Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

Via Electronic Submission (www.regulations.gov)

May 9, 2016

Acting Administrator Andrew Slavitt
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1670-P, Part B Drug Payment Model, Proposed Rule

Dear Acting Administrator Slavitt:

The Association of American Medical Colleges (the Association or the AAMC) is a not-for-profit association representing all 145 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and 93 academic and professional societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians. The Association welcomes the opportunity to comment on the proposed rule, Part B Drug Payment Model, 81 *Fed Reg* 13230, March 11, 2016.

Background

CMS has proposed a two phase mandatory nationwide model designed to address various methods for tackling the rising costs of Part B spending that are attributed to drugs which currently are paid at average sales price (ASP) + 6%, as mandated by law. The Agency states that in Phase 1 it will "test redistribution of the add-on payment on Part B drugs expenditures and outcomes" and in Phase 2 it will "test the application of a group of value-based purchasing tool that commercial and Medicare Part D plans use to improve patient outcomes and manage drug cost".

The payment model will divide providers and suppliers into two groups. During Phase 1 the control group will be paid ASP + 6% and the other group will be paid ASP + 2.5% + $16.80 per drug per day administered to maintain budget neutrality. This phase will start no earlier than 60 days after display of the final rule. Phase 2 will begin no earlier than January 2017. This phase will involve four groups with the following payments: ASP + 6%; ASP+ 6% with value based payment (VBP) tools; ASP + 2.5% + $16.80; and ASP + 2.5% + $16.80 with VBP tools. CMS

proposes that the model will run for five years. The Agency also proposes to include in this model beneficiaries, providers, and suppliers in the Medicare Shared Savings Program, the Medicare Intravenous Immune Globulin Demonstration, and other Innovation Center payment models such as the Oncology Care Model (OCM) and the Bundled Payments for Care Improvement (BPCI) initiative.

The AAMC agrees with CMS that one of the drivers of increased Part B spending is the rapidly rising cost of drugs and we appreciate that CMS has attempted to find a way to address the problem within its current authority. However, as proposed, the rule will harm hospitals, physicians, and the patients they serve. The AAMC urges CMS to tackle the issue of escalating drug cost from its root and ask Congress for the authority it needs to address the problem in other ways. Whether or not the Agency pursues this path, CMS can consider a more limited and targeted model, as the AAMC discusses below. Only after the results of this model are evaluated would there be a consideration about whether expansion is warranted.

The Proposal Should Be Significantly Revamped To Avoid Harming Patients, Hospitals, and Physicians

The CMS proposal seems to assume that changing the payment to hospitals and other providers will change physicians' prescribing behavior. The rule seeks to eliminate financial incentives for providers to prescribe more expensive drugs. However, physicians choose drugs based on what they believe to be the best course of treatment for their patients based on a variety of factors, including many clinical considerations. As currently structured, the proposed model can overpay for inexpensive drugs (for example, ASP +$16.80 for a drug that costs $10) and underpay for expensive drugs. Also problematic is that for many diseases and conditions, the drugs available for treatment do not include a less expensive alternative. Therefore, the model merely underpays for a drug that is needed by the patient and would have an adverse impact on access to clinically effective drugs for some patients.

CMS's assumption on behavior change also overlooks the fact that under the outpatient prospective payment system the majority of drugs that cost less than $95.00 per day are packaged and do not receive separate payment. As a result, the assumed benefits to prescribe low costs drugs as well as the premise upon which the experiment is designed do not apply for hospitals.

In addition, for some diseases costly diagnostic and genetic testing is needed to determine the exact drug regimen that will be most beneficial to the patient and monitoring is needed as the drug is administered. This type testing and support can only be found in hospital outpatient departments which the data show will be particularly hard hit if the rule is finalized as proposed.

The proposed rule will represent a significant payment cut to hospitals, including those that serve the most vulnerable patients. As MedPAC showed in its June 2015 report, starting in 2003 and continuing through 2013 (the most current data), Medicare hospital outpatient margins have been negative. On average, Medicare pays less than 90 cents for every dollar hospitals spend caring for Medicare beneficiaries in the outpatient setting. The margins include savings/benefits from

the 340B program. The Part B drug proposal will further reduce Medicare reimbursement for outpatient services and hurt hospitals that are providing services that cannot be found elsewhere. An Avalere analysis of the impact of the proposed rule found that hospital outpatient departments are project to lose the most revenue as a result of the changes, accounting for 60 percent of the payment reductions under the new model.

CMS projects that one of the effects of this proposal will be to redistribute payment from some physician specialties to others. Specifically, this proposal redistributes payment for Part B drugs from ophthalmologists, oncologists, and rheumatologists to family practice, orthopedic surgery, and internal medicine. Such a redistribution suggests that the financial impact of the experiment is mostly driven by the patient population served by different physician specialties, which is unrelated to physician prescribing behavior. For example, a large proportion of patients cared for by primary care physicians require low cost drugs, such as antibiotics or IV fluids, which leads to financial gains under the proposed formula. On the other hand, oncologists and rheumatologists tend to treat more critically ill and complex patients that require newer, first-in-class, more expensive drugs, and as a result would suffer financial loss under the model for merely providing the best care to their patients.

Finally, this program should not be layered on top of previously existing models such as the Medicare Shared Savings Program (MSSP), Bundled Payments for Care Improvement (BPCI), and the Oncology Care Model (OCM). Each of these programs already has established benchmarks and quality measures that are tied to financial incentives. To suddenly impose another demonstration on top of those that that already are on-going will introduce a confounding factor that weakens the assessment of individual programs. Even if and when a reconciliation methodology is finalized, the program overlap and corresponding methodology would introduce further unnecessary complexity into the Medicare payment system.

The potential adverse effects of the Part B Drug Payment model on other CMS models is especially pronounced in the case of OCM. As the proposed rule notes, Part B drug payments account for approximately 80 percent of oncology practice Medicare FFS revenue. OCM participants have been planning for implementation since March of 2015, and will begin accepting risk for their Medicare patients on July 1, 2016. Upon the request of CMS, these participants completed financial planning to demonstrate their ability to generate Medicare savings and internal savings under OCM given the payment methodology and their necessary resource investments. The underlying assumptions of these projections are based on the current Medicare Part B payment system. Dramatically and hastily altering Medicare Part B methodology would not only negate the extensive financial planning of OCM participants, but potentially hinder providers' ability to succeed under OCM.

A Slower, More Targeted Approach Could Be A First Step

CMS proposes a very aggressive timeline, with the possibility that even before CMS evaluates the impact of Phase I on access, outcomes, and other elements, Phase 2 would start. The rule also does not give specifics about the VBP tools that will be used. As with all quality programs, there is a need for specificity about the tools, including evidence that they are effective, and a

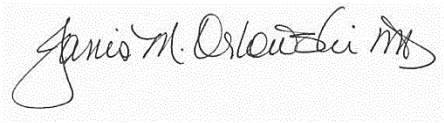
comment period on these tools is needed to allow stakeholders to provide feedback. CMS should not consider beginning Phase 2 prior to an evaluation of Phase 1 and also should look to lessons learned from other payment models.

As an alternative, CMS could try a smaller, voluntary model that is limited to treatments for which it is possible to identify classes of drugs for which there are alternatives that are equally clinically effective and available at lower prices. If an evaluation of this demonstration shows that it has positive effects on prescribing behavior, then CMS could consider taking the lessons learned and propose an expansion as part of rulemaking. Using this approach would also allow CMS to further examine and gather information on value-based purchasing tools that should be considered for testing.

CMS should also invest resources to convene experts to identify clinical pathways that reduce prescribing variability, maintain or improve quality of care, and reduce costs of care. This information could be shared with providers and implemented in future programs.

Thank you for your consideration of these comments. If you need additional information, please contact Ivy Baer, ibaer@aamc.org, 202-828-0499.

Sincerely,



Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

cc: Ivy Baer, AAMC

.