AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

December 18, 2018

Seema Verma, MPH
Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8016

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

Subject: [CMS-5528-ANPRM] Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) advanced notice of proposed rulemaking (ANPRM) regarding testing an International Pricing Index (IPI) Model for Medicare Part B drugs, published in the Federal Register on October 30, 2018.

AAOS appreciates CMS interest in reducing the cost of Medicare Part B drugs, biologicals and biosimilars. As the Department of Health and Human Services (HHS) pointed out in their recent analysis, 32 drugs accounted for $18 billion of the $27 billion total that was spent on Part B drugs in physician offices or HOPDs.[1] Putting patients first in any effort is paramount. Enabling physicians to help patients choose the medications best suited for their individual needs maintains patient safety, enhances treatment effectiveness, and strengthens the doctor-patient relationship. Additionally, AAOS recognizes the importance of ensuring that patients have access to affordable medications and supports efforts aimed at lowering the price of drugs for all Americans.

[1] "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" accessed via https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs.

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Model Overview

This proposed IPI Model for select Medicare Part B drugs makes several notable changes to the existing system for payment of drugs and biologicals. One proposal you note is to utilize the existing Competitive Acquisition Program (CAP) and expand it to allow a wide variety of entities to serve as a purchaser, title owner, and distribution manager (i.e. vendor) for the drugs listed in this proposal. This would change the current "buy and bill" model between providers and wholesalers or specialty distributers, and instead have the vendor work directly with providers to supply them with the drugs they need.

Several payment changes are also included in this proposal. In the current model physicians are paid +6 percent of the Average Sales Price (ASP), which you have estimated to be +4.3 percent after accounting for sequestration. We understand that you are proposing to pay the full +6 percent before sequestration, a +1.7 percent increase, and that this would not be tied to ASP, but instead be a fixed payment that correlates to +6 ASP. You also mention that payment for the drugs themselves will be given to model vendors and there will be no changes to drug administration payments.

While AAOS appreciates the increase in payment for the ASP add-on payment and related proposals, we have concerns related to the feasibility of this application. One such example was brought up in our April 27, 2016 comments in response to the initial CAP proposal. In that instance, multiple vendors participated in the initial bidding process, but only one vendor ended up signing a contract and participating in the program. While changes in the market and vendor distribution capabilities have changed since then, we ask what assurances in your current proposal will guarantee that there will be several vendors for providers to choose from, and that they will be effective in carrying out the responsibilities of this proposal? If there are not enough vendors in the program, will an alternative course of action be taken? What will ensure that the best suited, most innovative vendors participate and compete with one another? Without effective competition physicians could be left with an additional administrative layer that is cumbersome, restrictive, and disruptive to patient care and safety.

Mandatory Requirement

AAOS is particularly concerned that the model would **"require"** the participation of physician practices in selected areas across the U.S. and its territories. In CMS' own report from 2009 on the initial CAP program, they identified that "satisfaction with the CAP also appears to be correlated with the reasons that providers elected to participate in the CAP".[2]

[2] "Evaluation of the Competitive Acquisition Program for Part B Drugs" accessed via https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf

AAOS has consistently advocated that any new demonstration proposal should be *"voluntary"* and reward innovation and high-quality care. As with many new proposals, this is a complex arrangement for changing the collection, distribution use and payment of selected drugs and could put an undue regulatory burden on physician practices that are not currently aligned to handle such changes. Allowing those who have the capability, interest, and expertise to participate in a voluntary manner can help test the effectiveness of the new model while demonstrating if the proposal is useful for implementation across the broader healthcare ecosystem.

International Pricing Index (IPI)

Lastly, while AAOS appreciates CMS' interest in reducing drug prices, we have concerns regarding potentially confounding assumptions underlying the International Pricing Index (IPI) model that make it difficult to approximate the cost of drugs in the U.S. relative to other countries. Some of those differences include varying regulations and regulatory burden across countries, differing manufacturers, manufacturing processes, labeling of drugs, clinical indications and dosage recommendations, data collection processes and reporting, marketing practices, rebates and value-based arrangements and generic or biosimilar comparison equivalents. Many of these issues were brought up in the recently published HHS report on this topic. AAOS has concerns that the current proposed IPI does not sufficiently address these issues in the analysis nor accurately represents a true comparison of U.S. drugs to that of other countries. The lack of detail about reimbursement in the proposal makes it difficult to assess.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons' suggestions. We greatly appreciate the opportunity to comment on new models for reducing the cost of drugs in the U.S. AAOS commends CMS on their continued efforts to implement innovative new models to reduce costs and improve affordability. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

David Halsey MD

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President, AAOS

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