



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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April 27, 2016

Andrew M. Slavitt
Acting Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-1670-P, P.O. Box 8016,
Baltimore, MD 21244-8016.

Submitted electronically via <http://www.regulations.gov>.

Subject: [CMS-1670-P] Proposed Rule: Medicare Program; Part B Drug Payment Model

Dear Administrator Slavitt:

On behalf of the 18,000 board-certified orthopaedic surgeons who comprise the membership of the American Association of Orthopaedic Surgeons (AAOS), we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on the Medicare Program's Part B Drug Payment Model [CMS-1670-P] published in the Federal Register [42 CFR Part 511] on March 11, 2016. This request for information seeks public comments regarding several items related to the implementation of a new Medicare payment model (Part B drug payment model) under Section 1115A of the Social Security Act.

We are supportive of CMS' efforts to reduce Medicare expenditures while enhancing care for the most vulnerable beneficiaries based on the Administration's triple aim of "better care, smarter spending and healthier population." Please find our specific comments, below, in the order of their appearance in the proposed rule publication.

Model Overview

This proposed Medicare Part B prescription drug payment model includes two phases of implementation. Currently, Medicare pays physicians and hospital outpatient departments the average sales price of a drug plus 6 percent. Per these proposed rules, Phase I (expected to begin in late 2016) would test whether changing the add-on payment to 2.5 percent plus a flat fee of \$16.80 per drug per day would influence prescribing practices thereby improving value. We appreciate the well-considered design for evaluating this test and have additional comments on it below. Nevertheless, we would like to note that the proposed payment model will be most

successful for drugs which have lower cost therapeutic alternatives readily available.¹

Phase II would introduce value-based purchasing (VBP) tools to Part B drug payments by January 1, 2017. As you have noted in the proposed rules, commercial insurers in the United States (and some European countries)² have had positive results from implementation of VBP tools. AAOS supports the proposal to reduce or eliminate patient cost-sharing. This would reduce burden on fixed income seniors or low income individuals with disabilities who receive Medicare benefits. Between 2004 and 2014, Medicare's share of US drug expenditures increased from 2 percent of \$193 billion to 29 percent of \$298 billion. At the same time, about 1 in 4 people in the United States who take prescription drugs reported difficulty affording them.³ Generic substitution as targeted by Phase I of this model is likely to help with this as well. There is support in the literature on generic drugs reducing consumer costs. According to one estimate, in 2000, generic substitution for brand name outpatient drugs was expected to create median annual savings in drug expenditures per person of \$45.89 for adults younger than 65 years of age and \$78.05 for adults at least 65 years of age. For these age groups, the national savings would have been approximately \$5.9 billion and \$2.9 billion, respectively.⁴

AAOS also supports providing feedback on prescribing patterns and online decision support tools to providers. Information on a clinician's prescribing patterns as compared to geographic and national trends and related appropriate use guidelines are likely to be helpful. AAOS is a leader in developing appropriate use criteria (AUC) by combining "the best available scientific evidence with the collective judgment of physicians in order to determine the appropriateness of performing a procedure." For example, osteoporosis is common among Medicare's women beneficiaries who experience multiple chronic conditions (such as arthritis, osteoporosis, and hypertension) at higher rates than men, and this gender gap persists as they age.⁵ The United States Bone and Joint Initiative (USBJI) coordinated a multi-disciplinary work group on the Chronic Osteoarthritis Management Initiative (COAMI) which was tasked with "changing the paradigm of Osteoarthritis (OA) management". COAMI encouraged treatment of OA as a chronic condition and considered non-surgical patient centered treatments for OA such as

¹ Office of the Assistant Secretary of Planning and Evaluation (2016, March 8). Medicare Part B Drugs: Pricing and Incentives. Issue Brief. Washington, D.C.: U.S. Department of Health and Human Services. Retrieved from: <https://aspe.hhs.gov/sites/default/files/pdf/187581/PartBDrug.pdf>

² Grabowski, H., Guha, R., & Salgado, M. (2014, February). Biosimilar competition: lessons from Europe. *Nature Reviews/Drug Discovery*, 13.

³ Cox C, Kamal R, Jankiewicz A, Rousseau D, for the Kaiser Family Foundation. (2016). Recent Trends in Prescription Drug Costs. *JAMA*, 315(13):1326. doi:10.1001/jama.2016.2646.

⁴ Haas, J. S., Phillips, K. A., Gerstenberger, E. P., & Seger, A. C. (2005). Potential savings from substituting generic drugs for brand-name drugs: Medical Expenditure Panel Survey, 1997- 2000. *Annals of Internal Medicine*, 142, 891-897.

⁵ Kaiser Family Foundation (2013). Medicare's Role for Older Women. Retrieved from : <http://kff.org/womens-health-policy/fact-sheet/medicares-role-for-older-women/>

through activity modification, medication and physical therapy.⁶ AAOS has developed and published an AUC on “[Osteoarthritis of the Knee: Non-Arthroplasty Treatment](#).” More such nonsurgical AUCs need to be developed to support the development of VBP tools in prescription medication payment. We would also like to draw your attention to publically available and evidence-based orthopaedic Clinical Practice Guidelines (CPGs) developed by AAOS following the Institute of Medicine (IOM) standards and available through a web and mobile device based platform called *OrthoGuidelines* (<http://www.orthoguidelines.org/>).⁷

Implementation of VBP: Competitive Acquisition Program (CAP) vs. Episodic Payments

In terms of extending and updating the CAP, we at AAOS, would like you to refer to a detailed evaluation⁸ of this program for Medicare Part B drugs which found that although a number of vendors were found to be eligible bidders for the program, only one signed up to participate. Also, due to the small number of participating physicians, it was difficult to gain statistically valid results on whether the CAP program resulted in savings for the Medicare program. Physicians in the CAP program were overall satisfied with it, although they also reported confusion with this complex program.

Given the current focus of the Medicare program to shift fee-for-service payments to episode-based payments, it may be worthwhile to consider a bundled payment approach for Part B prescription drugs. That is, a single payment would cover prescription drugs and their administration costs across all settings and providers as well as related services during a defined period. As the Medicare Payment Advisory Commission’s (MedPAC) June 2015⁹ report pointed out, constructing bundles will be complex and some clinical areas may be more suitable to such bundles than others. However, the existing literature shows that such bundling will lead to better prices for acquiring drugs and biologics for Medicare beneficiaries.

Types of Providers and Suppliers Furnishing Part B Drugs

AAOS is mostly concerned with payment and costs for injections such as intra-articular steroid

⁶ Leahy, M. (2012). Changing the Paradigm for Diagnosing and Treating Arthritis. Retrieved from: <http://www.aaos.org/AAOSNow/2012/Nov/clinical/clinical6/>

⁷ American Academy of Orthopaedic Surgeons (AAOS). Orthoguidelines. Retrieved from: <http://www.orthoguidelines.org/>

⁸ Drozd, E.M., Healy, D.A., Greenwald, L.M., Morley, M.A., & Munevar, D. (2009, December). Evaluation of the Competitive Acquisition Program for Part B Drugs: Final Report. RTI International CMS Contract No. 500-00-0024, T.O. 24. Retrieved from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/CAPPartB_Final_2010.pdf

⁹ Medicare Payment Advisory Commission (2015, June) Value-based incentives for managing Part B drug use. Report to the Congress. Chapter 4. Washington, DC: MedPAC

and hyaluronic acid which are administered incident to a physician's service in the physician's office or hospital outpatient settings. Also, pediatric orthopaedic surgeons and sports medicine specialists inject Human Growth Hormone and other osteoporosis drugs. In response to your soliciting comments on the potential impact of this proposed payment model on types of providers, we would like CMS to consider that the new payment model may create disincentives for rural suppliers of prescription drugs who may have higher administrative costs. This coupled with the shortage of orthopaedic surgeons¹⁰ in rural areas may exacerbate access problems for rural Medicare beneficiaries. Related to this, is the issue of small and solo orthopaedic practices who may face additional barriers in receiving supplies of necessary injectables under the new payment methodology.

We would also like to express our concerns on including drugs in short supply in this proposed Medicare Part B payment model. AAOS has been working with the federal and state governments as well as other orthopaedic specialty organizations in ensuring that our patients have necessary access to critical prescription drugs. For example, hand, wrist, elbow, and upper extremity specialists, recently experienced shortage of phentolamine. Phentolamine is the only alpha blocker that is an antagonist to adrenaline vasoconstriction and has been shown to reliably reverse epinephrine vasoconstriction in the human finger, and is the antidote for prolonged epinephrine induced vasoconstriction caused by EpiPen injuries or wide awake hand surgery. The last American supplier of phentolamine stopped its production in January 2015. AAOS joined eight orthopaedic specialty societies in requesting the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research to overcome this drug shortage.¹¹ The AAOS is concerned that decreasing reimbursement will lead to an inability to finance the infrastructure for drug acquisition within a department or practice. That, in turn, may mean that a treatment is less available for Medicare members.

Proposed Participants, Selected Geographic Areas and Sampling

As an organization that upholds evidence-based medicine, we commend CMS on proposing a model evaluation design that accounts for selection bias, incorporates stratified random sampling and ensures adequate statistical power for sub-group analyses. While we understand the rationale behind proposing a mandatory model requiring participation of all providers furnishing Part B prescription drugs, we believe this may impose administrative and financial burden on providers. Instead, we would request CMS to consider rolling out the proposed model in limited Primary Care Service Areas (PCSA) as a pilot. Pilot PCSAs may be selected on the basis of the number of Medicare beneficiaries in each PCSA and the mean Part B drug expenditures per beneficiary.

¹⁰ Fu, M. C., Buerba, R. A., Gruskay, J., & Grauer, J. N. (2013). Longitudinal urban-rural discrepancies in the US orthopaedic surgeon workforce. *Clinical Orthopaedics and Related Research*, 471(10), 3074-3081.

¹¹ AAOS Advocacy Now (2015, October 27). Phentolamine Concerns Heard. Retrieved from: http://www.pwrnewmedia.com/2015/aaos/advocacy_now/oct27/pages/article6.html

The assignment on each PCSA to an arm of the study may still be based on the stratified random approach, as proposed.

Another alternative could be to test a “pilot” focused on the small number of Part B drugs that account for the highest proportion of Medicare payments. As noted in the referenced report from the Office of the Assistant Secretary for Planning and Evaluation (ASPE, 2016), the costliest 20 drugs account for 57 percent of Medicare’s payments for Part B drugs and the costliest 10 drugs account for 38 percent of total payments. However, as noted above, including single source drugs in the proposed payment model is likely to have additional burden on providers and hamper necessary, and often life-saving care.

While AAOS has largely been supportive of CMS’ recent initiatives, the plethora of new payment models, especially the mandatory ones such as the Comprehensive Care for Joint Replacement (CJR) model and the current Part B payment model, create heavy administrative burden on orthopaedic surgeons to ensure their participation. In conclusion, AAOS appreciates the opportunity to comment, and looks forward to continued partnership with CMS to improve the effectiveness, patient-centeredness, and value of Medicare’s payment models.

Sincerely,



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