JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

May 9, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1670-P
P.O. Box 8016
Baltimore, MD 21244-8016
Via Electronic Submission to https://regulations.gov

RE: Medicare Program; Part B Drug Payment Model; Proposed Rule, CMS 1670-P

Dear Acting Administrator Slavitt:

Justice in Aging is pleased to submit comments on the Part B Drug Payment Model.[1] Justice in Aging, formerly the National Senior Citizens Law Center, is a national advocacy organization that uses the power of law to fight senior poverty by securing access to affordable health care, economic security, and the courts for older adults with limited resources. We have decades of experience with Medicare and Medicaid, with a focus on the needs of low-income beneficiaries, including those dually eligible for both programs.

Justice in Aging supports the proposed Part B drug payment model. The proposal has the potential to improve quality and value for Medicare beneficiaries. As a national organization advocating on behalf of the 6.4 million seniors who live in poverty, we are particularly attuned to the needs of Medicare beneficiaries to have a high value health care system that increases quality while reducing costs. This proposal appropriately focuses on changing incentives for prescribers that currently favor high-cost drugs, even when lower-cost alternatives are available, while ensuring that Medicare beneficiaries can maintain access to the medications that they need.

Changing the trajectory of prescription drugs costs in Medicare is particularly important for lower income Medicare beneficiaries who cannot afford supplemental insurance and due to the strict income and asset requirements for Medicare Savings Programs, do not receive any assistance with Medicare cost sharing. The median income for Medicare beneficiaries is less than $25,000, and one in four

[1] Medicare Program; Part B Payment Model, 81 Fed. Reg. 13230 (Proposed March 11, 2016) (to be codified at 42 C.F.R. 511).

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beneficiaries have less than $12,000 in income.[2] Since there is no out-of-pocket limit for cost-sharing for Medicare beneficiaries, costs can soar, reaching as high as $100,000 or more.[3]

Support for demonstration's goals, size and scope

We agree with CMS that is appropriate to examine whether the current Medicare Part B reimbursement rules may incentivize the use of more expensive drugs, even when less expensive drugs are equally effective. By reducing the add-on payment from 6 percent to 2.5 percent, plus a flat-fee of $16.80, health care providers will have less of a financial incentive to use expensive drugs in treating patients when less expensive and equally effective drugs may be used. Health care providers remain able to choose the most appropriate treatment for their patients. This proposed model simply removes any embedded financial incentive for providers to choose more expensive treatment over equally effective lower cost treatment.

We do not believe that the model's proposed changes to reimbursement will adversely impact beneficiary access. In contrast, it may increase beneficiary access, as studies demonstrate that very high coinsurance can dissuade beneficiaries from receiving even needed care.[4] When drug prices go down, access can increase as more people can afford their copayments, and do not go without care.

We support the size and scope of this demonstration. This proposal is a continuation of CMS' overall strategy regarding payment reform. These proposals are consistent with other programs currently being pursued by CMMI. For example, certain strategies anticipated for Phase II of the demonstration are similar to those proposed through the Medicare Advantage Value-Based Insurance Design (MA V-BID) demonstration, beginning in 2017 in seven states.[5] The Part B Drug Payment Model will apply similar concepts to Original Medicare.

In keeping with the demonstration authority of CMMI, the proposed model appropriately targets known "deficits in care." As consumer advocates, we are aware that many beneficiaries cannot afford the 20 percent coinsurance on high-cost medications, while others struggle to find a pharmacy or supplier who will provide very low-cost prescription drugs. The Part B Drug Payment Model aims to address both of these challenges.

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[2] G. Jacobson, C. Swoope, and T. Neuman, "Income and Assets of Medicare Beneficiaries, 2014-2030," Kaiser Family Foundation, September 2015, available at http://kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2014-2030/.

[3] Government Accountability Office, *Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly to Beneficiaries*, October 2015, available at http://www.gao.gov/assets/680/673304.pdf.

[4] See Wallace, N.T. et. al. "How Effective are Copayments in Reducing Expenditures for Low-Income Adult Medicaid Beneficiaries? Experience from the Oregon Health Plan," Health Services Research, Vol. 43, No. 2, 2008, pp. 515-530; Tambryn, R. et al. "Adverse Events Associated with Prescription Drug Cost-Sharing Among Poor and Elderly Persons," JAMA, Vol. 285, No. 4, 2001, pp. 421-429; Swartz, K. "Cost-Sharing: Effects on Spending and Outcomes" (Robert Wood Johnson Foundation Research Synthesis Report No. 20: December 2010.

[5] See the CMS summary of Medicare Advantage Value-Based Insurance Design Model, available at https://innovation.cms.gov/initiatives/vbid/.

Recommendations on monitoring and oversight

Based on our extensive experience with the Financial Alignment Initiative demonstration, delivery system reform is most successful when there are strong opportunities for stakeholder engagement and robust feedback loops to monitor the beneficiary experience and respond in real time to problems. For example, in the recent RTI evaluation of the FAI, evaluators identified the ombuds program as widely acknowledged promising element in the demonstration model.[6] Further, in the preamble to the recently released final Medicaid managed care regulation, the Centers for Medicaid and CHIP Services (CMCS) acknowledged that the transition from one payment structure to another requires robust provider and stakeholder engagement,[7] and states that successful programs have developed a structure for engaging stakeholders regularly in the monitoring and oversight of the program.[8]

We suggest the Part B demonstration build on these successful strategies and:

- Create stakeholder advisory groups and multiple opportunities for input from a wide range of stakeholders. A stakeholder advisory group, made up of Part B providers, beneficiaries, pharmaceutical representatives, and others vested in the Part B drug community, will help provide CMS with important oversight during implementation. This advisory group will provide CMS with important input on the demonstration's impact on beneficiary access and help CMS implement any necessary course corrections to ensure that access is advanced and not harmed during implementation.
- Establish an ombudsman program. CMS can look to the Competitive Acquisition Ombudsman in the Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers (DMEPOS) Competitive Bidding Program[9] or the Financial Alignment Initiative Ombudsman program[10] as a model.
- Monitor for changes in prescribing and dispensing (e.g. Part B to Part D). Such shifts can have drastic effects on beneficiary cost sharing. CMS should review both Part B and part D claims data to monitor the difference in out of pocket expenses for beneficiaries.
- CMS should also monitor for any increases in shifting access for Part B medicines from individual providers to hospital based outpatient centers.
- Ensure transparency in the agency's plans for monitoring and any corrective actions taken.

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[6] Research Triangle International, "Report on Early Implementation of Demonstrations under the Financial Alignment Initiative," pg. 22, available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/MultistateIssueBriefFAI.pdf.

[7] Medicaid and Children's Health Insurance Program (CHIP) Programs Delivered in Managed Care, 81 Fed. Reg. at 27589 (May 6, 2016).

[8] Id. at 27562.

[9] Competitive Acquisition Ombudsman (CAO), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Competitive_Acquisition_Ombudsman.html.

[10] Financial Alignment Initiative Demonstration Ombudsman Program, https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/FundingtoSupportOmbudsmanPrograms.html.

Recommendations on beneficiary outreach and education

We also urge that CMS engage in active outreach and education to beneficiaries regarding the new model. These outreach and educational initiatives should:

- Leverage existing resources such as SHIPs
    - The State Health Insurance Programs (SHIPs) are trained to provide free, local, one-on-one health insurance counseling and educational outreach to Medicare beneficiaries. As CMS implements this Part B demonstration, it should provide SHIPs with training and resources to inform SHIP counselors about how Part B drug changes may impact their clients. CMS should also ensure that other consumer advocacy organizations, as well as 1-800-MEDICARE customer service representatives, are adequately trained.
- Be tested with beneficiary focus groups
    - Early testing with beneficiary focus groups can help new programs avoid costly challenges down the road. For example, the FAI evaluation noted that demonstration notices had to be redesigned months *after* implementation to incorporate feedback from beneficiary testing.[11] The Part B demonstration should involve beneficiary material testing and focus groups on the front-end to preserve resources and ensure efficient implementation.
- Be designed to promote language access
    - Any notice or information distributed to beneficiaries regarding the Part B demonstration should be translated to ensure meaningful access by individuals who are limited English proficient (LEP). Approximately 5 million older adults are LEP and they are protected by federal law from discrimination on the basis of language. We expect CMS will view this demonstration as an opportunity to advance health equity and translate all Part B demonstration written materials. We recommend CMS use longstanding Health and Human Services (HHS) guidance and translate all Part B demonstration documents when a non-English language group comprises at least 5% or 1,000 LEP individuals in that demonstration area's service area.[12]

Payment Methodology

We support the payment methodology proposed by CMS for Phase I. With appropriate monitoring and oversight, we expect that beneficiaries will retain access to needed medication under this model. Further, the proposal has the potential to minimize unaffordable cost sharing and increase access to medication where there are less costly alternatives. In 2010, 14 percent of beneficiaries had Original Medicare without supplemental coverage. This population includes a disproportionate share of

[11] RTI FAI Evaluation at 28.

[12] For more language access recommendations, see: Limited English Proficient Older Adults, Justice in Aging, http://www.justiceinaging.org/our-work/focus-populations/limited-english-proficient-older-adults.

people under age 65 with disabilities, those with annual incomes between $10,000 to $20,000, and African American beneficiaries.[13] This demonstration may prove particularly valuable to this group.

Under Phase II, a range of value based purchasing strategies will be incorporated for a limited number of Part B drugs. We support testing these strategies, again emphasizing the importance of real time monitoring and feedback to assess beneficiary experience.

We appreciate CMS's careful approach to value based purchasing, including providing opportunities for further public comment about proposed tools, appropriate Part B drugs, and specific pricing proposals. We again encourage robust opportunities for public feedback on materials and messaging, including with consumers themselves, as well as consumer advocacy organizations.

We were particularly pleased to see that CMS is testing models that lower and eliminate Part B cost sharing for high value medications, but do not increase cost sharing for any medications. We strongly support the proposal to eliminate or lower cost sharing without reducing overall payments to providers. This is another area where targeted notices would be particularly helpful.

We support the development of clinical support tools, as well as complementary shared decision making tools, to help both providers and beneficiaries with prescription choices.

We support CMS' testing of reference pricing, again with an emphasis on the need for transparency. Reference pricing has been used in other countries as an effective means of closing disparity gaps in the cost of prescription drugs.[14]

In cases where providers will be paid less based on reference pricing, we strongly support the prohibition on balance billing of beneficiaries. We were particularly pleased to see that the proposed rule clearly states that "any version of reference pricing implemented would not allow for balance billing of the beneficiary for any difference in pricing." Many low-income Qualified Medicare Beneficiaries (QMBs) are currently illegally balance billed for portions of their medical bills,[15] frequently as a result of provider confusion. We support the Part B demonstration and want to ensure implementation does not add to provider confusion and balance billing. We are encouraged by recent CMS efforts to increase provider education on balance billing, and we suggest this demonstration build on those provider education efforts to ensure implementation does not have any adverse beneficiary consequences.

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[13] Cubanski, J., Swoope, C., Boccuti, C., Jacobson, G., Casillis, G., Griffin, S., and T. Neuman, "A Primer on Medicare: Key Facts About the Medicare Program and the People it Covers, What Types of Supplemental Insurance do Beneficiaries Have?" (Kaiser Family Foundation: March 2015), available at: http://kff.org/report-section/a-primer-on-medicare-what-types-of-supplemental-insurance-do-beneficiaries-have/.

[14] *See* Joy Li-Yueh Lee et al. A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending, 18 Am. J. of Managed Care 429 (2012), available at http://scholar.harvard.edu/files/nkc/files/2012_reference_pricing_systematic_review_ajmc.pdf.

[15] Centers for Medicare & Medicaid Services, Access to Care Issues Among Qualified Medicare Beneficiaries (QMB), July 2015, available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf.

We also support the testing of additional value-based purchasing strategies, such as indications-based pricing and risk sharing agreements based on outcomes. To be effective and beneficial for the older adults and persons with disabilities who rely on Medicare, such strategies must be implemented with the highest degree of transparency, public input, and a base in strong research and evidence.

Pre-Appeals Payment Exceptions Review Process

Justice in Aging supports CMS' proposal to include a Pre-Appeals Process for prescribers, suppliers, and beneficiaries who wish to challenge the payment rate for a particular medication in Phase II of the Part B Drug Payment Model. We believe this is an essential consumer protection that will help prevent unintended access problems and other beneficiary burdens.

Targeted notice and ample outreach is needed to ensure the Pre-Appeals Process is truly accessible to people with Medicare. We urge CMS to consider the following:

Clarify that the Pre-Appeals Process can be used to request lowered or eliminated cost sharing. CMS writes that the proposed Pre-Appeals Process will be available to providers, suppliers, and beneficiaries "to raise issues regarding payment that are included in the VBP [value-based purchasing] tools...[16] CMS should clarify that beneficiaries and health care providers can use the Pre-Appeals Process to request lowered cost sharing in cases where an individual has a medical need for a prescription drug not identified as high-value, particularly among a grouping where lowered cost sharing is available for specific medications and not others.

We strongly encourage CMS to allow beneficiaries to the use the Pre-Appeals Process in such instances. An equivalent process under Medicare Part D is known as a tiering exception, where a beneficiary can request the lower cost sharing amount available for a therapeutic equivalent on a lower tier of his or her Part D formulary.

Adequate notice and education will be critical in this circumstance and all others where the Pre-Appeals Process is available. Even within the structure of a Part D plan that includes pre-defined tiers, we find that beneficiaries are often unaware of their right to seek an appeal for lowered cost sharing. Targeted outreach and notification—for both beneficiaries and health care providers—will be critically important to ensuring that people with Medicare are able to fully benefit from the Pre-Appeals Process.

Protect beneficiaries from increased cost sharing. CMS should establish a "hold harmless" mechanism to protect beneficiaries from increased cost sharing when their health care providers or suppliers successfully appeal for higher payment. People with Medicare do not have control over whether or not their provider requests increased payment for a medication. Further, some of the circumstances that could give rise to a successful appeal may have nothing to do with the beneficiary. A "hold harmless" provision should ensure that beneficiaries are only charged the 20 percent coinsurance for the original (pre-appeal) cost of their medication.

[16] Medicare Program; Part B Payment Model, 81 Fed. Reg. 13230, pg. 13250 (Proposed March 11, 2016) (to be codified at 42 C.F.R. 511)

Ensure that the process is beneficiary-friendly and accessible to consumers. First and foremost, there should be "no wrong door" for beneficiaries who want to use the proposed Pre-Appeals Process. The customer service representatives at 1-800-MEDICARE and other beneficiary-facing Medicare contractors, including the Part B Medicare Administrative Contractors (MACs), should be positioned to provide consumer-friendly information about how to initiate an appeal.

In final rulemaking, CMS should clarify what information a beneficiary, provider, and supplier must provide through the Pre-Appeals Process. Particularly for beneficiary-initiated appeals, CMS should be specific about what supporting documentation is needed, especially any content that needs to be supplied by the beneficiary's provider, such as a supportive letter or medical information. Further, targeted beneficiary notices should be developed that explain this process, drawing on the best practices for notice development described above.

Thank you for the opportunity to comment. If there are questions concerning this submission, I can be reached at JGoldberg@justiceinaging.org.

Sincerely,

Jennifer Goldberg
Directing Attorney