

**HUMAN SERVICES**

**DIVISION OF AGING SERVICES**

**Provision of Pharmaceutical Services Under the Senior Gold Program**

**Readoption: N.J.A.C. 10:167C**

Proposed: May 5, 2014, at 46 N.J.R. 741(a).

Adopted: July 14, 2014, by Jennifer Velez, Commissioner, Department of Human Services.

Filed: July 30, 2014, as R. 2014 d.133, **without change**.

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

Effective Date: July 30, 2014.

Expiration Date: July 30, 2021.

After publication of the notice of proposed readoption, N.J.A.C. 8:83E was administratively recodified as N.J.A.C. 10:167C (see 46 N.J.R. 1643(a)).

**Summary of Public Comment and Agency Response:**

**No comments were received.**

**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), (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 readopted rules 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 readopted rules. 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. 10:167C.