April 20, 2020

The Honorable Michael R. Pence
Vice President of the United States
The White House
1600 Pennsylvania Avenue N.W.
Washington, D.C. 20500

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Vice President Pence, Secretary Azar, Administrator Verma, and Commissioner Hahn:

Thank you for working to guide our country through this crisis. We are grateful for your efforts to serve the American people. Our goal is to ensure that all patients have access to needed medications during this crisis.

According to Vizient, a group purchasing organization utilized by hospitals and health care facilities, there is a 51% increase in demand for drugs to support COVID-19 patients, with only 63% of the orders being filled as of March 24.[1] The Drug Enforcement Agency has recognized the shortage of controlled substances for patients on ventilators and increased the aggregate production quotas for some and is increasing imports of others.[2] Patients with autoimmune diseases, including rheumatoid arthritis and lupus, are challenged to find hydroxychloroquine to continue treatment at their community pharmacy.

Access to medications – both those provided by the pharmaceutical manufacturers and those provided by pharmacists through compounding – are critical to caring for patients with COVID-19, and separately for those patients living with chronic conditions who utilize medications that are now in short supply due to ongoing drug shortages.

We urge the Administration to make two changes to existing federal guidance to better support patients during the COVID-19 Public Health Emergency (PHE). We also identify a third impactful step that the Department of Health and Human Services (HHS) can take right now to ensure a patient's ability to access essential medications in shortage that are provided by pharmacists through compounding. These are the requested changes:

1) 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

[1] https://www.statnews.com/pharmalot/2020/03/31/a-new-covid-19-problem-shortages-of-medicines-needed-for-placing-patients-on-ventilators/ Accessed 04/13/2020
[2] https://www.dea.gov/press-releases/2020/04/07/dea-takes-additional-steps-allow-increased-production-controlled Accessed 04/13/2020

include those that appear on the FDA drug shortage list and/or those identified by the American Society of Health-System Pharmacists .

2) The Centers for Medicare and Medicaid Services (CMS) should issue guidance directing Medicare Part D plans to reimburse for drugs that must be compounded from bulk drug substance Active Pharmaceutical Ingredients (APIs) due to shortages for the remainder of the COVID-19 PHE.

3) Finally, we ask that HHS designate pharmacies as an eligible entity that can apply for monies allocated to the Public Health and Social Services Emergency Fund (PHSSEF) for provision of COVID-19-related medications that are not covered by the patient's health insurance. Pharmacies would be eligible for reimbursement of the cost of the products plus the dispensing fee when patients are unable to pay for the product. This would have a meaningful positive impact for patients with autoimmune diseases, such as lupus and rheumatoid arthritis, who depend on hydroxychloroquine, a drug that is now in shortage due to its emerging use in treating COVID-19.

FDA should revise its definition of a shortage. The supply of these critical medications can be meaningfully improved by both compounding pharmacies and outsourcing facilities. Currently compounding pharmacies as defined under Section 503A of the Food, Drug, and Cosmetic Act can compound essential copies of FDA-approved medications when they are in shortage. However, FDA Guidance limits the definition of a shortage to drugs found on the Agency's own shortage list.[3] In contrast, the American Society of Health-Systems Pharmacists (ASHP) maintains a more robust drug shortage list, illustrating the scope of the unmet needs of the country. Most significantly, during a pandemic situation, the ASHP list recognizes shortages of critical drugs based on the real-time availability at the healthcare provider level.[4]

Because the FDA's definition does not accommodate the current disruptions in the supply chain, it is creating an access barrier for patients. FDA can take steps to temporarily modify the shortage definition so that patients can immediately have access to their medicine. We request that FDA 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 include those identified by the American Society of Health-Systems Pharmacists.

Patients need coverage for drugs that must be compounded due to shortages. Patients covered by Medicare Part D have a financial hurdle to obtain their medication if it must be compounded by a pharmacist. CMS allows Part D health plans to cover a compounded drug only when the drug's components meet the definition of a Part D drug. However, Medicare does not currently reimburse Part D plans for bulk drug substances and inactive ingredients when used in a compounded drug. In other words, CMS will reimburse a pharmacy for crushing tablets to try to incorporate them into a suspension, but will not reimburse the same pharmacy for using the pure ingredients to make the same suspension. To ensure patients with autoimmune conditions that benefit from compounded medications including hydroxychloroquine continue to have access to these therapies, we request that CMS, on a temporary

[3] https://www.fda.gov/media/98973/download Accessed 04/13/2020
[4] https://www.ashp.org/Drug-Shortages/Current-Shortages/FDA-and-ASHP-Shortage-Parameters Accessed 04/03/2020

basis during the COVID-19 pandemic, require Medicare Part D plans to reimburse pharmacies for drugs that must be compounded from bulk drug substances due to shortages when manufactured products are unavailable.

The PHSSEF has the ability to fund compounded medications during the PHE. Hydroxychloroquine is FDA approved for the treatment of both lupus and rheumatoid arthritis, and is frequently used in other chronic conditions, such as dermatomyositis and other serious light sensitive skin conditions. Patients with these conditions are losing access to this critical drug due to the shortage that has resulted from the interest in hydroxychloroquine as a potential treatment for COVID-19. In fact, Kaiser Permanente is actively converting patients to other medications or limiting refills.[5] While patient and provider groups are concerned with the diversion of this medication from those where the clinical benefits are proven, an alternative for these patients is available. Pharmacists can provide this medication through compounding, but Medicare patients, due to no fault of their own, would have to pay for this out of pocket due to limited insurance coverage of compounded medications. During the PHE we request that HHS permit reimbursement from the PHSSEF for pharmacists who compound hydroxychloroquine for patients with lupus and rheumatoid arthritis at no cost to the patient.

Thank you for your consideration of these requests. Our organizations are willing to serve as resources to help improve the lives of everyone during this crisis. Questions about these requests can be directed to Amy Shank, PCCA Director of Government Affairs, at 800.331.2498.

Sincerely,

PCCA

Arthritis Foundation

Alliance for Pharmacy Compounding

Help Us Solve The Cruel Mystery LUPUS FOUNDATION OF AMERICA

AAD 1938 AMERICAN ACADEMY of DERMATOLOGY | ASSOCIATION

NASPA NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS

AMERICAN COLLEGE of RHEUMATOLOGY Empowering Rheumatology Professionals

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

[5] https://about.kaiserpermanente.org/our-story/news/our-perspective/hydroxychloroquine-plaquenil-and-chloroquine-prescriptions Accessed 04/13/2020