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 and NJ FamilyCare program; however, billing for the ancillary supplies associated with parenteral nutrition and/or intravenous therapy are subject to the requirements of the Medical Supplier Chapter (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.

Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
Inserted references to NJ KidCare throughout; in (b)2i and (c)1, deleted "Medicaid" preceding "Provider"; in (c), deleted "Medicaid" preceding "fiscal agent" in the introductory paragraph; and in (d)1, rewrote i and ii.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
Substituted "NJ FamilyCare" for "NJ KidCare" throughout.

10:51–1.3 Conditions for participation as a provider of pharmaceutical services

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

(b) All drugs must be prescribed.

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

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

ii. Dispensed by licensed pharmacists in accordance with regulations promulgated by the New Jersey State Board of Pharmacy, N.J.A.C. 13:39; and

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

(c) Participating pharmacies shall permit properly identified representatives of the Division of Medical Assistance and Health Services to:

1. Inspect written prescriptions on file;

2. Audit records pertaining to covered persons;

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

i. Information pertaining to the patient's name, address, and prescriber will remain confidential within the limits of the law. Only the following items may be reviewed:

(1) Drug name;

(2) Quantity dispensed;

(3) Price;

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

(5) Date dispensed;

ii. The pharmacy shall provide sufficient information with regard to its contractual agreement(s) and payment history with other private third party prescription plans to identify and verify number of claims, amount paid, and dispensing fee paid by group contracts within the plan. Records and contracts shall be available on-site at the time of audit; or available within 10 working days of an on-site audit. Records shall include, but not be limited to:

(1) Payment vouchers;

(2) Contracts; and

(3) Agreements; and

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

10:51–1.4 Program restrictions affecting payment for prescribed drugs

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

1. Covered and noncovered pharmaceutical services as listed in N.J.A.C. 10:51–1.11 and 1.13, respectively;

2. Pharmaceutical service requiring prior authorization (see N.J.A.C. 10:51–1.14);

3. Pharmaceutical services requiring pharmacist intervention as part of the Medicaid and NJ FamilyCare prospective drug utilization review (PDUR) program (see N.J.A.C. 10:51–1.26).

4. Quantity of medication (see N.J.A.C. 10:51–1.15);

5. Dosage and directions (see N.J.A.C. 10:51–1.16);

6. Telephone-rendered original prescriptions (see N.J.A.C. 10:51–1.17);

7. Changes or additions to the original prescription (see N.J.A.C. 10:51–1.18);

8. Prescription refill (see N.J.A.C. 10:51–1.19);

9. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E–1 et seq.) (see N.J.A.C. 10:51–1.20);

i. Products listed in N.J.A.C. 8:71 (hereafter referred to as "the Formulary"), and all subsequent revisions, distributed to all prescribers and pharmacists; and

ii. Non-proprietary or generic dispensing (see N.J.A.C. 10:51–1.9).

10. Federal regulations (42 CFR 447.301, 331–334) that set the aggregate upper limits on payment for certain multi-source drugs if Federal Financial Participation (FFP) is to be made available. The limit applies to all "maximum allowable cost" drugs (see N.J.A.C. 10:51–1.5, Basis of payment);

11. Drug Efficacy Study Implementation (DESI): "Less than effective drugs" subject to a Notice of Opportunity for Hearing (NOOH) by the Federal Food and Drug Administration (see N.J.A.C. 10:51–1.21 and listing of DESI drugs in Appendix A herein incorporated by reference);

12. Drug Manufacturers' Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS) of the United States Department of Health and Human Services (see N.J.A.C. 10:51–1.22);

13. For claims with service dates on or after July 1, 1998, all drugs prescribed for the treatment of impotency shall be limited to male beneficiaries over the age of 18 years and to four treatments per month; and

14. For claims with service dates on or after August 1, 1998, prescribers must write "Diagnosis of Impotency" on the face of any prescription for impotency drugs. Claims for such prescriptions without this written statement shall be subject to recoupment by the State of New Jersey.

(b) If a prescription is not dispensed directly to the New Jersey Medicaid fee-for-service, NJ FamilyCare fee-for-service, or Work First New Jersey/General Assistance (WFNJ/GA) beneficiary for whom the prescription was written, and the claim charge exceeds $150.00, the individual picking up the prescription shall present the Medicaid Identification Card, the NJ FamilyCare Identification Card or the authorized documentation confirming WFNJ/GA eligibility of the beneficiary. Without the required proof of identity, the prescription shall only be dispensed in accordance with (b)1 and 2 below:

1. If the individual picking up the prescription cannot produce the beneficiary's eligibility documentation, then the non-beneficiary shall produce a valid driver's license as identification. Pharmacies shall record and maintain on file the driver's license number of the non-beneficiary picking up the prescription on the pharmacy signature log or a photocopy of the driver's license presented by the non-beneficiary. Payments for Medicaid fee-for-service or NJ FamilyCare fee-for-service covered pharmacy services not dispensed directly to the beneficiary for whom there is no documentation or a photocopy of the driver's license of the non-beneficiary picking up the prescription shall be subject to full recovery by the State.

2. This subsection shall not apply to prescription deliveries.

3. Such documentation shall be retained by the pharmacy for at least five years from the date the prescription was dispensed, and shall be available for review by the Division or its authorized representatives upon request.

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).
Amended by R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
In (a), changed N.J.A.C. references throughout.
Adopted concurrent proposal. R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 with changes, effective September 21, 1998.
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
In (a), inserted a reference to NJ KidCare in 3, and changed CFR reference in 10.
Amended by R.1999 d.264, effective August 16, 1999.
See: 31 N.J.R. 19(a), 31 N.J.R. 2400(a).
Added (b).
Amended by R.2001 d.124, effective April 16, 2001.
See: 32 N.J.R. 4392(a), 33 N.J.R. 1201(a).
In (a), added 13 and 14.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
In (a)9i, substituted "N.J.A.C. 8:71" for "the current New Jersey Drug Utilization Review Council (DURC) Formulary"; in (a)12, substituted "Centers for Medicare and Medicaid Services (CMS)" for "Healthcare Financing Administration (HCFA)"; in (b), inserted a reference to Work First New Jersey.

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 for both the Medicaid and NJ FamilyCare programs. 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).

2. For unit-of-use packaging, drugs shall be delivered to the resident's living area either in single unit packaging, bingo or punch cards, blister or strip packs, or other system where each drug is physically separate. Individually labeled unit-dose medications may be combined in a "bingo or punch card" to create a unit-of-use drug distribution system.

(e) For beneficiaries covered under a managed care contract, atypical antipsychotics shall be reimbursed fee-for-service through the State's fiscal agent.

(f) Anti-impotency drugs shall be covered, not to exceed four doses per month. Each prescription shall include a diagnosis related to impotency.

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.
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
In (b), inserted a new xi, recodified former xi through xv as xii through xvi, inserted a new xvii, recodified former xvi as xviii, inserted a new xix, and recodified former xvii through xxii as xx through xxv; and rewrote (c).
Amended by R.2003 d.131, effective March 17, 2003.
See: 34 N.J.R. 2897(a), 35 N.J.R. 1423(a).
Added (d).
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
In (b), added a new 2 and recodified former 2 and 3 as 3 and 4; added (e) and (f).

10:51–1.12 Personal contribution to care requirements for NJ FamilyCare–Plan C and copayments for NJ FamilyCare–Plan D

(a) General policies regarding the collection of personal contribution to care for NJ FamilyCare–Plan C and copayments for NJ FamilyCare–Plan D are set forth at N.J.A.C. 10:49–9.

(b) Personal contribution to care for NJ FamilyCare–Plan C services are $1.00 per dispensing for generics and $5.00 per dispensing for brand name drugs. Included in drugs are insulin, needles and syringes.

(c) Pharmacies are required to collect the personal contribution to care for the above-mentioned NJ FamilyCare–Plan C services if the NJ FamilyCare Identification Card indicates that a personal contribution to care is required and the beneficiary does not have a NJ FamilyCare form which indicates that the beneficiary has reached their cost share limit and no further personal contributions to care are required, until further notice. Personal contribution to care charges cannot be waived.

(d) The copayment for prescription drugs under NJ FamilyCare–Plan D shall be $5.00 per prescription:

1. If greater than a 34–day supply of a prescription drug is dispensed, a $10.00 copayment shall apply.

(e) Pharmacies shall collect the copayment specified in (d) above. Copayments shall not be waived.

New Rule, R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
Former N.J.A.C. 10:51–1.12, Noncovered pharmaceutical services, recodified to N.J.A.C. 10:51–1.13.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 without change.
Amended by R.1999 d.211, effective July 6, 1999 (operative August 1, 1999).
See: 31 N.J.R. 998(a), 31 N.J.R. 1806(a), 31 N.J.R. 2879(b).
In (a), added reference to copayments for NJ KidCare–Plan D; added (d) and (e).
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
Substituted "NJ FamilyCare" for "NJ KidCare" throughout.

10:51–1.13 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the New Jersey Medicaid or NJ FamilyCare fee-for-service programs. For beneficiaries 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 who are residing in a long-term care facility (except a nursing facility) or in the community. 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, with the exception of lipase inhibitors, when used in treatment of obesity (see N.J.A.C. 10:51–1.14, Prior authorization); coverage of lipase inhibitors shall be limited to obese individuals with a Body Mass Index (BMI) equal to or greater than 27 kg/m^2 and less than 30 kg/m^2 with co-morbidities of hypertension, diabetes or dyslipidemia; and obese individuals with a BMI equal to or greater than 30 kg/m^2 without co-morbidities;

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 sup-

plies; inhalation devices (pharmaceutical); insulin; and insulin needles and/or syringes;

i. Exception: Non-legend drugs described in N.J.A.C. 10:51–1.11, for beneficiaries 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. 10:51–1.14, 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. 10:51–1.21); 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. 10:51–1.22);

15. Any bundled drug service (see N.J.A.C. 10:51–1.23);

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

17. 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, PO Box 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 and/or unit-of-use packaging and dispensed to residents in a boarding home, residential care setting, alternative family care (AFC) home or other community type setting. Other community type settings shall not include certain assisted living settings, including assisted living residences (ALRs) or comprehensive personal care homes (CPCHs) licensed by the Department of Health and Senior Services.

i. Drug products commercially available only as a unit-dose packaged product are covered in all settings when not otherwise marketed as a chemically equivalent product. The potency of the 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. 10:51–1.19(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 or NJ FamilyCare program. (see N.J.A.C. 10:51–1.26).

(c) Reimbursement shall not be made for any claim submitted by a provider which involves a beneficiary 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).
Recodified from N.J.A.C. 10:51–1.12 and amended by R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
In (a) and (b), changed N.J.A.C. references throughout. Former N.J.A.C. 10:51–1.13, Services requiring prior authorization, recodified to N.J.A.C. 10:51–1.14.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 with changes, effective September 21, 1998.
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).

Changed N.J.A.C. references throughout; in (a), inserted a reference to NJ KidCare fee-for-service in the first sentence and added "who are residing in a long-term care facility (except a nursing facility) or in the community" at the end of the second sentence in the introductory paragraph, deleted a former i and recodified former ii as i in 7, deleted a former 16, and recodified former 17 and 18 as 16 and 17; and in (b)5, inserted a reference to NJ KidCare.
Amended by R.2002 d.278, effective August 19, 2002.
See: 34 N.J.R. 1239(a), 34 N.J.R. 2965(b).
Rewrote (a)2.
Amended by R.2003 d.131, effective March 17, 2003.
See: 34 N.J.R. 2897(a), 35 N.J.R. 1423(a).
Rewrote (b)3.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
Substituted "NJ FamilyCare" for "NJ KidCare" throughout.

10:51–1.14 Services requiring prior authorization

(a) The provider shall obtain prior authorization, when required by this chapter, by phone or in writing, from the professional staff of the Division's prior authorization agent for pharmacy services. The pharmacy prior authorization agent is available at a toll-free telephone number 24 hours a day, seven days a week. When a form is required by this chapter, 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 pharmacy prior authorization agent to the fiscal agent who, in turn, confirms the status of the authorization request by mail and provides the specific prior authorization number. Additional requirements regarding prior authorization for specific drugs or classes of drugs are contained in (b) below.

1. In an administrative emergency (see N.J.A.C. 10:49–6.1(b)3) when the pharmacy prior authorization agent 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 pharmacy prior authorization agent is unavailable, the provider may dispense a total of a five day's 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 pharmacy prior authorization agent 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, Infants and Children (WIC) Nutritional program;

i. Medically necessary enteral nutritional products for treatment of beneficiaries, which may be administered orally, via naso-gastric 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 the treatment of conditions approved by the New Jersey State Board of Medical Examiners at N.J.A.C. 13:35–6.7;

5. Lipase inhibitors, used in the treatment of obesity, as follows:

i. The provider shall telephone the pharmacy prior authorization agent, using the toll-free telephone number supplied by the Division. Pharmacy prior authorization is available 24 hours a day, seven days a week. The pharmacy prior authorization agent reviews the information provided and automatically prior-authorizes a 30–day supply. Subsequent authorizations are based on criteria established by the New Jersey Drug Utilization Review Board, as specified in ii below.

ii. The lipase inhibitors will be provided for an initial 30–day period. A prior authorization will be issued without clinical criteria for an initial prescription for a maximum 30–day supply. During this initial 30–day period, the pharmacy prior authorization agent will contact the physician to request justification for continuing the use of the lipase inhibitor. If justification is received by the pharmacy prior authorization agent, the lipase inhibitor will be prior authorized for an additional 30–day supply. After these two 30–day periods, any subsequent provision of lipase inhibitors shall not be dispensed without prior authorization. Such subsequent prior authorizations for lipase inhibitors shall be limited to 90–day supply; and

6. Any prescription claim for the same beneficiary, provided within the same calendar month, that exceeds the monthly prescription volume threshold of 12 prescriptions per month. This applies whether the prescriptions were dispensed by one or more pharmacies. The need for prior authorization shall be communicated to providers via the point of sale claims processing system. Prior authorization shall be requested as required by (a) above, except that prior authorization shall not be required in the following circumstances:

i. Pharmaceutical services provided to Medicaid beneficiaries residing in a nursing facility, assisted living residence, comprehensive personal care home, or residential health care facility;

ii. Certain drugs and specific therapeutic drug classes including clozapine, antihemophiliac drugs, immunosuppressants, and HIV/AIDS drugs (limited to

protease inhibitor, antiretroviral drugs, nucleoside analogs and reverse transcriptase inhibitors);

iii. Certain legend drugs, including oral contraceptives, ophthalmic preparations, otic preparations, nitroglycerin patches, vaginal preparations, and hemorrhoidal preparations;

iv. Drugs otherwise requiring prior authorization in accordance with this subsection;

v. Drugs otherwise requiring prior authorization by the Work First New Jersey/General Assistance program; and

vi. Drugs dispensed to beneficiaries in the pharmacy lock-in program.

Recodified from N.J.A.C. 10:51–1.13 by R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
Former N.J.A.C. 10:51–1.14, Quantity of medication, recodified to N.J.A.C. 10:51–1.15.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 without change.
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
In (b), deleted former 5.
Amended by R.1999 d.122, effective April 19, 1999 (operative May 1, 1999).
See: 30 N.J.R. 1014(a), 30 N.J.R. 2185(a), 31 N.J.R. 1064(a).
In (a), inserted a reference to State contractors in the first sentence of the introductory paragraph, and rewrote 1; and in (b), substituted a reference to drug classes for a reference to classes in the introductory paragraph, and added 5.
Amended by R.2002 d.278, effective August 19, 2002.
See: 34 N.J.R. 1239(a), 34 N.J.R. 2965(b).
In (a), rewrote the introductory paragraph and substituted "pharmacy prior authorization agent" for "MDO or State contractor" throughout 1 and 1i; added new (b)5 and recodified former (b)5 as (b)6.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
In (b), substituted "anorexiants" for "An orexiants" in 4, substituted "12" for "seven" preceding "prescriptions" in 6 and rewrote iii through vi.

10:51–1.15 Quantity of medication

(a) For claims with service dates on or after July 15, 1996, but prior to July 1, 1998, the quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or, if required, an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 34–day supply or 100 unit doses, whichever is greater.

(b) For claims with service dates on or after July 1, 1998, but prior to July 1, 1999, the quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or, if required, an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 34–day supply.

(c) For claims with service dates on or after July 1, 1999, the quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or, if required, an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 34–day supply or 100 unit doses, whichever is greater, for refill prescriptions.

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

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

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

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

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).
Amended by R.1997 d.251, effective June 16, 1997.
See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).
In (a), inserted "For claims with service dates on or after July 15, 1996," and changed allowable supply to 34 days from 60 days; and recodified former (a)1 through 3 as (b) through (d).
Recodified from N.J.A.C. 10:51–1.14 by R.1998 d.154, effective February 27, 1998 (operative March 1, 1998; to expire August 31, 1998).
See: 30 N.J.R. 1060(a).
Former N.J.A.C. 10:51–1.15, Dosage and directions, recodified to N.J.A.C. 10:51–1.16.
Adopted concurrent proposal, R.1998 d.487, effective August 28, 1998.
See: 30 N.J.R. 1060(a), 30 N.J.R. 3519(a).
Readopted the provisions of R.1998 d.154 without change.
Amended by R.2001 d.124, effective April 16, 2001.
See: 32 N.J.R. 4392(a), 33 N.J.R. 1201(a).
In (a), inserted ", but prior to July 1, 1998" following "after July 15, 1996"; added new (b) and (c); recodified former (b) through (d) as (d) through (f).

10:51–1.16 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;

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

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey 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 or NJ FamilyCare 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 and NJ FamilyCare programs, the new owner(s) shall apply to the Division of Medical Assistance and Health Services, Department of Human Services, by contacting the Provider Enrollment Unit. (See N.J.A.C. 10:49, Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit. (see Appendix D, Fiscal Agent Billing Supplement).

3. To enroll as a Medicaid and NJ FamilyCare provider of pharmaceutical services, a pharmacy shall contact the fiscal agent Provider Enrollment Unit (see Appendix D, 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 which supplies parenteral nutrition and/or intravenous therapy shall:

i. Comply with all the requirements of N.J.A.C. 13:39; 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 N.J.A.C. 13:39 is available from West Group at 1–800–808–WEST.

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 or NJ FamilyCare program; however, billing for the ancillary supplies associated with parenteral nutrition and/or intravenous therapy are subject to the requirements of the Medical Supplier Chapter, 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.

(d) Any new pharmacy, or any purchaser of an existing pharmacy possessing a valid permit described in (b)1 above, that has applied for approval as a provider of pharmaceutical services in the Medicaid, NJ FamilyCare and/or WFNJ/GA FFS programs may also apply for issuance of a temporary provider number. The temporary provider number, if issued by DMAHS, shall be effective on the date of issuance of the pharmacy permit, and shall be valid for up to 90 days. The temporary provider number may be utilized for the sole and limited purpose of accessing the point-of-sale system in order to determine whether Medicaid or NJ FamilyCare claims would be payable if the pharmacy is subsequently approved for provider status. However, no payments shall be made unless the application for provider status is approved and a permanent provider number is issued.

(e) DMAHS reserves the right to conduct prepayment and/or postpayment monitoring at any time of any pharmacy that is issued a temporary and/or permanent provider number.

Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
Inserted references to NJ KidCare throughout; and in (c)1, changed N.J.A.C. references throughout, and substituted a reference to West Group for a reference to the Office of Administrative Law at the end of ii.
Amended by R.2001 d.2, effective January 2, 2001.
See: 32 N.J.R. 3376(a), 33 N.J.R. 64(b).
Inserted (d) and (e); substituted "NJ KidCare/FamilyCare" for "NJ KidCare" throughout the section.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
In (b), inserted references to Appendix D in 2i and 3; substituted references to NJ FamilyCare and WFNJ for references to NJ KidCare throughout.

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 pharmacist's 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.

Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).

10:51–2.4 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. 10:51–2.10 and 2.11, respectively;

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

3. Pharmaceutical services requiring pharmacist intervention as part of the Medicaid/NJ FamilyCare prospective drug utilization review (PDUR) program (see N.J.A.C. 10:51–2.23);

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

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

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

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

8. 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 N.J.A.C. 8:71 (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);

9. Federal regulations (42 CFR 447.301, 331–334) 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);

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

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. 10:51–2.19);

12. For claims with service dates on or after July 1, 1998, all drugs prescribed for the treatment of impotency shall be limited to male beneficiaries over the age of 18 years and to four treatments per month; and

13. For claims with service dates on or after August 1, 1998, prescribers shall write "Diagnosis of Impotency" on the face of any prescription for impotency drugs. Claims for such prescriptions without this written statement shall be subject to recoupment by the State of New Jersey.

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
In (a), inserted a reference to NJ KidCare in 3, and changed CFR reference in 9.
Amended by R.2001 d.124, effective April 16, 2001.
See: 32 N.J.R. 4392(a), 33 N.J.R. 1201(a).
In (a)11, amended the N.J.A.C. reference; added (a)12 and (a)13.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a). 36 N.J.R. 558(a).
In (a), substituted reference to NJ FamilyCare for reference to NJ KidCare in 3, and amended N.J.A.C reference in 8i.

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 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;

10:51–2.8 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the Medicaid or NJ FamilyCare 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, aquaphor, eucerin cream, phenol, menthol, resorcinol, caffeine, talc, simple syrup, aromatic elixir distilled water, and glycerin.

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claims adjudication system approved by the Division. (See N.J.A.C. 10:51–2.22)

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

(c) Reimbursement for compounded prescriptions shall be based on the cumulative cost of the active ingredient(s), as described in N.J.A.C. 10:51–2.5, and/or pharmaceutical excipient(s).

(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 or NJ FamilyCare $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. 10:51–2.5, of the most costly active ingredient.

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

(g) 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 shall be among those covered by the Medicaid or NJ FamilyCare program. If a non-legend drug is not listed as covered in N.J.A.C. 10:51–2.10, the compounded prescription shall not be covered.

3. All legend ingredients which are contained in compounded prescriptions shall be among those covered by the Medicaid or NJ FamilyCare 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 shall not be covered.

4. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51–2.11 shall not be 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).
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
Inserted references to the NJ KidCare throughout; and in (b), substituted a reference to the Division for a reference to the Medicaid program.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
Rewrote (g) and substituted "NJ FamilyCare" for "NJ KidCare" throughout.

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 N.J.A.C. 8:71. 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.

Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
Inserted "N.J.A.C. 8:71" for "the DURC Formulary".

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 shall not be covered under the New Jersey Medicaid or NJ FamilyCare 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 and Senior Services.

(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;

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 and Senior Services.

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; and

4. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the Medicaid and NJ FamilyCare programs. (See N.J.A.C. 10:51–2.23)

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.
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
In (a) and (d), inserted references to NJ KidCare.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
In (a), substituted "shall not be covered" for "are not covered" following "drugs or conditions" in the introductory paragraph; and substituted "NJ FamilyCare" for "NJ KidCare" throughout.

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.