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 for 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) r*egarding 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*. 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 2013 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by April 30, 2013 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 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.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE

The American Cancer Society Cancer Action Network (ACS CAN), the Delaware Cancer Consortium, the Governor's Advisory Council for Exceptional Citizens (GACEC) and, the State Council for Persons with Disabilities (SCPD) offered the following observations and recommendations summarized below. The Division of Medicaid and Medical Assistance (DMMA) has considered each comment and responds as follows.

American Cancer Society Cancer Action Network (ACS CAN)

This letter is written on behalf of the American Cancer Society Cancer Action Network (ACS CAN) concerning the Department of Health and Social Services, Division of Medicaid and Medical Assistance proposed regulation on Medicaid Coverage for Prescribed Drugs published in the April 2013 Delaware Register of Regulations.

ACS CAN is very concerned that the proposed limitation of allowing prescribers to prescribe only 720 immediate release doses of opioid analgesics per 365 days will impede necessary medical care for Delaware's cancer patients.

Cancer is a particularly unique and complex disease. Limiting services for cancer patients and cancer prescriptions can have severe consequences. Adequate treatment of cancer and its side effects often requires frequent outpatient visits and multiple prescriptions. Other programs, such as Medicare, have recognized the unique nature of drugs used to treat cancer and the need to provide them (unimpeded) to beneficiaries.

Limiting quantities of opioids creates an additional administrative barrier that can discourage physicians from prescribing opioids, even if they're the most appropriate option for the patient, and can deter beneficiaries from seeking the recommended care. For cancer patients, such delays could be detrimental to their treatment success and quality of life.

We ask that you do not move forward with the proposed regulation and instead continue to provide cancer patients access to medically appropriate opioid analgesics that can improve health outcomes and quality of life.

Delaware Cancer Consortium

As stated in Delaware Register of Regulations, Vol. 16, Issue 10, dated Monday, April 10, 2013 as it relates to the proposed dosage limits of opioid analgesics from the current limit of 200 doses per 30 days to 720 immediate release doses per 365 days. The proposed regulation dosage limit would equate to just two doses per day, however in most cases cancer patients are prescribed and frequently require dosing every three to four hours of immediate release opioids for control of chronic cancer pain and acute cancer pain.

The DMMA's goal of regulations as it relates to quantity limits on opioid analgesics is appreciated; however, the Delaware Cancer Consortium requests that patients being diagnosed with cancer be exempt from this change. Including cancer patients in this requirement will be detrimental to the management of the chronic pain they suffer from. I would like to address key points as to why cancer patients should be exempt from the proposed regulation:

1. As quoted by the National Cancer Institute as it relates to opioids specifically it has been written "Opioids are very effective for the relief of moderate to severe pain. Many patients with cancer pain however become tolerant to opioids during long-term therapy. Therefore, increasing doses may be needed to continue to relieve pain. A patient's tolerance of an opioid or physical dependence on it is not the same as addiction (psychological dependence). Mistaken concerns about addiction can result in undertreating pain." National

Cancer Institute. (2013, February 27). *Management with Drugs - Basic Principles to Pain Management.* Retrieved April 24, 2013, from

http://www.cancer.gov/cancertopics/pdq/supportivecare/pain/patient/page4

2. As quoted by the Cleveland Clinic as it relates to the use of opioids for cancer pain it has been written "When used for cancer pain, tolerance to oral morphine (morphine taken by mouth) develops slowly. Tolerance to a drug means that as the body gets used to a drug, it needs more of the same drug to get the same effect. Often when cancer patients have more pain, it is not the increased tolerance level that makes them need more pain medication; it is the progression of the cancer that brings more pain, which increases the need for medication." The Cleveland Clinic. (n.d) *Concerns miss-concepts and Facts of Opioids (morphine derivatives) Active Therapy for Pain.* Retrieved April 24, 2013, from

http://www.clevelandclinic.org/myeloma/Pain%20Management.htm

In both citations above, it is clear that cancer patients requiring opioid analgesics as part of their treatment program will suffer immensely if the proposed regulation does not exclude them. Again, thank you for allowing the Delaware Cancer Consortium to provide comments. Cancer is a particularly unique and complex disease. We strongly believe that if cancer patients are not deemed exempt from this limitation, it will have severe consequences on the patient's quality of life.

GACEC and SCPD

First, for dual eligible (Medicare/Medicaid) individuals, Medicaid coverage for benzodiazepines ends and Medicaid coverage for barbiturates ends unless prescribed for a condition other than epilepsy, cancer, or a chronic mental health disorder. This change is required by federal law. Effective January 1, 2013, Medicare D will cover benzodiazepines and barbiturates prescribed to treat epilepsy, cancer, or a chronic mental health disorder. Therefore, there is no "net" loss of coverage for dual eligibles, i.e., they will be eligible for these drugs under the Medicare-D program rather than Medicaid.

Second, the Division is changing quantity limits on opioid analgesics. At 1033. The current limit is "200 doses per 30 days" which is roughly equivalent to 2,400 doses per year. The new limit will be "720 immediate release doses per 365 days". Lowering the quantity limit from 2,400 to 720 doses annually represents a 70% reduction. The Division indicates that the "720 immediate release doses per 365 days" reflects current practice. At 1030.

Overall, the Medicaid Plan changes are expected to result in $101,000.00 in savings. At 1030.

GACEC and SCPD endorse the change in benzodiazepines and barbiturates coverage for dual eligibles since required by federal law. However, we request clarification of the following: 1) the rationale for reducing the limits on opioid analgesics by 70%; and 2) the availability of an "override" based on compelling circumstances.

Agency Response: DMMA agrees that certain medical conditions such as cancer, sickle cell anemia, etc., may warrant exception to the established opioid limits when medically necessary. However, we also believe the responsible approach to administering opioids entails constant clinical oversight to achieve optimum results in pain relief as well as protection against inappropriate use of opioids by others not prescribed to receive these drugs.

From a clinical perspective, pain medication should be used in a way that provides a continuum of analgesia (pain relief) to reduce the number of doses a client needs throughout the day. By reviewing and appropriately adjusting the number of short-acting opioid doses administered to a patient each day, a clinician can reduce the number of peaks and troughs that often occur with patients undergoing pain control treatment, thereby assuring a better quality outcome.

DMMA is sensitive to the differentiation of need between cancer and non-cancer patients (and other equivalent medical conditions) and will cover additional quantities of opioids when prior approved through a timely verbal or written request by the treating physician prior to the expiration of the existing prescription. This exception procedure is currently in place and processed in real time. We believe this process will continue to serve the needs of our patient population and the administration of the pharmacy benefit in the most appropriate manner.

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, 2013 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation regarding discontinuation of Medicaid coverage of barbiturates and benzodiazepines for dual eligible recipients and update of quantity limits for opioid analgesics is adopted and shall be final effective June 10, 2013.

Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER REGULATION #13-19
REVISIONS:

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)

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)	☐ (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; Opthalmic Preparations; Topical Anesthestics; 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.

(Break in Continuity of Sections)

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.