(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 KidCare 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 the current New Jersey Drug Utilization Review Council (DURC) Formulary (hereafter referred to as "the Formulary"), and all subsequent revisions, distributed to all prescribers and pharmacists; and

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

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

12. Drug Manufacturers' Rebate Agreement with the Health Care Financing Administration of the United States Department of Health and Human Services (see N.J.A.C. 10:51–1.22).

(b) If a prescription is not dispensed directly to the New Jersey Medicaid fee-for-service, NJ KidCare fee-for-service, or General Assistance (GA) beneficiary for whom the pre-

New Jersey State Library

scription was written, and the claim charge exceeds $150.00, the individual picking up the prescription shall present the Medicaid Identification Card, the NJ KidCare Identification Card or the authorized documentation confirming 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 KidCare 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).

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 KidCare 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).

3. Federal regulations (42 CFR 447.301, 331–334) set the aggregate upper limits on payment for certain covered drugs in the Medicaid and NJ KidCare—Plan A pharmaceutical programs. The Division applies the limits to NJ KidCare—Plan B and C. The Division refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. The provider's usual and customary charge for legend or non-legend drugs (see (c) below), contraceptive diaphragms and legend or non-legend devices.

(b) Payment for legend drugs is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). Appendix B is the listing of MAC drugs, and is hereby incorporated by reference.

1. Maximum allowable cost is defined as:

i. The MAC price for listed multi-source drugs published periodically by the Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services; or

ii. For legend drugs not included in (b)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid or NJ KidCare program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. For information about the "regression categories and discounts," see N.J.A.C. 10:51–1.6 and for usual and customary charge see N.J.A.C. 10:51–1.10.

3. If the published MAC price as defined in (b)1i above is higher than the maximum allowable cost which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

(c) The maximum charge to the New Jersey Medicaid or NJ KidCare program for drugs, including the charge for the cost of medication and the dispensing fee, shall not exceed the provider's usual and customary and/or posted or advertised charge.

(d) The maximum allowance for protein replacement supplements, specialized infant formulas and food oils under the New Jersey Medicaid and NJ KidCare programs is the lesser of:

1. The product's AWP plus 50 percent; or

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

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

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

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

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 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;

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 KidCare 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.

10:51–1.14 Services requiring prior authorization

(a) The provider shall obtain prior authorization, when required, by telephone or in writing, from the Medicaid District Office (MDO) professional staff or State contractor. 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 or State contractor 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 or State contractor is unavailable or prior authorization is not immediately available from the MDO or State contractor, the provider may dispense a total of six days supply.

ii. If the drug is to be continued beyond a six-day period, the provider shall hold the claim and obtain prior authorization for the balance of the prescription from the MDO or State contractor prior to dispensing.

(b) The following drugs and specific therapeutic drug 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 treatment of conditions approved by New Jersey State Board of Medical Examiners at N.J.A.C. 13:35–6.7; and

5. Any prescription claim for the same beneficiary, provided within the same calendar month, that exceeds the monthly prescription volume threshold of seven 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. Drugs otherwise requiring prior authorization in accordance with this subsection; and

iv. Drugs otherwise requiring prior authorization by the General Assistance 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.

10:51–1.15 Quantity of medication

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

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

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

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

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

Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).
Amended by R.1997 d.251, effective June 16, 1997.
See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).
In (a), inserted "For claims with service dates on or after July 15, 1996," and changed allowable supply to 34 days from 60 days; and recodified former (a)1 through 3 as (b) through (d).
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.

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;

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).
Recodified from N.J.A.C. 10:51–1.15 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. 10:51–1.16, Telephone-rendered original prescriptions, recodified to N.J.A.C. 10:51–1.17.
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.

10:51–1.17 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 or NJ KidCare programs.

(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.

Recodified from N.J.A.C. 10:51–1.16 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. 10:51–1.17, Changes or additions to the original prescription, recodified to N.J.A.C. 10:51–1.18.
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), inserted a reference to NJ KidCare.

10:51–1.18 Changes or additions to the original prescription

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

Recodified from N.J.A.C. 10:51–1.17 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. 10:51–1.18, Prescription refill, recodified to N.J.A.C. 10:51–1.19.
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.
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.

10:51–1.19 Prescription refill

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

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

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

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

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

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

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

Amended by R.1996 d.144, effective March 18, 1996.
See: 27 N.J.R. 3907(a), 28 N.J.R. 1524(a).
Amended by R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).
See: 27 N.J.R. 4566(a), 28 N.J.R. 1526(a).
Amended by R.1997 d.251, effective June 16, 1997.
See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).
In (a)2, inserted reference to telephone prescriptions; and deleted (a)2i, relating to an exception for oral contraceptives.
Recodified from N.J.A.C. 10:51–1.18 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. 10:51–1.19, Prescription Drug Price and Quality Stabilization Act, recodified to N.J.A.C. 10:51–1.20.
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.

Case Notes

Reimbursement for prescriptions filled one to three days early affirmed. Downtown Pharmacy, Inc., T/A Nick's Drugs v. Division of Medical Assistance and Health Services, 97 N.J.A.R.2d (DMA) 71.

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

10:51–1.20 Prescription Drug Price and Quality Stabilization Act

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

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription for a drug product listed in the DURC Formulary, the pharmacist shall substitute from the list of interchangeable products and bill Medicaid or NJ KidCare accordingly.

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

3. For non-MAC drugs (see N.J.A.C. 10:51–1.5) when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill Medicaid or NJ KidCare for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51–1.5) plus applicable dispensing fee or the usual and customary charge, whichever is less for that product (see Appendix D, Fiscal Agent Billing Supplement for instructions about the claim form and Appendix E regarding the proper EMC claim format).

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

(b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid or NJ KidCare–Plan A may reimburse for certain multi-source drugs. The limit shall apply to all listed MAC drugs (see Appendix B) unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone rendered prescription (see N.J.A.C. 10:51–1.9) the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten statement and does not permit the use of alternatives such as a check-off box, initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a handwritten statement "Do No Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E–1 does not apply to drugs which have a Federal MAC limit. The Division shall also apply these Federal requirements to NJ KidCare–Plans B and C.

(c) Blanket authorization denying substitutions shall not be permitted. Each prescription order shall state "Brand Medically Necessary" in the prescriber's own handwriting. For non-MAC drugs, each prescription order shall follow the requirements of N.J.S.A. 24:6E–1 et seq. (see (a) above).

(d) The dispenser must always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the stock package size used to fill the prescription.

(e) The "Brand Medically Necessary" requirement for MAC prescriptions shall not apply for Medicaid or NJ KidCare beneficiaries enrolled in a Medicaid or NJ KidCare participating Health Maintenance Organization (HMO).

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. 10:51–1.19 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. 10:51–1.20, Drug Efficacy Study Implementation (DESI), recodified to N.J.A.C. 10:51–1.21.
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 (a), inserted references to NJ KidCare throughout; in (b), inserted a reference to NJ KidCare-Plan A in the first sentence, and added the last sentence; and added (e).

10:51–1.21 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:

i. The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962;

ii. The drug product is available only through prescription;

iii. The drug product is the subject of a notice of opportunity for hearing issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and

iv. The drug product is at present the subject of an efficacy review study performed by FDA (see 21 CFR 310.6 including all subsequent amendments and supplements). The FDA efficacy review potentially can determine justification for a drug product's medical need. If a drug product fails this review, the product is classified as a DESI drug.

2. Reimbursement is not available for the purchase or administration of any drug product that is identical, related or similar, as defined in 21 CFR 310.6 (including all subsequent amendments and supplements), to a drug product that meets the conditions of (a) above.

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 KidCare 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 the current New Jersey Drug Utilization Review Council (DURC) Formulary (hereafter referred to as "the Formulary"), and all subsequent revisions, distributed to all prescribers and pharmacists; and

ii. Non-proprietary or generic dispensing (see N.J.A.C. 10:51–2.9);

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); and

11. Drug Manufacturers' Rebate Agreement with the Health Care Financing Administration of the United States Department of Health and Human Services (see N.J.A.C. 10:51–2.18).

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.

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;

2. Price information as supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The drug price or ingredient cost shall not exceed the lower of the average wholesale price as supplied by the reference drug file contractor; the provider's usual and customary charge; or the drug's Maximum Allowable Cost, if applicable (see (b) below);

i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meet the criteria specified in N.J.A.C. 10:51–2.10 (Covered pharmaceutical services).

3. Federal regulations (42 CFR 447.301, 331–334) that set the aggregate upper limits on payment for certain covered drugs in the pharmaceutical program. The New Jersey Medicaid and NJ KidCare programs refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. The provider's usual and customary charge for legend drugs (see (c) below), contraceptive diaphragms and legend devices.

(b) Payment for legend drugs, contraceptive diaphragms, and reimbursable legend devices, is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). See Appendix B for the listing of MAC drugs.

1. Maximum allowable cost is defined as:

i. The MAC price for listed multi-source drugs published periodically by the Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services; or

ii. For legend drugs not included in (b)1i above, the Estimated Acquisition Cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid or NJ KidCare program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. For information about discounts, see N.J.A.C. 10:51–2.6.

3. If the published MAC price as defined in (b)1i above is higher than the maximum allowable cost which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

(c) For claims with service dates on or after the July 15, 1996, the maximum cost for each eligible prescription claim not covered by the Maximum Allowable Cost price, as defined in N.J.A.C. 10:51–2.5(b)1i is based on the average wholesale price (AWP) of a drug, as defined in (b)1ii above, less a discount of 10 percent.

(d) The maximum charge to the New Jersey Medicaid program for pharmaceutical services provided in a nursing facility, including the drug cost and related capitation fee, shall be equal to the lower of:

1. MAC/EAC plus capitation fee, as described in N.J.A.C. 10:51–2.7; or

2. A provider's usual and customary charge for long-term care pharmacy services which is defined as the charge for legend drugs, including drug costs and related pharmaceutical services provided to non-Medicaid residents in the same facility, based on terms within the same contractual agreement with the facility.

(e) Providers of pharmaceutical services in nursing facilities are required, upon request by the Division of Medical Assistance and Health Services (DMAHS) or its authorized agent, to provide documentation supporting their usual and customary charges, including any relevant contracts and/or agreements related to similar services.

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), deleted reference to non-legend drugs; in (b)1ii, inserted "For legend drugs not included in (b)1i above," and ", minus regression category or discount"; deleted the first sentence of former (b)1ii(1) and recodified the remaining text as (b)2; recodified former (b)2 as (b)3; in (b)3, substituted "maximum allowable cost" for "average wholesale price"; and added (c).
Amended by R.1997 d.526, effective December 15, 1997.
See: 29 N.J.R. 2614(a), 29 N.J.R. 5323(a).
Added (d) and (e).

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)3, changed CFR reference, and inserted a reference to NJ KidCare; and in (b), inserted a reference to NJ KidCare in 1ii, and deleted a reference to regression categories in 2.

10:51–2.6 Discounts

For claims with service dates on or after July 15, 1996, the discount shall be 10 percent for each eligible prescription claim not covered by the Maximum allowable cost price.

Amended by R.1995 d.104, effective February 21, 1995.
See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).
Amended by R.1996 d.17, effective January 2, 1996.
See: 27 N.J.R. 3539(a), 28 N.J.R. 182(a).
In (b) distinguished between service dates prior to and after January 2, 1996.
Amended by R.1997 d.251, effective June 16, 1997.
See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).
In (a) and (b), inserted "For pharmaceutical services provided prior to July 15, 1996,"; and added (c).
Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
Deleted former (a) and (b).

10:51–2.7 Prescription dispensing fee (capitation)

(a) The New Jersey Medicaid and NJ KidCare programs capitate the dispensing fee for each prescription for beneficiaries in Medicaid-approved nursing facilities in accordance with the total number of Medicaid and NJ KidCare fee-for-service beneficiary days in the facility(ies) serviced by the pharmacy. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following levels of services: Pharmacies with institutional permits shall be reimbursed as defined in (a) above, except that the daily per beneficiary capitation fee shall be 75 percent of the fee for pharmacies with retail permits.

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

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

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

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

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

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System. The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

(c) In order to receive any or all of the above increments, the provider shall certify annually to the Division on Form FD–70, that the service(s) as defined in (a) above, are being provided and/or that the provider is entitled to the impact increment as defined in (a) above.

1. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the New Jersey Medicaid or NJ KidCare program determines that the provider was not entitled to reimbursement for them.

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

1. A copy of the agreement between the servicing pharmacy provider and the nursing facility (Appendix G, incorporated herein by reference);

2. The provider number of the servicing pharmacy;

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

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

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

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

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

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

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

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

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

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

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

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 reference to NJ KidCare.

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

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

10:51–2.16 Prescription refill

(a) Refills are not allowed.

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

10:51–2.17 Prescription Drug Price and Quality Stabilization Act

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

1. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription or in-patient medication order for a drug product listed in the DURC Formulary, the pharmacist shall substitute from the list of interchangeable products and bill Medicaid or NJ KidCare accordingly.

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

3. When a prescriber authorizes, in accordance with (b) below, the dispensing of a brand MAC drug, the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill Medicaid or NJ KidCare, as appropriate, for the prescriber product. Reimbursement will be the estimated acquisition cost (EAC) (see N.J.A.C. 10:51–2.5) plus applicable dispensing fee or the usual and customary charge, whichever is less for that product (See Appendix D, Fiscal Agent Billing Supplement for instructions about the claim

form and Appendix E regarding the proper EMC claim format).

4. When the prescriber orders by the generic name, the DURC Formulary (see N.J.A.C. 10:51–2.4) does not apply. The pharmacist shall dispense the least expensive, therapeutically effective product available to him or her at the time of dispensing. The product need not necessarily be from the list of interchangeable products.

(b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid or NJ KidCare–Plan A may reimburse for certain multi-source drugs. This limit shall also apply to NJ KidCare–Plans B and C. The limit shall apply to all listed MAC drugs (see Appendix B) unless the prescriber indicates in his or her own handwriting on each written prescription or in-patient medication order or follow-up written prescription or in-patient medication order to a telephone-rendered prescription or technologically transmitted, (for example, Fax) (see N.J.A.C. 10:51–2.9) the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten statement and does not permit the use of alternatives such as a check-off box, initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a hand written statement "Do Not Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E–1 does not apply to drugs which have a Federal MAC limit.

(c) Blanket authorization denying substitutions shall not be permitted. Each prescription or in-patient medication order shall state "Brand Medically Necessary" in the prescriber's own handwriting. For non-MAC drugs, each prescription order shall follow the requirements of N.J.S.A. 24:6E–1 et seq. (see (a) above).

(d) The dispenser must always report the actual labeler code and drug product code of the drug dispensed. The package size code reported may differ from the stock package size used to fill the prescription.

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 references to NJ KidCare throughout, and inserted a reference to NJ KidCare fee-for-service in 2; and in (b), inserted a reference to NJ KidCare Plan-A in the first sentence, and inserted a second sentence.

10:51–2.18 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:

i. The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962;

ii. The drug product is available only through prescription;

iii. The drug product is the subject of a notice of opportunity for hearing issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and

iv. The drug product is at present the subject of an efficacy review study performed by FDA (see 21 CFR 310.6 including all subsequent amendments and supplements). The FDA efficacy review potentially can determine justification for a drug product's medical need. If a drug product fails this review, the product is classified as a DESI drug.

2. Reimbursement is not available for the purchase or administration of any drug product that is identical, related or similar, as defined in 21 CFR 310.6 (including all subsequent amendments and supplements), to a drug product that meets the conditions of (a) above.

3. The initial list of drugs and related drug products classified as "less than effective" by the FDA pending outcome of the NOOH appears at 21 CFR 310.6. Subsequent revisions to this list which are adopted, shall appear in the Federal Register.

10:51–2.19 Drug manufacturers' rebate agreement

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

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

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.

10:51–2.20 Bundled drug service

(a) "Bundled drug service" means a drug or service that is marketed or distributed by the manufacturer or distributor as a combined package which includes in the cost the drug product and ancillary services such as, but not limited to, case management services and laboratory testing.