CHAPTER 83E

PROVISION OF PHARMACEUTICAL SERVICES UNDER THE SENIOR GOLD PROGRAM

Authority

N.J.S.A. 30:4D-43 et seq., particularly 30:4D-50; and Reorganization Plan No. 001-1996.

Source and Effective Date

R.2007 d.134, effective April 5, 2007.
See: 38 N.J.R. 5295(a), 39 N.J.R. 1711(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 83E, Provision of Pharmaceutical Services under the Senior Gold Program, expires on April 5, 2014. See: 43 N.J.R. 1203(a).

Chapter Historical Note

Chapter 83E, Provision of Pharmaceutical Services under the Senior Gold Program, was adopted as emergency new rules by R.2001 d.202, effective May 18, 2001. See: 33 N.J.R. 1954(a). Chapter 83E, Provision of Pharmaceutical Services under the Senior Gold Program, expired on July 17, 2001.

Chapter 83E, Provision of Pharmaceutical Services under the Senior Gold Program, was adopted as new rules by R.2001 d.429, effective November 19, 2001. See: 33 N.J.R. 1954(a), 33 N.J.R. 3940(a).

Chapter 83E, Provision of Pharmaceutical Services under the Senior Gold Program, was readopted as R.2007 d.134, effective April 5, 2007. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

8:83E-1.1 Introduction

(a) It is intended that the Senior Gold Prescription Discount Program shall extend assistance to certain persons whose level of income disqualifies them for benefits and medical assistance under the New Jersey Medical Assistance and Health Services Act and for prescription benefits under the Pharmaceutical Assistance to the Aged and Disabled (PAAD) Act, but who have significant needs for more affordable prescription drugs.

(b) This chapter has been developed as a statement of policy and procedures and is applicable only to eligibility for the Senior Gold Prescription Discount Program.

8:83E-1.2 Participation of eligible providers

(a) A pharmacy, with a retail or institutional permit, may participate in the Senior Gold Program as a provider of pharmaceutical services.

(b) To be approved as a provider of pharmaceutical services, the pharmacy shall:

1. Operate under a valid retail and/or institutional permit issued by the Board of Pharmacy of the State of New Jersey. A pharmacy operating under an out-of-State retail or institutional pharmacy permit may not participate as an approved provider in the Senior Gold Program;

2. File an application and sign an agreement with the Department of Human Services (DHS), Division of Medical Assistance and Health Services (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 Program, the new owner(s) shall apply to the Division of Medical Assistance and Health Services, Department of Human Services, by contacting the Medicaid Provider Enrollment Unit (see N.J.A.C. 10:49, Administration) or the fiscal agent Provider Enrollment Unit.

ii. To enroll as a Senior Gold provider of pharmaceutical services, a pharmacy shall contact the Fiscal Agent Provider Enrollment Unit (see N.J.A.C. 10:51, Appendix D, Fiscal Agent Billing Supplement).

Amended by R.2007 d.134, effective May 7, 2007.
See: 38 N.J.R. 5295(a), 39 N.J.R. 1711(a).
In (a), substituted "of" for "or" following "provider"; and in (b)2ii, substituted "Senior Gold" for "Medicaid".

8:83E-1.3 Conditions for participation as a provider of pharmaceutical services

(a) All participating pharmacies shall provide complete prescription services, including injectables and injectable

anti-neoplastic agents, compounding, and prescription refill services, when allowable. Prescriptions must be dispensed in compliance with all current existing Federal and State laws.

(b) All drugs must be prescribed.

1. "Prescribed drugs" mean simple or compounded substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are:

i. Prescribed by a practitioner licensed or authorized by the State of New Jersey, or the state in which he or she practices, to prescribe drugs and medicine within the scope of his or her license and practice;

ii. Dispensed by licensed pharmacists in accordance with regulations promulgated by the New Jersey State Board of Pharmacy, N.J.A.C. 13:39; and additional prescription pricing information in accordance with P.L. 1994, c.67, as revised by P.L. 1995, c.5 (see N.J.A.C. 8:83E-1.13(b)); and

iii. Dispensed by a licensed pharmacist on the basis of a written prescription that is recorded and maintained in the pharmacist's records.

(c) Participating pharmacies shall permit properly identified representatives of the Division of Medical Assistance and Health Services or the Department to:

1. Inspect written prescriptions on file;

2. Audit records pertaining to covered persons;

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) Drug name;

(2) Quantity dispensed;

(3) Price;

(4) Prescription number (for reference purposes only); and

(5) Date dispensed.

ii. The pharmacy shall provide sufficient information with regard to its contractual agreement(s) and payment history with other private third party prescription plans to identify and verify number of claims, amount paid, and dispensing fee paid by group contracts within the plan. Records and contracts shall be available on-site at the time of audit; or available within 10 working days of an on-site audit. Records shall include, but not be limited to:

(1) Payment vouchers;

(2) Contracts; and

(3) Agreements; and

4. Inspect records of purchases of covered drugs for which claims have been made for reimbursement.

8:83E-1.4 Program restrictions affecting payment for prescribed drugs

(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 the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 8:83E-1.12 and 1.13, respectively;

2. Quantity of medication (see N.J.A.C. 8:83E-1.14);

3. Pharmaceutical services requiring pharmacist intervention as part of the Senior Gold Prospective Drug Utilization Review (PDUR) program (see N.J.A.C. 8:83E-1.26);

4. Dosage and directions (see N.J.A.C. 8:83E-1.15);

5. Telephone rendered original prescriptions (see N.J.A.C. 8:83E-1.16);

6. Changes or additions to the original prescription (see N.J.A.C. 8:83E-1.17);

7. Prescription refill (see N.J.A.C. 8:83E-1.18);

8. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 8:83E-1.19);

i. Products listed in N.J.A.C. 8:71, distributed to all prescribers and pharmacists; and

ii. Non-proprietary or generic dispensing (see N.J.A.C. 8:83E-1.10);

9. Federal regulations (42 CFR 447.301, 331-333) that set the aggregate upper limits on payment for certain multisource drugs if Federal Financial Participation (FFP) is to be made available. The limit applies to all "maximum allowable costs" (MAC) drugs (see N.J.A.C. 8:83E-1.5, basis of payment);

10. Drug Efficacy Study Implementation (DESI); "Less than effective drugs" subject to a Notice of Opportunity for Hearing (NOOH) by the Federal Food and Drug Administration (see N.J.A.C. 8:83E-1.20 and listing of DESI drugs in N.J.A.C. 10:51, Appendix A); and

11. Brand name prescription drugs shall be dispensed pursuant to the requirements for prior authorization set forth in the Fiscal Year 2007 Appropriations Act, P.L. 2006, c. 45, as amended and supplemented by subsequent State appropriations acts.

Amended by R.2007 d.134, effective May 7, 2007.
See: 38 N.J.R. 5295(a), 39 N.J.R. 1711(a).
In (a)8i, substituted "N.J.A.C. 8:71" for "the current New Jersey Drug Utilization Review Council (DURC) Formulary (hereafter referred to as 'the Formulary'), and all subsequent revisions"; in (a)9, deleted "and" from the end; in (a)10, substituted "; and" for a period at the end; and added (a)11.

8:83E-1.5 Basis of payment

(a) This section provides a summary of the elements involved in the calculation of the payment of legend or certain non-legend drugs. The elements include the following:

1. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 8:83E-1.4;

2. Price information as supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division of Medical Assistance (Medicaid) as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). If reimbursement for a drug is not covered under the Medicare Prescription Drug Program, the drug price shall not exceed the lower of the reimbursement standard set forth in the Fiscal Year 2007 Appropriations Act, P.L. 2006, c. 45, as amended and supplemented by subsequent State appropriations acts, the provider's usual and customary charge; or the drug's maximum allowable cost, if applicable (see (b) below);

i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meets the criteria specified in N.J.A.C. 8:83E-1.12, Covered pharmaceutical services;

3. Federal regulations (42 CFR 447.301, 331-333) that set the aggregate upper limits on payment for certain covered drugs in the Program. The New Jersey Medicaid program refers to these upper limits as the "maximum allowable cost" (see (b) below); and

4. Provider's usual and customary charge for legend drugs (see (c) below), insulin, insulin needles and syringes, or diabetic testing materials.

(b) Payment for legend drugs is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). See N.J.A.C. 10:51, Appendix B, incorporated herein by reference, for the listing of MAC drugs.

1. Maximum allowable cost is defined as:

i. The MAC price as stated for listed multi-source drugs published periodically by CMS and in accordance with the Deficit Reduction Act of 2005, Pub. L. 109-171, effective February 8, 2006; or

ii. For legend drugs not included in (b)1i above, the estimated acquisition cost (EAC), which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus regression category or discount.

2. For information about the "pharmacy discounts," see N.J.A.C. 8:83E-1.6 and for usual and customary charge, see N.J.A.C. 8:83E-1.11.

3. If the published MAC price as defined in (b)1i above is higher than the maximum allowable cost which would be paid as defined in (b)1ii above, then (b)1ii above shall apply.

(c) The maximum charge to the Program for drugs, including the charge for the cost of medication and the dispensing fee, shall not exceed the provider's usual and customary and/or posted or advertised charge.

(d) For claims with service dates on or after July 1, 2005, that are not covered by the Medicare Prescription Drug Program, the maximum cost for each eligible prescription claim not covered by the maximum allowable cost price, as defined in (b)1i above, shall be based on the pharmacy reimbursement standards defined in the Fiscal Year 2007 Appropriations Act, P.L. 2006, c. 45, as amended and supplemented by subsequent State appropriations acts, and for multi-source drugs, shall be in accordance with the Deficit Reduction Act of 2005, Pub. L. 109-171, effective February 8, 2006.

Amended by R.2007 d.134, effective May 7, 2007.
See: 38 N.J.R. 5295(a), 39 N.J.R. 1711(a).
Rewrote (a)2, (b)1i, and (d).

8:83E-1.6 Pharmacy discounts

(a) Those pharmacy providers who have been in business for less than one calendar year shall have their prescription volume projected for the entire year, to determine the appropriate dispensing fee.

(b) The Division of Medical Assistance (Medicaid) shall determine a provider's total prescription volume, which includes all prescriptions filled (both new and refills), including nursing facility prescriptions, for private patients, Medicaid, Senior Gold and other third party recipients for the previous calendar year.

(c) The pharmacy shall submit in writing an annual report on form FD-70 as required by N.J.A.C. 10:51, Appendix C to certify prescription volume.

Amended by R.2007 d.134, effective May 7, 2007.
See: 38 N.J.R. 5295(a), 39 N.J.R. 1711(a).
Deleted (d).

8:83E-1.7 Prescription drug dispensing fee

(a) The dispensing fee for each prescription, dispensed by providers having retail permits to recipients other than those in nursing facilities, is $3.73. Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following:

1. Twenty-four hour emergency service: $0.11. The provider shall have a 24-hour per day, 365 days per year prescription service available and shall have provided Senior Gold beneficiaries opportunities to utilize this service.

2. Patient consultations: $0.08. In addition to routinely monitoring recipient profiles for drug interactions, contraindications, allergies, etc., the provider shall, where appropriate, discuss the course of drug therapy with the recipient. This discussion must include emphasis on compliance with the prescriber's orders; proper drug utilization; cautions about possible side effects; foods to avoid; proper drug storage conditions; and any other information that will prove beneficial to the recipient while on drug therapy.

3. Impact area location: $0.15. The provider shall have a combined Medicaid and Senior Gold prescription volume equal to or greater than 50 percent of the provider's total prescription volume.

i. The nursing facility prescription volume shall be included for the determination of total prescription volume in determining entitlement to the impact allowance.

(b) Price information is supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The calculated price shall not exceed the lower of the average wholesale price (AWP) or the Federal Fund Participation Upper Limit (FFPUL) as supplied by the reference drug file contractor.

(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(s) 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. Each claimed increment is subject to audit and retroactive recovery with appropriate penalties, if warranted, if the Program determines that the provider was not entitled to reimbursement for them.

(d) Failure to submit this report annually shall result in retail pharmacy provider payments based on the basic dispensing fee of $3.73.

8:83E-1.8 Senior Gold Program co-payment

(a) Beneficiaries in the Program are responsible for a part of the cost of drugs and devices covered by the Program. At the point of sale, a Senior Gold beneficiary shall render to a pharmacy provider a fixed co-payment of $15.00 plus 50 percent of the remaining cost of the drug.

(b) A co-payment shall be rendered to a pharmacy provider for each original or refill prescription dispensed. The provider's usual and customary charge billed to the Program shall be inclusive of the co-payment amount which will be deducted by the New Jersey Medicaid Management Information System (NJMMIS).

1. Under no circumstances is the required rendered co-payment amount to be waived for reasons of promotion, advertisement and/or competitive considerations. Failure to comply with Program co-payment requirements may result in a suspension of a provider's approval to participate in the Program.

8:83E-1.9 Compounded prescriptions

(a) Compounded prescriptions may be reimbursed by the Program. Compounded prescriptions are extemporaneously prepared mixtures of an active ingredient or ingredients and/or a pharmaceutical excipient or excipients and are dispensed by approved providers.

1. Acceptable pharmaceutical excipients which do not contribute therapeutically to a compound, include, but are not limited to hydrophilic ointment, petrolatum, aquifer, eucerin cream, phenol, menthol, resorcinol, caffeine, talc, simple syrup, aromatic elixir, distilled water, and glycerin.

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claim adjudication system approved by the Program. (See N.J.A.C. 8:83E-1.25.)

1. A compounded prescription is indicated by the provider by the use of the "Compound drug" indicator field on a manual claim or in a similar field in the Electronic Media Claims (EMC) claim format.

(c) Reimbursement for compounded prescriptions shall not exceed the lower of:

1. The cumulative cost of the active ingredient(s), as described in N.J.A.C. 8:83E-1.5, and/or pharmaceutical excipient(s), plus a dispensing fee, as described in N.J.A.C. 8:83E-1.7; or

2. A provider's usual and customary charge.

(d) For compounded prescriptions without an active ingredient(s), reimbursement is based on the cumulative cost of the pharmaceutical excipient(s).