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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

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February 16, 2016

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Burwell and Acting Administrator Slavitt:

Over the past several years, we have worked to bring increased attention to the improper prescribing of mind-altering medications, known as psychotropic drugs, to children. While these medications are important for treating many disorders, they have serious side effects, and many times these medications are prescribed without sufficient knowledge about their safety and efficacy for treating children. This issue is not only of deep concern for the safety and wellbeing of these vulnerable patients but also raises questions about how these drugs are prescribed and used within private health care systems and federal health care programs such as Medicaid. It also raises questions about the capacity of our country's mental health care system to appropriately diagnose and treat young children with behavioral health conditions.

In 2011, the Government Accountability Office released the results of an investigation that found children in our nation's foster care system are prescribed psychotropic drugs at more than twice the rates of non-foster care children. The investigation also found that children were prescribed psychotropic drug combinations that medical experts have found no evidence to support and dosages that exceeded levels recommended by the Food and Drug Administration. Last year, news reports indicated infants and very young children across the country are increasingly receiving prescriptions for psychotropic drugs for treatment of behavioral disorders, despite the lack of scientific evidence to support this type of treatment for these very young populations.

In response to these findings and reports, the U.S. Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services (CMS), have taken several steps to improve cooperation between federal and state agencies and strengthen oversight and management of psychotropic

medications for children enrolled in Medicaid. In 2012, HHS organized a two-day summit that brought together child welfare, mental health, and Medicaid leaders from across the country to address the issue. CMS encouraged states to use Drug Utilization Reviews to provide states with additional tools to promote the appropriate use of psychotropic medications for children in foster care. In 2013, Medicaid issued guidance in a letter to state Medicaid Directors concerning the safe and effective use of psychotropic medications among children and encouraged states to monitor the use of these drugs. President Obama has also recommended that states implement stronger safeguards to ensure psychotropic drugs are used appropriately.

While we are encouraged by these steps, we want to ensure this work is effective. In 2015, the HHS Inspector General released a study examining a sample of Medicaid claims to determine the extent to which second-generation antipsychotics—a type of psychotropic medication used to treat psychiatric disorders such as schizophrenia and bipolar disorder—prescribed to children presented quality of care concerns.^[1] The study found quality of care concerns in 67 percent of medical records of children prescribed these drugs. Of the medical records with quality of care concerns, 53 percent lacked documentation of monitoring, 41 percent indicated provision of the wrong treatment, and 37 indicated that the patient was prescribed too many drugs.

Health care experts have also long pointed to a severe shortage of mental health care providers for both children and adults. For example, while nearly 1 in 5 children and adolescents deal with a behavioral or developmental disorder, the United States has less than 9,000 practicing child psychologists. As 1 in 3 children receive health care through Medicaid and the Children's Health Insurance Program, we need to ensure our federal health programs provide sufficient access to behavioral and developmental health care providers.

There is much work that remains to be done to protect and care for the most vulnerable of our society. Unless our public and private health care systems properly reflect the best medical standards and evidence-based practices, the result will damage not only the health care systems' financial bottom line, but also, more importantly, the health and welfare of our nation's children. We all have a responsibility to ensure that our health care programs work for all the children that it serves.

To better understand the progress HHS and CMS have made on this issue, please respond to the set of questions which we have enclosed with this letter by April 15, 2016. If you have any questions about this request, please feel free to contact Rebecca Maddox of Senator Carper's staff at (202) 224-2627 and Anne Dwyer and Laura Berntsen with the Senate Finance Committee at (202) 224-4515. Thank you very much for your assistance in this matter.

^[1] The U.S. Department of Health and Human Services, Office of Inspector General, *Second-Generation Antipsychotic Drug Use among Medicaid-Enrolled Children: Quality-of-Care Concerns* (March 2015), OEI-07-12-00320.

The Honorable Sylvia Burwell
The Honorable Andy Slavitt
February 16, 2015
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With best personal regards, we are

Sincerely yours,



Tom Carper
Ranking Member
Homeland Security and
Government Affairs Committee



Ron Wyden
Ranking Member
Finance Committee

Questions for U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services regarding Use of Psychotropic Drugs to Treat Infants and Children

1. How does CMS work with state Medicaid and child welfare agencies to monitor quality of care and appropriate physician prescribing practices for children and infants with behavioral health needs? What data is collected, if any, from state Medicaid and child welfare agencies or other relevant stakeholders regarding the prescribing of multiple psychotropic medications in children and infants? What barriers and opportunities exist for the successful reporting and oversight of quality of care for children and infants in Medicaid with high behavioral health needs?
2. How is CMS working with states to ensure access to medically necessary Early and Periodic Screening, Diagnostic and Treatment (EPSDT) for children and infants with behavioral health needs? How is CMS working with states to ensure appropriate provider participation by behavioral health providers, such as sufficient provider payment rates, as guaranteed under Medicaid's equal access provision? What are your recommendations and suggestions on how we could increase our behavioral health care workforce to ensure that families with young children have adequate resources to address behavioral health challenges? Please describe any other HHS and CMS efforts to ensure children enrolled in Medicaid or private health plans have access to other evidence-based treatments besides prescription drugs to address behavioral health concerns.
3. Of the initiatives taken thus far to strengthen oversight of improper prescribing of psychotropic medications to children enrolled in Medicaid, what has been most effective at reducing quality of care issues? Are there other policies such as those recommended in the President's 2017 Budget and previous proposals that HHS believes would further help to address the issue of over prescription of psychotropic medications to children?
4. In response to the Inspector General's recommendations to ensure the quality of the care provided to children enrolled in Medicaid who are receiving of antipsychotics drugs, we were pleased to hear of CMS's plans to work with states on several initiatives, including the use of its Medicaid Drug Utilization Review Program to monitor antipsychotic medications prescribed to children; encouraging states to conduct reviews through their External Quality Review Organizations; and convening a Medicaid Quality Technical Advisory Group meeting with states to find effective tools for promoting the safe use of antipsychotics among children. Please provide an update on the progress of these activities, specifically—
 - a. CMS's plans to collaborate with the Academy of Child and Adolescent Psychiatry to identify and share drug utilization review guidelines with State Medicaid programs and the results of this collaboration.
 - b. The status of reviews by State Medicaid Quality Review Organizations related to psychotropic medications and the outcome of those reviews.

- c. The results of the Medicaid Quality Technical Advisory Group meeting intended for promoting the safe use of antipsychotics among children.
 - d. CMS's plans to work with the Medicaid Pharmacy Administrators and the American Drug Utilization Review Society to share with state Medicaid pharmacy staff best practices from drug utilization review to promote appropriate oversight for quality of care for children with mental or behavioral issues and the outcomes of this collaboration.
 - e. CMS's plans to submit three new Healthcare Effectiveness Data and Information Set standards on psychotropic use into the Medicaid/Children's Health Insurance Program Child Core Set and the status of those standards.
5. According to a CMS Medicaid Drug Utilization Review Annual Report from 2014, six states had no plan to implement a program monitoring the appropriate use of psychotropic drugs in children.^[2] What authorities, if any, does CMS have to ensure these states implement a program to monitor the appropriate use of psychotropic drugs in children. What barriers or challenges, if any, exist to the successful implementation of such drug monitoring programs?

^[2] CMS, Medicaid Drug Utilization Review: State Comparison/Summary Report FFY 2014 Annual Report (Sept. 2014).