September 24, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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

RE: [CMS-1695-P] Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma,

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and health professionals, appreciates the opportunity to respond to the Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model. We are committed to working with the Administration on policy proposals that increase access to high-quality health care for Americans.

The ACR appreciates the Center for Medicare and Medicaid Innovation (CMMI) soliciting public comment on key design considerations for developing a potential model that would test private market strategies and introduce competition to improve quality of care for beneficiaries. Specifically, CMMI is requesting public feedback on a potential model design that would accelerate the move to a value-based health care system building upon the Competitive Acquisition Program (CAP).

The ACR has concerns regarding recreating a CAP for Part B drugs, which was previously unworkable. In fact, we would oppose a CAP program if it were unchanged or similar to the previous program, or if it would not ensure adequate protections for patient access to medicines. As just one example, in the past there have been functionality problems with regard to how physicians had to order specific treatments with the CAP vendor in advance of the patient’s visit, which limited their ability to adjust therapies or dosages based on different patient needs they might identify in the visit. Additionally, past analysis of the CAP program revealed CAP payments exceeded average sales price (ASP) payments. Furthermore, there was a high rate of use of the emergency stocking provision (46%), suggesting physician would still need to have drug on hand as CAP did not allow for stored drugs. This was a sign of the CAP’s
logistical failure—physicians were using drugs that were on hand for commercial patients as a stop-gap for CAP patients, and then asking for payment under the emergency stocking provision post facto.

We are wary of creating new PBM-like intermediaries in the Part B drug space. Any new health delivery program must not provide vendors, PBMs, or any other suppliers or entities the ability to impose Part D-like utilization management practices (UM) such as prior authorization and step therapy, or other formulary tactics that restrict patient access, on Part B drugs. Patient access to Part B therapies is currently much greater than patient access to Part D therapies, where UM is imposed and patient cost sharing is higher.

If in a voluntary alternative Part B payment model there is a payment to physicians for managing and coordinating patient treatments, reimbursement to the provider must be sufficient to cover managing and coordinating that treatment, and all of the time and costs that go into such management. This includes and is not limited to drug acquisition, transportation, storage, insurance against loss of drug and other overhead, scheduling, hardware and software for electronic documentation, and retrospective denials of reimbursement. Payments for treatment management and coordination should be in addition to the regular fee schedule payment for administering the drug, and should cover additional coordination costs not currently reimbursed under the fee schedule.

We also recommend that in any voluntary alternative Part B payment model, HHS consider allowing physician practices to bid to become vendors. To ensure that competition is created in the marketplace, multiple vendors must be available in any alternate program. Physicians have experience negotiating with manufacturers and other stakeholders, and are ideally positioned to manage access, monitor outcomes, and prioritize patient care.

The ACR urges HHS to put proposals and details of any new CAP or CAP-like program through the formal rulemaking process so that we and other stakeholders can review details of a proposed program in order to assess and comment on impacts to practices and patient access. We also continue to urge HHS to avoid compulsory demonstrations that could reduce patient access to treatments. **We also reiterate our request from the HHS Drug Pricing Blue Print RFI and ask that any drugs with no cheaper and equally effective alternatives be excluded from any mandatory demonstration projects or other programs or policies that would reduce patient access to those drugs.**

Additionally, we recommend HHS continue to facilitate development and voluntary uptake of alternative payment models (APMs) that could address challenges such as drug distribution and affordability problems. The ACR will be bringing forward an Alternative Payment Model (APM) for rheumatoid arthritis that will incorporate a management fee for coordination of patient care and use of a treatment pathway. We would be pleased to discuss our model specifics with HHS as we go through the submission process. For example, a voluntary Part B demonstration could incentivize use of a rheumatoid arthritis treatment pathway based on specialty guidelines. This would address drug utilization while allowing for practices to continue
to negotiate better overall drug prices through Part B than occurs in Part D, as suggested by HHS’s dashboard.

The ACR is dedicated to ensuring that rheumatologists and rheumatology health professionals have the resources they need to provide patients with high quality care. We believe that payment programs must be designed to reflect the way practices treat patients and allow for provision of high quality care. The American College of Rheumatology appreciates the work CMS/CMMI does in this area and the opportunity to respond to this request for information. We look forward to being a resource to you and to working with the agency as a potential model is developed. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

David I. Daikh, MD, PhD
President, American College of Rheumatology

---