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HUMAN SERVICES

DIVISION OF AGING SERVICES

Provision of Pharmaceutical Services Under the Senior Gold Program

Proposed Readoption: N.J.A.C. 8:83E

Authorized By: Jennifer Velez, Commissioner, Department of Human Services.

Authority: N.J.S.A. 30:4D-43 et seq., particularly 30:4D-50; and P.L. 2012, c. 17.

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

Proposal Number: PRN 2014-056.

Submit written comments by July 4, 2014, to:

Diane Giordano

Division of Aging Services

New Jersey Department of Human Services

PO Box 723

Trenton, NJ 08625-0723

Summary

The Department of Human Services (Department) proposes to readopt N.J.A.C. 8:83E, which has governed and would continue to govern the requirements for the provision of pharmaceutical services for the Senior Gold Prescription Discount Program. The Department has reviewed N.J.A.C. 8:83E and has determined the existing rules to be necessary, adequate, reasonable, efficient, understandable, and responsive to the

purposes for which they were promulgated. Pursuant to N.J.S.A. 52:14B-5.1.b, N.J.A.C. 8:83E will expire on April 5, 2014. Pursuant to N.J.S.A. 52:14B-5.1.c(2), the filing of this notice of proposal with the Office of Administrative Law prior to the expiration date operated to extend the expiration date of N.J.A.C. 8:83E 180 days to October 2, 2014.

Effective July 1, 2012, the functions, powers, and duties of the Division on Aging and Community Services in the former Department of Health and Senior Services were transferred to the newly established Division of Aging Services in the Department of Human Services. See P.L. 2012, c. 17. All references to "Department" for the time period on or after July 1, 2012, shall mean the Department of Human Services. All references to "Department" for the time period prior to that date shall mean the Department of Health.

The following is a summary of the regulatory history of N.J.A.C. 8:83E. The Senior Gold Prescription Discount Program (Program) was created as a result of the signing of the Senior Gold Prescription Discount Act, P.L. 2001, c. 96 (N.J.S.A. 30:4D-43 et seq.), on May 15, 2001. The Department initially adopted Chapter 83E, Provision of Pharmaceutical Services Under the Senior Gold Program, as emergency new rules and concurrently proposed new rules at 33 N.J.R. 1954(a). The emergency new rules became effective May 18, 2001. The Department subsequently adopted Chapter 83E as new rules, effective November 19, 2001, at 33 N.J.R. 3940(a).

The Department proposed amendments to N.J.A.C. 8:83E-1.2 to correct a grammatical error and to modify language to articulate the intent that providers are pharmacies participating in the Program. The Department proposed amendments to

N.J.A.C. 8:83E-1.4, 1.5, 1.18, and 1.19 to incorporate the requirements of Fiscal Year 2007 Appropriations Act (P.L. 2006, c. 45 at pages 90 to 92, 94, and 96 to 97). The Department proposed amendments to N.J.A.C. 8:83E-1.4, 1.10, and 1.19 to delete references to the Drug Utilization Review Council, due to the cessation of its functions, and substitute a cross-reference to N.J.A.C. 8:71, in order to fill the void for a list of interchangeable drug products. The Department proposed amendments to N.J.A.C. 8:83E-1.5 and 1.25 to incorporate the requirements of the Deficit Reduction Act of 2005, Pub. L 109-171, effective February 8, 2006. The Department proposed amendments to N.J.A.C. 8:83E-1. The Department proposed amendments to N.J.A.C. 8:83E-1.6 to delete a prescription discount standard for prescription claims not covered by the maximum allowable cost price. The Department proposed amendments to N.J.A.C. 8:83E-1.14 and 1.18 to provide that standards established pursuant to the Medicare Modernization Act will supercede any requirements contained in those sections. The Department proposed amendments to N.J.A.C. 8:83E-1.25 to correct a reference to N.J.A.C. 10:49-9.8 and 9.9. The Department proposed the foregoing amendments to N.J.A.C. 8:83E-1.2, 1.4, 1.5, 1.6, 1.10, 1.14, 1.18, 1.19, and 1.25 at 38 N.J.R. 5295(a) and subsequently adopted the amendments, with substantive changes to address matters governed by a State appropriations act as amended and supplemented by subsequent State appropriations acts at 39 N.J.R. 1711(a).

The following is a summary of the chapter proposed for readoption:

N.J.A.C. 8:83E-1.1 provides a statement of the intent of the Program.

N.J.A.C. 8:83E-1.2 sets forth the standards and requirements that a pharmacy must follow in order to be designated as a provider of pharmaceutical services under the

Program.

N.J.A.C. 8:83E-1.3 provides the requirements that a participating pharmacy must follow and the qualifications a participating pharmacy must have as a provider of pharmaceutical services under the Program.

N.J.A.C. 8:83E-1.4 sets forth the Program restrictions affecting payment for prescribed drugs.

N.J.A.C. 8:83E-1.5 sets forth the elements involved in the calculation of the payment for legend and non-legend drugs under the Program.

N.J.A.C. 8:83E-1.6 sets forth the standards for determining a participating pharmacy's prescription volume.

N.J.A.C. 8:83E-1.7 sets forth the prescription drug dispensing fees payable to participating pharmacies. N.J.A.C. 8:83E-1.7 also establishes a reporting requirement that participating pharmacies must comply with in order to receive any or all of the drug dispensing fees.

N.J.A.C. 8:83E-1.8 sets forth the requirements for co-payment by Program beneficiaries.

N.J.A.C. 8:83E-1.9 sets forth the standards and requirements that enable participating pharmacies to be reimbursed for prepared compounded prescriptions.

N.J.A.C. 8:83E-1.10 provides that when medication is prescribed by its non-proprietary or generic name, the pharmacist shall dispense the least expensive, therapeutically-effective equivalent product available.

N.J.A.C. 8:83E-1.11 establishes the standards to be utilized by the Program in establishing a participating pharmacy's usual and customary charge for the purpose of

reimbursing the participating pharmacy.

N.J.A.C. 8:83E-1.12 describes Program-covered pharmaceutical services and requires that covered pharmaceutical services comply with Program and Medicaid standards. N.J.A.C. 8:83E-1.12 also establishes that pharmaceutical services provided pursuant to the Program are billed through a fiscal agent.

N.J.A.C. 8:83E-1.13 provides an enumeration of prescription drug classifications and pharmaceutical services that are not covered by the Program. N.J.A.C. 8:83E-1.13 also provides that manufacturers and distributors may request the review of a denial of reimbursement for products within 30 days of the date of the denial.

N.J.A.C. 8:83E-1.14 provides the standards and requirements for submission of initial prescription claims and refill prescription claims and the requirements respecting splitting or reducing a quantity of prescribed prescription medication.

N.J.A.C. 8:83E-1.15 provides the dosage and directions standards and exceptions required with respect to the labeling of all prescription medication dispensed by participating pharmacies to Program beneficiaries.

N.J.A.C. 8:83E-1.16 provides the requirements for telephone-rendered prescriptions from prescribers to participating pharmacies.

N.J.A.C. 8:83E-1.17 provides the requirements respecting changes or additions to an original prescription by a prescriber.

N.J.A.C. 8:83E-1.18 provides the procedures and requirements applicable to participating pharmacies with respect to prescription refills.

N.J.A.C. 8:83E-1.19 provides that the requirements of the Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall be applicable to the

Program. N.J.A.C. 8:83E-1.19 also sets forth the requirements in dispensing medications when substitutions are permitted, are not permitted, or are not indicated by the prescriber and the reimbursement amounts to be provided in such circumstances.

N.J.A.C. 8:83E-1.20 provides the Program standards with respect to drug efficacy study implementation (DESI).

N.J.A.C. 8:83E-1.21 defines and provides Program requirements with respect to bundled drug services.

N.J.A.C. 8:83E-1.22 provides Program requirements for hard copy and electronic claims submission by participating pharmacies.

N.J.A.C. 8:83E-1.23 sets forth the Program eligibility standards for Program beneficiaries.

N.J.A.C. 8:83E-1.24 provides that participating pharmacies shall verify an individual's coverage under the Program and that the Department shall issue validation identification cards to Program beneficiaries.

N.J.A.C. 8:83E-1.25 sets forth the Program guidelines and requirements for submission of claims by participating pharmacies through a point-of-sale claims adjudication system.

N.J.A.C. 8:83E-1.26 sets forth Program guidelines, standards, and requirements respecting the prospective drug utilization review (PDUR) program.

N.J.A.C. 8:83E-1.27 describes and sets forth the requirements of the medical exception process for pharmacy claims that exceed drug utilitzation review (DUR) Board standards. N.J.A.C. 8:83E-1.27 also provides a process for Program beneficiaries or prescribers to appeal a claim denial.

N.J.A.C. 8:83E-1.28 provides that reimbursement for legend drugs shall be limited to manufacturers who have entered into a Senior Gold rebate agreement with the Department pursuant to N.J.A.C. 10:51-1.22.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement, as set forth at N.J.A.C. 1:30-3.1 and 3.2, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Senior Gold Prescription Discount Program is a State-funded prescription program that provides prescription discounts for eligible elderly and disabled New Jersey residents who do not qualify for prescription benefits through the Pharmaceutical Assistance to the Aged and Disabled (PAAD) Program. The rules proposed for readoption have assisted and would continue to assist eligible individuals to obtain discount prescriptions from their participating pharmacies. The rules proposed for readoption have set forth and would continue to set forth in detail the policies and procedures respecting the provision of pharmaceutical services by participating pharmacies under the Program.

Economic Impact

The rules proposed for readoption would continue to have a beneficial economic impact on pharmacies that participate in the Program because the rules allow eligible individuals to obtain prescription drugs from any participating pharmacy and assure subsidies to participating pharmacies for the prescription drugs dispensed. Participating

pharmacies would continue to experience additional business because more people will be able to afford their prescription drugs.

The rules proposed for readoption would not impose any additional economic burdens on the participating pharmacies. Participating pharmacies have incurred and would continue to incur varying administrative costs directly related to their participation in the Program. The rules proposed for readoption have imposed and would continue to impose limitations on charges that would be reimbursed by the Department and prescribe specific dispensing fees, both of which are necessary to continue to provide the Program benefits within budgetary limitations. Accordingly, the Department does not anticipate that the rules proposed for readoption would have an added economic impact on participating pharmacies.

There has not been and there would be no anticipated impact on New Jersey taxpayers as a result of the readoption of N.J.A.C. 8:83E. With the adoption of prescription coverage through the Medicare Prescription Drug Program established pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, effective December 8, 2003, and the regulations promulgated thereunder at 42 CFR 423.1 et seq., Program benefit costs have decreased because Program benefits are secondary to benefits provided through the Medicare Prescription Drug Program.

Federal Standards Statement

The Program establishes polices and requirements pursuant to N.J.S.A. 30:4D-43 et seq. The Program is completely State-funded. Therefore, there are no Federal

standards governing eligibility or services since these are established by State law. However, there are Federal requirements to be followed in other sections of the rules. In such cases, the Department imposes the same requirements as are imposed by the Federal government.

Federal regulations at 42 CFR 440.120 define what substances or mixtures may be covered as prescribed drugs. (See also 42 U.S.C. § 1396r-8(d)). The rebate requirements are set forth at 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 Social Security Act (42 U.S.C. § 1396r-8(k)(2)(A) and 21 CFR 310.6). Drug rebate requirements are set forth at section 1927(a) through (c) of the Social Security Act (42 U.S.C. § 1396r-8(a) through (c)). Payment for drugs is subject to Federal upper payment limits (42 CFR 447.301, 331-334) and section 1927(e) and (k) of the Social Security Act (42 U.S.C. §§ 1396r-8(e) and 8(k), respectively), as amended by the Deficit Reduction Act of 2005 (DRA), Pub. L. 109-171, effective February 8, 2006.

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" (collectively referred to as "HIPAA") apply to health information created or maintained by health care providers who engage in certain electronic transactions, health plans, and health care clearinghouses. The Program may be a covered entity, specifically, a health plan, within the meaning of HIPAA.

Pursuant to 45 CFR 164.512(d), a covered entity may disclose protected health information to a health oversight agency (such as the Centers for Medicare and Medicaid Services or “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 disclosure 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 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 and Senior Gold Programs, would not constitute a violation of HIPAA. To the extent the PAAD and Senior Gold Programs may be subject to HIPAA, the rules proposed for readoption meet but does not exceed the requirements of HIPAA.

Except as described above, there are no Federal standards applicable to the subject matter of the rules proposed for readoption. Since any Federal requirements applicable to the rules are met, but not exceeded, no Federal standards analysis is required.

Jobs Impact

The Department does not anticipate that the rules proposed for readoption would have an impact on employment in New Jersey. The rules proposed for readoption would continue the existing requirements imposed upon pharmacies participating in the Program.

Agriculture Industry Impact

The rules proposed for readoption would not have an impact on the agriculture industry.

Regulatory Flexibility Analysis

The rules proposed for readoption have imposed and would continue to impose reporting, recordkeeping, and compliance requirements on participating pharmacies, some of which may be considered small businesses as defined under the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Pharmacies seeking to become providers under the Program would continue to be required to operate under a valid retail and/or institutional permit issued by the State Board of Pharmacy, file an application with the Department and execute an agreement of participation. Participating pharmacies have been required and would continue to be required to provide complete prescription services, and all drugs under the Program must be prescribed. Participating pharmacies must continue to allow Department representatives to inspect various records.

The rules proposed for readoption would continue to establish the basis of payment to participating pharmacies and set various dispensing fees. Reimbursement for compounded prescriptions would continue to be subject to certain restrictions.

Housing Affordability Impact Analysis

The rules proposed for readoption would have no impact on affordable housing or change in the average costs associated with housing in New Jersey, because the rules pertain to pharmacies participating in the Senior Gold Prescription Discount Program and the provision of pharmaceutical services under the Program.

Smart Growth Development Impact Analysis

The rules proposed for readoption would have no impact on smart growth or change in housing production in Planning Areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:83E.