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, formerly 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). After R.1990 d.530, Chapter 51 was amended by the following: R.1991 d.353, effective July 1, 1991. See: 23 N.J.R. 1310(b), 23 N.J.R. 2041(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Chapter 51 was repealed and a new Chapter 51, Pharmaceutical Services Manual, was adopted as R.1993 d.434.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 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. 10:51–1.11 and 10:51–1.12, respectively;

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

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

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

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

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

7. Prescription refill (see N.J.A.C. 10:51–1.18);

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

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).

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. 10:51–1.5, Basis of payment);

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

11. 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);

(b) A properly completed claim form must be submitted or a properly formatted electronic media claim (EMC) must be transmitted to the fiscal agent for claims processing.

1. The claim form may be completed manually or by computer, but only one prescription shall be billed on each claim form. See Appendix Fiscal Agent Billing Supplement for instructions concerning the completion and submission of the specified claim form;

2. All claim forms must contain the National Drug Code (NDC). 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 must be included in all fields. For example, 00003–0234–01.

i. 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 actual stock package size used to fill the prescriptions.

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;

ii. 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.

(1) Maximum cost for each eligible prescription claim not covered by (b)1i above is based on the lower of the AWP minus regression (discount) category, if applicable, plus dispensing fee, or usual and customary charge. For information about the "regression (discount) categories," see N.J.A.C. 10:51–1.6, and for usual and customary charge, see N.J.A.C. 10:51–1.10.

2. If the published MAC price as defined in (b)1i above is higher than the average wholesale price 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 a legend drug, including the charge for the cost of medication and the dispensing fee, shall not exceed the lowest of the following:

1. Maximum allowable cost (MAC) as determined in (b)1 above, plus dispensing fee (see N.J.A.C. 10:51–1.7); or

2. 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 New Jersey Medicaid program is:

1. The product 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.

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 (discount) categories

(a) 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) is 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) 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 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.

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 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.

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 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.

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 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.

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 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.

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 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.

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 pharma-

cies, 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).

Amended by R.1995 d.104, effective February 21, 1995.
See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).

10:51–1.7 Prescription drug dispensing fee

(a) The dispensing fee for legend drugs, 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.

10:51–1.8 Compounded prescriptions

(a) Compounded prescriptions extemporaneously prepared and dispensed by approved pharmacy providers are reimbursable by the Medicaid program as follows:

1. Total ingredient cost is defined in N.J.A.C. 10:51–1.5. The provider may charge up to $0.25 for any ingredient whose "cost" is less than $0.25; plus

2. The dispensing fee is allowed in N.J.A.C. 10:51–1.7; plus

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

(b) 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.

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 anorexiants 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; and

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 (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 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.

(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.

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. Anorexiants 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) The quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or an amount sufficient to cover the interval between visits to the prescriber, but may not exceed a 60–day supply or 100 unit doses, whichever is greater. Any medication used continuously (that is, daily, three times daily, every other day, and so forth) for 14 days or more is considered a sustaining drug or maintenance medication and shall be prescribed in sufficient quantities to treat the recipient for at least 60 days or in 100 unit doses, whichever is greater. The pharmacist shall dispense the full quantity prescribed, within Program limits. 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 meet these limitations.

1. Exceptions:

i. Oral contraceptives may be prescribed and dispensed up to a supply of three ovulatory cycles; and

ii. When the full quantity prescribed (within Program limits) is not available at the time of dispensing, the pharmacist may dispense the quantity available and inform the Medicaid recipient accordingly. The pharmacist shall retain the claim form until the balance of the medication is dispensed.

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 prescri-

ber's directions for use, shall be entered in the "Days Supply" filed on the pharmacy claim form.

(b) Dosage for the medications, under (a)1 above, cannot be related to the number of days supply. The pharmacist shall enter a value of "1" in the "Days Supply" filed on the pharmacy claim form.

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 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 the original prescription, the number of refills are limited to a maximum of five refills within a six month period.

3. 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.

4. 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.

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

6. 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, the replacement prescription must be a new prescription with a unique prescription number.

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 checking "Medical Certification" on the claim form 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.)

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 multisource 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.

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 Electronic Media Claims (EMC) submission

(a) In order for a pharmacy provider to be eligible to submit electronic media claims, including magnetic tape, diskette, or modem transmission, 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."

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

(c) 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.

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".

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;

(2) Quantity dispensed;

(3) Price;

(4) Prescription number (for reference purposes only); and

(5) Date dispensed; and

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

10:51–2.4 Program restrictions affecting payment for prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescriber within the limits of applicable laws. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 10:51–2.10 and 2.11, respectively;

2. Quantity of medication (see N.J.A.C. 10:51–2.12);

3. Dosage and directions (see N.J.A.C. 10:51–2.13);

4. Prescriptions and in-patient medication orders rendered by telephone or technological devices (see N.J.A.C. 10:51–2.14);

5. Changes or additions to the original prescription or in-patient medication order (see N.J.A.C. 10:51–2.15);

6. Prescription refill (see N.J.A.C. 10:51–2.16);

7. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E–1 et seq.) (see N.J.A.C. 10:51–2.17);

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. 10:51–2.9);

8. 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. 10:51–2.5, Basis of payment);

9. 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. 10:51–2.18 and listing of DESI drugs in Appendix A); and

10. 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. 10:51–2.18).

(b) A properly completed claim form must be submitted or a properly formatted electronic media claim (EMC) must be transmitted to the fiscal agent for claims processing.

1. The claim form may be completed manually or by computer, but only one prescription shall be billed on each claim form. See Appendix, Fiscal Agent Billing Supplement for instructions concerning the completion and submission of the specified claim form. A dispensing fee is not reimbursed to providers providing pharmaceutical services to nursing facility recipients (see N.J.A.C. 10:51–2.7).

2. All claim forms must contain the National Drug Code (NDC). 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 must be included in all fields, for example, 00003–0234–01.

i. 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 actual stock package size used to fill the prescriptions.

10:51–2.5 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. 10:51–2.4;

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 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. 10:51–2.10 (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 drugs (see (c) below), contraceptive diaphragms and legend devices.

(b) Payment for legend drugs, contraceptive diaphragms, and reimbursable legend devices, 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. Maxium 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. 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.

(1) Maximum cost for each eligible prescription claim not covered by (b)1i above is based on the lower of the AWP minus regression (discount) category, if applicable, plus dispensing fee. For information about the "regression (discount) categories," see N.J.A.C. 10:51–2.6.

2. If the published MAC price as defined in (b)1i above is higher than the average wholesale price which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

10:51–2.6 Regression (discount) categories

(a) The maximum cost for each eligible prescription claim not covered by the maximum allowable cost price (see N.J.A.C. 10:51–2.5—basis of payment) is 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) 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 include: 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 Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51–2.5—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 Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51–2.5, 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 Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51–2.5, 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 Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51–2.5, 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 Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51–2.5, 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 Medicaid prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 10:51–2.5, 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 the claim processing by the New Jersey Medicaid Management Information System (NJMMIS).

Amended by R.1995 d.104, effective February 21, 1995.
See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).

10:51–2.7 Prescription Dispensing Fee (Capitation)

(a) The New Jersey Medicaid program capitates the dispensing fee for each prescription for recipients in Medicaid approved nursing facilities in accordance with the total number of Medicaid recipient days in the facility(ies) serviced by the pharmacy. Additional dispensing fees (add-

ons) per prescription shall be given to pharmacy providers who provide the following levels of services:

Pharmacies with institutional permits shall be reimbursed as defined in (a) above, except that the daily per recipient capitation fee shall be 75 percent of the fee for pharmacies with retail permits.

1. Twenty–Four Hour Unit Dose Service: Pharmacies with retail permits dispensing medication in a dispensing system in which a 24–hour supply of unit dose oral medication, both solid (for example, tablets, capsules) and liquid formulations, is delivered for each recipient daily, shall be reimbursed the cost of all reimbursable legend medication plus a fee of $0.656 per recipient day.

i. Exception: Certain liquid medications that are supplied in concentrate form only and are administered by drop dosage cannot be supplied in a 24–hour dose.

2. Modified Unit Dose Service: Pharmacies with a retail permit dispensing medication in a dispensing system in which up to a one month supply of oral unit dose solid medication is delivered for each recipient (for example, unit dose solids, "bingo" card), shall be reimbursed the cost of all reimbursable legend medication plus a fee of $0.544 per recipient day.

3. Traditional Service: Pharmacies with a retail permit dispensing medication in a dispensing system in which a maximum one month supply of medication is delivered monthly for each recipient shall be reimbursed the cost of legend medication plus a fee of $0.487 per recipient day.

4. Computerized Service: Pharmacies which provide ancillary computerized services, such as, but not limited to, continuously updated computerized recipient profiles, clinical records (med sheets and physicians' orders on at least a monthly basis), etc., receive an added increment of $0.05 per recipient day, thereby making the total fee $0.706, $0.594 or $0.537 depending upon the dispensing system used.

(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. 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) When a nursing facility changes its servicing pharmacy provider, the new pharmacy provider must notify the fiscal agent so that the provider file of the New Jersey Medicaid Management Information System (NJMMIS) may be updated. The following information is required in writing:

1. A copy of the agreement between the servicing pharmacy provider and the nursing facility;

2. The provider number of the servicing pharmacy;

3. The effective date of the change in servicing pharmacy provider if not clearly indicated in the agreement between the servicing pharmacy provider and the nursing facility;

4. The name and address of the previous servicing pharmacy provider for the nursing facility;

5. The level of service to be provided (for example: traditional, modified unit dose, or 24–hour unit dose); and

6. A statement indicating the provision of ancillary computerized services or recordkeeping for the nursing facility.

10:51–2.8 Compounded prescriptions

(a) Compounded prescriptions extemporaneously prepared and dispensed by approved pharmacy providers are reimbursable by the Medicaid program as follows:

1. Total ingredient cost is defined in N.J.A.C. 10:51–2.5. The provider may charge up to $0.25 for any ingredient whose "cost" is less than $0.25; plus

2. The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 10:51–2.12.

(b) Restrictions on 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. 10:51–2.19). 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. 10:51–2.10, the compounded prescription is not covered.

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. 10:51–2.18) drug, the compounded prescription is not covered.

4. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51–2.11 are not covered.

10:51–2.9 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.

10:51–2.10 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 Social Security Act. "Legend drugs" mean those drugs whose labels include the legend statement "Caution: Federal Law Prohibits Dispensing Without a Prescription."

10:51–2.11 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the New Jersey Medicaid program:

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

2. Antiobesics and anorexiants when used in treatment of obesity;

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 may 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;

8. Prescriptions and in-patient medication orders 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;

10. Methadone in any form (tablets, capsules, liquid, injectables, or powder) when used for drug detoxification or addiction maintenance;

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. 10:51–2.18); 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. 10:51–2.19);

15. Any bundled drug service (see N.J.A.C. 10:51–2.20); and

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

(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. 10:51–2.5, 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; and

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 (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 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.

Amended by R.1995 d.359, effective July 3, 1995.
See: 26 N.J.R. 3349(a), 27 N.J.R. 2615(a).
In (b)3 defined "other community-type setting", and added (b)3i.

10:51–2.12 Quantity of medication

When the quantity of a drug or medication is not indicated in writing by the prescriber, the pharmacy provider shall dispense an appropriate quantity of medication not to exceed a one month supply (see N.J.A.C. 10:51–2.16, Prescription Refill).

10:51–2.13 Dosage and directions

(a) Dosage and directions for use shall be included as part of all prescriptions or in-patient medication orders. Prescriptions or inpatient medication orders 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 for use, shall be entered in the "Days Supply" field on the pharmacy claim form.

(b) Dosage for the medications, under (a)1 above, cannot be related to number of days supply. The pharmacist shall enter a value of "1" in the "Days Supply" field on the pharmacy claim form.

10:51–2.14 Prescriptions and in-patient medication orders rendered by telephone or technological devices

(a) Telephone rendered and/or technologically transmitted (for example: Fax) original prescriptions shall be permitted in accordance with all applicable Federal and State laws and regulations.

(b) For purposes of reimbursement, a telephone rendered and/or a technologically transmitted (for example: Fax) authorization to refill an original prescription is considered a new prescription or in-patient medication order and requires a new prescription number. Stamping or writing a new number on the original prescription or in-patient medication order does not constitute a new prescription under the Medicaid program.

(c) When a prescriber chooses not to allow product interchange on a telephone rendered original prescription or in-patient medication 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 medication order. A rubber stamp bearing the statement is acceptable.

(d) When a prescriber chooses to certify "Brand Medically Necessary" on a telephone rendered original prescription or in-patient medication order for a product included on the Federal MAC list, a written signed prescription or in-patient medication order containing the certification, shall be sent to the pharmacist within seven days of the date of the telephone order. The written in-patient medication order 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.

10:51–2.15 Changes or additions to the original prescription or in-patient medication order

Changes or additions to the original prescription or in-patient medication order, 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.

10:51–2.16 Prescription refill

(a) Refills are not allowed.

(b) For purposes of reimbursement, an order for continuation of medication shall be considered a new prescription requiring a new written prescription and new prescription number.

10:51–2.17 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 or in-patient medication order 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" on the prescription blank, 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. When a prescriber authorizes, in accordance with (b) below, the dispensing of a brand MAC drug, the pharmacist shall indicate the prescriber's preference by checking "Medical Certification" on the claim form and shall dispense and bill Medicaid for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51–2.5) 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).

4. When the prescriber orders by the generic name, the DURC Formulary (see N.J.A.C. 10:51–2.4) 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 limits, for which Federal Financial Participation (FFP) is available, that Medicaid may reimburse for certain multisource 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 in-patient medication order or follow-up written prescription or in-patient medication order to a telephone rendered prescription or technologically transmitted, (for example: Fax) (see N.J.A.C. 10:51–2.9) 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 or in-patient medication 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.

10:51–2.18 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.

10:51–2.19 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.

10:51–2.20 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

10:51–2.21 Electronic Media Claims (EMC) submission

(a) In order for a pharmacy provider to be eligible to submit electronic media claims, including magnetic tape, diskette, or modem transmission, to the Medicaid and/or PAAD programs, a pharmacy provider or vendor of EMC services must complete the "New Jersey Medicaid Provider Electronic Billing Agreement."

(b) The completed agreement must be submitted to the fiscal agent and approved by the Division of Medical Assistance and Health Services.

(c) The pharmacy provider or vendor of EMC services must 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.

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".

SUBCHAPTER 3. CONSULTANT PHARMACIST SERVICES

10:51–3.1 Introduction

All services required of a consultant pharmacist in nursing facilities (that is, a skilled nursing facility, an infirmary section of a home for the aged, or a public medical institution) as stipulated in Federal and State statutes, rules and regulations, including, but not limited to, those listed as this subchapter, shall be provided.

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 recipient, are monitored for potential adverse reactions, allergies, drug interactions, contraindications, rationality, drug evaluation, and laboratory test modifications, and that the physician is advised promptly of any recommended changes;

6. 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.

7. Report in writing at least quarterly to the pharmaceutical services committee (pharmacy and therapeutic 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;

8. 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;

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

10. 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

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

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 must:

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).

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

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.

10:51–4.4 Program restrictions affecting payment for prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescriber within the limits of applicable laws. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 10:51–4.12 and 4.13, respectively;

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

3. Dosage and directions (see N.J.A.C. 10:51–4.15);

4. Telephone-rendered original prescriptions (see N.J.A.C. 10:51–4.16);

5. Changes or additions to the original prescription (see N.J.A.C. 10:51–4.17);

6. Prescription refill (see N.J.A.C. 10:51–4.18);

7. 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);

8. 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

9. 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).

(b) A properly completed claim form must be submitted or a properly formatted electronic media claim (EMC) must be transmitted to the fiscal agent for claims processing.

1. The claim form may be completed manually or by computer, but only one prescription shall be billed on each claim form. See Appendix Fiscal Agent Billing Supplement for instructions concerning the completion and submission of the specified claim form;

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

i. 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 actual stock package size used to fill the prescriptions.

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 established by the Division of Medical Assistance and Health Services; or

ii. 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.

(1) Maximum cost for each eligible prescription claim not covered by (b)1i above is based on the lower of the AWP minus regression (discount) category, if applicable, plus dispensing fee, or usual and customary charge. For information about the "regression (discount) categories," see N.J.A.C. 10:51–4.6 and for usual and customary charge, see N.J.A.C. 10:51–4.11.

2. If the published MAC price as defined in (b)1i above is higher than the average wholesale price 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 a legend drug, including the charge for the cost of medication and the dispensing fee, shall not exceed the lowest of the following:

1. Maximum allowable cost (MAC) as determined in (b)1 above, plus dispensing fee (see N.J.A.C. 10:51–4.7); or

2. 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 is:

1. The product 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.

10:51–4.6 Regression (discount) categories

(a) 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) is 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) 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 over 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).

Amended by R.1995 d.104, effective February 21, 1995.
See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).

10:51–4.7 Prescription drug dispensing fee

(a) The dispensing fee for legend drugs, 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 affects; 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 PAAD program determines that the provider was not entitled to reimbursement for them.

10:51–4.8 PAAD program copayment

(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 copayment of an amount determined appropriate by the Legislature.

(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.

10:51–4.9 Compounded prescriptions

(a) Compounded prescriptions extemporaneously prepared and dispensed by approved pharmacy providers are reimbursable by the PAAD program as follows:

1. Total ingredient cost is defined in N.J.A.C. 10:51–4.5. The provider may charge up to $0.25 for any ingredient whose "cost" is less than $0.25; plus

2. The dispensing fee is allowed in N.J.A.C. 10:51–4.7; plus

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

(b) 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.

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; and

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 residences (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 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.

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.

10:51–4.14 Quantity of medication

(a) The quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or an amount sufficient to cover the interval between visits to the prescriber, but may not exceed a 60–day supply or 100 unit doses, whichever is greater. Any medication used continuously (that is, daily, three times daily, every other day, and so forth) for 14 days or more is considered a sustaining drug or maintenance medication and shall be prescribed in sufficient quantities to treat the recipient for at least 60 days or in 100 unit doses, whichever is greater. The pharmacist shall dispense the full quantity prescribed, within Program limits. 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 meet these limitations.

1. Exceptions:

i. Oral contraceptives may be prescribed and dispensed up to a supply of three ovulatory cycles; and

ii. When the full quantity prescribed (within Program limits) is not available at the time of dispensing, the pharmacist may dispense the quantity available and inform the PAAD beneficiary accordingly. The pharmacist shall retain the claim form until the balance of the medication is dispensed.

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 for use, shall be entered in the "Days Supply" field on the pharmacy claim form.

(b) Dosage for the medications, under (a)1 above, cannot be related to number of days supply. The pharmacist shall enter a value of "1" in the "Days Supply" field on the pharmacy claim form.

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 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 twelve month period beginning with the date of the original prescription. There is no limit to the number of refills dispensed during the twelve month period.

3. 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.

4. 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.

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

6. 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, the replacement prescription must be a new prescription with a unique prescription number.

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 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 checking "Medical Certification" on the claim form 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.)

(b) 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.

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 Electronic Media Claims (EMC) submission

(a) In order for a pharmacy provider to be eligible to submit electronic media claims, including magnetic tape, diskette, or modem transmission, to the Medicaid and/or PAAD programs, a pharmacy provider or vendor of EMC services must complete the "New Jersey Medicaid Provider Electronic Billing Agreement."

(b) The completed agreement must be submitted to the fiscal agent and approved by the Division of Medical Assistance and Health Services.

(c) The pharmacy provider or vendor of EMC services must 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.

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".

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 plastic PAAD identification card or the Temporary Validation Identification Letter.

(b) The Division 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.

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:

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 C

PHARMACY PROVIDER CERTIFICATION STATEMENT

Pharmacy Name_____ Provider ID #_____

Address_____

_____ Telephone ( )_____

Section I. ANNUAL CERTIFICATION OF TOTAL PRESCRIPTION VOLUME FOR 1991

Prescriptions Filled: New_____ + Refills_____ = TOTAL *

*Total: Include all third party and non-third party Rxs.
Combine totals for both regular and LTCF numbers, if applicable.

Section II. FEE INCREMENTS ADDED TO BASIC DISPENSING FEE

1. 24-Hour Emergency Service Availability $0.11

Provider certifies availability of 24 hours/day 365 days/year prescription service.

____ Yes ____ No

If yes, service availability made known by:

____ Sign in store window ____ Sign at prescription counter

____ Other Note: If other is checked a complete description of how available must be given.

Telephone number for this service is ( )_____

Telephone number for this service must be a local call. If telephone number is not given, FD-70 will be returned.

2. Patient Consultation $0.08

Provider agrees to monitor all Medicaid and PAAD patient profiles for drug interactions, contraindications and adverse reactions. Provider will attempt to discuss therapy with the patient with emphasis on compliance and proper utilization of prescription. The pharmacist shall exercise good professional judgment at all times.

____ Yes ____ No

NOTE: If provider discontinues any of the above services, he/she must notify Unisys CN 4804, Trenton, N.J. 08650 in writing within 72 hours of such discontinuance and must immediately cease adding the increments to the basic dispensing fee.

Each of the above claimed increments is subject to audit. If the New Jersey Medicaid Program determines that the provider has an error rate of 5% or more for either increment, the New Jersey Medicaid Program will recover the total reimbursement paid for that increment, plus interest, retroactive to the date of this agreement.

3. Impact Allowance $0.15

This provider has a combined Medicaid/PAAD prescription volume (including LTCF Rxs) equal to or greater than 50% of the total Rx volume & qualifies for "Impact Allowance".

____ Yes ____ No

NOTE: If conditions for earning impact allowance change, provider must notify Unisys, CN 4804, Trenton, N.J. 08650 in writing within 30 days of change and must immediately cease adding the increment to the basic dispensing fee.

If the New Jersey Medicaid Program determines that the provider has not met the impact allowance requirements, the New Jersey Medicaid Program will recover the total reimbursement paid for this increment, plus interest, retroactive to the date of this agreement.

Section III. OWNERSHIP DISCLOSURE STATEMENT

1. Chain Store (4 or more stores). ____ Yes ____ No
2. Do you or does your organization have any legal or professional relationships with any other health care organizations or facilities? ____ Yes ____ No

   If yes, list all such relationships on a separate page.
3. Does any person in your organization own or have an interest in or any relationship with any other corporation, partnership or other organization providing services under the New Jersey Medicaid Program? ____ Yes ____ No

   If yes, explain on a separate page.

4. Indicate the Legal Status of your organization:
   ____ Sole Proprietor ____ Partnership ____ Non-Profit Corporation
   ____ For Profit Corporation ____ Government ____ Other (If so, specify)
5. List names, home addresses, professional degree and percentage of ownership of individual(s) for:
   All partners, directors, officers and/or stockholders as applicable.

	NAME	DEGREE	HOME ADDRESS	% OWNERSHIP
1.				
2.				
3.				
4.				
5.				

I HAVE THOROUGHLY READ THE PHARMACY PROVIDER CERTIFICATION STATEMENT AND AGREE TO THE TERMS AND CONDITIONS SET FORTH HEREIN; I UNDERSTAND THAT THE MAXIMUM CHARGE TO THE NEW JERSEY MEDICAID PROGRAM FOR A MEDICAID OR PAAD PRESCRIPTION FOR A COVERED LEGEND DRUG, MAY NOT EXCEED THE LOWEST OF THE FOLLOWING:

A. Cost plus dispensing fee is outlined in the New Jersey Medicaid Pharmacy Manual.
B. Usual and customary and/or posted or advertised charge.
C. Average of other third party prescription plan charges or agreements.

THE MAXIMUM CHARGE TO THE NEW JERSEY MEDICAID PROGRAM FOR A COVERED NON-LEGEND PRODUCT, MAY NOT EXCEED THE LOWEST OF THE FOLLOWING:

A. The manufacturer's published suggested selling price to the consumer.
B. The usual and customary retail price charged to other persons in the community.

Legal Signature of Principal:_____ Date:_____

Print Name:_____ Title:_____

Pharmacy Name:_____

NOTE: All of the above statements are subject to audit and review by Division personnel, its contractors, or other state & federal agencies.

AFFIX
PHARMACY LABEL
HERE

FD-70 (REV. 12/91)

APPENDIX D

FISCAL AGENT BILLING SUPPLEMENT

AGENCY NOTE: The Fiscal Agent Billing Supplement is filed as an incorporated Appendix of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to the fiscal agent billing supplement, replacement pages will be distributed to providers and copies will be filed with the Office of Administrative Law. For a copy of the Fiscal Agent Billing Supplement, 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 E

EMC MANUAL

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

Paramax/Unisys
CN 4801
Trenton, N.J. 08650

New Rule, R.1995 d.104, effective February 21, 1995.
See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).