

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

**FINAL**

**ORDER**

**Medicaid Coverage of Prescribed Drugs**

**NATURE OF THE PROCEEDINGS:**

Delaware Health and Social Services (“Department”) / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to submit a state plan amendment to the Centers for Medicare and Medicaid Services (CMS) regarding prescribed drug coverage, specifically, *changes to the coverage of barbiturates, benzodiazepines and agents used to promote smoking cessation*. The Department’s proceedings to amend its regulations were initiated pursuant to 29 **Delaware Code** Section 10114 and its authority as prescribed by 31 **Delaware Code** Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 **Delaware Code** Section 10115 in the April 2014 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by April 30, 2014 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

**SUMMARY OF PROPOSAL**

The proposed provides notice to the public that Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) intends to submit a state plan amendment to the Centers for Medicare and Medicaid Services (CMS) regarding prescribed drug coverage, specifically, *changes to the coverage of barbiturates, benzodiazepines and agents used to promote smoking cessation*.

**Statutory Authority**

- Patient Protection and Affordable Care Act, P.L. 111-148, enacted March 23, 2010 and the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, enacted March 30, 2010 (collectively referred to as the Affordable Care Act
- 1927(d)(7) of the Social Security Act, *Non-Excludable Drugs*
- 42 CFR §440.120, *Prescribed drugs*
- 42 CFR §447.205, *Public notice of changes in Statewide methods and standards for setting payment rates*

**Background**

Effective January 1, 2014, section 2502 of the Affordable Care Act amends section 1927(d)(2) of the Social Security Act (the Act) by removing barbiturates, benzodiazepines and agents used to promote smoking cessation from the list of drugs a state Medicaid program may exclude from coverage or otherwise restrict. It also added section 1927(d)(7) of the Act which explicitly prohibits states from excluding the following drugs, or their medical uses, from coverage: barbiturates, benzodiazepines and agents used to promote smoking cessation, including agents approved by the Food and Drug Administration (FDA) under the over-the-counter (OTC) monograph process for purposes of promoting, and when used to promote, tobacco cessation.

*State Plan Amendment*

In light of the statute, states will need to remove from the state plan any indication that the following drugs are restricted or otherwise excluded: barbiturates, benzodiazepines and agents used to promote smoking cessation. To the extent that the state needs to change its state plan to be consistent with these Medicaid coverage requirements, the state will need to submit a state plan amendment (SPA) to be effective January 1, 2014.

**Summary of Proposal**

Pursuant to 42 CFR 447.205 and the Delaware Administrative Procedures Act, public notice is hereby given that 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) in accordance with 42 CFR 430.12. Upon CMS approval, the proposed changes will update Attachment 3.1-A of the Medicaid State Plan regarding the coverage of barbiturates, benzodiazepines and agents used to promote smoking cessation.

Delaware Medicaid did not take an ‘exclusion’ approach and currently provides coverage for these excludable drugs.

Delaware treats these drugs as any other medically necessary therapeutic class. However, there are quantity limits in place to ensure appropriate use.

States were instructed by CMS to submit a state plan amendment (SPA) to remove benzodiazepines, barbiturates, and smoking cessation drugs from the list of drugs a state can exclude from coverage or restrict. If the language appears on the state plan page, the state cannot just uncheck the box, the language on the state plan page(s) needs to be removed, and also, revise the assigned numbering and/or lettering on the plan page(s).

### **Fiscal Impact Statement**

This is a technical change to the Medicaid State Plan with no financial impact as Delaware Medicaid has been covering these drugs.

### **SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE**

The Governor's Advisory Council for Exceptional Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) offered the following observations summarized below. The Division of Medicaid and Medical Assistance (DMMA) has considered each comment and responds as follows:

#### **GACEC**

Effective January 1, 2014 the Affordable Care Act (ACA) disallows restricting access to barbiturates, benzodiazepines, and agents used to promote smoking cessation. Therefore, the DMMA is proposing a technical amendment to conform to the ACA. The GACEC **endorses** the proposed regulation and has the following observations:

**Agency Response:** DMMA thanks the Council for its endorsement.

#### **SCPD**

SCPD endorses the proposed regulation and has the following observations:

Effective January 1, 2014 the Affordable Care Act (ACA) disallows restricting access to barbiturates, benzodiazepines, and agents used to promote smoking cessation. DMMA is therefore proposing a technical amendment to conform to the ACA. The anomaly is that the current restrictions were just added last year. See 16 DE Reg. 1028 (4/1/13) (proposed); 16 DE Reg. 1270 (6/1/13) (final)]. Consistent with the attached March 30, 2014 article, Medicaid beneficiaries are more likely to smoke than the general population and the CDC recommends Medicaid coverage of all proven cessation treatments.

**Agency Response:** DMMA thanks the Council for its endorsement.

There is no change to the regulation as a result of these comments.

#### **FINDINGS OF FACT:**

The Department finds that the proposed changes as set forth in the April 1, 2014 *Register of Regulations* should be adopted.

**THEREFORE, IT IS ORDERED**, that the proposed regulation regarding prescribed drug coverage, specifically, *to remove benzodiazepines, barbiturates, and smoking cessation drugs from the list of drugs a state can exclude from coverage or restrict* is adopted and shall be final effective June 10, 2014.

Rita M. Landgraf, Secretary, DHSS

#### **DMMA FINAL ORDER REGULATION #14-20a**

#### **REVISION:**

Attachment 3.1-A  
Page 5 Addendum

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

#### **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;
  - 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;
  - 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).

### Quantity and Duration

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.

### DMMA FINAL ORDER REGULATION #14-20b

#### REVISION:

Attachment 3.1.A.1  
Page 2a

## 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)

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

Provision (s)

- (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

**DMMA FINAL ORDER REGULATION #14-20c**

**REVISION:**

Attachment 3.1.A.1  
Page 2b

**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; Contraceptive Drugs; Laxatives & Stool Softeners; Lice Control Preparations; Nasal Drug Preparations; Nicotine Cessation Preparations; Ophthalmic Drug Preparations; Topical Anesthetics; Topical Antibacterials; Topical/Vaginal Fungicidals; and, Digestive Enzymes.
(h)	<del>Barbiturates: the Division of Medicaid &amp; 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-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)].</del>
(i)	<del>Benzodiazepines: the Division of Medicaid &amp; 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)].</del>
—	No excluded drugs are covered.