

HUMAN SERVICES

DIVISION OF AGING SERVICES

Senior Gold Prescription Program Manual

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

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 2014-055.

Submit written comments by July 4, 2014, to:

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The agency proposal follows:

Summary

The Department of Human Services (Department) proposes to readopt N.J.A.C. 8:83D, which has governed and would continue to govern the policy and procedures respecting beneficiary eligibility for the Senior Gold Prescription Discount Program. The Department has reviewed N.J.A.C. 8:83D 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. 8:83D 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 for readoption with the Office of Administrative Law prior to the expiration date operated to extend the expiration date of N.J.A.C. 8:83D 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. 8:83D. 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 83D, Senior Gold Prescription Program Manual, as emergency new rules and concurrently proposed new rules at 33 N.J.R. 1948(a). The emergency new rules became effective May 18, 2001. The Department subsequently adopted Chapter 83D as new rules at 33 N.J.R. 3934(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) through a notice of administrative change effective January 1, 2002, at 34 N.J.R. 935(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) through a notice of administrative change effective January 1, 2003, at 35 N.J.R. 1115(a).

The Department proposed the aforementioned amendments to the income eligibility limits for incorporation into N.J.A.C. 8:83D-6.2(a) and (b), at 35 N.J.R. 1336(a). The Department subsequently adopted the proposed amendments to N.J.A.C. 8:83D-6.2, effective October 6, 2003, at 35 N.J.R. 4722(a).

Pursuant to N.J.A.C. 8:83D-6.2(m), the Department published a public notice of income eligibility limits for 2004 pertaining to the Senior Gold Prescription Program Manual at 35 N.J.R. 5622(a).

The Department proposed amendments to N.J.A.C. 8:83D-6.2 to provide descriptions of the income eligibility limits for the Program and provide that the cost-of-living adjustment under N.J.A.C. 8:83D-6.2(m) be initiated by notice, published in the New Jersey Register, rather than by a rulemaking, at 36 N.J.R. 275(a). The Department subsequently adopted the proposed amendments to N.J.A.C. 8:83D-6.2, effective August 2, 2004, at 36 N.J.R. 3535(a).

The Department proposed amendments to N.J.A.C. 8:83D-2.1, adding definitions for "special needs trust" and "viatical settlement." The Department proposed a new rule at N.J.A.C. 8:83D-2.2 to establish provisions for a "special needs trust." The Department proposed amendments to N.J.A.C. 8:83D-6.2 to include other sources of income that are includable and excludable in determining income eligibility for the Program. The Department proposed the foregoing amendments to N.J.A.C. 8:83D-2.1 and 6.2 and a new rule at N.J.A.C. 8:83D-2.2 at 36 N.J.R. 1865(a) and subsequently adopted them,

effective September 20, 2004, at 36 N.J.R. 4313(b).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) effective January 1, 2005, through a notice of administrative change at 36 N.J.R. 5683(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) effective January 1, 2006, through a notice of administrative change at 37 N.J.R. 5001(a).

The Department proposed amendments to the definitions at N.J.A.C. 8:83D-2.1 and, additionally, amendments at N.J.A.C. 8:83D-2.1, 5.6, 6.9, and 6.11 that would enable the Department to coordinate the benefits provided under the Program with benefits available under the Federal Medicare Prescription Drug Program, at 38 N.J.R. 1124(a) and subsequently adopted the rulemaking, effective December 18, 2006, at 38 N.J.R. 5360(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) effective January 1, 2007, through a notice of administrative change at 38 N.J.R. 5362(a).

The Department proposed amendments to the definitions at N.J.A.C. 8:83D-2.1 and at N.J.A.C. 8:83D-4.4 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, and also proposed amendments to N.J.A.C. 8:83D-7.2 to limit the circumstances in which the Program can seek recovery of incorrectly paid benefits. The Department proposed the foregoing amendments to N.J.A.C. 8:83D-2.1, 4.4, and 7.2 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, effective May 7, 2007, at 39 N.J.R. 1711(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) effective January 1, 2008, through a notice of administrative change, at 40 N.J.R. 182(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) effective January 1, 2009, through a notice of administrative change, at 40 N.J.R. 6966(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) effective January 1, 2012, through a notice of administrative change, at 43 N.J.R. 3365(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) effective January 1, 2013, through a notice of administrative change, at 45 N.J.R. 33(a).

The Department updated the income eligibility limits for the Program pursuant to N.J.A.C. 8:83D-6.2(m) effective January 1, 2014, through a notice of administrative change at 46 N.J.R. 78(a).

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

N.J.A.C. 8:83D-1 identifies the purpose and scope of the Program and the legal authority for the promulgation of N.J.A.C. 8:83D.

N.J.A.C. 8:83D-2.1 contains the definitions of words and terms used throughout the chapter. N.J.A.C. 8:83D-2.2 sets forth the criteria required for designation of a trust as a special needs trust.

N.J.A.C. 8:83D-3 establishes the Department as the administrative unit of State government with control over the administration of the Program and establishes sub-units within the Department to oversee the operation and management of the Program.

N.J.A.C. 8:83D-4 establishes the limitations of the Program and sets forth the principles of reimbursement to participating pharmacies dispensing prescription drugs to eligible individuals and the co-payments to be made by those individuals receiving the prescription drugs.

N.J.A.C. 8:83D-5 contains the application process for individuals to enroll in the Program.

N.J.A.C. 8:83D-6 sets forth the eligibility requirements, the eligibility period, and the appeal process and it establishes the Program as the payer of last resort in cases where prescription drugs are covered under other programs or insurance plans.

N.J.A.C. 8:83D-7 sets forth the circumstances in which the Department may recover incorrectly paid benefits and the penalties associated with violating the Senior Gold Prescription Discount Act.

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. Eligible individuals are able and would continue to be able to obtain discount prescriptions from their participating pharmacy through the Program. Those eligible individuals who previously could not afford some or all of their prescription drugs have and will continue to have the financial assistance to receive all of their necessary medications. Eligible individuals should continue to experience improved health and a better quality of life. The rules proposed for re-adoption would assure that eligible individuals would continue to receive assistance through the Program without interruption.

Economic Impact

The rules proposed for re-adoption would continue to assure that prescriptions would be more affordable to eligible individuals. Participating pharmacies will experience additional business because more people will be able to afford their prescription drugs.

The rules proposed for re-adoption 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. The availability of subsidies allows eligible individuals to afford the medications necessary to improve or maintain their health.

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. Accordingly, the Department does not anticipate that the rules proposed for readoption would have an added economic impact on participating pharmacies or eligible individuals.

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. 8:83D. 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. The Department remains of the opinion that coverage available under the Medicare Prescription Drug Program to Program beneficiaries has resulted in a savings to New Jersey taxpayers. As of 2006, 20,000 of the 30,000 Program beneficiaries were enrolled in the Medicare Prescription Drug Program. The Program at N.J.A.C. 8:83D-6.5 requires the State to be the payer of last resort for the benefits provided under the Program.

Federal Standards Statement

The Program establishes policies 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 & 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 re adoption meet but do 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 re adoption. 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 re-adoption would have an impact on employment in New Jersey. The rules proposed for re-adoption would continue the current requirements imposed upon pharmacies participating in the Program.

Agriculture Industry Impact

The rules proposed for re-adoption would not have an impact on the agriculture industry.

Regulatory Flexibility Analysis

The rules proposed for re-adoption would continue to impose the basic 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 file an application with the Department and execute an agreement of participation. The types of businesses that would be affected have been and would continue to be pharmacies.

Housing Affordability Impact Analysis

The rules proposed for re-adoption will have no impact on affordable housing or change in the average costs associated with housing in New Jersey because the rules

pertain to prescription discounts for those elderly and disabled residents eligible for the Senior Gold Prescription Discount Program.

Smart Growth Development Impact Analysis

The rules proposed for re adoption will 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 because the rules pertain to prescription discounts for those elderly and disabled residents eligible for the Senior Gold Prescription Discount Program.

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