Leadership Council of Aging Organizations

ISSUE BRIEF
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Medicare Part D "Lock-In" Proposals Must Include Beneficiary Protections

Background:

Over the last several years, the proliferation of prescription drug waste, fraud and abuse in the Medicare program has gained the attention of lawmakers, regulators and the media.[i] Both the Office of the Inspector General (OIG) and the Drug Enforcement Administration (DEA) acknowledge that there are multiple parties involved in this issue, including: health care providers, beneficiaries, and pharmacies.[ii]

Across several reports, the OIG identifies an array of options available to the Centers for Medicare & Medicaid Services (CMS) to further combat Medicare prescription drug fraud and abuse.[iii] In its most recent report, the OIG suggests that Congress grant CMS the authority to implement "lock-in" controls—effectively allowing Part D plan sponsors to restrict beneficiaries with questionable prescription drug utilization patterns to a limited number of prescribers and pharmacies.[iv] This concept has appeared in both Senate and House legislative proposals.[v]

Position:

The Leadership Council of Aging Organizations (LCAO) remains supportive of administrative and legislative efforts to reduce waste, fraud and abuse in the Medicare program. In order to work effectively without harming those that need access to medically necessary prescription drugs, Medicare "lock-in" programs must be carefully designed. Thus, LCAO believes "lock-in" programs must be narrowly constructed to ensure no harm comes to beneficiaries with a legitimate medical need for pain medications or other commonly misused prescriptions.

By design, "lock-in" programs target an extremely vulnerable population, including beneficiaries with multiple chronic conditions, lower incomes and limited mobility as well as those who need to see multiple physicians and specialists. As such, LCAO does not support implementing Medicare prescription drug "lock-in" proposals absent critical beneficiary protections, including: clinically-determined criteria for targeting at-risk beneficiaries; an accessible and effective appeals process; increased and effective data sharing, monitoring, and oversight; and a targeted education campaign for health care providers.

Rationale for Needed Beneficiary Protections:

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, such as a taskforce or advisory council. Stakeholders that should be involved 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 any "lock-in" restriction, Part D plan sponsors should be required to provide beneficiaries who may experience addiction or overuse problems with referrals to appropriate behavioral health and medical services.

It is essential that "lock-in" criteria to identify at-risk beneficiaries is appropriately targeted, namely to ensure that those with a legitimate need for certain medications do not face unnecessary disruptions and retain access.

Any "lock-in" program should include a list of exempted conditions. Beneficiaries living with terminal conditions, including those enrolled in hospice, 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 preference for a specific prescriber or pharmacy should serve as the baseline determination for restrictions on access. Where this is not possible, geographic location and reasonable travel time should take precedence. Finally, programs that only "lock-in" potentially abused or diverted drugs are preferable to those that "lock-in" the beneficiary for all coverage.

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. Sponsors are required to provide appropriate beneficiary education and to follow mandated timelines when a beneficiary seeks access through an appeal.[vi] Questions remain about how well sponsors manage these processes.

Limited data is available on Part D utilization controls and appeals, yet the information that 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 vast majority failed to appropriately educate beneficiaries about the reason for denials, failed to conduct sufficient outreach to prescribers, made inappropriate denials, and more.[vii]

These findings suggest significant room for improvement in the use of utilization tools by Part D plan sponsors, and further 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.[viii] Any "lock-in" proposal should include enhancements to the existing appeals framework, such as clearer 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. CMS is already undertaking efforts to strengthen monitoring with respect to fraudulent prescribing, billing and utilization. For instance, starting in 2015, CMS is implementing a requirement that all prescribers must be registered with the Medicare program and must have a valid National Prescriber Identifier (NPI). Additionally, the federal government is making tools available to Part D plan sponsors to evaluate the validity of potentially suspect pharmacies or doctor's offices.[ix] Approaches like these are preferable to "lock-in" programs because they target and engage multiple actors within the system without disrupting beneficiary care or compromising access.

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.[x] Congress and CMS should explore options that allow Part D plan sponsors to overcome these limitations.

The implementation of "lock-in" controls must be coupled with public reporting, namely to discern disproportionate impact on vulnerable populations through the release of aggregate data. CMS should release the following information on "locked-in" beneficiaries, including: socio-demographic characteristics (including race, ethnicity, income, age and gender), location by ZIP code, and enrollment in low-income assistance programs (including Medicaid, Extra Help, Medicare Savings Programs and State Pharmaceutical Assistance Programs).

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 is severely limited. CMS conducts annual audits of only 10% (30 of 300) plan sponsors.[xi] Any "lock-in" proposal should be coupled with additional oversight to ensure Part D plan sponsors are appropriately carrying out existing data collection and monitoring responsibilities, as well as to evaluate any new policies that restrict beneficiary access.

Provider education must be incorporated. As demonstrated by research performed by the OIG and DEA, many parties, including prescribers and pharmacies, carry out Medicare prescription fraud. Similarly, as has been well documented, beneficiaries do not misuse drugs without help.[xii] 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 appropriate medical care and behavioral health services.

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[i] U.S. Senate Committee on Homeland Security & Governmental Affairs, "Hearing on Curbing Prescription Drug Abuse in Medicare," (June 2013), available at: http://www.hsgac.senate.gov/hearings/curbing-prescription-drug-abuse-in-medicare; ProPublica investigative series, "The Prescribers: Inside the Government's Drug Data," (2013 – 2014), available at: http://www.propublica.org/series/prescribers

[ii] 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

[iii] 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

[iv] 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

[v] For example, 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," (Amendment List:
An original bill to repeal the sustainable growth rate system and to consider health care extender, 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

[vi] CMS, "Prescription Drug Benefit Manual: Chapter 18," (Last Updated May 2014), available at: http://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/index.html

[vii] 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

[viii] 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," (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

[ix] CMS, "Press Release: CMS Makes Improvements to Medicare Drug and Health Plans," (May 2014), available at: http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-05-19.html; CMS, "Prescribers Be Aware. The NPI is here. The NPI is now. Do you have one? Are you using it?," (May 2014), available at: http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/Downloads/NPI-Requirements-for-Prescribers.pdf; Abankwah, R., "Presentation at the Medicare Advantage and Prescription Drug Plan Fall Conference: Combatting Drug Diversion" (CMS: September 2014), available at: http://www.cms.gov/Outreach-and-Education/Training/CTEO/Downloads/2014-MA-and-PDP-Fall-Conference/2014_MA_and_PDP_Fall_Conference_and_Webcast_Agenda-FINAL.pdf

[x] 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

[xi] 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) p. 1927 (to be codified at 42 CFR Parts 409, 417, 422, et al.)

[xii] 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