



Academy of
Managed Care
Pharmacy®

May 9, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. 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 (CMS-1670-P)

Dear Acting Administrator Slavitt:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) for the opportunity to provide comments 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. Under the proposed rule, CMS would implement a two-phase model to test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. Phase I would involve understanding the impact of changing the current payment methodology for Part B drugs from Average Sales Price (ASP) + 6% to ASP + 2.5% + a flat fee. Phase II would involve understanding the impact of implementing value-based purchasing (VBP) tools similar to those currently employed in the commercial market and Medicare Part D, such as reference pricing and indications-based pricing.

AMCP is 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. However, AMCP is concerned that the proposal, as written, does not fully consider the unintended consequences to beneficiaries that may result from the scope and design of the model. AMCP offers comments on the following elements that it believes are either missing from the proposed rule, can be improved upon, or require clarification:

- Scope & Breadth
- Role of the Pharmacist & Care Coordination
- Formulary & Utilization Management Tools
- Monitoring & Evaluation of VBP Tools
- Targeted Disease States
- Documentation of Part B Drug Claims
- Impact on Specialty Care Providers
- Evidence-Based Clinical Practice Guidelines
- Monitoring of Unintended Effects to Beneficiaries

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- Competing CMMI Initiatives
- Impact on Medicare Advantage Benchmarks
- Potential Market Shift

AMCP urges 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 recommends 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.

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.

The Model Should Narrow Its Scope & Breadth

AMCP is concerned that the proposed rule would require significant and complex changes and ultimately result in a mandatory nationwide pilot that would impact up to 75% of providers throughout the country. While some of the proposals offered by CMS have been successfully used in the commercial market, without further thought and consideration, Medicare beneficiaries may not be able to access critical medications. AMCP is also concerned that the proposal appears to be a departure from a true pilot where CMMI administers focused demonstrations and, if proven to be successful, moves forward with wider nationwide implementation. Therefore, AMCP strongly urges CMS to 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

AMCP is disappointed that the proposed rule does not reference the role of pharmacists or a team-based approach to improving value and patient outcomes. 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. Pharmacists' training and expertise support their role as the leader to develop and implement pharmaceutical care plans through medication therapy management and collaborative drug therapy management agreements. Through the delivery of patient care services, pharmacists, in collaboration with physicians, nurses, other health care providers and patients, provide valuable ongoing, comprehensive assessment and management of drug therapy resulting in improvement in quality of care, achievement of patient specific clinical outcomes, and reduction in overall costs of care. Pharmacists and the team-based approach to health care play an integral role in the successes demonstrated in Medicare Part D and the commercial market, and therefore AMCP strongly encourages CMS to 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

AMCP is concerned that the proposed rule does not include the use of Pharmacy and Therapeutics (P&T) Committees established by health plans and pharmacy benefit managers 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. Use of health plan or PBM-established formularies and allowance for utilization management tools are necessary for the success of the VBP initiatives. AMCP recommends that in CMS' reconsideration of the proposed rule, it propose a specific demonstration that will allow the specific use of formularies and utilization management tools to help facilitate the success of VBP initiatives.

AMCP supports the use of well-designed and evidence-based formularies that enhance the quality of pharmaceutical care while lowering medication costs. A drug formulary is a continually updated list of prescription medications that represents the current clinical judgment of providers who are experts in the diagnosis and treatment of disease. Formularies often contain additional prescribing and clinical information that assists health care professionals as they promote high quality, affordable care to patients. Generally, a formulary is developed and maintained by a P&T Committee, comprised of physicians, pharmacists, and other health care professionals, that meets regularly to review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experience, economic data, and provider recommendations to determine which drugs are the safest, most effective, and produce the best clinical outcomes. Since a formulary is a dynamic and continually revised document, the P&T Committee regularly evaluates the formulary and adjusts it to reflect the best medical practices, newly marketed medications, and new clinical and economic evidence that may have an impact on which drugs are included or excluded.

Furthermore, implementation of well-designed, evidence-based utilization management tools, such as prior authorization and step therapy, optimizes patient outcomes by ensuring patients receive the most appropriate medications while reducing waste, errors, adverse effects, and unnecessary prescription drug use and cost. Utilization management tools and requirements for coverage are based on clinical need, therapeutic rationale, and the desired outcome for the patient. Studies show that choice of the most appropriate drug results in fewer treatment failures, reduced hospitalizations, and better patient adherence to the treatment plan, fewer adverse side effects, and better overall outcomes. Such efficient and effective use of health care resources helps to keep overall medical costs down, improves the consumer's access to more affordable care, and provides the patient with an improved quality of life.

The success of VBPs in Part B relies on the use of formularies and utilization management tools, which have been successful in the commercial market and in Medicare Part D. Therefore, as noted above, AMCP requests that CMS 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

AMCP is concerned that the proposed rule fails to adequately detail how CMS will assess the impact of the model on the quality of care provided to Medicare beneficiaries. Release of detailed quality metrics and patient outcomes that will be used to determine what constitutes ultimate success is critical to outline in advance of initiation of the model. Quality metrics used in this model should be based on existing metrics proven to improve outcomes and not rely on process-based measures. Therefore, AMCP strongly encourages CMS to release detailed plans to evaluate success in the model and the clinical end points (such as quality of life, patient-reported outcomes, and survival rates) that it is striving to achieve.

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. AMCP recommends that CMS 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

AMCP is concerned that 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. Documentation of NDCs will allow for specific data analysis and meaningful assessment that can be actioned. Therefore, AMCP strongly encourages CMS to require documentation of the NDCs on all Medicare Part B claims. In the final rule “*Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016*,”¹ CMS noted that it will be developing an approach for using manufacturer-specific modifiers, such as NDC numbers, on Part B claims. AMCP strongly urges CMS to move forward with development of this process to require NDCs on all Part B claims to allow for meaningful assessment of the success of VBP tools under phase II of the model.

The Model Should Evaluate the Impact on Specialty Care Providers

AMCP appreciates the detailed analysis CMS conducted to determine which of five options represented the most appropriate geographic unit for the model. While AMCP does not disagree with CMS’s conclusion that Primary Care Service Areas (PCSAs) are the most appropriate geographic unit when compared to the other options, AMCP does question whether PCSAs are 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. Therefore, AMCP encourages CMS to 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

AMCP is concerned with the narrow approach outlined by CMS in the proposed rule for establishing evidence-based clinical practice guidelines. While AMCP appreciates the work of The Institute for Clinical and Economic Review (ICER) and believes that it is important and critical to help move health care in the United States towards a value-based model, ICER evaluations are one of many tools utilized by managed care pharmacists and other providers in determining whether medications are appropriate for patients. AMCP supports a comprehensive and holistic evaluation by P&T Committees and providers of all of the existing evidence, including the use of various methodologies such as comparative effectiveness research (CER), real world evidence (RWE), pharmaco-economic information, and other value frameworks. AMCP

¹ Available at <https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf>. Accessed May 4, 2016.

does not support the endorsement of one framework or clinical practice guideline, but rather CMS should support medication product selection by P&T Committees and providers using the totality of the evidence. Therefore, AMCP encourages CMS to be comprehensive in the type of information that is used to develop VBP frameworks and to not rely on a single source. In addition, as highlighted above, AMCP further encourages CMS to consider the role of pharmacists in evaluating and synthesizing the various information sources to help develop the VBP frameworks.

In addition, AMCP notes that CMS uses the term “competent and reliable scientific evidence” (CRSE) throughout the proposed rule regarding establishing the clinical value for a specific drug. CRSE is a statutory term referenced in Section 114 of The Food and Drug Administration Modernization Act (FDAMA) of 1997 which was created as a regulatory safe harbor with the goal of increasing the dissemination of health care economic information to those responsible for formulary decision making.² Although it has been nearly twenty years since passage and enactment of Section 114, the Food and Drug Administration (FDA) has yet to issue regulations or guidance on the provision, including a definition of CRSE. In March 2016, AMCP convened a forum with experts representing pharmaceutical companies, managed care organizations, pharmacoeconomic experts, health care providers, health policy experts, and patient advocates, to develop consensus recommendations to the FDA for how Section 114 should be clarified, including creating a consensus definition for CRSE.³ The recommendations from the forum are scheduled to be published in the July 2016 issue of the *Journal of Managed Care & Specialty Pharmacy*. The stakeholders defined CRSE as follows:

“Competent and reliable scientific evidence means truthful and non-misleading tests, analyses, research, studies, models, or other evidence. Such evidence would be based on the expertise of professionals in the relevant area, and be derived using methods that are transparent, disclosed, reproducible, accurate and valid.”

AMCP recommends that CMS define CRSE in the final rule as the consensus definition developed by the multi-stakeholder group to encourage alignment with the FDA and to avoid multiple definitions for a single term which often leads to confusion for affected parties.

The Model Should Monitor For Unintended Consequences to Beneficiaries

AMCP is concerned that the proposed rule does not adequately address how CMS plans to evaluate the model for unintended consequences to beneficiaries such as decreased access to care or a reduction in the quality of care provided. AMCP believes it is critical for CMS to have mechanisms in place to not only measure successes from the model, but also to measure any negative consequences that arise from the model and to have a system in place to suspend the model if harms to beneficiaries are identified. Therefore, AMCP strongly encourages CMS to 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.

² U.S. Food and Drug Administration. Food and Drug Administration Modernization Act (FDAMA) of 1997. <http://www.fda.gov/downloads/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCA/FDAMA/FullTextofFDAMA/UCM089145.pdf>. Accessed May 4, 2016.

³ For more information on the AMCP Partnership Forum, *FDAMA 114: Improving the Exchange of Pharmacoeconomic Data*, please visit <http://www.amcp.org/FDAMA114PartnershipForum/>.

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). In its proposal, CMS acknowledges the potential overlap but proposes to not exclude dual participation in test models. AMCP strongly urges CMS to carefully 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

AMCP is concerned that the proposed rule does not reference Medicare Advantage which covers approximately one-third of Medicare beneficiaries. AMCP is also concerned that the proposed rule may have unintended consequences on Medicare Advantage benchmarks as they are likely to decrease in correlation with Part B drug costs if expected savings are realized. Therefore, AMCP encourages CMS to 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 off-set reductions in benchmarks.

The Model Should Evaluate Potential Market Shifts

AMCP cautions CMS to carefully 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. For example, costs may shift to Medicare Part D should providers opt to cease maintaining an inventory of specific drugs for office administration and instead advise patients to purchase the drug from a pharmacy pursuant to a prescription and return to the office with the drug for administration. Alternatively, costs may also shift to Medicare Part D should prescribing patterns begin to favor oral therapeutic alternatives for injectable Part B drugs that are covered under Part D. Costs may also shift to care settings associated with greater costs as CMS notes that hospital outpatient departments (HOPD) are included in the model and physicians may opt to refer patients to HOPD's in lieu of treating them in-office. Finally, the potential shift towards HOPD's may also result in an increase in 340B payments to hospitals. Potential shifts would not only impact federal funding of these programs, but would also impact patient out-of-pocket costs and potentially impede access to care. Therefore, AMCP encourages CMS to carefully consider potential market shifts that may arise as a result of the model and address how increased expenditures would be addressed.

AMCP encourages CMS to carefully reevaluate the proposed rule and release a revised proposal with an opportunity for additional stakeholder feedback prior to finalization and adoption. AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS and CMMI. 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