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April 27, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1744-IFC
P.O. Box 8016

Submitted online via regulations.gov

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

Dear Administrator Verma:

Baltimore, MD 21244-8016

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist. Below, we provide feedback on the aforementioned interim final rule with comment (IFC).

Telehealth and Virtual Care Services

CSRO appreciates new flexibilities under the IFC for the delivery of telehealth and virtual care services. These policies have ensured our patients, many who are immunocompromised and more vulnerable during the public health emergency, have ongoing access to their rheumatologist for management of their rheumatic condition. Thus far, we have found telemedicine to be a useful tool in our specialty. We encourage CMS to consider implementing many of these temporary policies on a permanent basis, along with revised guidelines and appropriate program integrity criteria to prevent fraud, waste and abuse.

Nevertheless, we share concerns expressed by the rest of the medical community that CMS' recent activation of the telephone E/M services (CPT codes 98966-98968 and 99441-99443) have not addressed the challenges we face in delivering robust E/M services to beneficiaries with rheumatologic disease. Rheumatologists spend a considerable amount of time with their chronically ill patients, which is not adequately captured in the telephone E/M services, nor is the Medicare payment for these services adequate. Attempts

to deliver office/outpatient E/M services (CPT 99201-99205 and 99211-99215) via telehealth have also proven challenging, as a number of beneficiaries do not have audio/video technology, struggle with the video component, or flat out refuse to be "on camera." To address our concerns, we urge CMS to use its authority to waive the "video" requirement for furnishing office/outpatient E/M services via telehealth. Alternatively, CMS could increase reimbursement for the telephone E/M services to a level commensurate with the office/outpatient E/M services.

Revisions to Direct Supervision Requirements to Facilitate Home Administration of Part B Drugs

CMS has temporarily revised its direct supervision requirements, allowing physicians in a remote location to use audio/visual technology to observe patients and provide direction to clinical staff in the office. For physicians who need to self-isolate due to COVID exposure, this will enable them to keep their practices open for patients to receive important care, including drug administration services. We appreciate this temporary provision.

CMS' revisions also allows physicians to send their clinical staff or a contracted entity to the patients home to administer Part B drugs while observing remotely using audio/visual technology. We are deeply concerned about and strongly oppose this revision because it could create more issues than it solves.

First and foremost, Part B drugs used in rheumatologic care – similar to oncology – are highly complex agents. Many of these medications require advanced clinical skill to prepare and administer, special office-based equipment to handle infusion reactions, and tailored storage and handling conditions. In addition, some have serious safety warnings as well as the potential for adverse infusion reactions, which would be difficult to appropriately manage in the home by the physician's staff or a contracted entity. This could create serious risks for patients. Additionally, it would significantly increase liability to the physician's practice. Moreover, because many of our patients are immunocompromised, it would be wholly inappropriate to send clinical staff or a contracted entity from home-to-home, subjecting patients to an individual who has been in a number of different homes that day, increasing the risk of exposure to COVID-19 and other potential transmissible pathogens.

Most importantly, however our patients have not reported challenges in accessing medically necessary drug therapies since most rheumatology practices or the physician supervised infusion centers they refer to have remained open. Additionally, most of our patients do not want to be in their home for infusion, especially at this time: if anything, they are comforted by the fact that our physicians report spending more time with them responding to their concerns with COVID as it relates to their rheumatologic condition. More than ever, it seems that patients want to ensure that they are at a facility that can readily handle any concerns that may arise and one that brings them a sense of security in this time of crisis. In sum, since we have not heard reports of infusion access issues in the rheumatologic community and since home infusion is likely not something our patients would feel comfortable with and the possibility of improperly handled adverse reactions, we oppose at-home administration of Part B drugs and urge CMS to reconsider its policy on providing at-home administration of Part B drugs.

Thank you for considering our concerns. Should you have any questions, please contact Emily L. Graham, RHIA, CCS-P at egraham@hhs.com.

Sincerely,

Coalition of State Rheumatology Organizations Alabama Society for the Rheumatic Diseases Alaska Rheumatology Alliance Arizona United Rheumatology Alliance Arkansas Rheumatology Association California Rheumatology Alliance Connecticut Rheumatology Association Florida Society of Rheumatology Hawaii Rheumatology Society Kentuckiana Rheumatology Alliance Rheumatology Alliance of Louisiana New Jersey Rheumatology Association Midwest Rheumatology Association Michigan Rheumatism Society Massachusetts, Maine and New Hampshire Rheumatology Association Mississippi Arthritis and Rheumatism Society Nebraska Rheumatology Society North Carolina Rheumatology Association Ohio Association of Rheumatology Oregon Rheumatology Association Rheumatology Association of Iowa South Carolina Rheumatism Society **Tennessee Rheumatology Society** State of Texas Association of Rheumatologists Washington State Rheumatology Alliance West Virginia State Rheumatology Society Wisconsin Rheumatology Association