims with service dates on or after January 2, 1996, reimbursement shall be based on AWP less eight 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 shall be 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.1996 d.17, effective January 2, 1996.

See: 27 N.J.R. 3539(a), 28 N.J.R. 182(a).

In (b) distinguished between service dates prior to and after January 2, 1996.

Amended by R.1997 d.251, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).

In (a) and (b), inserted "For pharmaceutical services provided prior to July 15, 1996,"; and added (c).

10:51-1.7 Prescription 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 Medicaid recipients 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 service(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 New Jersey Medicaid 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.251, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).

Added (d).

10:51-1.8 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 pharmacy providers.

1. Acceptable pharmaceutical excipients which do not contribute therapeutically to a compound, include, but are not limited to hydrophilic ointment, petrolatum, aquaphor, 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 Medicaid program. (See N.J.A.C. 10:51-1.24)

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. 10:51-1.5, and/or pharmaceutical excipient(s), plus a dispensing fee, as described in N.J.A.C. 10:51-1.7; or

2. A provider's usual and customary charge.

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

1. For pharmaceutical excipients costing less than \$0.25, the provider may charge 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. 10:51-1.5, of the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 10:51-1.7.

1. For compounded prescriptions without an active ingredient(s), reimbursement is based on (d) above, plus a dispensing fee, as described in N.J.A.C. 10:51-1.7.

(f) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 10:51-1.14.

(g) Restriction in payments for compounded prescriptions are as follows:

1. All legend and non-legend (OTC) ingredients which are contained in compounded prescriptions must be covered by a manufacturer rebate agreement (see N.J.A.C. 10:51-1.21). If the labeler code of any single ingredient is not manufactured by an approved manufacturer, the compounded prescription is not covered. Chemical ingredients without NDC codes are excluded.

2. All non-legend ingredients which are contained in compounded prescriptions must be covered by the Medicaid program. If a non-legend drug is not listed as covered in N.J.A.C. 10:51-1.11, the compounded prescription is not covered.

i. All non-legend ingredients contained in compounded prescriptions dispensed to eligible Garden State Health Plan (GSHP) participants are covered by the Medicaid program.

3. All legend ingredients which are contained in compounded prescriptions must be covered by the Medicaid program. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 10:51-1.20) drug, the compounded prescription is not covered.

4. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51-1.12 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).

10:51-1.9 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.

10:51-1.10 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. 10:51-1.5, Basis of payment).

(b) The usual and customary charge to the Medicaid 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 Medicaid recipient. "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.

10:51-1.11 Covered pharmaceutical services

(a) All covered pharmaceutical services shall be provided within the scope of the 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, for which Federal Financial Participation (FFP) is available:

i. Contraceptive devices and contraceptive supplies (such as diaphragms, jellies, foams and condoms);

ii. Over-the-counter, family planning supplies (such as pregnancy test kits);

iii. Pharmaceutical inhalation devices;

iv. Diabetic testing materials;

v. Insulin needles and/or syringes;

vi. Insulin; and

vii. Antacids.

(3) In addition, coverage of non-legend drugs for beneficiaries under the age of 21 shall also include:

- i. Analgesics, Salicylates;
- ii. Analgesics/Antipyretics, Non-salicylate;
- iii. Antidiarrheals;
- iv. Anti-Emetics;
- v. Antiflatulents;
- vi. Antihistamines;
- vii. Antipruritics;
- viii. Antitussives, non-narcotic;
- ix. Cathartics;
- x. Cough and cold preparations;
- xi. Emetics;
- xii. Expectorants;
- xiii. Hematinics;
- xiv. Iron replacement supplements;
- xv. Laxatives;
- xvi. Multiple vitamin preparations;
- xvii. Pediatric vitamin preparations;
- xviii. Vitamins A, B, C, D, E, K, B1, B2, B6, B12 preparations;
- xix. Polymixin and derivatives;
- xx. Topical preparations, antibacterial;
- xxi. Topical antibiotics; and
- xxii. Topical anti-inflammatory preparations.

(c) For recipients in the Medically Needy component of the New Jersey Care . . . Special Medicaid programs, pharmaceutical services are only available to pregnant women and dependent children. For information on how to identify a Medicaid recipient, see N.J.A.C. 10:49, Administration.

Amended by R.1995 d.358, effective July 3, 1995.
See: 27 N.J.R. 1104(a), 27 N.J.R. 2614(b).
In (b) added 3.

10:51-1.12 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the New Jersey Medicaid program. For recipients in the Medically Needy component of the New Jersey Care . . . Special Medicaid programs, pharmaceutical services are not available to the aged, blind nor the disabled. For information on how to identify a covered person, see N.J.A.C. 10:49, Administration.

1. Prescriptions which are not for medically accepted indications as defined in Section 1927(k)(6) of the Social Security Act;

2. Antiobesics and anorexiant when used in treatment of obesity (see N.J.A.C. 10:51-1.13, Prior authorization);

3. 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;

4. Experimental drugs;

i. Exception: Drugs available only for treatment through an Investigational New Drug (IND) application shall be prior authorized;

5. Medication furnished by a prescriber or an employee of a prescriber;

6. Medication prescribed for hospital inpatients;

7. Non-legend drugs other than antacids; contraceptive devices and contraceptive supplies; diabetic testing materials; over-the-counter (OTC) family planning supplies; inhalation devices (pharmaceutical); insulin; and insulin needles and/or syringes;

i. Exception: Antihistamines, antacids, OTC analgesics, laxatives, anti-diarrheal medications, OTC dermatological preparations, cold and cough medications, insulin, diabetic testing materials, family planning supplies and protein replacement supplements are services covered by the Garden State Health Plan;

ii. Exception: Non-legend drugs described in N.J.A.C. 10:51-1.11, for recipients under 21 years of age.

8. Prescriptions written and/or dispensed with nonspecific directions;

9. Food supplements, milk modifiers, infant formulas, therapeutic diets, special liquid or powdered diets used in the treatment of obesity;

i. Exception: Enteral nutritional products and electrolyte replacement supplements;

10. Methadone in any form (tablets, capsules, liquid, injectables, or powder) when used for drug detoxification or addiction maintenance (see N.J.A.C. 10:51-1.13, Prior authorization);

11. Drug products for which final orders have been published by the Food and Drug Administration, withdrawing the approval of their new drug application (NDA);

12. Drugs or drug products not approved by the Food and Drug Administration, when such approval is required by Federal law and/or regulation;

13. Radiopaque contrast materials (for example, Telepaque);

14. 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. 10:51-1.20); and

ii. Drugs not covered by rebate agreements as defined in Section 4401 of OBRA '90 and Section 1927(a) of the Social Security Act (see N.J.A.C. 10:51-1.21);

15. Any bundled drug service (see N.J.A.C. 10:51-1.22);

16. 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 customary charge to the general public for delivery;

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

18. Drugs provided primarily for the treatment of infertility or which may be used to treat other conditions related to infertility, including fertility preparations and gonadotropic (follicle stimulating and luteinizing) hormones.

i. When a drug is provided that is ordinarily considered an infertility drug, but is provided for conditions unrelated to infertility, the claim must be sent with supporting documentation for medical review and approval of payment to the Division of Medical Assistance and Health Services, Office of Medical Affairs and Provider Relations, CN 712, (Mail Code # 14), Trenton, New Jersey 08625-0712.

(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. 10:51-1.5, Basis of payment;

2. Drug products in dosage forms whose labeling, prescription or promotional material indicate the primary use is cosmetic in nature; for example, hair restoration;

3. 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 residences (ALRs), comprehensive personal care homes (CPEHs) 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 covered when not otherwise marketed as a chemically equivalent product. The potency of equivalent products may or may not equal the potency of the unit-dose packaged product;

4. Prescriptions refilled too soon, as described in N.J.A.C. 10:51-1.18(a)5; and

5. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the Medicaid program. (See N.J.A.C. 10:51-1.25)

(c) Reimbursement shall not be made for any claim submitted by a provider which involves a recipient restricted to another pharmacy, except for an emergency situation (see N.J.A.C. 10:49, Administration).

Amended by R.1994 d.600, effective December 5, 1994.

See: 26 N.J.R. 3345(a), 26 N.J.R. 4762(a).

Amended by R.1995 d.358, effective July 3, 1995.

See: 27 N.J.R. 1104(a), 27 N.J.R. 2614(b).

In (a)7 added ii.

Amended by R.1995 d.359, effective July 3, 1995.

See: 26 N.J.R. 3349(a), 27 N.J.R. 2615(a).

Rewrote (b)3.

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).

10:51-1.13 Services requiring prior authorization

(a) The provider shall obtain prior authorization, when required, by phone or in writing, from the Medicaid District Office (MDO) professional staff. The appropriate form that must be used to request prior authorization is indicated in the Fiscal Agent Billing Supplement. Information on the form is transmitted, on-line, from the MDO to the fiscal agent who, in turn, confirms the status of the authorization request by mail and provides the specific prior authorization number.

1. In an administrative emergency (see N.J.A.C. 10:49-6.1(b)3) when the MDO is unavailable, the provider may dispense a 72 hour supply of the prescribed drug.

i. If the drug is to be continued beyond 72 hours, and the MDO is unavailable, the provider may dispense a total of a five days' supply. If the drug is to be continued either beyond the 72 hours or five days period, the provider shall hold the claim and obtain prior authorization for the balance of the prescription when the MDO is available during normal business hours.

(b) The following drugs and specific therapeutic classes require prior authorization:

1. Enteral nutritional products and special infant formulas may only be authorized when medically necessary and when not available from the Women, Infant and Children (WIC) Nutritional program;

i. Medically necessary enteral nutritional products for treatment of recipients, which may be administered orally, via nasogastric tube, gastrostomy tube or needle catheter jejunostomy must be prior authorized. Special liquid or powdered diets for treatment of obesity or regular infant formulas are not considered enteral nutritional products;

ii. Electrolyte replacement supplements are not considered enteral nutritional supplements and do not require prior authorization.

2. Methadone (not eligible for reimbursement when used for drug detoxification or for addiction maintenance);

3. Drugs available only for treatment through an Investigational New Drug (IND) application shall be prior authorized;

4. Anorexiant and antiobesics when used for treatment of conditions approved by New Jersey State Board of Medical Examiners at N.J.A.C. 13:35-6.7; and

5. Those legend and non-legend drugs or devices prescribed by physicians or other health care practitioners authorized by law to prescribe, as the result of a referral from a Garden State Health Plan Physician Case Manager (GSHP-PCM).

10:51-1.14 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.251, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).

In (a), inserted "For claims with service dates on or after July 15, 1996," and changed allowable supply to 34 days from 60 days; and recodified former (a)1 through 3 as (b) through (d).

10:51-1.15 Dosage and directions

(a) Dosage and directions for use shall be indicated on all prescriptions. Prescriptions written and dispensed with no specific directions, such as "prn," "as directed" or "ad lib," etc. are not eligible for reimbursement. Specific directions such as "1 tablet 4 times a day PRN" are required.

1. Exceptions:

i. Topical preparations including ophthalmic and otic drops and ointments;

ii. Aerosol inhalers; and

iii. Nitroglycerin.

2. For all oral medication and injectables, the number of days the medication should last, based on the prescriber's directions of use, shall be entered in the "Days Supply" field on the pharmacy claim form or similar field in the EMC claim format.

(b) The number of days reported for the days supply dispensed on the pharmacy claim or in the appropriate field on the EMC claim must accurately reflect the intended duration of drug utilization, or a reasonable estimation by the dispensing pharmacist of a drug's intended duration of use when a drug's dosage is unrelated to a specific days supply.

Amended by R.1996 d.144, effective March 18, 1996.

See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).

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

See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51-1.16 Telephone-rendered original prescriptions

(a) Telephone orders from prescribers for original prescriptions shall be permitted in accordance with all applicable Federal and State laws and regulations.

(b) For purposes of reimbursement, telephone authorization to refill an original prescription with no refill remaining is considered a new order and requires a new written prescription with a new prescription number. Stamping or writing a new number on the original prescription order does not constitute a new prescription under the Medicaid program.

(c) When a prescriber chooses not to allow product interchange on a telephone order, the statement "Substitution not permitted by prescriber-telephone 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.

(d) When a prescriber chooses to certify "Brand Medically Necessary" on a telephoned prescription for a product included on the Federal MAC list, a written signed prescription order containing the certification, shall be sent to the pharmacist within seven days of the date of the telephone order. The written prescription shall be retained by the pharmacist as the original prescription. Failure to comply will result in the payment for that prescription being reduced to the MAC reimbursement level.

10:51-1.17 Changes or additions to the original prescription

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

10:51-1.18 Prescription refill

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

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

2. When the prescriber indicates a prescription refill(s) on an original or telephone prescription for drugs, the number of refills shall be limited to a maximum of five refills within a six-month period.

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 shall 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).

Amended by R.1997 d.251, effective June 16, 1997.

See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).

In (a)2, inserted reference to telephone prescriptions; and deleted (a)2i, relating to an exception for oral contraceptives.

Case Notes

Prescription refills not reimbursable. *Park Pharmacy v. Division of Medical Assistance and Health Services*, 92 N.J.A.R.2d (DMA) 67.

10:51-1.19 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 New Jersey Medicaid 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 Formulary, the pharmacist shall substitute from the list of interchangeable products and bill Medicaid accordingly.

2. When the prescriber initials "Substitution Permissible," the pharmacist shall dispense and bill Medicaid for one of the less expensive products listed in the DURC Formulary as interchangeable with the brand name prescribed. The Medicaid recipient must accept the interchangeable product unless the recipient is willing to pay the pharmacy's full, usual and customary price. If that occurs, the pharmacist shall so note on the prescription blank and no claim shall be submitted to Medicaid.

3. For non-MAC drugs (see N.J.A.C. 10:51-1.5) 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 Medicaid for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51-1.5) 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 and Appendix E regarding the proper EMC claim format.)

4. When the prescriber orders by the generic name, the DURC Formulary (see N.J.A.C. 10:51-1.4) does not apply. The pharmacist shall dispense the least expensive, therapeutically effective product available to him or her at the time of dispensing. The product need not necessarily be from the list of interchangeable products.

(b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid may reimburse for certain multi-source drugs. The limit shall apply to all listed MAC drugs (see Appendix B) 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. 10:51-1.9) the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten 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) 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).

10:51-1.20 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 at present 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.

Case Notes

Reimbursement for vitamins to treat infant's biliary atresia. J.S. v. Division of Medical Assistance and Health Services, 92 N.J.A.R.2d (DMA) 51.

10:51-1.21 Drug manufacturers' rebate agreement

(a) In order for legend drug products to be reimbursed by the New Jersey Medicaid program, manufacturers must have in effect a rebate agreement pursuant to Section 4401 of OBRA 1990 and Section 1927 et seq. of the Social Security Act.

(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.

10:51-1.22 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 New Jersey Medicaid program.

1. This provision may be waived at the discretion of the Commissioner if he or she determines that a bundled drug service is less than or equal to the total cost of the unbundled components if reimbursed separately; or

2. The Commissioner may waive the provisions for reasons of medical necessity for a bundled drug or in accordance with terms approved by the Department as follows:

i. Those instances where discontinuation, withdrawal, or elimination of the use of the bundled drug by someone who has been receiving a bundled drug would result in the deprivation of the life saving or life prolonging benefits of the drug or would cause potential harm or serious exacerbation of the illness being treated; or

ii. Those instances where use of the bundled drug has shown marked improvement in the recipient's clinical status reflected in alleviation of symptoms, and elevation of level of function and independence.

(c) 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 total bundled drug service, discrete costs of each component of the bundled drug service, cost benefit analyses, 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.

1. If the Commissioner determines that a bundled drug is eligible for reimbursement under this section, New Jersey Medicaid recipients shall receive or continue to receive the bundled drug service if prior authorization is requested and approved. Prior authorization shall be obtained by completing the appropriate "Request for Authorization Form" requesting medication management authorization and providing sufficient documentation to establish that it is medically necessary to continue the bundled drug services. Mail all the information to:

Medical Director
Division of Medical Assistance and Health Services
CN 712
Trenton, NJ 08625-0712

10:51-1.23 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 or 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 shall 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 may differ from the actual stock package size code reported on the claim.

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

Case Notes

Reliance on welfare agency's system of telephone eligibility verification entitled pharmacy to reimbursement for otherwise ineligible pharmaceutical services. *Damiano Pharmacy v. Division of Medical Assistance*, 95 N.J.A.R.2d (DMA) 61.

10:51-1.24 Point-of-sale (POS) claims adjudication system

(a) Medicaid 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 Medicaid approved pharmacy provider, in accordance with N.J.A.C. 10:51-1.3, 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 shall 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 New Jersey Medicaid 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 Medicaid 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 Medicaid 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 Medicaid prior authorization number, if applicable;
4. The Garden State Health Plan (GSHP) prior authorization indicator, if applicable;
5. The compound drug indicator;
6. The other insurance indicator, if applicable; and
7. 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 Medicaid 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 message; 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 Medicaid beneficiary.

3. All prescriptions adjudicated to payment by the fiscal agent's computer shall be subsequently dispensed and their receipt by Medicaid beneficiaries properly documented on a Medicaid 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).

10:51-1.25 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 Medicaid beneficiaries. As a component of the Medicaid 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 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 (DUR) Board shall be applied to all Medicaid 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. 10:51-1.24.

(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 (that is, payment or denial) of Medicaid 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 pharmacists intervention requirements related to the PDUR program are in addition to beneficiary interactions related to 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).

SUBCHAPTER 2. PHARMACEUTICAL SERVICES TO MEDICAID RECIPIENTS IN A NURSING FACILITY

10:51-2.1 Introduction

This subchapter of the Manual provides information about the provision of reimbursable pharmaceutical services

provided to Medicaid recipients in Medicaid approved nursing facilities.

10:51-2.2 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, and as a provider of parenteral nutrition or intravenous therapy. The requirements for approval as a provider of pharmaceutical services are listed in (b) and (c) 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) 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, CN 301, Trenton, New Jersey 08625.

2. Parenteral nutrition and/or intravenous therapy may be provided by either a pharmacy/medical supplier or a medical supplier approved to provide these services by the New Jersey Medicaid program; however, billing for the ancillary supplies associated with parenteral nutrition and/or intravenous therapy are subject to the requirements of the Medical Supplier Manual, N.J.A.C. 10:59.

- i. "Ancillary supplies" means medical supplies and/or durable medical equipment which are medically necessary to facilitate administration of parenteral or intravenous therapy.

10:51-2.3 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 and compounding services, when allowable. Prescriptions and in-patient medication orders 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 compound 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

- iii. Dispensed by licensed pharmacists on the basis of a written prescription and/or in-patient medication order 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 and/or in-patient medication orders on file;

2. Audit records pertaining to covered persons;

3. Inspect private sector records, where deemed necessary to comply with the Federal regulations to determine a pharmacy's usual and customary charge 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;