



May 9, 2016

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1670-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

**RE: Medicare Program; Part B Drug Payment Model; Proposed Rule**

The Medicare Rights Center (Medicare Rights) is pleased to submit comments on the Part B Drug Payment Model.<sup>1</sup> Medicare Rights is a national, nonprofit 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. Medicare Rights provides services and resources to over two million beneficiaries, family caregivers, and professionals annually.

The following comments are informed by our experience working with Medicare beneficiaries and their families, particularly those who experience challenges accessing needed Part B prescription drugs, those receiving care through demonstration programs under the Center for Medicare & Medicaid Innovation (CMMI), and those in the Durable Medical Equipment Prosthetic Orthotic and Supplies (DMEPOS) competitive bidding program.

For additional information, please contact Casey Schwarz, Senior Counsel for Education and Federal Policy, at [CSchwarz@medicarerights.org](mailto:CSchwarz@medicarerights.org) or 212-204-6271 and Stacy Sanders, Federal Policy Director, at [SSanders@medicarerights.org](mailto:SSanders@medicarerights.org) or 202-637-0961.

**Background**

Medicare Rights supports the proposed Part B Drug Payment Model.<sup>2</sup> 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. Medicare Rights remains strongly supportive of commitments made by the U.S. Department of Health and Human Services (HHS) to transition the Medicare program to a high-value health care system, aiming to increase health care quality while reducing costs.

The proposed model seeks to achieve these goals by testing strategies that are consistent with other programs presented by CMMI. For example, select strategies identified in Phase II are similar to those proposed through the

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

<sup>2</sup> Letter from J. Baker to HHS Secretary Burwell and CMS Acting Administrator Slavitt (April 6, 2016), available at: <http://medicarerights.org/pdf/040616-ltr-on-proposed-partb-model.pdf>

Medicare Advantage Value-Based Insurance Design (MA V-BID) demonstration beginning in 2017 in seven states.<sup>3</sup> The MA V-BID demonstration will allow Medicare Advantage plans to lower or eliminate beneficiary cost sharing for high-value medications, services, and health care providers. The Part B Drug Payment Model applies these same concepts in Original Medicare.

In keeping with the demonstration authority of CMMI, the proposed model appropriately targets known “deficits in care.” We regularly counsel older adults and people with disabilities who cannot access Part B medications. Some of these 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, such as through adjustments to provider reimbursement in Phase I and direct reductions in beneficiary cost sharing in Phase II. The demonstration will also promote enhanced education among health care providers about evidence-based prescribing and test value-based purchasing tools already in use in the private market. These initiatives have the potential to increase beneficiary access to the highest value medications, while also slowing Medicare spending on prescription drugs.

Medicare Rights appreciates the opportunity to provide detailed comments on the proposal and applauds the Centers for Medicare & Medicaid Services (CMS) for engaging a wide range of stakeholders through formal notice-and-comment rulemaking. We urge CMS to formally involve Medicare beneficiaries and their advocates as the agency finalizes the model design and during implementation.

### **Recommendations on Monitoring and Oversight**

CMS should create robust feedback loops to monitor beneficiaries’ experiences throughout the proposed model and to respond in real time to potential problems. To facilitate this, we urge CMS to adopt the following strategies:

- Establish an ombudsman program, modeled after the DMEPOS competitive bidding program;
- Create formal processes to involve multiple, diverse stakeholders on an ongoing basis;
- Monitor for specific shifts in prescribing and dispensing (e.g., Part B to Part D); and
- Publicly release the agency’s plans for program monitoring and corrective action.

We understand that CMS expects to draw on the agency’s monitoring experience with the DMEPOS competitive bidding program for the Part B Drug Payment Model, namely through timely claims review.<sup>4</sup> We strongly encourage CMS to take this further by creating a dedicated ombudsman for the Part B Drug Payment Model, as exists for the DMEPOS competitive bidding program—the Competitive Acquisition Ombudsman (CAO).

The CAO provides timely information and assistance to both Medicare beneficiaries and suppliers. The CAO is also responsible for reporting on the successes and challenges associated with the DMEPOS competitive bidding program to both CMS and Congress. Our experience with the CAO is overwhelmingly positive. The CAO meets with consumer and patient advocates on a quarterly basis and is responsive to direct referrals from our helpline, in addition to managing casework escalated from CMS regional offices and 1-800-MEDICARE. Additionally, we find that CAO-generated materials are very useful, especially the beneficiary “Know Your Rights” pamphlets.

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<sup>3</sup> See here for more on the MA V-BID demonstration: <https://innovation.cms.gov/initiatives/vbid/>

<sup>4</sup> 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>

We believe the CAO model is particularly well suited to the Part B Drug Payment Model because it serves a dual purpose, serving both providers and beneficiaries. Like with the DMEPOS competitive bidding program, the Part B Drug Payment Model will directly affect health care providers and Medicare beneficiaries. Similar to the CAO, we envision a dedicated ombudsman in the Part B Drug Payment Model that would answer and track provider questions and complaints, resolve beneficiary problems, troubleshoot the Pre-Appeals Payment Exceptions Review Process (Pre-Appeals Process) proposed in Phase II, report to Congress and CMS on its findings, and more.

In addition to establishing a dedicated ombudsman, we encourage CMS to identify formal processes for regularly engaging and involving Medicare beneficiaries and the organizations that represent them as the agency carries out the proposed model. For this model and all other CMMI programs, we believe 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 mid-course corrections.

For instance, while we appreciate that the Part B Drug Payment Model includes a public comment process for identifying the prescription drugs included in Phase II, we would encourage more regular involvement and opportunities for comment by diverse groups. To serve this end, CMS could appoint a formal advisory committee, consisting of patient and consumer advocates, health care providers, pharmaceutical makers, and so forth. Alternative options include maintaining a list of interested parties from whom CMS will regularly solicit input or setting up Technical Expert Panels (TEPs) on topics where CMS is looking to revise or shift the model.

We strongly recommend that CMS establish a robust monitoring process for both Phase I and Phase II. While we anticipate that 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 encourage CMS to develop a robust plan to monitor for the following potential shifts in how Part B medications are prescribed and dispensed:

**Shifting from Part B to Part D:** We urge CMS to 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.

For example, a beneficiary with comprehensive Medigap coverage will likely pay more for a medication supplied by a pharmacy (covered under Part D) than one supplied by a physician (covered under Part B). We recently counseled a Medigap enrollee on our national helpline whose Part D copayment for an injectable osteoporosis medication totaled over \$400. When the beneficiary located a physician willing to supply the medication, her Medigap plan covered the Part B coinsurance in full—a \$0 cost to the beneficiary.

CMS should review Part D claims data to see how and whether the Part B Drug Payment Model affects the frequency of this practice and monitor for differences in beneficiary out-of-pocket costs, particularly where increases in cost sharing result. Further, reductions in Part B costs that are solely attributable to shifting between different parts of the Medicare program should be accounted for in the evaluation of the demonstration.

**Shifting from community-based to outpatient hospital settings:** Since the Part B drug payment model was initially proposed, we continue to hear concerns from some in the provider community 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.

We share 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.

We believe that concerns related to these potential shifts in site of service can be appropriately addressed through adequate and detailed monitoring—tracking prescription drug utilization according to provider type, geographic location, practice size, differences in provider acquisition costs, and other characteristics. Where CMS uncovers notable shifts, supported by data, as the proposal is implemented, we will encourage the agency to appropriately adjust the payment model. To the extent possible, CMS’ monitoring of these potential trends should account for outside variables that may also contribute to site of service shifts.

Finally, we urge CMS to make the agency’s full monitoring and oversight plans publicly available prior to carrying out the model. We also recommend that CMS develop and release a public plan for corrective action, should the agency observe unintended consequences, like those noted above, that limit beneficiary access to needed care.

### **Recommendations on Beneficiary Outreach and Education**

In addition to the monitoring and oversight mechanisms described above, CMS should carry out carefully designed outreach and educational initiatives. Specifically, we encourage the agency to:

- Leverage existing resources for beneficiary outreach and education;
- Conduct beneficiary focus groups and involve consumer advocates in content development; and
- Develop targeted Phase II notices on beneficiary cost sharing and the Pre-Appeals Process.

Drawing on current resources and tools, CMS should conduct active outreach and provide trainings on the model 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 Part B Drug Payment Model on Medicare.gov and in the Medicare & You handbook.

CMS should utilize beneficiary focus group testing and seek comment from consumer and patient advocates about the content and timing of wide-scale education efforts, in addition to more targeted beneficiary communications, such as notices. While we do not believe that all parts of the Part B Drug Payment Model require direct notice to beneficiaries, it is essential to develop Phase II notices on potential reductions in beneficiary cost sharing and the availability of the Pre-Appeals Process.

CMS should work closely with consumer advocates, utilize focus groups, consult readability experts, and promote language access as the agency designs these communications. We believe these are best practices that CMS should adhere to in the development of all beneficiary-facing notices and communication tools.

## **III. Payment Methodology**

### **A. Phase I**

Medicare Rights has long supported the need to reexamine provider reimbursement for Part B prescription drugs.<sup>5</sup> We appreciate that the proposed Part B Drug Payment Model seeks to address the perverse incentives to prescribe higher cost medications inherent in a purely percentage-based payment structure, currently Average Sales Price (ASP) + 6 percent. Some research is available to support the supposition that some health care 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 people with Medicare.<sup>6</sup>

Under Phase I of the Part B Drug Payment Model, CMS would alter this incentive, reimbursing some health care providers at ASP + 2.5 percent + a flat-fee (test group) and others at ASP + 6 percent (control group). 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.

CMS proposes to evaluate and compare the test group and control group. We appreciate CMS' consideration of how different add-on percentages or flat fees could incentivize different prescribing patterns. We support the payment methodology proposed by CMS and supported by the work of the Medicare Payment Advisory Commission (MedPAC).<sup>7</sup> We encourage the agency to refer to MedPAC's ongoing work in this area as CMS carries out the Part B Drug Payment Model and considers future options for testing.<sup>8</sup>

With appropriate monitoring and oversight, we believe 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. Health care providers are still paid more than the average cost of the medication and can continue to prescribe according to patient needs.

Importantly, the proposal has the potential to minimize unaffordable cost sharing and increase access for costly medications where there are equally effective, lower cost alternatives. This is particularly important for those who lack adequate supplemental coverage, exposing them to the 20 percent coinsurance for all Part B services.

In 2010, 14 percent of beneficiaries had Original Medicare without supplemental coverage. 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.<sup>9</sup> High coinsurance coupled with the absence of an out-of-

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<sup>5</sup> Sanders, S. and Veghte, B., "A Winning Strategy for Medicare Savings: Better Prices on Prescription Drugs," (Medicare Rights Center and Social Security Works: July 2014), available at: <http://www.medicarerights.org/pdf/drug-savings-brief-july-2014.pdf>

<sup>6</sup> 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-greatly-by-region-analysis-finds/2014/04/09/69ac93f0-c024-11e3-b574-f8748871856a\\_story.html](https://www.washingtonpost.com/business/economy/cost-of-drugs-used-by-medicare-doctors-can-vary-greatly-by-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>

<sup>7</sup> 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](http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-(june-2015-report).pdf?sfvrsn=0)

<sup>8</sup> Neuman, K., and N. Ray, "Part B Drug and Oncology Payment Issues," Presentation to MedPAC Commissioners (April 7, 2016), available at: <http://www.medpac.gov/documents/april-2016-meeting-presentation-medicare-part-b-drug-and-oncology-payment-policy-issues.pdf?sfvrsn=0>

<sup>9</sup> 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/>

pocket maximum on annual cost sharing expose these beneficiaries to catastrophic costs, which can reach as high as nearly \$100,000 per year.<sup>10</sup>

Medicare Rights is also encouraged by the potential to improve access to lower cost medications under the Part B Drug Payment Model. The most common example heard on our national helpline involving this issue concerns the use of insulin with an infusion pump. We regularly serve Medicare beneficiaries who cannot find a pharmacy or health care provider willing to supply insulin for use with an infusion pump because it would be covered under Part B. In 2013, the Medicare Ombudsman reported on this same trend in its annual report to Congress, citing increasing access challenges among older adults and people with disabilities who need insulin via an infusion pump.<sup>11</sup>

We note that DME infusion prescription medications are carved out from Phase I of the proposed model, and we understand the need to avoid complicated interactions with the DMEPOS competitive bidding program in the model's first phase. As such, we strongly urge CMS to identify mechanisms in Phase II to address this persistent access problem for people with diabetes whose insulin needs require an infusion pump.

Finally, CMS solicits comment on whether there are medications where an increase in the flat rate is warranted as a result of complicated or expensive packaging, storage, or administration requirements. Medicare Rights supports such adjustments where adequate evidence demonstrating the need for increased payment is provided. For example, payment adjustments may be appropriate for medications with specific temperature storage requirements, short shelf lives, or long infusion times requiring nurse management.

## **B. Phase II**

Under Phase II of the Part B Drug Payment Model, CMS will incorporate a range of value-based purchasing tools for a limited number of Part B medications. Medicare Rights supports the Phase II goals, which are aligned with global efforts to transition Medicare from a volume- to value-based payment system and to incentivize high-value clinical decision-making.

The agency outlines a 30-day public comment and 45-day notice process for identifying which prescription drugs are suitable for the identified value-based strategies, which we strongly support. We urge CMS to include any relevant research or evidence that the agency relied upon in identifying specific prescription drugs as part of the notice and comment process. For each of the proposed strategies, we strongly recommend that CMS use the highest-quality evidence, including randomized trial designs where possible, and to emphasize evidence from neutral and/or independent sources.

Additionally, ahead of the public comment and notice process, we recommend that CMS actively involve diverse stakeholders, most notably clinicians and experts in specific diseases or indications, as the agency evaluates medications for incorporation in Phase II. Further, to the extent possible, we urge CMS to make comments submitted through this process available to the public online or through the agency's published response.

As in Phase I, real-time monitoring and feedback loops will be an essential component for testing the value-based strategies identified for Phase II. Again, we believe that a dedicated ombudsman program, formal engagement of outside stakeholders, and well-planned outreach and education will be vital to the success of this testing.

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<sup>10</sup> 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>

<sup>11</sup> Office of the Medicare Ombudsman, "Fiscal Year 2013 Report to Congress," (2014, pg. 38), available at: <https://www.cms.gov/Center/Special-Topic/Ombudsman/2013-Ombudsman-Report-to-Congress-.pdf>

In particular, we strongly support testing the following value-based strategies:

**Lowering and eliminating Part B cost sharing** for high-value prescription drugs. 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—an ongoing trend observed on Medicare Rights’ national helpline.<sup>12</sup> 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.<sup>13</sup> We oppose increased cost sharing for low-value prescription drugs and services and applaud CMS for not proposing increased cost sharing as part of this model.

We strongly support CMS’ proposal to eliminate or lower the Part B coinsurance without reducing overall payment, which we expect will minimize potential conflicts between providers and beneficiaries and any related, unintended access concerns. As CMS implements this proposal, we urge the agency to 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. As noted above, we encourage CMS to involve outside experts in this decision-making process and to make all information related to these determinations publicly available.

Further, we strongly recommend that CMS develop targeted notices for beneficiaries who take Part B medications where lowered or eliminated coinsurance is available for specific medications within a grouping of similar prescription drugs. We find that beneficiaries are not typically knowledgeable about the full range of medications available to treat their condition, nor are they aware of related differentials in cost sharing. Notices are necessary to build this knowledge and ensure that people with Medicare fully benefit from this particular value-based tool. In addition, CMS should ensure that health care providers are adequately informed about which medications qualify for lowered cost sharing, through clinical decision support tools or otherwise

**Developing clinical decision support tools** to assist health care providers in making the best treatment and prescription choices for their patients, available for use on a voluntary basis. This strategy appropriately reflects that providers—rather than patients—determine health care utilization trends. In general, we find that our clients tend to follow the recommendations of their health care providers and are sometimes hesitant to inquire about their treatment options, even when cost sharing proves unaffordable.

Medicare Rights encourages CMS to develop complementary shared decision-making tools as a companion to the clinical decision support tools. We believe these materials would help providers explain options, including risks, benefits, and costs to their patients. Tools that adhere to shared decision-making principles and walk providers and patients through the process of making ‘preference sensitive’ decisions about treatment options could further enhance the benefit of the clinical decision support tools contemplated in the Part B Drug Payment Model.<sup>14</sup>

Model toolkits for certain specialty treatments include those developed by Dartmouth Hitchcock’s Center for Shared Decision-Making and the Informed Medical Decision Foundation.<sup>15</sup> Further, we encourage CMS to refer to

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<sup>12</sup> Swartz, K. “Cost-Sharing: Effects on Spending and Outcomes” (Robert Wood Johnson Foundation Research Synthesis Report No. 20: December 2010

<sup>13</sup> 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>

<sup>14</sup> Families USA, “Shared Decision Making: Engaging Patients to Improve Health Care,” (May 2013), available at: [http://familiesusa.org/sites/default/files/product\\_documents/Shared-Decision-Making.pdf](http://familiesusa.org/sites/default/files/product_documents/Shared-Decision-Making.pdf)

<sup>15</sup> See the Dartmouth-Hitchcock Center for Shared Decision Making website at: [http://med.dartmouth-hitchcock.org/csdm\\_toolkits.html](http://med.dartmouth-hitchcock.org/csdm_toolkits.html) and the Informed Medical Decisions Foundation website at: <http://www.informedmedicaldecisions.org/patient-resources/>



the standards developed by the International Patient Decision Aid Standards (IPADS) Collaboration in the use or development of any shared decision-making tools.<sup>16</sup>

Medicare Rights also supports the proposed testing of other value-based strategies, including:

**Using reference pricing** to establish a standard payment rate (or benchmark) for a group or class of medications, based on an average price, by determining the most clinically effective medication, or through another threshold appropriate to therapeutically similar prescription drugs. Under the proposed model, health care providers could be paid more or less than the cost of procurement for a specific medication. In cases where the provider is paid less, we strongly support CMS' 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.

Importantly, CMS must develop a transparent process for determining reference prices. Multiple stakeholders should be involved in both identifying the relevant reference class and in setting the appropriate price. Some research indicates that reference pricing can reduce spending without affecting utilization; yet, its widespread use and its use with complicated and interrelated diagnoses have not been studied.<sup>17</sup> For this reason, CMS should consider whether certain prescription drugs, patients, or geographic areas should be exempt from reference pricing. Urgently needed or emergency-provided medications, patients with a particularly complex health status or significant comorbidities, and rural areas with limited provider choice are likely inappropriate for reference pricing.

**Using indications-based pricing** to set payment for a particular prescription drug higher or lower depending on the medication's effectiveness with regard to a particular diagnosis. Health insurers, pharmaceutical manufacturers, and some providers view indications-based pricing as a promising concept, though it has not yet been tested on a wide scale.<sup>18</sup> Like reference pricing, this methodology is entirely dependent on transparent, evidence-based evaluations of comparative effectiveness and interchangeability.

While CMS' proposal depends heavily on one source of this information, the Institute for Clinical and Economic Review (ICER), Medicare Rights encourages CMS to supplement the independent analysis made available by ICER through the involvement of additional and diverse outside stakeholders, particularly clinicians and experts in specific diseases or indications.

**Entering into voluntary outcomes-based risk-sharing agreements** with pharmaceutical makers to initiate rebates if a prescription drug does not meet previously agreed upon outcome targets. Transparent evaluation processes for determining outcomes and ensuring accurate payment reconciliation will be important to the successful implementation of this value-based purchasing tool.

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<sup>16</sup> See the IPADS website at: <http://ipdas.ohri.ca/>

<sup>17</sup> Johnson, J.T., Neill, K.K., and D. A. Davis, "Five-Year Examination of Utilization and Drug Cost Outcomes Associated with Benefit Design Changes, Including Reference Pricing for Proton Pump Inhibitors, in a State Employee Health Plan," *Journal of Managed Care Pharmacy* 17, no. 3 (2011):200-212, available online at <http://www.amcp.org/data/jmcp/200-212.pdf>; Lopez-Casanovas, G. and J. Puig-Juoy, "Review of the Literature on Reference Pricing," *Health Policy*, no. 2 (2000): 87-123, available online at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=159230](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=159230)

<sup>18</sup> 2015 ICER Membership Policy Summit, "Indication-Specific Pricing of Pharmaceuticals In The United States Health Care System," (ICER: March 2016), available at: [http://icer-review.org/wp-content/uploads/2015/03/Final-Report-2015-ICER-Policy-Summit-on-Indication-specific-Pricing-March-2016\\_revised-icons-002.pdf](http://icer-review.org/wp-content/uploads/2015/03/Final-Report-2015-ICER-Policy-Summit-on-Indication-specific-Pricing-March-2016_revised-icons-002.pdf); Edlin, M., "Performance-based Pricing for Pharmaceuticals," *Managed Healthcare Executive*, September 30, 2015, available at: <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/performance-based-pricing-pharmaceuticals>; Bach, Peter B. *Indication Specific Pricing for Cancer Drugs*, Health Outcomes Research Group, Memorial Sloan-Kettering Cancer Center, *JAMA*, October 22/28, 2014, Volume 312, Number 16, pgs. 1629- 1630



Medicare Rights urges CMS to develop goals for each agreement in consultation with diverse stakeholders and to make the evaluation tools and results publically available. Where possible, we encourage CMS to incorporate patient-reported outcome measures in these agreements. Importantly, pharmaceutical manufacturers should only be permitted to enter into outcomes-based risk sharing agreements under the condition of full transparency by making all scientific evidence and identified outcome measures publicly available.

#### **IV. Provider, Supplier, and Beneficiary Protections**

##### **A. Pre-Appeals Payment Exceptions Review Process**

Medicare Rights strongly 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.

Additional information is needed to ensure the Pre-Appeals Process is truly accessible to people with Medicare. Our casework assisting beneficiaries with traditional Medicare appeals processes suggests that targeted notice and ample outreach is necessary. Based on the experiences communicated on our national helpline with the Part D coverage determination appeals process and the pre-certification process for certain DMEPOS, 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...”<sup>19</sup> 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 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 typically 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 provider or supplier successfully appeals for higher payment. Beneficiaries will 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.

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<sup>19</sup> 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. 1-800-MEDICARE customer service representatives 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.

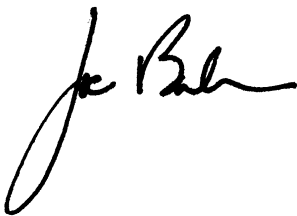
## **VI. Evaluation**

Medicare Rights supports CMS’ 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.

We strongly recommend that CMS incorporate surveys in the program evaluation, most importantly using patient-experience surveys to track the beneficiary experience under the model. We support the identified evaluation questions, but we urge that CMS’ evaluation 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.

Finally, we urge CMS to make its evaluation(s) publicly available—posting results throughout the course of the model in addition to summary results as the Part B Drug Payment Model comes to a close.

Thank you for the opportunity to provide comments.

A handwritten signature in black ink, appearing to read "Joe Baker". The signature is fluid and cursive, with a large loop at the end of the last name.

Joe Baker  
President  
Medicare Rights Center