1. Claim(s) of mistake, provided that disagreement with the outcome of a decision, or with the analysis upon which it is based, shall not constitute "mistake" for purposes of this section;

2. Newly discovered evidence likely to alter the outcome of a matter, if the evidence could not have been discovered previously by due diligence;

3. Newly ascertained misrepresentation or other misconduct of an adverse party, if the misrepresentation or misconduct could not have been known previously; or

4. (No change.)

(c) (No change.)

(d) The filing of a motion for clarification or reconsideration, in and of itself, shall not relieve the parties from compliance with any judgment or order of the Commissioner.

SUBCHAPTER 4. REVIEW AND DECISION

6A:4-4.1 Standard of review

(a) In determining appeals from decisions of the State Board of Examiners or the School Ethics Commission pursuant to this chapter, the Commissioner shall ascertain whether the decision is supported by sufficient credible evidence in the record and shall not disturb the decision unless the appellant has demonstrated the State Board of Examiners or the School Ethics Commission acted in a manner that was arbitrary, capricious, or contrary to law.

(b) In determining motions for stay or emergency relief, the Commissioner shall apply the following standards, pursuant to *Crowe v. DeGioia*, 90 *N.J.* 126 (1982):

1. The moving party will suffer irreparable harm if the requested relief is not granted;

2. The legal right underlying the moving party's claim is settled;

3. The moving party has a likelihood of prevailing on the merits of the underlying claim; and

4. When the equities and interests of the parties are balanced, the moving party will suffer greater harm than the respondent will suffer if the requested relief is not granted.

6A:4-4.2 Settlement and withdrawal

(a) (No change.)

(b) An appeal may be settled at any time prior to issuance of the Commissioner's decision, provided the parties shall notify the Commissioner of any proposed settlement and shall set forth the full settlement terms for the Commissioner's review and approval.

1. If a district board of education is party to an appeal, any proposed settlement shall indicate, by signature of the district board of education attorney or inclusion of a district board of education resolution authorizing settlement, the district board of education has consented to the settlement terms.

2. A proposed settlement shall not include terms that restrict access to records or information deemed public by law or that require disclosure of information protected by law from disclosure.

6A:4-4.4 Relaxation of rules

(a) The rules of this chapter shall be construed to secure a just determination, simplicity of procedure, fairness in administration, and elimination of unnecessary delay. Unless otherwise stated, any rule not reflecting a statutory requirement or an applicable rule of administrative procedure may be relaxed by the Commissioner, in his or her discretion, if strict adherence to the rule is deemed inappropriate or unnecessary or would result in injustice.

(b) Briefing on appeals and motions shall be in accordance with this chapter. If the Commissioner deems it necessary to expedite proceedings or protect the interests of the parties, the Commissioner may modify time schedules or direct additional submissions at his or her discretion or by leave upon motion of a party.

HUMAN SERVICES

(a)

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

Pharmaceutical Services Manual

Readoption with Amendments: N.J.A.C. 10:51

Proposed: July 18, 2016, at 48 N.J.R. 1412(a).
Adopted: October 26, 2016, by Elizabeth Connolly, Acting Commissioner, Department of Human Services.
Filed: November 17, 2016, as R.2016 d.180, **with a non-substantial change** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 30:4D-1 et seq., and 30:4J-8 et seq.

Agency Control Number: 16-A-02.

Effective Dates: November 17, 2016, Readoption;
December 19, 2016, Amendments.
Expiration Date: November 17, 2023.

Summary of Public Comment and Agency Response:
No comments were received.

Federal Standards Statement

Sections 1902(a)(10), 1905(a)12, and 2110(a)6 of the Social Security Act (42 U.S.C. §§ 1396(a)(10), 1396d(a)12, and 1397jj(a)6, respectively) allow a state Medicaid or NJ FamilyCare–Children's Program, at its option, to provide pharmaceutical services.

Federal regulations at 42 CFR 440.120 define what may be covered as prescribed drugs. Federal requirements regarding Medicaid outpatient drug coverage are also contained in Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8).

The Department has reviewed the Federal statutory and regulatory requirements and has determined that the rules readopted with amendments do not exceed Federal standards. Therefore, a Federal standards analysis is not required.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 10:51.

Full text of the adopted amendments follows (addition to proposal indicated in boldface with asterisks ***thus***; deletion from proposal indicated in brackets with asterisks *[thus]*):

SUBCHAPTER 1. PHARMACEUTICAL SERVICES

10:51-1.2 Participation of eligible providers

(a) A pharmacy with a retail or institutional permit may participate in the Medicaid or NJ FamilyCare program as a provider of pharmaceutical services and as a medical supplier providing medical supplies and durable medical equipment and as a provider of parenteral nutrition 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 and applying for approval as a retail pharmacy may not participate as an approved provider in the 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 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, Enroll-

ment Process) or the fiscal agent Provider Enrollment Unit (see Appendix D, Fiscal Agent Billing Supplement).

(c) To enroll as a Medicaid and NJ FamilyCare provider of pharmaceutical services, a pharmacy shall contact the fiscal agent Provider Enrollment Unit.

(d) A pharmacy may also apply to the Division to 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 or the fiscal agent Provider Enrollment Unit.

(e) 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 that supplies parenteral nutrition and/or intravenous therapy shall:

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

ii. (No change.)

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 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. (No change.)

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 any of the following requirements, or any of the requirements of this subchapter, are not met:

1. (No change in text.)

(b) (No change in text.)

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 FamilyCare programs. The elements include the following:

1.-2. (No change.)

3. Federal regulations (42 CFR Part 447, Subpart I) that set the aggregate upper limits on payment for certain covered drugs in the Medicaid and NJ FamilyCare-Plan A pharmaceutical program. The Division applies the limits to NJ FamilyCare-Plans B and C. The Division refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. (No change.)

(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). See Appendix B for the listing of MAC drugs, which is incorporated herein by reference.

1. (No change.)

2. For information about the usual and customary charge, see N.J.A.C. 10:51-1.10.

3. (No change.)

(c) (No change.)

(d) The maximum allowance for protein replacement supplements, specialized infant formulas, and food oils under the Medicaid and NJ FamilyCare program is the lesser of:

1. (No change.)

2. The usual over-the-counter (OTC) retail price charged to the other persons in the community.

(e)-(f) (No change.)

10:51-1.7 Prescription dispensing fee

(a) The dispensing fee for legend drugs, dispensed by providers having retail permits to beneficiaries other than those in long-term care facilities, including State-operated Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID), nursing facilities, and State- and county-operated long-term psychiatric hospitals, is $3.73. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following:

1.-3. (No change.)

(b)-(e) (No change.)

10:51-1.13 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the Medicaid or NJ FamilyCare fee-for-service programs. For beneficiaries in the Medically Needy component of the New Jersey Care... Special Medicaid Programs, pharmaceutical services are not available to the aged, blind, nor the disabled who are residing in a long-term care facility (except a nursing facility) or in the community. For information on how to identify a covered person, see N.J.A.C. 10:49, Administration.

1.-9. (No change.)

10. Methadone in any form (tablets, capsules, liquid, injectables, or powder) when used for drug detoxification or addiction maintenance;

11.-17. (No change.)

18. Preventive vaccines, biologicals, and therapeutic drugs distributed to hospital clinics and/or community health centers by the New Jersey Department of Health; and

19. (No change.)

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1.-3. (No change.)

4. Prescriptions refilled too soon, as described in N.J.A.C. 10:51-1.19(a)5; and

5. Drug products denied payment based on *[point-of-scale]* ***point-of-sale*** (POS) and prospective drug utilization review (PDUR) standards adopted by the Medicaid or NJ FamilyCare program. (see N.J.A.C. 10:51-1.26)

(c) (No change.)

10:51-1.14 Services requiring prior authorization

(a) The provider shall obtain prior authorization, when required by this chapter, by phone or in writing, from the professional staff of the Division's prior authorization agent for pharmacy services. The pharmacy prior authorization agent is available at a toll-free telephone number 24 hours a day, seven days a week. When a form is required by this chapter, the appropriate form that must be used to request prior authorization is indicated in the Fiscal Agent Billing Supplement. Information on the form is transmitted, on-line, from the pharmacy prior authorization agent to the fiscal agent who, in turn, confirms the status of the authorization request by mail and provides the specific prior authorization number.

1. (No change.)

(b) The following drugs and specific therapeutic classes require prior authorization:

1.-2. (No change.)

3. Drugs available only for treatment through an Investigational New Drug (IND) application;

4.-6. (No change.)

10:51-1.15 Quantity of medication

(a) The quantity of medication prescribed shall provide a sufficient amount of medication necessary for the anticipated duration of the illness or, if required, an amount sufficient to provide medication during intervals between prescriber visits. The amount of medication dispensed shall not exceed a 34-day supply for initial prescriptions and a 34-day supply or 100 unit doses, whichever is greater, for refill prescriptions.

Recodify existing (d)-(f) as (b)-(d) (No change in text.)

10:51-1.21 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:

i.-ii. (No change.)

iii. The drug product is the subject of a NOOH issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the

Federal Register on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and

iv. (No change.)

2. (No change.)

3. The initial identification of drugs and related drug products classified as "less than effective" by the FDA pending outcome of the NOOH appears at 21 CFR 310.6. Subsequent revisions that are adopted shall appear in the Federal Register.

10:51-1.23 Bundled drug service

(a) (No change.)

(b) Bundled drug service shall not be eligible for reimbursement by the Medicaid or NJ FamilyCare program.

1. This provision may be waived at the discretion of the Commissioner if the Commissioner determines that a bundled drug service is less than or equal to the total cost of the unbundled components if reimbursed separately; or

2. The Commissioner may waive the provisions for reasons of medical necessity for a bundled drug or in accordance with terms approved by the Department as follows:

i. Those instances where discontinuation, withdrawal, or elimination of the use of the bundled drug by someone who has been receiving a bundled drug would result in the deprivation of the lifesaving or life prolonging benefits of the drug or would cause potential harm or serious exacerbation of the illness being treated; or

ii. (No change.)

(c) In order to determine eligibility for reimbursement, manufacturers, or distributors of a bundled drug service shall submit complete product information, including the cost to the programs of the total bundled drug service, discrete costs of each component of the bundled drug service, cost benefit analyses, and other information as requested by the Department, to the Chief Pharmaceutical Consultant, Division of Medical Assistance and Health Services, Mail Code #20, PO Box 712, Trenton, New Jersey 08625-0712.

1. If the Commissioner determines that a bundled drug is eligible for reimbursement under this section, Medicaid or NJ FamilyCare beneficiaries shall receive or continue to receive the bundled drug service if prior authorization is requested and approved. Prior authorization shall be obtained by completing the appropriate "Request for Authorization Form" requesting medication management authorization and providing sufficient documentation to establish that it is medically necessary to continue the bundled drug services. Mail all the information to:

Assistant Director
Office of Utilization Management
Division of Medical Assistance and Health Services
Mail Code #15
PO Box 712
Trenton, NJ 08625-0712

10:51-1.25 Point-of-sale (POS) claims adjudication system

(a) Medicaid or NJ FamilyCare fee-for-service pharmacy claims may be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real time. The POS system is an alternative to other methods of claim submission, including magnetic tape, diskette, and paper claims. The pharmacist would be required to enter pharmacy claim detail data into a computer or POS device and transmit this data to the fiscal agent over a dedicated telephone line. Regardless of the method of claim submission, all claims will go through all New Jersey Medicaid Management Information System (NJMMIS) claims processing edits and the claims will be processed to determine their payment disposition (for example, paid or denied).

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.

(b)-(d) (No change.)

(e) All Medicaid and NJ FamilyCare 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.

(f) (No change.)

(g) Additional supplementary data requirements, which are claim specific, include:

1.-6. (No change.)

(h)-(k) (No change.)

(l) The following shall apply for coverage of prescriptions when provided to Medicaid or NJ FamilyCare or Work First New Jersey/General Assistance (WFNJ/GA) beneficiaries during an interruption in POS service:

1. Pharmacists shall confirm Medicaid or NJ FamilyCare 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.

2.-3. (No change.)

4. Pharmacies shall be responsible for, and shall not be reimbursed for, early refills and duplicate prescriptions dispensed by their own pharmacy. In the event that early refills or duplicate prescriptions submitted by the same pharmacy during a sustained interruption are paid, the Division of Medical Assistance and Health Services will institute recovery procedures subsequent to the restoration of service.

i. (No change.)

5.-6. (No change.)

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 or 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 (DOH). 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 (DOH) 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 (DOH) shall be applied to all pharmacy claims, regardless of mode of claim submission.

(b)-(c) (No change.)

(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.

(e)-(f) (No change.)

10:51-1.27 Medical exception process (MEP)

(a) For pharmacy claims with service dates on or after September 1, 1999, which exceed prospective drug utilization review (PDUR) standards recommended by the New Jersey DUR Board and approved by the Commissioner of the Department of Human Services (DHS) and the Commissioner of the Department of Health (DOH), 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) (No change.)

(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 DOH in accordance with the rules of those Departments.

(d) (No change.)

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

10:51-2.2 Participation of eligible providers

(a) A pharmacy with a retail or institutional permit may participate in the Medicaid and NJ FamilyCare programs as a provider of pharmaceutical services and as a provider of parenteral nutrition or intravenous therapy.

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

1. (No change.)

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 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.

(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 in this section, a pharmacy that supplies parenteral nutrition and/or intravenous therapy shall:

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

ii. (No change.)

2. (No change.)

(d) (No change.)

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

(a) (No change.)

(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.-iii. (No change.)

(c) (No change.)

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 any of the following requirements, or any of the requirements of the rules of this subchapter, are not met:

1. (No change in text.)

(b) (No change.)

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.-2. (No change.)

3. Federal regulations (42 CFR Part 447, Subpart I) that set the aggregate upper limits on payment for certain covered drugs in the pharmaceutical program. The Division refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. (No change.)

(b)-(e) (No change.)

10:51-2.11 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions shall not be covered under the Medicaid or NJ FamilyCare program:

1.-17. (No change.)

18. Preventive vaccines, biologicals, and therapeutic drugs distributed to hospital clinics and/or community health centers by the New Jersey Department of Health.

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1.-2. (No change.)

3. Drug products available in unit-dose packaging and dispensed to residents in a boarding home or residential care setting or other community type setting. Other community type setting shall not include certain assisted living settings, including assisted living residences (ALRs), comprehensive personal care homes (CPCHs), and alternative family care (AFC) homes licensed by the Department of Health.

i. (No change.)

4. (No change.)

10:51-2.14 Prescriptions and in-patient medication orders rendered by telephone or technological devices

(a) (No change.)

(b) For purposes of reimbursement, a telephone rendered and/or a technologically transmitted authorization to refill an original prescription is considered a new prescription or in-patient medication order and requires a new prescription number. Stamping or writing a new number on the original prescription or in-patient medication order does not constitute a new prescription under the Medicaid or NJ FamilyCare program.

(c)-(d) (No change.)

10:51-2.17 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall apply to the Medicaid and NJ FamilyCare programs. This law requires that every prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.

1. (No change.)

2. When the prescriber initials "Substitution Permissible," the pharmacist shall dispense and bill Medicaid or NJ FamilyCare for one of the less expensive products listed in the DURC Formulary as interchangeable with the brand name prescribed. The Medicaid or NJ FamilyCare fee-for-service beneficiary must accept the interchangeable product unless the beneficiary is willing to pay the pharmacy's full, usual, and customary price. If that occurs, the pharmacist shall so note on the prescription blank and no claim shall be submitted to Medicaid or NJ FamilyCare.

3.-4. (No change.)

(b) Federal regulations prescribe the aggregate upper limit, for which Federal Financial Participation (FFP) is available, that Medicaid or NJ FamilyCare-Plan A may reimburse for certain multi-source drugs. This limit shall also apply to NJ FamilyCare-Plans B and C. The limit shall apply to all listed MAC drugs (see Appendix B) unless the prescriber indicates in his or her own handwriting on each written prescription or in-patient medication order or follow-up written prescription or in-patient medication order to a telephone rendered prescription or technologically transmitted, the phrase "Brand Medically Necessary." The Federal regulation requires a handwritten statement and does not permit the use of alternatives such as a check off box, initials, or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a hand written statement "Do Not Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E-1 does not apply to drugs that have a Federal MAC limit.

(c) Blanket authorization denying substitutions shall not be permitted. Each prescription or in-patient medication order shall state "Brand Medically Necessary" in the prescriber's own handwriting. For non-MAC drugs, each prescription order shall follow the requirements of N.J.S.A. 24:6E-1 et seq.

(d)-(e) (No change.)

10:51-2.18 Drug Efficacy Study Implementation (DESI)

(a) "Less than effective drugs" are subject to a Notice of Opportunity for Hearing (NOOH) by the Food and Drug Administration (FDA).

1. Reimbursement is not available for the purchase or administration of any drug product that meets all of the following conditions:

i.-ii. (No change.)

iii. The drug product is the subject of a NOOH issued under Section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the Federal Register on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications; and

iv. (No change.)

2. (No change.)

3. The initial identification of drugs and related drug products classified as "less than effective" by the FDA pending outcome of the NOOH appears at 21 CFR 310.6. Subsequent revisions that are adopted, shall appear in the Federal Register.

10:51-2.20 Bundled drug service

(a) (No change.)

(b) Bundled drug service shall not be eligible for reimbursement by the Medicaid or NJ FamilyCare program.

1. (No change.)

2. The Commissioner may waive the provisions for reasons of medical necessity for a bundled drug or in accordance with terms approved by the Department as follows:

i. Those instances where discontinuation, withdrawal, or elimination of the use of the bundled drug by someone who has been receiving a bundled drug would result in the deprivation of the lifesaving or life prolonging benefits of the drug or would cause potential harm or serious exacerbation of the illness being treated; or

ii. (No change.)

(c) (No change.)

10:51-2.21 Claims submission

(a) Based on the level of service provided by an approved pharmacy to a nursing facility, a provider may choose to:

1. (No change.)

2. Submit an electronic media claim (EMC) by modem, diskette, or magnetic tape in an approved electronic format that complies with the National Council Prescription Drug Program (NCPDP) standards Version 5.1 and Version 1.1, incorporated herein by reference, as amended and supplemented. The Council's address is 4201 North 24th Street, Suite 365, Phoenix, Arizona 85016.

i. (No change.)

ii. The completed agreement shall be submitted to the fiscal agent and approved by the Division.

iii.-iv. (No change.)

3. (No change.)

(b) (No change.)

10:51-2.22 Point-of-sale (POS) claims adjudication system

(a)-(b) (No change.)

(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) (No change.)

(e) All Medicaid and NJ FamilyCare 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.

(f)-(k) (No change.)

10:51-2.23 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 beneficiaries. As a component of the Medicaid and 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. 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 approved by the New Jersey 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. (No change.)

(b)-(f) (No change.)

SUBCHAPTER 3. CONSULTANT PHARMACIST SERVICES

10:51-3.4 Responsibilities

(a) The consultant pharmacist shall in cooperation and consultation with the nursing facility staff:

1.-5. (No change.)

6. Assure that drugs prescribed for nursing facility beneficiaries are properly administered based on drug utilization standards common to the pharmacy profession, which may include, but not be limited to:

i.-vi. (No change.)

vii. Drug-pregnancy precautions, if applicable;

7. Review the drug regimen (for example, dosage form, route of administration, time of administration) of each beneficiary at least monthly and report any irregularities pertaining to medications to the attending physician, medical director, or director of nursing, as appropriate.

i. Irregularities in the administration of medications shall be reported promptly to the director of nursing.

8.-11. (No change.)

12. Devote a sufficient number of hours to carry out these responsibilities and maintain a written record of activities, findings, and recommendations.

APPENDIX A

DRUG EFFICACY STUDY IMPLEMENTATION (DESI)

(Update of Drug Products and Known Related Drug Products that Lack Substantial Evidence of Effectiveness)

Appendix A is a list of drugs that the Food and Drug Administration (FDA) has proposed to withdraw from the market. The list is updated periodically by the Centers for Medicare and Medicaid Services subsequent to published listing changes in the Federal Register, in accordance with 21 CFR 310.6.

AGENCY NOTE: Appendix A is filed as a part of this chapter/manual, but is not reproduced in the New Jersey Administrative Code. When revisions are made to Appendix A, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law.

For a copy of Appendix A, write to:

Molina Medicaid Solutions
PO Box 4801
Trenton, New Jersey 08650-4801

or contact:

Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX B

UPPER PAYMENT LIMITS FOR MAXIMUM ALLOWABLE COST (MAC) DRUGS

Appendix B lists the multiple source drugs which meet the criteria set forth in 42 CFR Part 447, Subpart I, which is updated periodically by the Centers for Medicare and Medicaid Services subsequent to published listing changes in the Federal Register.

AGENCY NOTE: Appendix B is filed as a part of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to Appendix B, replacement pages will

be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law.

For a copy of Appendix B, write to:
Molina Medicaid Solutions
PO Box 4801
Trenton, New Jersey 08650-4801
or contact:
Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX C

STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
AND
DEPARTMENT OF HEALTH
PHARMACY PROVIDER CERTIFICATION STATEMENT

Pharmacy Name _____. Provider ID #_____
Address _____ Telephone (__) _____

SECTION I. FEE INCREMENTS ADDED TO BASIC DISPENSING FEE

1. Impact Allowance..... $ 0.15

This provider has a combined Medicaid/NJ FamilyCare/PAAD/ADDP/CF/SGPD prescription volume (including LTCF Rxs) equal to or greater than 50 percent of the total Rx volume and qualifies for "Impact Allowance."

Actual Percentage: _____ __ Yes __ No

Note: If conditions for earning impact allowance change, the provider must notify Molina Medicaid Solutions, in writing, at PO Box 4804, Trenton, NJ 08650-4804, within 30 days of change, and must immediately cease adding the impact allowance increment to the basic dispensing fee. If the State determines that the provider has not met the impact allowance requirements, the State shall recover the total reimbursement for this increment, retroactive to the date of this Statement.

2. 24-Hour Emergency Service..... $ 0.11

Provider certifies availability of 24 hours/day, 365 days/year prescription service_____ __ Yes __ No

If yes, identify below the method used by your pharmacy to post notification of this service.

___ Window Sign___ Prescription Counter Sign

___ Other Note: If "Other" is checked, please attach a complete description of the notification method used by your pharmacy notifying beneficiaries of this service.

24-Hour Emergency Service Telephone Number (___)_____

The 24 Hour Emergency Service Telephone Number must be a local call for beneficiaries serviced by your pharmacy. Failure to provide this number will result in the return of this form.

Note: If a provider discontinues 24-hour emergency service, the provider must notify Molina Medicaid Solutions, in writing, at PO Box 4804, Trenton, NJ 08650-4804 within 72 hours of this decision, and must immediately cease adding the increment to the basic dispensing fee.

3. Patient Consultation..... $ 0.08

Provider agrees to monitor all Medicaid/NJ FamilyCare/PAAD/ADDP/CF/SGPD patient profiles, in accordance with New Jersey State Board of Pharmacy regulations (N.J.A.C. 13:39-7.14), and those requirements described by the Omnibus Budget Reconciliation Act (OBRA) of 1993. These requirements include, but are not limited to, offers to consult with beneficiaries concerning proper drug administration/storage, and potential drug interactions/conflicts identified by reviews of patient profiles, or as advised by the State's Point of Sale (POS)/Prospective Drug Utilization Review (PDUR) claims processing system. _____ __ Yes __ No

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SECTION II. OWNERSHIP DISCLOSURE STATEMENT

1. _____ Pharmacy Name

Chain Pharmacy ___ Yes ___ No

If yes, please indicate the number of pharmacies operating in the State of New Jersey: _____.

2. Does any person in your organization currently own or have an interest in or any relationship with any other corporation, partnership, or other organization providing services under the Medicaid, NJ FamilyCare, PAAD, ADDP, CF or SGPD programs?

___ Yes ___ No

If yes, please explain such affiliations on a separate page and attach to the Certification Statement.

3. Indicate the legal status of your organization below.

___ Sole Proprietor ___ Partnership
___ Non-Profit Corporation ___ For-Profit Corporation
___ Government ___ Other (Specify)

List names, professional degrees, home addresses, and percentage of ownership for all partners, directors, officers, and/or stockholders, as applicable:

	NAME	DEGREE	HOME ADDRESS	% OWNERSHIP
1.				
2.				
3.				
4.				
5.				

I HAVE READ THE PHARMACY PROVIDER CERTIFICATION STATEMENT AND AGREE TO THE TERMS AND CONDITIONS SET FORTH HEREIN. I UNDERSTAND THAT THE MAXIMUM CHARGE TO THE STATE OF NEW JERSEY FOR ALL MEDICAID, NJ FAMILYCARE, PAAD, ADDP, CF AND SGPD PRESCRIPTIONS FOR COVERED DRUGS AND RELATED PHARMACEUTICAL PRODUCTS/DEVICES MAY NOT EXCEED THE PRICING POLICIES OF THE STATE AS DESCRIBED IN N.J.A.C. 10:51-1.7 AND N.J.A.C. 8:83C-1.

Legal Signature of Principal: _____ Date: _____
Print Name: _____
Title: _____
Pharmacy Name: _____

NOTE: ALL STATEMENTS IN THIS CERTIFICATION ARE SUBJECT TO AUDIT AND REVIEW BY THE NEW JERSEY DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES (DMAHS) AND/OR THE NEW JERSEY DEPARTMENT OF HEALTH (DOH), THEIR CONTRACTORS, OR OTHER STATE AND FEDERAL AGENCIES.

AFFIX
PHARMACY LABEL
HERE
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APPENDIX D

FISCAL AGENT BILLING SUPPLEMENT

AGENCY NOTE: The Fiscal Agent Billing Supplement is filed as an incorporated appendix of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to the Fiscal Agent Billing Supplement, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law.

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Molina Medicaid Solutions
PO Box 4801
Trenton, New Jersey 08650-4801
or contact:
Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX E

ELECTRONIC MEDIA CLAIMS (EMC) MANUAL

AGENCY NOTE: The Electronic Media Claims (EMC) Manual is filed as an incorporated Appendix of this chapter/manual, but is not reproduced in the New Jersey Administrative Code. When revisions are made to the EMC Manual, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law.

For a copy of the EMC Manual, write to:

Molina Medicaid Solutions
PO Box 4801
Trenton, New Jersey 08650-4801

APPENDIX F

MEDICAID REBATE PROGRAM
MANUFACTURERS' LABELER CODE LIST

Appendix F is a list of drug manufacturers, identified by labeler code, whose drug products are covered by the Medicaid and NJ FamilyCare fee-for-service programs. These drug manufacturers have in effect a rebate agreement pursuant to 42 U.S.C. § 1396-r-8(a), (b) and (c). This list is updated periodically by the Centers for Medicare and Medicaid Services subsequent to published listing changes in the Federal Register.

AGENCY NOTE: Appendix F is filed as a part of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to Appendix F, replacement pages will be distributed to providers, placed on the website at www.njmmis.com and copies will be filed with the Office of Administrative Law.

For a copy of Appendix F, write to:

Molina Medicaid Solutions
PO Box 4801
Trenton, New Jersey 08650-4801

or contact:

Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX G

STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
NOTIFICATION OF PHARMACEUTICAL SERVICES IN NURSING FACILITIES

_____
(SERVICING PHARMACY)

_____
(PROVIDER NUMBER OF SERVICING PHARMACY)
(IF AVAILABLE)

PROVIDER AGREES:

1. To comply with State regulations, in accordance with N.J.A.C. 10:51, Subchapter 2, when providing pharmaceutical services to:

   _____
   (Nursing Facility)

   Nursing Facility Provider Number: _____
2. In accordance with N.J.A.C. 10:51-2.7(d), the servicing pharmacy shall notify the New Jersey Division of Medical Assistance and Health Services of any change in status regarding the provision of these pharmaceutical services described to avoid improper capitation payments.
3. In accordance with N.J.A.C. 10:51-2.7(d), the pharmacy identified by this agreement shall provide the Division with information requested below:
   (i) A copy of a fully executed agreement between the servicing pharmacy provider and the nursing facility.
   (ii) The effective date of initiating a new or changed pharmaceutical service to:

   _____ is _____
   (Nursing Facility) (Date)

   (iii) Level of Service to be provided: (Select One)

   ___ (01) Twenty-Four (24) Hour Unit Dose Services
   ___ (02) Modified Unit Dose Services (i.e., Bingo, Atromick; 30 day supply)
   ___ (03) Traditional Services (i.e., drug vial dispensing)
   ___ (04) Twenty-Four (24) Hour Unit Dose Services and ancillary computerized services
   ___ (05) Modified Unit Dose Services and ancillary computerized services
   ___ (06) Traditional Services and ancillary computerized services

   Note: Ancillary computerized services, if provided, shall include, but not be limited to, continuously updated computerized patient profile records medication sheets, treatment sheets and physician order sheets which must be supplied at least monthly.

The completed agreement must be returned by mail to:

Molina Medicaid Solutions
Provider Enrollment Unit
PO Box 4804
Trenton, NJ 08650-4804

PS-I-08(03/94)

_____

(a)

DIVISION OF MENTAL HEALTH AND ADDICTION SERVICES

Licensure of Outpatient Substance Abuse Treatment Facilities

Readoption with Amendments: N.J.A.C. 10:161B

Proposed: July 5, 2016, at 48 N.J.R. 1350(a).
Adopted: October 20, 2016, by Elizabeth Connolly, Acting Commissioner, Department of Human Services.
Filed: November 22, 2016, as R.2016 d.185**, with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:2B-7 et seq., in particular 26:2B-14, 26:2BB-5 through 6, 26:2G-1 et seq., and 30:1-12; and Reorganization Plan 002-2004.

Effective Dates: November 22, 2016, Readoption;
December 19, 2016, Amendments.
Expiration Date: November 22, 2023.

Summary of Public Comment and Agency Response:
No comments were received.

Summary of Agency Initiated Changes:

1. Throughout the chapter, the Department is changing "substance abuse" to "substance use disorder" for consistency with the DSM-5, which no longer uses the terms substance abuse; rather, it refers to substance use disorders, which are defined as mild, moderate, or severe to indicate the level of severity, which is determined by the number of diagnostic criteria met by an individual.

2. The Department is changing N.J.A.C. 10:161B-1.14(a) and 11.2(a) to recognize that the American Society of Addiction Medicine (ASAM) no longer offers board certification in addiction medicine; board certification is transitioning to the American Board of Preventive Medicine (ABPM). This is consistent with the Division's communication to licensed substance use disorder treatment providers in July 2016.

3. Due to a Departmental restructure, the Division of Addiction Services (DAS) merged with the Division of Mental Health Services (DMH). The merged division is identified as the Division of Mental Health and Addiction Services (DMHAS). Additionally, the licensing function within the former DAS, was transferred to the Department of Human Services, Office of Licensing (OOL). OOL has the responsibility for all aspects of the licensing process, and will monitor deficiency reports, quality assurance activities, complaints, emergencies, informal dispute resolution, hearings held by the Office of Administrative Law, injunctions, and settlement of enforcement actions. The Division maintains the oversight for program operations, data, and administrative