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December 30, 2018

VIA ELECTRONIC SUBMISSION

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-ANPRM
P.O. Box 8013
Baltimore, Maryland 21244-8013

Dear Administrator Verma:

On behalf of the American College of Osteopathic Family Physicians (ACOFP), we appreciate the opportunity to respond to the *Medicare Program; International Pricing Index (IPI) Model for Medicare Part B Drugs* advance notice of proposed rulemaking with comment (ANPRM).

The ACOFP is the professional organization representing more than 20,000 practicing osteopathic family physicians, residents, and students throughout the United States who are deeply committed to advancing our nation's health care system by improving health care delivery and outcomes, and ensuring that patients receive high-quality care.

Overall, as an organization our osteopathic family physicians practice in variety of settings, including in solo, small, group, rural, Native American Indian healthcare, and alternative payment models (APM). Generally, we are supportive of efforts to transition the health care system toward value-based care, which emphasizes holistic care, wellness, prevention, and avoiding unnecessary resource use. We also support proposals designed to leverage primary care to improve outcomes and reduce costs and to ensure vulnerable populations have sustained access to family physicians. Our members have witnessed firsthand how the rising prices of drugs adversely impact patient outcomes and lead to avoidable health care utilization and higher costs for federal health programs.

Our full comments are detailed on the following pages. Thank you for the opportunity to share these with you. Should you need any additional information or if you have any questions, please feel free to contact Debbie Sarason, Manager, Practice Enhancement and Quality Reporting at (847) 952-5523 or debbies@acofp.org.

Sincerely,

Duane G. Koehler, DO, FACOFP *dist.*
ACOFP President

ACOFP is concerned with the rising cost of drugs, both in Part D and Part B and we support agency efforts to address those costs and to increase transparency and competition. While we appreciate that there is much work to be done with regards to drug prices and costs, we have several concerns with the proposed IPI model. We welcome the opportunity to continue this discussion and to provide our firsthand experience with the cost of drugs and how it impacts overall patient care.

Most importantly, we strongly oppose any mandatory model that could greatly impact how physicians deliver care without a comprehensive understanding of how it might impact the quality of care and beneficiary outcomes. CMS solicits feedback on whether it should exclude small practices or establish a low-volume threshold to exclude such practices. We believe that this and any other similar models should be voluntary and initially low-risk to encourage physicians to participate, which would obviate the need for exclusions or low-volume thresholds. Our members participate in a variety of APMs and value-based care arrangements, regardless of the mandatory or voluntary nature of those models. Making a demonstration mandatory would only result in unfairly punishing the physicians who would be seriously disadvantaged or who do not have the administrative or financial capacity to meaningfully participate.

In the ANPRM, CMS expects participating physicians will be incentivized to prescribe lower-cost drugs, encourage "appropriate utilization," and therefore reduce beneficiary cost sharing. In fact, the agency suggests that financial incentives have necessitated this model and that alternative incentives are needed to ensure physicians use the cheaper available drug. ACOFP disagrees with this logic. Physicians, charged with providing the highest level of care to their patients, will use the medication that is most appropriate, regardless of whatever incentives might exist. Further, ACOFP has significant concerns with the agency's general position on incentivizing changes in utilization purely based on costs or prices. Tying physician behavior and practices to some financial incentive has never worked in a beneficiary's favor. Cost is but one of the many considerations when determining the most appropriate drug for a patient. In fact, the opioid crisis is an example of how incentivizing cheaper available opioids that are more addictive and subject to abuse can be counterproductive and can have significant, long-term consequences that are more expensive and problematic for beneficiaries.

We believe that the beneficiary's quality of care and health outcomes should be the primary driver; not cost-savings. ACOFP recognizes that more services do not necessarily result in improved outcomes, but we also believe that the cheapest option is not always the best option. Subsequently, we suggest CMS focus on developing appropriate quality measures associated with Part B drug use to correspond with patient outcomes. Once developed, CMS should be able to reward physicians based on performance, providing physicians with the flexibility to practice the highest standard of care in light of each beneficiary's unique characteristics and health care needs. Any attempt to directly manage how physicians deliver care is unlikely to result in improved outcomes or cost savings. One way to address this concern is to establish pricing for each type or category of medications that insurers will pay. If a pharmaceutical manufacturer agrees, then this would be the contracted price – there would be no prior authorization, tiered pricing, or any other barrier to ensuring patients receive the medications they need, when they need them.

ACOFP also recommends that in any future model related to drug prices, the agency include an element of price transparency. For example, vendors in the IPI model would have the ability to negotiate with manufacturers. The savings associated with this negotiation should be transparent. Further, we believe most of any accrued savings should be used to ensure participating physicians are not disincentivized from continuing to provide high quality care to beneficiaries. We also urge CMS to ensure that there are sufficient protections, oversight, and monitoring for adverse beneficiary

impacts to ensure that any incentives do not impact beneficiary access to needed or clinically appropriate care. Finally, with regards to beneficiary protections, we believe CMS should take specific steps to ensure vendors and stakeholders in the medication supply chain do not reap the benefits of lower prices by inflating prices for patients. Specifically, we urge CMS to consider ways to ensure patients experience the benefit of lower drug prices and that these savings are not solely accrued by insurers or some other third party.