April 27, 2020

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21224

Submitted via regulations.gov

RE: [CMS-1744-IFC] Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma:

The American College of Rheumatology (ACR), representing over 7,700 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the interim final rule outlining Medicare and Medicaid policy and regulatory revisions in response to the COVID-19 Public Health Emergency (PHE) as published in the Federal Register on April 6, 2020. We welcome the chance to share our concerns about the impact of these policies on our ability to provide quality care to the 50 million Americans living with rheumatic diseases during this pandemic.

Rheumatologists provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. Rheumatologists and rheumatology physician assistants, nurse practitioners, and occupational and physical therapists, provide face-to-face, primarily non-procedure-based care, and serve patients with severe conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases. Compared to treatment and therapies provided solely by primary care, early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly surgical or interventional procedures. Rheumatologists and rheumatology professionals continue to care for patients with rheumatic diseases during the PHE.

The ACR greatly appreciates the Centers for Medicare and Medicaid Services’ actions to exercise flexibilities for providers during the PHE. It is clear that CMS recognizes the challenges our providers face in a time of uncertainty, particularly with regard to adoption of telehealth and documentation requirements and the increasingly complex clinical decision making due to the risks associated with COVID-19. We thank the agency for their continued work.
While we appreciate the continued flexibility, we do have some concerns regarding provisions highlighted in the interim final rule (IFR). Specifically, we are concerned with 1) the need for parity between audio-only telehealth visits and audio/visual telehealth visits and 2) the direct supervision via telecommunications policy as it relates to home infusion.

**Audio Only Telehealth Visits**

The ACR appreciates the agency’s swift action in providing flexibilities and discretion in telehealth regulations following the public health emergency declaration. Like many of our colleagues, most rheumatology practices have transitioned to predominately telehealth visits. We appreciate that CMS has recognized this shift in practices during the PHE to allow telehealth visits for new patients and for relaxing other parameters, including the rural health provisions.

Rheumatologists and rheumatology health professionals are committed to continuing to provide top-level patient care during this unprecedented time. We appreciate that CMS has recognized the need to shift healthcare to a virtual platform by reimbursing telehealth evaluation and management (E/M) visits to be commensurate with traditional face-to-face E/M visits. Unfortunately, providers have faced additional barriers to providing care for their patients. These barriers include internet connectivity issues that have caused the visual and audio components to freeze during visits, patients who decline the visual portion of the visits, and patients who do not have computer access to fulfill the audio-visual requirements of telehealth visits. Many patients, especially within the elderly population, prefer to have their telehealth visits using audio-only technology. While the provider may not be able to see the patient, the provider is still employing the same medical decision making needed for a traditional E/M visit, including medication management and treatment plans.

The ACR appreciates that CMS has finalized policies to reimburse for audio-only telehealth visits. However, we remain concerned that the reimbursement rates of these audio-only visits are significantly reduced when compared to audio-visual telehealth visits. Therefore, we urge CMS to reimburse audio-only telehealth visits at levels that are comparable with that of audio-visual telehealth visits as these visits require the same degree of medical decision making and often require the same amount of physician time.

**Direct Supervision Via Telecommunications as it Relates to Home Infusion**

The ACR strongly supports all efforts to slow the spread of COVID-19, including social distancing. Rheumatologists and rheumatology health professionals have changed their practices to maximize the safety of their patients. We appreciate the efforts made by the Administration to improve a patient’s access to treatments during this PHE. On the surface, this may appear to improve patient safety by reducing the need for patients to travel to infusion centers. While transitioning selected patients to home infusions may be appropriate in select cases, it may result in reduced patient safety in others. Specifically, the ACR has several safety concerns with home infusions that are exacerbated by the COVID-19 pandemic:

- Inadequate evaluation of a patient’s health prior to administration of medication
- Inadequate resources to manage adverse reactions outside a medical facility
• Reduced availability of staff combined with increased volume of complex home infusions
• Difficulty ensuring safe transport of medications and equipment
• Inadequate oversight to ensure proper use of personal protective equipment to protect patients and staff

The ACR does not support the indiscriminate expansion of home infusion. Patient safety must remain paramount, and rheumatologists and rheumatology health professionals are in the best position, in careful consultation with patients, to consider a broad array of factors and to arrive at individualized recommendations to maximize patient safety. Regulations and policies that promote home infusion without patient consent and provider input bypass the critical need for expert and individualized evaluation of a patient’s unique circumstances.

The ACR appreciates the ongoing work at CMS and throughout the Administration to help ease burdens for providers as they shift practice models to ensure the safety of their patients and staff. We welcome the opportunity to be a resource to CMS and the Administration on any policies that will impact our patients and providers. Please contact Amanda Grimm Wiegreffe, MScHSRA, Director of Regulatory Affairs, at awiegrefe@rheumatology.org or (202) 991-1127 if we can be of assistance in this regard, or if you have questions.

Sincerely,

Ellen M. Gravallese, MD
President, American College of Rheumatology