

# **Critical Coverage:**

## **Benzodiazepines under Medicare Part D**

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### **Medicare Rights Center**

1460 Broadway, 17th Floor  
New York, NY 10036  
212-869-3850

1030 15th Street, NW Suite 250  
Washington, DC 20005  
202-589-1316

[www.medicarerights.org](http://www.medicarerights.org)

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#### **Medicare Rights Center**

Medicare Rights Center (MRC) is the nation's largest independent source of health care information and assistance for people with Medicare. Founded in 1989, MRC helps older adults and people with disabilities get high-quality, affordable health care. MRC provides telephone hotline services to individuals who need answers to Medicare questions or help securing coverage and getting the health care they need. MRC brings the consumer voice to the national debate on Medicare reform.

For more information, please contact:

Deane Beebe  
Director of Communications  
212-204-6219  
[dbeebe@medicarerights.org](mailto:dbeebe@medicarerights.org)

## Introduction

The Medicare Modernization Act (MMA), enacted in December 2003, introduces an outpatient prescription drug benefit (Part D) to Medicare.<sup>1</sup> Under the law, the benefit provides coverage for most medically necessary drugs for people with Medicare who choose to enroll in private prescription drug plans (Part D plans). Much attention has been paid to the fact that Part D plans are permitted – even encouraged – to limit coverage of drugs through the use of formularies, step therapy, prior authorization, and other so-called “cost management tools.” Less attention, however, has focused on the fact that entire categories of commonly-prescribed drugs are excluded from coverage under Part D by statute. These excluded drugs include benzodiazepines, a category of drugs prescribed to treat muscle spasms, anxiety, and panic and seizure disorders. As a result of this exclusion under the MMA, Part D plans cannot pay for benzodiazepines in their standard benefit plans under any circumstances.

MMA’s blanket exclusion of benzodiazepines could have serious consequences to the health and mental health of millions of older adults and people with disabilities who have Medicare. Benzodiazepines are critical tools for treating anxiety disorders or acute anxiety resulting from trauma, grief, phobias, or other significant life events. For patients with anxiety or seizures who are currently stabilized on medication regimens that include benzodiazepines, the MMA’s coverage exclusion could be harmful, or even dangerous if it results in rapid, unphased medication changes. The exclusion of benzodiazepines under Part D will inappropriately constrain doctors’ ability to develop the best individualized treatment plans for patients with acute debilitating mental conditions.

The legislative record of the MMA does not provide an explanation for the exclusion of benzodiazepines, nor has the U.S. Department of Health and Human Services (HHS) offered a rationale for this policy. If the MMA is implemented with this blanket exclusion in place, it could result in serious harm for millions of people with Medicare.

This exclusion of benzodiazepines can be modified or eliminated either with a simple, inexpensive legislative correction or through the exercise of the HHS Secretary’s administrative discretion. If both Congress and the HHS Secretary refuse to act on the benzodiazepine exclusion, state programs, at state expense, could cover benzodiazepines – and other excluded drugs – for those enrolled in pharmacy assistance programs.

Specifically, the Medicare Rights Center recommends:

- Congress should amend the MMA to eliminate the benzodiazepine exclusion. In doing so, Congress could clarify that benzodiazepines may be limited in clinically appropriate ways by Part D plans to minimize the potential for misuse or abuse.<sup>2</sup>

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<sup>1</sup> 42 U.S.C. 1395w-102 (2005); Part 1860D of the Social Security Act.

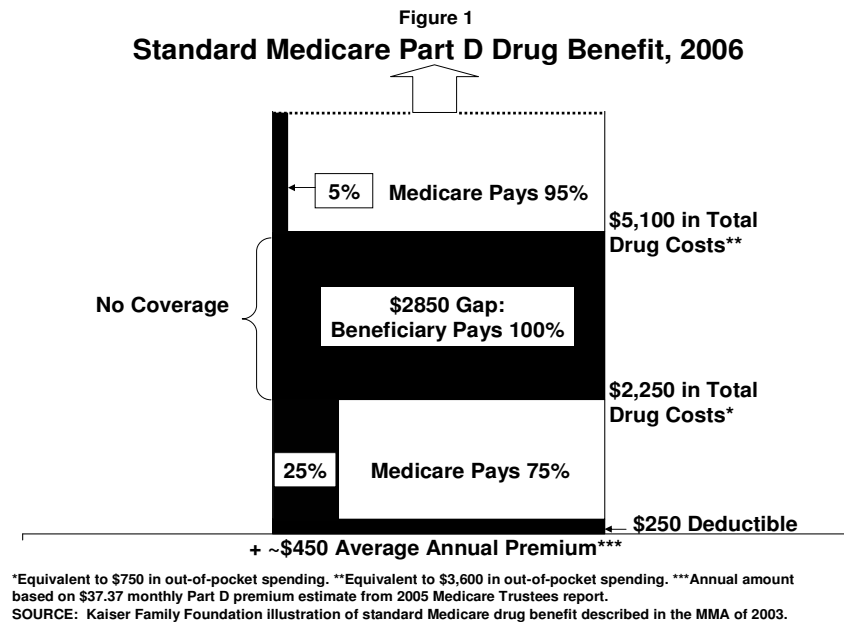
<sup>2</sup> Clinically appropriate limitations may include retrospective utilization review or dispensing limits, for example. Certain limitations, like prior authorization, may not be appropriate for psychotropic medications

- Alternatively, the Secretary of Health and Human Services should undertake a clinical review of the list of excludable and restrictable drugs under Medicaid and revise the list based on current clinical evidence and state practice. If the Secretary updated the list of drugs excludable under Medicaid, those updates would automatically apply to the exclusions under Medicare Part D.

- States, through Medicaid programs and state pharmacy assistance programs, should provide coverage for benzodiazepines (and other excluded drugs) for “dual eligibles” (people with both Medicare and Medicaid coverage) and for people with low and middle incomes who will have difficulty paying for excluded drugs.

### Medicare Part D Drug Coverage and Exclusions

Prescription drug coverage provided through a new “Part D” of Medicare will be available beginning on January 1, 2006 and offered through private drug plans that contract with Medicare. These private drug plans, “Part D plans,” may be stand-alone drug plans for people who are enrolled in fee-for-service, or “Original,” Medicare, or private drug plans that are provided by sponsors of private Medicare managed care plans for people enrolled in “Medicare Advantage.” Enrollees will pay a premium averaging \$37/month for standard coverage, and could pay substantially more for enhanced alternative coverage that Part D plans are permitted to offer. The standard coverage under Part D is limited. [See Figure 1]



In addition to requiring significant out-of-pocket costs, the MMA and its implementing regulations encourage Part D plans to use “cost management tools” such as

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including benzodiazepines. Centers for Medicare and Medicaid Services, “Psychotropic Medications: Addressing Costs without Restricting Access,” August 2, 2004.  
<http://www.cms.hhs.gov/promisingpractices/psychotropicmeds.pdf>

formulary restrictions, step therapy, “fail first” strategies, and prior authorization requirements.<sup>3</sup> The use of these tools will mean that a person with Medicare may not be able to obtain coverage for a particular medication simply by presenting a physician’s prescription to a pharmacist; in order to receive any particular drug, a physician might have to seek prior approval for the dispensing, or a patient might have to file an appeal and justify, with a physician’s assistance, why he or she needs that particular drug.

Even this limited coverage, however, is provided only for Part D covered drugs, which are defined to exclude “drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted” under the Medicaid statute.<sup>4</sup> These excluded drugs and classes include:

- Agents when used for anorexia, weight loss, or weight gain
- Agents when used to promote fertility
- Agents when used for cosmetic purposes or hair growth
- Agents when used for the symptomatic relief of cough and colds
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs
- Outpatient drugs for which the manufacturer seeks to require associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale
- Barbiturates
- Benzodiazepines

The exclusion of benzodiazepines under the MMA is a blanket exclusion, meaning that Medicare will not pay for the drugs under any circumstances. For people with low incomes who receive low-income subsidies (LIS) to reduce premiums, deductibles and coinsurance for prescription drugs under Medicare, the subsidies will not apply toward the purchase of benzodiazepines or towards enhanced alternative coverage. Similarly, appeals and exception processes that are available to Part D enrollees to seek coverage of medically necessary drugs not on their Part D plan’s formulary can never result in coverage of excluded drugs, no matter how compelling the clinical need for them is. In short, benzodiazepines can never be covered by a Medicare Part D plan unless the plan is providing “enhanced alternative coverage” for which it may charge an additional premium.<sup>5</sup>

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<sup>3</sup> Social Security Act (SSA) § 1860D-4(c)(1)(A); 70 Fed. Reg. 4277, 4326 (January 28, 2005).

<sup>4</sup> 1860D-2(e). One category of drugs **excludable** under Medicaid but explicitly covered under Medicare Part D is smoking cessation agents.

<sup>5</sup> 70 Fed. Reg. 4230. The preamble to the final rule also clarifies that drugs that are excluded if used for certain conditions may be covered under Part D if used for other conditions – for example, medicines that would be excluded if prescribed for the symptomatic relief of cough and colds may be covered if prescribed for allergies. Benzodiazepines are excluded in all cases, regardless of the indication for which they are prescribed. *Id.*

## The Controversy Over Benzodiazepines

Benzodiazepines are central nervous system depressants used for the management of acute anxiety, panic attacks, seizure disorders, and muscle spasms. Examples of benzodiazepines include lorazepam (Ativan), alprazolam (Xanax), clonazepam (Klonopin), triazolam (Halcion) and diazepam (Valium). Benzodiazepines are the 13<sup>th</sup> leading class of medications in the United States, with 71 million prescriptions dispensed in 2002.<sup>6</sup> Benzodiazepines have long been used to treat mental illness, and they are considered among the standard treatments for acute anxiety disorders.

Benzodiazepines are common treatments for older people and people with disabilities who are on Medicare. According to one recent study, 1.7 million of the 6.4 million “dual eligibles” (people who are covered by both Medicare and Medicaid), or 27 percent, take a benzodiazepine. Another study of prescriptions dispensed for “dual eligibles” living in nursing homes indicated that within an 18-month period, more than 12 percent of them had at least one prescription filled for a benzodiazepine.<sup>7</sup>

Benzodiazepines are frequently used for conditions that are common among older adults. For example, anxiety disorders are the most common mental illnesses among older adults, affecting more than 11 percent of people over the age of 55.<sup>8</sup> Similarly, benzodiazepines are commonly (although the practice is not without controversy) prescribed for the acute anxiety that often accompanies dementia caused by Alzheimer’s disease and other conditions. Dementia is believed to afflict one in ten adults over the age of 65, and nearly half over the age of 85.<sup>9</sup>

Notwithstanding their widespread use, benzodiazepines have been the subject of controversy over the last 30 years, and it is this controversy that ultimately, albeit indirectly, led to their exclusion under the MMA. Like many prescription drugs, benzodiazepines can have significant side effects. These may be exacerbated in older patients, and may include over-sedation, falls and hip fractures, and dependency.<sup>10</sup> Benzodiazepines, more than many other drugs, are subject to abuse and misuse in a small proportion of those who take them.<sup>11</sup>

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<sup>6</sup> Stefanacci, Richard. “The Cost of Being Excluded: Impact of Excluded Medications under Medicare Part D on Dually Eligible Nursing Home Residents.” February 2005: 12.

<sup>7</sup> Stefanacci, Richard. “The Cost of Being Excluded: Impact of Excluded Medications under Medicare Part D on Dually Eligible Nursing Home Residents.” February 2005: 4.

<sup>8</sup> Center for Policy and Advocacy of the Mental Health Associations of New York City and Westchester, Geriatric Mental Health Policy for the 21<sup>st</sup> Century (citing U.S. Department of Health and Human Services, *Mental Health: A Report of the Surgeon General* (1999)).

<sup>9</sup> Alzheimer’s Association, “Executive Summary: Comments on Proposed Regulation for Implementation of Medicare Prescription Drug Benefit.” October 2004.

<sup>10</sup> Ross-Degnan, Soumerai, et al., “A Controlled Study of the Effects of State Surveillance On Indicators of Problematic and Non-Problematic Benzodiazepine Use in a Medicaid Population,” 34 *Int’l J. Psychiatry in Medicine* 2, 102-123, 2004.

<sup>11</sup> U.S. Drug Enforcement Administration, <http://www.usdoj.gov/dea/pubs/abuse/6-depress.htm#Benzodiazepines>.

Concerns about benzodiazepines are not new. Throughout the 1980s and 1990s, articles and studies documented overuse and misuse of benzodiazepines in a variety of different settings, including nursing homes. A vigorous campaign by the Public Citizen Health Research Group popularized the concern about benzodiazepine use and suggested that physicians often inappropriately prescribed benzodiazepines for use on a long-term basis, with resulting addiction and adverse side effects in patients.<sup>12</sup> New York and a few other states with prescription monitoring programs (“triplicate prescription programs”) added benzodiazepines to the list of drugs requiring triplicate prescriptions, to allow monitoring of prescribing patterns and to discourage over-prescribing. Significant focus was placed on the use of benzodiazepines in the elderly. Physicians were urged to limit their use to short-term use in the elderly, and to consider carefully, according to the “Beers criteria,” before ever prescribing long-acting benzodiazepines to an older adult.<sup>13</sup>

This scrutiny of the appropriate uses of benzodiazepines motivated Congress’ effort, in the Omnibus Budget Reconciliation Act (OBRA) of 1990, to allow states to “exclude[] from coverage or otherwise restrict[]” certain categories of drugs – including benzodiazepines -- from their Medicaid drug programs. This is clear from the language of the provision, which provides that the Secretary should “periodically update the list of [excludable/restrictable] drugs which the Secretary has determined...*to be subject to clinical abuse or inappropriate use*”<sup>14</sup> (emphasis added), as well as from the Report accompanying OBRA ’90, which indicates that the list of drugs that could be excluded or restricted by state Medicaid plans were drugs that were commonly subject to restrictions at that time.<sup>15</sup> Furthermore, a former Capitol Hill staff member involved in drafting the Medicaid provision in 1990 recalled that benzodiazepines were added to the list of restrictable/excludable drugs at the eleventh hour of legislative negotiations in response to widely-publicized studies and concerns about the misuse of benzodiazepines and their addictive qualities.<sup>16</sup>

When Congress considered legislation to add a prescription drug benefit to Medicare from about 1999 to 2003, many of the major bills advanced by both Democrats and Republicans adopted some or all of the categories of drugs that are “excludable” under Medicaid and excluded them altogether from coverage under Medicare. Many of these bills, including the Clinton Administration’s Medicare Modernization Act of 2000, explicitly gave the Secretary of Health and Human Services broad authority to modify the

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<sup>12</sup> See, e.g., Testimony of Sidney Wolfe, Public Citizen Health Research Group, before the Food and Drug Administration Drug Abuse Advisory Committee, May 14, 1981; Bargmann, Wolfe and Levin, Stopping Valium, Centrax, Dalmane, Librium, Paximpam, Restoril, Serax, Tanxene and Xanax, Public Citizen health Research Group, 1982.

<sup>13</sup> Beers MH, Explicit criteria for determining potentially inappropriate medication use by the elderly. Archives of Internal Medicine 157:1531-1536 (1997). The Beers Criteria define medications that should generally be avoided in the ambulatory elderly, doses or frequencies that should generally not be exceeded, and medications that should be avoided in older persons for a range of common conditions.

<sup>14</sup> SSA § 1927(d)(3).

<sup>15</sup> Congressional Record, October 18, 1990 at S30515. [citation form is very creative]

<sup>16</sup> Interview with Andy Schneider, former Counsel, Subcommittee on Health and the Environment, House Committee on Energy and Commerce.

list of excluded drugs under Medicare;<sup>17</sup> others did not. Most, but not all, of the bills excluded coverage for benzodiazepines.

Meanwhile, benzodiazepines continue to be widely used drugs today, and a growing clinical consensus has developed around their appropriate use. First, benzodiazepines are effective short-term treatments for acute anxiety among older patients, according to a recent report of the U.S. Surgeon General.<sup>18</sup> Second, some experts believe that there are certain indications for which benzodiazepines are the only appropriate treatments.<sup>19</sup> Third, even though benzodiazepines are generally not recommended for long term use in the elderly, it is often appropriate to continue even long term use in a patient with mental conditions who is stabilized on a medication regime that includes benzodiazepines. Accordingly, if a physician has a new patient who has been taking benzodiazepines over a long period but appears stable and is not experiencing serious side effects, prudent practice would suggest maintaining that prescription regimen.

Finally, for the nearly one-sixth of people with Medicare who are not elderly – about 7 million Americans – benzodiazepines can be effective and appropriate treatments for those who suffer from anxiety, panic and seizure disorders and other mental conditions for which benzodiazepines can provide needed relief.

### **Why Excluding Benzodiazepines Will Harm People with Medicare**

The benzodiazepine exclusion raises serious concerns that people with Medicare who sign up for Part D plans will receive inappropriate care for conditions that are common in older and disabled adults. By substituting a “one-size-fits-all” coverage policy for individualized clinical judgments, Congress has reduced the number of tools available to physicians to treat conditions that cause untold suffering among people with Medicare and their families.

The impact of the exclusion is likely to be greatest on those who currently have coverage for benzodiazepines and will lose that coverage as a result of the MMA, as well as those with low incomes who may not be able to afford medications not covered by Part D. “Dually eligible” individuals fall into both categories. All people with Medicare and Medicaid coverage currently have access to benzodiazepines under Medicaid, although approximately one-third of state Medicaid programs impose limits on the number of prescriptions and/or require prior authorization to fill a benzodiazepine prescription. [See Figure 2]

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<sup>17</sup> S. 2342, 106<sup>th</sup> Congress. The Clinton proposal would not have excluded benzodiazepines, though it did exclude most of the other categories of drugs that were listed in section 1927 of the Medicaid statute.

<sup>18</sup> Surgeon General Report, above

<sup>19</sup> “[O]nly benzodiazepines can be used to arrest acute seizure disorders in residents with status epilepticus.” Stefanacci, at 12.

## State Medicaid Programs' Coverage of Benzodiazepines

<u>State</u>	<u>Category*</u>	<u>State</u>	<u>Category</u>
Alabama	3	Missouri	2
Alaska	2	Montana	2
Arizona	3	Nebraska	3
Arkansas	3	New Hampshire	3
California	2	New Jersey	2
Colorado	2	New Mexico	3
Connecticut	2	New York	2
Delaware	3	North Carolina	2
DC	2	North Dakota	2
Florida	2	Ohio	2
Georgia	3	Oklahoma	2
Hawaii	2	Oregon	3
Idaho	2	Pennsylvania	2
Illinois	2	Rhode Island	2
Indiana	2	South Carolina	2
Iowa	2	South Dakota	2
Kansas	3	Tennessee	2
Kentucky	3	Texas	3
Louisiana	3	Utah	2
Maine	3	Vermont	3
Maryland	2	Virginia	3
Massachusetts	2	Washington	3
Michigan	3	West Virginia	3
Minnesota	2	Wisconsin	2
Mississippi	2	Wyoming	2
<b>1= state excludes coverage of benzodiazepines</b> <b>2= state covers all medically necessary benzodiazepines</b> <b>3= state covers benzodiazepines but with some restrictions</b>			

\*With the assistance of the National Association of State Mental Health Program Directors (NASMHD), State Mental Health Directors were surveyed about Medicaid coverage of benzodiazepines in their respective states. Follow up was then conducted with the Directors and Medicaid state officials. Directors and officials responding to the survey chose Category 1 if their state excludes all benzodiazepines from Medicaid coverage; Category 2 if their state covers all medically necessary benzodiazepines under Medicaid; or Category 3 if their state restricts coverage of benzodiazepines under Medicaid.

There is a risk that some state Medicaid programs may attempt to end coverage of benzodiazepines and other drugs excluded from coverage under Part D.<sup>20</sup> This will leave some of the poorest people with Medicare worse off as a result of the MMA. Even if states continue providing coverage for benzodiazepines for individuals with Medicare and Medicaid coverage, some “dual eligibles” are likely to have difficulty accessing coverage because of the complexity of coordinating coverage and because they may have difficulty navigating benefits between two different sources of coverage.<sup>21</sup>

Other individuals with low incomes who enroll in Part D will also have difficulty accessing benzodiazepines. Those who are not eligible for or do not apply for Low-Income Subsidies will have to pay hundreds of dollars in Part D premiums and hundreds more for prescription drugs through deductibles and cost sharing; these individuals may not be able to pay “retail” prices – even for relatively inexpensive drugs like benzodiazepines -- entirely out-of-pocket. People transitioning from employer-sponsored coverage to Part D are also likely to experience a problematic coverage change, as many private health plans provide coverage for benzodiazepines.<sup>22</sup>

For people with Medicare who are currently being treated with benzodiazepines, a sudden cessation of benzodiazepine use may be catastrophic. People with mental and cognitive disorders can spend months or even years developing stable medication regimens. For these individuals, discontinuing any medication could result in serious clinical setbacks and painful efforts to regain function and stability. Among people with long-term use of benzodiazepines, discontinuation can result in severe withdrawal symptoms, including seizures and other acute emergencies.<sup>23</sup>

According to many experts, the only manner in which the transition from a benzodiazepine to another comparable drug can be successful and safe is if the transition is gradual and supervised.<sup>24</sup> Because many doctors are either unaware of the upcoming changes relating to the implementation of the MMA and Part D, or do not know exactly which patients this transition will affect, it is quite likely that many people with Medicare will face the abrupt cessation of their benzodiazepine regimens beginning January 1, 2006.

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<sup>20</sup> For example, California Governor Arnold Schwarzenegger’s proposed budget did not include funds for any wraparound coverage for dual eligibles who are enrolled in Part D plans. California Legislative Analyst’s Office, *Part D Stands for Deficit: How the Medicare Drug Benefit Affects Medi-Cal*, March 16, 2005.

<sup>21</sup> Nearly 40% of dual eligibles have cognitive impairments, and a disproportionate number have limited educations and limited English proficiency. MedPAC. Dual eligibles experience numerous barriers in coordinating their Medicare and Medicaid coverage. See Nemore, Patricia, *Dual Eligibles*, Center for Medicare Education, Vol. 5 No. 2 (2004) <http://www.futureofaging.org/PublicationFiles/V5N2Revised.pdf>

<sup>22</sup> Cigna <[https://secure.cigna.com/health/form/drug\\_list.html](https://secure.cigna.com/health/form/drug_list.html)>, CareFirst BlueCross Blue Shield <<http://notesnet.carefirst.com/formulary/formulary.nsf/vwprintcode/print?OpenDocument>> and Empire BlueCross Blue Shield <[http://www.empireblue.com/pdf/ebcbs057\\_web\\_formulary.pdf](http://www.empireblue.com/pdf/ebcbs057_web_formulary.pdf)> Also Letter from Stephen Soumerai, Professor of Ambulatory Care and Prevention, Harvard Medical School, September 29, 2004.

<sup>23</sup> Soumerai, et al, *New England Journal of Medicine*, 1994, 331:650-655.

<sup>24</sup> Stefanacci, Richard. “The Cost of Being Excluded: Impact of Excluded Medications under Medicare Part D on Dually Eligible Nursing Home Residents.” February 2005 (citing studies).

## Recommendations

A growing consensus among experts, consumers, and patient advocates is that benzodiazepines, while rarely appropriate for long-term use in older patients, are important tools for treating anxiety, panic disorders, seizures in older patients and those with mental disabilities. If these drugs are not covered under Medicare Part D, access is likely to be reduced, resulting in poor health outcomes and acute disturbances. Congress and the Department of Health and Human Services both have opportunities to improve the care that can be provided to people with Medicare under Part D. If the federal government fails to do so, states may also step in to meet this compelling need.

### 1. Congress should Change the MMA Exclusions.

The decision to exclude coverage of benzodiazepines in the MMA was not carefully considered by Congress when it enacted the 2006 prescription drug benefit. That is clear from a review of the legislative record. The subject was not discussed in hearings nor was a rationale spelled out in a conference report. Congress should revisit the decision and amend the MMA to more closely mirror Medicaid's treatment of benzodiazepines – in other words, it should allow but not require Part D plans to restrict coverage for benzodiazepines (and any other drug) in order to combat misuse or abuse. In order to ensure that Part D plans make clinical concerns paramount in controlling access to benzodiazepines, Congress should require that restrictions on benzodiazepines be based on clinical considerations only and be made only on the recommendation of a plan's Pharmacy and Therapeutic (P&T) Committee. The Centers for Medicare and Medicaid Services (CMS) should also ensure that any restrictions are consistent with promising practices it has identified in ensuring appropriate access of psychotropic drugs in Medicaid, such as aligning prescribing practices with best practice guidelines and treatment algorithms.<sup>25</sup>

The cost of such an amendment would probably be low, and might actually be cost neutral or result in limited cost savings. Benzodiazepines are available in generic form, and are rarely expensive, especially compared to drugs that could be used as alternatives to benzodiazepines.<sup>26</sup> Other health care costs could be avoided if benzodiazepines are available to people with Medicare, including costs for avoidable emergency room visits and hospital admissions.

### 2. HHS should update the list of excludable drugs under Medicaid.

If Congress does not move swiftly to correct its exclusion of benzodiazepine coverage from the Medicare drug benefit, the Secretary of Health and Human Services should update the list of Medicaid excludable drugs in section 1927(d)(2), which was added by OBRA 1990. Reflecting Congress' understanding that knowledge about

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<sup>25</sup> <http://www.cms.hhs.gov/promisingpractices/psychotropicmeds.pdf>

<sup>26</sup> One expert estimated that substituting Ambien for Restoril (a benzodiazepine) would actually cost \$20 million per year; substituting Zyprexa for Ativan (a benzodiazepine) could cost \$325 million per year. Stefanacci at 17.

medical treatment is constantly changing, in Section 1927(d)(3), titled “Update of Drug Listings,” the Secretary is directed “[to] periodically update the list of drugs . . . which the Secretary has determined based on data collected by surveillance and [Medicaid] utilization review programs to be subject to clinical abuse or inappropriate use.” In this way, Congress acknowledged that the list of excludable drugs should not remain frozen in time, but should be reevaluated with an eye toward minimizing “clinical abuse or inappropriate use” of prescription drugs. Since 1990, however, no Secretary has completed the statutorily-mandated review, and the list of drugs has never been updated. (See Appendix A for analysis of this review authority.)

If the Medicaid list of excludable drugs were updated, the MMA’s list of excluded drugs would automatically incorporate these changes. The MMA excludes coverage of drugs which “may be excluded from coverage or otherwise restricted under section 1927(d)(2)...**or under section 1927(d)(3)**. (emphasis added).”<sup>27</sup> By specifically referencing the provision that requires updates to the list of drugs that may be excluded or restricted under Medicaid, the MMA allows the list of excluded drugs to change as the Medicaid list changes through the Secretary’s authorized alterations.

Fifteen years after the original list of Medicaid excludable drugs was enacted, the Secretary has a duty to review the list to determine whether, in fact, all benzodiazepines are “subject to clinical misuse or inappropriate use” such that they should be unavailable to people with Medicare (and, at state discretion, Medicaid), or whether the list could be updated to eliminate reference to benzodiazepines altogether or to authorize only specific restrictions on certain medical uses. The fact that every state has chosen to provide coverage for benzodiazepines, notwithstanding their authority to exclude them, should be telling to the Secretary, as should the fact that the Surgeon General has characterized benzodiazepines as effective short-term treatments for certain mental conditions among older patients. Congress did not intend to impose restrictions on drug coverage that would be inappropriately frozen in time, and the Secretary should not allow outdated approaches to combat misuse and abuse to block access to important and commonly-prescribed drugs like benzodiazepines.

### **3. States should provide coverage to “dual eligibles” through Medicaid programs and to others through state pharmacy assistance programs.**

The MMA provides, and CMS has reiterated, that state Medicaid plans may provide coverage for drugs that are excluded under the MMA for people who are dually eligible for Medicare and Medicaid. States will receive federal matching funds for the cost of covering these excluded drugs.<sup>28</sup> Furthermore, CMS has recently clarified that Medicaid’s requirement of “comparability” applies to coverage of excludable drugs.<sup>29</sup> Accordingly, if states provide coverage of excludable drugs, including benzodiazepines, to their general Medicaid population, then they will be required to continue coverage for

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<sup>27</sup> 42 U.S.C. 1395w-102(e)(2)(A) (2005)

<sup>28</sup> 70 Fed. Reg. 4194, 4230 (January 28, 2005).

<sup>29</sup> CMS Region IX, *MMA State Issue Log 041505*, p. 3. CMS officials have also described this interpretation at meetings of stakeholders around the implementation of the MMA.

“dual eligibles”. While this should encourage states to continue coverage of benzodiazepines to “dual eligibles”, it could have the unintended consequence of encouraging states to eliminate coverage for the rest of their Medicaid population as a cost-cutting measure.

States with operating pharmacy assistance programs (SPAPs) should also ensure that SPAPs provide coverage for benzodiazepines for people enrolled in the SPAP. The coverage could be provided through the purchase of supplemental coverage from Part D plans or by providing secondary coverage for benzodiazepines directly.

While these measures would help to reduce the harm caused by the benzodiazepine exclusion for some people, many people in need would be unprotected. First, as noted above, states may choose to impose limits on the coverage of benzodiazepines and other excluded drugs for their entire Medicaid populations rather than add payments for excluded drugs to the other costs imposed on them by the MMA.

Further, very few states have large state pharmacy assistance programs that can provide wraparound drug coverage for excluded drugs to any significant number of state residents. People with Medicare living in states like New York, New Jersey, and Pennsylvania might find a source of benzodiazepine coverage through their state-funded programs, but many others will not.

Finally, having two different sources of drug coverage – Part D plans and state Medicaid or SPAP programs –will result in difficult coordination of benefits problems.<sup>30</sup> Patients may have to show different cards to receive coverage for different prescriptions, and therefore the likelihood of gaps in coverage is high.

### **Conclusion**

The exclusion of benzodiazepines under the MMA could result in serious harm to people with Medicare who suffer from acute anxiety, seizures, and other serious disorders. While the history of the exclusion shows that Congress intended to protect patients with a policy that allowed a state to restrict coverage of drugs that were subject to misuse, its modification and adoption in the MMA will hurt the very patients Congress intended to protect. A fifteen-year-old coverage policy was frozen in time, and, under the MMA, is allowed to substitute for careful clinical judgment. Congress should amend the MMA and allow doctors, with appropriate clinical guidance, to decide whether benzodiazepines are appropriate treatment in individuals with Medicare. If Congress does not act, the Secretary should engage in a statutorily-mandated review of the exclusion and apply up-to-date clinical judgments about the costs and benefits of benzodiazepine use by people with Medicare.

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<sup>30</sup> See Nemore, Patricia, *Dual Eligibles*, Center for Medicare Education, Vol. 5 No. 2 (2004) <http://www.futureofaging.org/PublicationFiles/V5N2Revised.pdf>

## Appendix A Analysis of 1927(d)(3) of the Social Security Act

Section 1927(d)(3) of the Social Security Act, added by OBRA 90, directs the Secretary of HHS to “periodically update the list of drugs ... which the Secretary has determined based on data collected by surveillance and utilization review programs to be subject to clinical abuse or inappropriate use.” Through this language, Congress has directed HHS to reevaluate the appropriateness of excluding certain drugs or classes of drugs from Medicaid coverage, as medical practice and knowledge evolve. Following passage of the MMA, these reassessments will now affect Medicare coverage of these medications as well.

Although the provision requires the Secretary periodically to update the list of drugs, it also gives the Secretary wide discretion to determine what the list should look like and include. For example, by using the word “update,” the provision clearly gives the Secretary the authority to remove drugs or classes of drugs from the list of those that could otherwise be subject to restriction by the State Medicaid programs. The common definition of the word “update” is “to bring up to date.”<sup>31</sup> By using this broad word, Congress intentionally chose not to limit the Secretary’s authority in making changes to the (d)(2) list. The Secretary can both add items to and delete items from the list to bring it up-to-date. For example, it would be well within the Secretary’s authority to conclude and issue regulations stating that benzodiazepines as a class do not belong on the list of excludable drugs because they are not, as an entire class, widely subject to clinical abuse or misuse, but that long-term use of benzodiazepines for chronic insomnia could be excluded.

The Secretary once took the view that she did not have the authority to remove drugs from the list of excludable drugs. A proposed Health and Human Services rule from 1995 interpreted section 1927(d)(3) to only allow the Secretary to add, not remove, drugs from the list.<sup>32</sup> The impetus behind HHS’ argument was that granting the Secretary too much discretion would place a financial burden on state Medicaid programs, which are forced to pay for the medications removed from the list. This rule was never finalized, however, and the interpretation it advanced is inconsistent with the provision’s text and legislative history.

A Senate Report accompanying the first draft of the statute in 1990<sup>33</sup> explains that the list found in 1927(d)(2) “represents drugs which, currently, are commonly subject to exclusion or restriction from State Medicaid programs.”<sup>34</sup> The inclusion of the word “currently” reflects Congressional understanding that the list should reflect up-to-date drug trends. Congress’ understanding of the statute is more explicitly laid out in the legislative history of the 1995 Omnibus Budget Reconciliation Act. That bill included a

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<sup>31</sup> Random House Webster’s College Dictionary, New York: Random House, 1996.

<sup>32</sup> See, 60 FR 48442 (Sept. 19, 1995).

<sup>33</sup> 136 Cong. Rec. 30515 (October 18, 1990).

<sup>34</sup> Id.

provision that would amend the title of section 1927(d)(3) to read “Additions to drug listings,” rather than “Update of drug listings.”<sup>35</sup> Clearly, Congress’ understanding was that the current language, “update of drug listing,” called for the Secretary to consider both adding *and* deleting drugs from the (d)(2) list. In order to restrict the Secretary to the addition and not removal of drugs, Congress realized it would have to amend subsection (d)(3). However, the OBRA 1995 was vetoed by President Clinton and never enacted, leaving in place the original demand that the Secretary “update” the list of excludable drugs.

Furthermore, analogous statutory uses of the word “update” have been interpreted to permit additions and deletions. Section 1834 of the SSA,<sup>36</sup> provides that “[t]he Secretary may...periodically update a list of items for which payment may be made...that the Secretary determines...are frequently subject to unnecessary utilization.” This provision was passed in response to the over-utilization of certain pieces of durable medical equipment (“DME”). The list is distributed to carriers and the DME included are those for which the Secretary will pre-approve reimbursement. Originally included on this list were a number of items, including seat-lift mechanisms, transcutaneous electrical nerve stimulators, and motorized scooters. In 2001, however, the Secretary removed all three of these items from the prior-authorization list, leaving just wheelchairs.<sup>37</sup> In this instance, the word “update” was clearly interpreted as giving the Secretary the authority to both add and remove items from a specific list.

If the Medicaid list of excludable drugs is updated, the MMA’s list of excluded drugs would incorporate the changes. In limiting coverage of Medicare’s new outpatient drug benefit, the MMA excludes coverage of drugs which “may be excluded from coverage or otherwise restricted under section 1927(d)(2)...or under section 1927(d)(3).”<sup>38</sup> By specifically adopting the updates to the statutory list that must be made by the Secretary under section 1927(d)(3), the MMA does not adopt the (d)(2) list in its current version, making it permanent as is. Instead, the MMA has created a list which will change as the Medicaid list changes through the Secretary’s authorized alterations under (d)(3). In referencing (d)(3), Congress made the choice to defer to the Secretary’s decisions made under the authority and mandate they created in section 1927(d)(3).

Fifteen years after the original list of Medicaid excludable drugs was enacted, the Secretary has a duty to review the list to determine whether, in fact, the entire class of benzodiazepines are “subject to clinical misuse or inappropriate use” such that they should be unavailable to people with Medicare, or whether the list could be updated to eliminate reference to benzodiazepines altogether or to include more specific restrictions on certain medical uses. The fact that every state has chosen to provide coverage for benzodiazepines, notwithstanding their authority to exclude them, should be telling to the Secretary. Congress did not intend to impose restrictions in statute that would be inappropriately frozen in time.

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<sup>35</sup> 104 H. Rpt. 280.

<sup>36</sup> 42 U.S.C. 1395m (1994).

<sup>37</sup> See Letter to DMERCs, *Prior Authorization Eliminated for POVs, TENS, and Seat Lift Mechanisms*, no. 58.4.1 (effective September 1, 2001).