No. 20-1642

In the United States Court of Appeals for the Second Circuit

Lee Barrows, on behalf of herself and all others similarly situated, Michael Savage, on behalf of himself and all others similarly situated, George Renshaw, on behalf of himself and all others similarly situated, Shirley Burton, on behalf of herself and all others similarly situated, Denise Rugman, on behalf of herself and all others similarly situated, Ann Pelow, Executor of Estate of Richard Bagnall, James Mulcahy, Executor of Estate of Sarah Mulcahy, *Plaintiffs-Appellees*,

Brenda Hardy, Executrix of the Estate of Loretta Jackson, Gary Goodman, Estate of Dorothy Goodman, Christina Alexander, Representative of Estate of Bernice Morse, Mary Smith, Representative of the Estate of Martha Leyanna, Peggy Leider, for Irma Becker, Peter Zavidniak, for Louis Dziadzia, Michael Holt, Executor of the Estate of Charles Holt, *Intervenors-Plaintiffs-Appellees*,

Richard Bagnall, on behalf of himself and all others similarly situated, Sarah Mulcahy, on behalf of herself and all others similarly situated, *Plaintiffs*,

Jessie Ruschmann, Representative of the Estate of Frederick Ruschmann, Bernice Morse, Frederick Ruschmann, Louis Dziadzia, Loretta Jackson, Martha LeYanna, Charles Holt, on behalf of themselves and all others similarly situated, Irma Becker, Dorothy Goodman, on behalf of herself and all others similarly situated, *Intervenors-Plaintiffs*,

v.

Norris Cochran, Acting Secretary of Health and Human Services, *Defendant-Appellant*.

On Appeal from the United States District Court for the District of Connecticut, Case No 11-cv-1703

BRIEF *AMICI CURIAE* OF THE AMERICAN MEDICAL ASSOCIATION AND CONNECTICUT STATE MEDICAL SOCIETY IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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Corporate Disclosure Statement and FRAP 29(c)(5) Disclosure

Pursuant to FRAP 26.1, *amici*, American Medical Association ("AMA") and Connecticut State Medical Society ("CSMS") state that they are not- for-profit corporations and no publicly held corporation owns 10% or more of the stock of either *amicus*.

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Identification and Interest of *Amici* and Source of Authority[1]

The AMA is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in the AMA's House of Delegates, substantially all U.S. physicians, residents and medical students are represented in the AMA policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in all states and in all areas of medical specialization.

CSMS is comprised of physicians and medical students who practice in the State of Connecticut.[2] CSMS is represented in the AMA House of Delegates and share the objectives of the AMA to promote the science and art of medicine and the betterment of public health.

Together, *amici* represent tens of thousands of physicians in Connecticut and across the country. *Amici* are concerned that those patients covered under the Medicare Program should receive the benefits to which they are legally entitled

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[1] Pursuant to FRAP 26(c)(5), *amici* state that no party or party's counsel authored this brief in whole or in part or contributed money intended to fund preparing or submitting this brief. *Amici* further state that no other person contributed money intended to fund preparing or submitting this brief.

[2] The AMA and CSMS join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

and that the relationship between patient and physician is not corroded by undue influence of payers, like the federal government in this case.

The source of authority to file this brief is consent of all parties.

Summary of Argument

The issue in this appeal is whether the Fifth Amendment Due Process Clause requires the Department of Health and Human Services (HHS) to afford a Medicare patient a means to challenge decisions affecting her coverage status as a hospital inpatient.[3] The outcome of this status determination can have profound financial repercussions for the patient and for the hospital. Because of such repercussions, coverage determinations can affect the patient's ability and even desire to obtain further medical care. The determination process, by pitting the physician's obligation to conform with complex and ever-changing government mandates against the physician's ethical obligation to advocate for the patient's best interests, also degrades the patient-physician relationship and thus health care generally.

This court has earlier held that the instant plaintiff-appellees would qualify for due process rights if they could prove that their treating physicians had determined their status as hospital inpatients, but that status was reversed by

[3] The Medicare regulations and guidelines define "inpatient" circularly as a patient admitted to a hospital for purposes of receiving inpatient hospital services. *See* 42 U.S.C. §§ 1395d (a) & 1395x(i); 42 CFR § 412.3(a).

hospitals' Utilization Review Committees (URCs), if the URCs were acting under financial and other HHS pressures. *Barrows v. Burwell*, 777 F.3d 106 (2d Cir. 2015). The court below found that the plaintiff-appellees did, indeed, prove this, but HHS has appealed.

While *amici* incorporate the arguments advanced by the plaintiff-appellees' brief, we choose to focus this brief on two points: 1) the District Court was correct in determining that there is a sufficiently close nexus between HHS and URCs to establish government action, because the URC is, *de facto*, an arm of HHS, and; 2) allowing HHS to deprive patients of their inpatient status violates their rights because it infringes on the protections of 42 U.S.C. §1395; it causes personal financial hardship while drawing arbitrary distinctions, and it infringes on the patient-physician relationship, which is critical to health care. The District Court should therefore be affirmed.

Argument

I. The District Court was Correct in Finding That There Is a Sufficiently Close Nexus Between HHS and Hospital Utilization Review Committees to Establish State Action Because the URC Is, *De Facto*, an Arm of HHS.

To demonstrate that "state action"—action attributable to a state or the federal government and not the action of a separate private entity—deprived a person of liberty or property without due process, a complainant must show that

the contested activity is "fairly attributable" to the state.[4] *Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass'n*, 531 U.S. 288, 295 (2001). "Actions of a private entity are attributable to the State if there is a sufficiently close nexus between the State and the challenged action of the . . . entity so that the action of the latter may be fairly treated as that of the State itself." *Cooper v. U.S. Postal Service*, 577 F.3d 479, 491 (2d Cir. 2009).

A "sufficiently close nexus" exists when "the state exercises coercive power, is entwined in the management or control of the private actor, or provides the private actor with significant encouragement, either overt or covert, or when the private actor operates as a willful participant in joint activity with the State or its agents, is controlled by an agency of the State, has been delegated a public function by the state, or is entwined with governmental policies." *Flagg v. Yonkers Sav. And Loan Ass'n, FA*, 396 F.3d 178, 187 (2d Cir. 2005). "Entwinement will support a conclusion that an ostensibly private organization ought to be charged with a public character and judged by constitutional standards[.]" *Brentwood*, 531 U.S. at 302. This analysis is a "necessarily fact-bound inquiry," meaning that the underlying facts of a case cannot be glossed over and must instead be carefully weighed. *Id*. at 298.

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[4]Or in this case, the federal government.

In the present case, to support its conclusion that hospital URC determinations constitute state action, the District Court compared the Supreme Court's analysis in *Blum v. Yaretsky*, 457 U.S. 991, 1012 (1982), which *did not* consider the activity of URCs and which found no state action, to this Court's later analysis in *Kraemer v. Heckler*, 737 F.2d 214, 223 (2d Cir. 1984), which *did* consider the activity of URCs and which found a "far stronger basis for finding state action in the decisions of URCs" before remanding for further proceedings. *Id*. at 219. And, like this Court in *Kraemer*, the District Court found the decision and influence of URCs to be significant and thus, that *Blum* was distinguishable. *Alexander v. Azar*, No. 3:11-CV-1703 (MPS), 2020 WL 1430089, at *44 (D. Conn. 2020) ("unlike in Blum, which concerned terminations originated by the patients' own doctors or by hospital directors or nursing home administrators, the *Kraemer* case involved only the determinations of utilization review committees.") (internal quotations omitted). The District Court and this Court understand that a physician who has examined a patient, and thus has established a treating relationship with that patient, is not in a similar factual position as a physician who serves on an HHS-mandated billing review committee, and should, therefore, be considered separately. Unfortunately, the Secretary does not see this distinction, and instead repeatedly conflates the decisions made by a treating physician who has examined

the patient with the activities of the URC, contending that *Blum* "considered a similar factual scenario." Brief for Appellant at 50.

The Secretary is wrong. Two physicians who merely inhabit the same hospital are not equivalent. Apart from a physician's specialty, training, and experience, this logic negates the relationship a physician has with her patient. The "clinical encounter between a patient and a physician" is the "embodiment of medical practice" and its importance cannot be overstated. AMA Code of Medical Ethics, *Opinion 1.1.1. Patient-Physician Relationship*. And the treating relationship between physician and patient is different from the relationship the patient may have with a hospital or health care facility. *See, e.g., Baptist Health v. Murphy*, 2010 Ark. 358 (2010) (finding that a hospital's interference with the physician-patient relationship was tortious). But HHS confuses this distinction and instead assigns the underlying and conflicting judgment of the treating physician and the URC to the decision of the hospital, generally. Brief for Appellant at 52-3. ("Even if some hospitals are acting to ensure that they only submit bills that are properly payable by Medicare, it is still their evaluation of whether inpatient care is medically reasonable and necessary that determines whether the patient is an inpatient.")

Treating physicians are responsible for making inpatient admission determinations as a function of their medical practice. But as a function of required

coverage review, those decisions are then scrutinized for "reasonableness" to determine whether they fit the criteria for Medicare-reimbursable claims. As the District Court states, "[m]any of the Plaintiffs, including all those who testified at trial, were initially admitted as inpatients by their treating physicians, but were subsequently placed on observation…as a result of a determination by the hospital's URC that they did not satisfy CMS's criteria for Part A coverage." *Alexander*, No. 3:11-CV-1703 (MPS), 2020 WL 1430089, at *45.

In other words, URCs do not arise out of any patient-centered care need. Instead, they are a condition of participation in the Medicare program, imposed by HHS to ensure compliance with *its* coverage standards. 42 C.F.R. § 482.30(c). In fact, while these standards allow for consultation with the treating physician, there is no *requirement* that the treating physician's opinion be given any particular weight –the URC is at perfect liberty to disregard the examining physician's opinion if it determines the opinion does not comport with coverage standards. And conversely, as the District Court notes, "[e]ven if the treating physician refuses to comply with the UR team's request to change the patient's status, once the UR team has determined that an inpatient admission does not satisfy CMS's requirements, the hospital cannot bill Medicare under Part A." *Alexander*, No. 3:11-CV-1703 (MPS), 2020 WL 1430089, at *47.

The URC is not only free to minimize the treating relationship, but there is no requirement that a physician member of a URC practice in the same specialty as the treating physician, be licensed in the same state, or be located within the same institution. HHS only requires that two members of the URC be a doctor of medicine or osteopathy. 42 C.F.R. § 482.30(b).

Thus, out-of-state utilization management (UM) firms, which are contracted by some hospitals to perform required UR functions, are free to change the admissions status of hospital patients, overriding the medical judgment and decision-making authority of treating physicians.[5] Under HHS regulations the judgment of the on-site, treating physician may carry but little force. To CMS, the neurosurgeon licensed in Texas who examined the patient in Texas may be outweighed by a urologist licensed in New York, who has never been in the same zip code as the patient, let alone performed a comparable examination. It would defy human nature to supposed that this second-guessing does not impact the making of admission decisions. For years, the AMA has urged HHS to modify these standards.[6]

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[5] *See* REPORT OF THE COUNCIL ON MEDICAL SERVICE, CMS Report 1-I-14, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-medical-service/i14-cms-report1.pdf.
[6] *See* Letter from James L. Madara, MD, CEO, AMA, to Joanne Chiedi, Acting Inspector General, HHS (Dec. 20, 2019), https://bit.ly/3edjRtl.; Letter from James

Moreover, just as utilization review regulations allow for the treating physician's opinion, but then, in practice, afford it inconsequential weight, inpatient admission decisions, which are based on treating physicians' contemporaneous assessment of 'complex medical factors,' 42 C.F.R. § 412.3(d)(3), can be overridden by *post hoc* reviews based on one factor: whether a patient stay did, in fact, cross two midnights. *Medicare Inpatient Hospital Probe and Educate Status Update*, CMS (Feb. 24, 2014), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/UpdateOnProbeEducateProcessForPosting02242014.pdf; 42 C.F.R. § 412.3(d)(1). Physicians are then "educated" by these CMS-contracted reviewers under fear of draconian penalties. *See Alexander*, No. 3:11-CV-1703 (MPS), 2020 WL 1430089, at *99 ("CMS contractors…continue to conduct post-payment reviews of a sample of each hospital's inpatient claims and conduct one-on-one calls with providers to educate them on the proper application of CMS's inpatient criteria.").

L. Madara, MD, CEO, AMA, to Seema Verma, Administrator, CMS (Nov. 18, 2019), https://bit.ly/3edjRtl.; Letter from James L. Madara, MD, CEO, AMA, to Seema Verma, Administrator, CMS (Aug. 9, 2019), https://bit.ly/3edjRtl.

CMS contractors' blind application of billing regulations such as the 'Two Midnight Rule' can produce absurd results. Consider the following example:[7] Patient A is hospitalized for chest pain from 11 p.m. Sunday to 4 a.m. Tuesday for a total of 29 hours. Patient A is presumed by reviewers to be an inpatient because his stay spanned two midnights. The patient is covered by Medicare Part A and responsible for a one-time deductible of $1,260 for services received. Patient B, on the other hand, presents with chest pain at the hospital *two hours after* Patient A—at 1 a.m. Monday—and is discharged at 10 p.m. Tuesday for a total stay of 45 hours. Patient B, however, is classified by reviewers as an outpatient because his stay did not cross two midnights. Patient B is therefore responsible for 20 percent copayments for each service provided during his stay as well as the costs of any self-administered medications. U.S. DEP'T OF HEALTH & HUM. SERVS., HOW MEDICARE COVERS SELF-ADMINISTERED DRUGS GIVEN IN HOSPITAL OUTPATIENT SETTINGS (2017), https://www.medicare.gov/sites/default/files/2018-07/11333-self-administered-drugs-outpatient.pdf.

Regulators have the incentive to accept these absurd results if claims can be processed with mechanical efficiency. Certainly, it would be easier for HHS if

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[7] *See* AMA, Inpatient versus observation care (2016), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-medical-service/issue-brief-inpatient-v-observation-care.pdf.

physician decision making or medical practice, for that matter, could be reduced to a series of algorithms. But this is simply not how medicine works. The practice of medicine is a fundamentally human endeavor that must take into consideration the unique needs and characteristics of each patient and the unique context in which each patient presents for treatment. In this way medicine is just as much an art as it is a science. And for this reason, true deference, and not mere passing mention, must be afforded to physicians who have a treating relationship with the patient and the treatment decisions they order.

While often illogical and unrelated to the care of patients, billing requirements may carry disproportionate weight in the exam room due to the significant coercive power HHS wields to enforce its standards. Coverage denials or recoupment practices by the various contractors Medicare employs are just the tip of the iceberg. HHS, through its Office of Inspector General, has coordinated with the Department of Justice to subject health care professional's medical judgment to False Claims Act liability.[8] The False Claims Act allows for treble

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[8]*See Winter ex. rel. U.S. v. Gardens Regional Hosp.*, 953 F.3d 1108, 1123 (9th Cir. 2020); *U.S. ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 101 (3d Cir. 2020) (holding that "for purposes of FCA falsity, a claim may be 'false' under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements," and that "a physician's judgment may be scrutinized and considered 'false'"); *U.S. v. AseraCare, Inc.*, 938 F.3d 1278, 1305 (11th Cir. 2019) (considering "whether AseraCare's certifications that patients were terminally ill satisfied Medicare's statutory and regulatory requirements for reimbursement"); *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 746 (10th Cir. 2018) (holding that "a doctor's

damages in addition to a fine of $11,000 per individual claim as well as criminal penalties. It presents a formidable threat to those who might disregard rules like the Two Midnight Rule. 31 U.S.C.A. § 3729; 18 U.S.C.A. § 371.

In *Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr.*, the Ninth Circuit held that a nurse who had been contracted to perform after-the-fact review of hospital records using commercially available screening criteria had sufficiently alleged that the defendant hospital had falsely certified that patients' inpatient hospitalizations were medically necessary. 953 F.3d 1108, 1112 (9th Cir. 2020). Contrary to what the Secretary argues in the present case, the Ninth Circuit determined that "[t]he Medicare program…does not give [physicians] unfettered discretion to decide whether inpatient admission is medically necessary[.]" *Id*. at 1114. (internal quotations omitted). Further, "the regulations consider medical necessity a question of fact: [n]o presumptive weight shall be assigned to the physician's order[.]" *Id*. HHS-directed reviews, therefore, operate on physicians not merely with the specter of coverage denials and access to care issues looming, but with the threat of False Claims Act litigation. HHS cannot credibly claim

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certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase"); *U.S. v. Paulus*, 894 F.3d 267, 280 (6th Cir. 2018); *U.S. ex rel Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 381 (5th Cir. 2004); *U.S. v. Prabhu*, 442 F.Supp.2d 1008, 1036 (D. Nev. 2006) (noting that "claims are not 'false' under the FCA unless they are furnished in violation of some controlling rule, regulation or standard").

deference to physician judgment while it not only directs contractors to perform targeted audits using its administrative, non-medical criteria, but then refers the results of these audits for after-the-fact consideration of sanctions.

II. Bureaucratic Deprivation of Inpatient Status Infringes on 42 U.S.C. §1395 Protections, Draws Arbitrary Distinctions, Causes Financial Hardships, and Undercuts the Patient-Physician Relationship.

To determine whether the plaintiff-appellees were deprived of a significant private interest without due process of law, this Court must consider three factors: 1) the private interest at stake, 2) the risk of erroneous deprivation of the private interest through the procedures available, and the probable value of additional procedural safeguards; and 3) the government's interest. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). *Amici* will focus on the first factor, the private interest at stake.

Amici agree with both the District Court, and this Court in *Kraemer v. Heckler* that, "the private interest at stake should be weighted more heavily than in Eldridge because of the astronomical nature of medical costs." 737 F.2d at 222. But even aside from cost, the impact on the patient-physician relationship is severe and must be considered.

The District Court properly considered the prohibitive expense of rehabilitative and skilled nursing care and the cost-sharing responsibilities associated with Part B. But it is also worth noting that, in practice, "observation" is

no more than a billing distinction—without a substantive difference—from inpatient admission.[9] And while the same services may be provided for patients regardless of this distinction, the same services are not *covered* for patients who are classified as under "observation" versus those who are "inpatient." So, self-administered medications would be covered under Part A, but must be paid out-of-pocket for Part B. U.S. DEP'T OF HEALTH & HUM. SERVS., HOW MEDICARE COVERS SELF-ADMINISTERED DRUGS GIVEN IN HOSPITAL OUTPATIENT SETTINGS (2017), https://www.medicare.gov/sites/default/files/2018-07/11333-self-administered-drugs-outpatient.pdf.

It is also important to consider the impact of more than one hospital stay at a time, since "Medicare beneficiaries who must revisit the hospital may have greater cumulative costs under observation care versus inpatient care." Shreya Kangovi *et al.*, *Patient Financial Responsibility for Observation Care*, 10 J. Hosp. Med. 718, 723 (Nov. 2015), https://cdn.mdedge.com/files/s3fs-public/pdfs/journals/jhm2436.pdf**.** The Part A inpatient deductible, for example, covers a "benefit period" that does not end until the patient has gone without inpatient care for 60 days. 42 C.F.R. §§ 409.60, 409.82. If a patient is re-admitted to the hospital on the 59th day, for example, that patient will not have to repay the deductible, and, the benefit period will be extended for another 60 days. *Id.* Patients classified as

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[9] Jennifer L Wiler *et al.*, *National study of emergency department observation services*, 18 Acad. Emergency Med. 959–965 (2011).

outpatients and thus covered under Part B would have the same cost-sharing responsibilities for each visit, with no comparable analogy to the "benefit period" under Part A. *See* 42 U.S.C. § 1395l.

Finally, these cost implications can overwhelm patients. They inspire fear of financial ruin and influence the care decisions that will follow. Indeed, the consequences can be life-threatening. In a letter to CMS, the AMA noted that "[e]mergency physicians are reporting [that] patients [who come] to the emergency department often ask whether they are being admitted as inpatients. If these patients are not given assurances that they will be treated as an inpatient, they leave—even when they clearly require medical attention."[10] Similarly, when her patient's status was changed from inpatient to observation, one physician testified at trial:

> "The patient said to me, "I just want to die." And having known her for many, many years, she was very sincere about this. And I said "Why -- why are you saying this?" And she said, "Because if my care is not covered, if I can't get rehab and I can't return home, this will bankrupt my family and everything that we have worked for all of our lives. In this case, I just want to die.""

Testimony of Dr. Julia Kyle, A848-A867.

These expenses undermine the foundation of medical practice, which relies on the trust a patient must afford to his physician to be able to treat and advocate in

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[10] *Available at* https://bit.ly/3edjRtl.

his best interest. As with Dr. Kyle, a physician should have the ability to make the medical determination that a patient who has suffered eight fractures and has an underlying neuromuscular condition would benefit from rehabilitative care without having to fight an administrative battle to ensure their patient's status is coded correctly so that the patient can access that needed care.

Nonsensical administrative hurdles jeopardize the patient-physician relationship. But when a care directive is changed by an administrator, it also interferes with the physician's ethical commitment to quality of care, which directs physicians to "[hold] themselves accountable to patients, families, and fellow health care professionals for communicating effectively and coordinating care appropriately." AMA Code of Medical Ethics, *Opinion 1.1.6 Quality*.

Patients made vulnerable by an illness or injury so severe that they require hospitalization must be able to trust that the physician with whom they have a treating relationship, who has examined the patient personally, and has made a determination based on his or her unique medical needs, is credible and is not instead undermined by an unknown regulator seeking to reduce costs. This behavior threatens the foundation of our care delivery system. A safeguard against this behavior is the patient's right to defend the treating physician's decision through fair process.

Conclusion

For the foregoing reasons, *amici* urge this Court to affirm the District Court judgment and afford plaintiff-appellees the process they are due.

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Certificate of Compliance

I hereby certify that:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7) and Local Rule 32.1(a)(4) because it contains 3,696 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared it a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

s/ Erin G. Sutton
Erin G. Sutton

Certificate of Service

I hereby certify that on March 5, 2021, an electronic copy of the foregoing was filed with the Clerk of Court using the ECF system and thereby served upon all counsel appearing in this case.

s/ Erin G. Sutton
Erin G. Sutton