AMERICAN OSTEOPATHIC ASSOCIATION

1090 Vermont Ave, Suite 500, Washington, DC 20005-4949 ph (202) 414-0140 | (800) 962-9008 | www.osteopathic.org

May 9, 2016

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

Re: Medicare Program; Part B Drug Payment Model

Dear Mr. Slavitt:

Thank you for the opportunity to comment on the proposed Part B Drug Payment Model. The American Osteopathic Association (AOA), which represents more than 123,000 osteopathic physicians (DOs) and osteopathic medical students nationwide, has long supported a health care payment system that rewards physicians on the quality of care they provide rather than volume.

The Centers for Medicare and Medicaid Services' (CMS) overall goals in the Part B drug proposed rule – reducing Medicare expenditures while preserving or improving the quality of care provided to Medicare beneficiaries are embedded in the Medicare Access and CHIP Reauthorization Act (MACRA). MACRA's Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APM) will enable a Medicare that can ensure high quality, person-centered care for all beneficiaries with more efficient spending, including efficient controls on spending for drugs. We therefore are concerned with the proposed timing to implement the Part B Drug Payment Model later this year, shortly before MACRA's first performance year begins on January 1, 2017.

Osteopathic physicians practice their patient-centered philosophy of medicine in every medical specialty with 56 percent of DOs practicing in primary care. Osteopathic physicians also comprise 40 percent of all physicians who practice in medically underserved areas. We appreciate that in creating this model CMS recognized the need for further support for primary care physicians, yet the proposed rule's approach to do so by increasing drug payments to primary care practices will only have a negligible impact. Since primary care practices have low spending on drugs, a percentage increase on this low amount will overall still only yield a small increase to the practice's revenue. Primary care services, rather than drugs, make up the majority of these practices' charges and are still significantly undervalued. We are also concerned that CMS' method of shifting payments will come at the detriment of specialty physicians, impeding access to needed medications and negatively impacting the quality of patient care, particularly in underserved areas.

The AOA appreciates the agency's specific concerns about rising drug costs and preserving patient access to medications that improve their quality of life and are oftentimes life-saving. We agree that action must be taken to encourage more rational spending. However, the agency's premise that

prescribing habits are financially motivated with "no clear incentives for providing high value care" does not adequately factor in that prescribing decisions are motivated by the individual needs of the patient. We recommend that the agency take additional steps to strike the proper balance between managing health care costs and preserving patient access to medically appropriate therapies and specialty care services in the payment model.

High value care must be considered in the full context of comprehensive, coordinated, patient-centered care. Individual patients respond differently to drug therapies and require different regimens depending on the course of their disease or chronic condition. The needs of the patient dictate the selection of the drug. Oftentimes the more expensive drug is the most appropriate drug, and may be the only option for a particular patient's condition.

While the payment model is not meant to interfere with medical judgment or the physician's ability to order reasonable and necessary Part B drugs as appropriate, the model is meant to affect prescribing behavioral responses. There is a fine line between affecting behavior and controlling medical care. The medical decision-making authority and professional autonomy of the physician must be safeguarded in this payment model. We encourage the agency to take the following recommendations and insights into consideration:

- **Quality of Care:** Cost efficiencies should not be at the expense of high quality care. If the payment model so incentivizes low-cost drug alternatives, it also may incur low quality. CMS must ensure that the payment model does not penalize physicians for treating patients who suffer from complex chronic illnesses, disabilities, and/or face behavioral health challenges that exacerbate their conditions. Drugs are not always interchangeable; less expensive treatment may be less effective than higher cost drugs which may be necessary and appropriate based on the patient's individual needs.

- **Physician Impact:** The proposed payment model may cause small physician practices, particularly in rural and underserved areas, to stop providing drug therapies to their patients in the office setting because these practices have less purchasing power and higher acquisition costs. Physician practices that make low-volume purchases do not have access to high-volume discounts and rebates as do outpatient departments that are part of a larger hospital system. Physicians may be forced to send their patients to these hospital outpatient departments for drug therapies, which would be counterproductive to the agency's intent to lower costs. Hospital outpatient departments are paid at least 25 percent more than physician practices for providing the same service. As well, these small practices continue to face pressure to consolidate or be bought out by a system, and this model could exacerbate these pressures further.

- **Geographic Area Selection:** According to CMS, in determining the most appropriate geographic unit for this model, the areas need to be large enough so that most providers and suppliers do not have practice locations in multiple areas which could create opportunities to influence a patient to receive a medically appropriate drug at a practice location that provides higher payment. CMS acknowledges that under the Primary Care Service Area (PCSA), large practices may have practice locations in more than one PCSA. These practices will be exposed to different payment methods simultaneously, which will most likely create administrative confusion. In addition, the opportunity still exists for some providers and

suppliers to unfairly take advantage of the payment system by sending patients to their locations that provide higher payment. The payment model also creates an additional level of competition, placing some practices at a financial disadvantage to their nearby peers in a different service area, depending on the payment method chosen for their own service area. The agency needs to more clearly explain how it will address these issues to alleviate any negative consequences.

- **Patient Impact:** The Part B Drug Payment Model also could result in patients receiving different standards of care depending on which payment model approach applies to their community. Patients living in rural and underserved areas could be hit hard if they lose access to health care services in communities that may only have one provider. Those patients would be faced with higher copayments and other personal financial burdens such as travel costs in order to receive services in a hospital outpatient department. Outpatient facilities may not be easily accessible for Medicare beneficiaries, particularly those who face socioeconomic difficulties and/or physical limitations due to their medical conditions. The payment model should be evaluated to determine whether health care disparities are exacerbated for patients who lose access to health care services in their communities.

- **Phase II:** We agree with CMS that value-based purchasing (VBP) tools should be used in a limited manner in the payment model. We also support the agency's goal to ensure that the model promotes integrity, transparency and accountability. As CMS considers which VBP tools to use to improve patient outcomes and manage costs, we agree that research findings should be valid, competent, reliable and generalizable to the Medicare population. Some guidelines and research results may lack sufficient data on certain patient populations, making the data inadequate for wide scale use. We also believe a clinical decision support (CDS) tool should focus primarily on enhancing patient-centered care by helping physicians engage patients in shared decision-making in order to tailor their care and drug treatment to the patient's specific needs and preferences. We support the agency's plan to solicit feedback on the evidence basis for information that is included in the CDS tool before it is finalized.

- **Step Therapy:** VBP and CDS tools should not lead to a de facto system of step therapy, forcing physicians to first try less expensive drugs when higher cost drugs may be more appropriate. We realize step therapy is a cost-saving tool used by insurance companies; however, it should not be used to restrict a physician's judgment or interfere with the practice of medicine. Step therapy can in fact increase costs of patient care when the less expensive drug proves to be ineffective, potentially causing complications to a patient's condition, and requiring additional appointments. Since many details of the VBP strategy need to be determined, CMS should issue a Request for Information prior to its proposed 30-day comment period to allow additional stakeholder input.

- **Cost-sharing:** When implementing a cost-sharing waiver, a safeguard should be in place to ensure the reduction or elimination of cost-sharing is not shifted back to Medicare beneficiaries in some other form. CMS also needs to specify what criteria it would use to determine high value services for the cost-sharing proposal. A cost-sharing waiver should make drugs and services more affordable for patients and provide incentive to adhere to necessary treatments, which in some cases may require the use of higher priced drugs.

- **Evaluation/MACRA:** We agree that the payment model should be evaluated. CMS should provide the results of its evaluation in annual reports and use the results to determine whether modifications are necessary as the model progresses. But first, CMS needs to clarify how it intends to obtain accurate data to assess the payment model given that the payment changes take effect concurrently with MACRA's implementation, which begins with its first performance year in 2017. APMs such as physician-led ACOs, which are responsible for the total cost of care, including drugs, and certain clinical practice improvement activities under MIPS will have an impact on prescribing habits of physicians in their effort to improve the quality of care while controlling costs. We are concerned that CMS will be unable to discern whether changes in prescribing patterns, quality of care, access, costs, outcomes, as well as unintended consequences, are the direct result of the payment model or the new requirements under MACRA. Without accurate data specific to the payment model, it will be extremely difficult, if not impossible, to assess whether improvements will be necessary.

Finally, we understand the need for mandatory participation in the payment model in order to prevent selection bias inherent in a voluntary participation model. However, the AOA is disappointed that the proposed model was developed with little, if any, input from stakeholders. The agency needs to specify what methods it will use, in addition to public comment periods and appeals process, to solicit direct input from physicians, hospitals and patients for the duration of the program to ensure that access to quality care and specialty services is not compromised.

In addition, physician practices will be given little time to adjust to the complexities of the payment model with Phase I expected to begin later this year and Phase II expected in 2017. We strongly recommend that CMS collaborate with physician organizations in developing outreach and educational material and provide a timeline for the release of these materials to ensure a smooth transition for practices that will be participating in the payment model. We look forward to working with CMS on this and other issues of importance to the osteopathic profession.

Sincerely,

John W. Becher, DO
President

The American Osteopathic Association (AOA) represents more than 122,000 osteopathic physicians (DOs) and osteopathic medical students; promotes public health; encourages scientific research; serves as the primary certifying body for DOs; is the accrediting agency for osteopathic medical schools; and has federal authority to accredit hospitals and other health care facilities. More information on DOs/osteopathic medicine can be found at www.osteopathic.org.