AARP
Real Possibilities

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May 9, 2016

The Honorable Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Submitted via www.regulations.gov

Re: Medicare Program: Part B Drug Payment Model CMS-1670-P

Dear Administrator Slavitt:

AARP is pleased to comment on the proposed rule: Medicare Program: Part B Drug Payment Model ("the model"). AARP is a nonprofit, nonpartisan organization, with a membership of nearly 38 million, that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse.

Background

Older Americans use prescription drugs more than any other segment of the U.S. population, typically on a chronic basis. For older adults, prescription drugs are critical in managing their chronic conditions, curing diseases, keeping them healthy and improving their quality of life.

Last year Medicare Part B spent $22 billion on prescription drugs, double the amount spent in 2007. Beneficiary cost sharing is 20 percent with no out-of-pocket limit, leaving some older adults and people with disabilities with out-of-pocket costs that can reach as much as $100,000 per year[1] or more. Like all Americans, Medicare beneficiaries cannot continue to absorb the costs associated with skyrocketing prescription drug prices

[1] Government Accountability Office, *Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly to Beneficiaries*, October 2015.

indefinitely; the median annual income for Medicare beneficiaries is less than $25,000 and one in four have less than $12,000 in savings.[2]

Ensuring that beneficiaries can afford their prescriptions is essential. Equally important is ensuring that prescribing decisions are appropriately focused on value or choosing the lowest cost therapy to effectively treat a patient. Unfortunately, Medicare Part B current payment policies provide weak incentives for health care providers to consider value when making treatment decisions.

AARP generally supports the Centers for Medicare & Medicaid Services' (CMS) demonstration project that modifies how Medicare pays for certain prescription drugs administered by physicians and other clinicians. The proposed model aligns with ongoing efforts to shift U.S. health care away from a volume-based system to one that reimburses based on health care quality and innovation.

Given prescription drug price and spending trends, it is imperative that policymakers find ways to ensure that treatments are chosen based on how well they work and not their price tag. Thoughtful efforts to move towards higher value and improved quality of care in the Medicare Part B program are far preferable to the unsustainable escalations in beneficiary and taxpayer spending that would accompany maintaining the status quo. In what follows, we offer our comments on specific aspects of the proposed rule.

Medicare Part B reimbursement methodology is problematic

Currently, Medicare Part B pays prescribers for prescription drugs based on Average Sales Price (ASP) plus an unexplained[3] but statutorily mandated 6 percent add-on. The payment amount does not vary based on the price an individual provider or supplier pays to acquire the drug. It also does not take into account the effectiveness of a particular drug or the cost of clinically comparable drugs. Some experts have raised concerns that this methodology encourages the use of more expensive drugs -- since 6 percent of a more expensive drug generates more revenue than 6 percent of a lower priced drug, selection of the higher priced drug has the potential to generate more profit.

Multiple studies indicate the current reimbursement method may create incentives to use higher priced drugs. For example, one study found that the implementation of ASP+6 percent resulted in providers shifting patients to newer, more expensive drugs which had a higher profit margin under the new methodology.[4] Another study found that, compared with medical oncologists who were paid a fixed salary, those who were in fee-for-service Medicare practices or were paid a salary with a productivity incentive were more likely to report that their income would increase if they administered more

[2] G. Jacobson, C. Swoope, and T. Neuman, "Income and Assets of Medicare Beneficiaries, 2014-2030," Kaiser Family Foundation, September 2015.
[3] There is no consensus on the original intent of the 6 percent add-on to ASP. MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, June 2015.
[4] MedPAC, *Report to the Congress: Effects of Medicare Payment Changes on Oncology*, January 2006.

chemotherapy.[5] While more definitive study is needed, AARP believes the likelihood that the current methodology is influencing providers to use more expensive drugs over less expensive alternatives is reason enough to warrant change.

Phase I

AARP appreciates CMS' thorough review prior to suggesting changes to the current ASP+6 percent methodology. CMS evaluated several options and ultimately chose to utilize an add-on that is a fixed percentage of 2.5 percent and a flat fee of $16.80 per drug per day. CMS chose 2.5 percent because they agree with the Medicare Payment Advisory Commission's (MedPAC) assessment that this value should be sufficient to cover markups from wholesalers, such as prompt pay discounts that are not passed on to purchasers.[6] There is no credible information that suggests this percentage will not be adequate for such purposes.

AARP does not believe CMS should consider testing additional add-on approaches, such as ASP + a tiered percentage add-on amount, as it is unlikely there will be enough differences to warrant study. In addition, while AARP appreciates CMS' concerns about profit-oriented overprescribing of inexpensive drugs, we do not believe CMS should consider additional measures to limit add-on amounts. Rather than potentially dilute the incentive to prescribe what are typically generic drugs, AARP strongly encourages CMS to closely monitor provider behavior to ensure that only reasonable and necessary medications are prescribed.

CMS should only increase the flat rate for medications that have complicated or expensive packaging, storage, or administration requirements if there is adequate evidence that these factors are negatively affecting providers' ability to obtain and administer such products. For example, payment adjustments may be appropriate for medications with specific temperature storage requirements, short shelf lives, or long infusion times requiring nurse management.

AARP is aware that some providers believe that reducing the Part B add-on will make it difficult for them to purchase prescription drugs for less than the Medicare payment rate. Fortunately, drug manufacturers' responses to previous payment changes can help alleviate some of these concerns. When Medicare began paying ASP+6 percent in 2005, manufacturers responded by reducing the variation in prices across purchasers.[7] In addition, a recent MedPAC analysis found that drug makers responded to the provider payment cuts included in sequestration by lowering prices for those paying at the high end of the price range.[8] There is no reason to believe drug manufacturers will not respond similarly to a new Part B drug payment model.

[5] MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, June 2015.
[6] MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, June 2015.
[7] MedPAC, *Report to the Congress: Effects of Medicare Payment Changes on Oncology*, January 2006.
[8] J. Wilkerson, "MedPAC: Rx Makers Cut Part B Prices to Mitigate Sequester Effect on Docs," *Inside CMS*, March 10, 2016.

With appropriate monitoring and oversight, AARP is confident that beneficiaries should retain access to needed medications under the proposed model. Nevertheless, AARP strongly urges CMS to monitor the impact of the new Part B drug payment model on providers' ability to procure necessary medications. Should patient access become a legitimate concern, CMS must respond immediately.

Phase II

AARP is equally encouraged by Phase II of the Part B drug payment model. Introducing value-based purchasing tools to Medicare Part B will lead to better value and higher quality of care for Medicare beneficiaries. Many of these tools are already being used in the private sector.[9] Since CMS intends to utilize value-based purchasing tools only when there is strong clinical evidence to support their use, only a limited number of drugs will be impacted.

This proposal is consistent with other programs created by the Center for Medicare & Medicaid Innovation (CMMI). For example, the Medicare Advantage Value-Based Insurance Design demonstration beginning in 2017 will allow Medicare Advantage plans to lower or eliminate beneficiary cost sharing for high-value medications, services, and health care providers.[10] The model applies these same concepts in original Medicare.

CMS proposes to implement one or more of the following value-based purchasing strategies: reference-pricing, pricing based on safety and cost-effectiveness for different indications, outcomes-based risk-sharing agreements, and discounting or elimination of patient coinsurance amounts. Research indicates that value-based purchasing tools can lead to cost savings. For example, reference-based pricing has resulted in savings of up to 24 percent for targeted drug classes in countries like Germany, Spain, and Sweden.[11] Similarly, multiple studies indicate that risk-sharing agreements can result in savings based on experiences in both the U.S. and abroad.[12]

Importantly, beneficiary cost-sharing responsibilities under Phase II will not increase, with the option of reducing or waiving them entirely. AARP strongly supports cost

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[9] S. Barlas, "Health Plans and Drug Companies Dip Their Toes Into Value-Based Pricing," *P&T*, Vol 41(1): 39-53.

[10] Centers for Medicare & Medicaid Services, Medicare Advantage Value-Based Insurance Design Model. Available at: https://innovation.cms.gov/initiatives/vbid/

[11] J.L.-Y. Lee, M.A. Fischer, W.H. Shrank, J.M. Polinski, and N.K. Choudhry, "A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending," *American Journal of Managed Care,* Vol 18(11):e429-e437

[12] J.J Carlson, S.D. Sullivan, L.P. Garrison, P.J. Neumann, and D.L. Vennstra, "Linking payment to health outcomes: a taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers," Health Policy Vol 96(3):179-190. J.J. Carlson, L.P. Garrison, Jr., and S.D. Sullivan, "Paying for Outcomes: Innovative Coverage and Reimbursement Schemes for Pharmaceuticals," *American Journal of Managed Care*, Vol 15(8): 683-687. H.K. Leida and L.M. Wachenheim, *Risk Adjustment and Shared Savings Agreements*, Milliman Healthcare Reform Briefing Paper, January 2015. J.J. Carlson , K.S. Gries, K. Yeung, S.D. Sullivan, and L.P. Garrison, Jr., "Current status and trends in performance-based risk-sharing arrangements between healthcare payers and medical product manufacturer," *Applied Health Economics and Health Policy*, Vol 12(3): 231-238.

sharing that encourages appropriate use of high-value prescription drugs based on the clinical benefits achieved. CMS should consider utilizing this tool for high value drugs as determined by value-based purchasing tools. Reducing or eliminating cost sharing will help reduce the possibility of cost-related nonadherence and could improve health outcomes over time. CMS must be fully transparent about the evidence-base used to determine which prescription drugs are determined to be high-value and therefore eligible for reduced or eliminated cost sharing.

AARP also strongly supports CMS' decision to prohibit balance billing—a practice where a provider charges the beneficiary for the difference between the reimbursement rate and the cost of buying the prescription drug from the manufacturer. Balance billing would simply allow providers to shift higher costs to beneficiaries.

AARP is aware that some groups have raised concerns that value-based purchasing could reduce patient access to medications. However, AARP is confident that patient access should remain the same or even improve. Currently, Medicare Part B beneficiaries are responsible for 20 percent of their Part B drug costs with no limit, leaving some beneficiaries with extremely high out-of-pocket costs. Ensuring that beneficiaries are receiving the least costly effective treatment could lead to a reduction in their out-of-pocket costs, making it easier for beneficiaries to access the drugs that they need.

CMS has also repeatedly stated that patient access is their primary concern and that the proposed model will not prevent doctors from prescribing effective treatments for their patients. Furthermore, providers, suppliers and beneficiaries who decide to use a drug that is subject to value-based purchasing will have access to the existing claims approval process as well as the proposed pre-appeals payment exceptions review process.

Overall, AARP is confident that patients who require complex or unusual prescription drug regimens should not face undue hardship as a result of Phase II of this proposal. There will likely be little or no clinical evidence to guide the treatment of patients in such circumstances—meaning value-based purchasing tools will not be a factor—or they will be able to request an exception through the existing appeals processes. Nevertheless, AARP urges CMS to monitor the impact of value-based purchasing tools on providers' ability to prescribe necessary medications. Should patient access become a legitimate concern, CMS must respond immediately.

Clinical decision support tool

AARP commends CMS' proposal to create a clinical decision support tool that will support appropriate drug use and safe prescribing. The tool would be voluntary and provide transparent education and data on the use of certain Part B drugs to prescribers; such information would not interfere with or substitute for medical decision-making. CMS believes that the availability of this tool could provide physicians with better access to up-to-date information such as guidelines for effective treatments as

well as safe and appropriate drug use for specific diagnoses. AARP believes that this information will be extremely helpful for providers and could help improve quality of care. CMS must solicit feedback from providers to help ensure that the tool's content is helpful and easy-to-use. In addition, AARP strongly urges CMS to develop incentives to help encourage provider participation.

Monitoring

AARP applauds CMS' public commitment to monitoring the impact of the Part B drug payment model. We strongly recommend that CMS establish a transparent, comprehensive, and publicly available monitoring process for both Phase I and Phase II. While we anticipate the model will encourage trends in prescribing that ultimately benefit people with Medicare, we encourage the agency to carefully monitor for unintended consequences that may increase costs or present access barriers among people with Medicare.

We understand CMS expects to draw on the agency's monitoring experience with Durable Medical Equipment Prosthetic Orthotic and Supplies (DMEPOS) competitive bidding program for the model, namely through timely claims review.[13] We strongly encourage CMS to take this even further by also creating a dedicated ombudsman similar to what exists for the DMEPOS competitive bidding program. More specifically, we envision a dedicated ombudsman in the model that would answer and track provider questions and complaints, track and help resolve beneficiary problems, and troubleshoot the pre-appeals payment exceptions review process proposed in Phase II.

AARP encourages CMS to utilize a variety of monitoring techniques, including patient experience surveys and focus groups. CMS should also draw on existing resources like the Medicare Ombudsman, 1-800-MEDICARE, and the State Health Insurance Programs, among others, and ensure that they have adequate dedicated funding and personnel to perform this role.

In addition to establishing a dedicated ombudsman, we encourage CMS to identify formal processes for regularly engaging and involving Medicare beneficiaries and their advocates. AARP believes it is critically important that multiple, diverse stakeholders have the opportunity to weigh in during implementation, both to share lessons learned and to provide input on any needed mid-course corrections.

We also urge CMS to monitor how the proposed changes in payment may influence practices that require a beneficiary to obtain their medication from a pharmacy and have it brought or delivered to their health care provider for administration. This practice, known as "brown bagging," shifts coverage from Part B to Part D and can affect beneficiary cost sharing. CMS should monitor Part D claims data to see how and whether the model affects the frequency of this practice and any beneficiary cost sharing differences, particularly where increases in cost sharing result.

[13] M. Andel, "The Pew Charitable Trusts Hosts Panel Discussion on Medicare Part B Prescription Drug Payment Reform," *Applied Policy*, April 11, 2016.

Finally, CMS should develop a clear, transparent process for prompt corrective action should it become aware of widespread problems through its monitoring efforts.

Public comment and stakeholder input

AARP commends CMS for its efforts to solicit stakeholder input as it implements the model. For example, CMS intends to gather information on proposed value-based pricing tools, including which specific Part B drugs are suitable candidates for the application of specific tools. CMS also plans to post the evidence base for the content in the clinical decision support tool and consider feedback from the public before the content is finalized.

AARP also commends CMS for requesting input on a number of important and salient aspects of the proposed rule and urges CMS to ensure that any concerns are considered and addressed. The final rule should draw on this feedback to ensure the final model is designed to drive enhanced value and tested programs do not adversely affect beneficiary access or quality of care.

Appeals processes

AARP commends CMS for creating a new pre-appeals payment exceptions review process to resolve disputes arising from the policies implemented by Phase II of this model. It is intended to resolve payment disputes before the appeals process is needed. We believe this is an essential consumer protection that will help prevent unintended access problems and other beneficiary burdens.

Beneficiaries should have a variety of avenues to access the proposed pre-appeals process, including 1-800-MEDICARE and other beneficiary-facing Medicare contractors, such as Part B Medicare Administrative Contractors. CMS should also clarify what information a beneficiary, provider, and supplier must provide through the pre-appeals process. 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 clearly explain this process.

Both the appeals and pre-appeals payment exceptions review processes should be transparent, easy-to-understand, and fair in order for it to function as a true recourse for enrollees. CMS must also be willing to regularly revisit and make changes to these processes as necessary to ensure beneficiary access. CMS must also ensure researchers have access to complete appeals and pre-appeals payment exceptions review process data, and this data should be readily and publicly available.

Educational activities

AARP strongly supports CMS' commitment to engaging in educational activities, particularly those that support the implementation and testing of value-based pricing strategies. Beneficiary and provider education will also be integral to the new pre-appeals payment exceptions review process included in this payment model; both must have access to materials that inform them about new and existing appeals processes and how to navigate them properly.

CMS should carry out robust outreach and educational initiatives by drawing on existing resources. In particular, CMS should conduct active outreach and provide trainings for organizations that represent people with Medicare, State Health Insurance Assistance Programs (SHIPs), and 1-800-MEDICARE customer service representatives. We also strongly encourage including information about the model on Medicare.gov and in the Medicare & You handbook.

CMS should also utilize beneficiary focus group testing for all major communication efforts and seek feedback from consumer advocates about the content and timing of wide-scale education efforts, in addition to more targeted beneficiary communications. CMS should work closely with readability experts as the agency designs these communications.

Overall, we strongly encourage CMS to ensure that beneficiaries are well-informed about any impact this model will have on their benefits or care experience and urge CMS to make the agency's full outreach and education plans publicly available prior to implementing the model.

Model scope

AARP believes that the Part B proposal is in line with CMMI's statutory charge and authority. CMMI's ability to independently test the effectiveness and scalability of promising new payment and delivery models is critical to ensuring that policymakers and regulators have unbiased evidence to help guide their decision-making. Further, the proposed model appropriately targets a known "deficit in care," as evidenced by the number of Medicare beneficiaries who are struggling to afford necessary prescription drugs.

AARP also appreciates CMS' thoughtful approach to determining the scope of the payment model, which stems from its real-world experience implementing and evaluating other 1115A model initiatives. Full participation will help ensure that the model does not suffer from selection bias inherent to voluntary participation and that observed outcomes are generalizable. It is notable that CMS considered whether the model should only be limited to specific specialties or drugs that only treat a specific indication. However, these approaches would not allow it to observe the full impact of the proposed model, limiting their usefulness. Nonetheless, should CMS decide to

consider adjustments to the scope of the demonstration, AARP strongly urges CMS to ensure that it provides results that are generalizable to the broader population.

AARP is also pleased that CMS' implementation timeline is appropriately conservative. Phase I would begin no earlier than 60 days after the rule is finalized and Phase II would begin no sooner than January 1, 2017. Flexible timelines will give CMS adequate time to assess public input. Further, the structure of the model will allow CMS to evaluate the impact of Phase I and Phase II both together and separately. Barring unforeseen circumstances, AARP believes that the proposed five-year duration will provide CMS with enough time to fully evaluate changes and collect sufficient data.

Impact on small and/or rural practices

Although the impact on rural providers and hospitals is expected to be minimal or even favorable, CMS has explicitly solicited comments on the potential effect that this model may have on rural practices, how rural practices may differ from non-rural practices, and whether rural practices should be considered separately from other practice locations. Similarly, CMS has solicited comments on the potential effect that this model may have on small practices, how small practices may differ from large practices, and whether small practices should be considered separately from other practices. This comment opportunity will allow providers to voice any concerns and give CMS the ability to respond accordingly prior to implementation.

AARP is aware of concerns that the model might force practices that are small, rural and/or located in economically disadvantaged areas to send their Medicare patients to hospitals for outpatient drug treatment. It is notable that a similar argument was made prior to the switch to ASP+6 percent in 2005. However, MedPAC was unable to quantify the number of patients who switched their site of care due to the payment change[14] and another study found that the number of patients who received chemotherapy in a physician's office actually increased.[15]

AARP strongly urges CMS to closely monitor the model's impact on small and/or rural practices throughout the entire 5-year evaluation. CMS should consider appropriately adjusting the payment model if it discovers clear and quantifiable evidence that the Part B drug payment model is leading to shifts in care. Should patient access become a legitimate concern, CMS must respond immediately.

Drug shortages

AARP supports CMS' efforts to respond to the complications presented by drugs that are in short supply. Due to access concerns related to drug shortages, CMS will exclude drugs that are in short supply from the new payment model and instead continue utilizing the current ASP+6 percent payment amount. This safeguard will prevent the

[14] MedPAC, *Impact of Changes in Medicare Payments for Part B drugs*, January 2007.
[15] M. Jacobson, C.C. Earle, M. Price, and J.P. Newhouse, "How Medicare's Payments Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment," *Health Affairs*, 29(7): 1394-1402.

use of a payment amount that is lower than that determined using the existing statutory methodology if a drug is in short supply. AARP agrees with CMS' conclusion that there is no evidence that increasing reimbursement will have a meaningful positive effect on the resolution of drug shortages, which are typically due to factors unrelated to payment.[16]

Drug manufacturer contributions

AARP strongly supports CMS' proposal to have manufacturers provide the scientific evidence needed to create an accurate picture regarding clinical value for a specific drug. Such research would help create evidence-based competition and reduce spending on unnecessary or ineffective treatments. Several countries require drug manufacturers to provide CER as part of their coverage determination processes.[17] For example, Germany requires drug manufacturers to provide a dossier of CER studies to demonstrate that their product is better than the previously existing standard treatment. Consequently, it would not be burdensome or even unusual if CMS asked drug manufacturers to provide such studies as well. Similarly, manufacturers should be required to provide outcome measures for any outcome-based risk-sharing pricing agreement.

Evaluation guidelines

AARP appreciates CMS' explanation of how it plans to evaluate the Medicare Part B drug payment model, which will focus on whether the intervention reduces costs while improving quality of care. Key evaluation questions include important considerations like changes in Part B drug spending, changes in utilization and prescribing patterns, changes in the prices at which provider and suppliers are able to obtain Part B drugs, and the impact on quality of care, access to care, timeliness of care, and the patient experience of care. AARP also appreciates CMS' willingness to solicit comments regarding other potential questions for inclusion in the evaluation of the model. This will help ensure that the evaluation criteria reflect the needs and concerns of all stakeholders.

Conclusion

AARP applauds CMS for its commitment to improving the quality of care for Medicare beneficiaries. In light of current prescription drug price and spending trends, it is simply common sense to pursue solutions that help ensure that treatments are chosen based on how well they work. Despite some criticism, there is longstanding and widespread support for the ideas underpinning this proposal.[18] [19] Indeed, given the outlook for the

[16] Food and Drug Administration, Frequently Asked Questions About Drug Shortages, http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q3
[17] Hogan Lovells International LLP, EU Pricing & Reimbursement Newsletter, November 2014.
[18] The CMS Blog, "Wrapping up HHS's Pharmaceutical Forum: Putting Patients First and Finding a Path Forward," December 2015, https://blog.cms.gov/2015/12/10/wrapping-up-hhss-pharmaceutical-forum-putting-patients-first-and-finding-a-path-forward/

U.S. health care system, taxpayers, and beneficiaries, it is critical that CMS be able to evaluate ways to more effectively hold down prescription drug spending.

Thank you for the opportunity to comment on this important proposed rule. If you have any questions, please do not hesitate to contact me or KJ Hertz on our Government Affairs staff at khertz@aarp.org or 202-434-3770.

Sincerely,

David M. Certner
Legislative Counsel & Legislative Policy Director
Government Affairs

[19] A. Goldstein, "Sharp increases in drug costs draw hundreds to government forum," *Washington Post*, November 20, 2015, https://www.washingtonpost.com/news/to-your-health/wp/2015/11/20/sharp-increases-in-drug-costs-draw-hundreds-to-government-forum/