

CHAPTER 51

PHARMACEUTICAL SERVICES MANUAL

Authority

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

Source and Effective Date

R.1998 d.488, effective August 28, 1998.
See: 30 N.J.R. 2169(b), 30 N.J.R. 3538(a).

Executive Order No. 66(1978) Expiration Date

Chapter 51, Pharmaceutical Services Manual, expires on August 28, 2003.

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Chapter 51, Pharmaceutical Services Manual, was repealed and a new Chapter 51, Pharmaceutical Services Manual, was adopted by R.1993 d.434, effective September 7, 1993.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

10:51-1.2 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the Medicaid or NJ KidCare program as a provider of pharmaceutical services; as a medical supplier providing medical supplies and durable medical equipment; and/or as a provider of parenteral nutrition and/or intravenous therapy. The requirements for approval as a provider of these services are listed in (b) through (d) 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) A pharmacy may also participate as a medical supplier. 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).

(d) 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 who 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 and NJ KidCare programs; 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.

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 KidCare 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 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. 10:51-1.9).

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 Health Care Financing Administration of the United States Department of Health and Human Services (see N.J.A.C. 10:51-1.22).

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 (a), 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).

In (a), inserted a reference to NJ KidCare in 3, and changed CFR reference in 10.

Case Notes

Pharmaceutical provider disqualified from participation in programs must be licensed to practice pharmacy by the State Board of Pharmacy before applying for reinstatement. Div. of Medical Assistance and Health Services v. Kares, 8 N.J.A.R. 517 (1983).

10:51-1.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation of the payment of a legend or non-legend drug for both the Medicaid and NJ KidCare programs. The elements include the following:

1. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 10:51-1.4;

2. Price information as supplied from a reference drug file contracted 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 drug price or ingredient cost shall not exceed the lower of the average wholesale price as supplied by the reference drug file contractor; the provider's usual and customary charge; or the drug's maximum allowable cost, if applicable (see (b) below);

i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meet the criteria specified in N.J.A.C. 10:51-1.11 (Covered Pharmaceutical Services).

3. Federal regulations (42 CFR 447.301, 331-334) set the aggregate upper limits on payment for certain covered drugs in the Medicaid and NJ KidCare—Plan A pharmaceutical programs. The Division applies the limits to NJ KidCare—Plan B and C. The Division refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. The provider's usual and customary charge for legend or non-legend drugs (see (c) below), contraceptive diaphragms and legend or non-legend devices.

(b) Payment for legend drugs is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). Appendix B is the listing of MAC drugs, and is hereby incorporated by reference.

1. Maximum allowable cost is defined as:

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.

(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 approved by the Medicaid Drug Utilization Review (DUR) Board. 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 approved by the Medicaid DUR Board shall be based on standards 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 adopted by the Medicaid Drug Utilization Review (DUR) Board shall be applied to all Medicaid and NJ KidCare pharmacy claims, regardless of the 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 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 interactions;
2. Maximum/minimum daily dosage alerts;
3. Therapeutic duplication;
4. Drug age conflicts;

- 5. Days supply alerts;
- 6. Drug-disease precautions; and
- 7. Drug-pregnancy precautions.

(d) The PDUR program may apply adopted standards based on a severity index approved by the Medicaid DUR Board to determine appropriate pharmacist intervention and/or claim disposition (that is, payment or denial) of Medicaid and NJ KidCare pharmacy claims.

(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.

ments 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 neces-

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 Medicaid 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 require-

sary 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