



March 30, 2016

Mark E. Miller, Ph.D.  
Executive Director  
Medicare Payment Advisory Commission  
425 I St, NW – Suite 701  
Washington, DC 20001

**Re: MedPAC Draft Recommendation on Protected Classes in Medicare Part D**

Dear Dr. Miller:

The Partnership for Part D Access (the Partnership) and other key stakeholders would like to express our concerns regarding the Medicare Payment Advisory Commission's (MedPAC) March 3, 2016, draft recommendation on the Medicare Part D protected classes, particularly removing anti-depressant and immunosuppressant medicines' protected-class status.<sup>1</sup>

The Partnership is a coalition of healthcare stakeholders committed to maintaining access to medications under Medicare Part D, especially the categories and classes of drugs identified for unique patient protections at section 1860D-4(b)(3)(G)(iv) (the protected classes). These medications are vital to the treatment of: (1) epilepsy; (2) mental illness; (3) cancer; (4) HIV-AIDS; and (5) organ transplants. The Partnership was founded to combat efforts to undermine consumer access to appropriate treatment by increasing policymaker awareness of the vulnerability of patients with these conditions and the potential impact of delayed or denied care. The Partnership's membership currently includes a variety of patient advocacy organizations, such as the National Council for Behavioral Health (National Council), the National Alliance on Mental Illness (NAMI), Mental Health America (MHA), the Depression and Bipolar Support Alliance (DBSA), The AIDS Institute, the Epilepsy Foundation, and the National Kidney Foundation (NKF), as well as industry representatives.

**The Partnership strongly urges MedPAC to abandon its draft recommendation weakening the protected classes.** The protected classes policy has been a cornerstone of Part D's success: helping to assure that Part D formularies serve the needs of all Medicare beneficiaries (including the most vulnerable patients with the greatest need for drug coverage); making Part D a popular new part of Medicare; and making plans compete based on quality and efficiency instead of seeking to reduce costs by driving away people with serious illnesses. It is imperative that any Commission recommendation be based on solid, validated data, and the evidence on which MedPAC is relying is

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<sup>1</sup> Transcript of the March 3 MedPAC meeting, available [here](#).

both inadequate and inconclusive to serve as the basis for such a drastic policy change. The draft recommendation would undermine long-standing and congressionally directed protections that guarantee access to life-saving drugs for patients with the most severe health conditions. The Partnership would like to address several misconceptions underlying the draft recommendation before MedPAC reconvenes for its April 2016 public meeting. Specifically, the Partnership would like to clarify that:

- MedPAC's draft recommendation to remove anti-depressants and immunosuppressants from the protected classes would not lead to Medicare program cost savings, contrary to MedPAC staff assumptions;<sup>2</sup>
- The draft recommendation would have devastating health implications for some of Medicare's most vulnerable beneficiaries;
- Congressional intent clearly articulates the purpose and the permanence of the protected classes policy; and
- Part D plans already have substantial flexibility to manage costs for protected-class medicines.

Below, we address these points in greater detail:

#### **MEDPAC DRAFT RECOMMENDATION DOES NOT PORTEND COST SAVINGS**

At the March 3 public meeting, MedPAC staff asserted that a package of draft Part D recommendations, including the protected-class proposal, would lead to unspecified cost savings.<sup>3</sup> However, a recent literature review by Avalere Health, which we are attaching for your convenience, illuminates the broader implications of rescinding protected-class status and calls into question any claims of reduced Medicare expenditures.<sup>4</sup> The literature review found that managed care formulary restrictions, which would more adversely affect beneficiary access to protected-class medicines if MedPAC's draft recommendation were adopted, have problematic impacts on utilization, costs, and adherence.<sup>5</sup> The review found:

- While formulary restrictions often lead to lower drug spending, they were accompanied by increases in inpatient and outpatient medical care that outweigh savings on prescription drugs.
- After formulary restrictions were implemented, the rates of non-adherence increased, especially among older beneficiaries, and forced some patients to move to new drug treatments.
- Patients who were less adherent or who switched their therapies had higher hospitalization rates. When a non-adherent patient utilized health care services, they required longer hospital stays, higher use of inpatient psychiatric days, and higher frequency of visits.

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<sup>2</sup> *Ibid.*

<sup>3</sup> *Ibid.*, p. 143-144.

<sup>4</sup> Avalere Health, "Literature Review: Impact of Formulary Restrictions on Adherence, Utilization, and Costs of Care," March 2016.

<sup>5</sup> *Ibid.*

The Partnership urges the Commission to take these broader cost implications into account as it reconsiders its position on the draft recommendation affecting the protected classes.

### **DRAFT RECOMMENDATION RISKS JEOPARDIZING THE HEALTH OF BENEFICIARIES**

If the draft recommendation is implemented, beneficiaries with mental health conditions and organ transplants would face new barriers to accessing life-saving medications. Historically, due to the unique and variable ways in which patients respond to different drugs, and the complicated interplay of co-morbidities and drug interactions, it has been widely recognized that doctors need to have complete discretion to prescribe the most appropriate medicines for patients with these and other conditions addressed by the protected classes. To illustrate the diversity in depressed patients, under the American Psychiatric Association's Diagnostic and Statistical Manual V, major depressive disorder is diagnosed based on the individual having five out of nine listed symptoms associated with clinically significant distress or impairment in social, occupational or other areas of functioning;<sup>6</sup> this means that there are over 200 different variations of major depression that someone could present with and one would not look like the other. Given the heterogeneity of the patient population and multi-factorial nature (e.g., age, gender, sex, socioeconomic status, childhood history of sexual abuse, and recent stressful life events) of this disease in patients' response to therapy, it seems inconceivable that availability of one, two or even 20 medications is enough. Further, people with mental illness who may relapse, not respond to, or frequently experience varying side effects to medications.

Additionally, it is well established that MDD is significantly associated with a wide variety of chronic physical disorders, including arthritis, asthma, cancer, cardiovascular disease, diabetes, hypertension, chronic respiratory disorders, and a variety of chronic pain conditions.<sup>7, 8, 9, 10, 11</sup> The strong link between depression and various comorbid medical conditions suggest that management of all conditions are needed for optimal patient care. Comorbidities can limit the type of antidepressants a person can tolerate -- thus heightening the need for a broad range of antidepressant choices, as a drug's tolerability may affect adherence to the prescribed treatment regimen.<sup>12, 13</sup> Delays in receiving the correct depression medication and/or patient lack of adherence (e.g., because coverage restrictions bar access to an antidepressant with fewer side effects) can adversely affect both the patient's mental health and the treatment of the patient's medical

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<sup>6</sup> The nine DSM criteria for depression are as follows and a combination of any five criteria supports a diagnosis of MDD where at least one of the symptoms is either depressed mood or loss of interest or pleasure: (1) Depressed mood; (2) Decreased interest or pleasure; (3) Significant weight change; (4) Insomnia; (5) agitation or psychomotor retardation noticed by others; (6) Fatigue or loss of energy; (7) Guilt/worthlessness; (8) Diminished concentration; (9) Recurrent thoughts of death.

<sup>7</sup> See RJ Anderson et al., The Prevalence of Comorbid Depression in Adults with Diabetes: A Meta-Analysis, 24 *Diabetes Care* 1069, 1069–78 (2001);

<sup>8</sup> M.A. Buist-Bouwman MA et al., Comorbidity of Physical and Mental Disorders and the Effect on Work-Loss Days, 111 *Acta Psychiatrica Scandinavica* 436, 436–43 (2005).

<sup>9</sup> Daniel P. Chapman et al., The Vital Link Between Chronic Disease and Depressive Disorders, 1 *Preventing Chronic Disease Pub. Health Res., Prac. and Pol'y* A14 (2005).

<sup>10</sup> L.R. Derogatis et al., The prevalence of psychiatric disorders among cancer patients, 249 *JAMA* 751, 751–57 (1983).

<sup>11</sup> C.B. Nemeroff et al., Depression and Cardiac Disease: A Review, 19 *Cardiology in Review* 130, 130-142 (2011).

<sup>12</sup> Goethe JW. et al. *J Clin Psychopharmacol.* 2007;27(5):451-458.

<sup>13</sup> Bull SA. et al. *Ann Pharmacother.* 2002;36(4):578-584.

comorbidity and overall health<sup>14</sup> - - with all the associated expenses necessary to treat both the MDD and the comorbid condition after these problems have grown worse. These circumstances will cause Medicare to pay for avoidable hospitalizations, ER visits, physician visits, and other interventions that would not have been necessary if the patient had ready access to the right antidepressant.

Immunosuppressive medications are not interchangeable but rather are prescribed in combinations tailored to meet the unique needs of the individual transplant recipient in order to achieve sufficient immunosuppression while minimizing the toxicity associated with individual agents. Physicians prescribe the most appropriate combination for the individual patient to achieve sufficient immunosuppression while minimizing the adverse side effects. Often the first combination doesn't work and the physician has to revise the regimen, further underscoring the need to have all drugs available. Restrictive formularies limit physicians' ability to prescribe the right combination of medications.

Nearly 9 million (six percent) Americans under age 65 also qualify for Medicare coverage because they are totally and permanently disabled<sup>15</sup> many of which receive the low income subsidy (LIS). They are more likely than the elderly to live in poverty, to be in poor health, and to experience difficulties living independently and performing basic daily tasks. Because they require affordable access to a wide variety of medicines to meet their complex health needs, they may be particularly susceptible to any treatment disruptions and would be disproportionately impacted by the CMS-proposed regulations in coverage.

No other protections in Medicare Part D guarantee medication access to patients with these serious health conditions, which often require physicians and patients to fine-tune medications to achieve clinically necessary treatment outcomes. Removing these critical protections may have dire health consequences for beneficiaries, such as rejection of a transplanted organ, hospitalization, or possibly death. It is therefore urgent that MedPAC reconsider its draft recommendation.

#### **CONGRESSIONAL INTENT SUPPORTS PROTECTED CLASSES**

Congress repeatedly has supported and strengthened the protected classes. In a Senate colloquy just before the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Senators repeatedly emphasized the role of protections, including the protected classes, available to beneficiaries who need "exactly the right medicine for them."<sup>16</sup> The full text of the colloquy is attached to this correspondence. Senators made no mention of the protected-class protections being a temporary or stop-gap measure until protected-class medicines faced greater generic competition.<sup>17</sup>

More recently, Congress reaffirmed the importance of the original protected classes in Section 3307 the Affordable Care Act (ACA). Every Member of the Senate Finance Committee opposed the Centers for Medicare and Medicaid Services' 2014 proposed rescission of protected-class protections, echoed

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<sup>14</sup> Dan V. Iosifescu, et. al., The Impact of Medical Comorbidity on Acute Treatment in Major Depressive Disorder. *Am. J. Psychiatry*; 160:2122-2127.

<sup>15</sup> U.S. Department of Health and Human Services: 2013 US Statistics.

<sup>16</sup> 149 Cong. Rec. S5882-03.

<sup>17</sup> *Ibid.*

by a separate letter from 50 Members of the House Energy and Commerce Committee.<sup>18</sup> Both letters are attached. A MedPAC recommendation to alter the existing classes would undermine the clear legislative history and intent.

#### **PART D PLANS ALREADY HAVE SUBSTANTIAL FLEXIBILITY**

Despite assumptions that Part D plans are constrained in their flexibility, plans already have significant latitude in managing the utilization of protected-class drugs and negotiating rebates with drug manufacturers. CMS guidance generally permits plans' use of prior authorization and step therapy to manage therapies for any beneficiary initiating therapy with a protected-class drug.<sup>19</sup> Generic dispensing rates (GDR) within the protected classes are on par with other therapeutic classes.<sup>20</sup> These existing flexibilities suggest that additional legislative and regulatory action is unnecessary, particularly when beneficiary access to critical medications would be jeopardized.

Moreover, MedPAC found that from 2006-2010 prices for protected-class drugs rose less than Part D prices overall.<sup>21</sup> Cumulative Part D price growth from 2006-2010 was 23% overall and 21% for protected class drugs; after accounting for generic substitution, cumulative price growth was 2% overall and minus 2% for protected-class drugs.<sup>22</sup> Accordingly, any theory that protected class drugs have higher prices or lower Part D rebates is unsupported and unproven. It cannot justify restricting access for Part D patients who need antidepressants to fight depression.

The Partnership appreciates the Commission's deliberative process to developing its recommendations. Again, we strongly urge the Commission to reconsider its draft recommendation on the protected classes and ensure these critical beneficiary protections remain in place. Please do not hesitate to contact Chuck Ingoglia, National Council for Behavioral Health if you have any questions regarding these comments or attachments or if we can provide additional information.

Sincerely,

ADAP Advocacy Association  
AIDS Institute  
American Association of Child & Adolescent Psychiatry  
American Association on Health and Disability  
American Society of Consultant Pharmacists  
American Society of Transplant Surgeons  
American Society of Transplantation  
Anxiety and Depression Association of America  
Association for Ambulatory Behavioral Healthcare  
Cancer Support Community

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<sup>18</sup> Senate Finance Committee, Letter to Administrator Tavenner, February 5, 2014; and House Ways & Means and Energy & Commerce Committees, Letter to Administrator Tavenner, March 4, 2014.

<sup>19</sup> Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5

<sup>20</sup> Medicare Payment Advisory Commission, "Data Book: Health Care Spending and the Medicare Program: Chapter 10—Prescription Drugs," June 2013, p. 24, available [here](#).

<sup>21</sup> MedPAC, March 2013 Report to the Congress, Medicare Payment Policy, at 355-56.

<sup>22</sup> *Ibid.*

Clinical Social Work Association  
Community Access National Network  
Depression and Bipolar Support Alliance  
Epilepsy Foundation  
Lakeshore Foundation  
Lupus Foundation of America  
Mental Health America  
National Alliance of State & Territorial AIDS Directors  
National Alliance on Mental Illness  
National Association for Rural Mental Health  
National Association of County Behavioral Health and Developmental Disability Directors  
National Council for Behavioral Health  
National Register of Health Service Psychologists  
Parkinson's Action Network  
Transplant Recipients International Organization  
Transplant Support Organization  
Women Against Prostate Cancer

#### **ATTACHMENTS**

1. Avalere Literature Review
2. Senate Colloquy
3. Sen. Gordon H. Smith Statement of Introduction on S. 1887
4. Senate Finance Committee Letter to the Centers for Medicare and Medicaid Services (CMS) Opposing 2014 Proposed Changes to the Protected Classes
5. House Committee Letter to CMS Opposing Protected-Class Changes



# Literature Review: Impact of Formulary Restrictions on Adherence, Utilization, and Costs of Care

Prepared for The Partnership for Part D Access  
Avalere Health | An Inovalon Company  
March, 2016

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## Project Overview

# Purpose of Literature Review

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- As policymakers seek savings opportunities for the Part D program, MedPAC and others are exploring changes to Part D's classes of clinical concern (protected classes) which include antidepressants and antipsychotics
- For antidepressants and antipsychotics, literature suggests that patients benefit from access to broad formularies because individuals may respond differently to the same drug and need to find a drug that works best for them<sup>1</sup>
- The Partnership for Part D Access (Partnership) seeks evidence to illustrate the clinical and economic benefits of Medicare Part D's classes of clinical concern
- The goals of this targeted literature review are to identify select studies that demonstrate the potential negative impact that formulary restrictions can have on medication use, utilization of health care services, and total cost of care

1, S.B. Soumerai. "Benefits and Risks of Increasing Restrictions on Access to Costly Drugs in Medicaid." *Health Affairs*, January 2004.

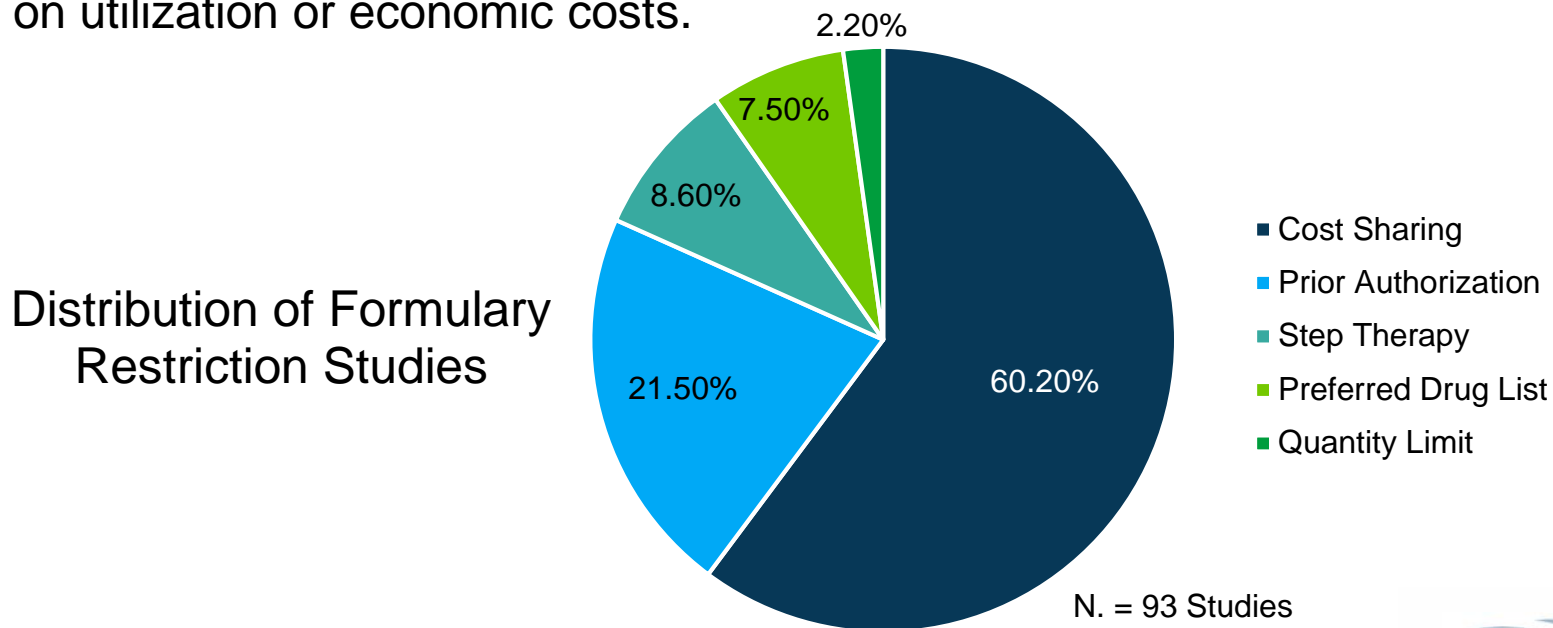
# Methodology of Literature Review

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- The literature review focused on studies that examine the impact of formulary restrictions, including preferred drug lists and step therapy requirements, on:
  - Medication Use: medication adherence, therapy changes, discontinuation
  - Costs of Care: inpatient and outpatient medical utilization, total cost of care
- Avalere searched academic databases for studies published within the prior 25 years
  - All conditions were included in the search; studies on behavioral health conditions were prioritized for inclusion in the results
  - Research was focused on Medicare and Medicaid populations; however it included other populations where the findings were relevant
- Articles were selected for inclusion in this project based on relevance to the key research questions
- The studies are organized into three categories:
  - Impact of Formulary Restrictions on Utilization and Cost of Care
  - Impact of Formulary Restrictions on Adherence and Therapy Changes
  - Impact of Adherence and Therapy Changes on Utilization and Cost of Care

# Avalere Focused on the Small Subset of Articles Most Directly Relevant to the Research Questions of Interest

- A 2014 literature analysis<sup>1</sup> found 811 articles had been published since 1993 on the relationship between managed care formulary restrictions and medication adherence, clinical outcomes, economic outcomes, and health care resource utilization
  - Only 93 studies analyze the outcomes of such restrictions on a U.S. managed care population
  - Over 82 percent of the 93 relevant studies focused exclusively on cost-sharing or prior authorization restrictions.
- Only seven studies evaluated preferred drug lists, and only three looked at its impact on utilization or economic costs.



1. Laura E. Happe, Deanna Clark, Edana Holliday & Tramaine Young. "A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization." (2014) J Manag Care Pharm. 20(7):677-84.



## Executive Summary

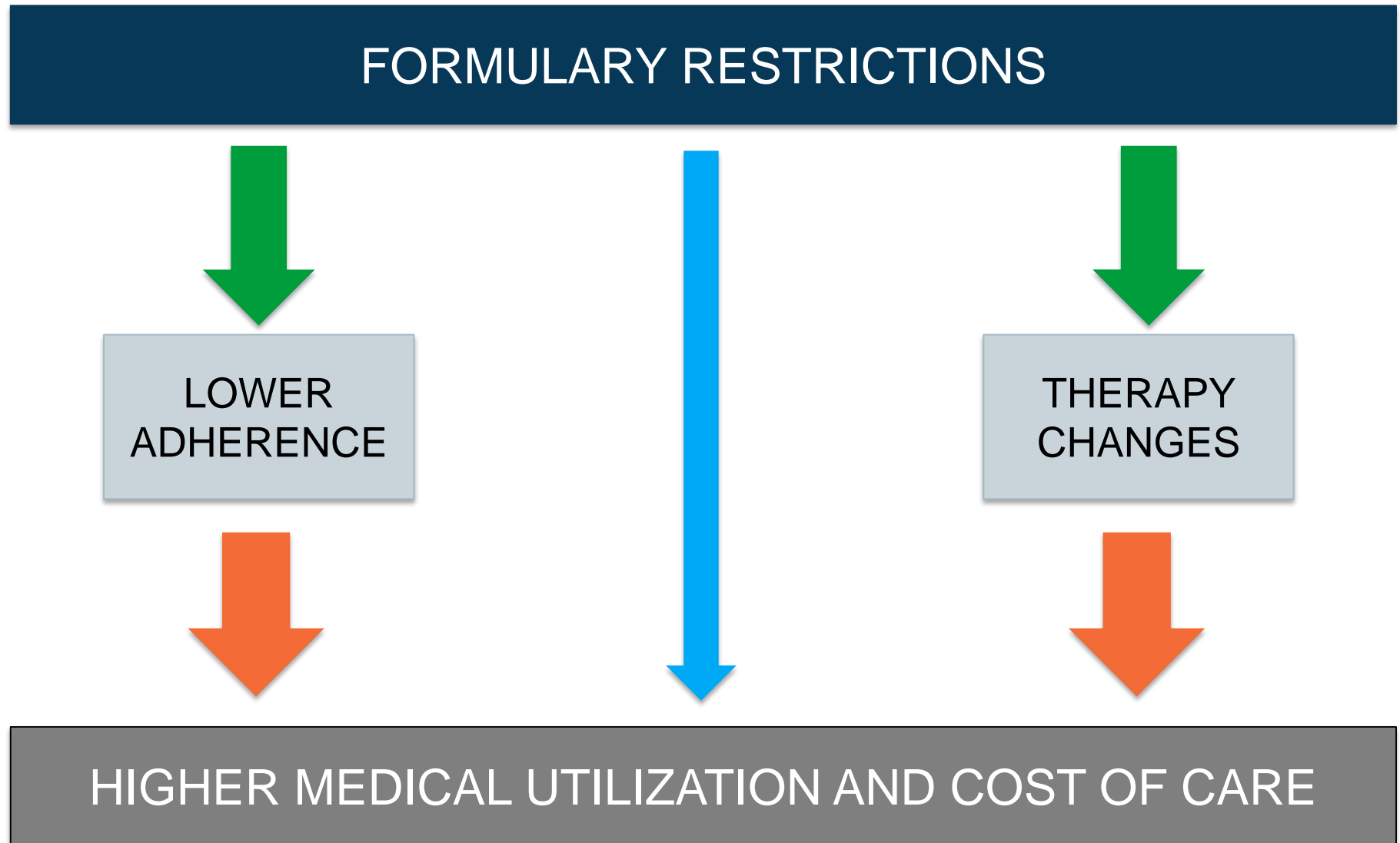
# Executive Summary

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- Impact of Formulary Restrictions on Utilization and Cost
  - Findings: while formulary restrictions often lead to lower drug spending, they were accompanied by increases in inpatient and outpatient medical care that outweigh savings on prescription drugs.
  - Number of studies included: 4
- Impact of Formulary Restriction on Adherence and Therapy Changes
  - After formulary restrictions were implemented, the rates of non-adherence increased, especially among older beneficiaries, and forced some patients to move to new drug treatments.
  - Number of studies included : 4
- Impact of Adherence and Therapy Changes on Utilization and Costs
  - Patients who were less adherent or who switched their therapies had higher hospitalization rates. When a non-adherent patient utilized health care services, they required longer hospital stays, higher use of inpatient psychiatric days, and higher frequency of visits.
  - Number of studies included : 6

# The Literature Review Identifies Evidence Linking Formulary Restrictions To Suboptimal Medication Use And Higher Utilization And Total Cost Of Care

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## Results of Targeted Literature Review





## Impact of Formulary Restrictions on Utilization and Cost

# “Formulary Restrictions on Atypical Antipsychotics: Impact on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Seth A. Seabury, Dana P. Goldman, Iftekhar Kalsekar, John J. Sheehan, Kimberly Laubmeier, and Darius N. Lakdawalla</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Medicaid: Patients diagnosed with <b>schizophrenia</b> or <b>bipolar disorder</b> in 24 state Medicaid programs</li><li>• 2001 to 2008</li><li>• Retrospective analysis of claims data</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• American Journal of Managed Care, 2014</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• Bristol-Myers Squibb</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To measure the impact of state Medicaid formulary policies on costs for patients with schizophrenia and bipolar disorder.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Adherence:</b> Patients with schizophrenia had 2% worse adherence. For patients with bipolar disorder, formulary restrictions had no significant effect on adherence.</li><li>• <b>Hospitalization Rates, Inpatient Costs and Total Cost:</b><ul style="list-style-type: none"><li>• Patients with schizophrenia were 113% more likely to be hospitalized, had 23% higher inpatient costs, and 16% higher total costs.</li><li>• Patients with bipolar disorder were 107% more likely to experience a hospitalization, had 20% higher inpatient costs, and had 10% higher total costs.</li></ul></li><li>• <b>Pharmacy Expenditures:</b> Formulary restrictions were not associated with statistically significantly lower pharmacy expenditures for either patient sample</li></ul>

# “Implications of an SSRI Generic Step Therapy Pharmacy Benefit Design: An Economic Model in Anxiety Disorders”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Patt Ellen Panzer, Timothy S. Regan, Evelyn Chiao, and Matthew W. Sarnes</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• General: Patients who initiated therapy with an <b>SSRI agent</b> within one year</li><li>• N/A</li><li>• Literature Review</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• American Journal of Managed Care, 2005</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To determine the economic implications of a generic step therapy (GST) formulary compared with an open formulary for selective serotonin reuptake inhibitors (SSRIs) in patients with anxiety disorders.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Therapy Changes and Medication Use:</b> GST resulted in greater frequency of therapy change than the open formulary (41.3% vs 36.8%) and a lower frequency of continuous therapy for at least 6 months (25.3% vs 29.8%).</li><li>• <b>Pharmacy Cost:</b> Costs of SSRI medication were lower for the GST formulary than for the open formulary (\$11.6 million vs \$14.8 million).</li><li>• <b>Total Cost of Care:</b> Medical costs were greater for the GST formulary than for the open formulary, (\$178.7 million vs \$174.9 million, respectively), with a total cost of \$190.3 million for the GST formulary versus \$189.6 for the open formulary.</li></ul>

# “Exploration of the Impact of Preferred Drugs Lists on Hospital and Physician Visits and the Costs to Medicaid”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Matthew M. Murawski and Tanner Abelgawad</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Medicaid: Patients with cardiovascular conditions</li><li>• December 2001 to May 2003</li><li>• Analysis of patient-level data</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• American Journal of Managed Care, 2005</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• Pfizer, Inc.</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To conduct an exploratory investigation of the possible effects of the implementation of a state Medicaid preferred drug list (PDL) on the average number of visits by Medicaid patients to hospitals and physicians, and to provide preliminary estimates of the Medicaid reimbursement costs of these additional visits.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Utilization:</b> Medicaid patients with cardiovascular conditions who were restricted by PDLs faced a statistically significant increase in number of outpatient hospital visits (41% as compared to 35%) six months after PDL implementation (there was also a positive but statistically insignificant increase in the number of inpatient hospital visits), in comparison to non-Medicaid patients with cardiovascular conditions who were not restricted by PDLs.</li><li>• <b>Costs:</b> Average Medicaid cardiovascular patient incurred a \$162 to \$185 increase in reimbursements for inpatient procedures compared with non-Medicaid patients in the year following the implementation of the PDL.</li></ul>

# “The Effects of Antidepressant Step Therapy Protocols on Pharmaceutical and Medical Utilization and Expenditures”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Tami L. Mark, Teresa M. Gibson, Kimberly McGuigan, and Bong Chul Chu</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Employer Plans: Patients prescribed <b>antidepressants</b></li><li>• 2003-2006</li><li>• Analysis of claims databases</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• The American Journal of Psychiatry, 2010</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• Pfizer, Inc.</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• This study examined the effects of step therapy for antidepressants on prescription drug and other medical utilization and spending.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Medication Cost:</b> Antidepressant days supplied and medication costs decreased after step therapy was implemented, relative to the comparison group.</li><li>• <b>Utilization and Cost:</b> Overall and mental health-specific inpatient and emergency room utilization and costs increased. Step therapy may have the unintended effect of reducing overall antidepressant use and increasing medical use and costs.</li></ul>





## Impact of Formulary Restriction on Adherence and Therapy Changes

# “Impact of Medicare Part D on Antidepressant Treatment, Medication Choice, and Adherence Among Older Adults With Depression”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Julie M. Donohue, Yuting Zhang, Subashan Perera, Judith R. Lave, Joseph T. Hanlon</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Behavioral Health, Medicare: <b>Older adults with depression</b> (ICD-9: 296.2, 296.3, 311, 300.4) continuously enrolled in a <b>Medicare</b> managed care plan</li><li>• 2004-2007</li><li>• Observational claims-based study</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• Presented at Academy Health Annual Research Meeting, 2008</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• Highmark Inc.</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• Examine the impact of improved prescription drug coverage under Medicare Part D on use of antidepressants, medication choice, and adherence.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Medication Use:</b><ul style="list-style-type: none"><li>• Medicare Part D was associated with increased odds of any antidepressant use among those who previously lacked coverage.</li><li>• All three groups whose coverage improved with Part D had significantly higher odds (80%) of days covered with an antidepressant.</li></ul></li></ul>



# “Impact of Medicaid Preferred Drug Lists on Therapeutic Adherence”

<b>Authors</b>	<ul style="list-style-type: none"><li>• David B. Ridley and Kirsten J. Axelsen</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Medicaid: Beneficiaries treated with statins</li><li>• 2001 to 2005</li><li>• Retrospective cohort study</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• Pharmacoconomics, 2006</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• Duke University</li><li>• Pfizer, Inc.</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To estimate rates of non-adherence for statins following implementation of a preferred drug list (PDL).</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Adherence:</b><ul style="list-style-type: none"><li>• Following the implementation of a PDL in Alabama, Medicaid beneficiaries treated with statins had an 82% higher relative odds of becoming non-adherent with statin therapy compared with North Carolina (which had no PDL), and with pre-PDL Alabama.</li><li>• Patients taking a restricted statin were 42% more likely to be non-adherent than unrestricted patients. Among Medicaid beneficiaries taking a restricted statin, people aged 65 years or older were 33% more likely to be non-adherent than their younger counterparts after the PDL.</li><li>• Fifty-one per cent of patients in the Alabama sample were non-adherent with statin therapy after the PDL, compared with 39% before. Non-adherence was 36% in North Carolina in both periods.</li></ul></li></ul>





# “Selective Contracting and Patient Outcomes: A Case Study of Formulary Restrictions for Selective Serotonin Reuptake Inhibitor Antidepressants”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Dan A. Streja, Rita L. Hui, Elani Streja, and Jeffrey S. McCombs</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Managed Care plans: Patients newly prescribed <b>SSRIs</b> in a single California group practice</li><li>• N/A</li><li>• Analysis of prescription drug and medical record data</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• American Journal of Managed Care, 1999</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To investigate the effect of “single-drug” formulary restrictions on the likelihood of drug therapy completion for new patients, controlling for initial SSRIs used and other factors.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Drug Therapy Completion:</b><ul style="list-style-type: none"><li>• Patients from the HMO with a single preferred SSRI (paroxetine) were 80% less likely to complete therapy than were patients from the HMO with 2 preferred SSRIs (fluoxetine and paroxetine). This formulary effect was independent of the initial drug used to treat the patient.</li><li>• Drug selection was also found to affect completion rates.</li><li>• These results suggest that the use of single-product formularies may have unintended consequences on patient completion rates.</li></ul></li></ul>

# “Medicaid Prescription Drug Access Restrictions: Exploring the Effect on Patient Persistence with Hypertension Medications”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Jerome Wilson, Kirsten Axelsen, and Simon Tang</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Medicaid: Patients prescribed hypertension medications</li><li>• June 2000 to May 2003</li><li>• Retrospective cohort study</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• American Journal of Managed Care, 2005</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To compare rates of discontinuation of prescription therapy for hypertension in Medicaid patients with and without medication access restrictions.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Therapy Change:</b><ul style="list-style-type: none"><li>• After the PDL, Medicaid patients were significantly more likely to switch medications from a restricted to an unrestricted drug.</li></ul></li><li>• <b>Discontinuation:</b><ul style="list-style-type: none"><li>• Medicaid patients taking prescription medications commonly used to treat hypertension were 39% more likely to discontinue hypertension therapy after the restriction was implemented compared with Medicaid patients one year earlier when there were no restrictions.</li></ul></li></ul>



## Impact of Adherence and Therapy Changes on Utilization and Costs

# “Pharmacy Data Identify Poorly Adherent Patients with Schizophrenia at Increased Risk at Admission”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Marcia Valenstein, Laurel A. Copeland, Frederic C. Blow, John F. McCarthy, John E. Zeber, Leah Gillon, C. Raymond Bingham, and Thomas Stavenger</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• VA: Patients with <b>schizophrenia</b></li><li>• October 1, 1998 to September 30, 1999</li><li>• Cohort study linking pharmacy and utilization data for veterans with schizophrenia</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• Medical Care, 2002</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• HSR&amp;D Research Career Development Award</li><li>• Mental Health Strategic Group of the Veterans Health Administration Headquarters</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To determine whether a pharmacy-based measure of outpatient adherence, the medication possession ratio (MPR), is associated with adverse outcomes among patients with schizophrenia, as evidenced by increased psychiatric admission.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Hospital Utilization:</b><ul style="list-style-type: none"><li>• Among patients on one antipsychotic, patients with poor adherence were 2.4 times as likely to be admitted as patients with good adherence.</li><li>• 23% of poorly adherent patients, but only 10% of adherent patients, were admitted. Once admitted, poorly adherent patients had more hospital days. Patients who received excess medication also had higher admission rates.</li></ul></li><li>• <b>Psychiatric Inpatient Utilization:</b><ul style="list-style-type: none"><li>• Patients who had poor compliance had a greater total number of psychiatric inpatient days (a mean of 33 days per year) compared with patients who had good compliance (a mean of 24 days per year).</li></ul></li></ul>

# “Impact of Long-Acting Injectable Antipsychotics on Medication Adherence and Clinical, Functional, and Economic Outcomes of Schizophrenia”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Gabriel Kaplan, Julio Casoy, and Jacqueline Zummo</li></ul>
<b>Study Population</b>	<ul style="list-style-type: none"><li>• General: Patients with <b>schizophrenia</b></li></ul>
<b>Study Period</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Study Type</b>	<ul style="list-style-type: none"><li>• Literature Review</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• Patient Preference and Adherence, 2013</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• N/A</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• Review the impact of nonadherence with antipsychotic drug therapy overall, and highlight the potential benefits of having access to and using Long-Acting Injectable (LAIs) as compared with oral prescription treatments.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Hospital Utilization:</b><ul style="list-style-type: none"><li>• At 12 months after switching from oral to LAI antipsychotics, the percentage of patients who did not require hospitalization (89.1% vs 67.0%) and did not relapse (85.4% vs 47.8%) was higher with LAIs than with oral antipsychotics.</li><li>• Compared to baseline, greater reduction in hospitalizations (66.2% reduction vs 29.2%) and in the length (68% reduction vs 0%) and number (80.0 vs 14.3) of hospital stays were observed for those who completed therapy versus those who discontinued LAIs, and these differences remained at 24 months.</li></ul></li></ul>



# “Partial Compliance and Risk of Rehospitalization Among California Medicaid Patients with Schizophrenia”

<b>Authors</b>	<ul style="list-style-type: none"><li>• Peter J. Weiden, Chris Kozma, Amy Grogg, and Julie Locklear</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Medicaid: Patients prescribed treatment for <b>schizophrenia</b> in California</li><li>• 1999 to 2001</li><li>• Patient observation and regression analysis</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• Psychiatric Services, 2004</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• Janssen Pharmaceutical Products, L.P.</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To evaluate the relationship between compliance with an antipsychotic medication regimen and risk of hospitalization in a cohort of California Medicaid patients with schizophrenia.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Hospital Utilization:</b><ul style="list-style-type: none"><li>• Lower compliance was associated with a greater risk of hospitalization over and above any other risk factors for hospitalization.</li><li>• The presence of any gap in medication coverage was associated with 198% increased risk of hospitalization, including gaps as small as one to ten days. A gap of 11 to 30 days was associated with a 281% greater likelihood of hospitalization, and a gap of more than 30 days was associated with a 396% greater risk.</li><li>• Patients who were less than 70 percent compliant by the MPR had higher rates of hospitalization than those who were at least 70 percent compliant (22.3 percent and 13.8 percent, respectively).</li><li>• Patients who were identified as being less than 90 percent compliant had higher rates of hospitalization than those who were identified as being at least 90 percent persistent (25.1 percent and 14.5 percent, respectively).</li></ul></li></ul>



# “Patterns of Anti-Depressant Use and Their Relation to Costs of Care”

<b>Authors</b>	<ul style="list-style-type: none"><li>• David Thompson, Don Buesching, Karl J. Gregor, and Gerry Oster</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Commercial: Plan members beginning <b>depression</b> therapy in New England</li><li>• January 1, 1991 through June 30, 1993</li><li>• Analysis of claims data</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• American Journal of Managed Care, 1996</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• Grant from Eli Lilly &amp; Co.</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To assess how differences in patterns of antidepressant use may be associated with important differences in costs of care.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Costs:</b><ul style="list-style-type: none"><li>• Overall costs of medical care were highest for patients in the switching/augmentation group (\$7,590) and early discontinuation group (\$5,610) and lowest for those in the upward titration, partial compliance, and 3-month use groups (\$3,822, \$4,479, and \$3,393, respectively).</li><li>• The study concluded that differences in patterns of antidepressant use are associated with significant differences in the cost of medical care. These costs are highest among patients whose therapy is switched or augmented, or who discontinue therapy early.</li></ul></li></ul>

# “The Impact of Medicare Part D on Hospitalization Rates”

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<b>Authors</b>	<ul style="list-style-type: none"><li>• Christopher C. Afendulis, Yulei He, Alan M. Zaslavsky, Michael E. Chernew</li></ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"><li>• Medicare: Part D Beneficiaries</li><li>• 2005-2007</li><li>• Differences-in-Differences before and after Part D was implemented</li></ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"><li>• Health Services Research, 2011</li></ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"><li>• Pharmaceutical Research and Manufacturers of America and the Marshall J. Seidman Program in Health Economics in the Department of Health Care Policy at Harvard Medical School</li></ul>
<b>Objective</b>	<ul style="list-style-type: none"><li>• To determine whether the change in prescription drug insurance coverage associated with Medicare Part D reduced hospitalization rates for conditions sensitive to drug adherence.</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• <b>Hospital Utilization:</b> The increase in drug coverage associated with Medicare Part D had positive effects on the health of elderly Americans, which reduced use of nondrug health care resources.</li></ul>





# “Effects of a Limit on Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia”

<b>Authors</b>	<ul style="list-style-type: none"> <li>• Stephen B. Soumerai, Thomas J. McLaughlin, Dennis Ross-Degnan, Christina S. Casteris, and Paola Bollini</li> </ul>
<b>Study Population</b> <b>Study Period</b> <b>Study Type</b>	<ul style="list-style-type: none"> <li>• Medicaid: Patients with schizophrenia in New Hampshire and New Jersey</li> <li>• July 1980 to December 1983</li> <li>• Interrupted time-series design</li> </ul>
<b>Journal, Year</b>	<ul style="list-style-type: none"> <li>• New England Journal of Medicine, 1994</li> </ul>
<b>Funder(s)</b>	<ul style="list-style-type: none"> <li>• Grant from the National Institute of Mental Health</li> <li>• Agency for Health Care Policy and Research</li> <li>• Robert Wood Johnson Foundation</li> <li>• Harvard Community Health Plan Foundation</li> </ul>
<b>Objective</b>	<ul style="list-style-type: none"> <li>• To determine whether the limit on drug reimbursement was followed by reductions in the use of antipsychotic agents, drugs for mood disorders, and anxiolytic and hypnotic agents and by an increase in the use of mental health services among low-income adults with schizophrenia.</li> </ul>
<b>Results</b>	<ul style="list-style-type: none"> <li>• <b>Adherence:</b> The cap resulted in immediate reductions (range, 15 to 49 percent) in the use of antipsychotic drugs, antidepressants and lithium, and anxiolytic and hypnotic drugs.</li> <li>• <b>Utilization:</b> It also resulted in coincident increases of one to two visits per patient per month in visits to CMHCs (range of increase, 43 to 57 percent) and sharp increases in the use of emergency mental health services and partial hospitalization (1.2 to 1.4 episodes per patient per month), but no change in the frequency of hospital admissions.</li> <li>• <b>Costs:</b> The estimated average increase in mental health care costs per patient during the cap (\$1,530) exceeded the savings in drug costs to Medicaid by a factor of 17.</li> </ul>



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that hearing, I believe committee members had a solid grasp of the legitimate problems that still remain after the numerous legislative reforms of COLI over the last 20 years.

Mr. GRASSLEY. I agree. The hearing was informative and prepared the committee to come to an agreement on the reforms that ought to take place.

Mr. CONRAD. Since the hearing, the chairman and I have worked toward the development of a COLI proposal that would garner the support of the broadest possible consensus in the committee and in the full Senate. I believe that last week we were close to an agreement on a proposal that responded to every legitimate criticism of COLI heard during the course of the October 23 hearing.

I regret that the crush of Finance Committee legislation on the Senate floor in October and November has so far prevented the chairman from scheduling a markup. Unfortunately, it is now clear that the markup agreed to on October 1 cannot be before the end of this session of Congress.

Mr. GRASSLEY. I share this regret. Let me pledge to have this markup on a COLI provision at the Finance Committee's first opportunity in 2004. I look forward to completing the action we began in October.

#### CANCER CARE REIMBURSEMENT

Mrs. FEINSTEIN. Mr. President, the Medicare conference report, which includes a reform of the Part B drug payment system, includes significant payment reductions to providers of cancer care. I understand that Senator GRASSLEY does not intend for these payment reductions to force efficient cancer clinics to close, jeopardizing access to care for thousands of cancer patients.

Mr. GRASSLEY. That is correct, Senator. The Medicare conference agreement contains a number of significant reforms, which will save billions of dollars in overpayments from Medicare covered drugs, while also substantially increasing payments to physicians. I intend to preserve continued access to high-quality cancer care.

Mrs. FEINSTEIN. Many physicians depend on overpayments on Part B drugs to make up for inadequate practice expenses. Is it the intent of the Senator from Montana that physicians' practice expenses will be increased sufficient to ensure access to care?

Mr. BAUCUS. Yes, that is my intent. And I am committed to monitoring this new payment system as it is implemented, in order to ensure access to high-quality cancer care.

Mrs. FEINSTEIN. Is it the intent that if this new payment system does not suffice to ensure access to care, that you will revisit the system and revise the payment methodology?

Mr. BAUCUS. That is correct.

Mrs. FEINSTEIN. Finally, it is my understanding that practice expense increases for oncology are expected to be about \$500 million in 2004, \$600 million in 2005, and \$560 million in 2006, as shown in the summary which I will

submit for the RECORD. Is it your understanding that the payment expense increases will allow efficient cancer care providers to continue serving cancer patients and not close their doors?

Mr. GRASSLEY. Yes. I would also note that the Senator from Kansas, Mr. BROWNBACK, has some concerns over this issue. He has been a forceful advocate for the oncology community. And while I think the package for cancer care is a fair one, I understand that he has some concerns.

Mr. BROWNBACK. I thank the chairman, both for his commitment to this legislation and for keeping my staff and me informed throughout the drafting of these provisions. I would note that from the time he first spoke on this issue during consideration of the tax bill the chairman has expressed his intent to, "ensure that seniors and their caregivers have adequate payment for, and continued access to, important cancer therapies." I would ask of the chairman, is it his intent that the changes to outpatient drug reimbursement in Sections 303 and 304 of this bill will not have a significantly adverse impact on access to cancer treatment?

Mr. GRASSLEY. The Senator from Kansas is correct. My commitment to cancer patients has not changed. Indeed, according to estimates from the Congressional Budget Office, this bill is expected to actually increase net payments to oncologists in 2004. Also, CBO estimates that the new Average Sales Price Reimbursement model, when coupled with the changes in practice expense reimbursement, will amount to net reductions to cancer care of \$4.2 billion over the next 10 years.

Mr. BROWNBACK. I would like to thank my friends for the progress that was made in the conference. The bill passed by the Senate several months ago contained a net cut of \$16 billion as a result of Part B drug payment reforms. The reduction in the Conference report before us is now \$11.4 billion.

However, I would also note to my friend from Iowa that the Secretary of Health and Human Services is given the discretion to reduce reimbursements further based on studies preformed by the Inspector General of the Department. I would ask my friend if it was the intent of the conferees that any future adjustments to the reimbursements be based on average of prices available to and paid by a wide range of physicians in the marketplace.

Mr. GRASSLEY. The Senator is correct.

Mr. BROWNBACK. I thank my friends.

Mrs. FEINSTEIN. I ask unanimous consent to print the following in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

#### MEDICARE CONFERENCE REPORT CANCER CARE CHANGES

Payments for Part B drugs are currently based on Average Wholesale Price (AWP).

The difference between the AWP and the actual sales price often results in a profit to providers when they administer such drugs. For example, an oncologist may buy a chemotherapy agent, called doxorubicin, for about \$10.00, while Medicare's reimbursement for that same dose was approximately \$42.00, resulting in a profit to the physician of \$32.00. Because beneficiaries must pay 20% co-payments on Medicare covered drugs, beneficiaries are paying \$8.40 for a dose of doxorubicin. That is 20% of the \$42.00, rather than 20% of the \$10.00 that the oncologist paid for the drug, which is \$2.00. The HHS Inspector General estimated that inflated AWP's caused beneficiaries to pay an extra \$175 million in coinsurance in 2001.

The Medicare conference agreement reforms the Part B drug payment system, saving \$4.2 billion from the oncology specialty over the 10-year period 2004-2013. This reform is effected mostly by using an Average Sales Price (ASP) system, which accounts for the true costs of these drugs. An additional \$7.3 billion is saved by applying these reforms to other physician specialties. Most of these savings occur in the later years of the budget window. Under the Medicare conference agreement, oncologists will receive an approximate \$100 million increase in payments in 2004, net of reductions in reimbursement for Part B drugs.

Following is an estimated overview of what oncologists will receive in increased practice expense payments, starting in 2004.

2004: Approximately \$500 million increase in practice expense (increase to oncology in 2004, net of drug payment reductions, is about \$100m).

2005: ASP+6%; approximately \$600 million increase (\$200m for Average Sales Price+6%, \$400m increase in practice expense).

2006 and thereafter: ASP+6%; approximate \$560 million increase (\$200m for Average Sales Price+6%, \$360m increase in practice expense).

#### FORMULARIES FOR MEDICARE BENEFICIARIES LIVING WITH HIV/AIDS

Mrs. FEINSTEIN. Mr. President, I am concerned about the impact the Medicare conference report will have on low-income Medicare beneficiaries who are living with HIV/AIDS. I have heard a lot of opposition to this bill from the HIV/AIDS community. My concern is with their access to drug treatment therapy under the Medicare prescription drug benefit. Is it your understanding that the Medicare conference report will not prevent low-income Medicare beneficiaries who are living with HIV/AIDS from getting all the drugs they need through Medicare Part D?

Mr. BAUCUS. That is correct, Senator. One of the things I am particularly proud about in this bill is the strong beneficiary protections that will ensure that all Medicare beneficiaries get access to the appropriate medicine they need. You know, Senator GRASSLEY, that there are certain diseases and conditions—like AIDS, and epilepsy—where having access to just the right medicine is especially important.

Mr. GRASSLEY. I did know that, and I know that certain mental illnesses also fall in that category. This bill contains a number of protections for people who need exactly the right medicine for them.

Mrs. FEINSTEIN. Victims of HIV/AIDS are somewhat unique since the

treatment for HIV/AIDS varies with the individual. To be clear, no low-income Medicare beneficiaries who have HIV/AIDS will be denied access to the drugs they need in Medicare Part D?

Mr. BAUCUS. Exactly. The bill asks the US Pharmacopeia to develop model formularies with therapeutic classes that can't be gamed. Then we require drug plans to offer at least two drugs in each therapeutic class. And for drugs that treat AIDS, epilepsy, or mental illness, we would expect that plans would carry all clinically appropriate drugs.

Mr. GRASSLEY. I agree. And I am pleased with the backup protections in this bill. That if a plan doesn't carry or doesn't treat as preferred a drug needed by, say, a person with AIDS, a simple note from a doctor explaining the medical need for that particular drug could get that drug covered.

Mrs. FEINSTEIN. Will that apply to all covered drugs required by a person with HIV/AIDS and in all cases?

Mr. BAUCUS. That is correct. These beneficiary protections are crucial for these vulnerable Medicare beneficiaries. I would expect that the Secretary will take into account their special medication needs when he writes regulations on this provision and when he is evaluating plan bids. If a plan can't adequately ensure all of the proper medication for beneficiaries living with HIV/AIDS, epilepsy, and certain mental illnesses, that plan should not be doing business with Medicare.

Mr. GRASSLEY. I agree with my good friend.

Mrs. FEINSTEIN. I would like to quote from a letter I received from Secretary of Health and Human Services Tommy Thompson, the full text of which I will include for the RECORD. Secretary Thompson says, "I would not approve a plan for participation in the Part D program if I found that the design of the plan and its benefits, including any formulary and any tiered formulary structure, would substantially discourage enrollment in the plan by any group of individuals. If a plan, however, complies with the USP guidelines then it would be considered to be in compliance with this requirement. Thus, if a plan limited drugs for a group of patients (individuals living with HIV/AIDS) it would not be permitted to participate in Part D." Secretary Thompson goes on to say, "Under the Conference Report, the beneficiary protections in the Medicare drug benefit are more comprehensive than the protections now required of State Medicaid programs. This will ensure access to a wide range of drugs. For example, there are extensive information requirements so that beneficiaries will know the drugs the plan covers before they enroll in the plan. Beneficiaries can also appeal to obtain coverage for a drug that is not on their plan's formulary if the prescribing physician determines that the formulary drug is not as effective for the individual as another drug, or if there are

adverse effects. As a result, access to all drugs in a category or class will be available to a beneficiary when needed."

Is this your understanding as well?

Mr. BAUCUS. Absolutely.

Mr. GRASSLEY. I agree.

Mrs. FEINSTEIN. I thank the distinguished Senators from Montana and Iowa.

I ask unanimous consent to print the above-referenced letter in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION, Washington, DC.

HON. DIANNE FEINSTEIN, U.S. Senate, Washington, DC.

DEAR SENATOR FEINSTEIN: Recently, you have expressed concern with the Conference Report over access to drugs for individuals living with HIV/AIDS. Your major concern appears to be whether or not individuals living with HIV/AIDS will have access to all drugs within a therapeutic class under the Conference Report and whether or not a Prescription Drug Plan (PDP) could limit the number of drugs that are covered within a therapeutic class. You also expressed concern that dual eligible individuals will lose the coverage that is currently available to them in Medicaid if they enroll in any of the new Medicare drug plans.

Let me assure you that in the Conference Report there are significant safeguards in place for the development of PDP formularies to ensure a wide range of drugs will be available to Medicare beneficiaries. These plans will have the option to use formularies but they are not required to do so. If a plan uses a formulary, it must include at least two drugs in each therapeutic category or class, unless the category or class only has one drug.

I will be requesting the U.S. Pharmacopeia (USP), a nationally recognized clinically based independent organization, to develop, in consultation with other interested parties, a model guideline of therapeutic categories and classes. In designing this model it is essential that categories and classes be established to assure that the most appropriate drugs are included on a plan's formulary. I am confident they will design the categories and classes to meet the needs of patients; USP's work in clinically based and patient oriented.

Plans will also use pharmacy and therapeutic committees that consist of practicing physicians and pharmacists to design their formularies. The committees will be independent and free of conflict with respect to the plan. They will have expertise in care for the elderly and in individuals with disabilities. The committees will also use both a clinical and scientific basis for making its decisions relating to formularies.

Further, I would not approve a plan for participation in the Part D program if I found that the design of the plan and its benefits, including any formulary and any tiered formulary structure, would substantially discourage enrollment in the plan by any group of individuals. If a plan, however, complies with the USP guidelines then it would be considered to be in compliance with this requirement. Thus, if a plan limited drugs for a group of patients (individuals living with HIV/AIDS) it would not be permitted to participate in Part D.

Under the Conference Report, the beneficiary protections in the Medicare drug ben-

efit are more comprehensive than the protections now required of State Medicaid programs. This will ensure access to a wide range of drugs. For example, there are extensive information requirements so that beneficiaries will know the drugs the plan covers before they enroll in the plan. Beneficiaries can also appeal to obtain coverage for a drug that is not on their plan's formulary if the prescribing physician determines that the formulary drug is not as effective for the individual as another drug, or if there are adverse effects. As a result, access to all drugs in a category or class will be available to a beneficiary when needed.

On the other hand, because of the optional nature of the Medicaid drug benefit today, States can drop their drug benefit entirely, as well as restrict access to their drug plan through preferred drug lists or prior authorization processes. According to the IG, from 1997 to 2001, Medicaid expenditures for prescription drugs grew at more than twice the rate of total Medicaid spending. This has put extreme pressures on state budgets and has led to Medicaid coverage restrictions for drugs and the use of cost control measures that will not be used in the Part D program.

For example, eighteen States contain Medicaid drug costs by limiting the number of prescriptions filled in a specific time period, limiting the maximum daily dosage or limiting the frequency of dispensing a drug. Some states also limit the number of refills. In addition, six States have pharmacy lock-in programs, which require beneficiaries to fill their prescriptions in one designated pharmacy.

The new Medicaid benefit will not result in a loss of coverage for dual eligibles. In fact, the Conference Report provides generous coverage to dual eligibles. The Report preserves the universality of Medicare for all eligible beneficiaries including those dually eligible for both Medicare and Medicaid. Unlike Medicaid, the new Medicare Part D benefit will provide a guaranteed benefit to all eligible seniors—a benefit they can count on without fear of loss of benefits when State budgets become tight.

Dual eligibles, who currently have full Medicaid benefits, will automatically be given generous subsidies and will pay no premium, no deductible and only minimal cost-sharing regardless of their actual income, even though it can be higher than 135 percent of the Federal poverty level in many cases.

In addition, full dual eligibles with incomes under 100 percent of poverty will pay no premiums, no deductibles, and reduced copayments of \$1 for generic and other multiple source preferred drugs, and \$3 for all other drugs. Note under current Medicaid regulations, States can choose to increase coinsurance to 5%. This is clearly more than what will be permitted for dual eligibles under the new Medicare benefit.

Finally, dual eligibles residing in nursing homes and other institutions only have a small personal needs allowance. Under Medicare, they will be exempt from copayments altogether.

I hope that this addresses all of your concerns. I look forward to continuing to work with you on this and other issues related to Medicare and Medicaid. Please call me if you have any further concerns.

Sincerely,

TOMMY G. THOMPSON.

Ms. LANDRIEU. Mr. President. I have been listening to the debate over the past few days, and I think that a common theme on both sides of the aisle has been this is not a perfect bill. There are those on this side of the aisle who rightly say that this bill does not go as far as it could; that it doesn't

July 26, 2007

[[[Page S10156](#)]]

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By Mr. Smith (for himself and Mr. Kerry):

[S. 1887](#). A bill to amend title XVIII of the Social Security Act in order to ensure access to critical medications under the Medicare Part D prescription drug program; to the Committee on Finance.

Mr. Smith. Mr. President, today I am introducing the Access to Critical Medications Act ACMA, a bill that will vastly improve the coverage millions of vulnerable Medicare beneficiaries receive through the Medicare prescription drug program, known as Part D. The new drug benefit has been a tremendous success, providing access to affordable prescription drug therapies to millions of beneficiaries, some for the very first time. But many of our most vulnerable seniors, especially those suffering from serious health conditions like mental illness, HIV/AIDS or cancer, often have difficulty obtaining the vital drug therapies they need to remain functional, or in some cases, to survive. To remedy these problems, the bill I am introducing today will give the Centers for Medicare and Medicaid Services, CMS, the regulatory tools it needs to ensure that all prescription drug plans, PDP, provide unfettered access to medically essential drug therapies.

My connection to this issue began long before Medicare's new prescription drug benefit went into effect. As chairman of the Aging Committee, I held a hearing in the spring of 2005 to explore how well CMS was preparing to transition dual-eligible beneficiaries, those who qualify for both Medicare and Medicaid, into Medicare Part D. At that hearing, advocates expressed a number of concerns with the implementation of the new drug benefit, and chief among them was guaranteeing that vulnerable beneficiaries had access to important drug therapies that either stabilized or improved their health condition. I made a personal request to then CMS Administrator Dr. Mark McClellan to work with prescription drug plans to ensure that their formularies provide access to all available drugs in certain pharmaceutical classes, including those that contain innovative treatments for mental illness, epilepsy, cancer and HIV/AIDS. The result of that conversation was the creation of the "all or substantially all" policy for six protected drug classes. CMS initially included this new policy as part of the sub-regulatory formulary guidance it issued to plans in 2005 and again in 2006.

While I was pleased with CMS providing this additional protection for the vital drug therapies in the six protected classes, its actual impact on beneficiaries gaining access to the medications they need has been uneven at best. For one, the policy was issued as sub-regulatory guidance, which limits CMS' ability to enforce it. While it is true that the annual contracts CMS develops with prescription drug plans generally include a requirement that they abide by the "all or substantially all" guidance, the agency's record of enforcing the policy has been quite poor. Instead of plans covering all drugs in the six protected classes, as CMS claims plan contracts require, beneficiaries, often the most frail and vulnerable, have had extensive access problems because their PDPs do not include their medication on its formulary. In fact, data from a study being conducted by the American Psychiatric Institute for Research and Education, APIRE, released earlier this year, showed that roughly 68 percent of surveyed

beneficiaries, many of them dual eligibles, experienced some sort of problem accessing the prescription drug they needed because their PDP's formulary did not cover it. This would suggest that CMS' current approach to enforcing the ``all or substantially all'' policy is woefully lacking.

I should note that beneficiaries often are able to access a drug that should be covered on their plan's formulary by filing a coverage appeal. However, that process is usually long and difficult to complete, and results in the problem only being solved for one beneficiary. I appreciate the responsiveness of drug plans to specific beneficiaries' difficulties with accessing the drugs they need, but if they are not addressing the concerns raised through the appeals process on a broader scale, problems will only continue to occur. I believe we need a system-wide approach to ensuring that beneficiaries have access to the life-saving and life-improving medications they need and I believe that solution lies within the legislation I am filing today.

The Access to Critical Medications Act ACMA would codify, for a 5-year period, the current policies in CMS existing ``all or substantially all'' sub-regulatory guidance. I am hopeful that providing this statutory authority will signal to plans that it is no longer an option to cover all available drugs in the six protected classes. It is a legal requirement that must be adhered to in order to participate in Medicare Part D. Accordingly, I would expect that this change will empower CMS to take a more proactive role in ensuring that prescription drug plan sponsors are not placing arbitrary barriers to accessing these critical medications covered by the ``all or substantially all'' policy.

During the 5 year period that the ``all or substantially all'' policy will be effective, the ACMA directs CMS to establish a process through regulation, that would allow for this important policy to be updated and enforced in future years. None of us hold the knowledge of the pharmaceutical and medical developments of tomorrow. In a decade, there could be major breakthroughs in treating any number of debilitating illnesses, which may require the creation of or modification of pharmaceutical classes covered by this important policy. CMS needs to have the authority to update the classes and categories it covers and the process the ACMA creates will provide them the tools to do that.

In order to use those tools, the ACMA defines specific, clinically-based criteria that the Secretary must follow when evaluating whether a drug class should be added or removed from coverage under the policy. This will ensure that there is consistency in the manner by which the policy is evaluated in future years, so that the Secretary is not arbitrarily determining which medications are important enough so that all plans must provide access to them. The ACMA also makes modest changes to the appeals process, to ensure that plans and CMS resolve beneficiary complaints in a timely manner, and that access to medications is guaranteed while the appeals process runs its course.

The existing ``all or substantially all'' policy was a step in the right direction at the time it was created. However, as we approach the third year of Medicare's prescription drug benefit, beneficiaries' actual experience in the program provides overwhelming support that we need a more robust approach to helping vulnerable beneficiaries get the medications they need.

[[[Page S10157](#)]]

As importantly, CMS must have a regulatory process in place that will



enable it to modify the classes covered by the policy in response to changes in medical and pharmaceutical science. I believe the ACMA clearly addresses both those needs, and I hope my colleagues will agree. It is a well thought out policy that strikes a careful balance between flexibility and enforceability. Advocacy groups such as the American Psychiatric Association, the National Alliance for Mental Illness, Mental Health America, the AIDS Institute, the HIV Medicine Association and the Epilepsy Foundation all contributed to the development of ACMA and all now support the finished product. The Senate likely will consider Medicare legislation this fall, and I have already mentioned to Chairman Baucus that I would like to see this bill advance as part of that effort.

I ask unanimous consent that the text of the bill and letters of support be printed in the Record.

There being no objection, the material was ordered to be printed in the Record, as follows:

MAX BAUCUS, MONTANA, CHAIRMAN

JOHN D. ROCKEFELLER IV, WEST VIRGINIA  
RON WYDEN, OREGON  
CHARLES E. SCHUMER, NEW YORK  
DEBBIE STABENOW, MICHIGAN  
MARIA CANTWELL, WASHINGTON  
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MICHAEL B. ENZI, WYOMING  
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ROB PORTMAN, OHIO  
PATRICK J. TOOMEY, PENNSYLVANIA

# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

AMBER COTTLE, STAFF DIRECTOR  
CHRIS CAMPBELL, REPUBLICAN STAFF DIRECTOR

February 5, 2014

## Via Electronic Transmission

The Honorable Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Tavenner:

The United States Senate Committee on Finance (Committee) has exclusive jurisdiction over the Medicare program in the Senate. As members of this Committee, we have a responsibility to ensure that its beneficiaries have access to high quality health care. We are writing to express our concern over the recent proposal to reduce the number of “protected classes” under the Medicare prescription drug benefit known as Part D, and strongly urge the Centers for Medicare & Medicaid Services (CMS) to continue this important beneficiary protection as it exists today.

Since the creation of Medicare Part D, Congress and the Administration have recognized that for certain types of conditions and therapies beneficiaries should have access to all available medication. However, in an attempt to reduce Medicare costs, CMS is proposing to limit these protections. While we applaud any effort to reduce unnecessary spending, we strongly believe this proposal will diminish access to needed medication, and we remain unconvinced significant cost savings will be achieved.

We are very concerned this change will lead to decreased access to medication, especially for those beneficiaries afflicted by mental health problems. These vulnerable individuals rely on multiple medications to control and treat their illnesses. Unfortunately, over the course of treatment, certain medications may cause undesired side effects or become ineffective. As a result, certain beneficiaries must have a wide range of treatment options available. By limiting the number and type of medications offered under a Part D plan, a beneficiary may be forced to rely, if only temporarily, on medication that simply does not work or results in adverse side effects.

We are unconvinced this change will lead to significant cost savings. CMS presents little data to support its claim and relies in part on a Department of Health and Human Services Office of Inspector General (OIG) report that describes interviews with unnamed Part D plans. However, the OIG report concedes the information gathered by these limited interviews, “is not

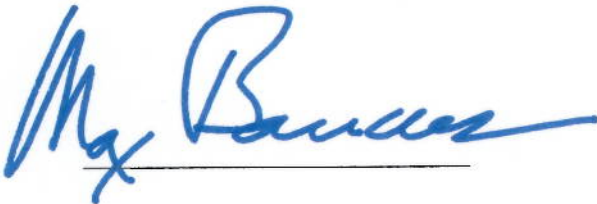
generalizable to all [Part D plans]" and the report as a whole "presents general information and does not include specifics about the rebate amounts and rebate agreements." We feel that a stronger case must be presented to the public before making such a dramatic change to Part D.

Further, we remain concerned that if beneficiaries do not have access to needed medication, costs will be incurred as a result of unnecessary and avoidable hospitalizations, physician visits, and other medical interventions that are otherwise preventable with proper adherence to medication. In fact, the Congressional Budget Office recently affirmed policies that increase access to prescription drugs actually decrease spending on medical services, such as hospitals and physicians. We are concerned that the attempt to find cost savings in Part D could result in cost increases for the Medicare program at large.

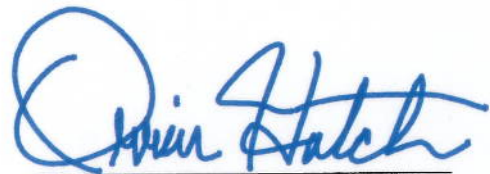
Finally, if this limitation were to be finalized, many beneficiaries would be forced to rely on the Part D appeals process to receive coverage of a drug not provided on a Part D plan's formulary. Unfortunately, this appeals process is inadequate and confusing to beneficiaries. The Medicare Payment Advisory Commission (MedPAC) recently conducted focus groups and interviews with beneficiaries, physicians and beneficiary counselors. MedPAC found "most interviewees were unaware of how the exceptions and appeals process works" and "a majority [of beneficiaries] did not know they had appeal rights." MedPAC also found that physicians "pointed to at least one [Part D] plan with processes that were especially burdensome." We recommend improving the Part D appeals process before any change to drug coverage. For instance, we encourage CMS to explore ways to allow the beneficiary to initiate the appeals process at the pharmacy counter when he/she is first notified the drug is not covered by the Part D plan.

Part D has been successful in providing affordable drug coverage to Medicare beneficiaries. We know you share our goal of continuing this success. Unfortunately, we are concerned that limiting the number of protected classes under Part D jeopardizes the fulfillment of this goal. We ask that you retain the six protected classes as they exist today. We look forward to working with you on this important issue.

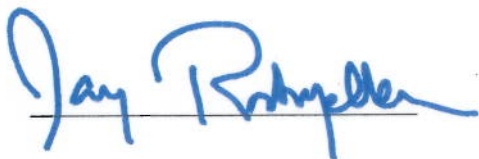
Sincerely,



Max Baucus



Orrin Hatch



Jay Byrnes



Chuck Grassley

Nicky

Chuck Sch

Rebekah Starnow

Maria Cantwell

Bill Nelson

Robert Menendez

Tom Lapsen

Ben Cardin

Shirley Brown

Max F. Baucus

Bob Casey, Jr.

Mike Cryer

Pat Roberts

Michael B. Enzi

John Cornyn

John Sh

Bob

Johnny

Rob Portman

Pat Romney

**Congress of the United States**  
**Washington, DC 20515**

March 4, 2014

The Honorable Kathleen Sebelius  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Ms. Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Secretary Sebelius and Administrator Tavenner,

Congress created the Medicare Part D program in 2003 with an emphasis on creating a prescription drug benefit that would provide access to prescription medications for all Medicare beneficiaries. Congress deliberated over this policy for many years before finally enacting the Medicare Modernization Act. While Part D was not originally supported by all Members of Congress, it has in time demonstrated the ability to provide access to important life-saving and life-enhancing medications for the vast majority of America's seniors and non-elderly people with severe disabilities.

A critically important component of what has made Part D successful over the past eight years is the six protected classes policy. Created by CMS in 2005 through subregulatory guidance, and later codified by Congress in 2008, the six protected classes policy has enjoyed strong bipartisan, bicameral support. The six classes of medications were deemed by Congress to be the correct classes for inclusion in 2008 and that position was reaffirmed in 2010.

For this reason, we are extremely troubled by the proposed rule CMS issued regarding Medicare parts C & D on January 6, which removed the protections for anti-depressants, immunosuppressants used for organ rejection and anti-psychotics. We believe this proposed policy will place harmful limits on Medicare beneficiaries' access to necessary medications that would otherwise be covered by protected status.

We also believe these policy changes will inextricably tie the hands of physicians who treat these individuals, many of whom have complex medical needs. For instance, limiting the type of immunosuppressants a physician can prescribe places a transplant patient at risk for organ rejection or other health complications. Similarly, hindering access to anti-depressants, and eventually anti-psychotics, may put someone with mental illness at greater risk for suicide and destabilization of their condition. These restrictions on appropriate access also impact persons with other challenging health conditions like cancer, HIV or epilepsy that have higher rates of depression as a comorbidity.

Furthermore, the proposed rule relies upon what is widely known to be ineffective exceptions, appeals, and grievance processes to ensure sick individuals enjoy timely access to necessary medications. Removal of protected status for the anti-psychotic, anti-depressant and

immunosuppressant classes and allowing coverage of as few as two medications in these classes is certain to overwhelm an already overburdened process under Part D.

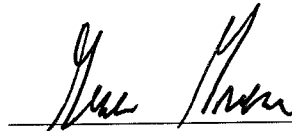
Finally, given the broad public support for increasing patient access to care, especially in the area of mental health, and recognizing further the significant challenges your Department faces in its efforts to implement healthcare reform, we are perplexed by your decision to move forward with such a proposal. Given the overwhelming evidence that all six classes of the current six protected classes policy are appropriate and necessary to ensure clinically necessary access to needed medications, we urge you to maintain this important policy and not finalize this proposed rule.

Thank you for your prompt attention to this critical matter. We look forward to your response.

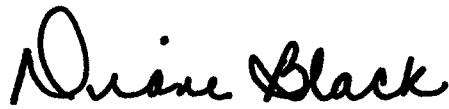
Sincerely,



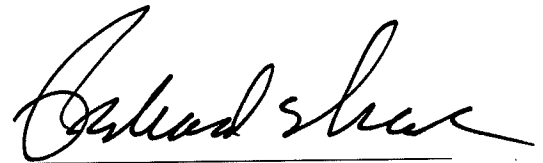
Leonard Lance  
Member of Congress



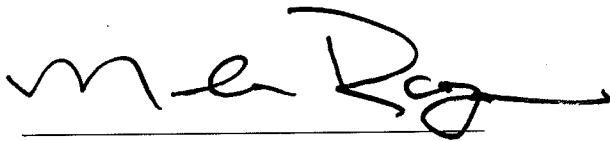
Gene Green  
Member of Congress



Diane Black  
Member of Congress



Richard Neal  
Member of Congress



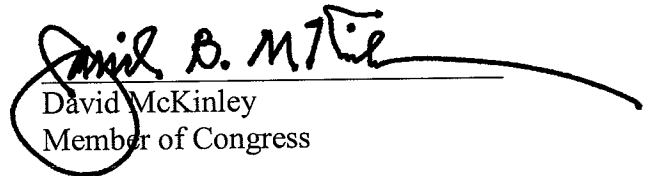
Mike Rogers  
Member of Congress



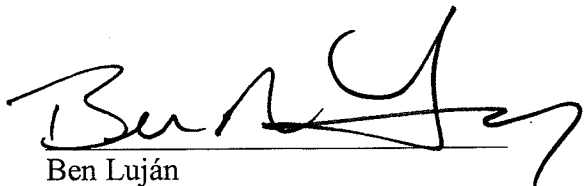
Pat Tiberi  
Member of Congress



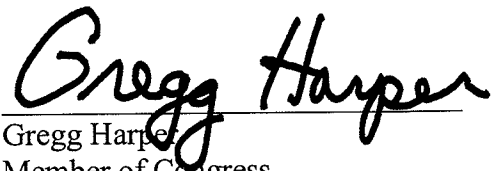
Earl Blumenauer  
Member of Congress



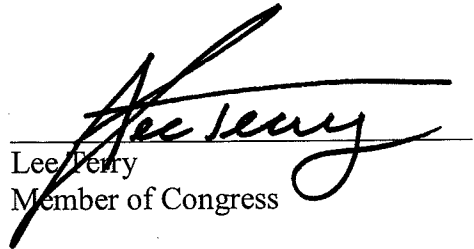
David McKinley  
Member of Congress



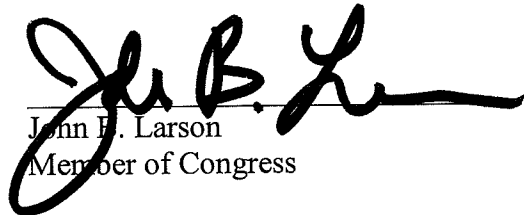
Ben Luján  
Member of Congress



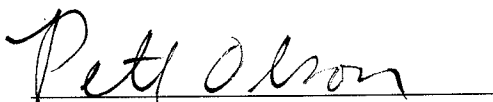
Gregg Harper  
Member of Congress



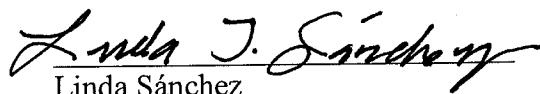
Lee Terry  
Member of Congress



John F. Larson  
Member of Congress



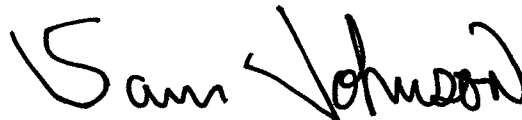
Pete Olson  
Member of Congress



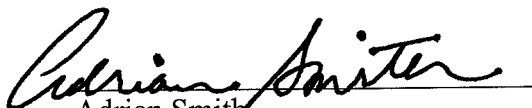
Linda Sánchez  
Member of Congress



Mike Pompeo  
Member of Congress



Sam Johnson  
Member of Congress



Adrian Smith  
Member of Congress



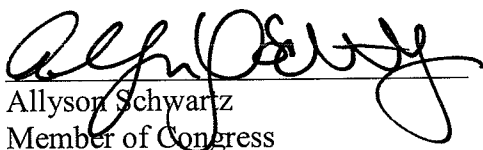
Bill Pascrell, Jr.  
Member of Congress



Erik Paulsen  
Member of Congress



Brett Guthrie  
Member of Congress



Allyson Schwartz  
Member of Congress



Tim Griffin  
Member of Congress



Billy Long  
Member of Congress



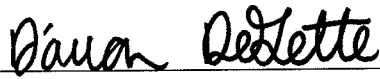
Devin Nunes  
Member of Congress



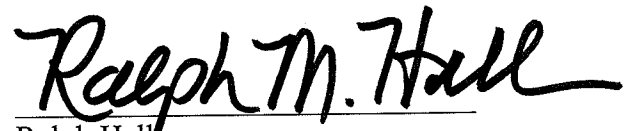
Paul Tonko  
Member of Congress



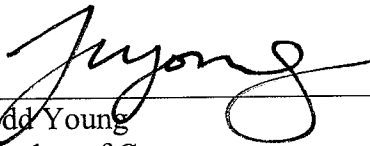
Jim Matheson  
Member of Congress



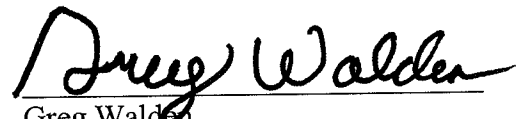
Diana DeGette  
Member of Congress



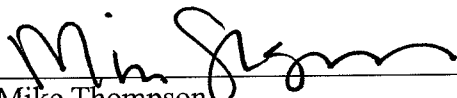
Ralph Hall  
Member of Congress



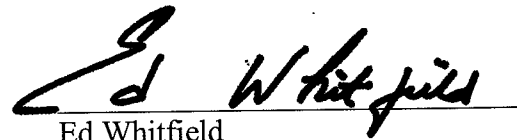
Todd Young  
Member of Congress



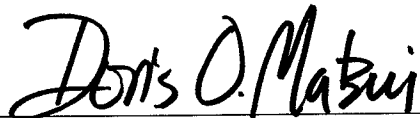
Greg Walden  
Member of Congress



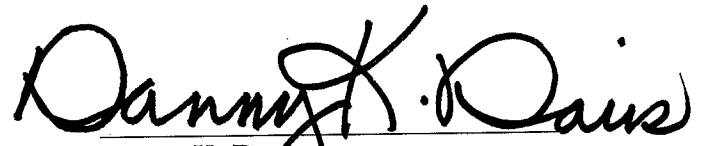
Mike Thompson  
Member of Congress



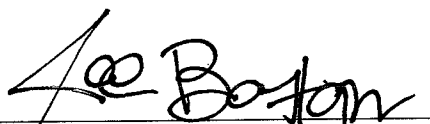
Ed Whitfield  
Member of Congress



Doris Matsui  
Member of Congress



Danny K. Davis  
Member of Congress



Joe Barton  
Member of Congress



Adam Kinzinger  
Member of Congress





Kenny Marchant  
Member of Congress



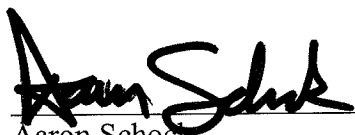
Gus Bilirakis  
Member of Congress



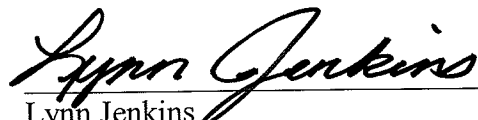
Bill Cassidy  
Member of Congress



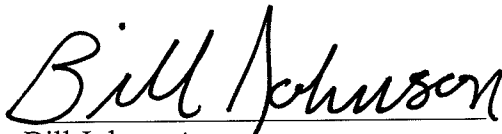
Lois Capps  
Member of Congress



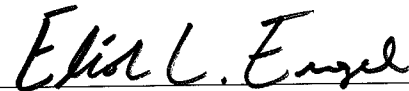
Aaron Schock  
Member of Congress



Lynn Jenkins  
Member of Congress



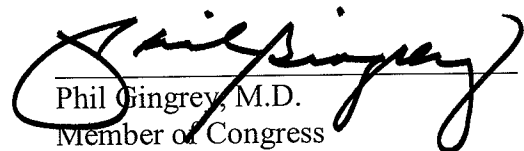
Bill Johnson  
Member of Congress



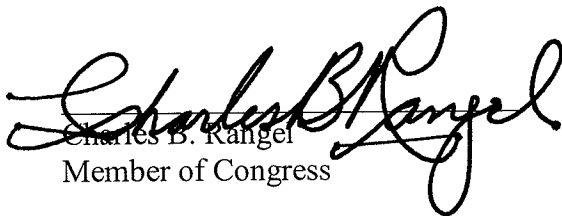
Eliot L. Engel  
Member of Congress



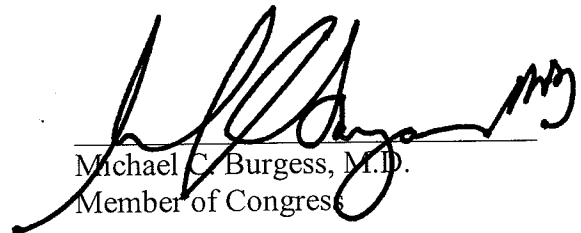
Renee Ellmers  
Member of Congress



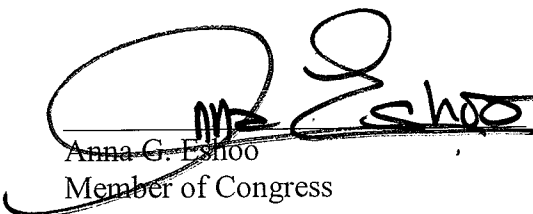
Phil Gingrey, M.D.  
Member of Congress



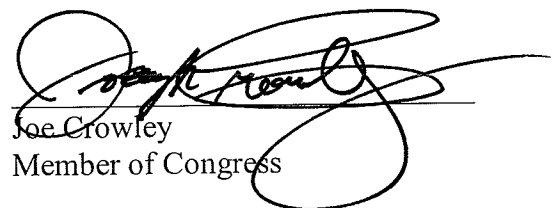
Charles B. Rangel  
Member of Congress



Michael C. Burgess, M.D.  
Member of Congress



Anna G. Eshoo  
Member of Congress



Joe Crowley  
Member of Congress