

1. Drug interactions;
2. Maximum/minimum daily dosage alerts;
3. Therapeutic duplication;
4. Drug age conflicts;
5. Duration of therapy;
6. Drug-disease precautions; and
7. Drug-pregnancy precautions.

(d) The PDUR program may apply adopted standards based on a severity index recommended by the New Jersey DUR Board to determine appropriate pharmacist intervention and/or claim disposition (that is, payment or denial) of Medicaid and NJ KidCare fee-for-service pharmacy claims. (See N.J.A.C. 10:51-1.27)

(e) Based on the severity of a potential PDUR conflict or interaction, pharmacists shall be required to consult with the beneficiary and/or prescriber to resolve matters indicated by PDUR messages returned by the POS system.

(f) The pharmacists intervention requirements related to the PDUR program are in addition to beneficiary interactions related to the "offer to consult" as described in N.J.A.C. 13:39-7.14, Patient profile record system.

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. 10:51-1.25 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 (b), substituted a reference to N.J.A.C. 10:51-1.25 for a reference 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).

Inserted references to NJ KidCare throughout; and in (a), inserted a reference to NJ KidCare fee-for-service.

Amended by R.1999 d.232, effective July 19, 1999 (operative September 1, 1999).

See: 31 N.J.R. 245(a), 31 N.J.R. 1956(a).

Rewrote (a); in (c), inserted "fee-for-service" following "KidCare" in the introductory paragraph, and rewrote 5; and in (d), substituted "recommended by the New Jersey" for "approved by the Medicaid" following "index", inserted "fee-for-service" following "KidCare", and added N.J.A.C. reference at the end.

10:51-1.27 Medical exception process (MEP)

(a) For pharmacy claims with service dates on or after September 1, 1999, which exceed PDUR standards recommended by the New Jersey DUR Board and approved by the Commissioners of DHS and DHSS, the Division of Medical Assistance and Health Services has established a medical exception process (MEP) for Medicaid and NJ KidCare fee-for-service pharmaceutical services.

(b) The medical exception process shall be administered by a contractor, referred to as the MEP contractor, under contract with the Department of Human Services (DHS).

(c) The medical exception process shall apply to all pharmacy claims, regardless of claim media, unless exempted by the New Jersey DUR Board and the Commissioners of DHS and DHSS in accordance with the rules of those Departments.

(d) The medical exception process is as follows:

1. Pharmacy providers shall be notified when submitting a claim that a prescription is limited to a maximum 30-day supply.

2. The pharmacy shall be responsible to contact the MEP contractor to decide if a medical exception is needed. If an exception is needed, the pharmacist may dispense medication for up to a 30-day calendar period. During this period, the MEP contractor shall issue a Prescriber Notification Letter which may include, but is not limited to, requesting from the prescriber the reason for the medical exception, diagnosis, expected duration of therapy, and the expiration date for the medical exception.

3. Following review and approval, if appropriate, of a prescriber's written justification, the MEP contractor shall override existing PDUR edits through the issuance of a prior authorization number.

4. The MEP contractor shall notify the pharmacy and prescriber of the results of the review by the close of the 30-day calendar period, and shall include, at a minimum, the beneficiary's name, mailing address, HSP number, the reviewer, service description, service date, and prior authorization number, if approved, the length of the approval and the appeals process if the pharmacist does not agree with the results of the review.

5. Pharmacies may request a fair hearing to appeal decisions rendered by the MEP contractor concerning denied claims (see N.J.A.C. 10:49-10, Notices, Appeals and Fair Hearings.)

6. Claims subject to the medical exception process which have exhausted the 30-day allowance period and for which prior authorization has not been issued by the MEP contractor shall be denied payment by the Medicaid/NJ KidCare programs.

New Rule, R.1999 d.232, effective July 19, 1999 (operative September 1, 1999).

See: 31 N.J.R. 245(a), 31 N.J.R. 1956(a).

SUBCHAPTER 2. PHARMACEUTICAL SERVICES TO MEDICAID OR NJ KIDCARE FEE-FOR-SERVICES BENEFICIARIES IN A NURSING FACILITY

10:51-2.1 Introduction

This subchapter provides information about the provision of reimbursable pharmaceutical services provided to Medic-

aid or NJ KidCare fee-for-service beneficiaries in Medicaid approved nursing facilities.

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

Inserted a reference to NJ KidCare fee-for-service.

10:51-2.2 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the Medicaid and NJ KidCare programs as a provider of pharmaceutical services, and as a provider of parenteral nutrition or intravenous therapy. The requirements for approval as a provider of pharmaceutical services are listed in (b) and (c) below.

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

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey or by the board of pharmacy of the state in which the pharmacy is located. A pharmacy operating under an out-of-State institutional permit may not participate as an approved provider in the New Jersey Medicaid or NJ KidCare program; and

2. File an application and sign an agreement with the Division of Medical Assistance and Health Services.

- i. Upon sale or other change of ownership of an approved pharmacy, the agreement is automatically terminated. To execute a new agreement to participate in the New Jersey Medicaid and NJ KidCare programs, the new owner(s) shall apply to the Division of Medical Assistance and Health Services, Department of Human Services, by contacting the Provider Enrollment Unit. (see N.J.A.C. 10:49—Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit. (see Appendix D, Fiscal Agent Billing Supplement).

3. To enroll as a Medicaid and NJ KidCare provider of pharmaceutical services, a pharmacy shall contact the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

(c) Requirements for approval as a provider of parenteral nutrition and/or intravenous therapy are as follows:

1. In addition to the requirements for approval as a pharmacy provider listed under (b) above, a pharmacy which supplies parenteral nutrition and/or intravenous therapy shall:

- i. Comply with all the requirements of N.J.A.C. 13:39; or

- ii. Comply with similar applicable requirements of the state in which the applicant is located and submit a copy of the requirements of that state when applying for participation. A copy of N.J.A.C. 13:39 is available from West Group at 1-800-808-WEST.

2. Parenteral nutrition and/or intravenous therapy may be provided by either a pharmacy/medical supplier or a medical supplier approved to provide these services by the New Jersey Medicaid or NJ KidCare program; however, billing for the ancillary supplies associated with parenteral nutrition and/or intravenous therapy are subject to the requirements of the Medical Supplier Chapter, N.J.A.C. 10:59.

- i. "Ancillary supplies" means medical supplies and/or durable medical equipment which are medically necessary to facilitate administration of parenteral or intravenous therapy.

Amended by R.1998 d.488, effective September 21, 1998.

See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).

Inserted references to NJ KidCare throughout; and in (c)1, changed N.J.A.C. references throughout, and substituted a reference to West Group for a reference to the Office of Administrative Law at the end of ii.

10:51-2.3 Conditions for participation as a provider of pharmaceutical services

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

(b) All drugs must be prescribed.

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

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

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

- iii. Dispensed by licensed pharmacists on the basis of a written prescription and/or in-patient medication order that is recorded and maintained in the pharmacist's records.

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

1. Inspect written prescriptions and/or in-patient medication orders on file;

2. Audit records pertaining to covered persons;

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

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

- (1) Drug name;
- (2) Quantity dispensed;
- (3) Price;
- (4) Prescription number (for reference purposes only); and
- (5) Date dispensed; and

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

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

10:51-2.4 Program restrictions affecting payment of prescribed drugs

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

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 10:51-2.10 and 2.11, respectively;
2. Quantity of medication (see N.J.A.C. 10:51-2.12);
3. Pharmaceutical services requiring pharmacist intervention as part of the Medicaid/NJ 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