The National CONSUMER VOICE for Quality Long-Term Care formerly NCCNHR

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March 6, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3255-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs - CMS–4159–P

Dear Administrator Tavenner:

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) appreciates the opportunity to submit comments on CMS's proposed rule regarding policy and technical changes to the Medicare Advantage and Medicare Part D Prescription drug benefit programs. Consumer Voice is a national non-profit organization that advocates on behalf of long-term care consumers across care settings, many of whom rely upon Medicare approved plans for their prescription drug coverage. Our membership consists primarily of consumers of long-term care and services, their families, long-term care ombudsmen, individual advocates, and citizen advocacy groups. Consumer Voice has nearly 40 years of experience advocating for quality care.

Our organization commends CMS's commitment to identifying ways to revise the existing regulations to better protect consumers and strengthen the long-term fiscal health of the Medicare prescription drug programs. We are strongly in favor of many of the proposed rule's provisions, such as those that would improve protections for beneficiaries and enhance drug plan oversight and accountability.

However, we express strong opposition to the removal of antidepressants, immunosuppresants and antipsychotics from the six protected drug classes under Medicare Part D. While we understand the importance of identifying cost-savings to ensure the longetivity of the Part D program, we believe that this proposed change is short-sighted and would harm the health and well-being of countless beneficiaries who are reliant upon these medications. We also have concerns related to other provisions in the proposed rule that we discuss below.

Despite these concerns, we are fervently against the retraction of the rule in full, as we view many of the proposed changes to be considerably beneficial for consumers. We instead urge CMS to improve upon the proposed rule by removing the harmful provision to modify the six protected drug classes and addressing other concerns expressed by consumer advocates.

Our detailed comments follow.

<u>We would like to express particularly strong support for the following provisions in the NPRM:</u>

- **The expansion of the authority for CMS to implement intermediate sanctions and civil monetary penalties on Part D plans for marketing and enrollment violations**

  We strongly support this provision of the rule that would provide CMS with the authority to impose sanctions on an organization that enrolls an individual without his or her prior consent or transfers an individual to a new plan without prior consent. In addition, we are also supportive of the new requirement that would make it a contract violation for plans to violate marketing requirements. We believe that codifying these new authorities, which were mandated through the Affordable Care Act, will help to ensure better plan oversight and accountability and serve to enhance protections for consumers.

- **The consolidation of the number of Part D plans offered to beneficiaries**

  We are in favor of the proposed requirement to consolidate Part D plans by allowing sponsors to offer one basic and one enhanced plan per region. Like other consumer advocates, we agree that many seniors enrolled in the Part D program find the large number of plans available far too confusing. Limiting Part D plans to those that are meaningfully different from one another will help seniors better understand their options and subsequently choose the most appropriate and beneficial plans.

- **The mandated reporting of negotiated drug prices**

  We are supportive of CMS's proposed requirement that would better ensure the accuracy of any reported negotiated payment amounts pharmacies receive from plans for covered Part D drugs. As CMS notes in the proposed rule, Part D sponsors continue to report costs and price concessions in differing ways, and sometimes this information fails to be reflected in negotiated drug prices. By mandating that all pharmacy price concessions must be reflected in the negotiated price, CMS will ensure that consumers have access to accurate premium and cost amount information through the Medicare Plan Finder, allowing them to better evaluate plans.

- **Codifying requirements that preferred pharmacies actually save money for Medicare**

  We agree that this proposed change is needed to address problems with preferred pharmacy arrangements. Currently, some plan sponsors use cost-sharing structures to drive consumers to expensive mail order pharmacies as opposed to more affordable retail pharmacies. This practice is costly to Medicare and does nothing to aid the long-term vitality of the program.

- **Applying the "any willing pharmacy" standard to preferred networks**

  Expanding access to preferred networks to any pharmacy willing and able to meet the terms and conditions of such networks would benefit seniors significantly by providing them with a greater number of pharmacy choices in preferred drug plans. Under the current regulations, in which the "any willing pharmacy" standard is not applied to preferred cost sharing contracts, smaller, independent pharmacies are often unable to participate in plans' preferred networks, whether or not they are able to offer the necessary level of negotiated prices that the network requires. Expanding access to these networks to any pharmacy that can meet these preferred prices will give consumers more choice and better access to pharmacies. It will also help to increase competition in these networks, resulting in the lowering of overall costs.

- **Timely Access to Mail Order Services**

  We support CMS's provision to provide more timely access for beneficiaries reliant upon mail order pharmacy services. Many long-term

care consumers that participate in the Part D program use the services of mail order pharmacies to receive needed medications. Requiring mail order fulfillment of prescriptions to be made within the proposed 3 or 5-day time periods will help to prevent unnecessary and even harmful delays in the delivery of medications to these vulnerable beneficiaries.

- **Annual Notice of Change (ANOC) available to beneficiaries 15 days prior to the Medicare annual election period**

  Although many plans already make Annual Notices of Change available to beneficiaries 15 days prior to the plan enrollment period, making this requirement explicit through rulemaking will help to ensure that all beneficiaries are sufficiently informed about any changes in their plans' drug coverage and cost-sharing amounts when considering plan options for the following year. We support this proposed change and also urge CMS to increase the time frame to 30 days prior to the plan enrollment period. We feel that fifteen days is an insufficient amount of time for consumers to review plan changes and potentially seek assistance regarding any questions they may have about information in the ANOC. Requiring these notices to be provided to consumers 30 days prior to the enrollment period will better enable consumers to make the most informed decisions about their prescription drug coverage options.

- **Expansion of Medication Therapy Management Services**

  We support the broad expansion of medication therapy management (MTM) services to individuals with two chronic conditions, who are using at least two Part D prescription drugs, and whose spending meets a cost threshold based on the cost of two generic drugs. MTM services have been shown to be beneficial in improving outcomes and drug therapies among beneficiaries. Expansion would also give more beneficiaries access to these services, thereby helping to reduce adverse events among vulnerable individuals.

- **Increasing oversight of Medicare's contracts with Medicare Advantage and Part D plans**

  We strongly commend CMS for the provisions in the proposed rule that will strengthen the monitoring and oversight of Part D plans. As CMS is aware, fraud, waste and abuse have become prevalent problems in the Part D program, and several OIG reports have found that there are insufficient protections in place to prevent pharmacies from engaging in potential fraud schemes such as inappropriate billing practices and drug

diversions and kickbacks.[1] We believe that the proposed provisions to require plans to have a minimum level of experience; improve the authority to terminate contracts; measure plan improvements through star ratings metrics; and demonstrate that private plans are using federal Medicare funds appropriately will all serve to ensure that consumers are receiving quality care and that Part D plans are spending taxpayer money appropriately.

In addition to the requirements in the proposed rule, we also encourage CMS to require plan sponsors to report data on fraud and abuse and to develop processes for the agency to confirm the accuracy of such data. Currently, Medicare Part D plans only encourage plans to voluntarily report data on anti-fraud activities. A recent OIG report found that that "no more than 40 percent of sponsors reported any fraud and abuse data between 2010 and 2012 and that CMS does not have data on incidents of potential fraud and abuse for plans covering almost half of the beneficiaries enrolled in Part D."[2] Without accurate information on the extent of these issues and among plan sponsors, CMS will be unable to sufficiently monitor plans' programs and prevent abuse in the system.

<u>While we are supportive of CMS's intentions in the following provision, we remain concerned of how this change would impact consumers:</u>

- **Allowing non-CMS entities to implement the good cause process**

  While we understand that CMS is seeking to make the good cause review process more efficient, we are very much concerned about allowing a non-CMS entity, including plans themselves as well as independent contractors, to implement either part or all of this process. It would be an inherent conflict of interest to grant Part D plans this role in overseeing the process in which evidence is evaluated to determine whether or not consumers should have been involuntary disenrolled from plans or reinstated into plans following disenrollment. This proposed revision would greatly undermine the intent of the good cause process and result in diminishing consumer confidence in the Part D program as a whole.

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[1] OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, OEI-03-07-00380, 2008; and OIG, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, 2009.

[2] OIG, Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse, OEI-03-13-00030, 2014; http://oig.hhs.gov/oei/reports/oei-03-13-00030.pdf

Lastly, we express strong opposition to the following provision in the proposed rule:

- **Removal of Drugs from the six protected drug classes**

In the proposed rule, CMS puts forward changes to the six protected classes that would eliminate the requirements for plans to cover all products in the antidepressants and immunosuppresants classes for CY 2015 and, for the antipsychotic class in CY 2016. We strongly urge CMS to rescind this provision, as removing any of the medications from protected class status would result in significant harm to consumers that are reliant upon these drugs for their mental and/or physical well-being.

It is vital for consumers participating in Part D plans to have access to all products in these classes, as many times individuals must try a range of different antidepressants, immunosuppresants and antipsychotics before finding either the right medication or the right combination of medications that provide optimal care. Removing the range of available drugs in these classes will result in beneficiaries losing access to medications that cannot easily be replaced by alternative treatments. Furthermore, the ongoing issues with the CMS exceptions, appeals and grievance processes will make it difficult for consumers who lose access to needed medications under this rule change to have this access reinstated in a timely manner. A 2006 Kaiser Family Foundation report on the Part D appeals process found that "the existing processes for appealing unfavorable decisions for drug coverage are complex and varied" and that "current aspects of the appeals system may "inadvertently create barriers for patients to access needed medication."[3] Without these drugs being covered under the six protected classes, consumers will either lose treatments entirely or have treatments unreasonably delayed, resulting in poorer health outcomes among beneficiaries and an increase in overall costs to the Medicare program.

In addition, while we commend CMS for acknowledging in its proposed rule the continued misuse of antipsychotic medications among residents with dementia in long-term care facilities, we do not believe this proposed change would help to resolve this problem. The inappropriate use of

[3] Kaiser Family Foundation, *Beneficiary Challenges in Using the Medicare Part D Appeals Process To Obtain Medically Necessary Drugs,* 2006**;** http://kff.org/medicare/issue-brief/beneficiary-challenges-in-using-the-medicare-part/

antipsychotics is a separate issue from whether these drugs should remain a protected class.

Instead CMS should continue efforts already underway and take additional steps to address and prevent the misuse of antipsychotic medications.

Current efforts

- **The National Partnership to Improve Dementia Care and the enforcement of federal nursing home regulations**

  In 2012, CMS launched an initiative, the National Partnership to Improve Dementia Care in Nursing Homes with a goal of reducing antipsychotic drug use by 15 percent by the end of that year. As of 2014, the agency has yet to meet this goal, although it is close to doing so. Given how much time and resources CMS has already invested in the Partnership, the agency should continue the initiative, but greatly increase the reduction goal of the campaign.

- **Enforcement of the misuse of antipsychotics**

  According to a study by the Center for Medicare Advocacy and Dean Lerner Consulting, 95% of antipsychotic drug deficiencies cited by seven states in 2011 and 2012 were cited at a no-harm level[4], regardless of how many residents were harmed or how serious the harm. When deficiencies are labeled as no-harm, few to no penalties are imposed against facilities, creating no incentive for nursing homes to improve in this area. We urge CMS to work with surveyors on how to better identify harm to residents or to revise its system for assessing scope and severity.

Additional steps CMS should take

- **Regulations requiring the independence of consultant pharmacists**

[4] Center for Medicare Advocacy and Dean Lerner Consulting, *Examining Inappropriate Use of Antipsychotic Drugs, Part Three: How Seven States Cite Antipsychotic Drug Deficiencies*, 2013; http://www.theconsumervoice.org/sites/default/files/ExaminingInappropriateUseOfAntipsychoticDrugsPartI.pdf

In October 2011, CMS asked the public to comment on whether it should promulgate regulations to require consultant pharmacists to be independent of long-term care pharmacies and pharmaceutical manufacturers. These regulations would have stopped drug manufacturers and long-term care pharmacies from subsidizing or employing consultant pharmacists who advise nursing home physicians. Commenters, including many consultant pharmacists, overwhelmingly supported the need for regulations to stop conflicts of interest that jeopardized residents. However, CMS chose to abandon its plans to promulgate these regulations. The agency concluded that its concern over consultant pharmacists' financial ties to the drug industry having a harmful impact on residents was "well-founded," but elected to allow the industry to police itself.

We urge the agency to revisit this matter and promulgate regulations requiring the independence of consultant pharmacists, which would greatly aid in reducing improper antipsychotic prescribing practices.

- **Informed consent for the prescribing of antipsychotic medications among nursing home residents**

  Families and nursing home residents themselves may not know always that an antipsychotic drug is being administered or that they have the right to refuse the medication. Informed consent requirements should be properly enforced and, where necessary, strengthened. Federal law requires residents to be fully informed in advance about planned care or treatment, to participate in planning for their care and treatment, and to refuse treatment (regardless of whether doing so may be detrimental). Yet in a 2012 review of 375 randomly selected resident records, the Office of the Inspector General found that 91 percent did not contain evidence that the resident or the resident's family or legal representative participated in the care planning process. Every resident in this study was administered an antipsychotic drug[5].

  CMS should strengthen enforcement of current protections and promulgate the proposed rules it issued in 1992, which would have implemented informed consent requirements for chemical restraints (and physical restraints as well).

[5] OIG, *Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs*, OEI-07-08-00151, 2012

- **Medication therapy management for all nursing home residents who receive antipsychotic drugs.**

  We encourage CMS to require plans to provide MTM services for any nursing home resident that is receiving antipsychotic medications. This would help ensure greater oversight and monitoring of beneficiaries in nursing homes and assist in reducing unnecessary prescribing of these medications.

- **Antipsychotic Drug/Dementia Care Compliance Report**

  We strongly support the recommendation put forth in the Center for Medicare Advocacy and Dean Lerner Consulting's 2013 report, *Examining Inappropriate Use of Antipsychotic Drugs, Part Three: How Seven States Cite Antipsychotic Drug Deficiencies,* for CMS to 'develop, test, evaluate, and implement a new approach to both the Requirements of Participation and the survey process'.

  According to the report:

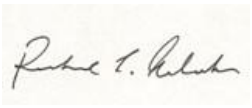
  > "[This] approach would place responsibility on each facility to assemble, maintain, and update, in a single location, essential information about each resident's use of antipsychotic drugs and would require Surveyors to read and analyze the information as they determine whether the facility is in substantial compliance with Requirements or not […] CMS would require facilities to complete and timely update a specific 'Antipsychotic Drug/Dementia Care Compliance Report' for each resident taking one or more antipsychotic medications. The Compliance Report would be both a CMS-mandated form and a CMS-mandated process that would require a facility's interdisciplinary team to demonstrate how it evaluated and complied with federal Requirements for antipsychotic drug use. The form and process would require the team to identify the resident's diagnosis (with accompanying dates and background), all attempted non-pharmaceutical interventions (with accompanying dates, results, and other background), consents, and recommendations for, and physician responses to, gradual dose reductions. The Compliance Report would be signed by all members of the interdisciplinary team, certifying that they have complied with all federal Requirements and explaining in detail how they have done so. Facilities would certify their statements and the information contained in the Compliance Reports. Surveyors would

review these Reports as part of their determination of facilities compliance with federal Requirements for antipsychotic drug use."[6]

The development and implementation of such a tool would better enable CMS to track and prevent the misuse and overprescribing of antipsychotic medications among nursing home residents with dementia.

The Consumer Voice thanks you for your consideration of these comments. If you have any questions, please feel free to contact Robyn Grant at (202) 332-2275, ext. 205.

Sincerely,



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[6] Center for Medicare Advocacy and Dean Lerner Consulting, *Examining Inappropriate Use of Antipsychotic Drugs, Part Three: How Seven States Cite Antipsychotic Drug Deficiencies*, 2013; http://www.theconsumervoice.org/sites/default/files/ExaminingInappropriateUseOfAntipsychoticDrugsPartIII.pdf