Biosimilars
FORUM

November 16, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

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

Re: CMS-3321-NC

Dear Acting Administrator Slavitt:

The Biosimilars Forum appreciates the opportunity to submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS's) Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models."

The Biosimilars Forum is a non-profit organization whose mission is to advance biosimilars in the United States with the intent of expanding access and availability of biological medicines and improving health care. The Forum is a voluntary group working on a consensus basis to develop policy positions to ensure the United States has a competitive, safe, and sustainable biosimilars market, providing more options to patients and physicians.

Eliminating the SGR formula was the first step towards moving to a higher performing Medicare program. The Medicare Access and CHIP Reauthorization Act (MACRA) will introduce unprecedented provider accountability into the system; therefore, it is imperative that all stakeholders continue to have the opportunity to participate in the implementation details. Accordingly, we look forward to working with the Agency in their efforts to move the Medicare program to a system focused on the delivery of quality care and value.

Our comments focus on a primary aspect of the Request for Information –Alternative Payment Models.

Alternative Payment Models (APMs)

MACRA establishes a process whereby eligible providers may seek to participate in Alternative Payment Models (APMs) and be reimbursed under a different set of rules from those that apply pursuant to the Merit Based Incentive Payment System (MIPS). An APM can be a model under the Center for Medicare and Medicaid Innovation (CMMI), a Medicare Shared Savings Program, a Demonstration under the Health Care Quality Demonstration Program (Section 1866C of the Social Security Act), or a demonstration required by federal law. An eligible professional can only participate in an APM through an Eligible Alternative Payment Entity. Such an entity must (i) require the participants in its APM to use electronic health records, (ii) pay for covered services based on quality measures comparable to those

used in MIPS, and (iii) bear more than nominal risk for losses incurred under the APM (or, alternatively, be a medical home expanded by CMMI).

The most prominent move toward value has been the development of alternative payment models (APMs), which have grown exponentially in variety and scale over the last decade. However, if structured inappropriately and without the safeguards necessary to ensure high-quality care, APMs could have unintended consequences that limit patient access to innovative treatments and vital services. These consequences could derail the advancements in medicine that have the potential to treat complex diseases that could never before be treated.

To date, there have been few efforts to promote quality measurement that captures the value gained from interventions that improve a patient's quality of life and/or functional status. Coupled with robust outcome measurement and appropriate weighting in determining payment, quality measurement plays a vital part in determining what behavior change(s) are likely to occur within APMs. Therefore, for APMs to be ultimately successful, quality measurement must be comprehensive and accurate enough to ensure that every patient receives the highest quality of care, while also being appropriately valued as part of a payment mechanism so that providers are incentivized in a truly patient-centered manner.

As CMS continues to implement an array of alternative payment models and as physicians are at greater financial risk for the care they provide, it is critical for the Agency to consider the impact these payment and delivery reforms will have on the development and use of biosimilars. In short, if new and existing models begin to hamper access to the highest quality innovative treatments it could impede the pace of innovation in products like biosimilars and subsequently diminish the promise for treating unmet medical needs.

Additionally, the Forum urges CMS to provide guidance on how payments for biosimilars will be made under these programs. These and other issues will impact the acceptance of biosimilars by providers and patients alike, dictating the clinical success of biosimilars as well as their ability to drive down overall health care spending.

Conclusion

These considerations are essential to ensuring a meaningful program. We appreciate your consideration of our view points on this important proposal. Please contact Michael Werner at michael.werner@hklaw.com should you have any questions.