

**DEPARTMENT OF HEALTH AND SOCIAL SERVICES**  
**DIVISION OF MEDICAID AND MEDICAL ASSISTANCE**  
Statutory Authority: 31 Delaware Code, Section 512 (31 Del.C. §512)

**PROPOSED**

**PUBLIC NOTICE**

**Medicaid Coverage for Prescribed Drugs**

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code) and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512, Delaware Health and Social Services (DHSS) / Division of Medicaid and Medical Assistance (DMMA) intends to submit a state plan amendment to the Centers for Medicare and Medicaid Services (CMS) *regarding discontinuation of Medicaid coverage of barbiturates and benzodiazepines for dual eligible recipients*. An additional amendment is proposed to *update the quantity limits for opioid analgesics*.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to Sharon L. Summers, Planning & Policy Development Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906 or by fax to 302-255-4425 by April 30, 2013.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

**SUMMARY OF PROPOSAL**

The proposed provides notice to the public that the Division of Medicaid and Medical Assistance (DMMA) intends to submit a Title XIX Medicaid State Plan Amendment (SPA) to conform with the mandatory provisions of section 175 of Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) which amended section 1860D-2(e)(2)(A) of the Social Security Act regarding the discontinuation of Medicaid coverage of barbiturates and benzodiazepines for dual eligible recipients. An additional amendment is proposed to update the quantity limits for opioid analgesics.

**Statutory Authority**

- Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)
- 1860D-2(e)(2)(A) of the Social Security Act
- Social Security Act, Title 19, Section §1927

**Background**

With respect to prescriptions dispensed on or after January 1, 2013, section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) amended section 1860D-2(e)(2)(A) of the Social Security Act to include Medicare Part D coverage of **barbiturates** "used in the treatment of epilepsy, cancer, or a chronic mental health disorder" and **benzodiazepines** for all medically accepted indications. This coverage change will affect Medicaid beneficiaries that also have Medicare (dual eligible beneficiaries). Medicare will be responsible for payment for these drugs as previously indicated for dual eligible individuals as of January 1, 2013.

Since coverage of barbiturates under Medicare Part D is limited to the treatment of epilepsy, cancer or a chronic mental health disorders, DMMA proposes to continue to cover barbiturates for conditions other than the three covered by Medicare Part D. The coverage of benzodiazepines under Medicare Part D is inclusive of all medically accepted indications, so DMMA proposes to provide coverage for only non-dually eligible beneficiaries. This will assure coverage for all Medicaid-eligible beneficiaries, either through Medicare or Medicaid, with no duplication of coverage.

**Summary of Proposal**

*Description of State Plan Amendment (SPA) and Effective Date*

Currently, Delaware's Medicaid State Plan provides drug coverage for certain drug classes not provided under Medicare Part D, including the drug classes of barbiturates and benzodiazepines.

This proposed regulatory change proposes to discontinue Medicaid coverage for two classes of drugs, benzodiazepines for all conditions and barbiturates, for patients with a diagnosis of epilepsy, cancer, or a chronic mental health disorder for full benefit dual eligibles (Medicaid recipients who are also eligible for Medicare benefits). Effective January 1, 2013, these drugs will be covered for dual eligibles under their Medicare Part D Drug Benefit. A state that covers these drugs under its drug benefit will continue to be required to cover barbiturates to the extent it covers that drug for a

condition other than the three covered by Part D, and must amend its Medicaid state plan to be consistent with the requirements of Part D.

Therefore, to comply with section 175 of the MIPPA, the Division of Medicaid and Medical Assistance (DMMA) will be submitting a SPA no later than March 31, 2013. This SPA, effective January 1, 2013, will remove (1) barbiturates used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and (2) benzodiazepines as drugs DMMA will cover for people who have both Medicare and Medicaid (dual eligible individuals). DMMA will continue to cover barbiturates for full benefit dual eligibles for diagnoses other than epilepsy, cancer, and chronic mental health disorders. These recipients will need to obtain a prior authorization for barbiturates from their prescribing provider indicating a medical condition other than the three specified in the amended section of the MIPPA.

With this new coverage of barbiturates and benzodiazepines under Medicare Part D for dual eligibles, Medicaid no longer needs to offer this benefit and, as such, the State is simply clarifying coverage with this SPA.

Additionally, DMMA proposes to amend the state plan to update limitations on the quantity of drugs that can be prescribed, as clinically appropriate. To ensure that quantity limits are placed on therapeutic categories that will allow for coordinated care and improve outcomes, and to reflect current practice, *Opioid Analgesics* are limited to 720 immediate release doses per 365 days.

The provisions of this state plan amendment are subject to approval by the Centers for Medicare and Medicaid Services (CMS).

### Fiscal Impact Statement

This plan amendment is expected to result in an aggregate savings for federal fiscal year 2013 in the amount of \$101,000.00.

### DMMA PROPOSED REGULATION #13-13 REVISIONS:

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## STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: DELAWARE

### MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

Citation (s)

Provision (s)

- 1927(d)(2) and 1935(d)(2) 1. The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.
- The following excluded drugs are covered:**
  - (a) agents when used for anorexia, weight loss, weight gain (see specific drug categories below)
  - (b) agents when used to promote fertility (see specific drug categories below)
  - (c) agents when used for cosmetic purposes or hair growth (see specific drug categories below)
  - (d) agents when used for the symptomatic relief cough and colds see specific drug categories below)
  - (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride (see specific drug categories below)
  - (f) nonprescription drugs (see specific drug categories below)

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### MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

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1927(d)(2) and 1935(d)(2)

- (g) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee (see specific drug categories below)
- (h) barbiturates ALL [Except for dual eligible individuals, effective January 1, 2013, when used in the treatment of epilepsy, cancer or a chronic mental health disorder as Part D will cover those indications per 1860D-2(e)(2)(A) of the Social Security, as amended by Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)] (see specific drug categories below)
- (i) benzodiazepines ALL [Except for dual eligible individuals, effective January 1, 2013, as Part D will cover all indications per 1860D-2(e)(2)(A) of the Social Security, as amended by Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)] (see specific drug categories below)  
 (The Medicaid agency lists specific category of drugs below)  
 (a) Agents when used for anorexia, weight loss, weight gain: Megestrol Acetate, Somatropin, Lipase Inhibitor. Products in these categories require prior authorization.  
 (d) Agents when used for the symptomatic relief cough and colds: Antihistamines, Antitussive, Decongestants, and Expectorants.  
 (e) Prescription vitamins and mineral products, except prenatal vitamins and fluoride: Single entity vitamins, Multiple vitamins w/ minerals, Nicotinic acid, Calcium salts, and Dialysis replacement products

**STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT  
STATE: DELAWARE**

**MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY**

Citation (s)

Provision (s)

1927(d)(2) and 1935(d)(2)

CONTINUED

- (f) Nonprescription drugs: Analgesic oral and rectal; Heartburn; Antiflatulents; Antidiarrheal; Antinauseants; Cough & Cold, oral; Cough & Cold, topical; Contraceptives; Diabetic supplies; Hemantinics; Laxatives & Stool Softeners; Lice Control Preparations; Magnesium Supplement, oral; Nasal Preparations; Nicotine Cessation Preparations; Ophthalmic Preparations; Topical Anesthetics; Topical Antibacterials; Topical/Vaginal Fungicidals; Vitamins & Minerals; Digestive Enzymes; and, Miscellaneous Colloidal Oatmeal Baths).
- (h) Barbiturates: the Division of Medicaid & Medical Assistance covers all medications in these therapeutic categories [except for dual eligible individuals, effective January 1, 2013, when used in the treatment of epilepsy, cancer or a chronic mental health disorder as Part D will cover those indications per 1860D-(e)(2)(A) of the Social Security, as amended by Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)].
- (i) Benzodiazepines: the Division of Medicaid & Medical Assistance covers all medications in these therapeutic categories [except for dual eligible individuals, effective January 1, 2013, as Part D will cover all indications per 1860D-2(e)(2)(A) of the Social Security, as amended by Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)].
- No excluded drugs are covered.

## LIMITATIONS

### 12.a. Prescribed Drugs: Drug Coverage

- 1) Drug products are covered when prescribed or ordered by a physician, or other licensed practitioner within the scope of their practice and when obtained from a licensed pharmacy. Covered drugs, as defined in Section 1927(k)(2) of the Act, are those which are prescribed for a medically accepted indication, medically necessary, and produced by any pharmaceutical manufacturer, which has entered into and complies with a drug rebate agreement under Section 1927(a) of the Act.
- 2) Drugs excluded from coverage by Delaware Medicaid as provided by Section 1927(d)(2) of the Act, include:
  - a. Drugs designated less than effective by the FDA (DESI drugs) or which are identical, similar, or related to such drugs;
  - b. Drugs when used for cosmetic purposes or hair growth (products, such as Minoxidil Lotion and Retin A are not covered for adults, except for certain medical conditions);
  - c. Drugs when used to promote fertility;
  - d. Drugs that have an investigational or experimental or unproven efficacy or safety status;
  - e. Drugs when used for anorexia, weight loss or weight gain. Drugs for the purpose of weight control may be reimbursed when prior authorized following established criteria as reviewed and approved by the DUR Board and deemed medically necessary-;
  - f. Effective January 1, 2013, barbiturates for dual eligible individuals, when used in the treatment of epilepsy, cancer, or a chronic mental health disorder (as Medicare Part D will cover);
  - g. Effective January 1, 2013, benzodiazepines for dual eligible individuals (as Medicare Part D will cover).
- 3) Non-covered services also include: drugs used to correct sexual dysfunction and compound drugs (compound prescriptions must include at least one medication that on its own would be a covered entity).
- 4) Participating manufacturers' new drugs are covered (except excluded/restricted drugs specified in Section 1927[d][1]-[2] of the Social Security Act) for six months after FDA approval and upon notification by the manufacturer of a new drug.

### Quantity and Duration

1. Dosage limits: Medications are limited to a maximum dose recommended by the FDA and appropriate medical compendia described in section 1927(k) of the Social Security Act, that indicate that doses that exceed FDA guidelines are both safe and effective or doses that are specified in regional or national guidelines published by established expert groups such as the American Academy of Pediatrics, or guidelines recommended by the Delaware Medicaid Drug Utilization Review (DUR) Board and accepted by the DHSS Secretary.
2. Quantity limits are placed on therapeutic categories that will allow for coordinated care and improve outcomes. Limits exist for:
  - a. Sedative hypnotics-15 doses per 30 days
  - b. Triptans, acute treatment of migraines, 9 doses per 45 days
  - c. Opioid analgesics-~~200 doses per 30 days~~ 720 immediate release doses per 365 days
  - d. Skeletal muscle relaxants-120 tablets/capsules per 30 days
  - e. Benzodiazepines-120 tablets per 30 days
  - f. Tramadol-240 tablets per 30 days
  - g. Narcotic cough medications-480ml per 30 days
  - h. Adjunctive anticonvulsants-240 tablets/capsules per 30 days
  - i. Nebulizer solutions-3 acute exacerbations per 30 days
  - j. Clients utilizing greater than 15 unique medications per 30 days
  - k. Medications that are dosed once a day are limited to one dose per day unless that total dosage required is within the limits stated above and require more than one tablet/capsule to obtain the required therapeutic amount.