



Submitted via regulations.gov

May 29, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1744-IFC

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

Dear Administrator Verma:

The American Autoimmune Related Diseases Association, Inc. (AARDA) and the additional undersigned organizations appreciate the opportunity to comment on the interim final rule with comment period titled *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (IFC)*, issued by the Centers for Medicare and Medicaid Services (CMS or the Agency).¹ We commend CMS's ongoing efforts, through the IFC and otherwise, to help facilitate access to safe and affordable health care during the public health emergency (PHE) for the 2019 novel coronavirus (COVID-19) pandemic.

AARDA is dedicated to the eradication of autoimmune diseases and the alleviation of suffering and the socioeconomic impact of autoimmunity. AARDA is the only national nonprofit organization dedicated to bringing a national focus to autoimmune diseases, which are a major cause of serious and chronic health conditions for millions of individuals. AARDA is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of 40 organizations representing numerous diseases. The NCAPG's mission is to convene, support, and amplify the voice of autoimmune disease patients and autoimmune patient groups to enhance capacity, collaboration, and impact through advocacy, education, awareness, and research concerning all aspects of autoimmune disease.

The IFC makes important additions to CMS's efforts to help ensure safe and affordable access to care. This is especially critical for patients with underlying conditions, such as autoimmune diseases, for whom it is imperative that they continue receiving medically necessary treatments, including physician-administered therapies, but who may be at higher risk for negative outcomes if they contract COVID-19, or who may need to stay home to protect others. For example, AARDA and the additional undersigned organizations applaud CMS for taking swift action to facilitate increased access to medically necessary care in patients' homes when clinically appropriate. By allowing physicians and non-physician practitioners (NPPs) to provide direct supervision via telehealth technology when appropriate,² and by clarifying that patients may qualify as

¹ 85 Fed. Reg. 19230 (Apr. 6, 2020).

² *Id.* at 19245-46.

“homebound” under the Medicare home health benefit when it is medically contraindicated for the patient to leave the home,³ CMS has taken meaningful steps to help ensure access to care for high-risk patients.

In these comments, we discuss a number of important actions CMS has taken to date, and we recommend additional steps we believe CMS should pursue to help facilitate clinically appropriate care for all patients during the COVID-19 PHE, including those with autoimmune diseases. Specifically, we suggest that CMS:

1. Facilitate a patient-centered approach to continuity of care, including for physician-administered medicines, by ensuring appropriate patient involvement in, and notice regarding, site-of-treatment options and decisions.
2. Protect patients’ access to critical medicines by ensuring continuity of coverage and out-of-pocket (OOP) costs for patients who receive medical care at their homes due to and during a PHE.
3. Provide additional clarifications and flexibilities relating to Part B coverage requirements in connection with in-home services provided during the COVID-19 PHE.
4. Support and further strengthen the workforce for clinically appropriate in-home services by clarifying federal flexibilities, encouraging state and local governments to implement similar policies during a PHE, and facilitating increased information sharing.
5. Reinforce and build upon the important flexibilities provided under the IFC with respect to the application and requirements of National and Local Coverage Determinations (NCDs and LCDs).
6. Monitor and take steps as necessary to ensure that patients with existing serious and chronic conditions have continued access to medically necessary treatments for which there is (or may in the future be) increased demand during the COVID-19 PHE.

We address these points in further detail below, with particular focus on the needs and circumstances of individuals living with autoimmune diseases. We appreciate your consideration of our input, and we look forward to continuing to work together to support the needs of patients in this challenging environment.

I. Facilitate a patient-centered approach to continuity of care, including for physician-administered medicines, by ensuring appropriate patient involvement in, and notice regarding, site-of-treatment options and decisions.

While we applaud the flexibilities included in the IFC to facilitate access to therapies and other services in a patient’s home when clinically appropriate, we emphasize the importance of ensuring that continuity of care is provided in a patient-centered manner, and that there is appropriate patient involvement in site-of-treatment decisions. To this end, we appreciate CMS’s recognition in the IFC that circumstances will vary for different patients, and that “individual practitioners are in the best position to make decisions based on their clinical judgement [*sic*] in particular circumstances.”⁴ We encourage CMS to further reinforce the important point that decisions regarding whether or not administration services should be provided in the home should be made at the individual patient level, with appropriate patient involvement and in close consultation with the patient’s treating clinician. In addition, we urge CMS to take additional steps to ensure that patients receive information and notice regarding the site-of-treatment options that may be available, so that patients can participate meaningfully in their care plans and have informed discussions with their

³ *Id.* at 19246-47.

⁴ *Id.* at 19245.

treating physicians and NPPs. We believe these steps are critical to promoting patient-centered care and to protecting the central role of patients, in close consultation with their treating physicians and NPPs, in clinical decision-making.

A. Ensuring appropriate patient involvement in site-of-treatment decisions

CMS appropriately recognizes in the IFC that, “in some cases, the physical proximity of the physician or practitioner might present additional exposure risks, especially for high risk patients isolated for their own protection or cases where the practitioner has been exposed to the virus but could otherwise safely supervise from another location using telecommunications technology.”⁵ Accordingly, the IFC provides for important flexibilities to allow direct supervision to be provided via telehealth technology when clinically appropriate. At the same time, CMS also appropriately notes that, “even in the context of the PHE for the COVID-19 pandemic and the inherent exposure risks for Medicare beneficiaries, physicians and other health care providers, we believe that in many cases furnishing services without the physical presence of the physician in the same location would not be appropriate.”⁶

We appreciate that CMS included language in the IFC’s preamble and regulatory language stating that the decision to provide direct supervision through telehealth technology—and thus to facilitate in-home services for certain patients—should reflect the individual physician or NPP’s clinical judgment based on each patient’s specific circumstances.⁷ We agree, and we underscore the critical importance of each patient’s individual circumstances. Particularly for patients with serious and chronic conditions, such as autoimmune disorders, the specific circumstances of each patient’s disease state, the nature of the patient’s necessary therapies, the details of the particular patient’s treatment regimen, and the relevant risk-benefit factors and considerations will vary significantly. We therefore appreciate CMS’s recognition that treatment decisions during a PHE must be made at the individual patient level, and we feel strongly that patients should not be forced or required to receive treatment in a setting where they feel uncomfortable or unsafe.

We note, as well, that this position is consistent with guidance from medical experts, including those with significant experience treating patients with autoimmune disorders. For example, the American College of Rheumatology (ACR) notes there are myriad factors to consider for rheumatology infusion patients during the COVID-19 crisis, and “decisions about patient therapies and site of therapy must be individualized” and must be made with consideration of “each patient’s unique circumstance and the risks related to potential disease flares and risk of infection.”⁸ The ACR’s guidance further states that, “[g]iven the complexity of balancing these considerations and the need for tailoring any response to the individual patient, all decisions need to be made by the treating rheumatologist or rheumatology professional *in consultation with the patient in question.*”⁹ In addition, the ACR underscores that these decisions must be “made by the physician and the patient rather than insurance companies or other entities.”¹⁰

⁵ *Id.*

⁶ *Id.*

⁷ *See id.* (“[W]e believe that individual practitioners are in the best position to make decisions based on their clinical judgement [*sic*] in particular circumstances.”); *id.* at 19286 (revising 42 C.F.R. § 410.32(b)(3)(ii) to add the following language at the end: “During a PHE, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology *when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.*” (emphasis added)).

⁸ ACR, *Infusion Guidance During COVID-19 Crisis*, at 1 (Apr. 11, 2020), available at <https://www.rheumatology.org/Portals/0/Files/ACR-Infusion-Guidance-COVID-19.pdf>.

⁹ *Id.* (emphasis added).

¹⁰ *Id.*

For these reasons, we urge CMS to reinforce patients' critically important role in site-of-treatment decisions. Specifically, we recommend that CMS incorporate express language to this effect in the preamble to the final rule, if an additional publication will be issued, and/or any related Agency guidance. In addition, we suggest that CMS further revise the regulatory language at 42 C.F.R. § 410.32(b)(3)(ii) to incorporate an express reference to patient involvement in the relevant clinical decision-making. For example, CMS could further revise the relevant regulatory provision as follows, with our suggested additional revisions indicated with underlined text below:

(ii) Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. During a PHE, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is clinically appropriate and is indicated to reduce exposure risks for the beneficiary or health care provider, as determined by the patient's treating health care provider in consultation with, and based on the specific needs of, the patient.

B. Providing information and notice to patients regarding site-of-treatment options

As an additional safeguard to facilitate patient-centered care and appropriate patient involvement in clinical decision-making during the COVID-19 PHE, we recommend that CMS encourage and facilitate the provision of information and notice to patients regarding available treatment options, particularly with respect to physician-administered therapies. One potential model for the type of information and notice that could be provided is outlined in Section 5012 of the 21st Century Cures Act, which established a new Medicare home infusion therapy benefit for coverage of home infusion therapy-associated professional services for certain drugs and biologicals, effective January 1, 2021.¹¹ Under this provision, the requirements related to the new home infusion therapy benefit include the provision of “notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician’s office, hospital outpatient department) for the furnishing of infusion therapy” to the patient.¹² Although CMS has not yet promulgated regulations to implement this notification requirement under Section 5012 of the 21st Century Cures Act,¹³ we believe that CMS could take meaningful steps to facilitate the provision of similar notifications and related information to patients regarding infusion therapy options during a PHE. That, in turn, could help facilitate informed patient involvement in the decision regarding where to receive infused therapy.

For example, CMS could encourage or require providers to inform patients of all site-of-treatment options, and to discuss with the patient potential risks and benefits associated with each option, prior to moving forward with in-home or with office- or facility-based services during a PHE. Alternatively or in addition, CMS could create a resource (such as a webpage) for patients and providers noting potential options for patients to access physician-administered therapies during the COVID-19 PHE, and discussing examples of potential factors for consideration in connection with site-of-treatment decisions. Such factors might include, for example, the type of treatment/therapy the patient requires, the potential for adverse clinical reactions or side effects, whether there are home infusion options in the patient’s geographical area, whether there are safe facility-based options in the patient’s geographical area, whether there are specific risk factors for the patient and/or provider related to COVID-19 exposure, and whether the different therapy administration

¹¹ 21st Century Cures Act, Pub. Law No. 114-255, § 5012, 130 Stat. 1033, 1198-1202 (2016).

¹² *Id.* § 5012(b) (codified at 42 U.S.C. § 1395m(u)(6)).

¹³ See 84 Fed. Reg. 60478, 60624 (Nov. 8, 2019).

options potentially could impact a patient's OOP costs. We believe this type of information would be meaningful and helpful to patients and health care providers as they discuss and evaluate treatment options during the PHE.

II. Protect patients' access to critical medicines by ensuring continuity of coverage and OOP costs for patients who receive medical care at their homes due to and during a PHE.

AARDA and the additional undersigned organizations support and appreciate the Agency's clarification that the definition of "confined to the home" (or "homebound") includes situations where it is medically contraindicated for the patient to leave the home, *e.g.*, in the context of the COVID-19 PHE, when a patient has a suspected or confirmed diagnosis of COVID-19 or where the patient would be at higher risk if they contracted COVID-19.¹⁴ This may allow many high-risk and vulnerable patients, including patients with autoimmune diseases, to access medically necessary care in the home when it is determined to be clinically appropriate. We also support CMS's statement that the "clarification is not limited to the PHE for the COVID-19 pandemic, but would also apply for other outbreaks of an infectious disease and instances where the condition of a patient is such that it is medically contraindicated for the patient to leave his or her home."¹⁵ We believe this is a helpful clarification for both patients and health care providers.

With respect to these clarifications, however, as well as certain other flexibilities provided under the IFC, we are concerned about the potential implications for patients' coverage options and cost-sharing obligations for the care they receive. In particular, we share the concerns of other stakeholders that complications and confusion may arise in situations where a patient receives in-home care pursuant to the clarifications and flexibilities provided in the IFC, but typically in the past has received office- or facility-based care for such services. These concerns are of particular importance in the context of Medicare Part B and Part D coverage rules and patient OOP costs, which, as CMS is well aware, are different and can have varying effects for patients depending on where and how care is delivered or administered, and by whom.¹⁶

For these reasons, we urge CMS to exercise its regulatory and waiver authority to the fullest extent possible to ensure continuity of coverage and OOP costs for patients who receive medical care at home due to and during a PHE. For example, in situations where it is medically contraindicated for patients to leave home, the patient should not be subjected to increased levels of OOP costs as a result of the need to receive in-home care. Similarly, patients who receive care at home due to and during a PHE should not be forced to battle with step therapy or prior authorization requirements that can cause harmful delays in access to care. Accordingly, we urge CMS to ensure that Medicare beneficiaries do not face added coverage barriers or increased OOP costs as a result of a clinically appropriate site-of-treatment change that may occur due to and during a PHE.

III. Provide additional clarifications and flexibilities relating to Part B coverage requirements in connection with in-home services provided during the COVID-19 PHE.

As noted above, we appreciate the flexibilities under the IFC that set forth pathways for physicians and NPPs to provide direct supervision via telehealth technology when clinically appropriate,¹⁷ and that clarify that

¹⁴ 85 Fed. Reg. at 19246-47.

¹⁵ *Id.* at 19247.

¹⁶ *See generally* Medicare Prescription Drug Benefit Manual, ch. 6, App. C – Medicare Part B Versus Part D Coverage Issues; *see also, e.g.*, Medicare Benefit Policy Manual, ch. 7 (Home Health Services), § 40.1.2.4 ("Although drugs and biologicals are specifically excluded from coverage by the statute (§1861(m)(5) of the Act[]), the services of a nurse that are required to administer the medications safely and effectively may be covered if they are reasonable and necessary to the treatment of the illness or injury.").

¹⁷ 85 Fed. Reg. at 19245-46.

patients may qualify as “homebound” under the Medicare home health benefit when it is medically contraindicated for the patient to leave the home.¹⁸ While these flexibilities are significant and helpful, we are concerned that they will be difficult to operationalize in many cases and circumstances. We therefore believe that additional steps are needed to help ensure adequate and appropriate access to medical care for patients during the COVID-19 PHE. These considerations are especially important for patients—including many individuals with autoimmune diseases—who rely on physician-administered therapies to treat and manage their serious and chronic conditions.

In particular, we suggest two ways that CMS can provide additional support for appropriate patient access to therapies covered under Part B during the COVID-19 PHE. We believe these suggestions are within the Agency’s existing authority and are important to the IFC’s critical goals. Those stated goals include, for example, to “offer providers flexibilities in furnishing services to combat the COVID-19 pandemic” and to “provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health.”¹⁹

First, we encourage CMS to clarify that, during a PHE (as defined in 42 C.F.R. § 400.200), home health physicians and NPPs can act as a “supervising physician (or other practitioner)” under the existing Medicare Part B “incident to” rules in situations where it is clinically appropriate to administer a drug that is typically covered under Part B in a patient’s home due to and during the PHE. This would allow such physicians and NPPs—in PHE circumstances and when clinically appropriate for the patient—to purchase, administer, and bill Medicare directly under Part B for “incident to” services and supplies, rather than under the home health benefit. That, in turn, could help ensure continuity of care, coverage, and OOP costs for patients who, but for the PHE, would receive Part B-covered medicines in an office- or facility-based setting.

Second, because Medicare Part B may cover services and supplies that are incident to the service of an NPP,²⁰ we urge CMS to issue guidance noting and clarifying the availability of this option, and encouraging states to consider expanding the scope of services that certain NPPs can provide during the COVID-19 PHE. This could facilitate a patient’s access to Part B-covered therapy in the home, when clinically appropriate, even if the patient’s physician is unable to provide direct supervision in person or via telehealth technology.

We believe these suggestions are consistent with the Agency’s existing authority, and with points that CMS makes elsewhere in the IFC, including statements reflecting the Agency’s desire to “maintain overall relativity under the [Medicare Part B Physician Fee Schedule] for similar services and eliminate potential financial deterrents to the clinically appropriate use of telehealth” during the COVID-19 PHE.²¹ Further, we believe these suggestions also are consistent with policies under the IFC that instruct providers to focus principally on the nature of the care that is provided for coding and reporting purposes, rather than focusing exclusively on the physical location of the patient at the time of care. For example, CMS states in the IFC that, when providing telehealth services because of and in the context of the PHE for the COVID-19 pandemic, “practitioners should report the E/M code that best describes the nature of the care they are providing,” and should do so “regardless of the physical location or status of the patient.”²²

¹⁸ *Id.* at 19246-47.

¹⁹ *Id.* at 19232.

²⁰ See 42 C.F.R. § 410.26(b) (“Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).”); Medicare Benefit Policy Manual, ch. 15, § 50.3 (“Drugs and biologicals furnished by other health professionals may also meet these [incident to] requirements.”).

²¹ 85 Fed. Reg. at 19233.

²² *Id.* at 19234.

IV. Support and further strengthen the workforce for clinically appropriate in-home services by clarifying federal flexibilities, encouraging state and local governments to implement similar policies during a PHE, and facilitating increased information sharing.

We appreciate and applaud CMS’s efforts to increase the number available health care workers, including for home infusions and other in-home treatments, during the COVID-19 PHE. For example, we support and appreciate CMS’s “blanket waivers” of the requirement that out-of-state practitioners be licensed in the state in which they are providing services,²³ as well as the toolkit that CMS has made available to states regarding expanding the scope of practice for certain medical personnel.²⁴ Such efforts are helpful to ensure that patients have access to the treatment options, flexibilities, and policies that CMS has set forth to date.

Regarding the “blanket waivers” that CMS has temporarily applied to requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state, the criteria for such waivers currently include a requirement that the practitioner is “furnishing services . . . *in order to contribute to relief efforts* in his or her professional capacity.”²⁵ We are concerned that this phrasing potentially could be construed to apply unduly narrowly, such as in a manner that might be limited only to those patients who are receiving care for a suspected or diagnosed case of COVID-19. We believe, however, that the intent of the language is—and should be—to apply broadly, including with respect to services provided to patients who are receiving in-home care for underlying, non-COVID-19 conditions to reduce their (or their loved ones’) exposure risk, or because of the potential exposure of their typical health care provider. To mitigate potential confusion or undue restrictions of the application of these waivers, we urge CMS to clarify that CMS interprets the phrase “in order to contribute to relief efforts” broadly for purposes of these waivers, and that it includes circumstances such as those noted above.

In addition, CMS stated in its notice of “blanket waivers” of certain licensure requirements for health care providers that the Agency’s waiver action “does not have the effect of waiving state or local licensure requirements or any requirement specified by the state or a local government as a condition for waiving its licensure requirements.”²⁶ While many states and local governments have issued their own emergency orders to relax licensing restrictions for out-of-state medical personnel,²⁷ many have not. Accordingly, we ask CMS to go a step further and issue guidance expressly encouraging states to allow out-of-state licensed medical personnel to provide services in the state and to expand providers’ ability to provide services up to the fullest extent allowed by their training and licensure.

As an additional measure to further strengthen the workforce for clinically appropriate in-home services, we also encourage CMS to facilitate information sharing regarding resources and strategies for health care providers who seek to enter into arrangements for the provision of in-home care when clinically appropriate,

²³ CMS, *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers*, at 30 (May 15, 2020), available at <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf> [hereinafter *Blanket Waivers*].

²⁴ See, e.g., CMS, *Trump Administration Launches New Toolkit to Help States Navigate COVID-19 Health Workforce Challenges* (Apr. 22, 2020), available at <https://www.cms.gov/newsroom/press-releases/trump-administration-launches-new-toolkit-help-states-navigate-covid-19-health-workforce-challenges>; see also *Toolkit on COVID-19 Scope of Practice Expansions*, available at <https://asprtracie.hhs.gov/technical-resources/135/covid-19-scope-of-practice-expansions/99#general>.

²⁵ *Blanket Waivers*, *supra* note 23, at 30.

²⁶ *Id.*

²⁷ See, e.g., Georgia Composite Medical Board, *Emergency Practice Permit/Temp License in Response to COVID-19* (Mar. 16, 2020), available at <https://medicalboard.georgia.gov/press-releases/2020-03-16/gcmb-emergency-practice-permit-temp-license-response-covid-19>; Office of the Texas Governor, *Governor Abbott Fast-Tracks Licensing for Out-of-State Medical Professionals* (Mar. 14, 2020), available at <https://gov.texas.gov/news/post/governor-abbott-fast-tracks-licensing-for-out-of-state-medical-professionals>.

as contemplated and permitted under the IFC. For example, CMS could create a website that lists all providers who are available to provide in-home services in specified geographical areas, and the scope and types of services that such practitioners can provide. Such information could help both patients and providers to be and stay informed of potential care options during the COVID-19 PHE, and could help mitigate some of the operational challenges that may be presented by the option of direct supervision by telehealth technology or other issues relating to in-home care when clinically appropriate.

V. Reinforce and build upon the important flexibilities provided under the IFC with respect to the application and requirements of NCDs and LCDs.

We applaud CMS’s policies under the IFC that provide important flexibilities with respect to the application and requirements of certain NCDs and LCDs during the PHE for the COVID-19 pandemic. In particular, the IFC provides that, during the PHE for the COVID-19 pandemic, CMS will (1) relax the requirement for a face-to-face or in-person encounter to evaluate and/or certify a patient’s need for in-home oxygen and other DME and related supplies; (2) not enforce the clinical indications for coverage across respiratory, home anticoagulation management, and infusion pump NCDs and LCDs (including articles), “allowing for maximum flexibility for practitioners to care for their patients”; and (3) provide flexibility with respect to additional NCD and LCD requirements, such as certain consultation and supervision requirements.²⁸

As CMS recognizes in the IFC, “[d]uring the PHE for the COVID-19 pandemic, it is possible that patients receiving services for respiratory related indications will be required to receive care in unexpected settings, including the home.”²⁹ We appreciate the Agency’s recognition of these realities and its appropriate and meaningful response to exercise its regulatory authority and enforcement discretion to relax these restrictions that typically apply under various NCDs and LCDs, which “include, but are not limited to,” those expressly identified in the IFC.³⁰ This is an important and meaningful step to protect and facilitate patients’ access to necessary therapies and services during the PHE for the COVID-19 pandemic.

We encourage CMS to issue additional guidance that reinforces and educates patients and health care providers regarding these important flexibilities that apply during the COVID-19 PHE. In addition, we urge CMS to engage with stakeholders to explore additional policies and flexibilities that the Agency can apply to help leverage the DME benefit—and the use of both DME and therapies administered through DME—during the PHE. For example, expanded use of (and coverage for) remote patient monitoring and other treatment options can facilitate improved access to care—and reduced exposure to COVID-19 risks—for individuals with chronic conditions, such as autoimmune diseases, who typically require frequent office visits. Through such policies, CMS can use its existing authority to take additional steps that improve patients’ ability to manage their conditions while remaining in their homes and minimizing their exposure risk.

VI. Monitor and take steps as necessary to ensure that patients with existing serious and chronic conditions have continued access to medically necessary treatments for which there is (or may in the future be) increased demand during the COVID-19 PHE.

Finally, and importantly, we wish to express our deep concern about access challenges that patients with autoimmune diseases currently face—and may continue to face—with respect to important therapies on which they rely to treat and manage their serious chronic conditions.

²⁸ 85 Fed. Reg. at 19266-67.

²⁹ *Id.* at 19266.

³⁰ *Id.*

We are especially concerned about patients' access to certain treatments that are and have been under investigation as potential treatments for COVID-19. To date, for example, significant issues have arisen with respect to hydroxychloroquine, IL-1 and IL-6 and JAK antagonists, and C5 inhibitors, as evidenced by the ACR's guiding principles for scarce resource allocation during the COVID-19 pandemic for each of these therapies,³¹ and as a number of NCAPG member organizations have noted in public statements and letters to elected officials and to federal agencies.³² These concerns have been echoed by certain lawmakers who have likewise noted similar issues and concerns in communications to FDA and other agencies.³³

We underscore those critical considerations here in this letter, and we ask CMS to work with stakeholders, other federal agencies, and states to closely monitor issues of patient access to important therapies that provide standard-of-care treatments for patients with autoimmune disorders. We also urge CMS to take action as necessary and appropriate to ensure that existing patients who rely on these therapies have continued access to these medically necessary therapies notwithstanding the increased demand that may result as their use is investigated for or provided in connection with the treatment of COVID-19. Disruptions in patients' continuity of care is devastating and can lead to life-threatening complications as well as incapacitating exacerbations of autoimmune diseases that are harmful to patients and add avoidable costs and burdens on the health care system. We recognize the profound and urgent global need to find safe and effective treatments for COVID-19, and we simply want to ensure that there is awareness and consideration of the lives of patients with autoimmune diseases who will suffer harmful and potentially life-threatening consequences if they experience a lapse in treatment or a disruption of the therapy dosing on which they rely.

* * *

We appreciate the opportunity to provide our comments and recommendations in response to the IFC. We share CMS's goals to ensure access to safe and affordable care for patients at all times, including during the COVID-19 PHE. We also encourage CMS to take additional steps, as outlined in this letter, to facilitate a patient-centered approach and to ensure appropriate access to the medically necessary care and treatments upon which so many patients with autoimmune diseases rely for their health and well-being.

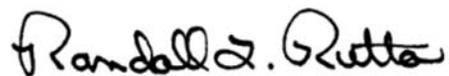
Thank you for your consideration of our comments. We look forward to continuing to work with you on these important issues.

³¹ See ACR, *Guiding Principles from the American College of Rheumatology for Scarce Resource Allocation During the COVID-19 Pandemic: The Case of Hydroxychloroquine* (Apr. 22, 2020), <https://www.rheumatology.org/Portals/0/Files/Guiding-Principles-Scarce-Resource-Allocation-During-Covid-19.pdf>; ACR, *Guiding Principles from the American College of Rheumatology for Scarce Resource Allocation During the COVID-19 Pandemic: The Case of IL-1 and IL-6 and JAK Antagonists* (Apr. 11, 2020), <https://www.rheumatology.org/Portals/0/Files/Guiding-Principles-Scarce-Resource-Allocation-IL-6-IL-1-JAK.pdf>; ACR, *Guiding Principles from the American College of Rheumatology for Scarce Resource Allocation During the COVID-19 Pandemic: The Case of C5 Inhibitors* (Apr. 11, 2020), <https://www.rheumatology.org/Portals/0/Files/Guiding-Principles-Scarce-Resource-Allocation-C5-Inhibitors.pdf>.

³² See, e.g., Joint Statement on Hydroxychloroquine by Lupus Foundation of America, American College of Rheumatology, American Academy of Dermatology, and Arthritis Foundation to Vice President Pence and Others (March 2020), available at <https://www.lupus.org/s3fs-public/pdf/Joint-Statement-on-HCQ-LFA-ACR-AADA-AF.pdf>; Sjogren's Foundation Letter to FDA (March 2020), available at <https://www.sjogrens.org/news/2020/letter-to-fda-on-plaquenil-shortage>.

³³ See, e.g., Letter from Senator Patty Murray to FDA Commissioner Stephen M. Hahn (Apr. 16, 2020), available at <https://www.help.senate.gov/imo/media/doc/04162020%20Letter%20from%20Senator%20Murray%20to%20Commissioner%20Hahn.pdf>.

Sincerely,



Randall Rutta
President and Chief Executive Officer
AARDA

On behalf of:

Advocacy & Awareness for Immune Disorders Association
Alliance for Patient Access
American Autoimmune Related Diseases Association (AARDA)
American Behcet's Disease Association
APS Foundation of America, Inc.
Beyond Celiac
Immune Deficiency Foundation
International Foundation for Autoimmune and Autoinflammatory Arthritis
International Pemphigus and Pemphigoid Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Scleroderma Foundation
Sjogren's Foundation
The Myositis Association
Vasculitis Foundation