2. Reimbursement for compounded prescriptions without an active ingredient(s) shall be provided under a common drug code assigned by DMAHS.

(e) Reimbursement for compounded prescriptions submitted manually or as an EMC claim is calculated based on the ingredient cost, as described in N.J.A.C. 10:51–1.5, of the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 10:51–1.7.

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

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

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

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

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

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

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

4. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51–1.12 are not covered.

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51–1.9 Non-proprietary or generic dispensing

When medication is prescribed by its non-proprietary or generic name, the pharmacist shall dispense the least expensive, therapeutically effective equivalent product available, preferably one listed in the DURC Formulary. The labeler code and drug product code of the actual product dispensed must be reported on the claim form. The package size code reported may differ from the stock package size used to fill the prescription.

10:51–1.10 Provider's usual and customary charge or advertised charge

(a) The provider's usual and customary charge or advertised charge is an element considered in the calculation of the basis of payment for legend drugs (see N.J.A.C. 10:51–1.5, Basis of payment).

(b) The usual and customary charge to the Medicaid program is defined as the amount a provider charges the general public for a prescription for the same drug product (same NDC number) in the same quantity as the prescription being dispensed to a Medicaid recipient. "Usual and customary charge" means the actual charge made to the majority (51 percent) of the total patient population served by the individual pharmacy.

1. The provider shall not charge the Program more than would be charged to a cash customer when the general public, including private third party plans, accounts for more than 50 percent of a provider's total prescription volume.

i. In the event Medicaid and/or PAAD represent more than 50 percent of a provider's total prescription volume, then, for reimbursement purposes, the provider's usual and customary charge may be considered the amount the Program would reimburse for the same services.

10:51–1.11 Covered pharmaceutical services

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

(b) Covered pharmaceutical services include:

1. Prescribed legend drugs (for their medically accepted indication) as defined in Section 1927(k)(6) of the Social Security Act. "Legend drugs" mean those drugs whose labels include the legend statement "Caution: Federal Law Prohibits Dispensing Without a Prescription."

2. Non–legend drugs, as follows, for which Federal Financial Participation (FFP) is available:

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

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

iii. Pharmaceutical inhalation devices;

iv. Diabetic testing materials;

v. Insulin needles and/or syringes;

vi. Insulin; and

vii. Antacids.

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

i. Analgesics, Salicylates;

ii. Analgesics/Antipyretics, Non-salicylate;

iii. Antidiarrheals;

iv. Anti–Emetics;

v. Antiflatulents;

vi. Antihistamines;

vii. Antipruritics;

viii. Antitussives, non-narcotic;

ix. Cathartics;

x. Cough and cold preparations;

xi. Emetics;

xii. Expectorants;

xiii. Hematinics;

xiv. Iron replacement supplements;

xv. Laxatives;

xvi. Multiple vitamin preparations;

xvii. Pediatric vitamin preparations;

xviii. Vitamins A, B, C, D, E, K, B1, B2, B6, B12 preparations;

xix. Polymixin and derivatives;

xx. Topical preparations, antibacterial;

xxi. Topical antibiotics; and

xxii. Topical anti-inflammatory preparations.

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

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

10:51–1.12 Non–covered pharmaceutical services

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

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

2. Antiobesics and 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;

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;

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

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

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

Amended by R.1994 d.600, effective December 5, 1994.
See: 26 N.J.R. 3345(a), 26 N.J.R. 4762(a).
Amended by R.1995 d.358, effective July 3, 1995.
See: 27 N.J.R. 1104(a), 27 N.J.R. 2614(b).
In (a)7 added ii.
Amended by R.1995 d.359, effective July 3, 1995.
See: 26 N.J.R. 3349(a), 27 N.J.R. 2615(a).
Rewrote (b)3.
Amended by R.1996 d.144, effective March 18, 1996.
See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51–1.13 Services requiring prior authorization

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

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

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

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

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

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

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

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

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

4. 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 if required an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 60–day supply or 100 unit doses, whichever is greater.

1. Any medication continuously prescribed regardless of the frequency of administration, for a period of 14 days or more shall be considered a maintenance medication.

2. The pharmacist shall dispense the full quantity of medication prescribed within the limitations described in (a) above.

3. Prescriptions shall not be split or reduced in quantity, unless the quantity prescribed exceeds Program limits, in which case the quantity shall be reduced to Program limits described in (a) above.

i. Exception: When the full quantity prescribed (within Program limits) is not available when a prescription is ready to be dispensed, the pharmacist shall retain the claim form or submit an EMC claim after the balance of the medication is dispensed. The pharmacist may dispense the quantity available and shall notify the beneficiary accordingly.

Amended by R.1996 d.146 effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51–1.15 Dosage and directions

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

1. Exceptions:

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

ii. Aerosol inhalers; and

iii. Nitroglycerin.

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

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

Amended by R.1996 d.144, effective March 18, 1996.
See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51–1.16 Telephone-rendered original prescriptions

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

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

(c) When a prescriber chooses not to allow product interchange on a telephone order, the statement "Substitution not permitted by prescriber-telephone Rx" plus the pharmacist's full signature next to or below the statement, shall appear on the prescription order. A rubber stamp bearing the statement is acceptable.

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

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

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

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

10:51–1.23 Claim submission

(a) An approved pharmacy provider may choose to:

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

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

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

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

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

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

3. Enter into an agreement with a point-of-sale (POS) intermediary or directly provide a similar telecommunication network approved by DMAHS to submit claims to the fiscal agent for adjudication. POS claims require an electronic format which complies with the National Council Prescription Drug Program standards, Version 3.2, as amended and supplemented, incorporated herein by reference. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

i. The approved POS intermediary or provider established network shall enter into an agreement with the State of New Jersey to provider on-line telecommunication services, including transmission of pharmacy claim detail data, access to the fiscal agent's POS computer and return of adjudicated claim data to the provider.

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

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

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

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

3. All Medicaid pharmacy claims submitted to the fiscal agent for payment consideration shall be adjudicated based on the outcome of established POS and PDUR edits, regardless of the mode of claim submission.

Repeal and New Rule, R.1995 d.104, effective February 21, 1995.
See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).
Formerly "EMC Incentive Program".
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

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

(a) Medicaid pharmacy claims may be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real-time. The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette and paper claims. The pharmacist would be required to enter pharmacy claim detail data into a computer or POS device and transmit this data to the fiscal agent over

a dedicated telephone line. Regardless of the method of claim submission, all claims will go through all New Jersey Medicaid Management Information System (NJMMIS) claims processing edits and the claims will be processed to determine their payment disposition (for example, paid or denied).

(b) In order for a Medicaid approved pharmacy provider, in accordance with N.J.A.C. 10:51–1.3, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly provide a similar telecommunications network approved by the New Jersey Division of Medical Assistance and Health Services.

1. In order to become an approved POS intermediary or provider established network, a firm shall notify the Division at the following address:

Division of Medical Assistance and Health Services
Office of Information Systems
CN 712—Mail Code #4
Trenton, New Jersey 08625–0712
Telephone: 609–588–2802

2. The Division shall send the interested party a summary of the program and instructions on how to submit an application.

3. The Division shall consider the following in evaluating an application:

i. The applicant's general approach and plans to meet the requirements of the POS project;

ii. The applicant's detailed approach and plans to meet the requirements of the POS project;

iii. The applicant's documented qualifications, expertise, and experience on similar projects;

iv. The applicant's proposed staff's documented qualifications, expertise, and experience on similar projects; and

v. The applicant's adherence to the requirements of the Health Care Financing Administration.

(c) A POS participating pharmacy or intermediary shall supply the computer hardware or POS device and required software to generate electronic media claims (EMC) in a format consistent with POS standards adopted by the New Jersey Medicaid program.

(d) A POS participating pharmacy or intermediary shall supply modem capability required to properly transmit claim detail data to the approved POS intermediary or to participate in the provider established telecommunication network.

(e) All Medicaid pharmacy providers choosing to submit claims through the POS system shall submit claims in the approved electronic format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.

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

(f) Claim data requirements for electronic media claims (EMC) generated by POS participating pharmacies include:

1. The first five alpha characters of the last name and the first three alpha characters of the Medicaid beneficiary's first name;

2. The 12 digit Medicaid identification number;

3. The date of birth, if applicable;

4. The date of service or dispense date;

5. The pharmacy prescription number;

6. The actual 11 digit National Drug Code (NDC) of the drug dispensed;

7. The metric quantity dispensed;

8. The days supply;

9. The prescriber's Medicaid provider service number;

10. The third party payment, if applicable;

11. The provider's usual and customary charge; and

12. The pharmacy provider number.

(g) Additional supplementary data requirements, which are claim specific, include:

1. The medical certification indicator;

2. The nursing facility residency indicator;

3. The Medicaid prior authorization number, if applicable;

4. The Garden State Health Plan (GSHP) prior authorization indicator, if applicable;

5. The compound drug indicator;

6. The other insurance indicator, if applicable; and

7. The carrier code(s), if applicable.

(h) A POS participating pharmacy or intermediary shall be required to implement software changes requested by the Division within 60 days of notification of such a request to ensure the generation of electronic claims acceptable to the Medicaid program.

10:51–3.2 Definition of consultant pharmacist

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

10:51–3.3 Qualifications

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

10:51–3.4 Responsibilities

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

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

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

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

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

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

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

i. Drug interactions;

ii. Maximum/minimum daily dosage alerts;

iii. Therapeutic duplication;

iv. Drug age conflicts;

v. Days supply alerts;

vi. Drug–disease precautions; and

vii. Drug–pregnancy precautions, if applicable.

7. Review the drug regimen (for example, dosage form, route of administration, time of administration) of each recipient at least monthly and report any irregularities pertaining to medications to the attending physician, medical director or director of nursing, as appropriate.

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

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

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

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

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

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

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

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

10:51–4.1 Introduction

This subchapter provides information about the provision of pharmaceutical services under the PAAD program which shall extend assistance to certain persons whose level of income disqualifies them for medical assistance under the Medical Assistance and Health Services Act, but who have medical needs for prescribed drugs and/or insulin, insulin needles, insulin syringes and diabetic testing materials and are unable to fully meet the cost of such items. For additional information regarding PAAD eligibility, see N.J.A.C. 10:69A.

10:51–4.2 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the PAAD program as a provider of pharmaceutical services.

(b) To be approved as a provider of pharmaceutical services, the pharmacy 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 of prescribed drugs

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

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

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

3. Pharmaceutical services requiring pharmacist intervention as part of the PAAD Prospective Drug Utilization Review (PDUR) program (see N.J.A.C. 10:51–4.23).

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

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 may be reimbursed by the Medicaid program. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and/or a pharmaceutical excipient or excipients and are dispensed by approved providers.

1. Acceptable pharmaceutical excipients which do not contribute therapeutically to a compound, include, but are not limited to hydrophilic ointment, petrolatum, aquifer, eucerin cream, phenol, menthol, resorcinol, caffeine, talc, simple syrup, aromatic elixir, distilled water, and glycerin.

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claims adjudication system approved by the PAAD program. (See N.J.A.C. 10:51–4.25)

1. A compounded prescription is indicated by the provider by the use of the "compound drug" indicator field on a manual claim or in a similar field in the EMC claim format.

(c) Reimbursement for compounded prescriptions shall not exceed the lower of:

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

2. A provider's usual and customary charge.

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

1. For pharmaceutical excipients costing less than $0.25, the provider may charge Medicaid $0.25 for each ingredient.

2. Reimbursement for compounded prescriptions without an active ingredient(s) shall be provided under a common drug code assigned by DMAHS.

(e) Reimbursement for compounded prescriptions submitted manually or as an EMC claim is calculated based on the ingredient cost, as described in N.J.A.C. 10:51–4.5, of

the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 10:51–4.7.

1. For compounded prescriptions without an active ingredient(s), reimbursement is based on (d) above, plus a dispensing fee, as described in N.J.A.C. 10:51–4.7.

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

(g) Restrictions on payments for compounded prescriptions are as follows:

1. All legend ingredients which are contained in compounded prescriptions must be covered by the PAAD program. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 10:51–4.20) drug, the compounded prescription is not covered.

2. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51–4.13 are not covered.

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51–4.10 Non-proprietary or generic dispensing

When medication is prescribed by its non-proprietary or generic name, the pharmacist shall dispense the least expensive, therapeutically effective equivalent product available, preferably one listed in the DURC Formulary. The labeler code and drug product code of the actual product dispensed must be reported on the claim form. The package size code reported may differ from the stock package size used to fill the prescription.

10:51–4.11 Provider's usual and customary charge or advertised charge

(a) The provider's usual and customary charge or advertised charge is an element considered in the calculation of the basis of payment for legend drugs (see N.J.A.C. 10:51–4.5, Basis of payment).

(b) The usual and customary charge to the PAAD program is defined as the amount a provider charges the general public for a prescription for the same drug product (same NDC number) in the same quantity as the prescription being dispensed to a PAAD beneficiary. "Usual and customary charge" means the actual charge made to the majority (51 percent) of the total patient population served by the individual pharmacy.

1. The provider shall not charge the Program more than would be charged to a cash customer when the general public, including private third party plans, accounts for more than 50 percent of a provider's total prescription volume.

i. In the event Medicaid and/or PAAD represent more than 50 percent of a provider's total prescription volume, then, for reimbursement purposes, the provider's usual and customary charge may be considered the amount the Program would reimburse for the same services.

10:51–4.12 Covered pharmaceutical services

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

(b) Covered pharmaceutical services include:

1. Prescribed legend drugs (for their medically accepted indication) as defined in Section 1927(k)(6) of the Social Security Act. "Legend drugs" mean those drugs whose labels include the legend statement "Caution: Federal Law Prohibits Dispensing Without a Prescription."

2. Non-legend drugs, as follows:

i. Diabetic testing materials;

ii. Insulin needles and/or syringes; and

iii. Insulin.

10:51–4.13 Non–covered pharmaceutical services

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

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

2. Drug products for which adequate and accurate information is not readily available, such as, but not limited to, product literature, package inserts and price catalogues;

3. Experimental drugs;

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

5. Medication prescribed for hospital inpatients;

6. Non-legend drugs other than diabetic testing materials; insulin; and insulin needles and/or syringes;

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

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

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

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

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

12. Drugs for which Federal Financial Participation (FFP) is not available, including:

i. Drug Efficacy Study Implementation (DESI) drugs and identical, similar and related drugs (see N.J.A.C. 10:51–4.20);

13. Any bundled drug service, except drug product cost which is a component of a bundled drug service (see N.J.A.C. 10:51–4.21);

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

15. If the provider has a delivery service, he or she may waive or discount delivery charges to the recipient but is prohibited from charging more than his or her usual and customary charge to the general public for delivery.

(b) In addition to the products specified in (a) above, products shall be excluded from payment, under the following condition(s):

1. Products whose costs are found to be in excess of defined costs outlined in N.J.A.C. 10:51–4.5, Basis of payment;

2. Covered diabetic testing materials which do not offer significant price and/or therapeutic advantage. The criteria shall be cost and improvement in accuracy over existing reimbursable products. Therapeutic advantage (in the case of diabetic testing materials, improvement in accuracy) shall be determined by evaluation of literature and/or cost effectiveness data submitted in support of a request for admission of a diabetic testing material for inclusion in the list of reimbursable products;

3. Manufacturers and distributors may request the review of a denial of reimbursement for products under this subsection by providing supportive information not previously submitted, within 30 days of the date of the denial. Agency decision after review of support material is final;

4. Drug products available in unit-dose packaging and dispensed to residents in a boarding home or residential care setting or other community-type setting. Other community-type setting shall not include certain assisted living settings, including Assisted Living 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;

5. A prescription refilled too soon as described in N.J.A.C. 10:51–4.18(a)5; and.

6. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the PAAD program. (See N.J.A.C. 10:51–4.26)

Amended by R.1995 d.359, effective July 3, 1995.
See: 26 N.J.R. 3349(a), 27 N.J.R. 2615(a).
Added (b)4.
Amended by R.1996 d.144, effective March 18, 1996.
See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

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 if required an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 60–day supply or 100 unit doses, whichever is greater.

1. Any medication continuously prescribed regardless of the frequency of administration, for a period of 14 days or more shall be considered a maintenance medication.

2. The pharmacist shall dispense the full quantity of medication prescribed within the limitations described in (a) above.

3. Prescriptions shall not be split or reduced in quantity, unless the quantity prescribed exceeds Program limits, in which case the quantity shall be reduced to Program limits described in (a) above.

i. Exception: When the full quantity prescribed (within Program limits) is not available when a prescription is ready to be dispensed, the pharmacist shall retain the claim form or submit an EMC claim after the balance of the medication is dispensed. The pharmacist may dispense the quantity available and shall notify the beneficiary accordingly.

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51–4.15 Dosage and directions

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

1. Exceptions:

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

ii. Aerosol inhalers; and

iii. Nitroglycerin.

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

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

Amended by R.1996 d.144, effective March 18, 1996.
See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

10:51–4.16 Telephone-rendered original prescriptions

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

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

(c) When a prescriber chooses not to allow product interchange on a telephone order, the statement "Substitution not permitted by prescriber-telephoned Rx" plus the pharmacist's full signature next to or below the statement, shall appear on the prescription order. A rubber stamp bearing the statement is acceptable.

10:51–4.17 Changes or additions to the original prescription

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

10:51–4.18 Prescription refill

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

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

2. The original prescription is valid for the 12 month period beginning with the date of the original prescription. There is no limit to the number of refills dispensed during the 12 month period.

i. Exception: Oral contraceptives originally prescribed for three ovulatory cycles may be refilled up to three times within one year if so indicated by the prescriber on the original prescription.

3. Refill instructions indicating "refill prn" or indicating more than five refills, shall be subject to the limits imposed in (a)2 above, and shall be reimbursed up to these limits only.

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

5. Prescription refills shall not be dispensed until a reasonable quantity (approximately 75 percent) of the medication originally dispensed or refilled could have been consumed in accordance with the prescriber's written directions for use.

i. Exception: When a prescription is lost or destroyed, requiring a replacement prescription to be dispensed before the original prescription could have been consumed in accordance with the prescriber's written directions for use, an original pharmacy claim with written justification must be submitted to the fiscal agent for payment consideration.

Amended by R.1996 d.144, effective March 18, 1996.
See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).

Case Notes

Denial of reimbursement for prescription refills was appropriate. Crestview Pharmacy v. Division of Medical Assistance and Health Services, 94 N.J.A.R.2d (DMA) 40.

10:51–4.19 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E–1 et seq., shall apply to the PAAD program. This law requires that every prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.