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April 14, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Improving Access to Hydroxychloroquine for Autoimmune Patients

Dear Secretary Azar:

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.

First and foremost, we thank you for your commitment and dedication to protecting the health and safety of Americans during these unprecedented times. CSRO, and the undersigned organizations, applaud you for taking swift action to ensure clinicians and other healthcare providers have the necessary flexibility to continue caring for our patients, many of which are among the frailest and most vulnerable during the COVID-19 pandemic.

Access to Hydroxychloroquine

Patients with autoimmune diseases, such as rheumatoid arthritis (RA) and lupus, are facing great difficulty accessing hydroxychloroquine – a clinically-proven, evidence-based treatment for these chronic conditions. We appreciate the increased demand for hydroxychloroquine given its emerging and potentially promising use as a treatment for COVID-19. Nevertheless, rheumatology patients that already depend on hydroxychloroquine should not be denied access to this vital medication when alternatives exist, such as compounding.

Pharmacies can compound hydroxychloroquine from bulk drug substances (or Active Pharmaceutical Ingredients, API) and make this medication available to Medicare beneficiaries. However, most insurers, including Medicare Advantage and Prescription Drug Programs (PDP), Medicaid, and private plans, do not cover or reimburse medications when they are prepared by compounding pharmacies from bulk substances. For the duration of the public health emergency, we ask HHS to take specific action that would make compounded

hydroxychloroquine available to patients when the manufactured product is not available.

First, the U.S. Food and Drug Administration (FDA) should revise its guidance entitled “Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act” to allow for drugs in shortage to be defined as those that are unavailable from the 503A pharmacy’s wholesaler.

Second, the Centers for Medicare and Medicaid Services (CMS) should issue guidance directing Medicare Advantage and PDPs, Medicaid and private plans, to reimburse pharmacies for compounded hydroxychloroquine, when manufactured products are unavailable.

Last, HHS should use the appropriate mechanism to ensure pharmacies would be eligible for reimbursement of the cost of the bulk substances plus the dispensing fee when patients are unable to pay for the product.

Again, on behalf of the undersigned organizations, we thank you for taking quick action to address this issue of concern to rheumatologists and autoimmune patients. If you have any questions, we would be pleased to speak with you further about this issue and look forward to a positive, albeit temporary, framework to implement the aforementioned action. Should you have any questions, please contact Emily L. Graham, RHIA, CCS-P at egraham@hhs.com.

Sincerely,

Coalition of State Rheumatology Organizations
Florida Society of Rheumatology
Arizona United Rheumatology Alliance
California Rheumatology Alliance
Midwest Rheumatology Association
Alabama State Rheumatology
Massachusetts, Maine, & New Hampshire Rheumatology Association
Rheumatology Association of Iowa
Georgia Society of Rheumatology
Michigan Rheumatism Society
Arkansas Rheumatology Association
Nebraska Rheumatology Society
Rheumatology Association of Nevada
Ohio Association of Rheumatology
Virginia Society of Rheumatologists
North Carolina Rheumatology Association
South Carolina Rheumatism Society
Oregon Rheumatology Alliance
West Virginia Rheumatology Society
Wisconsin Rheumatology Association