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Energy & Commerce Committee, Subcommittee on Health

"The Obama Administration's Medicare Drug Experiment:
The Patient and Doctor Perspective"

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**Introduction:**

Chairman Pitts, Ranking Member Green, and distinguished members of the Subcommittee on Health, I am Joe Baker, President of the Medicare Rights Center (Medicare Rights). Medicare Rights is a national, non-profit 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.

Thank you for the opportunity to testify on the proposed Part B Drug Payment Model.[1] Medicare Rights supports the proposed model.[2] The model seeks to realign perverse payment incentives, while ensuring that health care providers can continue to prescribe the Part B medications best suited to the needs of individual patients. It also brings innovative, value-based payment strategies being used in the private market to the Medicare program.

Through the notice-and-comment rulemaking process, our organization submitted detailed comments on the proposal, including recommendations to strengthen the model through enhanced monitoring and oversight, well-planned outreach and education, and established processes for consumer and patient engagement.[3]

We applaud the Centers for Medicare & Medicaid Services (CMS) for soliciting input on the payment model, and we encourage CMS to carefully weigh comments submitted by diverse stakeholders. Similarly, we urge members of Congress to ensure that the payment model moves forward with refinements that reflect reasonable concerns and recommendations identified through the comment process.

[1] Medicare Program; Part B Payment Model, 81 Fed. Reg. 13230 (Proposed March 11, 2016) (to be codified at 42 C.F.R. 511) (hereafter Part B Drug Payment Model)
[2] Letter from Joe Baker, Medicare Rights Center, to HHS Secretary Slyvia Mathews Burwell and CMS Acting Administrator Andy Slavitt (April 6, 2016), available at: http://medicarerights.org/pdf/040616-ltr-on-proposed-partb-model.pdf
[3] Medicare Rights Center, "RE: Medicare Program; Part B Drug Payment Model; Proposed Rule," (May 9, 2016), available at: http://medicarerights.org/pdf/050916-comments-partb-rx-payment-model.pdf

As defined in statute, Center for Medicare & Medicaid Innovation (CMMI) demonstrations are intended to address documented "…deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."[4] Through over two decades of experience counseling people with Medicare and their families, we can attest that the proposed payment model has the potential to alleviate persistent "deficits in care."

Medicare Rights answers nearly 17,000 questions on its national helpline and provides educational tools and resources to over two million beneficiaries, family caregivers, and professionals annually. Challenges affording needed health care are a common theme heard on our helpline, affecting nearly one in five callers.[5] Sky-high cost sharing for Part B prescription drugs is a notable concern, most often for cancer and immunosuppressant medications.[6]

Many of these cases involve beneficiaries with Original Medicare who lack adequate supplemental coverage. Estimates suggest that between 10 to 14 percent of beneficiaries have only Original Medicare, and are therefore responsible for a 20 percent coinsurance on all Part B services.[7] This population includes a disproportionate share of people under age 65 with disabilities, those with annual incomes between $10,000 to $20,000, and African American beneficiaries.[8] High coinsurance coupled with the absence of an out-of-pocket maximum on annual cost sharing expose these beneficiaries to catastrophic costs, which can range from as high as $1,900 to $107,000 for the most expensive Part B medications.[9]

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[4] 42 U.S.C 1315a (b)(2)(A)

[5] Morales, S., Bennett, R., and S. Sanders, "Medicare Trends and Recommendations: An Analysis of 2013 Call Data from the Medicare Rights Center's National Helpline," (March 2015), available at: http://www.medicarerights.org/pdf/2013-helpline-trends-report.pdf

[6] Unpublished analysis of Medicare Rights Center national helpline calls from January 2015 through March 2016

[7] Government Accountability Office (GAO), "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; 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/;

[8] 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/

[9] Government Accountability Office (GAO), "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

In addition to our direct experiences serving people with Medicare, our support for the Part B Drug Payment Model is informed by our commitment to transforming how the Medicare program pays for care. The proposed model is aligned with ongoing efforts in delivery and payment system reform to shift payment away from a volume-based system to one that reimburses on the basis of health care quality and promotes innovation. The goals behind the payment model are entirely consistent with bipartisan reforms advanced through the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. MACRA was overwhelming supported by members of Congress and is now being implemented.[10]

Transitioning Medicare to a system that reimburses on the basis of value is an aim supported by diverse voices throughout the health care system, including patients and consumers, physicians, hospitals, health insurers, and more.[11] This objective will not be realized if pursued only in silos, meaning that prescription drugs—including Part B medications—must be a part of these reforms. The proposed payment model provides a platform to achieve this end, through the testing and evaluation of multiple strategies.

Beyond improving the quality of care delivered to beneficiaries, the proposed model may also help to support the Medicare program by promoting more efficient use of program funds. Last year, Medicare Part B spent $22 billion on prescription drugs—double the amount spent in 2007.[12] This presents yet another reason why Congress should support CMS in moving the Part B Drug Payment Model forward.

Calls to withdraw the Part B Drug Payment Model fail to acknowledge the very real and unrelenting beneficiary access challenges that exist under the current payment system—not merely hypothetical ones. We applaud CMS for proposing to test solutions that have the

[10] See, CMS, "Quality Payment Program: Delivery System Reform, Medicare Payment Reform, & MACRA," (2016), available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html

[11] For example, see the Committed Partners of the Health Care Payment and Learning Action Network (HCP LAN): https://hcp-lan.org/about-us/committed-partners/; Also, see the membership of the Health Care Transformation Taskforce: http://www.hcttf.org/members/. Medicare Rights Center is a member of the Consumer/Patient Affinity Group of the HCP LAN and the Advisory Group for Consumer Priorities for the Health Care Transformation Taskforce.

[12] Part B Drug Payment Model, pg. 13231

potential to alleviate calamitous cost burdens, which cause too many older adults and people with disabilities to forgo necessary care. We urge members of Congress to support and strengthen the proposal by recommending improvements that put patients at the center of the payment model and all other CMMI programs.

**Current Reimbursement System for Part B Prescription Drugs:**

Under the current system, Part B medications are reimbursed at Average Sales Price (ASP) plus 6 percent. According to the Medicare Payment Advisory Commission (MedPAC), there is no clear historical basis for this percentage-based add-on, which is mandated through statute.[13] This reimbursement scheme does not account for actual acquisition, storage, or dispensing costs, clinical effectiveness, or the cost of clinically comparable prescription drugs.

CMS expresses concern that the current reimbursement formula indiscriminately favors higher-priced medications, writing in the proposed rule, "Under this methodology, expensive drugs receive higher add-on payment amounts than inexpensive drugs while there are no clear incentives for providing high value care, including drug therapy."[14] Similarly, MedPAC states, "Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs."[15]

Some research is available to support the supposition that some providers may be more likely to prescribe a medication that will increase payment over an equally effective lower-cost medication, leading to increased costs for the Medicare program and higher cost sharing for

[13] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System, Chapter 3: Part B Drug Payment Policy Issues," (June 2015), available at: http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-(june-2015-report).pdf?sfvrsn=0

[14] Part B Drug Payment Model, pg. 13231

[15] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System, Chapter 3: Part B Drug Payment Policy Issues," (June 2015, pg. 61), available at: http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-(june-2015-report).pdf?sfvrsn=0

people with Medicare.[16] Given this, Medicare Rights supports moving away from the perverse incentives inherent to a purely percentage-based payment formula. The model presents an opportunity to test multiple payment strategies to realign the incentives in the current system.

**Phase I:**

Under Phase I of the Part B Drug Payment Model, CMS proposes to reimburse some health care providers at ASP + 2.5 percent + a flat-fee (test group) and others at the current formula, ASP + 6 percent (control group) and then to evaluate and compare those groups. Decreasing the difference in the reimbursement rates between higher- and lower-cost prescription drugs among those in the test group is intended to neutralize the payment incentive favoring higher-cost medications, allowing health care providers to make clinically-driven—rather than economically-pressured—decisions.

Our organization supports the payment methodology proposed by CMS and informed by MedPAC analysis.[17] With appropriate monitoring and oversight, Medicare Rights believes that beneficiaries will retain access to needed medications under the proposed model. The payment change in the Phase I test group simply redistributes the incentive to encourage prescribing of high-value medications where there is a choice.

The changes contemplated in Phase I could prove to both lower costs and improve care quality. Health care providers may be encouraged to prescribe lower-cost medications when appropriate, leading to improved affordability and access among people with Medicare. Additionally, a revised payment model may exert downward pressure on overall drug prices. That, in turn, will also help will lower costs for both the Medicare program and beneficiaries.

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[16] For example, see: Whoriskey, P., Keating, D., and L.H. Sun, "Cost of drugs used by Medicare doctors can vary greatly by region, analysis finds, (April 19, 2014) *Washington Post*, available at: https://www.washingtonpost.com/business/economy/cost-of-drugs-used-by-medicare-doctors-can-vary-greatlyby-region-analysis-finds/2014/04/09/69ac93f0-c024-11e3-b574-f8748871856a_story.html; Jacobson, M. et al., "Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?" (March 2006) Health Affairs Vol. 25, No. 2, available at: http://content.healthaffairs.org/content/25/2/437.full

[17] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System, Chapter 3: Part B Drug Payment Policy Issues," (June 2015), available at: http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-(june-2015-report).pdf?sfvrsn=0

**Phase II:**

Medicare Rights is similarly encouraged by the value-based purchasing strategies incorporated in Phase II of the payment model. The concepts and goals reflected in Phase II are aligned with efforts to transition Medicare from a volume- to value-based payment system and to incentivize high-value clinical decision-making. By testing a variety of reimbursement methods and value-based purchasing innovations already in use in the private insurance market, Phase II will promote utilization of the most clinically effective medications—not the most costly.

Specifically, CMS proposes to test reference pricing, indication-specific pricing, outcomes-based risk-sharing agreements, and discounting or eliminating Part B coinsurance amounts. The model also incorporates clinical decision support tools that reflect up-to-date literature and consensus guidelines for use on a voluntary basis.

Medicare Rights appreciates that the payment model incorporates a transparent process for determining which prescription medications are appropriate for Phase II testing. For each of the value-based purchasing tools identified, it is critically important that CMS engage in—and Congress encourage—an open and deliberative dialogue for determining which medications are best suited to each of the specific tools. Our organization recommends the following options to strengthen the notice and comment process proposed to select medications for Phase II:

- Engage diverse stakeholders, especially clinicians, prior to notice and comment;
- Rely on the highest-quality evidence, including randomized trial designs where possible;
- Emphasize evidence from neutral and/or independent sources; and
- Release all evidence used as part of the notice and comment process.

In particular, Medicare Rights strongly supports lowering or eliminating Part B cost sharing for high-value medications through Phase II. Empirical literature on patient behavior makes clear that indiscriminate increases in cost sharing are shown to deter access to both necessary and unnecessary health care and that such increases have a disproportionate impact on lower-income,

vulnerable populations.[18] Conversely, evidence demonstrates that decreases in cost sharing can improve adherence and may contribute to improved outcomes, such as through reduced hospitalizations and emergency room visits.[19]

As discussed above, a transparent process for determining which Part B medications are "high-value" and therefore eligible for lowered or eliminated coinsurance is essential. Adequate beneficiary notice and provider education are also fundamentally important to promoting the successful use of this particular value-based tool.

Medicare Rights also strongly supports developing clinical decision support tools to assist health care providers in making the best treatment and prescription choices for their patients. This Phase II strategy appropriately reflects that health care providers—rather than patients—determine health care utilization trends. Our organization encourages CMS to develop complementary shared decision-making tools as a companion to the clinical decision support tools in order to further promote truly person-centered care.

Additionally, Medicare Rights commends CMS for including essential consumer protections specific to the value-based tools selected for Phase II. For example, with respect to reference pricing, our organization strongly supports the agency's proposed prohibition on 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.

Importantly, Phase II also includes a Pre-Appeals Payment Exception Review Process (Pre-Appeals Process) for use by health care providers, suppliers, and beneficiaries who wish to challenge a particular payment rate under each of the proposed value-based purchasing tools. This is a crucial protection that will help prevent unintended access problems and other

[18] Swartz, K. "Cost-Sharing: Effects on Spending and Outcomes" (Robert Wood Johnson Foundation Research Synthesis Report No. 20: December 2010

[19] V-BID Center, "The Evidence for V-BID: Validating an Intuitive Concept," (November 2012), available at: http://vbidcenter.org/wpcontent/uploads/2014/11/V-BID-brief-Evidence-Nov2012.pdf

beneficiary burdens. Yet, additional information is needed to ensure the Pre-Appeals Process is truly accessible to people with Medicare.

First and foremost, CMS should clarify how the Pre-Appeals Process will affect beneficiary cost sharing. Medicare Rights encourages CMS to allow beneficiaries and providers to 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. In addition, the agency should implement a "hold harmless" provision to shield beneficiaries from higher cost sharing when their provider or supplier successfully appeals for higher payment.

In addition, CMS must make explicit what information will be required for beneficiaries, providers, and suppliers to successfully request a pre-appeal, including any medical information or provider statements. For people with Medicare, information about how to access the Pre-Appeals Process should be made available in beneficiary-friendly formats and through multiple avenues, including 1-800-MEDICARE and all relevant contractors.

**Model Design:**

Throughout the notice-and-comment rulemaking process, CMS sought input on overarching design elements of the Part B Drug Payment Model, applicable to both Phase I and Phase II. Below our organization provides recommendations on several such elements:

**Demonstration size and scope:** As noted above, Medicare Rights believes that the Part B Payment Model is in line with CMMI's statutory charge and authority. CMMI serves an important function, providing policymakers and regulators with unbiased evidence on the effectiveness and scalability of promising new payment and delivery models. Our organization appreciates that CMS designed the proposed payment model with this purpose in mind.

Full participation by Medicare providers will help ensure that the payment model does not suffer from selection bias inherent to voluntary participation and that observed outcomes are

generalizable. Medicare Rights recommends that CMS carry out a demonstration that allows for generalizable results and adequate comparisons among varying payment strategies, and we urge members of Congress to support CMS in carrying out this objective.

**Monitoring and oversight:** Medicare Rights anticipates that the proposed model will encourage trends in prescribing that ultimately benefit people with Medicare, such as by promoting enhanced access to Part B medications through lowered cost sharing where there is a choice among equally-effective but differently-priced alternatives. Recognizing that changes to payment may result in unintended consequences, CMS should be proactive in anticipating these and identifying mechanisms to guard against any beneficiary harms, such as diminished access. For this reason, our formal comments on the Part B Drug Payment Model detail extensive recommendations on monitoring and oversight policies that CMS should adopt in the final rule.

Specifically, Medicare Rights recommends that CMS create robust feedback loops to monitor beneficiaries' and providers' experiences throughout the proposed model and respond in real time to potential problems. To facilitate this process, CMS should:

- Establish a dedicated ombudsman program;
- Create formal processes to involve multiple, diverse stakeholders on an ongoing basis;
- Monitor for specific shifts in prescribing and dispensing; and
- Publicly release the agency's plans for program monitoring and corrective action.

According to CMS, the agency will draw on its monitoring experience with the Durable Medical Equipment Prosthetic Orthotic and Supplies (DMEPOS) competitive bidding program for the Part B Drug Payment Model, namely through timely claims review.[20] In our view, claims monitoring is not the only consumer protection that should be carried over from the DMEPOS

[20] Comments by Dr. Patrick Conway at Pew Charitable Trusts, "Public Forum on the Medicare Part B Drug Payment Model," (April 11, 2016), recording available at: http://www.pewtrusts.org/en/about/events/2016/public-forum-on-the-medicare-part-b-drug-payment-model

program. In 2008, Congress mandated the establishment of a dedicated ombudsman for the DMEPOS program through the Medicare Improvements for Patients and Providers Act.[21]

Similar to this, our organization envisions a dedicated ombudsman for the Part B Drug Payment Model that would answer and track provider questions and complaints, resolve beneficiary problems, troubleshoot appeals, and report to Congress and CMS on its findings. This is only one example of a constructive recommendation that Congress can endorse to ensure the proposal incorporates adequate mechanisms to monitor the experiences of both beneficiaries and health care providers as the payment model is implemented.

In addition to developing adequate oversight tools, it is critical that CMS track potential shifts in Part B prescribing and dispensing identified through notice-and-comment rulemaking. Medicare Rights anticipates two such potential trends, including:

Shifting from Part B to Part D: CMS should monitor for how the proposed changes in payment may influence "brown bagging" and "white bagging" practices wherein a beneficiary must obtain their medication from a pharmacy or specialty pharmacy and bring it or have it delivered to their health care provider for administration. This practice shifts coverage from Part B to Part D and can significantly affect beneficiary cost sharing. Depending on the individual's Medicare coverage, some see lower cost sharing as a result of this shift, while others pay more.

Shifting from community-based to outpatient hospital settings: Since the Part B drug payment model was initially proposed, our organization continues to hear concerns about the potential for the proposed changes in reimbursement to result in limited access to Part B medications among beneficiaries who see individual practitioners or who receive care in community-based settings, shifting those individuals to outpatient hospitals and hospital-affiliated clinics that can afford to supply the medications.

[21] CMS, "Competitive Acquisition Ombudsman, Frequently Asked Questions (FAQ)," (March 2015), available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Competitive_Acquisition_Ombudsman_FAQ.html

Medicare Rights shares this concern, though we note that these shifts are already an observable trend among our helpline callers, where we hear from individuals who must pay facility fees in addition to standard cost sharing amounts for Part B services. Some experts attribute this trend to widespread consolidation in the health care market and notable increases in the acquisition of independent physician practices by hospital systems.[22]

CMS should monitor for these potential shifts in site of service—tracking prescription drug utilization according to provider type, geographic location, practice size, provider acquisition costs, and other characteristics. Where the agency uncovers notable shifts resulting from the model, supported by data, Medicare Rights will encourage CMS to adjust the demonstration.

It is noteworthy that CMS solicited specific comment on how the proposed model could affect rural health care providers. While the impact on such providers is expected to be minimal or even favorable, CMS should be responsive to the potential for site of service shifts in rural communities, while also ensuring that a demonstration can go forward that allows for adequate testing of the identified payment strategies.

Again, Medicare Rights believes concerns related to shifts in coverage or site of service would be best addressed through comprehensive monitoring and oversight systems, like those recommended above. Congress should embrace these tools to address the concerns raised by some in provider and insurer communities about potential shifts in prescribing practices, including from Part B to Part D coverage as well as from community-based to hospital settings.

**Outreach and education:** In addition to the monitoring and oversight mechanisms described above, Medicare Rights encourages CMS to carry out carefully designed outreach and educational initiatives. Specifically, our organization recommends that CMS:

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[22] Comments by Dr. Peter Bach at Pew Charitable Trusts, "Public Forum on the Medicare Part B Drug Payment Model," (April 11, 2016), recording available at: http://www.pewtrusts.org/en/about/events/2016/public-forum-on-the-medicare-part-b-drug-payment-model; See also, B. Kutscher, "Making physicians pay off. Hospitals struggle to balance current costs with future benefits of employing docs," *Modern Health Care* (February 22, 2014), available at: http://www.modernhealthcare.com/article/20140222/MAGAZINE/302229986

- Leverage existing resources for beneficiary outreach and education;
- Conduct beneficiary focus groups to test language describing the model;
- Involve consumer advocates in content development; and
- Develop targeted beneficiary notices where necessary.

CMS should work closely with consumer advocates, utilize focus groups, consult readability experts, and promote language access as the agency designs communications related to the Part B Drug Payment Model. These are best practices that CMS should adhere to—and Congress should encourage—in the development of all beneficiary-facing notices and resources.

**Program evaluation:** Medicare Rights supports the agency's plan to collect representative information from a wide and diverse array of health care providers, suppliers, and beneficiaries to evaluate the impact of the Part B Drug Payment Model on cost and quality. CMS proposes to use Part B claims data as the primary source of information for the program evaluation and suggests that the agency may also use surveys.

Medicare Rights strongly recommends that CMS incorporate surveys in the program evaluation, most importantly using patient-experience surveys to track the beneficiary experience under the model. The program evaluation should also directly address the potential shifts in prescribing and dispensing described above, specifically from Part B to Part D coverage as well as from community-based to hospital settings.

**Conclusion:**

As Congress evaluates the Part B Drug Payment Model, we encourage members to support the merits of the proposed adjustments to reimbursement incorporated in Phase I, the private market value-based payment strategies selected for Phase II, and the thoughtfully designed consumer protections outlined in the proposal. While improvements can and should be made—including those recommended above—Medicare Rights strongly believes the model should proceed.

Prohibiting the payment model from moving forward would perpetuate a system that allows those with less to go without needed care, halt progress in transforming how the Medicare program pays for care, and saddle taxpayers with the mounting and unrestrained cost of prescription drugs. People with Medicare and taxpayers deserve a Medicare program that pays for high-value, innovative health care. The Part B Drug Payment Model presents an important opportunity to ensure that the Medicare program meets this high bar.