



Academy of
Managed Care
Pharmacy®

July 8, 2016

The Honorable Orrin G. Hatch
Chairman, Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member, Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

Re: “Examining the Proposed Medicare Part B Drug Demonstration”

Dear Chairman Hatch and Ranking Member Wyden:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to submit comments for the record on the hearing titled “Examining the Proposed Medicare Part B Drug Demonstration” held on June 28, 2016. AMCP submitted detailed comments¹ to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed rule titled “Medicare Program; Part B Drug Payment Model (CMS-1670-P)” published in the Federal Register on March 11, 2016.

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

While AMCP was pleased to see a commitment by CMS to evaluate methods to move from quantity and process-orientated payments for drugs under Medicare Part B to payment policies focused on rewarding higher quality and improved patient outcomes, AMCP expressed concern that the proposal, as written, did not fully consider the unintended consequences to beneficiaries that may result from the scope and design of the model. AMCP offered comments on several elements that we believe were either missing from the proposed rule, could be improved upon, or required clarification. AMCP urged CMS to carefully consider comments received and release a revised proposed rule with an opportunity for additional stakeholder feedback prior to finalization and adoption to ensure that the perspectives of managed care pharmacy and other stakeholders are considered. AMCP recommended that after consideration of comments, CMS re-issue the proposal focused on areas that could successfully achieve the objectives of improving outcomes and quality and lowering costs without jeopardizing beneficiary access to medications.

¹ AMCP comments to CMS Re “*Medicare Program; Part B Drug Payment Model (CMS-1670-P)*.” Available at <http://bit.ly/27biTT5>. Accessed June 28 2016.

Specifically, AMCP commented that:

- **The Scope and Breadth of the Model Should be Narrowed** - The proposed rule would require significant and complex changes and could ultimately result in a mandatory nationwide pilot that would impact up to 75 percent of providers. CMS should narrow the scope in consultation with providers and health plans and pharmacy benefit management companies (PBMs) that have implemented value-based purchasing initiatives in the commercial market to determine the potential for success under Medicare Part B.
- **The Model Should Include Pharmacists as Key Members of the Health Care Team** – Pharmacists play a critical role as members of the health care team by serving as the medication management experts to help patients achieve clinical goals, reduce overall health care costs, and improve patient satisfaction. CMS should include pharmacists as key members of the health care team for phase II of the model to achieve enhanced benefits to Medicare beneficiaries through a collaborative approach to medication management.
- **The Model Should Create an Allowance for Formularies and Utilization Management Tools** - The proposed rule does not accommodate the use of pharmacy and therapeutics (P&T) committees established by health plans and PBMs to develop formularies for Medicare Part B or allow for the use of utilization management tools, which are elements that have been key to the success in decreasing costs, improving quality, and increasing value in Medicare Part D and the commercial market. CMS should consider the inclusion of a requirement to establish a Part B formulary with appropriate utilization management tools facilitated by health care providers, health plans, and PBMs under phase II of the model.
- **The Model Should Detail How VBP Tools Will be Monitored & Evaluated** - CMS should release detailed plans for how it will evaluate the model's success, including specific clinical end points (such as quality of life, patient-reported outcomes, and survival rates).
- **The Model Should Focus on Targeted Disease States** - AMCP is concerned that the proposed rule is overly ambitious in including Part B drugs for all disease states in the model. CMS should reevaluate the scope of the model and focus on specific disease states that are prevalent in the Medicare population that have multiple therapies available with non-significant differences in clinical benefit but significant differences in cost of therapy, such as the treatment of age-related macular degeneration. In addition, CMS should also consider disease states and drug categories where biosimilars are entering the marketplace such as psoriasis, rheumatoid arthritis, and white blood stimulants.
- **The Model Should Require Documentation of Part B Drug Claims Using NDC Numbers** - A barrier to evaluating the success of VBP tools in Part B is the current method of documenting drugs under Part B using Healthcare Common Procedure Coding System (HCPCS) codes and not National Drug Code (NDC) numbers. The ability to track the drug administered to the specific NDC number is critical to truly implement VBP tools as they are used today in Medicare Part D and in the commercial market. CMS should require documentation of NDCs on all Medicare Part B claims.
- **The Model Should Evaluate the Impact on Specialty Care Providers** - Primary Care Service Areas (PCSAs) may not be the most appropriate geographic unit for specialty care providers, as

specialty care providers are typically located in very different geographical areas and practice settings than a traditional primary care provider, and often entail networks that may span across multiple PCSAs. CMS should evaluate the impact of using PCSAs on specialty care providers and whether there is sufficient correlation between the two or whether consideration of an alternate geographic unit for specialty care providers is warranted.

- **The Model Should Use a Comprehensive Approach to Develop Evidence-Based Clinical Practice Guidelines** - CMS should support medication product selection by P&T Committees and providers using the totality of the evidence. Therefore, CMS should be comprehensive in the type of information that is used to develop VBP frameworks, and to avoid relying on a single source.
- **The Model Should Monitor for Unintended Consequences to Beneficiaries** - CMS should amend the proposed rule to include a mechanism for monitoring unintended consequences to beneficiaries and a strategy for suspending the model, in part or in its entirety, if beneficiary harms are identified.
- **The Model Should Evaluate the Impact of Competing CMMI Initiatives** - AMCP is concerned about the impact and potential overlap of the proposed Part B payment model with other CMMI initiatives, such as the Oncology Care Model, and alternative payment models under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). CMS should consider the potential overlap in test models and ensure a mechanism is in place to encourage active participation in ongoing and future test models to allow for meaningful assessment for improving value in the United States health care system.
- **The Model Should Evaluate the Impact on Medicare Advantage Benchmarks** - The proposed rule does not reference Medicare Advantage, which covers approximately one-third of Medicare beneficiaries. CMS should clarify how Medicare Advantage plans are accounted for in the proposed rule and whether Medicare Advantage plans will have access to the same VBP tools to help offset reductions in benchmarks.
- **The Model Should Evaluate Potential Market Shifts** – CMS should consider how the proposed rule may result in a market shift of costs from Medicare Part B to other payment areas and care settings with greater costs.

AMCP appreciates your concern with the proposed rule and the opportunity for stakeholders to be heard. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer