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INSURANCE

DEPARTMENT OF BANKING AND INSURANCE

OFFICE OF CONSUMER PROTECTION SERVICES

Pharmacy Benefits Managers

Proposed New Rules: N.J.A.C. 11:4-62

Authorized By: Richard J. Badolato, Commissioner, Department of Banking and Insurance.

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

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

Proposal Number: PRN 2017-193.

Submit written comments by October 20, 2017, to:

Denise M. Illes, Chief

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The agency proposal follows:

Summary

N.J.S.A. 17B:27F-1 et seq., effective April 10, 2016, sets forth various requirements for contracts between a pharmacy benefits manager (PBM) and a contracted pharmacy. A PBM acts on behalf of an insurer to reimburse contracted pharmacies for the costs of drugs covered under

an insurance or health benefits contract. Given the volatility in the costs for generic drugs, PBMs may be reimbursing pharmacies using out-of-date sources that do not reflect the actual available costs of such drugs at the time reimbursement is made. The statute seeks to address this issue by establishing various requirements for contracts between a PBM and a contracted pharmacy, including: the provision of the sources utilized to determine multiple source generic drug pricing, including, if applicable, the maximum allowable costs or any successive pricing formula utilized by the PBM; the updating of that pricing information every seven days; and establishing a reasonable process by which contracted pharmacies have a method to access relevant maximum allowable cost pricing lists and any successive pricing formulas in a timely manner. The statute also sets forth requirements for placing prescription drugs on multiple source generic lists, and requires that contracts between a PBM and a contracted pharmacy include a process to appeal, investigate, and resolve disputes. The statute also directs the Commissioner of Banking and Insurance (Commissioner) to adopt rules to effectuate the purposes of the statute, including any penalty provisions the Commissioner deems necessary.

The Department of Banking and Insurance (Department) is proposing these new rules to implement the statute. The rules generally reiterate the statutory requirements, with additional provisions as described more fully below.

A summary of the proposed new rules follows.

Proposed N.J.A.C. 11:4-62.1 sets forth the purpose and scope of the proposed new rules.

Proposed N.J.A.C. 11:4-62.2 sets forth the definitions of terms used throughout the subchapter. The definitions track those in N.J.S.A. 17B:27F-1.

Proposed N.J.A.C. 11:4-62.3 sets forth requirements to be included in a contract between a PBM and a contracted pharmacy. These proposed requirements track N.J.S.A. 17B:27F-3.

The statute and proposed new rules require that contracts between a PBM and a contacted pharmacy:

1. Include in the contract the sources utilized to determine multiple source generic drug pricing, including, if applicable, the maximum allowable costs or any successive pricing formula of the PBM;

2. Update the pricing information every seven calendar days; and

3. Establish a reasonable process by which contracted pharmacies have a method to access relevant maximum allowable costs pricing lists and any successive pricing formulas in a timely manner. The Department proposes to set forth examples of such a process to include providing online access to the maximum allowable cost pricing, the sources therefor and the date of last update of such pricing, and providing such information through e-mail to contracted pharmacies or by similar means.

The proposed new rules also reflect the statutory requirement that a PBM maintain a procedure to eliminate drugs from the list of drugs subject to multiple source generic drug pricing or modify allowable cost rates in a timely fashion, but in no event any later than 15 days from the date of any change. Further, the proposed new rule reflects the statutory requirement for a PBM to place a particular prescription drug on a multiple source generic list and that a PBM shall not penalize a pharmacist or pharmacy on audit if the pharmacist or pharmacy performs a generic substitution pursuant to the Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq.

Proposed N.J.A.C. 11:4-62.4 sets forth requirements for the appeals process, investigation, and dispute resolution, as set forth in N.J.S.A. 17B:27F-4.

Proposed N.J.A.C. 11:4-62.5 provides that, with respect to all pharmacy benefits contracts executed or renewed between a PBM and a contracted pharmacy, the PBM shall file a certification with the Department in the form of proposed N.J.A.C. 11:4-62 Appendix Exhibit A, incorporated herein by reference, that such contracts shall comply with the requirements set forth in N.J.S.A. 17B:27F-1 et seq., and the proposed new rules. The certification shall be filed with the Department no later than 30 days after the effective date of the subchapter, or within 30 days of commencing business as a pharmacy benefits manager, with respect to any existing and future contracts. The proposed new rule also provides that, if no renewal date is specified in the contract between a PBM and a contracted pharmacy, such contract shall be deemed to renew at such time that there is a change in any substantive term of the contract.

Proposed N.J.A.C. 11:4-62.6 sets forth penalties for violations of this subchapter. Specifically, the proposed new rule provides that a PBM that fails to file a certificate of compliance as required by N.J.A.C. 11:4-62.5 may, after notice and opportunity for a hearing, be subject to a penalty of up to $1,000 for each violation. A PBM that fails to comply with the requirement of N.J.S.A. 17B:27F-1 et seq., or N.J.A.C. 11:4-62.3 and 62.4 may, after notice and opportunity for a hearing, be subject to penalty of not less than $5,000 or more than $10,000 for each violation. These proposed penalties are consistent with those established for violations of the New Jersey Insurance Producer Licensing Act of 2001, N.J.S.A. 17:22A-26 et seq. Penalties shall be imposed in accordance with the procedures set forth in N.J.A.C. 11:17D.

The proposed new rules thus implement the intent of the Legislature as expressed in N.J.S.A. 17B:27F-1 et seq., to ensure that PBMs provide requisite information to contracted pharmacies with respect to the sources for generic drug pricing and modifications thereto in a

timely manner, as well as the provision of an appeals process for disputes between a contracted pharmacy and a PBM.

A 60-day comment period is provided for this notice of proposal, and, therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, the notice is excepted from the provisions of N.J.A.C. 1:30-3.1 and 3.2 governing rulemaking calendars.

Social Impact

As set forth in the Summary above, the proposed new rules implement N.J.S.A. 17B:27F-1 et seq., with respect to contracts between PBMs and contracted pharmacies. The proposed new rules help to ensure that generic drug pricing information is updated regularly, and the sources for such pricing are provided to contracted pharmacies. In addition, the proposed new rules set forth the appeals process required under the statute for disputes between a contracted pharmacy and a PBM. The proposed new rules thus will have a positive social impact.

Economic Impact

The primary economic impact is imposed by the statute as set forth in the Summary above. The Department does not anticipate that the proposed new rules should impose any significant additional economic impact on PBMs. PBMs will be required to incur costs associated with compliance with the statute, for example, ensuring that contracts between the PBM and contracted pharmacies include the required terms and conditions as set forth therein. PBMs will be required to provide a reasonable process by which contracted pharmacies may access relevant maximum allowable cost pricing lists and any successive pricing formulas in a timely manner. The statute and the proposed new rules, therefore, should have a positive economic impact on contracted pharmacies by ensuring that the pricing for reimbursement for generic drugs is updated regularly to reflect current pricing, and that contracted pharmacies have

access to maximum allowable cost pricing lists in a timely manner. The professional services required to comply with the proposed new rules would include legal, information technology, and administrative services. PBMs should already possess or contract for such services. As noted above, the majority of the requirements are imposed by the statute, not by the proposed new rules.

As noted in the Summary above, the purpose of the statute and the proposed new rules is to help ensure that contracted pharmacies are reimbursed at proper levels based on current pricing lists. These requirements should result in a negligible negative economic impact on PBMs. Accordingly, the benefits of the proposed new rules as set forth above outweigh any costs that may be imposed.

Federal Standards Statement

The proposed new rules are not subject to any Federal requirements or standards.

Jobs Impact

The Department does not anticipate that any jobs will be generated or lost as a result of the proposed new rules. The Department invites commenters to submit any data or studies on the potential jobs impact of the proposed new rules together with their comments on other aspects of the proposal.

Agriculture Industry Impact

The proposed new rules will not have any impact on the agriculture industry in New Jersey.

Regulatory Flexibility Analysis

The proposed new rules may apply to "small businesses," as that term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. To the extent the proposed new rules

apply to such small businesses, they will apply to PBMs and contracted pharmacies, resident and transacting business in this State. The economic impact and professional services required to comply with the proposed new rules are set forth in the Summary and Economic Impact above. As noted in the Economic Impact, the impacts are generally imposed by the statute and not the proposed new rules. The costs of compliance to PBMs with respect to the proposed new rules, including provision of a reasonable process by which contracted pharmacies may access relevant maximum allowable cost pricing in a timely manner and a requirement that PBMs file a one-time certificate of compliance, should be minimal. The proposed new rules implement the requirements in N.J.S.A. 17B:27F-1 et seq., with respect to contracts between PBMs and contracted pharmacies. These requirements do not vary based on business size. Accordingly, no differentiation in compliance requirements is provided in the proposed new rules based on business size.

Housing Affordability Impact Analysis

The proposed new rules will not have an impact on housing affordability in this State and are unlikely to evoke a change in the average costs associated with housing in that the proposed new rules relate to contracts between PBMs and contracted pharmacies.

Smart Growth Development Impact Analysis

The proposed new rules will not have an impact on smart growth in this State and there is an extreme unlikelihood that the proposed new 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 in that the proposed new rules relate to contracts between PBMs and contracted pharmacies.

Full text of the proposed new rules follows:

SUBCHAPTER 62. PHARMACY BENEFITS MANAGERS

11:4-62.1 Purpose and scope

(a) This subchapter sets forth the requirements for contracts between a pharmacy benefits manager and a contracted pharmacy pursuant to N.J.S.A. 17B:27F-1 et seq., and requires pharmacy benefits managers to certify that new or existing contracts, upon renewal, comply with the requirements set forth in N.J.S.A. 17B:27F-1 et seq., and this subchapter.

(b) This subchapter shall apply to all contracts between a pharmacy benefits manager and a contracted pharmacy pursuant to N.J.S.A. 17B:27F-1 et seq.

11:4-62.2 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Carrier" means an insurance company, health service corporation, hospital service corporation, medical service corporation, or health maintenance organization authorized to issue health benefits plans in this State.

"Commissioner" means the Commissioner of the New Jersey Department of Banking and Insurance.

"Contracted pharmacy" means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with:

1. The pharmacy benefits manager directly;

2. A pharmacy services administration organization; or

3. A pharmacy group purchasing organization.

"Covered person" means a person on whose behalf a carrier or other entity, who is the sponsor of the health benefits plan, is obligated to pay benefits pursuant to a health benefits plan.

“Department” means the New Jersey Department of Banking and Insurance.

“Drug” means a drug or device as defined in N.J.S.A. 24:1-1.

“Health benefits plan” means a benefits plan that pays hospital or medical expense benefits for covered services, or prescription drug benefits for covered services, and is delivered or issued for delivery in this State by or through a carrier or any other sponsor, including, but not limited to, a carrier, self-insured employers that self-fund their employee benefits plans, or unions. For the purposes of this chapter, health benefits plan shall not include the following plans, policies, or contracts: accident only, credit disability, long-term care, Medicare supplement coverage, CHAMPUS supplement coverage, coverage for Medicare services pursuant to a contract with the United States government, coverage arising out of a worker's compensation or similar law, coverage under a policy of private passenger automobile insurance issued pursuant to N.J.S.A. 39:6A-1 et seq., or hospital confinement indemnity coverage.

“Multiple source generic drug” means a prescription drug that is: (1) listed as therapeutically and pharmaceutically equivalent or "A," "B," "NR," or "NA" rated in the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book"; and (2) is available for purchase without limitations by all pharmacies in the State from national or regional wholesalers and is not obsolete or temporarily unavailable.

“Pharmacy” means any place in the State where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist, but shall not include a medical office under the control of a licensed physician.

“Pharmacy benefits management services” means the provision of any of the following services on behalf of a purchaser: the procurement of prescription drugs at a negotiated rate for

dispensation within this State; the processing of prescription drug claims; or the administration of payments related to prescription drug claims.

"Pharmacy benefits manager" means a corporation, business, or other entity, or unit within a corporation, business, or other entity, that administers prescription drug benefits on behalf of a purchaser.

"Prescription" means a prescription as defined in N.J.S.A. 24:6E-4.

"Prescription drug benefits" means the benefits provided for prescription drugs and pharmacy services for covered services under a health benefits plan contract.

"Purchaser" means any sponsor of a health benefits plan who enters into an agreement with a pharmacy benefits management company for the provision of pharmacy benefits management services to covered persons.

11:4-62.3 Pharmacy benefits manager contracts

(a) Upon execution or renewal of each contract, a pharmacy benefits manager shall, with respect to contracts between a pharmacy benefits manager and a contracted pharmacy:

1. Include in the contract the sources utilized to determine multiple source generic drug pricing, including, if applicable, the maximum allowable cost or any successive pricing formula, of the pharmacy benefits manager;

2. Update that pricing information every seven calendar days; and

3. Establish a reasonable process by which contracted pharmacies have a method to access relevant maximum allowable cost pricing lists and any successive pricing formulas in a timely manner. Examples of such a process include: providing online access to the maximum allowable cost pricing, the sources thereof and the date of the last update of such

pricing; providing such information through e-mail to contracted pharmacies; or, by similar means.

(b) A pharmacy benefits manager shall maintain a procedure to eliminate drugs from the list of drugs subject to multiple source generic drug pricing or modify maximum allowable cost rates in a timely fashion, but in no event any later than 15 days from the date of any change.

(c) In order to place a particular prescription drug on a multiple source generic list, the pharmacy benefits manager shall, at a minimum, ensure that:

1. The drug is listed as therapeutically and pharmaceutically equivalent or "A," "B," "NR," or "NA" rated in the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book"; and

2. The drug is available for purchase without limitations by all pharmacies in the State from national or regional wholesalers and is not obsolete or temporarily unavailable.

(d) A pharmacy benefits manager shall not penalize a pharmacist or pharmacy on audit if the pharmacist or pharmacy performs a generic substitution pursuant to the "Prescription Drug Price and Quality Stabilization Act," N.J.S.A. 24:6E-1 et seq.

11:4-62.4 Appeals

(a) All contracts between a pharmacy benefits manager and a contracted pharmacy shall include a process to appeal, investigate, and resolve disputes regarding multiple source generic drug pricing. The contract provision establishing the process shall include the following:

1. The right to appeal shall be limited to 14 calendar days following the initial claim;

2. The appeal shall be investigated and resolved by the pharmacy benefits manager through an internal process within 14 calendar days of receipt of the appeal by the pharmacy benefits manager; and

3. A telephone number at which a pharmacy may contact the pharmacy benefits manager and speak with an individual who is involved in the appeals process.

(b) In addition to (a) above, the contract shall also provide that:

1. If the appeal is denied, the pharmacy benefits manager shall provide the reason for the denial and identify the national drug code of a drug product that is available for purchase by contracted pharmacies in this State from wholesalers registered pursuant to N.J.S.A. 24:6B-1 et seq., at a price which is equal to or less than the maximum allowable cost for the appealed drug as determined by the pharmacy benefits manager; and

2. If the appeal is approved, the pharmacy benefits manager shall make the price correction, permit the reporting pharmacy to reverse and rebill the appealed claim, and make the price correction effective for all similarly situated pharmacies from the date of the approved appeal.

11:4-62.5 Certification of compliance

(a) All pharmacy benefits managers shall file a certification with the Department in the form of N.J.A.C. 11:4-62 Appendix Exhibit A, which is incorporated herein by reference, attesting that all pharmacy benefits contracts executed or renewed between the pharmacy benefits manager and all contracted pharmacies located in this State comply with the requirements set forth in N.J.S.A. 17B:27F-1 et seq., and this subchapter. Such certification shall be filed with the Department no later than (30 days after the effective date of this

subchapter), or within 30 days of commencing business as a pharmacy benefits manager, with respect to any existing and future contracts. Certifications shall be mailed to:

New Jersey Department of Banking and Insurance

Office of Life and Health

20 West State St.

PO Box 325

Trenton, NJ 08625-0325

(b) For purposes of this section, if no renewal date is specified in the contract between a pharmacy benefits manager and a contracted pharmacy, such contract shall be deemed to renew at such time that there is change in any substantive term of the contract.

11:4-62.6 Penalties

(a) Failure to comply with the terms of this subchapter shall result in the imposition of penalties as authorized by law.

(b) A pharmacy benefits manager that fails to file a certificate of compliance as required by N.J.A.C. 11:4-62.5 may, after notice and opportunity for a hearing, be subject to a penalty of up to $1,000 for each violation.

(c) A pharmacy benefits manager that fails to comply with the requirements of N.J.S.A. 17B:27F-1 et seq., or N.J.A.C. 11:4-62.3 and 62.4 may, after notice and opportunity for a hearing, be subject to a penalty of not less than $5,000 or more than $10,000 for each violation.

(d) Penalties shall be imposed in accordance with the procedures set forth in N.J.A.C. 11:17D.

APPENDIX

EXHIBIT A

CERTIFICATION OF COMPLIANCE

I, _____(Name of Individual Acting on Behalf of the Pharmacy Benefits Manager)___, hereby certify that with respect to all pharmacy benefits contracts executed or renewed between _____(Name of Pharmacy Benefits Manager)_____ and a contracted pharmacy located in this State, such contracts comply with the requirements set forth in N.J.S.A. 17B:27F-1 et seq. and N.J.A.C. 11:4-62. I further certify that I am authorized to make this certification on behalf of ____(Name of Pharmacy Benefits Manager)._____

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

_____

Signature

_____

Print Name

_____

Title

_____

Date