AMGA
Advancing High Performance Health

May 9, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Mr. Slavitt:

On behalf of AMGA, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) proposed rule titled, "Medicare Program: Part B Drug Payment Model" (CMS-1670-P). AMGA, founded in 1950, represents more than 450 multi-specialty medical groups and integrated delivery systems representing about 177,000 physicians who care for one-in-three Americans. Our member medical groups are particularly interested in Part B drug pricing for numerous reasons. AMGA members have a strong interest in improving the quality and effectiveness of drug prescribing and are interested in learning what relevant value based purchasing (VBP) tools work successfully to better manage Medicare Part B health benefits and drug utilization.

Part B drug costs place a significant burden on Medicare beneficiaries. As the Government Accountability Office (GAO) reported in November 2015, nearly two-thirds of new Part B drugs or those drugs approved by the FDA between 2006 and 2013 "had expenditures per beneficiary," the GAO stated, "in excess of $9,000 in 2013." The beneficiary share of the cost of these drugs ranged from $1,900 to $107,000 per drug. Medicare beneficiaries' share in these costs is significant. Kaiser Family Foundation data indicates half of all Medicare beneficiaries had an annual income below $24,150 and 25% had an income below $14,350 in 2014. Therefore, using Value Based Purchasing (VBP) tools in an attempt to reduce overall drug spending, and improve clinical effectiveness, is a worthy goal.

The proposed rule states, "Medicare Part D plans, Pharmacy Benefit Managers (PBMs) other third party payers, and entities like hospitals use a variety of VBP tools, such as value-based pricing, clinical decision support tools, and rebates and discounts to improve patient outcomes and manage costs." VBP tools, where and when appropriate, should also be used to better manage Part B drug utilization. As CMS recognizes, the current Average Sales Price (ASP) payment formula does not account for the effectiveness of a particular drug. Along with Medicare Payment Advisory Committee (MedPAC) and others, AMGA recognizes pricing formulas can create selection bias. Therefore, it is important to study and measure behavioral responses to alternative pricing and pricing combined with VBP or clinical decision support, reference, indications and outcome-based pricing, risk sharing, VBP arrangements with manufacturers, beneficiary co-pay waivers and other VBP tools. CMS has appropriately chosen to exclude certain drugs, such as certain vaccines, Durable Medical Equipment (DME) covered and End Stage Renal Disease (ESRD) drugs, blood and blood products and drugs in short supply. Using

Primary Care Service Areas (PCSAs), CMS proposes to conduct a formal, stratified random intervention using four test arms: a control group; a group receiving the alternative payment method, or ASP plus 2.5% plus a $16.80 flat fee; and, under phase two, a group receiving the current payment formula with one or more of the VBP tools and another group receiving the alternative payment with one or more VBP tools. CMS also proposes to conduct a formal evaluation. CMS will not exclude beneficiaries in the Medicare Shared Savings Program or in ACOs, i.e., CMS will not "apply reconciliation processes" since, as CMS states, "Part B payment amounts will typically represent a small proportion of the beneficiary's total payments for care." Finally, while CMS intends to achieve savings in phase two, the agency is unable to quantify these savings. Nevertheless, regardless of any the savings derived, efforts to improve Part B medication clinical effectiveness and spending efficiency can only serve to improve Medicare beneficiary health.

These points aside, AMGA does have the following concerns.

Proposed Model Payment and Modifications

CMS proposes an alternative to the ASP add-on payment, specifically ASP plus 2.5% plus a $16.80 flat fee. The proposed rule makes no mention of sequestration. AMGA assumes, as have others, the 2.5% is subject to the 2% sequestration reduction. CMS should clarify the actual plus percent and add on dollar amount.

Under "Additional Tests of Add-On Modifications," CMS questions whether “it would be helpful to test additional variations of the ASP add-on" or "whether other variations of the ASP add-on percentage would be a useful complement to the proposed ASP + 2.5 percent + flat fee." CMS notes, for example, creating quartiles based annual per beneficiary payments. CMS also notes varying the flat fee across groups of drugs due to the necessity of cold handling, special packaging, or other cost contributors. While we do not have any empirical data that would justify testing variations, we recommend CMS continuously work to refine the demonstration year-over-year as evaluative evidence suggests.

Rural and Small Providers

CMS recognizes, or is concerned, the demonstration may have unintended negative effects on small and/or rural providers including rural hospitals. Column nine of impact Table 2 estimates the rural total drug payment expressed as a percent change ranges from 82% to -3.2% with only 12 of the 32 categories showing a negative percent change. For all rural hospital outpatient departments the estimated change is -0.3 percent. Since it is impossible to know with certainty the effect the alternative payment will have on these providers the evaluation can be designed to produce quarterly, semi-annual or annual data that compares prescribing patterns or utilization for these providers to their historic patterns. CMS also notes the agency is considering surveying providers, beneficiaries, and suppliers. Surveying these subsets of demonstration participants, for example after the first year of the demonstration, could prove useful.

VBP and the Beneficiary

CMS is proposing "a value-based pricing strategy that involves discounting or eliminating patient coinsurance amounts for services that are determined to be high in value in an attempt to tailor incentives." Therefore, CMS is proposing to “waive beneficiary cost sharing from the current 20 percent." CMS also notes the potential of sharing rebates from manufacturers with beneficiaries. These appear to be the only VBP options relevant to the beneficiary. Though CMS also states, "we would engage in educational activities to support implementation and testing of value-based pricing strategies," the intended audience for these activities is not clear. Absent potentially financially

advantaging the beneficiary, the demonstration apparently takes no interest in or accounting for the beneficiary, or more specifically changes in beneficiary behavior. It seems altogether reasonable the beneficiary would want access to the same clinical decision support information, or the same "up-to-date scientific and medical evidence such as well-designed and conducted clinical trials, updated information on drug safety, and practice guidelines," CMS will make available to physicians and other health professionals. It also is reasonable to assume the beneficiary would want to know if, for example, a drug being prescribed is based on value or indication-based pricing since such pricing is based on clinical effectiveness.

Interactions with the Oncology Care Model (OCM) Demonstration

There is substantial provider discussion concerning the interactions or overlap between and among the many CMS demonstrations, specifically, the OCM demonstration. In the proposed rule, CMS states OCM practices and matched comparison groups "could account for up to 40 percent of total Part B drug spending." Therefore, CMS concludes, "the remaining oncology spending would not be representative of Part B spending." This would exclude OCM model participants and would render the Part B drug demo meaningless. This reasoning however leaves unaddressed other concerns. For example, including OCM participants in the Part B drug demo may discourage oncologists from participating in the OCM. The demonstration also may negatively affect the ability of private practice oncologists to treat their patients effectively particularly if and when there are no less expensive comparable medications. We recognize the OCM demo will pay a monthly $160 per member per month care management and coordination fee and OCM demo participants face no downside financial risk at least initially. Regardless, concerns related to the effect payment changes will have on oncology practices argues for beginning the demonstration's two phases simultaneously particularly because CMS notes the agency will pursue using in the demo episode-based or bundled VBP tools as it does in the Bundled Payments for Care Improvement (BPCI) and Comprehensive Joint Replacement (CJR) bundled payment demonstrations and as the agency intends to use in the five-year OCM demo.

The Competitive Acquisition Program (CAP)

CMS discusses the CAP that was suspended in 2009. CMS is well aware that MedPAC this past March examined a restructured CAP under which vendors bid a price, both vendor and physicians share in savings if Medicare spending declines and beneficiaries save through lower cost sharing. In principle, a Part B CAP would provide savings similar to any bulk purchasing arrangements. Investigating or re-investigating a Part B drug CAP would align with the agency's interest in creating successful alternative payment models. For example, the Medicare ACO community has discussed for some while creating program or accountable care-specific drug formularies.

Quality Performance

The proposed rule notes CMS will provide "feedback to physicians in the VBP arms of the model." CMS states this feedback will include, "Part B claim patterns and identify opportunities for individual improvement." CMS further states feedback will include "metrics such as cost and quality measures." CMS also states that under the "Evaluation" section, the agency will measure the "impact of quality of care." This language is vague as CMS does not explain how or if participants in any of the test arms will be held accountable for quality measures and/or how specifically the evaluator will design and measure quality performance. For example, will quality for intervention groups be measured against the control group?

VBP: More Specificity

In querying AMGA members, we frequently heard there was insufficient detail concerning how VBP or

decision support tools would be made available at the point of care. CMS notes before implementing all VBP tools, the agency will allow for public comment 45 days ahead of implementation. We encourage CMS to provide as much advance notice as possible.

Timing

CMS provides no rationale why there are two phases to the demonstration, or why the phases are implemented sequentially. CMS simply states "phase I would begin in the fall of 2016" and "phase II would begin no sooner than January 1, 2017." CMS and the provider community are largely concerned with payments falling below acquisition costs for expensive drugs, "particularly for providers and suppliers," where, as CMS states "acquisition costs are near or above the drug's ASP." The demonstration's phase two is designed to allow physicians to, on balance, prescribe more cost efficient or less expensive medications. It is unclear why there are two phases or why the demonstration is not rolled out in a single phase.

Thank you for your consideration of our comments. AMGA would be pleased to discuss these further. Please contact David Introcaso, Ph.D., Senior Director, Regulatory and Public Policy at 703.838.0033, extension 335, or via dintrocaso@amga.org, with any questions.

Sincerely,

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President and CEO