

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.

(f) For claims with service dates on or after July 15, 1996, the maximum cost for each eligible prescription claim not covered by the Maximum Allowable Cost price, as defined in (b)1i above, shall be based on the Average Wholesale Price (AWP) of a drug, as defined in (b)1ii above, less a discount of 10 percent.

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

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

In (b)1ii, inserted "For legend drugs not included in (b)1i above" and ", minus regression category or discount"; deleted the first sentence of former (b)1ii(1) and recodified the remaining text as (b)2; recodified former (b)2 as (b)3; in (b)3, substituted "maximum allowable cost" for "average wholesale price"; in (c), substituted "for drugs" for "for a legend drug" and deleted provision that the maximum charge not exceed the MAC price determined in (b)1 plus a dispensing fee if lower than the usual and customary/advertised or posted charge; in (d), substituted "for claims with service dates prior to July 15, 1996, shall be:" for "is:," and added (f) and (g).

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 (a), inserted "for both the Medicaid and NJ KidCare programs" at the end of the first sentence, and rewrote 3; deleted a former (d); and recodified former (e) through (g) as (d) through (f).

Case Notes

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

10:51-1.6 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).

Rewrote the section.

10:51-1.7 Prescription dispensing fee

(a) The dispensing fee for legend drugs, dispensed by providers having retail permits to beneficiaries other than those in long-term care facilities, including State operated Intermediate Care Facilities/Mentally Retarded (ICFs/MR), nursing facilities and State and county operated long-term psychiatric hospitals, is \$3.73. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following:

1. Twenty-Four Hour Emergency Service: \$0.11. The provider shall have a 24-hour per day, 365-days-per-year prescription service available and shall have provided

Medicaid or NJ KidCare beneficiaries opportunities to utilize this service.

2. Patient Consultation: \$0.08. In addition to routinely monitoring beneficiary profiles for drug interactions, contraindications, allergies, etc., the provider shall, where appropriate, discuss the course of drug therapy with the beneficiary. This discussion must include emphasis on compliance with the prescriber's orders; proper drug utilization; cautions about possible side effects; foods to avoid; proper drug storage conditions; and any other information that will prove beneficial to the beneficiary while on drug therapy.

3. Impact Area Location: \$0.15. The provider shall have a combined Medicaid, NJ KidCare, and PAAD prescription volume equal to or greater than 50 percent of the provider's total prescription volume.

i. The nursing facility prescription volume shall be included for the determination of total prescription volume in determining entitlement to the impact allowance.

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

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

1. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the Division determines that the provider was not entitled to reimbursement for them.

(d) Failure to submit this report annually shall result in retail pharmacy provider payments based on the basic dispensing fee of \$3.73.

Amended by R.1997 d.251, effective June 16, 1997.
See: 28 N.J.R. 2481(a), 28 N.J.R. 3221(a), 29 N.J.R. 2690(a).

Added (d).

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), rewrote the first sentence, and inserted references to NJ KidCare in 1 and 3; and in (c)1, substituted a reference to the Division for a reference to the New Jersey Medicaid program.

10:51-1.8 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the Medicaid and NJ KidCare programs. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and/or a pharmaceutical

excipient or excipients and are dispensed by approved pharmacy providers.

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

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claims adjudication system approved by the Division. (See N.J.A.C. 10:51-1.25).

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

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

1. The cumulative cost of the active ingredient(s), as described in N.J.A.C. 10:51-1.5, and/or pharmaceutical excipient(s), plus a dispensing fee, as described in N.J.A.C. 10:51-1.7; or

2. A provider's usual and customary charge.

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

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

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

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

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

(f) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 10:51-1.15.

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

1. All legend and nonlegend (OTC) ingredients which are contained in compounded prescriptions must be covered by a manufacturer rebate agreement (see N.J.A.C. 10:51-1.22). If the labeler code of any single ingredient is not manufactured by an approved manufacturer, the compounded prescription is not covered. Chemical ingredients without NDC codes are excluded.

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

3. All legend ingredients which are contained in compounded prescriptions must be covered by the Medicaid or NJ KidCare fee-for-service programs. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 10:51-1.21) drug, the compounded prescription is not covered.

4. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 10:51-1.13 are not covered.

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

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

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 (b), (f) and (g), 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).

Inserted references to NJ KidCare throughout; in (b), substituted a reference to the Division for a reference to the Medicaid program in the introductory paragraph; and deleted former (g)2i

10:51-1.9 Non-proprietary or generic dispensing

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

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

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

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

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

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

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 references to NJ KidCare throughout.

10:51-1.11 Covered pharmaceutical services

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

(b) Covered pharmaceutical services include:

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

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

- i. Contraceptive devices and contraceptive supplies (such as diaphragms, jellies, foams and condoms);
- ii. Over-the-counter, family planning supplies (such as pregnancy test kits);
- iii. Pharmaceutical inhalation devices;
- iv. Diabetic testing materials;
- v. Insulin needles and/or syringes;
- vi. Insulin; and
- vii. Antacids.

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

- i. Analgesics, Salicylates;

ii. Analgesics/Antipyretics, Non-salicylate;

iii. Antidiarrheals;

iv. Anti-Emetics;

v. Antiflatulents;

vi. Antihistamines;

vii. Antipruritics;

viii. Antitussives, non-narcotic;

ix. Cathartics;

x. Cough and cold preparations;

xi. Decongestants

xii. Emetics;

xiii. Expectorants;

xiv. Hematinics;

xv. Iron replacement supplements;

xvi. Laxatives;

xvii. Lice treatment products;

xviii. Multiple vitamin preparations;

xix. Oral anti-inflammatory agents;

xx. Pediatric vitamin preparations;

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

xxii. Polymixin and derivatives;

xxiii. Topical preparations, antibacterial;

xxiv. Topical antibiotics; and

xxv. Topical anti-inflammatory preparations.

(c) For beneficiaries in the Medically Needy component of the New Jersey Care ... Special Medicaid programs, pharmaceutical services are available to pregnant women, dependent children and aged, blind or disabled Medically Needy beneficiaries residing in nursing facilities. For information on how to identify a Medicaid beneficiary, see N.J.A.C. 10:49, Administration.

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

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

In (b) added 3.

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).

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

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

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

(d) The copayment for prescription drugs under NJ KidCare-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).

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 KidCare/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 anorexiant, 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/m² and less than 30 kg/m² with co-morbidities of hypertension, diabetes or dyslipidemia; and obese individuals with a BMI equal to or greater than 30 kg/m² 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 supplies; 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 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 (CPCs) 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 Kid-Care 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.

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, online, 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. An orexiants and antiobesics when used for 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 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, antihemophilic 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.

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.

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 for initial prescriptions and 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).

(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) For claims with service dates on or after July 1, 1999, the pharmacist shall dispense the least expensive, therapeutically effective nutritional supplement or specialized infant formula, at the time of dispensing, unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone rendered prescription the phrase "Brand Medically Necessary."

(e) 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.

(f) 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).

Amended by R.2001 d.124, effective April 16, 2001.

See: 32 N.J.R. 4392(a), 33 N.J.R. 1201(a).

Added new (d) and recodified former (d) and (e) as (e) and (f).

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.

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.

Recodified from N.J.A.C. 10:51-1.20 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. 10:51-1.21, Drug manufacturers' rebate agreement, recodified to N.J.A.C. 10:51-1.22.

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

10:51-1.22 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 1927 et seq. of the Social Security Act (42 U.S.C. § 1396r-8(i)).

(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.

Recodified from N.J.A.C. 10:51-1.21 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. 10:51-1.22, Bundled drug service, recodified to N.J.A.C. 10:51-1.23.

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 a reference to NJ KidCare, and deleted OBRA reference.

10:51-1.23 Bundled drug service

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

(b) Bundled drug service shall not be eligible for reimbursement by the New Jersey Medicaid or NJ KidCare program.

1. This provision may be waived at the discretion of the Commissioner if he or she determines that a bundled

drug service is less than or equal to the total cost of the unbundled components if reimbursed separately; or

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

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

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

(c) In order to determine eligibility for reimbursement, manufacturers or distributors of a bundled drug service shall submit complete product information, including the cost to the programs of the total bundled drug service, discrete costs of each component of the bundled drug service, cost benefit analyses, and other information as requested by the Department, to the Chief Pharmaceutical Consultant, Division of Medical Assistance and Health Services, Mail Code #20, PO Box 712, Trenton, New Jersey 08625-0712.

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

Medical Director

Division of Medical Assistance and Health Services

Mail Code #14

PO Box 712

Trenton, NJ 08625-0712

Recodified from N.J.A.C. 10:51-1.22 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. 10:51-1.23, Claim submission, recodified to N.J.A.C. 10:51-1.24.

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 references to NJ KidCare throughout.

10:51-1.24 Claim submission

(a) An approved pharmacy provider may choose to:

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

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

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

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

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

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

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

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

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

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

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

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

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

Repeal and New Rule, R.1995 d.104, effective February 21, 1995.

See: 26 N.J.R. 4136(a), 27 N.J.R. 684(a).

Formerly "EMC Incentive Program".

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

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

Recodified from N.J.A.C. 10:51-1.23 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. 10:51-1.24, Point-of-sale (POS) claims adjudication system, recodified to N.J.A.C. 10:51-1.25.

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)2i and (b)1 inserted references to NJ KidCare; and in (b)3, inserted a reference to NJ KidCare fee-for-service.

Case Notes

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

10:51-1.25 Point-of-sale (POS) claims adjudication system

(a) Medicaid or NJ KidCare fee-for-service pharmacy claims may be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real time. The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette and paper claims. The pharmacist would be required to enter pharmacy claim detail data into a computer or POS device and transmit this data to the fiscal agent over a dedicated telephone line. Regardless of the method of claim submission, all claims will go through all New Jersey Medicaid Management Information System (NJMMIS) claims processing edits and the claims will be processed to determine their payment disposition (for example, paid or denied).

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

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

Division of Medical Assistance and Health Services
Office of Information Systems
Mail Code #4
PO Box 712
Trenton, New Jersey 08625-0712
Telephone: (609) 588-2802

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

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

- i. The applicant's general approach and plans to meet the requirements of the POS project;
- ii. The applicant's detailed approach and plans to meet the requirements of the POS project;
- iii. The applicant's documented qualifications, expertise, and experience on similar projects;
- iv. The applicant's proposed staff's documented qualifications, expertise, and experience on similar projects; and
- v. The applicant's adherence to the requirements of the Health Care Financing Administration.

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

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

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

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

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

1. The first five alpha characters of the last name and the first three alpha characters of the Medicaid or NJ KidCare beneficiary's first name;
2. The 12-digit Medicaid or NJ KidCare identification number;
3. The date of birth, if applicable;
4. The date of service or dispense date;
5. The pharmacy prescription number;
6. The actual 11 digit National Drug Code (NDC) of the drug dispensed;
7. The metric quantity dispensed;
8. The days supply;
9. The prescriber's Medicaid or NJ KidCare provider service number;
10. The third party payment, if applicable;
11. The provider's usual and customary charge; and
12. The pharmacy provider number.

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

1. The medical certification indicator;
2. The nursing facility residency indicator;
3. The Medicaid or NJ KidCare prior authorization number, if applicable;
4. The compound drug indicator;
5. The other insurance indicator, if applicable; and
6. The carrier code(s), if applicable.

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

(i) Pharmacy software must have the capability to display on-line adjudicated claim data returned to the pharmacy by the fiscal agent, including:

1. Payment disposition;
2. Error code message; and
3. Claim pricing data, including drug cost reimbursement, dispensing fee and applicable copayment amounts.

(j) Pharmacy software must provide the pharmacy with the capability of claim reversal and resubmission, if required.

1. A pharmacy may initiate a claim reversal of a previously submitted pharmacy claim for a period of 12 months from the initial date of claim service.

2. Pharmacies are required to initiate claim reversals for those services in which a claim was generated and adjudicated to payment by the fiscal agent's POS computer and the service was not subsequently provided to a Medicaid or NJ KidCare fee-for-service beneficiary.

3. All prescriptions adjudicated to payment by the fiscal agent's computer shall be subsequently dispensed and their receipt by Medicaid or NJ KidCare fee-for-service beneficiaries properly documented on a Medicaid/NJ KidCare-approved certification statement/signature log. (see N.J.A.C. 10:49-9.6).

(k) Pharmacies are required to interact with prescribers and/or beneficiaries at POS to resolve matters related to on-line messages resulting from claim adjudication by the fiscal agent.

(l) The following shall apply for coverage of prescriptions when provided to Medicaid, NJ KidCare or General Assistance (GA) beneficiaries during an interruption in POS service:

1. The quantity of prescription drug dispensed shall not exceed a five-day supply. The State will reimburse providers for an entire pharmaceutical package when the package cannot be "broken" to provide a five-day supply.

2. Pharmacists shall confirm Medicaid, NJ KidCare or GA program eligibility by reviewing the respective eligibility card/letter, or by contacting the Recipient Eligibility Verification System (REVS) at 1-800-676-6562. If eligibility cannot be confirmed, pharmacists should follow the "good faith" guidelines as described in N.J.A.C. 10:49-2.10.

3. Pharmacies may transmit claims for services provided during the service interruption to the fiscal agent in a batch environment after POS service has resumed. These claims should be submitted during off-peak hours. As an alternative, the claims may be submitted via tape, diskette on modem using the EMC format.

4. Pharmacies may experience denied claims for a duplicate claim or an early refill provided by a different pharmacy. A properly completed paper claim (MC-6) shall be submitted to the fiscal agent for payment consideration (see Appendix D, Fiscal Agent Billing Supplement for additional information). Claims with quantities exceeding a five-day supply will be denied payment by the State.

New Rule, R.1996 d.146, effective March 18, 1996 (operative April 1, 1996).

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

Recodified from N.J.A.C. 10:51-1.24 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. 10:51-1.25, Prospective drug utilization review (PDUR) program, recodified to N.J.A.C. 10:51-1.26.

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).

Inserted references to NJ KidCare throughout; in (a) and (j), inserted references to NJ KidCare fee-for-service throughout; in (c), substituted a reference to the Division for a reference to the New Jersey Medicaid program; in (g), deleted a former 4, and recodified former 5 through 7 as 4 through 6; in (h), substituted a reference to the Division for a reference to the Medicaid program; and added (l).

10:51-1.26 Prospective drug utilization review (PDUR) program

(a) The Division of Medical Assistance and Health Services has established a prospective drug utilization review (PDUR) program to assist pharmacy providers with monitoring drug utilization by Medicaid and NJ KidCare fee-for-service beneficiaries. As a component of the Medicaid/NJ KidCare point-of-sale (POS) claims adjudication system, the State's fiscal agent will review drug utilization based on claims submitted on-line and provide pharmacists with responses in real-time regarding utilization within PDUR standards recommended by the New Jersey Drug Utilization Review (DUR) Board, and approved by the Commissioner of the Department of Human Services (DHS) and the Commissioner of the Department of Health and Senior Services (DHSS). Similar responses related to EMC or paper claims processed by the New Jersey Medicaid Management Information System (NJMMIS) shall be received by pharmacies on the Remittance Advice statement.

1. PDUR standards recommended by the New Jersey DUR Board and approved by the Commissioners of the DHS and DHSS shall be based on standards in official compendia and accepted medical literature as included in those established by First Data Bank (FDB) as part of the FDB DUR information system. The FDB standards are incorporated herein by reference and may be obtained from First Data Bank, The Hearst Corp., 1111 Bayhill Dr., San Bruno, CA 94066.

2. PDUR standards recommended by the New Jersey Drug Utilization Review (DUR) Board and approved by the Commissioners of DHS and DHSS shall be applied to all pharmacy claims, regardless of mode of claim submission.

(b) POS participating pharmacy providers shall be required to meet the conditions described in N.J.A.C. 10:51-1.25.

(c) In addition to POS responses related to adjudication of Medicaid or NJ KidCare fee-for-service pharmacy claims returned to the pharmacy, pharmacists shall be notified regarding drug utilization inconsistent with adopted PDUR standards which may include, but not be limited to: