CHAPTER 51

PHARMACEUTICAL SERVICES MANUAL

Authority

N.J.S.A. 30:4D-6, 7 and 12.

Source and Effective Date

R.2004 d.26, effective December 16, 2003.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).

Chapter Expiration Date

Chapter 51, Pharmaceutical Services Manual, expires on December 16, 2008.

Chapter Historical Note

Chapter 51, Pharmacy Manual, was adopted as R.1971 d.29, effective March 5, 1971. See: 3 N.J.R. 25(a), 3 N.J.R. 62(b).

Pursuant to Executive Order No. 66(1978), Chapter 51, Pharmacy Manual, was readopted as R.1985 d.594, effective October 28, 1985. See: 17 N.J.R. 2223(a), 17 N.J.R. 2772(a).

Pursuant to Executive Order No. 66(1978), Chapter 51, Pharmaceutical Services Manual, was readopted as R.1990 d.530, effective October 9, 1990. See: 22 N.J.R. 2217(a), 22 N.J.R. 3372(a).

Chapter 51, Pharmaceutical Services Manual, was repealed and a new Chapter 51, Pharmaceutical Services Manual, was adopted by R.1993 d.434, effective September 7, 1993. See: 24 N.J.R. 3053(a), 25 N.J.R. 4082(a).

Pursuant to Executive Order No. 66(1978), Chapter 51, Pharmaceutical Services Manual, was readopted as R.1998 d.488, effective August 28, 1998. See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).

Subchapter 4, Pharmaceutical Assistance to the Aged and Disabled (PAAD), was recodified as N.J.A.C. 8:83C by R.1998 d.464, effective September 8, 1998. See: 30 N.J.R. 2197(a), 30 N.J.R. 3309(a).

Chapter 51, Pharmaceutical Services Manual, was readopted as R.2004 d.26, effective December 16, 2003. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 1. PHARMACEUTICAL SERVICES

10:51-1.1 Introduction

(a) This chapter provides information about the provision of pharmaceutical services under the New Jersey Medicaid program and NJ FamilyCare program. It is divided into three subchapters.

1. N.J.A.C. 10:51-1 provides a pharmacy operating under a retail permit with the policies and procedures relevant to the provision of services to New Jersey Medicaid and NJ FamilyCare fee-for-service beneficiaries, excluding those residing in a nursing facility.

2. N.J.A.C. 10:51-2 pertains to a pharmacy providing pharmaceutical services to Medicaid beneficiaries in a nursing facility.

3. N.J.A.C. 10:51-3 explains the responsibility of a pharmacist acting as a consultant in a nursing facility or other public medical institution.

(b) Incorporated by reference into this chapter as Appendix D is the Fiscal Agent Billing Supplement that provides information about claim processing and related activities.

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), substituted references to the NJ KidCare program for references to the Pharmaceutical Assistance to the Age and Disabled program in the introductory paragraph, inserted a reference to NJ KidCare fee-for-service beneficiaries in 1, and deleted a former 4.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
In (a), substituted "NJ FamilyCare" for "NJ KidCare" throughout.

10:51-1.2 Participation of eligible providers

(a) Effective July 1, 2006, P.L. 2006, c. 45 requires the Division to institute a moratorium on new Medicaid/NJ FamilyCare providers of, among other services, pharmaceutical services.

1. Any provider that was not an approved Medicaid or NJ FamilyCare fee-for-service provider of pharmaceutical services prior to July 1, 2006 is ineligible to become an approved fee-for-service provider of such services for Medicaid or NJ FamilyCare, unless the Division determines that the provider meets the special needs criteria established by the Division.

2. Special needs criteria for pharmacy provider applicants are as follows:

i. Sufficient access analysis: Using geo-accessing, the Division will determine whether the beneficiaries living in an area in which the provider is located, or intends to locate, have sufficient access to the Medicaid or NJ FamilyCare-covered service that the provider intends to offer. For example, if a mileage standard for a service is one provider in five miles or two providers in 10 miles, sufficient access exists under the moratorium for that service when a beneficiary has access to a minimum of one participating provider within five miles or two participating providers within 10 miles of the beneficiary's residence. Mileage standards are set forth below:

Miles per One Provider-Urban	Miles per Two Providers-Urban	Miles per One Provider-Non urban	Miles per Two Providers-Non urban
5 Miles	10 Miles	12 Miles	15 Miles

ii. Special needs analysis: After the Division performs a sufficient access analysis, the Division will perform a special needs analysis utilizing the following criteria:

(1) The number of beneficiaries in the area in question who may have special needs;

(2) Capacity limits and service offerings of existing providers and the provider applicant;

(3) The provider applicant's number of personnel who speak a language other than English, which is culturally appropriate to the local community;

(4) The provider applicant's availability, as revealed in its proposed minimum and maximum hours of service, including whether the provider will offer a level of service not currently available, such as a 24-hour access system, emergency services and home delivery of services;

(5) Whether the provider applicant is a specialty pharmacy deemed by DMAHS to fill a need for specific prescription drugs that would not otherwise be filled; and

(6) In the case of an institutional provider (for example, an existing long-term care pharmacy), whether the provider meets the criteria at N.J.A.C. 10:51-2.2(a)1.

3. Situations not subject to the moratorium for fee-for-service providers of pharmacy services are as follows:

i. A change of ownership only;

ii. A change of location only: A provider that has not changed ownership on or after July 1, 2006, which changes location on or after July 1, 2006, and continues to operate as a Medicaid or NJ FamilyCare provider at the new location, continues to provide the same level of services and delivery and meets all applicable State and Federal rules and regulations; and

iii. Medicare as the primary payer: Situations in which Medicare is the primary payer and the provider bills for cross-over claims and wraparound Medicare Part D payments.

prior to July 1, 2006 is ineligible to become an approved provider for Medicaid or NJ FamilyCare payments, unless the applicant's services as a new provider are deemed necessary to meet the special needs criteria in (a)1 below as determined by the Division.

1. The special needs criteria for new institutional provider applicants are contained in (a)1i and ii below. The provisions of N.J.A.C. 10:51-1.2(a)2i and ii(1) to (5) are not applicable to such applicants.

i. A provider that is selected to provide institutional pharmaceutical services to a facility that is a newly licensed institution, or a replacement provider that shall provide identical services to an existing licensed institution, shall be approved for participation under the moratorium if the provider provides a level of services acceptable to the Department of Health and Senior Services and complies with all applicable State and Federal rules and regulations.

ii. Institutional providers of pharmaceutical services may be approved as providers of medical supply services for the purpose of billing Medicare Part B for covered medical supply services and Medicare Part D services.

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

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

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

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

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

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

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

i. Comply with all the requirements of N.J.A.C. 13:39 (providers may view or print a copy of N.J.A.C. 13:39 by accessing the LexisNexis website at www.LexisNexis.com/njoal); 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.

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

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

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

Amended by R.1998 d.488, effective September 21, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).
Inserted references to NJ KidCare throughout; and in (c)1, changed N.J.A.C. references throughout, and substituted a reference to West Group for a reference to the Office of Administrative Law at the end of ii.
Amended by R.2001 d.2, effective January 2, 2001.
See: 32 N.J.R. 3376(a), 33 N.J.R. 64(b).
Inserted (d) and (e); substituted "NJ KidCare/FamilyCare" for "NJ KidCare" throughout the section.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
In (b), inserted references to Appendix D in 2i and 3; substituted references to NJ FamilyCare and WFNJ for references to NJ KidCare throughout.
Amended by R.2007 d.238, effective August 6, 2007.
See: 39 N.J.R. 1388(a), 39 N.J.R. 3377(a).
Rewrote (a); in (c)1, substituted "that" for "which"; in (c)1i, inserted "(providers may view or print a copy of N.J.A.C. 13:39 by accessing the LexisNexis website at www.LexisNexis.com/njoal)"; in (c)1ii, deleted the last sentence; deleted (d); and recodified (e) as (d).

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. Funding may be denied if the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 10:51-2.10 and 2.11, respectively;

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

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

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

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

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

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

8. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 10:51-2.17);

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

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

9. Federal regulations (42 CFR 447.301, 331-334) that set the aggregate upper limits on payment for certain multisource 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 Manufacturer's Rebate Agreement with the Health Care Financing Administration of the United States Department of Health and Human Services (see N.J.A.C. 10:51-2.19).

(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.

1. The face of the prescription shall contain the statement "Diagnosis of erectile dysfunction," written by the prescriber.

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

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

In (a), substituted reference to NJ FamilyCare for reference to NJ KidCare in 3, and amended N.J.A.C reference in 8i.
Amended by R.2007 d.109, effective April 16, 2007.
See: 38 N.J.R. 5304(a), 39 N.J.R. 1485(a).

In (a)10, inserted "and" at the end; in (a)11, substituted a period for the semicolon at the end; deleted (a)12 and (a)13; and added (b).

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;