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Chapter 51, Pharmaceutical Services Manual, was repealed and a new Chapter 51, Pharmaceutical Services Manual, was adopted by R.1993 d.434, effective September 7, 1993.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.

Case Notes

Out-of-state applicant could not be deemed an institutional pharmacy because: (1) the applicant's Wisconsin license stated only that it was a "pharmacy" and did not further describe the licensee as either retail or institutional; (2) the Justice Department registration recognized petitioner as a retail pharmacy; (3) an "institutional pharmacy" under New Jersey regulations must be within a healthcare facility or system licensed as such by the Board; and (4) the New Jersey regulations also state that the term "pharmacy" standing alone indicates a retail pharmacy. Because the applicant was not deemed an institutional pharmacy, its authorization as a Medicaid provider was not proscribed under N.J.A.C. 10:51-2.2(b)1. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

New Jersey Division of Medical Assistance and Health Services' policy of not authorizing out-of-state pharmacies that service in-state affiliated facilities was an unwarranted expansion of the clear language of the regulations. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

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.

4. A pharmacy provider that meets the special needs criteria in (a)2 above is not automatically approved as a provider of medical supply services. Licensed pharmacies are required to file a separate provider application to request participation as a provider of medical supply services and will be subject to the special needs criteria for new medical supply providers pursuant to N.J.A.C. 10:59-1.3(a)2.

(b) A pharmacy, with a retail or institutional permit, may apply to participate in the Medicaid or NJ FamilyCare program as a provider of pharmaceutical services and/or as a medical supplier providing medical supplies and durable medical equipment and/or as a provider of parenteral nutrition and/or intravenous therapy. Only those applications to provide services determined by the Division of Medical Assistance and Health Services to meet the special needs criteria will be approved. The requirements for approval as a provider of these services are listed in (c) through (e) below.

(c) 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. However, an application for approval as a retail pharmacy submitted by a pharmacy operating under an out-of-State institutional permit will be denied; a pharmacy operating under an out-of-State institutional permit and applying for approval as a retail pharmacy 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).

(d) 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).

(e) A pharmacy that wishes to participate as a medical supplier, is subject to the moratorium in effect July 1, 2006. Only those applications for services determined by the Division of Medical Assistance and Health Services to meet the special needs criteria will be approved. The Medical Supplier chapter, N.J.A.C. 10:59, available from the fiscal agent, provides information concerning the provision of and reimbursement for covered medical supplies and durable medical equipment provided by a medical supplier.

1. A pharmacy may apply to participate as a medical supplier 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).

(f) 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 in this section, a pharmacy who 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 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.

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 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. 10:51-1.5, 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.

i. "Sustained interruption" means the period of time that POS service has been interrupted during which the Division of Medical Assistance and Health Services has notified pharmacies by fax and/or email of a sustained interruption in the POS system.

ii. "Brief interruption" means the period of time that POS service has been interrupted during which the Division of Medical Assistance and Health Services has not notified the pharmacies that the interruption is sustained.

5. The Division of Medical Assistance and Health Services will reimburse pharmacies for early prescription refills and duplicate prescriptions provided by another pharmacy during a sustained interruption in POS service.

6. After POS service is restored, pharmacies should submit claims which could not be processed during the interruption in POS service during off-peak hours. This will allow all pharmacies to receive timely responses to routine claims submitted immediately after service has been restored.

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*).
Amended by R.2003 d.131, effective March 17, 2003.
See: 34 N.J.R. 2897(a), 35 N.J.R. 1423(a).
Rewrote (*l*).
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)3v, substituted "Centers for Medicare and Medicaid Services" for "Healthcare Financing Administration"; in (*l*), inserted "or Work First New Jersey/General Assistance (WFNJ/GA)" preceding "beneficiaries" in the introductory paragraph; substituted references to NJ FamilyCare for references to NJ KidCare throughout.

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 FamilyCare fee-for-service beneficiaries. As a component of the Medicaid/NJ FamilyCare 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 FamilyCare 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:

1. Drug-drug interactions;
2. Maximum/minimum daily dosage;
3. Therapeutic duplication;
4. Drug-age conflicts;
5. Duration of therapy;
6. Drug-pregnancy precautions;
7. Drug-gender conflicts;
8. Under-usage; and
9. Weight-based.

(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 FamilyCare 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.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
In (c), inserted "-drug" following "Drug" in 1, deleted "alerts" following "dosage" in 2, deleted 6, recodified former 7 as 6 and added new 7 through 9; substituted references to NJ FamilyCare for references to NJ KidCare throughout.

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 FamilyCare 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 FamilyCare 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).
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
Substituted references to NJ FamilyCare for references to NJ KidCare throughout.

SUBCHAPTER 2. PHARMACEUTICAL SERVICES TO MEDICAID OR NJ FAMILYCARE 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 Medicaid or NJ FamilyCare 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.
Amended by R.2004 d.26, effective January 20, 2004.
See: 35 N.J.R. 3788(a), 36 N.J.R. 558(a).
Substituted reference to NJ FamilyCare for reference to NJ KidCare.

10:51-2.2 Participation of eligible providers

(a) Any pharmacy with an institutional permit that was not a Medicaid or NJ FamilyCare approved provider of pharmaceutical services, parenteral nutrition or intravenous therapy

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).

Case Notes

Out-of-state applicant could not be deemed an institutional pharmacy because: (1) the applicant's Wisconsin license stated only that it was a "pharmacy" and did not further describe the licensee as either retail or institutional; (2) the Justice Department registration recognized petitioner as a retail pharmacy; (3) an "institutional pharmacy" under New Jersey regulations must be within a healthcare facility or system licensed as such by the Board; and (4) the New Jersey regulations also state that the term "pharmacy" standing alone indicates a retail pharmacy. Because the applicant was not deemed an institutional pharmacy, its authorization as a Medicaid provider was not proscribed under N.J.A.C. 10:51-2.2(b)1. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

New Jersey Division of Medical Assistance and Health Services' policy of not authorizing out-of-state pharmacies that service in-state affiliated facilities was an unwarranted expansion of the clear language of the regulations; to the extent that the Division may deny out-of-state provider applications for reasons not articulated in the regulations, such decisions will be reviewable under the arbitrary, capricious, or unreasonable standard. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

Division did not present any cogent reason for denying an out-of-state pharmacy's application for Medicaid provider authorization where the applicant's 24-hour emergency response arrangement with a New Jersey-based pharmacy resolved any question about emergency services, as that arrangement did not constitute prohibited steering as defined in the regulations, and the Division admitted that out-of-state mail order services had been authorized. Thus, the Division's decision denying the out-of-state provider's application was arbitrary, capricious, and unreasonable as well as otherwise not in accordance with law. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

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