UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

RICU LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

NORRIS W. COCHRAN IV, in his official capacity as Acting Secretary of Health and Human Services,

CENTERS FOR MEDICARE & MEDICAID SERVICES, and

ELIZABETH RICHTER, in her official capacity as Acting Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. As the COVID-19 pandemic rages across the United States, hospitals are facing shortages of critical-care physicians, who are overwhelmed by patient volume and are themselves at risk of contracting the deadly virus. These critical-care doctors—or intensivists—are the ones who care for COVID-19 (and other) patients in the worst condition in hospital Intensive Care Units (ICUs). Critical care meeting the medically accepted standard of care can often mean the

difference between life or death. As one hospital executive has recently explained: "Care is about more than a room with a hospital bed. It's about medical professionals taking care of patients. If you don't have the staff to do that, people are going to die."[1]

2. One solution to the urgent shortage in critical-care physicians—especially in rural areas—is telehealth: the provision of medical services through telecommunications systems by doctors who are not physically at the same location as patients.

3. Although Congress mandated that Medicare pay for certain telehealth services, *see* 42 U.S.C. § 1395m(m) (the "Telehealth Statute"), the Department of Health and Human Services (HHS) has historically not included critical care on its "Telehealth List."

4. That changed with the COVID-19 pandemic. In March 2020, HHS issued an interim final rule that added critical-care services to the Telehealth List for the duration of the COVID-19 pandemic (and perhaps beyond), and HHS issued a final rule in December 2020 (the "Telehealth Waiver").

5. RICU LLC ("RICU") was established in 2009 for the purpose of solving the national shortage of critical-care doctors—a serious problem that predated, but has been severely exacerbated by, the COVID-19 pandemic. RICU brought two innovations to the market. First, RICU recognized that a significant number of U.S.-trained and U.S.-licensed intensivists have been lost to the American healthcare system because, for a variety of personal and professional reasons, they live overseas part time or fulltime. RICU realized that these well-trained physicians could be brought back into the American healthcare system through the use of telehealth. Second, RICU realized that for critical-care telehealth to serve patients well and gain the trust of hospitals,

[1] *See* Olivia Goldhill, *'People are Going to Die': Hospitals in Half the States are Facing a Massive Staffing Shortage as Covid-19 Surges*, Stat News (Nov. 19, 2020), https://tinyurl.com/1ktu8s34.

the technology has to be robust and reliable. Accordingly, RICU invested substantial sums in constructing a sophisticated, highly reliable telehealth infrastructure. Today, RICU provides tele-ICU services in more than 250 hospitals in 34 states.

6. With the Telehealth Waiver in place, RICU sought to expand its services with existing clients and to hospitals that cannot afford telehealth without Medicare coverage. RICU believed it could do this because, under the Telehealth Statute, once a service is on the Telehealth List, Medicare "shall pay for telehealth services … notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary." 42 U.S.C. § 1395m(m)(1).

7. But HHS has instead adopted a policy that disallows payment for telehealth services if the physician is located outside the United States (the "Critical Care Ban"). After an "exhaustive review," and "complete reevaluation" of that exhaustive review, HHS declared that it deems telehealth services to be delivered at both the physician's location and the patient's location. And because RICU's physicians are overseas, HHS posits that Medicare cannot pay hospitals for use of these services because the Medicare Act prohibits payment for "services … which are not provided in the United States." 42 U.S.C. § 1395y(a)(4).

8. HHS's Critical Care Ban is unlawful, as it is directly contrary to statute and rule.

9. The Telehealth Statute states in express terms that the patient "receives a telehealth service furnished at an originating site," which is the site "at which a [patient] is located." *Id.* §§ 1395m(m)(4)(B), (C)(i). And it states that Medicare must pay for telehealth services "*notwithstanding* that the individual physician … is not at the same location as the beneficiary." 42 U.S.C. § 1395m(m)(1). Despite this clear language, HHS denies payment *precisely because* of the physician's location and in spite of the patient's location.

10. HHS's own regulation implementing the Telehealth Statute, 42 C.F.R. § 410.78 (the "Telehealth Regulation"), states that "Medicare Part B pays for covered telehealth services" and that "[t]he services are furnished to a beneficiary at an originating site," which is defined as "the location of an eligible Medicare beneficiary." *Id.* §§ 410.78(a)(4), (b), (b)(3). Despite this clear language, HHS refuses to pay for covered services because it now departs from its own regulation and concludes the services are furnished at the doctor's location.

11. RICU brings this action to compel HHS to comply with the law. But this case is about more than that. It is a matter of life and death for the many COVID-19 patients—Medicare patients, often in the age group most vulnerable to COVID-19—who so desperately need the critical care that RICU can provide hospitals if HHS fulfills its vital obligation to pay for these services.

PARTIES

12. Plaintiff RICU LLC is a Delaware limited liability company. Organized in 2009, RICU specializes in the provision of healthcare services via telehealth, especially Intensive Care Unit ("ICU")—or critical care—services. RICU physicians provide critical care to patients in more than 250 hospitals located in 34 states. Many of the hospitals where RICU provides care are located in rural areas that have been devastated by the COVID-19 pandemic. All RICU physicians providing critical care are U.S. board-certified critical-care specialists, and they are licensed to practice medicine in the states in which their patients are located. RICU physicians live abroad.

13. Defendant United States Department of Health and Human Services ("HHS") is a federal cabinet-level department tasked with administering various healthcare-related statutes. It is headquartered at 200 Independence Avenue, SW, Washington, DC, 20201.

14. Defendant Norris W. Cochran IV is the Acting Secretary of Health and Human Services. Secretary Cochran is sued in his official capacity. He maintains offices at 200 Independence Avenue, SW, Washington, DC, 20201.

15. Defendant Centers for Medicare & Medicaid Services ("CMS") is an agency within HHS that administers the Medicare and Medicaid programs. CMS is headquartered at 7500 Security Boulevard, Baltimore, Maryland, 21244.

16. Defendant Elizabeth Richter is the Acting Administrator of CMS. Administrator Richter is sued in her official capacity. She maintains offices at 7500 Security Boulevard, Baltimore, Maryland, 21244.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346. This action arises under, among other federal statutes, the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. These provisions allow RICU to pursue statutory challenges to the Critical Care Ban. If the Court failed to exercise jurisdiction, the result would be no review at all of a substantial statutory challenge.

18. This Court also has subject matter jurisdiction pursuant to 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A). RICU has presented this matter to HHS, which has engaged in an "exhaustive review" and a further "complete reevaluation" of that exhaustive review, with a final determination transmitted to RICU on behalf of the Secretary of HHS.

19. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e)(1) because a substantial part of the events or omissions giving rise to the claim occurred in this district.

FACTUAL ALLEGATIONS

I. Telehealth Generally

20. Telehealth is the delivery of medical care through telecommunications technology, with the healthcare provider and patient in different physical locations. Telehealth services are usually provided in real time and are interactive.

21. Using telehealth, a physician can advise, diagnose, and treat patients from a distance. Accordingly, telehealth can be used in a variety of clinical settings, from primary care to critical care and other specialties. Telehealth services can be employed effectively in both outpatient and inpatient settings to diagnose and treat physical, behavioral, and psychological ailments, ranging from routine wellness visits to emergency and critical care.

22. Telehealth offers several advantages. First, it allows physicians to bring high-quality healthcare to otherwise underserved areas, especially rural regions that suffer a shortage of physician specialists. Accordingly, telehealth services can minimize or eliminate the burden, expense, and significant risk of traveling long distances for essential medical care. Second, telehealth can optimize staffing levels for peak performance and elimination of serious medical errors—for example, by ensuring that physicians covering a night shift are working on a daytime schedule from their remote location.[2] Third, in certain circumstances—like when a patient has a highly communicable disease—telehealth can minimize risks for healthcare professionals and

[2] The only way to have a physician cover a night shift during the physician's local daytime hours is by having the physician located in a time zone overseas. Ordinary sleep schedules and reduced fatigue can improve physician performance and decrease serious errors. *See* Saranea Ganesan, *et al.*, *The Impact of Shift Work on Sleep, Alertness and Performance in Healthcare Workers*, 9 Sci. Reports 4635 (2019), https://tinyurl.com/3rmv5llb ("Alertness and performance remain most impaired during night shifts given the lack of circadian adaptation to night work."); Christopher P. Landrigan, *et al.*, *Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units*, 351 New England J. Med. 1838 (2004), https://tinyurl.com/4zdg67uk.

other patients and persons who come into contact with these healthcare professionals. The COVID-19 pandemic has demonstrated these very real benefits.

23. High quality, audio-visual interactive telehealth is made possible by high-speed, reliable telecommunications technology, which developed, matured, and proliferated in the late 1990s and early 2000s.

24. Telehealth ICU ("tele-ICU") services are provided as follows: An intensivist (a physician specializing in critical care) is stationed at a remote command center in front of a bank of monitors, from which he can see and hear his patient in an ICU bed at a hospital. The intensivist has real-time access to bedside telemetry ICU monitors ("waveforms") and read-and-write access to the "electronic medical record," a centralized file that includes current and historical patient notes, the patient's current and historical orders, general history and current and previous diagnoses, current and historical lab reports, radiology, and more. The intensivist also has access to a high-definition pan-tilt-zoom video camera, which can be pointed in every direction by remote control of the remote intensivist to observe the equipment being used (for example, ventilators and ventilator settings), and to observe and communicate interactively with the patient and with other healthcare providers in the patient room. The intensivist can also place orders in the electronic chart to be carried out by bedside clinical staff and can discuss the patient's care plan with other physicians and nurses. The intensivist can also speak with the patient and patient's family through the audio-visual camera system.

25. There is mounting evidence that tele-ICU services save lives, permit hospitals to increase case volume, decrease patients' required length of stay in the hospital's ICU, and reduce costs. *See* Abt Associates, Evaluation of Hospital-Setting HCIA Awards, at 44 (Nov. 1, 2016) (showing a "decrease of roughly $1,486 in average Medicare spending per episode" as well as a

"2.1 percentage point decrease in the rate of 60-day inpatient readmissions" to the ICU with tele-ICU program); Press Release, HicuityHealth, Tele-ICU's Contribution to Population Health Highlighted at SCCM (Jan. 24, 2017), https://tinyurl.com/qsy8zuwp (finding ICU length of stay was 36 percent lower than predicted and mortality rate was 29 percent lower than predicted with tele-ICU programs); Craig M. Lilly, *et al.*, *ICU Telemedicine Program Financial Outcomes*, 151 CHEST J. 286 (Feb. 2017) (centralized tele-ICU program improved hospitals' contribution margins by 376 percent "due to increased case volume, higher case revenues relative to direct costs, and shorter length of stay").

II. RICU's Business Model

26. RICU is one of the largest inpatient telehealth companies in the United States. Organized in 2009, RICU brings critical care to places where it is essential and severely lacking, including rural and other underserved areas where access to high-quality healthcare is in short supply. RICU's proprietary technology expands the reach of tele-ICU capabilities and maximizes the number of patients who can receive critical care.

27. Today, RICU works with 59 highly-skilled U.S.-licensed and board-certified intensivists who received their training, and have significant practice experience, in the United States. RICU physicians have attended medical school and completed fellowships at distinguished universities including Yale, Harvard, and Stanford, and have completed residencies and fellowships at renowned American hospitals including Beth Israel Deaconess Medical Center, Albert Einstein College of Medicine, Lenox Hill Hospital, and the Cleveland Clinic. All RICU physicians are U.S. board-certified critical-care specialist physicians, licensed in one or more U.S. jurisdictions, who provide care to patients in hospital intensive care units. Board certification is a specialty-specific credential beyond a state license that requires extensive medical training and

periodic comprehensive evaluation. To qualify to take the board certification exam, a physician must have undergone medical training in the United States, including three to five years of medical residency after medical school, and one to three years of a critical-care fellowship after residency. A board-certified physician must also possess an unrestricted license to practice medicine in the United States and must renew the board certification every ten years by passing another board exam.

28. In addition to their board certifications, RICU's physicians have years or decades of practice experience in the United States. For example, one of RICU's physicians completed her medical residency in internal medicine at Albert Einstein College of Medicine in New York in 2000. She further completed a fellowship in pulmonary medicine and critical care medicine at the University of Southern California in 2009 and a fellowship in heart-lung/lung transplant and cystic fibrosis at Stanford University in 2010, and she was the Medical Director of the Respiratory Department at Kaiser Permanente Hospital in California. She now lives in Israel where she supports her family. Through RICU's telehealth network, she is able to continue delivering high-quality patient care in the country where she trained and practiced for her entire career.

29. Another of RICU's physicians completed her medical residency in internal medicine at Maimonides Medical Center in New York in 1995. In 1996, she completed a fellowship in critical-care medicine. After working in a community hospital in Michigan for four years, she completed a fellowship in pulmonary medicine at New York Hospital Weill Cornell Medical Center in 2002. She then completed a fellowship in sleep disorders at Stanford University School of Medicine in 2003. For the next thirteen years, she worked as a pulmonologist and critical-care specialist physician at multiple hospitals in the United States, including Kaiser Permanente in California, Beth Israel Hospital in New York, and Northshore Long Island Jewish

Hospital in New York. She then moved to India to take care of her aging and ill parents. She continues today to live with and take care of her 93-year-old mother while working full-time with RICU to provide tele-ICU services to U.S. hospitals.

30. Although RICU's physicians live abroad, they serve as full-time, permanent staff members of the U.S. hospitals at which they care for patients. By working with U.S.-licensed intensivists who live overseas, RICU has enabled intensivists previously lost to the American healthcare system to provide their services to alleviate the ongoing shortage of healthcare professionals in American hospitals. RICU's arrangement also takes advantage of the differences in time zones around the world: Physicians can cover an American night shift during their own daylight hours, resulting in decreased fatigue and improved physician performance, which, in turn, can improve patient outcomes. Otherwise, the tele-ICU services provided by RICU's physicians located overseas are indistinguishable from the same telehealth services provided by a physician stationed in the United States.

31. The technological requirements for tele-ICU are extraordinary. A tele-ICU telecommunications system must be capable of transmitting vast amounts of data in real time, and it must be extremely reliable because any down-time can come at the cost of a patient's wellbeing. In addition, as with other telehealth systems, a tele-ICU system must be secure to protect the strict confidentiality of the patient's treatment.

32. RICU's telecommunications system was built and is maintained through a substantial financial investment. RICU uses a global private network of dedicated T1 lines (meaning no other data traffic travels on those lines) and employs varying combinations of highly sophisticated data accelerators and compressors. Every RICU physician site features redundant communications networks so that, in the unlikely event one line fails, there is always at least one

(and usually two) other independent network path(s) from the physician to the hospital. Every RICU office is served by two independent telecommunications companies, each of which uses independent communication networks. Every RICU physician site also has at least one (and often two) alternative source(s) of electricity. RICU also employs a highly trained and dedicated private IT help desk (available 24 hours a day, 365 days a year) to address any technological issues that may occur during a physician's shift.

33. Many of RICU's client hospitals are located in rural or other areas that are underserved by traditional healthcare infrastructure. All told, RICU physicians provide critical care to patients in more than 250 hospitals located in 34 states, accessible to more than 35 million Americans.

34. RICU maintains two types of service contracts: (1) contracts with hospitals and hospital systems, through which RICU physicians provide telehealth ICU care to the hospitals' patients; and (2) contracts with third-party intermediaries, which in turn contract with hospitals to provide telehealth critical care to the hospitals' patients. Client hospitals and third-party intermediaries pay RICU for its physicians' services on an hourly basis.

III. The Telehealth Statute and HHS's Reimbursement Approvals

35. Congress initially authorized Medicare reimbursement for telehealth services in 2000. Pub. L. 106–554, § 223, 114 Stat. 2763, 2763A-487–90 (Dec. 21, 2000); *codified at* 42 U.S.C. § 1395m(m) (the "Telehealth Statute").

36. The Telehealth Statute states "the Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician … or a practitioner … to an eligible telehealth individual enrolled [in Medicare] notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary." 42

U.S.C. § 1395m(m)(1). In other words, the Telehealth Statute requires payment based on the location of the patient, notwithstanding—that is, regardless of—the physician's location.

37. The Telehealth Statute defines "eligible telehealth individual" as "an individual enrolled [in Medicare] who receives a telehealth service furnished at an originating site." *Id.* § 1395m(m)(4)(B). An "originating site" is where "the eligible telehealth individual is located at the time the service is furnished via a telecommunications system." *Id.* § 1395m(m)(4)(C)(i). In other words, the Telehealth Statute plainly states that telehealth services are provided at the *patient's* location.

38. The Telehealth Statute carefully restricts where an originating site can be located, and thus were a patient can be located. An "originating site" must be located in a designated rural health professional shortage area, an area that is not included in a Metropolitan Statistical Area, or in an entity that is participating in a federal telemedicine demonstration project. *Id.* And it must be a physician's office, a critical access hospital, a rural health clinic, a federally qualified health center, a hospital, a hospital-based or certain other renal dialysis center, a skilled nursing facility, a community mental health center, and, in some limited circumstances, a patient's home. *Id.* § 1395m(m)(4)(C)(ii).

39. In contrast, the Telehealth Statute puts no restrictions on "the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system," simply defining it as a "distant site." *Id.* § 1395m(m)(4)(A). The lack of restrictions on the physician site is consistent with the statutory command to pay for telehealth services "notwithstanding that the individual physician … is not at the same location as the beneficiary." The focus is entirely on the patient's location.

40. In the Telehealth Statute, Congress designated several specific telehealth services (by Current Procedural Technology, or CPT, Code[3]) that are reimbursable by Medicare (including "professional consultations, office visits, and office psychiatry services"), and it delegated to the Secretary of Health and Human Services the authority to identify additional telehealth services for Medicare reimbursement. 42 U.S.C. § 1395m(m)(4)(F).

41. In 2001, HHS published a proposed rule implementing the Telehealth Statute. 66 Fed. Reg. 40372, 40391–94 (Aug. 2, 2001). That proposed rule explained the terms of the Telehealth Statute and proposed several policies and regulatory provisions regarding, *inter alia*, the scope of telehealth benefits, conditions of payment, and documentation and coding requirements. The 2001 proposed rule did not create the initial Telehealth List, but instead solicited input from the public regarding the guidelines that should be used to add or delete services from the Telehealth List. A notice-and-comment period followed. On November 1, 2001, HHS responded to public comments on the proposed rule in a preamble published in the Federal Register. *See* 66 Fed. Reg. 55246 (the "2001 Preamble"). On that same day, HHS adopted a final rule implementing the Telehealth Statute, which was codified at 42 C.F.R. § 410.78 (the "Telehealth Rule").

42. Echoing the Telehealth Statute, the Telehealth Rule restricts the locations that may be used as an originating site. *See* 42 C.F.R. §§ 410.78(a)(4), (b)(3), (b)(4). And, like the Telehealth Statute, the Telehealth Rule puts no limitations on the distant site at which a physician can be located. *See id.* § 410.78(a)(2).

[3] CPT refers to a series of standardized five-digit codes published by the American Medical Association. CPT codes identify specific medical and surgical services and procedures.

43. The Telehealth Rule establishes a "General Rule" for reimbursement of telehealth services: "Medicare Part B pays for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system if the following conditions are met…." *Id.* § 410.78(b). The conditions are: (1) the practitioner must be licensed under State law, (2) the practitioner must be one of several types of healthcare providers, (3) "the services are furnished to a beneficiary at an originating site," (4) the medical examination of the patient is under the control of the practitioner at the distant site. *Id.* The Rule does not list any other conditions for payment.

44. The "telehealth list" (hereinafter "Telehealth List") referenced in the Telehealth Rule's "general rule" is "maintain[ed]" by CMS and "changes … are made through the annual physician fee schedule rulemaking process." *Id.* § 410.78(f). Accordingly, each year, CMS updates the list of approved telehealth services through a notice-and-comment rulemaking process, to be published along with its annual update to the Medicare physician fee schedule.[4]

45. The Telehealth List ordinarily identifies two categories of telehealth services that are payable by Medicare. *Category 1* lists services that the agency deems similar to services specifically approved for reimbursement in the Telehealth Statute (that is, "professional consultations, office visits, and office psychiatry services"). *Category 2* lists additional services for which there is evidence of clinical benefit when provided via telehealth but which are not similar to the services listed in the statute.

46. Historically, CMS has not included critical-care services (identified by CPT Codes 99291 and 99292) on the Telehealth List (in either category). Most recently in 2015 and 2016, CMS rejected proposals by the American Telemedicine Association and others to reimburse

[4] *See* Ctrs. for Medicare & Medicaid Servs., *Physician Fee Schedule* (last modified Feb. 3, 2021), https://tinyurl.com/nh51kpds (identifying rulemaking documents pertaining to telehealth services and the physician fee schedule for calendar years 2018 through 2021).

critical-care services when furnished by telehealth. *See* 81 Fed. Reg. 80170, 80196–97 (Nov. 15, 2016). Consequently, hospitals could not bill Medicare for telehealth critical-care services.

IV. The Pre-Pandemic Shortage of Critical-Care Physicians

47. For many years, the United States has suffered from a significant and growing shortage of critical-care specialists. This shortfall in intensivists has been widely publicized and well known for well over a decade. *See, e.g.*, Neil A. Halpern, *et al.*, *Critical Care Medicine in the United States: Addressing the Intensivist Shortage and Image of the Specialty*, 41 Critical Care Medicine J. 2754, 2754 (Dec. 2013) ("[T]here is a nationwide shortage of intensivists that has occurred despite years of well publicized warnings of an impending workforce crisis...."). In fiscal year 2015, for example, 48 percent of community hospitals in the United States did not have a single intensivist on staff. Neil A. Halpern, *et al.*, *Intensivists in U.S. Acute Care Hospitals*, 47 Critical Care Medicine J. 517, 519–20 (2019).

48. As HHS's Chief Medical Officer recently explained to RICU: "It is clear there was a shortage of intensivists prior to March 2020, and though the gap was partially covered (though to an undetermined extent) by ICU telehealth contracts, there is a recognition that the workforce has been depleted with an estimated shortfall of 7,900 intensivists. This gap is going to have the greatest impact in acute care hospitals in rural areas without privileged intensivists on staff." Ex. 1 (December 29, 2020 email from Leith States to Seth Rabinowitz).

49. The intensivist shortage is especially acute in rural areas. Since 2010, at least 129 rural hospitals in the United States have closed. At present, 25 percent of rural hospitals are at high risk of closing and, in some states, that figure exceeds 50 percent. Guidehouse, 2020 Rural Hospital Sustainability Index (Apr. 8, 2020). "Predictably, financial distress is the strongest driver for risk of closure." Exec. Order 13941, *Improving Rural Health and Telehealth Access*, 85 Fed.

Reg. 47881, 47881 (Aug. 6, 2020). Hospitals that serve poverty-stricken and underinsured patients simply cannot remain financially viable without the ability to recoup the costs of their services. Because profit margins for services reimbursed by Medicare are generally very low, hospitals are particularly at risk for closure when Medicare reimbursements comprise a large portion of their revenues. When Medicare refuses to reimburse services provided to Medicare beneficiaries, hospitals' financial prospects are especially bleak, accelerating closures and further restricting their communities' already limited access to care.

50. For critically ill patients, immediate critical-care treatment can be the difference between life and death. Limited access to care forces patients to travel long distances for treatment, and travel itself is dangerous for the critically ill and increases the likelihood of negative outcomes and death.

51. The severe shortage of critical-care specialists has drawn significant attention to tele-ICU as a potential solution, not only in the medical field but also in the national press. *See, e.g.*, Spyridon Fortis, *et al.*, *A Health System-Based Critical Care Program with a Novel Tele-ICU: Implementation, Cost, and Structure Details*, 219 J. Am. Coll. Surgeons 676, 682 (October 2014) ("ICU mortality was significantly lower in 2012 after tele-ICU implementation. We observed similar findings in ICU readmission rates."); Laura Landro, *5 High-Tech Fixes for Patients*, Wall Street J. (Dec. 23, 2013), https://tinyurl.com/j30los4o ("The eICU helps especially in rural areas where there can be a shortage of specialists.").

52. The intensivist shortfall in the United States does not mean critically ill patients are simply treated by intensivists who have to take on more rounds and work harder. It means that critically ill patients are not treated by intensivists *at all*, instead being attended to by nurses and/or

non-specialist doctors. For patients, this intensivist shortage thus results in increased morbidity (illness) and mortality (death).

53. Despite the potential for telehealth ICU services to alleviate healthcare shortages and improve patient outcomes in rural and underserved areas, HHS's refusal to reimburse for such services has limited the growth of this ready solution. Financially precarious rural hospitals simply cannot afford to deliver care that HHS will not reimburse.

V. The Effect of COVID-19 on the Nationwide Critical-Care Shortage

54. The COVID-19 pandemic has caused the death of hundreds of thousands of Americans and serious illness in millions more.

55. One of the groups most at risk from death and serious illness due to COVID-19 is the elderly—the very same population that relies upon Medicare. According to the Centers for Disease Control, the cumulative COVID-19 hospitalization rate for those 65 years and older is 1341 per 100,000 cases. Centers for Disease Control, *Laboratory-Confirmed COVID-19-Associated Hospitalizations: Preliminary Cumulative Rates as of Feb 06, 2021*, https://tinyurl.com/55f28um4. That hospitalization rate is more than double the rate for 50-64 year-olds and more than five times higher than the rate for 18-49 year-olds. *Id.*

56. With the onset of the COVID-19 pandemic, America's critical-care shortage has gone from alarming to deadly.

57. Throughout the pandemic and continuing to the present, hospitals across the United States have endured excruciating ICU staff shortages. *See* Carla K. Johnson & Nicky Forster, *2 in 5 Americans Live Where COVID-19 Strains Hospital ICUs*, Assoc. Press (Jan. 24, 2021), https://tinyurl.com/24vapq64; Lauren Leatherby, *et al.*, *There's No Place for Them to Go: I.C.U. Beds Near Capacity Across U.S.*, N.Y. Times (Dec. 9, 2020), https://tinyurl.com/pp4tyvdc; Reed

Abelson, *Covid Overload: U.S. Hospitals Are Running Out of Beds for Patients*, N.Y. Times (Nov. 27, 2020), https://tinyurl.com/3o6ljmhp; Annie Gowen & Holly Bailey, *'Catastrophic' Lack of Hospital Beds in Upper Midwest as Coronavirus Cases Surge*, Wash. Post (Nov. 12, 2020), https://tinyurl.com/263o99el.

58. According to a recent publication by the George Washington University, it is estimated that by February 15, 2021, thirty-four states required more ICU care than their current number of intensivists could provide. *See* Fitzhugh Mullan Institute for Health Workforce Equity, *State Hospital Workforce Deficit Estimator Projects Shortages in Next 30 Days as COVID-19 Cases Surge*, at 2 (Jan. 16, 2021), https://tinyurl.com/lh4qzf9m. An additional twelve states had less than 50 percent intensivist capacity for non-COVID-19 cases. *Id.* And these shortages are not evenly distributed: They are especially punishing in rural areas, where healthcare shortages were already alarming well before the pandemic. *See* Will Stone, *Getting Health Care Was Already Tough in Rural Areas. The Pandemic Has Made It Worse*, NPR (Oct. 7, 2020), https://tinyurl.com/put55hah ("People are hundreds of miles away and many rural hospitals have been deciding, 'Can I take anybody else but COVID?'").

59. As HHS's Chief Medical Officer explained to RICU: during the pandemic, "there is still a shortfall [of intensivists] and increasing [COVID-19] cases in a number of states with high proportions of rural residents." Ex. 1.

60. This acute shortage of critical care during the COVID-19 pandemic has shone a spotlight on the potential for telehealth to fill the gap. *See* Chad Terhune, *Hospital ICUs Lean on Telemedicine Amid COVID-19 Crisis*, Reuters (Sept. 14, 2020), https://tinyurl.com/xq034s96 ("Camden [South Carolina] is among a growing number of communities relying on this elaborate form of telemedicine to cope with an unrelenting COVID-19 case load and to manage

unpredictable surges."); Michelle Meyers, *How eICUs Are Helping Hospitals Deal with Coronavirus Overload*, CNET (Sept. 6, 2020), https://tinyurl.com/w6r2e7l4 ("COVID-19 brought on the third phase, when the eICU 'became an absolutely necessary component of being able to respond to surges'"); Jaspal Singh, *et al.*, *Telecritical Care Clinical and Operational Strategies in Response to COVID-19*, Telemedicine and e-Health (Aug. 17, 2020), https://tinyurl.com/yrgeedyp ("By emphasizing efficiency, safety, and quality, the health care system's [tele-ICU] program evolved from a luxury to a necessity").

VI. March 2020 Legislation and Temporary Approval of Telehealth ICU Services

61. In March 2020, when the novel coronavirus had begun to take hold in the United States, Congress enacted a series of statutes enhancing HHS's authority to waive or modify Medicare requirements to ensure "that sufficient health care items and services are available" and "that health care providers … may be reimbursed for such items and services." 42 U.S.C. § 1320b-5(a)(1), (2); *see* Pub. L. 115–123 (Mar. 6, 2020); Pub. L. 115–127 (Mar. 18, 2020); Pub. L. 115–136 (Mar. 27, 2020). Those enactments expressly authorized HHS "to temporarily waive or modify the application of" Medicare requirements and regulations "pertaining to … a telehealth service." 42 U.S.C. § 1320b-5(b)(8).

62. HHS, through CMS, acted promptly. On April 6, 2020, the agency published an interim final rule (with comment period) which, among other things, dramatically expanded the reimbursable services on the Telehealth List. Interim Final Rule, 85 Fed. Reg. 19230 (Apr. 6, 2020) (the "COVID-19 Telehealth IFR" or "IFR"). This expansion, retroactive to March 1, 2020, included telehealth critical-care services (CPT Codes 99291 and 99292). The agency also used its waiver authority to temporarily remove certain restrictions on the location and environment of a patient receiving telehealth care.

63. In promulgating the COVID-19 Telehealth IFR, HHS explained that it was "facilitat[ing] the use of telecommunications technology as a safe substitute for in-person services" by "adding many services to the list of eligible Medicare telehealth services." 85 Fed. Reg. at 19232. HHS explained that "[w]hen furnished under the telehealth rules, many of these specified Medicare telehealth services are still reported using codes that describe 'face-to-face' services but are furnished using audio/video, real-time communication technology instead of in-person." *Id.*

64. The IFR specifically recognized that due to the public health emergency created by the COVID-19 pandemic "the demand for physicians in areas heavily impacted by COVID-19 or under served by clinicians may intensify, resulting in a need for critical care services for patients with suspected or diagnosed COVID-19 and those who are in acute care settings due to other conditions." *Id.* at 19234. HHS thus "recognize[d] the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology." *Id.*

65. To the same end, on August 3, 2020, President Trump issued an executive order directing the Secretary of Health and Human Services to take steps to increase rural hospitals' access to telehealth and streamline Medicare reimbursement for rural hospitals' services. Exec. Order 13941, 85 Fed. Reg. 47881 (Aug. 6, 2020). The executive order observed that telehealth can "increase access to, improve the quality of, and improve the financial economics of rural healthcare," and noted that "the expansion of telehealth services is likely to be a more permanent feature of the healthcare delivery system." *Id.* at 47881. The executive order directed the Secretary of Health and Human Services to "propose a regulation to extend … the additional telehealth services offered to Medicare beneficiaries" on a permanent basis. *Id.* at 47882.

66. President Biden has kept Executive Order 13941 in place. Moreover, within hours of taking office on January 20, 2021, President Biden signed Executive Order 13987, emphasizing

that "[t]he Federal Government must act swiftly and aggressively to combat coronavirus disease 2019 (COVID-19)." Exec. Order 13987, 86 Fed. Reg. 7019, 7019 (Jan. 25, 2021).

67. President Biden signed two additional executive orders the following day. The president observed that "[t]he COVID-19 pandemic has exposed and exacerbated severe and pervasive health and social inequities in America," including in "rural" and "geographically isolated communities." Exec. Order 13995, 86 Fed. Reg. 7193, 7193 (Jan. 26, 2021). He continued, "[a]ddressing this devastating toll is both a moral imperative and a pragmatic policy. It is impossible to change the course of the pandemic without tackling it in the hardest-hit communities." *Id.* In a companion order, President Biden declared that "[i]t is the policy of my Administration to improve the capacity of the Nation's healthcare systems to address coronavirus disease 2019 (COVID-19), to accelerate the development of novel therapies to treat COVID-19, and to improve all Americans' access to quality and affordable healthcare." Exec. Order 13997, 86 Fed. Reg. 7201, 7201 (Jan. 26, 2021). President Biden directed the Secretary of HHS to "promptly ... provide targeted surge assistance to critical care … facilities." *Id.* President Biden also directed the Secretary of HHS to "identify barriers to maximizing the effective and equitable use of existing COVID-19 treatments" and to "evaluate Medicare ... and take any available steps to promote insurance coverage for safe and effective COVID-19 treatments and clinical care." *Id.* at 7202.

68. On December 28, 2020, HHS converted the Telehealth Waiver IFR into a final rule. *See* 85 Fed. Reg. 84472 (Dec. 28, 2020). In the final rule, HHS rehashed the discussion in the IFR and stated that it "in the context of the [public health emergency] for COVID-19," it "believed that all of the services [it] added" to the telehealth list in the IFR served "a patient population that would otherwise not have access to clinically appropriate treatment." *Id.* at 84503. Further, HHS

"recognized the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology as opposed to the potential lack of access that could occur to mitigate the risk of disease exposure." *Id.*

69. HHS explained that in adopting the final rule, it was creating a new Category 3 of reimbursable services, which would include telehealth services for which HHS "could foresee a reasonable potential likelihood of clinical benefit … outside the circumstances of the [public health emergency] for COVID-19 and that [HHS] anticipate[d] would be able to demonstrate that clinical benefit in such a way as to meet [its] Category 2 criteria in full." *Id.* at 84507. In other words, HHS telehealth services approved under the Telehealth Waiver are likely to become permanently reimbursable under Medicare even after the pandemic subsides.

70. The final rule included critical-care services on the new list of reimbursable Category 3 telehealth services. *Id.* at 84516, 84529.

71. By statute, HHS is authorized to pay for medical services only if those services are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The addition of tele-ICU services to the Telehealth List thus signals the agency's view that tele-ICU services are medically reasonable and necessary. Indeed, as HHS's Chief Medical Officer wrote to RICU's president, "Though telehealth restrictions have been loosened … there is still a shortfall [of intensivists] and increasing cases [of COVID-19] in a number of states with high proportions of rural residents. It is a reasonable course of action to exhaust all possible avenues in the pursuit of decreasing morbidity and mortality, and truly doing the most good for those with the greatest need." Ex. 1.

72. Consistent with Executive Order 13941 and HHS's own prior suggestions, HHS encouraged clinicians to take advantage of the temporary reimbursement of telehealth services to develop clinical evidence of effectiveness and to advocate for permanent addition to the Telehealth List in the future. Acknowledging that "practice patterns are shifting as a result of the [public health emergency]," HHS encouraged stakeholders to take the "opportunity to use information developed during the [public health emergency] to support requests for permanent changes to the Medicare telehealth services list." 85 Fed. Reg. at 84507.

VI. HHS Adopts the Critical Care Ban

73. After HHS promulgated the COVID-19 Telehealth IFR, RICU contacted HHS and CMS officials, asking for confirmation that, under the IFR, RICU's client hospitals could now bill Medicare for telehealth ICU services provided to Medicare beneficiaries. *See* Ex. 2 (April 22, 2020 email exchange between Seth Rabinowitz and Brian Pabst); Ex. 3 (April and May 2020 email exchange among Seth Rabinowitz, Martha Kuespert, and Laura Dash).

74. On June 1, 2020, Jason E. Bennett, Acting Director for CMS's Chronic Care Policy Group replied, stating that RICU had raised an "important matter" and that CMS had therefore "conducted an exhaustive review of the statute and regulations to determine if Medicare can pay for these services." Ex. 4 (June 1, 2020 letter from Jason E. Bennett to Seth Rabinowitz).

75. Acting Director Bennett stated that after this exhaustive review, the agency had concluded that Medicare could not reimburse RICU's client hospitals for RICU's services because the Medicare Act "prohibits Medicare payment for services that are not furnished within the United States." Ex. 4.

76. Acting Director Bennett cited section 1862(a)(4) of the Social Security Act, which is codified at 42 U.S.C. § 1395y(a)(4). That section states that, with some exceptions, Medicare ordinarily cannot reimburse for items and services that are "not provided within the United States."

77. Even though the Telehealth Statute states that an "eligible telehealth individual … receives a telehealth service furnished at an originating site," 42 U.S.C. § 1395m(m)(4)(B), and the Telehealth Rule states that "services are furnished to a beneficiary at an originating site," 42 C.F.R. § 410.78(b)(3), Acting Director Bennett asserted the "2001 final rule … indicates that a telehealth service is furnished at the originating site and also at the distant site." Ex. 4. As support for this assertion, however, Acting Director Bennett cited only the preamble commentary to the Telehealth Rule rather than the rule itself (and did not even cite a specific discussion in that commentary, but rather just its first page). *See id.* ("see 66 FR 55246").

78. After receiving notice of the conclusion HHS reached after its exhaustive review, RICU sought reconsideration at more senior levels of HHS. In response, on July 9, 2020, Kimberly Brandt, Principal Deputy Administrator for CMS Operations and Policy, informed RICU that HHS's "senior Medicare team and General Counsel's Office" had reviewed the issue and that the agency was now reaffirming "the letter from Jason [Bennett] for CMS's answer to the issues [RICU] raised." Ex. 5 (July 2020 email exchange between Kimberly Brandt and Seth Rabinowitz).

79. Throughout the summer and early fall, RICU asked HHS and CMS to reconsider their position, including reconsideration requests to Deputy Secretary of Health and Human Services Eric Hargan and Secretary Alex Azar. On October 14, 2020, RICU was granted a meeting with high-ranking CMS officials to discuss the issue. Ex. 6 (October 14, 2020 Email correspondence between Paul Heath and Seth Rabinowitz).

80. Following that meeting, on October 28, 2020, Demetrios Kouzoukas, Principal Deputy Administrator of CMS, issued a letter to RICU stating he was responding on behalf of Secretary Azar. Principal Deputy Administrator Kouzoukas "assure[d] [RICU] that [HHS] appreciate[d] the significance of this issue and ha[d] taken a fresh look at the matter, including a complete reevaluation of all the legal analysis …." Ex. 7 (October 28, 2020 Letter from Demetrios L. Kouzoukas to Seth Rabinowitz). This "careful review" led the agency to "again confirm[ ] the findings that were detailed in the June 1, 2020 letter from Jason Bennett and affirmed in the July 9, 2020 email from Kim Brandt, CMS Principal Deputy Administrator for Policy and Operations." *Id.*

VII. HHS's Policy Is Unlawful and Is Causing Irreparable Harm

81. HHS's Critical Care Ban is unlawful, as it directly contradicts the Telehealth Statute and the Telehealth Rule.

82. The Critical Care Ban violates the Telehealth Statute because that statute places no restrictions on the location of the doctor providing telehealth services. To the contrary, the Telehealth Statute mandates that Medicare "shall pay for telehealth services … *notwithstanding* that the individual physician … is not at the same location as the beneficiary." 42 U.S.C. § 1395m(m)(1) (emphasis added). And the Telehealth Statute states that the patient "receives a telehealth service furnished at an originating site," which is the site "at which the [patient] is located." *Id.* §§ 1395m(m)(4)(B), (C)(i).

83. The Critical Care Ban also violates HHS's own Telehealth Rule, which states "Medicare Part B pays for covered telehealth services" and that "[t]he services are furnished to a beneficiary at an originating site," which is defined as "the location of an eligible Medicare beneficiary." *Id.* §§ 410.78(a)(4), (b), (b)(3).

84. HHS's unlawful Critical Care Ban is causing irreparable harm to RICU, to hospitals, and to patients who are suffering or dying needlessly in the ICU for want of ICU physicians to treat them, which grows by the day. RICU is harmed because it is being unlawfully blocked from potential business and reputation enhancement that cannot be recouped. Before the pandemic, RICU's business increased at a rate of about 35 percent per year, and at the beginning of the COVID-19 crisis, its business grew at an even faster rate. Since the Telehealth Waiver and Critical Care Ban took effect, however, several large hospitals have refused to do business with RICU expressly on the basis that they understand that Medicare will not pay for RICU's services. Representatives of those hospitals also indicate their concern that HHS may eventually approve tele-ICU services permanently but that RICU's services will continue to be excluded from payment.

85. More importantly, and tragically, HHS is denying Medicare beneficiaries desperately needed medical assistance in the midst of a global pandemic. HHS has no good reason for letting this harm continue. The result of the Critical Care Ban is that some hospitals simply go without intensivists at all, leaving their communities without access to essential care during a public health crisis. As HHS's own Chief Medical Officer has explained to RICU: "It is a reasonable course of action to exhaust all possible avenues in the pursuit of decreasing morbidity and mortality, and truly doing the most good for those with the greatest need." Ex. 1.

COUNT ONE

(Declaratory Judgment Act and Administrative Procedure Act: The Critical Care Ban Is Contrary to Law)

86. RICU realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

87. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

88. The Administrative Procedure Act ("APA") provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

89. The APA also provides that "final agency action for which there is no other adequate remedy in a court" is "subject to judicial review." 5 U.S.C. § 704.

90. The APA directs that a reviewing court "shall … hold unlawful and set aside agency action, findings, and conclusions found to be … "not in accordance with law … [or] in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. §§ 706(2)(A), (C).

91. Critical-care services are now on HHS's list of reimbursable services. 85 Fed. Reg. at 84529.

92. Under the Critical Care Ban, HHS denies payment for critical-care services based on the overseas location of the intensivist.

93. The Critical Care Ban violates the Telehealth Statute, which mandates that Medicare "shall pay for telehealth services … *notwithstanding* that the individual physician … is not at the same location as the beneficiary," and dictates that the patient "receives a telehealth

service furnished at an originating site," which is the site "at which the [patient] is located." 42 U.S.C. §§ 1395m(m)(1), (4)(B), (C)(i).

94. The Critical Care Ban violates the Telehealth Rule, which states that "Medicare Part B pays for covered telehealth services" and that "[t]he services are furnished to a beneficiary at an originating site," which is "the location of an eligible Medicare beneficiary." 42 C.F.R. §§ 410.78(a)(4), (b), (b)(3).

95. The only statutory authority HHS invokes in support of its Critical Care Ban is 42 U.S.C. § 1395y(a)(4), which prohibits payment for services that are "not provided within the United States." But all the patients at issue here are physically located in the United States, and thus the services are provided within the United States pursuant to the plain language of both the Telehealth Statute and Telehealth Rule.

96. Alternatively, if HHS is correct that the services at issue are simultaneously provided in the United States and abroad, then Medicare payment is still mandated by 42 U.S.C. § 1395f(f).

97. Accordingly, the Critical Care Ban must be set aside because it is "not in accordance with law" and exceeds statutory authority. 5 U.S.C. § 706(2)(A).

COUNT TWO

(Declaratory Judgment Act and Administrative Procedure Act: The Critical Care Ban Is Arbitrary and Capricious)

98. RICU realleges and incorporates by reference the allegations contained in all of the preceding paragraphs.

99. The APA directs that a reviewing court "shall … hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary [or] capricious." 5 U.S.C. § 706(2)(A).

100. Agency action is arbitrary and capricious if the agency has relied on factors that Congress has not intended it to consider, when it has contradicted its own positions, when its explanation is not sufficient to enable the Court to conclude that its decision was the product of reasoned decisionmaking, when it has entirely failed to consider an important aspect of the problem it addressed, when it has committed a clear error of judgment, or when its explanation was so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

101. The Critical Care Ban is arbitrary and capricious because HHS refused to consider whether payment is warranted "notwithstanding that the individual physician … is not at the same location as the beneficiary." 42 U.S.C. § 1395m(m)(1). In other words, the agency relied on a factor that Congress has not intended it to consider.

102. The Critical Care Ban is also arbitrary and capricious because HHS refused to consider whether payment is warranted in light of 42 U.S.C. § 1395f(f).

103. The Critical Care Ban is also arbitrary and capricious because it is contradicted by the agency's own positions. HHS's Telehealth Rule states that "[t]he services are furnished to a beneficiary at an originating site," which is "the location of an eligible Medicare beneficiary," 42 C.F.R. §§ 410.78(a)(4), (b), (b)(3). This is precisely the opposite of HHS's conclusion in the Critical Care Ban: that services are provided at the physician's location.

104. The Critical Care Ban is also arbitrary and capricious because it is inconsistent with Defendants' position as to the physical location of domestically sited physicians. In the 2001 preamble announcing the Telehealth Rule, HHS clarified that certain geographic limitations on telehealth services applied only to the patient's location, not the physician's location. 66 Fed. Reg. at 55282 ("We clarify that, as a condition of payment under Medicare, the originating site must be

located in a rural [health professional shortage area] or non-[metropolitan statistical area] county. The physician or practitioner at the distant site, who provides the telehealth service, is not subject to these limitations."). Put differently, when a physician located in an MSA county "provides" a telehealth service to a patient in a non-MSA county, HHS (sensibly) deems the service to be provided ***at the patient's location***, and the geographic restriction on telehealth is thereby satisfied. *See* 42 C.F.R. § 410.78(b)(4). Without explanation, HHS has drawn the exact opposite conclusion regarding doctors who are sited abroad.

105. The Critical Care Ban is also arbitrary and capricious because HHS's explanation for it is insufficient to permit the Court to conclude it was the product of reasoned decisionmaking. HHS's only explanation for why it treats RICU's telehealth services as not "provided within the United States" was a single citation to the first page of a 259-page Federal Register notice announcing the adoption of the final Telehealth Rule in 2001. *See* Ex. 4 ("The 2001 final rule implementing payment for telehealth services indicates that a telehealth service is furnished at the originating site and also at the distant site (see 66 FR 55246)."). But nothing in that Federal Register publication requires the Critical Care Ban—and, indeed, the *actual rule* adopted in that publication dictates precisely the opposite.

106. The Critical Care Ban is also arbitrary and capricious because HHS failed to consider important aspects of the issue, including the urgent need for critical-care telehealth services and national shortage of intensivists, evidence regarding the quality and efficiency of tele-ICU care, and the risk of hospital closures in rural and underserved areas resulting from financial distress. The ban is especially incongruous and unconscionable given that the agency's indication that tele-ICU services are medically "reasonable and necessary," and given that HHS's own Chief Medical Officer has admitted that "[i]t is a reasonable course of action to exhaust all possible

avenues in the pursuit of decreasing morbidity and mortality, and truly doing the most good for those with the greatest need." Ex. 1.

107. Moreover, the Critical Care Ban is arbitrary and capricious because it defies common sense. By focusing on the physician's physical location rather than the patient's location, it permits a scenario in which a Medicare beneficiary who resides in the middle of the United States, taken down the road to his local hospital for life-saving care, is charged the full amount for his medical bill because HHS believes his care was "not provided within the United States."

108. Finally, given the flexibility afforded by Congress to HHS to waive or modify Medicare requirements in the midst of the COVID-19 national crisis, it was arbitrary and capricious for HHS to foreclose Medicare payment for a desperately needed service, knowing that the need for RICU's services is dire and that RICU's physicians are not replaceable because of the preexisting nationwide shortage of critical-care physicians and the sharply increased demand for such physicians during the pandemic. It was particularly unreasonable in light of Congress and the President's exhortations that the agency should take *all necessary steps* to meet the needs of Medicare beneficiaries and ensure reimbursement for health care providers that furnish essential healthcare services in good faith, in particular those providers who serve under-resourced areas.

PRAYER FOR RELIEF

WHEREFORE, RICU prays that this Court:

A. Issue an order and judgment declaring that Defendants violated the Medicare Act and the APA in announcing a policy that Medicare will not pay for critical-care telehealth services provided to patients located in the United States by physicians physically located outside the

United States at the time of service because the stated policy is contrary to law and is arbitrary and capricious;

B. Preliminarily and permanently enjoin the Defendants from denying Medicare reimbursement for telehealth services on the basis of a physician's or practitioner's physical location outside of the United States at the time of service;

C. Award costs and attorneys' fees pursuant to any applicable statute or authority; and

D. Provide such other and further relief as the Court may deem just and appropriate.

Dated: February 22, 2021

Respectfully submitted,

Jesse Panuccio (*pro hac vice forthcoming*)
Scott E. Gant (DC Bar No. 455392)
William Bloom (*pro hac vice forthcoming*)
Paul A. Hoversten (DC Bar No. 1644268)

/s/ Paul A. Hoversten

BOIES SCHILLER FLEXNER LLP
1401 New York Avenue, NW
Washington, D.C. 20005
Phone: (202) 237-2727
Fax: (202) 237-6131
Email: jpanuccio@bsfllp.com

Counsel for RICU LLC