

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.

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

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

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

Inserted references to NJ KidCare throughout; in (b)2i and (c)1, deleted "Medicaid" preceding "Provider"; in (c), deleted "Medicaid" preceding "fiscal agent" in the introductory paragraph; and in (d)1, rewrote i and ii.

Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).

Substituted "NJ FamilyCare" for "NJ KidCare" throughout.
Amended by R.2007 d.238, effective August 6, 2007.
See: 39 N.J.R. 1388(a), 39 N.J.R. 3377(a).

Rewrote the section.
Amended by R.2008 d.277, effective September 15, 2008.
See: 40 N.J.R. 2186(a), 40 N.J.R. 5238(a).

Deleted former (a); recodified former (b) through (f) as new (a) through (e); in (a), deleted the former second sentence and substituted "(b) through (d)" for "(c) through (e)"; in the introductory paragraph of (d), substituted "may also apply to the Division" for "that wishes", deleted ", is subject to the moratorium in effect July 1, 2006" following the first occurrence of "supplier", and deleted the former second sentence.

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

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

(b) All drugs must be prescribed.

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

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

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

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

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

1. Inspect written prescriptions on file;
2. Audit records pertaining to covered persons;
3. Inspect private sector records, where deemed necessary to comply with the Federal regulations to determine a pharmacy's usual and customary charge to the public;

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

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

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

- (1) Payment vouchers;
- (2) Contracts; and
- (3) Agreements; and

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

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

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

1. Covered and noncovered pharmaceutical services as listed in N.J.A.C. 10:51-1.11 and 1.13, respectively;
2. Pharmaceutical service requiring prior authorization (see N.J.A.C. 10:51-1.14);

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

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

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

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

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

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

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

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

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

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

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

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

(b) On and after July 1, 2006, payments for erectile dysfunction drugs shall be limited to four treatments per month for male beneficiaries over the age of 18 who have a diagnosis of erectile dysfunction and who are not registered on New Jersey's Sex Offender Registry.