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Medicare Payment Advisory Commission (MedPAC)
425 Eye Street NW, Suite 701
Washington, DC 20001

Dear Commissioners:

On behalf of the Medicare Rights Center (Medicare Rights), I am writing to provide comment on MedPAC's recent inquiry into potentially inappropriate opioid use in Medicare. Specifically, we will share input on proposed Medicare "lock-in" programs. We appreciate having the opportunity to provide feedback on this important issue involving the health and safety of seniors and people with disabilities as well as the integrity of the Medicare program.

Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights answers 15,000 questions on our national helpline each year from older adults, people with disabilities, and those that help them—family caregivers, social workers, attorneys, and other service providers. Through our educational initiatives, including our online learning tools, we reach over 1.5 million Medicare beneficiaries and their families annually.

As noted during MedPAC's October 9th meeting, the potential overuse of opioids by Medicare beneficiaries has garnered the attention of multiple parties, including members of Congress, the Office of Inspector General (OIG), and the Government Accountability Office (GAO).[1] As a response, the OIG and some members of Congress have suggested granting the Centers for Medicare & Medicaid Services (CMS) the

[1] OIG, "Retail Pharmacies with Questionable Part D Billing," (May 2012), available at: http://oig.hhs.gov/oei/reports/oei-02-09-00600.pdf; OIG, "Prescribers with Questionable Patterns in Part D," (June 2013), available at: http://oig.hhs.gov/oei/reports/oei-02-09-00603.pdf; OIG, "Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs," (August 2014), available at: http://oig.hhs.gov/oei/reports/oei-02-11-00170.pdf; GAO, "Instances of Questionable Access to Prescription Drugs," (September 2011), available at: http://www.gao.gov/new.items/d11699.pdf; For legislative proposals, see: Senator Carper, Senator Toomey and Senator Brown, "Amendment #4: Improvements to Medicare Procedures to Prevent Fraudulent Diversion and Medically Unnecessary or Unsafe Use of Prescription Drugs," (December 2013), available at: http://www.finance.senate.gov/legislation/details/?id=a275e061-5056-a032-5209-f4613a18da1b; Congressman K. Brady, "Discussion Draft: Protecting Integrity in Medicare Act of 2014 (PIMA)," (August 2014), available at: http://waysandmeans.house.gov/news/documentsingle.aspx?DocumentID=390502

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authority to implement "lock-in" controls—effectively allowing Part D plan sponsors to restrict certain beneficiaries to a limited number of prescribers and pharmacies when there is suspected drug abuse.[2]

We agree that both CMS and Congress should consider additional interventions to stem the growth of fraud, including diversion and doctor-shopping, and to ensure that beneficiaries addicted to prescriptions medications receive the appropriate medical treatment and behavioral health care. Yet, proposals that would allow Part D plan sponsors to employ additional point-of-sale edits on beneficiary access to medications are concerning to us, largely given our experience assisting clients denied access to prescription drugs. Additionally, as detailed by the *New York Times*, recent CMS audit findings and resulting sanctions illustrate that Part D plan sponsors fail to adequately manage coverage determinations, appeals, and grievances to an alarming degree.[3]

As such, we do not support the development of a Medicare prescription drug "lock-in" program absent critical beneficiary protections, including: an accessible and effective appeals process; increased and effective data sharing, monitoring and oversight; clinically-determined criteria for targeting at-risk beneficiaries; and a targeted education campaign for health care providers. Should the Commissioners decide to make recommendations on "lock-in" proposals, we ask that you consider the following:

- **A straightforward, accessible beneficiary appeals process must be defined.** Part D plan sponsors are already granted the ability to control or limit beneficiary access to medications through utilization tools, like prior authorization, step therapy, and quantity limits. Limited public data is available on how well plan sponsors manage these processes, and what information is available presents cause for alarm.

  According to the agency's 2013 audit of select Medicare Advantage (MA) and Part D plan sponsors, CMS found that the majority of plan sponsors failed to appropriately educate beneficiaries about the reason for drug denials, failed to conduct sufficient outreach to prescribers to make a coverage determination, made inappropriate denials when processing coverage determinations, applied unapproved utilization management controls, and more.[4]

  These findings suggest significant room for improvement in the use of utilization tools by Part D plan sponsors, and underscore the need for both well-defined consumer protections and enhanced oversight of any proposed "lock-in" programs. The traditional Part D appeals process is unlikely to serve as an appropriate safeguard, given its documented shortcomings.[5] Any "lock-in" proposal should include

[2] OIG, "Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs," (August 2014), available at: http://oig.hhs.gov/oei/reports/oei-02-11-00170.pdf; For legislative proposals, see: Senator Carper, Senator Toomey and Senator Brown, "Amendment #4: Improvements to Medicare Procedures to Prevent Fraudulent Diversion and Medically Unnecessary or Unsafe Use of Prescription Drugs," (December 2013), available at: http://www.finance.senate.gov/legislation/details/?id=a275e061-5056-a032-5209-f4613a18da1b; Congressman K. Brady, "Discussion Draft: Protecting Integrity in Medicare Act of 2014 (PIMA)," (August 2014), available at: http://waysandmeans.house.gov/news/documentsingle.aspx?DocumentID=390502

[3] Pear, R., "U.S. Finds Many Failures in Medicare Health Plans," *New York Times* (October 12, 2014), available at: http://www.nytimes.com/2014/10/13/us/us-finds-many-failures-in-medicare-health-plans-.html?_r=0

[4] CMS, "Common Conditions, Improvement Strategies, and Best Practices based on 2013 Program Audit Reviews," (Memo from G. Mulcahy to All Medicare Advantage Organizations and Prescription Drug Plans; August 27, 2014), available at: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Program-Audits.html

[5] Medicare Rights Center, "Facts & Faces: Refused at the Pharmacy Counter, How to Improve Medicare Part D Appeals," (Winter 2013), available at: http://www.medicarerights.org/pdf/2013-Facts-and-Faces-Pharmacy-Counter.pdf; Sanders, S. "Letter to MedPAC on Medicare Part D Appeals,"

enhancements to the existing appeals framework, such as clearer and more detailed beneficiary education at the pharmacy counter and defined processes to ensure plans are communicating with prescribers about clinical needs.

- **Efforts to strengthen data sharing, monitoring, and oversight must be prioritized.** As discussed at MedPAC's recent meeting, CMS is already undertaking efforts to strengthen monitoring with respect to fraudulent prescribing, billing and utilization.[6] Approaches like these are preferable to broader "lock-in" programs because they target and engage multiple actors within the system without compromising beneficiary access to needed medications, and where beneficiary access is restrained, it is done so in collaboration with treating providers. Effective efforts to combat fraud must address existing data gaps and monitoring limitations.

  Most notably, as acknowledged by CMS, stand-alone Part D plan sponsors are not well equipped to identify trends because they do not have access to prescriber or pharmacy data beyond the transactions they manage for their own enrollees, making it more difficult for them to identify outliers. They also do not have a direct relationship with prescribers and access to enrollee medical records that could help them determine whether an enrollee's behavior is problematic or in line with accepted medical practice.[7] MedPAC should explore options that allow Part D plan sponsors to overcome these limitations.

  Additionally, CMS' current capacity to audit Part D plan sponsor compliance with current requirements related to data review, monitoring, and reporting of fraud and abuse are severely limited. CMS conducts annual audits of only 10% (30 of 300) plan sponsors.[8] At the same time, reporting by Part D plan sponsors about suspected fraud and abuse is merely encouraged—not required.[9] Any "lock-in" proposal should be coupled with additional oversight and requirements to ensure Part D plan sponsors are appropriately carrying out data collection, program implementation and monitoring responsibilities, as well as to evaluate any new policies that restrict beneficiary access.

- **Lock-in criteria must be developed according to clinical standards.** The criteria for identifying at-risk beneficiaries who may be subject to "lock-in" controls and other aspects of the program design must be developed through a transparent, multi-stakeholder process. Stakeholders that should be consulted include: beneficiary advocates and consumer representatives, Part D plan sponsors, and clinicians.

  In particular, specialists with knowledge and experience in treating conditions for which frequently abused and diverted medications are commonly prescribed should have a key role in developing the criteria, as should addiction and recovery specialists. Concurrently with or prior to the implementation of

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(September 2013), available at: http://www.medicarerights.org/pdf/092013-part-d-appeals-medpac.pdf; MedPAC, "Report to the Congress, Chapter 14: Status Report on Part D," (March 2014, pgs. 368-369), available at: http://www.medpac.gov/documents/reports/mar14_ch14.pdf?sfvrsn=0

[6] Shinobu, S., "Potentially inappropriate opioid use in Medicare Part D," (Presentation to MedPAC: October 9, 2014), available at: http://www.medpac.gov/documents/october-2014-meeting-presentation-potentially-inappropriate-opioid-use-in-medicare-part-d-.pdf?sfvrsn=0

[7] Blum, J., "Testimony on Curbing Prescription Drug Abuse in Medicare," (CMS: June 2013), available at: http://www.hsgac.senate.gov/hearings/curbing-prescription-drug-abuse-in-medicare

[8] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule" 79 Fed. Reg. 7 (Jan. 10, 2014)

[9] OIG, "Retail Pharmacies with Questionable Part D Billing," (May 2012), available at: http://oig.hhs.gov/oei/reports/oei-02-09-00600.pdf; CMS, "Medicare Prescription Drug Manual: Chapter 9, 50.6.2" (Last Updated January 2013), available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf

any "lock-in" restriction, Part D plan sponsors should be required to provide beneficiaries who may suffer from addiction with referrals to appropriate behavioral health and medical services.

It is essential that a "lock-in" criteria to identify at-risk beneficiaries is appropriately targeted, namely to ensure that beneficiaries with a legitimate medical need for certain medications retain access. To facilitate this, any "lock-in" program should include a list of exempted conditions. Terminal oncology patients, for example, should not be subject to this review.

In addition, clear criteria must be developed to guarantee that beneficiary choice is protected when restrictions are placed on access to prescribers and pharmacies. Beneficiary preferences for a specific prescriber or pharmacy should be given special consideration to facilitate reasonable access. Geographic location and reasonable travel time should also be considered. Finally, programs that only "lock-in" potentially abused or diverted drugs are preferable to those that "lock-in" the beneficiary for all prescription drug coverage.

- **Provider education must be incorporated.** Many parties, including prescribers and pharmacies, carry out Medicare prescription fraud.[10] Similarly, as has been well documented, beneficiaries do not abuse drugs without help. Given this, "lock-in" programs must be accompanied by targeted education for prescribers and pharmacies to assist with the identification of at-risk individuals, to enhance reporting to enforcement entities, and to ensure that addicted individuals receive the appropriate medical care and behavioral health services.

In closing, we believe Congress and CMS can do more to stem the growth of prescription drug fraud and abuse in the Medicare program. An inquiry into viable solutions serves a critical purpose, namely to protect the health and well-being of seniors and people with disabilities. With respect to "lock-in" proposals, this purpose can only be advanced through a carefully designed program that balances the need to ensure access to medically necessary prescription drugs with the need to reduce fraud and assist beneficiaries addicted to prescription medications. Thank you for the opportunity to provide comment.

Sincerely,

Joe Baker
President
Medicare Rights Center

[10] Cantrell, G. and S. Wright, "Testimony on Curbing Prescription Drug Abuse in Medicare," (OIG: June 2013), available at: http://www.hsgac.senate.gov/hearings/curbing-prescription-drug-abuse-in-medicare;; Rannazzisi, T., "Testimony on Curbing Prescription Drug Abuse in Medicare," (Department of Justice, Office of Diversion Control, Drug Enforcement Administration: June 2013), available at: http://www.hsgac.senate.gov/hearings/curbing-prescription-drug-abuse-in-medicare