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May 9, 2016

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Room 445-G  
Washington, DC 20201

***RE: CMS-1670-P, Medicare Program; Part B Drug Payment Model; Proposed Rule (Vol. 81, No. 48), March 11, 2016.***

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on the Medicare Part B Drug Payment Model.

**The AHA commends CMS for taking on the issue of rapidly rising drug prices.** We appreciate the agency's efforts to reform how Medicare pays for prescription drugs, particularly the notion of testing a variety of approaches beyond reimbursement, such as pricing, beneficiary outcomes and value- and evidence-based decision tools. Just like the Medicare program, hospitals and their patients bear the burden of escalating drug costs. Indeed, our members have expressed deep concern over their ability to provide the highest quality care due to the impact that high-drug costs, including unexpected price increases, have on hospital budgets. **As such, the AHA supports finding ways to rein in rapidly rising drug prices. However, the responsibility for unsustainable drug pricing ultimately lies with drug manufacturers, not with hospitals.**

Hospitals have little control over which drugs physicians prescribe in hospital-based settings, yet this model would hold them accountable for such decisions to an inappropriate degree. Even if hospitals could influence physicians' decisions, there is a dearth of lower-cost, clinically meaningful alternatives available for many of the common conditions treated in hospitals. Further, as the Medicare Payment Advisory Commission (MedPAC) has recently acknowledged, **there is no convincing evidence that physicians who practice in hospital outpatient department (HOPD) settings consider profitability over clinical effectiveness when deciding which drugs to prescribe or order. It is clear that hospitals are inappropriate for inclusion in this model.**

**However, if the agency believes it is necessary to move forward with including hospitals in Phase I of the model, we strongly recommend that the model be implemented on a much smaller scale by excluding cancer drugs and narrowing the number of geographic areas that are affected.** Specifically, Medicare currently pays for most Part B drugs at the rate of the average sales price (ASP) plus 6 percent. However, the agency speculates that this methodology may encourage the use of more expensive drugs. Therefore, it proposes this nationwide Part B Drug Payment Model, in which participation in the model would be mandatory for all providers and suppliers furnishing Part B drugs who are located in the geographic areas selected for inclusion. In the first phase of the model, scheduled to begin no earlier than fall 2016, physicians and hospitals located in half of the nation would receive payment for Part B drugs at an alternate rate of ASP plus 2.5 percent, plus a flat fee, while the other half would continue to receive Part B drug payments at ASP plus 6 percent.

We are concerned that, while Phase I is intended to be budget neutral across Part B, it would redistribute drug payments with the overall effect of reducing payment to HOPDs and certain physician specialties (such as oncology, ophthalmology and rheumatology) that use higher-priced drugs, and increasing payment to physician specialties that use lower-priced drugs. In fact, HOPDs would bear 60 percent of this payment reduction, despite the fact that Medicare margins in HOPDs are already *negative* 12.4 percent. Imposing additional cuts in payments to Part B drugs would further erode HOPD margins and put access and quality of care at risk for the most vulnerable of Medicare beneficiaries. As such, we also **urge CMS to consider other alternative payment options that would help narrow the considerable over- and under-payments for Part B drugs that would be created by the 102.5 percent of ASP plus a \$16.80 payment methodology.** We present two such options in our detailed comments.

Beginning no sooner than Jan. 1, 2017, the second phase of the model would implement value-based purchasing (VBP) tools in certain areas, similar to those employed by commercial health plans, pharmacy benefit managers and other entities that manage health benefits and drug utilization. The agency intends Phase II to generate savings to the Medicare program. We believe that **several of the Phase II VBP proposals hold promise. However, we are concerned that the proposed scale and the timing set forth in the rule are unrealistic.** We cannot adequately comment on these proposals until they are more fully developed using clinical evidence that is reliable and vetted with experts from hospital, physician, pharmacy and other stakeholder groups. **The AHA recommends that CMS oversee this work and then re-propose, through notice-and-comment rulemaking, detailed Phase II VBP tool proposals for additional public review.**

**We also have serious concerns about the lack of quality measures included in the Medicare Part B Drug Payment Model.** While we agree that the Center for Medicare and Medicaid Innovation (CMMI) has broad authority to conduct demonstration projects, it does not appear that CMS will track beneficiary quality of care during the two phases

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of the model. In particular, CMS does not describe how it proposes to meet the dual programmatic objectives required in statute that CMMI models reduce program expenditures while simultaneously preserving or enhancing the quality of care for those individuals who receive Medicare benefits. In fact, the statute explicitly instructs CMMI to give preference to testing models that “also improve the coordination, quality, and efficiency of health care services” furnished to Medicare beneficiaries. The proposed rule includes no discussion of how it will evaluate the quality and safety impact of the model’s proposals on Medicare beneficiaries, nor does it propose any measures of patient-level outcomes and patient-centeredness criteria. Such measures would be critical to ensuring that the model does not reduce the quality of care while it reduces spending.

**Finally, while this proposed rule focuses on Part B spending, it is important that CMS recognize that there is significantly greater opportunity to reduce drug costs in other parts of the Medicare program and, more broadly, through greater transparency in pricing and enhanced competition in the drug industry.** For example, CMS estimates that total Part B payments for separately paid drugs have increased by an average of 8.6 percent annually since 2007, totaling \$22 billion in 2015. Certainly these are substantial figures, but spending under Part D is far greater – it has increased by an average of 6.8 percent annually since 2007 and is projected to total over \$85 billion in 2015. In the comments below, we propose several approaches that would address drug price escalation in Medicare Part D, as well as a set of efforts that go beyond Medicare and would improve transparency in the drug pricing process, increase competition, and incorporate value in drug approval, coverage and pricing decisions.

Our detailed comments are attached. If you have any questions concerning our comments, please feel free to contact Roslyne Schulman, AHA director for policy, at (202) 626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Thomas P. Nickels  
Executive Vice President

Attachment

## **American Hospital Association (AHA) Detailed Comments**

### **PHASE I: MODIFICATIONS TO THE ASP ADD-ON PERCENTAGE FOR PART B DRUGS**

CMS states that its goal in Phase I is to “minimize providers’ and suppliers’ (including physicians’) financial incentives to prescribe more expensive drugs.” Therefore, it proposes to implement an alternative to the Part B ASP drug payment methodology in different geographic areas of the country. Specifically, it would change the add-on payment from 6 percent to 2.5 percent plus a budget-neutral flat-fee payment, estimated in the proposed rule at \$16.80 per drug per day. This alternative payment methodology would increase payment for lower-cost Part B drugs and reduce payment for higher-cost drugs, with the break-even amount estimated at \$480 per drug per day.

**The AHA is concerned that Phase I does not directly address the problem of rapidly escalating drug prices. Instead, it puts hospitals in the middle of a situation over which they have little control. Therefore, we recommend that CMS exclude hospitals from Phase I.** As noted above, hospitals have little control over which drugs physicians order in HOPD settings. Yet, this model would hold them accountable for these decisions – to the extent that they would bear 60 percent of the aggregate payment reduction. This is because hospitals treat the most severely ill patients, including those with multiple co-morbidities, who often require treatment using the newest and most costly drugs.

Even if hospitals could influence physicians’ decisions, for many conditions, there is only one primary drug or biologic available to treat patients. **If there is no lower-cost substitute available, any financial incentive CMS has set forth to prescribe such a substitute is unworkable.** For instance, R-CHOP, the standard first line chemotherapy regimen for patients with non-Hodgkin’s lymphoma, has no clinically appropriate substitute. This regimen requires the biologic Rituximab, a monoclonal antibody, for which there also is no substitute. Yet, among the Part B drugs in the model, Rituximab injection is slated to receive the largest aggregate reduction in reimbursement during Phase I – a cut of \$20.3 million. Another example is Infliximab, which is the only intravenous form of treatment for rheumatoid arthritis. Yet, among the Part B drugs in the model, this injection is slated to receive the fourth-largest aggregate reduction in reimbursement – a cut of \$11.5 million. Moreover, even if there are drugs that are generally considered to be substitutable for a particular disease or condition, individual patients often respond in idiosyncratic ways. One drug may be better suited for one subset of patients while another drug works better in a different subset due to differences in disease subgroups, severities or comorbidities.

**Further, we feel that it is important to emphasize that the driving factor in prescribing a drug in hospitals is clinical appropriateness, not cost.** Even MedPAC acknowledges that there is no convincing evidence that physicians who practice in HOPD

settings consider profitability over clinical effectiveness when deciding which drugs to prescribe or order. In its June 2015 report, MedPAC states, “However, few studies exist that examine whether the 6 percent add-on is influencing providers’ choice of drugs ... Thus, it is difficult to know the extent to which the percentage add-on to ASP has the potential to affect drug prescribing patterns and the resulting spending levels.” In fact, we contend that the opposite is true – physicians in hospitals prescribe drugs based on clinical considerations, choosing drugs that are most effective in treating the individual patients for whom they care, while minimizing side effects and dangerous drug interactions. Increasingly, many follow evidence-based clinical care pathways to determine which drugs are best-suited for their patients. They may try a first-line drug with a patient and, if the patient’s condition does not improve, may turn to a higher-level, likely more costly, second-line drug. The level of Medicare reimbursement does not enter into this determination.

**Options to Narrow the Scope of Phase I. As noted above, the AHA recommends that CMS exclude hospitals from Phase I. However, if, despite all the concerns described previously, CMS believes it is necessary to move forward with hospitals included, we strongly recommend that Phase I be implemented on a much smaller scale.**

**Specifically, CMS should exclude drugs used in the treatment of cancer from the model.** The AHA is very concerned with the notion of adjusting the rate of reimbursement for life-saving oncology drugs and the possible impact this could have on the access to and quality of care for very ill and vulnerable Medicare beneficiaries. Further, in many cases there are no lower-cost, clinically meaningful alternatives available for the treatment of cancer. For example there are no lower-cost, clinically meaningful alternatives for Rituximab (used to treat non-Hodgkin’s lymphoma), Sipuleucel-T (used to treat prostate cancer), Ipilimumab (used to treat melanoma) or Melphalan (used to treat multiple myeloma cancer for patients who are not candidates for transplant). In addition, reimbursement reductions under Phase I run directly counter to the need to support the development of powerful new “precision medicine” drugs that are tailored to specific patient characteristics, such as the genetic profile of their tumor. These drugs are helping to transform the way cancer is treated, enabling physicians to select treatments that improve chances of survival and reduce exposure to adverse effects.

In addition, the AHA is concerned about interactions between the Part B Drug Payment Model and CMS’s Oncology Care Model (OCM). Under the OCM, practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. CMS proposes to include these practices in the Part B model because they, and their matched comparison group practices, account for 70 percent of Part B spending on oncology drugs. It notes that, if it were to exclude OCM practices and their matched comparison group, oncology spending would not be representative of Part B spending overall or Part B oncology spending. We agree with these conclusions. Yet, we also believe that superimposing the Part B Drug Payment Model on top of OCM would confound and

undermine the infrastructure and planning that has been put into place to support the OCM. The best solution is to exclude all cancer drugs from Phase I – doing so would preserve the integrity of the OCM, as well as avoid testing a model that includes non-representative samples of Medicare spending on certain drugs.

**We also urge CMS to scale back the number of primary care service areas (PCSAs) to which the model would apply.** Given the possible unintended consequences of applying an untested new Medicare payment methodology nationwide, it is much more prudent to apply Phase I in substantially fewer geographic areas. As currently constructed, CMS proposes to use 7,048 of the 7,144 PCSAs in the United States, only excluding hospitals in Maryland because of its All-Payer Model. In Phase I, hospitals in 50 percent of these geographic areas would be subject to the model test arm, and by Phase II hospitals in 75 percent of the United States would be subject to one of the model test arms of this demonstration. The percentage of hospitals affected, however, could be much higher, as hospitals are not necessarily evenly distributed across the PCSAs. Furthermore, we believe the proposed model is a nationwide demonstration, as hospitals in any part of the country (except Maryland) have a likelihood of being chosen for one of the model test arms of the demonstration based on the nationwide sampling frame.

**In addition, CMS could tailor the demonstration (Phase I and Phase II) to apply to only select specialties or conditions that are treated by multiple drugs that are substitutable and that vary considerably in price, or to clinically complex conditions with several therapeutically equivalent treatment options.** On the other hand, CMS could exclude conditions or specialists who treat conditions for which there is little or no competition among drugs. If this approach is used, we would urge CMS to work closely with experts in the specialties selected and the conditions identified to ensure that the policy is evidence-based and reasonable.

Alternate Payment Approaches Under Phase I. **The AHA is concerned about the possible unintended consequences of cutting the add-on payment for drugs at the proposed level. Specifically, we are concerned that the proposed payment rate of ASP plus 2.5 percent plus a \$16.80 flat fee creates both considerable underpayments and overpayments compared to the cost of a drug.** Regarding underpayments, the Phase I payment reductions are heavily concentrated on a subset of Part B drugs. Specifically, in the HOPD setting, 56 percent of the payment reduction, or \$97.5 million, would derive from 10 drugs. Six of these drugs are used to treat cancer and the others treat osteoporosis, rheumatoid arthritis, severe diarrhea and multiple sclerosis. In an environment with rapidly escalating drug prices, some smaller providers may have difficulty purchasing the more costly drugs within the model's reduced rate. This could result in physician practices in these specialty areas sending beneficiaries requiring more costly drugs to HOPDs for their treatment. Doing so would not only pose a significant inconvenience for some of the most vulnerable beneficiaries, but also would further magnify the financial penalty on hospitals, already underpaid for outpatient care.

On the other side of this equation are very low-cost drugs commonly prescribed in physician offices, which would experience significant pay increases under CMS's Phase 1, due to the \$16.80 flat fee. We are concerned that overpaying for very low-cost drugs could create an incentive for misuse and overtreatment, which could pose patient safety and quality of care concerns. It also provides manufacturers with an incentive to increase the price of the drug. For instance, Medicare reimbursement for Healthcare Common Procedure Coding System (HCPCS) code 3420, Cyanocobalamin (Vitamin B-12 injection) is slated to increase by 802.5 percent. CMS has already identified Vitamin B-12 injections as a Part B drug about which it is concerned. In fact, the agency includes it on its Drug Price Dashboard as one of the top 10 Part B drugs with the highest annual increase in cost per unit in 2014. And the agency, by virtue of the local coverage determination CMS has established for Vitamin B-12 injections, also feels the need to take extraordinary steps to ensure that it is only being paid for when its use is medically necessary, including by requiring providers to list the diagnosis codes and clinical documentation that support its use. We are concerned that the 802.5 percent increase in payment could magnify the potential for this drug to be overprescribed and misused. In addition, several opioid drugs also would see significant increases: Hydromorphone injection (60 percent increase), Meperidine injection (437 percent increase), Morphine injection (728 percent increase) and Fentanyl Citrate injection (2,118 percent increase). Substantial increases in payments for opioids, which could result in misuse and overtreatment, is especially troubling at a time in which urgent national action is needed to address the opioid epidemic. There also are many other drugs with substantial increases in payment, such as Lidocaine injection (38,619 percent increase), Prochlorperazine maleate 5 mg (30,345 percent increase), Dexamethasone comp unit (12,712 percent increase) and Diphenhydramine HCL 50 mg (11,445 percent increase).

Furthermore, CMS notes that it selected the 2.5 percent add-on to ASP for Phase I because it agreed with MedPAC's assessment that this increase should be sufficient to cover markups from wholesalers, such as prompt-pay discounts, that are not passed on to purchasers. It is true that the ASP plus 6 percent statutory formula was intended to serve as a buffer to help address the gap between the manufacturer-reported ASP rate and the average purchase price across providers, which varies due to factors such as prompt-pay discounts, wholesaler markups and sales tax. However, the 6 percent add-on was implemented for other reasons as well, and we are concerned that 2.5 percent may not be sufficient to fulfill these purposes for certain drugs. Specifically, due to the two-quarter lag in the data used to set the ASP plus 6 percent payment rate, the percentage add-on also provides protection for hospitals and physicians when price increases occur and the payment rate has not yet caught up. This protection already has been eroded by the impact of the budget sequester on the current ASP add-on, making the effective add-on after sequester only ASP plus 4.3 percent, according to CMS and MedPAC. Under the proposed Phase I alternate payment model, the 2.5 percent add-on effectively becomes only 0.9 percent after sequester. It is unlikely that this 0.9 percent add-on would provide enough "head-room" between HOPDs' and physicians' acquisition cost and the Phase I Medicare payment rate, particularly for expensive drugs needed for patient care.

In addition, we believe that the add-on to ASP also is intended to cover pharmacy overhead costs, such as drug storage and handling costs. Many of the drugs used in hospitals require special handling, especially antineoplastic agents. They may be hazardous for health care workers with repeated exposure, as the use of these drugs requires costly handling, storage and training. Retaining an adequate add-on to ASP is critical to ensuring continued access to drug therapies for beneficiaries receiving care in hospitals and in physician practices that utilize such drugs with high handling expenses.

**Therefore, we believe that there is value to considering a different Phase I payment option that would lessen the extent to which drugs are under- and over-paid compared to their cost.** In particular, the AHA modeled the impact of two-tiered payment options.

Option A is a two-tiered payment structure as described below:

Tier 1: For drugs with an ASP of less than or equal to \$100, the payment rate would be 102.5 percent of ASP plus a \$5 flat fee.

Tier 2: For drugs with an ASP greater than \$100, the payment rate would be 102.5 percent of ASP plus a \$31.97 flat fee.

We selected the \$100 tier break to recognize the current \$100 packaging threshold under the outpatient prospective payment system (OPPS) for Part B drugs. We chose the \$5 flat fee to allow very inexpensive drugs to still remain profitable, but without providing them with the large windfall profit that occurs under CMS's proposed \$16.80 flat fee.

Option B has three tiers:

Tier 1: For drugs with an ASP less than or equal to \$100, the payment rate would be 102.5 percent of ASP plus a \$5 flat fee.

Tier 2: For drugs with an ASP greater than \$100 and less than or equal to \$480, the payment rate would be 102.5 percent of ASP plus a \$16.80 flat fee.

Tier 3: For drugs with an ASP greater than \$480, the payment rate would be 102.5 percent of ASP plus a \$47.98 flat fee.

We selected the \$480 tier break for the third tier because, in a model paid at 102.5 percent of ASP plus \$16.80, as is proposed by CMS, the "break even" ASP amount that would result in drugs being paid the same under the model versus at the existing ASP plus 6 percent is approximately \$480.



**In analyzing these options, the AHA found that both would help moderate the extreme underpayment and overpayment of drugs that result from CMS’s proposal.**

Tables 1 through 4 below show the percent payment increases and decreases in HOPDs and in physician offices under CMS’s Phase I alternative payment proposal and under Options A and B. For example, as shown in Table 1, in HOPDs, under CMS’s proposal, the median percent payment increase for drugs with increases would be 7.1 percent. However, Options A and B moderate this increase. Specifically, under Option A, the two-tiered payment structure, the median percent payment increase would be only 5.2 percent; under Option B, it would be even more moderate, 3.3 percent.

## HOPDs

**Table 1: Percent Payment Increase**

**Table 2: Percent Payment Decrease**

	CMS Payment Alternative			CMS Payment Alternative		
	Option A	Option B	Option A	Option B	Option B	
Number of Drugs	86	117	136	175	144	125
Percent of Unique Drugs	33%	45%	52%	67%	55%	48%
Minimum Value	0.1%	0.03%	0.01%	-3.4%	-3.2%	-3.2%
25th Percentile	2.3%	2.0%	1.5%	-3.1%	-2.8%	-2.7%
<b>Median</b>	<b>7.1%</b>	<b>5.2%</b>	<b>3.3%</b>	<b>-2.8%</b>	<b>-2.4%</b>	<b>-2.1%</b>
Weighted Average	2.9%	4.7%	1.8%	-1.3%	-1.0%	-0.9%
75th Percentile	12.4%	14.8%	5.8%	-2.0%	-1.7%	-1.4%
Maximum Value	246.0%	256.3%	133.1%	-0.05%	-0.1%	-0.2%

In addition, as shown in Table 2, under CMS’s proposal the median percent payment decrease for drugs with payment decreases would be 2.8 percent. However, under Option A, the median percent payment decrease would be only 2.4 percent; under Option B, it would be even more moderate, 2.1 percent.

The same patterns can be found when looking at payment for drugs in physician offices, although they are more pronounced. For example, as shown below in Table 3, under CMS’s proposal, the median percent payment increase for drugs with increases would be 102 percent – more than double the current payment. However, Options A and B yield much more moderate payment rates. Specifically, under Option A, the two-tiered payment structure, the median percent payment increase would be only 24.5 percent; under Option B, it would be even more moderate, 18.8 percent.

## Physicians

**Table 3: Percent Payment Increase**

	CMS		
	Payment Alternative	Option A	Option B
Number of Drugs	289	314	325
Percent of Unique Drugs	70%	76%	79%
Minimum Value	0.01%	0.1%	0.04%
25th Percentile	17.6%	7.3%	4.9%
<b>Median</b>	<b>102.0%</b>	<b>24.5%</b>	<b>18.8%</b>
Weighted Average	20.5%	8.8%	5.7%
75th Percentile	488.6%	140.1%	127.7%
Maximum Value	66119.0%	19675.9%	19675.9%

**Table 4: Percent Payment Decrease**

	CMS		
	Payment Alternative	Option A	Option B
	123	98	87
	30%	24%	21%
	-3.3%	-3.2%	-3.2%
	-3.0%	-2.8%	-2.7%
	<b>-2.6%</b>	<b>-2.3%</b>	<b>-1.9%</b>
	-2.4%	-2.1%	-1.6%
	-1.8%	-1.7%	-1.2%
	-0.02%	-0.05%	-0.05%

Finally, as shown in Table 4, under CMS's proposal, the median percent payment decrease for drugs with payment decreases would be 2.6 percent. However, under Option A, the median percent payment decrease would be only 2.3 percent; under Option B, it would be even more moderate, 1.9 percent.

### Other Recommendations for Phase I.

*Inflation adjuster for the flat fee should be the Producer Price Index-Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003). CMS proposes to update the flat fee add-on each year based on the percentage increase in the Consumer Price Index (CPI) for Medical Care (MC) for the most recent 12-month period. The agency notes that it proposed the CPI MC because it believes that the flat fee addresses many different services included in drug acquisition activities similar to the services included in furnishing clotting factors (for which CPI MC also is used) and it is widely available and based on an accepted methodology. CMS requests comment on whether a different update factor would be more appropriate.*

**The AHA strongly recommends that the flat fee add-on instead be adjusted for inflation using the Producer Price Index (PPI)-Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003).** This is the same PPI that is used as a price proxy for pharmaceutical costs in the calculation of the market basket for updating payments in the various CMS payment systems (including the OPSS). It also is widely available. As can be seen from the table below, when comparing the CPI MC and the PPI-commodities for pharmaceuticals for human use over time, the CPI MC is clearly inadequate compared to the PPI, which is designed specifically to measure pharmaceutical costs.

### 12-Month Percent Change

Year	CPI-U Medical Care (CUUR0000SAM)	PPI-Commodities Pharmaceuticals for Human Use, Prescription (WPUSI07003)
2007	4.4	4.2
2008	3.7	7.2
2009	3.2	7.1
2010	3.4	7.6
2011	3.0	6.6
2012	3.7	8.1
2013	2.5	6.9
2014	2.4	6.3
2015	2.6	8.9

Source: data.bls.gov

Furthermore, by CMS’s own admission, the PPI is the preferred option to use as an inflation adjuster for the flat fee add-on:

“The primary data source for price proxies is Bureau of Labor Statistics data and includes Producer Price Indexes, Consumer Price Indexes, and Employment Cost Indexes. Producer Price Indexes (PPIs) measure changes in the prices producers receive for their output. **PPIs are the preferable price proxies for goods and services that facilities purchase as inputs since these facilities generally make purchases in the wholesale market.** Consumer Price Indexes (CPIs) measure changes in the prices of final goods and services purchased by the typical consumer. **We use CPIs only if an appropriate PPI is not available, or if the expenditure more closely resembles a retail rather than wholesale purchase**”<sup>1</sup> (emphasis added).

Similar language can be found in the various payment rules that CMS publishes when describing the market basket and the different price proxies used.

*CMS should update the flat fee, which is based on 2014 claims (or whichever year of claims data is used in the final rule), to 2016 dollars to reflect changes in price levels.* The proposed rule states, “Having established the flat fee for the initial year in 2016, we propose to update the flat fee amount each year...” (page 13239). However, although

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<sup>1</sup> <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/downloads/info.pdf>

CMS established this flat fee in 2016, the initial year of the model, it has done so using 2014 claims data. Therefore, \$16.80 is a 2014 dollar amount that achieves budget neutrality, not a 2016 dollar amount. We are concerned that CMS is not proposing to adjust its 2014 (or 2015, if more recent data is used in the final rule) calculations so as to update them to 2016. We believe that using a 2014 flat fee amount in the initial year of the model is inappropriate and will unduly penalize providers. **Therefore, the AHA recommends that CMS update the flat fee to 2016 dollars to reflect changes in drug price levels.**

*The use of a G-code for the flat fee add-on would be administratively burdensome.* In the proposed rule, CMS states that hospitals and physicians in geographic areas assigned to the alternative payment methodology would use a G-code to bill for the flat fee portion of the payment. **We are concerned that using a G-code will be difficult to operationalize from a systems standpoint. Therefore, the AHA urges CMS to find a different way to ensure that the flat fee add-on payment is properly paid.** In HOPD settings, the flat fee add-on will only apply to drugs that are separately payable under the OPSS, i.e. those drugs with a per-day cost of more than \$100. Drugs with a per-day cost of \$100 or less are packaged under OPSS policy and are not proposed to be included in the Part B Drug Payment Model. This means that hospitals' billing systems will need to flag separately paid drugs when they are charged on an outpatient claim to incorporate the appropriate number of G-codes for each of different drugs administered. In addition, because CMS proposes to exclude drugs on the Food and Drug Administration's (FDA) drug shortage list from the Part B Drug Payment Model, hospitals also would need to ensure, most likely through a manual process, that a G-code is not added to a claim that includes a charge for a shortage drug. Further, if a Part B drug is subject to a local coverage decision, the situation is even more complicated. In the event that the charge for the Part B drug needs to be removed from the claim, hospital billing systems also would need to reduce the G-code quantity by one. Such a process needlessly complicates hospital billing. **In contrast, CMS will have full knowledge of which specific Part B drugs are included in the model and on the hospital claim. As such, the AHA urges CMS to instead program its systems to calculate the correct payment rate for drugs including the flat-fee amount.**

## **PHASE II: APPLYING VALUE-BASED PURCHASING TOOLS**

In Phase II, which would be implemented no sooner than January 2017, CMS proposes to implement VBP tools for Part B drugs similar to those used by commercial health plans, Medicare Part D plan sponsors, pharmacy benefit managers and other entities that manage health benefits and drug utilization. These VBP strategies include: reference pricing, indications-based pricing, risk-sharing agreements based on outcomes, discounting or eliminating patient cost-sharing for high-value drugs, online clinical decision support (CDS) tools and feedback on physician prescribing patterns. However, specific details on these tools and their application are not presented in the rule. Instead, CMS proposes to use a sub-regulatory process to notify the public of the application of

any VBP tools. CMS also seeks feedback on several other VBP approaches, including: creating other VBP arrangements with manufacturers for Medicare fee-for-service (FFS) payment for drugs, whether it should consider implementing an updated version of the Competitive Acquisition Program (CAP), and whether it should pursue a more bundled or episode-based approach that moves beyond an FFS payment structure.

The AHA is supportive of the commitments made by CMS to transition Medicare to a high-value system through testing and innovations intended to enhance health care quality and lower costs. **We believe that the range of VBP tools outlined in Phase II of CMS's model appear to be aligned with these goals and several hold promise.** For instance, we feel that indications-based pricing, risk-sharing agreements based on outcomes, reducing cost-sharing for high-value drugs, CDS and feedback tools have potential to promote value in Medicare Part B, depending on how and when they are developed and implemented.

However, these proposals are not set forth in sufficient detail to allow us to fully judge their potential. Further, the development of a robust comparative effectiveness evidence base is critical to support these VBP tools proposed by CMS. Yet, the federal government does not have the processes or infrastructure in place at this time to systematically and comprehensively collect and evaluate such data.

**Therefore, the AHA does not believe that these proposals will be ready to be implemented in the timeframe described in the proposed rule, and we strongly discourage CMS from using the sub-regulatory process to finalize or implement any of the tools described.** Instead, we encourage the agency to use the feedback received through this rulemaking to further flesh out the most promising of these proposals, vet them carefully with stakeholders in an organized way and then re-propose the more fully developed tools through notice-and-comment rulemaking. To that end, we provide our initial thoughts below.

**In addition, we believe that these VBP approaches should be tested individually, on a much smaller scale than proposed, through several voluntary demonstrations in well-defined therapeutic categories.** Lastly, we strongly support the collection and use of comparative effectiveness data and encourage CMS to pursue the development of such an evidence base, in collaboration with the Patient-Centered Outcomes Research Institute (PCORI), the FDA, the National Institutes of Health (NIH) and other emerging public-private initiatives.

Reference Pricing. This policy would set a standard payment rate – a benchmark – for a group of therapeutically similar drug products. CMS believes that this approach would promote price competition and generate savings for the program and beneficiaries. **However, the AHA is concerned that reference pricing does not directly address manufacturer price inflation and, instead, would put hospitals and physician practices at risk for price differences between drugs that may or may not be**

**“therapeutically similar” for individual patients.** That is, patients’ medical conditions are not uniform; a drug that is effective on average may be ineffective, or even dangerous, for a particular patient. In addition, this approach assumes that, by setting a benchmark price based on the average ASP for the drugs in the group, or based upon the most effective drug in the group, manufacturers would have an incentive to lower their price below their competitors’ in order to make their product more attractive and garner market share. However, one also could foresee just the opposite happening. That is, a manufacturer with a product priced below the benchmark could reason that there would be no harm in increasing their price to the average rate so as to maximize their profit. This would have the impact of driving the average up and increasing overall spending for drugs in the group.

Indications-based Pricing. This tool would vary the payment for a drug based on its clinical effectiveness for the different indications for which it has been approved. CMS would use evidence from published studies and reviews or evidence-based clinical practice guidelines that are competent and reliable. In the proposed rule, CMS provides the example of evidenced-based clinical practice guidelines, such as those issued by the Institute for Clinical and Economic Review (ICER). **The AHA believes that indications-based pricing holds promise as a tool that can be further developed for future use in the Medicare program, with attention towards development of administrative measures to indicate feasibility.** However, additional work is necessary to determine the clinical effectiveness of particular drugs for their various indications; we strongly support the collection and use of comparative effectiveness data for this purpose. Furthermore, we do not believe that hospital information systems are currently able to operationalize the coding that would be needed to correctly implement indications-based pricing. In order for this tool to be used, hospitals’ electronic health records and claims processing systems would need to be able to easily link a particular drug to the indication for which it was prescribed. In addition, CMS and the FDA would need to provide an authoritative, verified cross walk of each drug to the various indications for which payment will vary that will need to be maintained over time. In that process, CMS and FDA would need to determine whether the existing ICD-10 coding system sufficiently captures the indications for which payment will be varied. This is because the current claim standard only includes diagnosis codes, without separate fields for drug indication.

Risk-sharing Agreements Based on Outcomes. This policy would allow CMS to enter into voluntary outcomes-based risk-sharing contracts with drug manufacturers to link price adjustments for a drug to patient health outcome goals. CMS intends to base these goals on outcome measures submitted as part of a package of scientific evidence submitted by the manufacturer regarding the clinical value of a drug. The outcome-based agreements tie the final price of a drug to results achieved by specific patients rather than using a predetermined price based on historical population data. Manufacturers agree to provide rebates, refunds or price adjustments if the product does not meet targeted outcomes.

**While this approach shows potential, we do not believe that hospital information systems are ready to implement it. Furthermore, there are programmatic and operational challenges that must be addressed.** First, drug manufacturers and providers must agree upon appropriate outcomes that can be tracked and achieved within a reasonably short period of time. In addition, hospital information systems must be able to readily provide the data to demonstrate whether the chosen outcome has been achieved. Finally, the outcome must be able to be linked directly to the drug therapy.

Discounting or Eliminating Patient Cost-sharing. This policy would decrease or eliminate cost-sharing to improve beneficiaries' access and appropriate use of high-value drugs. CMS notes that any reduction in beneficiary cost-sharing would not change the overall payment amount for the drug paid to the provider or supplier.

**The AHA supports reducing or eliminating patient cost-sharing for high-value drugs.** Linking the level of cost-sharing to the effectiveness of a drug regimen supports greater compliance with treatment plans and, therefore, could help decrease unnecessary utilization across the health care system, such as unplanned emergency department visits and hospitalizations. As noted above, the AHA strongly supports the collection and use of comparative effectiveness data to support the determination of the value of drugs and appropriate levels of beneficiary cost-sharing. However, we recognize that the federal government does not have the processes or infrastructure in place at this time to systematically and comprehensively collect and evaluate such data, and we again encourage CMS to pursue the development of such an evidence base in collaboration with PCORI, FDA, NIH and emerging public-private initiatives.

Feedback on Prescribing Patterns and Online Decision Support Tools. CMS proposes the use of a two-component CDS tool for physicians in the VBP arms of the model. Physicians participating in the model would voluntarily access the education tool online. The tool would use high-quality evidence to educate physicians on best practices for prescribing. It also would provide clinicians with feedback on their prescribing patterns compared to others.

**The AHA supports the development and use of CDS tools that provide prescribers with evidence-based and timely information to help them select the most clinically effective drugs for their patients and promote safe prescribing. The AHA also supports the development and use of provider report cards to enable providers to compare their performance with their peers at the local, state and national levels.** Similar tools already in use in some hospitals and health systems have been effective in changing clinicians' practice patterns to better align with evidence-based developments and best practices.

Episode-based or Bundled Pricing Approach. CMS also seeks feedback on (but does not propose) a number of other VBP options, including whether the agency should pursue a more bundled pricing or episode-based approach for Part B drugs in both HOPDs and

physician offices, that moves beyond an FFS payment structure. **The AHA supports and encourages CMS to develop models under which the provider would be responsible for managing the cost of an entire episode of care, rather than just on one component of care, such as Part B drug costs.** We believe that this could promote greater incentives for improved patient outcomes and financial accountability for the whole course of treatment for Medicare beneficiaries.

## QUALITY MEASURES

**The AHA also has serious concerns about the lack of quality measures included in the Medicare Part B Drug Payment Model.** While we agree that CMMI has broad authority to conduct demonstration projects, it does not appear that CMS will track beneficiary quality of care during the two phases of the model. In particular, CMS does not describe how it proposes to meet the dual programmatic objectives required in the statute that CMMI models reduce program expenditures while simultaneously preserving or enhancing the quality of care for those individuals who receive Medicare benefits. In fact, the statute explicitly instructs CMMI to give preference to testing models that “also improve the coordination, quality, and efficiency of health care services” furnished to Medicare beneficiaries. The proposed rule includes no discussion of how it will evaluate the quality and safety impact of the model’s proposals on Medicare beneficiaries nor does it propose any measures of patient-level outcomes and patient-centeredness criteria. Such measures would be critical to ensuring that the model does not reduce the quality of care while it reduces spending.

## OTHER ALTERNATIVES CMS SHOULD EXPLORE FOR THE MEDICARE PROGRAM

One of the primary goals of the proposed model is to reduce spending on drugs while improving the effectiveness and quality of care. While this opportunity focuses on Part B spending, there is significant opportunity to reduce costs on prescription drugs in other parts of the Medicare program, and more broadly through greater transparency in pricing and enhanced competition writ large. As noted above, CMS estimates that total Part B payments for separately paid drugs have increased by an average of 8.6 percent annually since 2007, totaling \$22 billion in 2015. Certainly these are substantial figures, but spending under Part D is far greater – it has increased by an average of 6.8 percent annually since 2007 and is projected to total over \$85 billion in 2015. Therefore, we encourage CMS to consider the options below for reducing spending in the Part D program. We also encourage CMS to work with the FDA and NIH on the broader reforms that are necessary to redirect the pharmaceutical industry toward value.

Increase the Part D Reinsurance Threshold or Discontinue the Program Altogether. Under the Part D prescription drug program, the federal government covers 80 percent of the costs for enrollees who have spending above the out-of-pocket threshold. Insurers and beneficiaries share the responsibility for the remaining 20 percent, at 15 and 5 percent, respectively. These “reinsurance” payments are substantial: in 2013, the federal



government's portion totaled nearly \$20 billion for approximately 2 million Medicare beneficiaries.<sup>2</sup> Further, since the program's inception, the percentage of costs covered through reinsurance payments has increased. **We are concerned that this program shields Part D plan sponsors from high costs to an inappropriate degree, and, therefore, may create disincentives for plan sponsors to aggressively negotiate drug prices with manufacturers and manage enrollees' care.**

**Therefore, we urge CMS to consider designing a pilot project to test a new Part D payment model that either reduces or eliminates reinsurance payments while making appropriate adjustments to the direct subsidy rate.** CMS could test whether shifting more of the financial risk to insurers leads to appropriate reductions in program spending, such as through stronger negotiations with drug manufacturers or improved care management. This alternative is consistent with MedPAC's recent recommendation on improvements to the Part D program.

**ASP Inflation Cap. Another option that CMS should consider to put downward pressure on drug prices is an ASP inflation cap** – an approach that MedPAC has discussed in recent meetings. Such a cap could be operationalized through a manufacturer rebate to Medicare when the ASP for a drug increases faster than a specified inflation benchmark. This policy would protect the program and beneficiaries from dramatic increases in the Medicare payment rate for drugs, such as the increases of 78, 68 and 44 percent that occurred in the cost per unit of Cyanocobolamin (Vitamin B-12), Cyclophosphamide 100 ml and Aminolevulinic acid HCl respectively, in just one year, between 2013 and 2014. Such a policy also could potentially generate savings for drugs with ASP growth above the inflation benchmark. While there is some concern that an inflation cap could incentivize drug manufacturers to protect their revenues by setting a very high launch price for new drugs, we believe that there are other ways to address this issue.

This approach is similar to the inflation portion of the Medicaid rebate program which has consistently achieved better pricing on drugs than the Medicare program. For example, in 2012, the Office of the Inspector General (OIG) found that Medicaid programs achieved rebates worth 47 percent of Medicaid expenditures, while Medicare Part D plan sponsors achieved rebates worth only 15 percent of their expenditures. Medicaid programs also were able to negotiate net unit costs of less than half of the amount paid by Part D sponsors for 110 of the 200 drugs evaluated by the OIG. Part D sponsors were only successful in negotiating lower net unit prices for five of the drugs. The primary driver behind the lower net unit costs were required by statute, additional rebates that kick in when the average manufacturer price for a drug increases faster than inflation.

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<sup>2</sup> MedPAC, "[Chapter 6: Sharing Risk in Medicare Part D](#)," June 2015.

Other evidence suggests consistent findings for other drugs purchased for Medicare beneficiaries through Part B of the program. In a 2013 report, the OIG found that Medicare could have saved \$2.4 billion (or 26 percent) in Part B spending in 2010 if drug manufacturers had provided Medicare with the same rebates they give to Medicaid programs for just 20 high-cost drugs.

**The AHA encourages CMS to evaluate a payment model that implements mandatory additional rebates to purchasers when a drug manufacturer increases the price of a Part B drug at a rate higher than inflation. If CMS were to establish such a model, we would urge it to ensure that both beneficiaries and providers benefit from the savings achieved from the rebate. This model also could be tested in Part D of the Medicare program.**

#### **OTHER APPROACHES NEEDED TO ADDRESS DRUG PRICES**

While we commend CMS for tackling this challenging issue, high and rising drug prices cannot be solved through Medicare payment policy alone. A multi-faceted effort is needed that improves transparency in the drug pricing process, increases competition, and incorporates value in drug approval, coverage and pricing decisions. This framework – transparency, competition and value – is reflected in the Campaign for Sustainable Rx Pricing’s (CSRxP) [Proposal for Change](#), which identifies policies to address drug pricing while encouraging innovation.<sup>3</sup> The AHA participates in the CSRxP effort. While we recognize that many of the policy options included in the proposal are outside of the jurisdiction of CMS, we believe it is important that all federal agencies understand the various challenges leading to high and rising drug prices and work collaboratively to address these issues.

Transparency. Today, we have very little evidence of what it actually costs to develop a new drug, and who incurs the cost of that development. For example, drug manufacturers routinely cite investment in research and development as a primary driver of high prices. However, for any given drug, we do not have full information on what investment the submitting manufacturer made into the research and development process. We know that, in many instances, a substantial portion of those costs may be borne by other parties, including the NIH, academic medical centers and other drug manufacturers. In aggregate, we do know that drug manufacturers spend far more on marketing than they do on research and development.<sup>4</sup> Given taxpayers’ significant investment in drugs – both through financing research and coverage through public programs – it is appropriate to require manufacturers to provide evidence to support drug prices, particularly when those prices are prohibitively expensive for many patients, the providers who treat them and payers, including state governments. This information will be critical for the government

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<sup>3</sup> “Proposals for Change,” the Campaign for Sustainable Rx Pricing, April 25, 2016. Accessible at: <http://www.csrpxp.org/wp-content/uploads/2016/04/CSRxP-Policy-Platform-Summary.pdf>

<sup>4</sup> Spiro, T., et. al., “Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices,” Center for American Progress, September 2015.

and other payers as they make coverage and pricing decisions, as well as create a public “check” on any drug manufacturer who raises prices to indefensible levels.

Competition. The federal government recognizes that drug manufacturers that are first to market with a therapy likely have made a considerable investment in the development of the drug and, therefore, brand drugs are given a period of market exclusivity to provide them with an opportunity to recoup that investment. This market exclusivity period also provides an incentive for manufacturers to develop new, innovative drugs where therapies do not currently exist.

Unfortunately, some manufacturers abuse market exclusivity protections and attempt to block competition from entering the market when their period expires. We have seen manufacturers attempt to extend these exclusivity periods by making slight modifications to existing drugs (“evergreening”), paying generic manufacturers to delay entry into the market (“pay-for-delay”), abusing Risk Evaluation and Mitigation Strategies to withhold critical drug information from generic manufacturers, and seeking orphan-drug status for drugs that they ultimately intend to sell for multiple indications, not all of which would qualify as orphan diseases. In addition to these more egregious abuses by manufacturers, the FDA does not appear to have the resources to address the significant backlog of generic applications, which could, if approved, apply downward pressure on prices.

Value. The U.S. health care system is reorienting toward value. However, while most providers are participating in some form of value-based purchasing through which reimbursement is either all or in part based on health outcomes, efficiency and quality, very few drug manufacturers have contracted on such terms. A significant part of the challenge is that we have very little data on which treatments are more and less effective – on both a population and individual basis. We need to develop this evidence base to support providers in making care decisions, to help payers make coverage decisions and develop value-based purchasing models, and to support policymakers in evaluating and advancing appropriate drug policy.

Conclusion. We look forward to working with Congress, CMS and other stakeholders as we work to explore alternatives to achieving sustainable drug prices while maintaining critical investments in innovative new therapies.