HUMAN SERVICES

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

Pharmaceutical Services Manual

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

Authorized By: Elizabeth Connolly, Acting Commissioner, Department of Human Services.

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Agency Control Number: 16-P-02.

Proposal Number: PRN 2016-109.

Submit comments by September 19, 2016, to:

Margaret Rose

Attn: 16-P-02

Division of Medical Assistance and Health Services

PO Box 712

Trenton, NJ 08625-0712

Fax: (609) 588-7343

E-mail: Margaret.Rose@dhs.state.nj.us

Delivery: 6 Quakerbridge Plaza

Mercerville, NJ 08619

The agency proposal follows:

Summary

Pursuant to N.J.S.A. 52:14B-5.1, the Pharmaceutical Services Manual, N.J.A.C. 10:51 is scheduled to expire on June 10, 2016. Pursuant to Executive Order 66 (1978), the Department of Human Services (Department) has made the determination that N.J.A.C. 10:51 continues to be reasonable, necessary, and proper for the purpose for which the rules were originally adopted and should be readopted at this time with amendments. As the Department has filed this notice of readoption with the Office of Administrative Law prior to June 10, 2016, the expiration date is extended 180 days to December 7, 2016, pursuant to N.J.S.A. 52:14B-5.1.c(2).

The Pharmaceutical Services Manual regulates the provision of pharmaceutical services under the New Jersey Medicaid and the NJ FamilyCare fee-for-service (FFS) pharmacy benefit programs and reimbursement for services under those programs. There are three subchapters and seven appendices to N.J.A.C. 10:51.

N.J.A.C. 10:51-1, Pharmaceutical Services, provides notice of the policies and procedures relevant to the provision of pharmaceutical services to New Jersey Medicaid/NJ FamilyCare beneficiaries. This subchapter includes an introduction to pharmaceutical services, participation of eligible providers, and conditions for participation, as well as program restrictions. It also includes basis of payment, discounts, dispensing fees, compounded and generic prescriptions, and the providers' usual and customary or advertised charge. The subchapter also lists the covered and non-covered pharmaceutical services, prior authorization requirements, quantity, dosage, and direction for medication and personal contribution to care requirements for

NJ FamilyCare-Plan C and copayment requirements for NJ FamilyCare Plan D. Prescriptions, such as telephone-rendered original prescriptions, changes or additions to the original prescription, and refills are covered. Also described in this subchapter is the Prescription Drug Price and Quality Stabilization Act, Drug Efficacy Study Implementation (DESI), drug manufacturers rebate agreement, and rules for bundled drug service. The last sections provide the rules for claim submission, the point-of-sale (POS) claims adjudication system, prospective drug utilization review, and the medical exception process.

N.J.A.C. 10:51-2, Pharmaceutical Services to Medicaid or NJ FamilyCare Fee-For-Services Beneficiaries in a Nursing Facility, provides the rules for pharmaceutical services to beneficiaries in a nursing facility, participation of eligible providers, and conditions for participation, as well as program restrictions. It also covers the rules for basis of payment, discounts, dispensing fees, compounded prescriptions, dosage and direction for medication, and generic prescriptions. The subchapter lists the covered and non-covered pharmaceutical services to beneficiaries in a nursing facility, prescriptions, and inpatient medication orders rendered by telephone or technological devices, changes or additions to the original prescriptions and refills. Also described in this subchapter is the Prescription Drug Price and Quality Stabilization Act, Drug Efficacy Study Implementation (DESI), Drug manufacturers rebate agreement, and bundled drug service. The last sections provide the rules for claim submission, Point-of-sale (POS) claims adjudication system, and the Prospective Drug Utilization Review (PDUR) program.

N.J.A.C. 10:51-3, Consultant Pharmacist Services, provides an introduction to the services provided by a consultant pharmacist, the definition of a consultant pharmacist, as well as the qualifications required to fulfill the responsibilities of a pharmacist. Finally, the responsibilities of a pharmacist acting as a consultant are delineated.

Appendix A, Drug Efficacy Study Implementation (DESI), contains the drugs designated for withdrawal from the market by the United States Food and Drug Administration.

Appendix B, Upper Payment Limits for Maximum Allowable Cost (MAC) Drugs, contains the multiple source drugs designated by the Centers for Medicare and Medicaid Services (CMS).

Appendix C is Form FD-70, the Pharmacy Provider Certification Statement.

Appendix D, the Fiscal Agent Billing Supplement, contains billing instructions for providers.

Appendix E, Electronic Media Claims (EMC) Manual, contains instructions to providers regarding the submission of claims via electronic media.

Appendix F, Medicaid Rebate Program, is a list of drug manufacturers who have a rebate agreement established in accordance with Federal law.

Appendix G, Notification of Pharmaceutical Services in Nursing Facilities, is an agreement form to be completed by pharmacies servicing nursing facilities in accordance with the requirements of N.J.A.C. 10:51-2.7.

Throughout the chapter the name of the “Department of Health and Senior Services (DHSS)” is being changed to the “Department of Health (DOH)” to reflect the

current name of this department and the name of the Medicaid/NJ FamilyCare fiscal agent is being changed from “Unisys” to “Molina Medicaid Solutions” to reflect the name of the Division’s current fiscal agent. Additionally, in the chapter appendices, the addresses of Molina Medicaid Solutions and the Office of Administrative Law are updated to reflect the most current mailing addresses of each organization. Finally, throughout the chapter, minor non substantive revisions of grammar, style, spelling, and punctuation are proposed and unnecessary cross-references, as well as any duplicative or otherwise unnecessary text, are eliminated.

Specific amendments are proposed as follows:

At N.J.A.C. 10:51-1.4(a), a list of specific sections within Chapter 51 would be replaced with a general reference to the subchapter. Related revisions of grammar are also proposed. All of the rules in the subchapter were previously legally applicable and remain so. At N.J.A.C. 10:51-1.4(b), a provision regarding erectile dysfunction drugs that is partially duplicative of a requirement that is found elsewhere in the chapter, and partially superseded by controlling current law (see P.L. 2015, c. 63), is proposed for elimination. Since the issue is controlled by legislation, the amendment would have no substantive effect.

At N.J.A.C. 10:51-1.7(a), out-of-date terminology is replaced with current and appropriate language.

At N.J.A.C. 10:51-1.13(b), a provision regarding erectile dysfunction drugs that is duplicative of a requirement that is found elsewhere in the chapter is eliminated.

At N.J.A.C. 10:51-1.15, currently non-functioning subsections (a) and (b), which relate to issues that will no longer arise, are proposed for deletion. Recodified

subsection (a) is proposed for amendment to delete an old date reference that is no longer applicable.

At N.J.A.C. 10:51-1.21(a), a “notice of opportunity for hearing” is replaced with “NOOH,” as the use of the acronym is already set forth in the section.

At N.J.A.C. 10:51-1.25, paragraph (e)1 is relocated as new paragraph (a)1, with no change in text. N.J.A.C. 10:51-1.25(l)4ii is proposed for deletion as the definition is not used in the rule.

At N.J.A.C. 10:51-2.2(c), a cross-reference to a specific subsection is replaced with a cross-reference to the already legally applicable section in its entirety and an unnecessary reference to a website is eliminated.

At N.J.A.C. 10:51-2.4(a), the term “funding” is replaced with “reimbursement” for clarity and the list of specific sections within Chapter 51 would be replaced with a general reference to the subchapter. All of the rules in the subchapter were previously legally applicable and remain so.

At N.J.A.C. 10:51-2.5(a)3, a cross-reference to several specific sections of the Code of Federal Regulations is replaced with a cross-reference to Part 447, Subpart I.

N.J.A.C. 10:51-2.11(b)5, pertaining to erectile dysfunction is proposed for deletion for the reasons set forth above.

At N.J.A.C. 10:51-2.18, a “notice of opportunity for hearing” is replaced with “NOOH,” as the use of the acronym is already set forth in the section.

N.J.A.C. 10:51-2.22(e)1 is proposed for deletion as it is duplicative.

The Department has determined that the comment period for this notice of proposal will be 60 days; therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is excepted from the rulemaking calendar requirement.

Social Impact

In State Fiscal Year 2015, there were approximately 2,056 pharmaceutical providers rendering services to Medicaid and NJ FamilyCare beneficiaries.

During State Fiscal Year 2015, an estimated 42,684 beneficiaries received fee-for-service prescriptions each month.

The rules proposed for readoption with amendments should have a positive social impact on Medicaid and NJ FamilyCare fee-for-service beneficiaries since the readoption of the rules will ensure continued coverage of pharmaceutical services to those beneficiaries.

Economic Impact

During State Fiscal Year 2015, the Division spent approximately $67.6 million (Federal and State shares combined) for approximately 1.7 million fee-for-service prescriptions.

There will be no economic impact on the beneficiaries as a result of the rules proposed for readoption with amendments. There are no costs to providers specifically associated with these rules, beyond the costs of maintaining records adequate for billing purposes. The rules proposed for readoption with amendments will have a positive

economic impact on providers of the services covered by these rules because they will continue to be reimbursed for those services.

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 proposed for readoption with amendments do not exceed Federal standards. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department does not anticipate that the rules proposed for readoption with amendments will result in the creation or loss of jobs in the State of New Jersey.

Agriculture Industry Impact

Since the rules proposed for readoption with amendments concern the provision of pharmaceutical services to Medicaid and NJ FamilyCare beneficiaries, the Department anticipates that the rules proposed for readoption with amendments will have no impact on the agriculture industry in the State of New Jersey.

Regulatory Flexibility Analysis

Some pharmaceutical services providers may be considered small businesses under the terms of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The rules proposed for readoption with amendments contain minimal recordkeeping, reporting, or compliance requirements on providers.

All providers, regardless of size, are required to maintain records to fully disclose the name of the beneficiary who received the service, date of service, and any additional information as may be required by N.J.A.C. 10:49 and N.J.S.A. 30:4D-1 et seq., specifically 30:4D-12. This information, along with identifying information for the provider and the beneficiary, is all that is needed to request prior authorization and/or reimbursement for the provision of pharmaceutical services.

There are no new capital costs or compliance costs and no need to hire any professional staff as a result of the rules proposed for readoption with amendments. Neither the rules proposed for readoption nor the proposed amendments impose requirements on providers regarding the hiring of professional staff beyond those imposed by existing applicable State and Federal requirements. Any capital costs incurred by a provider would be incurred in the normal course of business when operating a pharmacy and would not be a direct result of the proposed readoption of these rules or the proposed amendments.

Housing Affordability Impact Analysis

The rules proposed for readoption with amendments will have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing because the rules concern the provision of pharmaceutical services to Medicaid and NJ FamilyCare beneficiaries.

Smart Growth Development Impact Analysis

The rules proposed for readoption with amendments will have an insignificant impact on smart growth and there is an extreme unlikelihood that the rules would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the rules concern the provision of pharmaceutical services to Medicaid and NJ FamilyCare beneficiaries.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 10:51.

Full text of the proposed amendments follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. PHARMACEUTICAL SERVICES

10:51-1.2 Participation of eligible providers

(a) 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]

and as a medical supplier providing medical supplies and durable medical equipment [and/or] **and** as a provider of parenteral nutrition [and/or] **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] **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] **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).

(c) 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)].

(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 [(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)].

(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 [who] **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. (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 [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. (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 [the following rules] **this subchapter,** 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.] **1.** (No change in text.)

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

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

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

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

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

[(c)] **(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 [447.301, 331-334] **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). [Appendix B is the listing of MAC drugs, and is hereby incorporated by reference.] **See Appendix B for the listing of MAC drugs, which is incorporated herein by reference.**

1. (No change.)

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. (No change.)

(c) (No change.)

(d) The maximum allowance for protein replacement supplements, specialized infant formulas**,** and food oils under the [New Jersey] 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[, whichever is less].

(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] **State-operated** Intermediate Care [Facilities/Mentally Retarded (ICFs/MR)] **Facilities for Individuals with Intellectual Disabilities (ICFs/IID)**, nursing facilities**,** and [State and county operated] **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 [New Jersey] 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 [(see N.J.A.C. 10:51-1.14, Prior authorization)];

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 Senior Services.]**; 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 (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)[; and]

[6. No funding shall be provided for erectile dysfunction drugs for individuals who are registered on New Jersey's Sex Offender Registry.]

(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. [Additional requirements regarding prior authorization for specific drugs or classes of drugs are contained in (b) below.]

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 [shall be prior authorized];

4.-6. (No change.)

10:51-1.15 Quantity of medication

[(a) For claims with service dates on or after July 15, 1996, but prior to July 1, 1998, 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 or 100 unit doses, whichever is greater.

(b) For claims with service dates on or after July 1, 1998, but prior to July 1, 1999, 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.]

[(c)] **(a)** [For claims with service dates on or after July 1, 1999, the] **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 [notice of opportunity for hearing] **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 [which] **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 [New Jersey] Medicaid or NJ FamilyCare program.

1. This provision may be waived at the discretion of the Commissioner if [he or she] **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 [life saving] **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, [New Jersey] 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.

[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) (No change.)

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

1.-6. (No change.)

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

(l) The following shall apply for coverage of prescriptions when provided to [Medicaid/NJ] **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/NJ] **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.)

[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.-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/NJ] **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 [and Senior Services (DHSS)] **(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 [(DHSS)] **(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 [(DHSS)] **(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. [(See N.J.A.C. 10:51-1.27)]

(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[s] of [DHS and DHSS] **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 [DHSS] **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. [The requirements 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. (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 [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] **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] **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 [(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. (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 [pharmacist's] **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. [Funding] **Reimbursement** may be denied if **any of** the **following** requirements**, or any of the requirements** of the [following] rules **of this subchapter,** 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.] **1.** (No change in text.)

[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

11. Drug Manufacturer's Rebate Agreement with the Health Care Financing Administration of the United States Department of Health and Human Services (see N.J.A.C. 10:51-2.19).]

(b) (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 [447.301, 331-334] **Part 447, Subpart I**) that set the aggregate upper limits on payment for certain covered drugs in the pharmaceutical program. The [New Jersey Medicaid and NJ FamilyCare programs] **Division** refer**s** 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 [New Jersey] 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 [and Senior Services].

(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 [and Senior Services].

i. (No change.)

4. (No change.)

[5. Erectile dysfunction drugs for individuals who are registered on New Jersey's Sex Offender Registry.]

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 [(for example: Fax)] 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 [New Jersey] 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**,**" [on the prescription blank,] the pharmacist shall dispense and bill Medicaid or NJ FamilyCare[, as appropriate,] 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, [(for example, Fax) (see N.J.A.C. 10:51-2.9)] 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 [which] **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. [(see (a) above).]

(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 [notice of opportunity for hearing] **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 [which] **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 [life saving] **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[, incorporated herein by reference]. 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 [of Medical Assistance and Health Services].

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 [New Jersey Medicaid and NJ FamilyCare programs] **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.

[1. Pharmacy services provided to nursing facility and residential care residents utilizing 24 hour unit-dose or modified unit-dose or modified unit-dose drug delivery systems are precluded from the POS 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 [Medicaid] **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 [also] 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 [C.F.R.] **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] **www.njmmis.com** and copies will be filed with the Office of Administrative Law.

For a copy of Appendix A, write to:

[Unisys] **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 [447.301, 331-333] **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] **www.njmmis.com** and copies will be filed with the Office of Administrative Law.

For a copy of Appendix B, write to:

[Unisys] **Molina Medicaid Solutions**

PO Box 4801

Trenton, New Jersey 08650-[0049]**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 [AND SENIOR SERVICES]

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 [Unisys] **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 [Unisys] **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_____

FD-70 (REV. (10/02)**)**

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 [New Jersey] 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 [AND SENIOR SERVICES (DHSS)] **(DOH)**, THEIR CONTRACTORS, OR OTHER STATE AND FEDERAL AGENCIES.

AFFIX

PHARMACY LABEL

HERE

FD-70 (REV. 10/02)

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] **www.njmmis.com** and copies will be filed with the Office of Administrative Law.

For a copy of the Fiscal Agent Billing Supplement, write to:

[Unisys] **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] **www.njmmis.com** and copies will be filed with the Office of Administrative Law.

For a copy of the EMC Manual, write to:

[Unisys] **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 [New Jersey] 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] **www.njmmis.com** and copies will be filed with the Office of Administrative Law.

For a copy of Appendix F, write to:

[Unisys] **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:

[Unisys] **Molina Medicaid Solutions**

Provider Enrollment Unit

PO Box 4804

Trenton, NJ 08650-4804

PS-I-08(03/94)