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POLICY & ACTION FROM CONSUMER REPORTS

May 9, 2016

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

Submitted via www.regulations.gov

RE: CMS --1670-P: Proposed Rulemaking for CMS Part B Drug Program

Dear Administrator Slavitt:

Consumers Union, the policy and advocacy division of Consumer Reports,[1] submits these comments in support of the proposed rule regarding the Medicare Part B Drug Payment Model Program. We are deeply concerned about the affordability of drugs for consumers and the growth of health system costs, both due, in part, to rising drug costs. It is imperative that we get these costs under control; they threaten our healthcare system, as well as household, federal and state budgets.

As the notice of proposed rulemaking highlighted, in 2015 Medicare spending on Part B drugs reached $22 billion, representing an average annual increase of 8.6% in Part B spending since 2007. These costs are unsustainable for our health care system and becoming farther out of reach and less affordable for many Medicare beneficiaries. The non-partisan MedPAC issued a report showing that, in general, Part B overpays for drugs and that the current payment methodology may incentivize the use of higher cost drugs. [2]

Under Medicare Part B, beneficiary cost-sharing is 20% with no out-of-pocket limit. The median income for Medicare beneficiaries is $25,000 and one in four beneficiaries has less than $12,000 in savings. [3] Many Medicare beneficiaries are financially unprepared to afford extremely expensive and potentially life-saving medicines when they are very sick.

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[1] Founded in 1936, *Consumer Reports* is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers. Using more than 50 labs, its auto test center, and survey research center, the non-profit organization rates thousands of products and services annually. Consumer Reports has over 8 million subscribers to its magazine, website, and other publications. Its policy and advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and the marketplace. This division employs a dedicated staff of policy analysts, lobbyists, grassroots organizers, and outreach specialists who work with the organization's more than 1 million online activists to change legislation and the marketplace in favor of the consumer interest.

[2] Kim Neuman, MedPAC, March 2016, http://www.medpac.gov/documents/march-2016-meeting-presentation-part-b-drug-payment-policy-issues.pdf?sfvrsn=0

[3] G. Jacobson, C. Swoope, and T. Neuman, *Income and Assets of Medicare Beneficiaries, 2014-2030*, Kaiser Family Foundation, September 2015.

Consumers are rightfully concerned about high prescription drug prices and their ability to afford them. A recent public opinion poll found that prescription drug prices and affordability are the top healthcare worry for Americans.[4] A majority (77%) responded that ensuring expensive treatments such as HIV, hepatitis, and cancer drugs are affordable to those who need them is the top priority, with government action to lower prescription drug prices a close second (63%).[5]

With high rates of annual increases in drug prices and seniors' grave concerns about affording their medications, it is critical that we not overpay for drugs or use more expensive versions when cheaper ones are a therapeutic equivalent. We share the concern stated in the Executive Summary of the proposed rule that the current payment methodology for drugs administered in a physician's office or hospital outpatient department incentivizes the use of more expensive drugs because of the higher percentage add-on.

While we believe that providers generally have their patients' best medical interest at heart and make decisions based upon this, they may not be aware of their patients' financial situation. Moreover, research shows that financial incentives and reimbursement payments to providers play a part, even if subconsciously, in provider decision making.[6] It is important to get these incentives right so that providers are able to treat their patients with the safest and most effective treatments, without unnecessarily driving up health system costs--or out-of-pocket costs for their patients.

Consumers Union strongly believes that providers, and not consumers, are the appropriate focus for payment reform initiatives designed to improve value and quality. In general, consumers only direct a very small amount of healthcare spending. [7] When it comes to Part B, they cannot make meaningful choices when it comes to the drugs covered under Part B. For these reasons, we strongly support the focus on providers as the target of payment reform measures put forth in this notice.

It is with this context in mind, that Consumers Union provides the following set of comments.

§511.1 Basics and scope

Consumers Union supports the proposed payment change for Part B Drugs from the Average Sales Price (ASP) plus 6% to ASP plus 2.5% plus an additional, flat $16.80 add-on in designated geographic areas. We share CMS's concern that the current payment model based on the 6% add-on incentivizes the use of more expensive drugs. These expensive and often life-saving drugs paid for under Part B are becoming more unaffordable for many Medicare beneficiaries as costs continue to rise, especially since beneficiaries are responsible for 20% cost-sharing with no cap on out-of-pocket costs.

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[4] Bianca DiJulio, Jamie Firth, Mollyann Brodie, *Kaiser Family Foundation Health Tracking Poll*, October 2015, http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/.
[5] Ibid.
[6] MedPAC, *Report to the Congress: Effects of Medicare Payment Changes on Oncology*, January 2006.
[7] Amanda Frost, David Newman, and Lynn Quincy, *Health Care Consumerism: Can The Tail Wag The Dog?*, Health Affairs Blog, March 2, 2016.

We believe that CMS should monitor several key areas during the demonstration project: whether the change in the payment formula leads to a change in treatment location, such as if there is a shift to more patients being treated in hospitals or hospital outpatient departments as opposed to doctors' offices. While such a shift could be due to a number of factors, including the trend of large health systems purchasing independent physician practices, we believe it should be watched closely and adjusted when necessary.

We also believe CMS should monitor beneficiary access throughout the duration of the demonstration project to ensure that it is not unintentionally hampered by the payment change. While we do not anticipate an adverse effect on beneficiary access to medically necessary medications as a result of this demonstration process, it is crucial that this be closely examined.

We suggest that CMS develop a detailed plan for monitoring issues of potential consumer concern and for addressing and adapting concerns if necessary. We urge the Agency to make this plan public and to solicit feedback from diverse stakeholders.

§511.100 Included providers and suppliers

Consumers Union supports the inclusion of all providers and suppliers who furnish Part B drugs in the Primary Care Service Areas (PCSA) included in the demonstration project. We believe that this is the best way to test the effectiveness of the model and to capture the diversity of the Medicare population.

§511.205 Model structure and duration

Consumers Union supports the stated intention to carry out this demonstration in a measured and phased manner, including the use of a control group. We support the randomization of the assignments (control or in the pilot) and mandatory participation of all who provide medications under Part B within the PCSAs that are assigned to participate in the model.

§511.305 Determination of VBP tools (phase II)

Consumers Union supports the testing of carefully calibrated value-based purchasing (VBP) tools that contain strong consumer protections. We believe that to truly make progress on our health care costs, we must collect the type of evidence that CMS proposes to collect. The duration and controlled setting that CMS proposes will greatly inform our move towards a system of payment that rewards value and quality. To safeguard Medicare beneficiaries, we suggest the following.

§*511.305(b)(1)(i) Reference pricing*

We strongly support CMS' proposed ban on balance billing in the case where Medicare providers and suppliers charge more than the "reference price" for a drug. We believe the correct target for this type of payment reform is providers, not consumers. Consumers should never be on the hook for additional charges because the provider they saw charged more than the reference price. We believe this is a crucial consumer protection and applaud the Agency for including it in the demonstration.

We also urge CMS to develop a transparent process for determining the reference price of a given treatment and to monitor for any unintended beneficiary cost or access issues throughout the duration of the project. We believe diverse stakeholders should be involved in this process, especially those who represent the best interest of beneficiaries.

§*511.305(b)(1)(ii) Indications-based pricing*

We support CMS's proposal to allow for adjustment to drug prices based on safety and cost-effectiveness--based on validated evidence--as an effective tool to incentivize providers to prescribe the most effective treatment for each individual consumer.

However, we want to ensure that consumers are adequately protected. We have several pressing questions regarding this part of the model such as: (1) how will the indication-based pricing actually work, (2) who will be responsible for making these determinations, and (3) what type of evidence will be used and will this information be made public?

While Consumers Union is supportive of the theory of using indications-based pricing as part of this demonstration project, we are concerned about the lack of a detailed proposal and how these final decisions would be made. We strongly urge CMS to be transparent in its evidence determination and to consistently engage with a diverse group of stakeholders.

§*511.305(b)(1)(iv) Discounting or eliminating patient co-insurance amounts*

We strongly support the inclusion of lower consumer cost-sharing for high-value treatments and believe this is a crucial element of VBP tools. High consumer cost-sharing affects consumer behavior and can lead consumers to forego needed treatment;[8] this should never be the case. In particular, the form of cost-sharing which is the subject of this section-- coinsurance-- is the least understood form of cost-sharing for consumers: an unknown and unknowable dollar amount.[9] We urge CMS to tie lower consumer cost-sharing to treatments that have an evidence-backed high value for specific indications, and replacing coinsurance with the better understood copay for any cost-sharing that remains.

§*511.305(b)(2) Clinical decision support*

We support the proposal to offer evidence-based clinical decision support for providers, which--if well-designed and adopted by providers--would encourage appropriate use of health care services.

At the same time, we note that in some limited instances--such as the federal HHS antiretroviral treatment guidelines and the hepatitis C recommendations developed by the American Association of the Study of Liver Disease and the Infectious Disease Society of America--guidelines initially may not be peer-reviewed because the peer review process simply has not caught up with the pace at which new drugs are approved and/or treatment data is released. We,

[8] The Commonwealth Fund, *The Problem of Underinsurance and How Rising Deductibles Will Make It Worse, Findings from the Commonwealth Fund Biennial Health Insurance Survey*, (2014); http://www.commonwealthfund.org/publications/issue-briefs/2015/may/problem-of-underinsurance.
[9] *What's Behind the Door: Consumers' Difficulties Selecting Health Plans* (January 2012). Health Policy Brief from Consumers Union.

therefore, recommend that clinical decision support tools be inclusive of specialty guidance especially during the period between when new treatments become available and when peer-reviewed guidance is published.

§*511.305(c) Beneficiary cost-sharing*

We support the statement that beneficiary cost-sharing should not exceed the current 20% limit on cost-sharing. Yet, at the same time, consumer cost-sharing set at 20% does not do enough to make Part B medicines affordable for many beneficiaries. We therefore urge CMS to develop and test beneficiary cost-sharing reductions during Phase II of the payment demonstration project.

§511.315 Pre-appeals Payment Exceptions Review Process

Consumers Union strongly supports the inclusion of a pre-appeals process as we believe a robust appeals process is a critical consumer protection. We believe CMS should extend the pre-appeals process to consumers who want to appeal for lower cost-sharing for a drug that has not been identified as high-value, but for which they have a pressing medical need.

We have concerns about this process applying to beneficiaries, providers, and suppliers in the same manner. Not only are providers and suppliers much better equipped to deal with this type of process in terms of the sophisticated knowledge and time required to file an appeal, but they also are the least vulnerable to the effects of financial incentives. To this end, we urge the Agency to create a separate, beneficiary-only appeals channel that streamlines and simplifies this process for consumers.

Additionally, we strongly believe CMS should make clear in the final rule that consumers will be held harmless in the case where a provider or supplier successfully appeals for a higher payment. We urge this clarification to ensure that beneficiaries only have to pay the maximum 20% cost-sharing on the original, pre-appeals cost of their treatment.

Conclusion

Consumers Union supports the Part B demonstration project and applauds CMS' attention to the serious problem of drug affordability. We believe CMS is right to test a new payment model to see if it improves value and helps control rising costs. In order to make progress on the pressing issue of healthcare costs, we must move towards a value-based payment system. We believe the best way to do so is through this type of carefully planned and implemented demonstration.

We urge the Agency to implement the proposed demonstration project and to monitor and analyze the effects on beneficiary access, cost-sharing, and overall costs.

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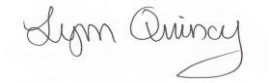
Respectfully submitted,



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