COMMUNITY AFFAIRS ADOPTIONS

Certificate of Continuing Program Compliance to NJHMFA. The Owner's Certificate of Continuing Program Compliance shall be sent annually to NJHMFA for each year of the compliance period for the preceding 12-month period and contain the following:

1.-12. (No change.)

13. That if the owner received its credit allocation from the Nonprofit Set Aside (section 42(h)(5) of the Code), that the nonprofit entity materially participated in the operation of the development within the meaning of section 469(h) of the Code; *[and]*

14. That there has been no change in the ownership or management of the project or that there was a change and a description of the change*[.]**;*

15. That the rent charged to each existing tenant (excluding any rental assistance) has not increased by more than 5.00 percent annually, including due to changes in utility allowance calculations*[.]**; and*

16. That the property management office had office hours of at least 20 hours a week.

(g) (No change.)

HUMAN SERVICES

(a)

DIVISION OF AGING SERVICES

Provision of Pharmaceutical Services Under the Pharmaceutical Assistance to the Aged and Disabled Program (PAAD)

Readoption with Amendments: N.J.A.C. 10:167A Adopted Repeal: N.J.A.C. 10:167A-1.4

Proposed: October 3, 2016, at 48 N.J.R. 2005(a).

Adopted: December 22, 2016, by Elizabeth Connolly, Acting Commissioner, Department of Human Services.

Filed: January 31, 2017, as R.2017 d.035, without change.

Authority: N.J.S.A. 30:4D-24.

Effective Dates: January 31, 2017, Readoption;

March 6, 2017, Amendments and Repeal.

Expiration Date: January 31, 2024.

Summary of Public Comment and Response: No comments were received from the public.

Federal Standards Statement

N.J.A.C. 10:167A establishes policies and requirements, with regard to the PAAD Program, which is completely State-funded after payment by primary payers such as Part D. Therefore, there are no Federal standards governing eligibility or services under PAAD, as these are established by State law. However, there are Federal requirements followed by PAAD in several other sections of the rules. In these cases, the Department imposes the same requirements as are imposed by the Federal government. Federal regulations at 42 CFR 440.120 define what may be covered as prescribed drugs. See also 42 U.S.C. § 1396r-8(d). Rebate requirements are contained in 42 U.S.C. §§ 1396r-8(b) through (c) and (k). Federal restrictions regarding payment for less than effective drugs (known as DESI) are included in Section 1927(k) of the Act (42 U.S.C. § 1396r-8(k)(2)(A) and 21 CFR 310.6).

Payment for drugs is subject to Federal upper payment limits (42 CFR 447.500 through 447.520) and Section 1927(e) and (k) of the Act (42 U.S.C. §§ 1396r-8(e) and 8(k), respectively).

The Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, and the regulations promulgated thereunder by the United States Secretary of Health and Human Services at 45 CFR Parts 160 and 164, known as the "Standards for Privacy of Individually Identifiable Health Information," hereinafter collectively referred to as "HIPAA," apply to health information created or maintained by health plans and health care clearinghouses. The Department's PAAD Program complies with the requirements of HIPAA.

Pursuant to 45 CFR 164.512(d), a covered entity may disclose protected information to a health oversight agency (such as CMS) for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of the health care system, government benefit programs for which health information is relevant to beneficiary eligibility, entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or entities subject to civil rights laws for which health information is necessary for determining compliance.

Moreover, pursuant to 45 CFR 164.514(d)(3)(iii)(A), when making disclosures permitted under 45 CFR 164.512, a covered entity may reasonably rely on the representation of a public official that the information requested is the minimum necessary for the stated purpose.

Therefore, for example, the disclosure of PAAD applicant, reapplicant, or beneficiary information protected under HIPAA to CMS and its endorsed agents, for the purpose of coordination of benefits between the Medicare Prescription Drug Program and the PAAD program would not constitute a violation of HIPAA. To the extent the PAAD Program may be subject to HIPAA, the rules readopted with amendments and a repeal would meet but not exceed the requirements of HIPAA.

Except as described above, there are no Federal standards applicable to the subject matter of the rules readopted with amendments and a repeal. Since any Federal requirements applicable to the rules are met, but not exceeded, no Federal standards analysis is required.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 10:167A.

Full text of the adopted amendments follows:

SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

10:167A-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

"Active pharmaceutical ingredient" means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient of the drug product.

...

"Applicant" means an individual who applies or reapplies for PAAD, either personally or through an authorized agent.

"Bulk drug substance" means a bulk drug substance as defined in 21 CFR 207.3(a)(4), that includes any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or finished dosage form of the drug. "Bulk drug substance" does not include intermediates

used in the synthesis of such substances.

. . .

"Electronic Media Claim" or "EMC" means an electronic media claim processed by the State's fiscal agent, including claims submitted as real-time claims via modem or electronic bulletin board through the World Wide Web (www), in an electronic format that complies with the standards of the National Council on Prescription Drug Plans (NCPDP), DCPDP D.0/1.2 Payer Sheet, version D.0, which is incorporated herein by reference, as amended and supplemented. The NCPDP standards can be obtained from the NCPDP at 9240 East Raintree Drive, Scottsdale, Arizona 85260-7516, or by accessing the Pharmacy NCPDP-HIPAA Payer Sheet at https://www.njmmis.com/downloadDocuments/NJ_D-0_NCPDP_Payer_Sheet.pdf.

"Excipient" means an ingredient that does not contribute therapeutically to a compound, including, but not limited to, fillers, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

. . .

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"Interchangeable drug product" means those drug products, with therapeutic equivalence ratings of "A," identified in the publication of the Office of Generic Drugs in the Office of Pharmaceutical Science of the Center for Drug Evaluation and Research of the Food and Drug Administration (FDA) of the United States Department of Health and Human Services, Approved Drug Products with Therapeutic Equivalence Evaluations, 34th Edition, incorporated herein by reference, as amended and supplemented, commonly known as the "Orange Book," promulgated pursuant to the Federal Food, Drug, and Cosmetic Act, at 21 U.S.C. § 355(j)(7); and those drug products approved by the FDA with therapeutic equivalence ratings of "A" that appear on the FDA's "Drugs@FDA" website, bearing formal internet address http:// www.accessdata.fda.gov/scripts/cder/drugsatfda/, incorporated herein by reference, as amended and supplemented. The Orange Book can be obtained by contacting the United States Government Printing Office at PO Box 979050, St. Louis, MO 63197, or at (866) 512-1800, or it is available on-line at http://www.accessdata.fda.gov/scripts/cder/ob/.

"National drug code" or "NDC" means the three-segment identification number for a specific drug product issued by the U.S. Food and Drug Administration pursuant to 21 U.S.C. § 360 of the Federal Food, Drug and Cosmetic Act.

"National Provider Identifier" or "NPI" means a national identifier issued to a healthcare provider by the National Plan and Provider Enumeration System (NPPES) established pursuant to 45 CFR Part 162, Subpart D.

..

"Prescription drugs" means all approved legend drugs, including any interchangeable drug products and in conformance with the provisions of the "Prescription Drug Price and Quality Stabilization Act," and insulin, insulin syringes, and insulin needles when prescribed.

- 1. The term "prescription drugs" includes:
- i. (No change.)
- ii. Every product considered to be a legend prescription drug;
- iii. (No change.)
- iv. Syringes and needles for injectable medicines.
- 2. (No change.)

..

10:167A-1.3 Participation of eligible providers

- (a) (No change.)
- (b) To be approved as a provider of pharmaceutical services, the pharmacy shall:
- 1. Operate under a valid retail or institutional permit issued by the Board of Pharmacy of the State of New Jersey and be assigned a national provider identifier. A pharmacy operating under an out-of-State retail or institutional pharmacy permit may not participate as an approved provider in the PAAD program, except for a voluntary prescription drug mail-order program or specialty pharmacy in a Medicare Part D Plan or a mail order prescription drug program required by a PAAD beneficiary's primary payer and, which maintain a permit from the Board of Pharmacy of the State of New Jersey.
- 2. File an application and sign an agreement with the Department of Human Services (DHS), Division of Medical Assistance and Health Services (DMAHS) and maintain a Medicaid provider number issued by DMAHS.
- 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 PAAD program, the new owner(s) shall apply to the Division, by contacting the Medicaid Provider Enrollment Unit (see N.J.A.C. 10:49, Administration Chapter, Enrollment Process) or the fiscal agent Provider Enrollment Unit.
- 3. To enroll as a Medicaid provider of pharmaceutical services, a pharmacy shall obtain a copy of the provider application on-line at www.njmmis.com or contact the Fiscal Agent Provider Enrollment Unit (see N.J.A.C. 10:51, Appendix D, Fiscal Agent Billing Supplement).

10:167A-1.4 (Reserved)

10:167A-1.5 Conditions for participation as a provider of pharmaceutical service

- (a) All participating pharmacies shall provide services within the scope of the permit issued by the Board of Pharmacy of the State of New Jersey. Prescriptions must be dispensed in compliance with all current existing Federal and State laws.
 - (b) All drugs must be prescribed.
- 1. "Prescribed drugs" means simple or compounded substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are:
 - i. (No change in text.)
- ii. Dispensed by licensed pharmacists on the basis of a written, telephonic, or electronic prescription that is recorded and maintained in the pharmacist's records.
- (c) Participating pharmacies shall permit properly identified representatives of the Department to:
 - 1.-2. (No change.)
- 3. Inspect private sector records, where deemed necessary to determine a pharmacy's usual and customary charges to the public.
- i. Information pertaining to the patient's name, address, and prescriber will remain confidential within the limits of the law. Only the following items may be reviewed:
 - (1) (No change.)
 - (2) Quantity dispensed (including refills);
 - (3) (No change.)
 - (4) Prescription number (for reference purposes only);
 - (5) Date written and date dispensed;
 - (6) National Drug Code;
 - (7) Brand-drug dispensing authorizations;
 - (8) Other insurance payments;
 - (9) Patient payment liability amounts;
 - (10) Days supply;
 - (11) Usual and customary charge;
 - (12) Drug acquisition cost; and
- (13) Customer certifications, such as manual or electronic signature log entries.
 - ii. (No change.)
- 4. Inspect acquisition records for the purchase of covered drugs based on the NDC numbers.

10:167A-1.6 Program restrictions affecting payment for prescribed

- (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, or any of the requirements of this chapter are not met:
- 1. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 10:167A-1.21) and Non-Proprietary or generic dispensing (see N.J.A.C. 10:167A-1.12);
- 2. Federal regulations (42 CFR 447.500, 512-516) 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. 10:167A-1.7, Basis of payment); and
 - 3. (No change in text.)

10:167A-1.7 Basis of payment

- (a) Subject to the requirements of the annual State appropriations act, this section provides a summary of the elements involved in the calculations of the payment of legend or certain non-legend drugs. The elements include the following:
 - 1.-4. (No change.)
 - (b)-(c) (No change.)

10:167A-1.9 Prescription drug dispensing fee

(a) The dispensing fee for each prescription dispensed to recipients by providers having retail permits, and where PAAD is the primary payer is \$3.73 to \$3.99. Additional dispensing fees (add-ons) per prescription

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shall be given, when PAAD is the primary payer, to pharmacy providers who provide the following:

- 1. (No change.)
- 2. Impact area location: \$0.15. The provider shall have a combined Medicaid and PAAD primary prescription volume, as calculated by DMAHS, equal to or greater than 50 percent of the provider's total prescription volume.
 - i. (No change.)
 - (b) (No change.)
- (c) In order to receive any or all of the above increments, the provider shall certify annually to the Division on Form FD-70, that the services, as defined in (a) above, are being provided and/or that the provider is entitled to the impact increment as defined in (a) above.
 - 1. (No change.)
- (d) Failure to submit the report required by (c) above annually shall result in retail pharmacy provider payments based on the basic dispensing fee of \$3.73.

10:167A-1.10 PAAD program copayment

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

10:167A-1.11 Compounded prescriptions

- (a) Compounded prescriptions may be reimbursed by the PAAD program. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and are dispensed by approved providers.
- (b) Claims for compounded prescriptions shall be electronically submitted to the fiscal agent through a point-of-sale (POS) claim adjudication system approved by the PAAD program. (See N.J.A.C. 10:167A-1.27).
- 1. A compounded prescription is indicated by the provider by the use of the "compound drug" indicator field in the EMC claim format.
 - (c) Reimbursement for compound prescriptions shall be:
- 1. In accordance with N.J.A.C. 10:167A-1.7 plus a dispensing fee, as described in N.J.A.C. 10:167A-1.9; or
 - 2. (No change.)
 - (d) (No change in text.)
- (e) Restrictions on payments for compounded prescriptions are as follows:
- 1. All legend ingredients that are contained in compounded prescriptions shall be covered by the PAAD program in accordance with N.J.A.C. 10:167A-1.14 and 1.15.
 - 2. (No change.)

10:167A-1.12 Non-proprietary or generic dispensing

When medication is prescribed by its non-proprietary or generic name, the pharmacist shall dispense the least expensive, therapeutically effective equivalent product available, preferably one listed in the list of interchangeable drug products. The labeler code, drug product code, and package size code of the actual product dispensed must be reported on the claim form.

10:167A-1.14 Covered pharmaceutical services

- (a) All covered pharmaceutical services shall be provided within the scope of the Medicaid or PAAD programs, and billed to the fiscal agent using the NCPDP claim format available at https://www.njmmis.com/downloadDocuments/NJ_D-0_NCPDP_Payer_Sheet.pdf.
 - (b) Covered pharmaceutical services include:
- 1. Prescribed legend drugs (for their medically accepted indication) as defined in Section 1927(k)(6) of the Social Security Act.
 - 2. Non-legend drugs, as follow:
 - i.-ii. (No change.)
 - iii. Syringes and needles for injectable medicines.

10:167A-1.15 Non-covered pharmaceutical services

- (a) The following classes of prescription drugs or conditions are not covered under the PAAD program:
 - 1.-13. (No change.)
- 14. Preventive vaccines, biologicals, and therapeutic drugs distributed to hospital clinics and/or community health centers by the New Jersey Department of Health;

- 15. If the provider has a delivery service, he or she may waive or discount delivery charges to the recipient but is prohibited from charging more than his or her usual and customary charge to the general public for delivery;
 - 16. Diabetic testing materials;
 - 17. Vitamins;
 - 18. Cough and/or cold medications;
 - 19. Drugs used for the treatment of erectile dysfunction;
- 20. Drugs used for alopecia, hair removal or hair restoration, eyelash growth, weight loss, and skin conditions; and
- 21. Active pharmaceutical ingredients, bulk drug substances, and excipients that are not a covered outpatient drug as defined in the Social Security Act at 42 U.S.C. § 1396r-8(k)(2).
- (b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):
 - 1.-4. (No change.)
- 5. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the PAAD program. (See N.J.A.C. 10:167A-1.28);
- 6. Drugs prescribed by practitioners not assigned a National Provider Identifier;
- 7. Drugs prescribed by excluded practitioners, as defined under the Patient Protection and Affordable Care Act regulations at 42 CFR Part 455;
- 8. Adjudicated claims for drugs not dispensed within 14 calendar days;
- 9. Brand-name drug dispensing at the request of a PAAD beneficiary when the substitution and reimbursement requirements of N.J.A.C. 10:167A-1.21 apply;
- 10. Drug products subject to the medical exception process that do not receive authorization in accordance with N.J.A.C. 10:167A-1.29; and
- 11. Legend drugs distributed by a manufacturer that has not entered into a rebate agreement with the Department as required by N.J.A.C. 10:167A-1.30.

10:167A-1.16 Quantity of medication

- (a) Days supply limitations for an Initial Prescription Claim for PAAD beneficiaries shall be different from days supply limitations for a Refill Prescription Claim.
 - 1.-2. (No change.)
- 3. For PAAD claims where PAAD is the primary payer, the following days supply limitations shall apply:
 - i.-ii. (No change.)
 - 4. (No change.)
 - (b)-(d) (No change.)

10:167A-1.19 Changes or additions to the original prescription

Changes or additions to the original prescription, when approved by the prescriber, shall be clearly indicated (including date and time) and signed by the dispensing pharmacist. No changes (for example, dosage, quantity, number of refills, days supply, etc.) are permitted on the original prescription order after the claim is submitted for payment.

10:167A-1.20 Prescription refill

- (a) The provider shall submit an electronic claim in the proper EMC claim format to the fiscal agent for reimbursement of an allowable refill. An allowable refill shall comply with the following instructions in order to be reimbursed as such:
- 1. Refill instructions shall be indicated in writing by the prescriber on the original prescription, on a facsimile of the prescription, in the electronic prescription, or verbally when telephoning the original prescription to the pharmacist. Verbal instructions shall be reduced to writing by the pharmacist.
 - 2.-3. (No change.)
- 4. An authorized refill for a prescription with no refill remaining must be assigned a new prescription number.
- 5. Prescription refills shall not be dispensed until 85 percent of the medication originally dispensed or refilled could have been consumed in accordance with the prescriber's written directions for use.

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- 10:167A-1.21 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 PAAD program. 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. When the prescriber does not initial "Substitution Permissible" or the "Do Not Substitute" statement on a prescription for a drug product, the pharmacist shall substitute from the list of interchangeable products and bill PAAD accordingly.
- 2. When the prescriber initials "Substitution Permissible," the pharmacist shall dispense and bill PAAD for one of the less expensive products listed as an interchangeable drug product with the brand name prescribed.
- 3. When the prescriber orders by generic name, the pharmacist shall dispense the least expensive, therapeutically effective product available to him or her at the time of dispensing. The product is not required to be from the list of interchangeable products.
- 4. Whenever the prescriber does not specify that substitution is not permitted and an interchangeable drug product is available for the prescription written, the PAAD program shall reimburse the pharmacy only for the maximum allowable cost of the interchangeable product, less the PAAD program co-payment.
- i. For non-MAC drugs (see N.J.A.C. 10:167A-1.7), when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be in accordance with N.J.A.C. 10:167A-1.7 (see N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions about the claim form or N.J.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format); or
- ii. For MAC drugs and in those situations in which a prescriber authorizes, in accordance with (b) below, the dispensing of a brand drug, the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be in accordance with N.J.A.C. 10:167A-1.7 (see N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions about the claim form or N.J.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format).
 - (b) (No change.)
- (c) A blanket authorization denying substitutions shall not be permitted. Each prescription 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) (No change.)
- 10:167A-1.22 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 the 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 list 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 to this list that are adopted, shall appear in the Federal Register.
 - (b) (No change.)

10:167A-1.23 Bundled drug service

(a) (No change.)

(b) Bundled drug service shall not be eligible for reimbursement by the PAAD program. The cost of the drug product which is a component of a bundled drug service (see N.J.A.C. 10:167A-1.14, Covered Pharmaceutical Services) shall be covered by the PAAD program.

10:167A-1.24 Claim submission

- (a) An approved pharmacy provider shall enter into an agreement with a point-of-sale (POS) intermediary in accordance with the requirements of N.J.A.C. 10:167A-1.27 or directly provide a similar telecommunication network approved by DMAHS to submit claims to the fiscal agent for adjudication. POS claims require an electronic format, which complies with the EMC National Council Prescription Drug Program standards.
 - 1. (No change in text.)

10:167A-1.26 PAAD beneficiary identification

- (a) (No change.)
- (b) The PAAD program shall issue to all PAAD eligibles a Validation Identification Card. The document shall contain the patient's name, PAAD identification number, effective date, and expiration date.
 - (c) (No change.)

10:167A-1.27 Point of sale (POS) claims adjudication system

- (a) PAAD pharmacy claims shall be submitted through a POS system and adjudicated by the State's fiscal agent on-line and in real-time. The pharmacist shall 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 delivery systems are precluded from the POS system.
- (b) In order for a PAAD-approved pharmacy provider, in accordance with N.J.A.C. 10:167A-1.5, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly provide a similar telecommunications network approved by the Division.
 - 1.-2. (No change.)
- 3. The Division shall consider the following in evaluating an application:
 - i.-iv. (No change.)
 - v. The applicant's adherence to the requirements of CMS.
- (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 PAAD program.
 - (d) (No change.)
- (e) All PAAD pharmacy providers shall submit claims in the EMC format, and transmit these claims on-line for adjudication by the fiscal agent's POS computer system.
- (f) Claim data requirements for EMCs generated by POS participating pharmacies include:
 - 1.-12. (No change.)
 - (g)-(j) (No change.)
- (k) Pharmacies are required to interact with prescribers and beneficiaries at POS to resolve matters related to on-line messages resulting from claim adjudication by the fiscal agent.
- 10:167A-1.29 Medical exception process (MEP)
- (a) For pharmacy claims with service dates on or after May 3, 1999, that exceed DUR Board standards, the PAAD program shall utilize the medical exception process (MEP) to allow the override of a claim denial, when medically necessary.
 - 1. (No change.)
- 2. All pharmacy claims shall be subject to the MEP regardless of claims media, except that claims from long-term care facility providers shall be exempt from the PDUR and MEP until notice is issued otherwise.
 - (b)-(d) (No change.)

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10:167A-1.30 Drug rebate program

Reimbursement for legend drugs shall be limited to manufacturers who have entered into a PAAD rebate agreement, including an agreement to pay rebates on claims for which PAAD is a secondary payer, with the Department of Human Services through the Division of Medical Assistance and Health Services pursuant to N.J.A.C. 10:51-1.22.

INSURANCE

(a)

DEPARTMENT OF BANKING AND INSURANCE DIVISION OF INSURANCE

Small Employer Health Benefits Program Readoption: N.J.A.C. 11:21-7A, 9, 15, and 16 and 11:21 Appendix Exhibit GG

Proposed: September 19, 2016, at 48 N.J.R. 1902(a).

Adopted: February 8, 2017, by Richard J. Badolato, Commissioner,

Department of Banking and Insurance.

Filed: February 8, 2017, as R.2017 d.041, without change.

Authority: N.J.S.A. 17:1-8.1 and 15.e and 17B:27A-17 et seq.

Effective Date: February 8, 2017. Expiration Date: October 12, 2023.

Summary of Public Comment and Agency Response:

No comments were received.

Federal Standards Statement

The readopted rules comply with the Federal Patient Protection and Affordable Care Act, Public Law 111-148, as amended by the Health Care and Education Reconciliation Act, Public Law 111-152. The readopted rules do not expand upon the requirements set forth in the Federal law.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 11:21-7A, 9, 15, and 16 and 11:21 Appendix Exhibit GG.

LAW AND PUBLIC SAFETY

(b)

DIVISION OF CONSUMER AFFAIRS BOARD OF MASSAGE AND BODYWORK THERAPY

Application for Licensure; License Without Examination Based on Licensure in Another State: Renewal of License

Adopted Amendments: N.J.A.C. 13:37A-2.1, 2.2, and 2.3

Proposed: August 15, 2016, at 48 N.J.R. 1586(a).

Adopted: December 7, 2016, by the Board of Massage and Bodywork Therapy, Cynthia Sinicropi-Philibosian, Chair.

Filed: February 1, 2017, as R.2017 d.037, without change.

Authority: N.J.S.A. 45:11-67. Effective Date: March 6, 2017. Expiration Date: September 4, 2019.

Summary of Public Comment and Agency Response:

The official comment period ended October 14, 2016. The Board received no comments.

Federal Standards Statement

A Federal standards analysis is not required because there are no Federal standards or requirements applicable to the subject matters of the adopted amendments.

Full text of the adoption follows:

SUBCHAPTER 2. LICENSURE

13:37A-2.1 Application for licensure

(a) (No change.)

(b) An individual who applies for a license under (a)1 above shall submit to the Board:

1.-3. (No change.)

- 4. Proof that the applicant has current certification in CPR, Firstaid, and use of an automated external defibrillator (AED) from courses offered by the American Heart Association or a substantially similar course approved or offered by the American Red Cross, the National Safety Council, Coyne First Aid, Inc., the American Safety and Health Institute, EMP International Inc., or EMS Safety Services Inc.; and
 - 5. (No change.)
- (c) An individual who applies for a license under (a)2 above shall submit to the Board:
 - 1.-3. (No change.)
- 4. Proof that the applicant has current certification in CPR, Firstaid, and use of an automated external defibrillator (AED) from courses offered by the American Heart Association or a substantially similar course approved or offered by the American Red Cross, the National Safety Council, Coyne First Aid, Inc., the American Safety and Health Institute, EMP International Inc., or EMS Safety Services Inc.; and

5. (No change.) (d)-(g) (No change.)

- 13:37A-2.2 License without examination based on licensure in another state
 - (a) (No change.)
- (b) An applicant for license who is licensed or certified in another state shall submit to the Board:
 - 1.-3. (No change.)
- 4. Proof that the applicant has current certification in CPR, Firstaid, and use of an automated external defibrillator (AED) from courses offered by the American Heart Association or a substantially similar course approved or offered by the American Red Cross, the National Safety Council, Coyne First Aid, Inc., the American Safety and Health Institute, EMP International Inc., or EMS Safety Services Inc.; and
 - 5. (No change.)
 - (c) (No change.)

13:37A-2.3 Renewal of license

(a) Licenses shall be renewed biennially on a form provided by the Board. Each applicant shall attest that the continuing education requirements of N.J.A.C. 13:37A-4.1 have been completed during the prior biennial period and that the applicant is currently certified in CPR and use of an automated external defibrillator (AED) from courses offered by the American Heart Association or a substantially similar course approved or offered by the American Red Cross, the National Safety Council, Coyne First Aid, Inc., the American Safety and Health Institute, EMP International Inc., or EMS Safety Services Inc.

(b)-(g) (No change.)

(h) Upon application to the Board, the Board may permit a licensee who has been on inactive status to return to active status provided such applicant completes the continuing education credits that are required per biennial period for each biennial period that the applicant is on inactive status and holds current certification in CPR, Firstaid, and use of an automated external defibrillator (AED) from courses offered by the American Heart Association or a substantially similar course approved or offered by the American Red Cross, the National Safety Council, Coyne First Aid, Inc., the American Safety and Health Institute, EMP International Inc., or EMS Safety Services Inc.