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, Anne 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 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*,

(*For continuation of caption see inside cover*)

On Appeal from the United States District Court for the District of Connecticut

BRIEF OF AARP, AARP FOUNDATION, NATIONAL DISABILITY RIGHTS NETWORK, AND DISABILITY RIGHTS CONNECTICUT AS AMICI CURIAE IN SUPPORT OF INTERVENOR-PLAINTIFFS-APPELLEES

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(*caption continued*)

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, *Intervenors-Plaintiffs*,

v.

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

CORPORATE DISCLOSURE STATEMENTS

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) of the Internal Revenue Code and is exempt from income tax. The Internal Revenue Service has determined that AARP Foundation is organized and operated exclusively for charitable purposes pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. AARP and AARP Foundation are also organized and operated as nonprofit corporations under the District of Columbia Nonprofit Corporation Act. Other legal entities related to AARP and AARP Foundation include AARP Services, Inc., and Legal Counsel for the Elderly. Neither AARP nor AARP Foundation has a parent corporation, nor has either issued shares or securities.

The National Disability Rights Network ("NDRN") is a nonprofit organization. NDRN has no parent corporation, and no publicly held corporation owns a portion of NDRN.

Disability Rights Connecticut ("DRCT") is a non-profit organization that has no parent corporation and that issues no stock. Accordingly, no publicly held corporation owns ten percent or more ownership interest in DRCT.

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STATEMENT OF INTEREST[1]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial resilience, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity. Among other things, AARP and AARP Foundation advocate for access to quality healthcare and older adults' right to participate in healthcare decisions that can adversely affect their financial security, including through participation as amici curiae in state and federal courts. *See, e.g.*, *California v. Texas*, Nos. 19-840, 19-1019 (2020); *Stewart v. Azar*, Nos. 19-5095, 19-5097 (D.C. Cir. Aug. 1, 2019); *Guillermo Tabraue, III v. Doctors Hospital, Inc.*, SC19-685 (Fla. 2019).

[1] No party's counsel authored this brief either in whole or in part and no party or party's counsel, or any person or entity other than AARP, AARP Foundation, NDRN, and Disability Rights Connecticut, their members, and their counsel, contributed money intended to fund the preparation or submission of this brief. Counsel of record for all parties received timely notice Amici's intent to file this brief and consented to same.

NDRN is the non-profit membership organization for the federally-mandated Protection and Advocacy (P&A) and Client Assistance Program (CAP) agencies for individuals with disabilities. The P&A and CAP agencies were established by the United States Congress to protect the rights of people with disabilities and their families through legal support, advocacy, referral, and education. There are P&As and CAPs in all 50 states, the District of Columbia, Puerto Rico, and the U.S. Territories (American Samoa, Guam, Northern Mariana Islands, and the US Virgin Islands), and there is a P&A and CAP affiliated with the Native American Consortium which includes the Hopi, Navajo, and San Juan Southern Paiute Nations in the Four Corners region of the Southwest. Collectively, the P&A and CAP agencies are the largest provider of legally-based advocacy services to people with disabilities in the United States.

DRCT is an independent non-profit organization that has been designated as Connecticut's protection and advocacy system. Conn. Gen. Stat. § 46a-10a. DRCT's mission is to advocate for the human, civil, and legal rights of people with disabilities in Connecticut. As the protection and advocacy system for the State of Connecticut, DRCT has extensive experience representing individuals with disabilities. DRCT recognizes that this case has implications for every individual with a disability, including those with age-related disabilities, who are Medicare beneficiaries.

Amici submit this brief because this Court's decision will determine whether the U.S. Constitution affords older adults and people with disabilities covered by Medicare the opportunity to challenge outpatient hospital classifications at the point when the health-related and financial harms that flow from that coverage-altering designation can be avoided. Absent expedited due process hearings to challenge a hospital's outpatient classification of a Medicare beneficiary during that hospital stay, the beneficiary will lack an adequate remedy to reverse the cascading, adverse financial and health-related consequences of an erroneous classification. Post-hospitalization review and reversal of an erroneous outpatient classification will, of course, affect the beneficiary's financial responsibility for the hospital services themselves. But it cannot adequately redress the health-related consequences of forgone post-hospital rehabilitative care or the financial consequences of debt incurred by the beneficiary as a result of the misclassification while any appeal is pending. The health-related and financial consequences of outpatient observation classifications for Medicare beneficiaries are concrete and significant. These concrete harms warrant the constitutional procedural safeguards that protect Medicare beneficiaries from Centers for Medicare and Medicaid Services ("CMS") regulations that simultaneously drive the misclassification of beneficiaries' hospitals stays and deny them a timely opportunity to challenge these errors.

SUMMARY OF THE ARGUMENT

The Court's decision will have broad ramifications for older adults and people with disabilities covered by Medicare who require hospital and post-hospital skilled nursing facility ("SNF") services. Older adults and people with disabilities heavily utilize these services. Yet they can face significant financial consequences for receiving them when they are designated as outpatients under observation during their hospital stay. Dangerously, beneficiaries classified as outpatients while hospitalized can and do forgo needed post-hospital rehabilitative services not covered by Part A.

Because hospitals fear Medicare overpayment actions if they classify Medicare beneficiaries as inpatients and CMS' auditors disagree with that designation, hospitals can err in favor of outpatient classifications that deprive beneficiaries of Medicare Part A coverage for costly post-hospital SNF stays. As hospitals' use of observation status (including for long outpatient stays) increases, the potential costs to Medicare beneficiaries who require hospital and subsequent SNF care not covered by Medicare Part A grow commensurately. Medicare beneficiaries must bear these costs without a timely opportunity, under current CMS regulations, to challenge coverage-altering hospital classifications that can be financially devastating. Medical debt resulting from outpatient hospital stays and uncovered post-hospital SNF care can lead to protracted financial insecurity, even

bankruptcy, and threaten Medicare beneficiaries' ability to avoid unnecessary institutionalization.

Medicare beneficiaries suffer real deprivations as a result of CMS' policies governing payment and overpayment recovery and its prohibition on expedited due process hearings to challenge hospital classifications of their care. The lower court properly found that CMS must address these deprivations through its administrative procedures. Amici respectfully urge the Court to affirm the lower court's decision.

ARGUMENT

I. Hospital and Skilled Nursing Facility Services Are Critical Healthcare Resources for Older Adults and People with Disabilities Who Are Medicare Beneficiaries.

Hospital and post-hospital SNF services are critical healthcare resources for many of Medicare's 54.1 million beneficiaries. *See* U.S. Dep't of Health and Hum. Servs., *Putting America's Health First,* 76 (2020), https://bit.ly/3uY4FWP. "In 2016, nearly one-third [of Medicare beneficiaries] [] had a functional impairment; one quarter [] reported being in fair or poor health; and more than one in five [] had five or more chronic conditions." Kaiser Family Found., *An Overview of Medicare* 1-2, Feb. 13, 2019, https://bit.ly/3uRZzLQ. Fifteen percent of Medicare beneficiaries were under age 65 and living with a long-term disability. *Id*. at 2; *see also* Mary L. Adams, *Differences Between Younger and Older US Adults with Multiple Chronic Conditions*, 14 Prev. Chronic Dis. 1606, 1607, 1609 (2017)

(finding 61.4% of adults with multiple chronic conditions ("MCC") were younger than 65 and a high rate of cognitive impairment among younger adults with MCC).

A. Older Adults and People with Disabilities Heavily Utilize Hospital Services.

Older adults and people with disabilities covered by Medicare heavily utilize hospital services. Nearly forty percent of hospitalized adults are age 65 and older. Melissa Mattison, *Hospital Management of Older Adults*, UPTODATE (2020), https://bit.ly/387rnSv. "Those 65 years and older are hospitalized three times as often as those 45 to 64." *Id*. (internal citation omitted).

Older adults also account for a disproportionate share of emergency services. Inst. of Med., Comm. on the Future Health Care Workforce for Older Am., *Retooling for an Aging America: Building the Health Care Workforce* (2008), https://bit.ly/2OsavPp. "In 2015, nearly 57,000 adults over age 65 visited the emergency department, and 33.6% of those patients were admitted to the hospital[.]" Debra Bakerjian, *Hospital Care and Older Adults*, Merck Manual (2020), https://bit.ly/2MPNMMY. Older adults seen in emergency departments often present with higher-acuity conditions that are more complex because they are accompanied by multiple co-morbid conditions, atypical presentations of common diseases, and medical complications that result in traumatic injury. Jesse M. Pines et al., *National Trends in Emergency Department Use, Care Patterns, and Quality of Care of Older Adults in the United States*, 61 J. Am. Geriatrics Soc'y 12, 12

(2013). The result is often high emergency resource use in the form of more-advanced imaging, laboratory and urine testing, time-consuming care coordination, long emergency department stays, and more-frequent hospital admissions than younger cohorts. Lesley P. Latham & Stacy Ackroyd-Stolarz, *Emergency Department Utilization by Older Adults: A Descriptive Study*, 17 Can. Geriatrics J. 118, 118 (2014).

B. Hospital Classifications of Patient Stays as Outpatient Observation Do Not Accurately Reflect Medicare Beneficiaries' Medical Need for Inpatient Hospital Services.

While CMS regulations governing inpatient admission and outpatient observation seem to contemplate distinct levels of medical need, in practice, the hospital services provided to inpatients and outpatients under observation are often indistinguishable. As such, hospital admission and billing classifications do not reliably reflect Medicare beneficiaries' actual need for services that they must seek in a hospital. "Patients undergoing short hospital stays may be treated similarly to inpatients but classified as outpatients receiving observation services." Am. Med. Ass'n., *Payment and Coverage for Hospital Admissions: Inpatient Versus Observation Care* (2016), https://bit.ly/2PATrrh; *see also* Soc'y of Hosp. Med., *The Hospital Observation Care Problem: Perspectives and Solutions from the Society of Hospital Medicine* 2-3 (September 2017), https://bit.ly/30en0kA (hereinafter "Hospital Observation Care Problem"). A 2017 report by the Society of Hospital

Medicine confirms that "[CMS'] definition of observation is not reflective of current clinical practice." *Id*. "Observation care often spans longer than 48 hours, muddles the line between inpatient services and outpatient care . . . [and], in its current form, is often indistinguishable from inpatient care." *Id*.

As Harold Engler and his wife, Sylvia, learned following his ten-day stay in a Boston hospital for complications following emergency hernia surgery, what "seemed like textbook hospital care" had been classified as outpatient observation. Liz Kowalczyk, *Status of Medicare Patients Can Result in Huge Bills*, Boston Globe (Aug. 25, 2013, 12:00 AM), https://bit.ly/3sQYMco. Even though nurses provided Mr. Engler around-the-clock treatment, including changing his catheter and administering intravenous drugs for suspected pneumonia for an extended period, he and his wife learned from a nurse at the nursing home where Mr. Engler was sent for rehabilitation that Mr. Engler had never been admitted as an inpatient. *Id*.

Like Mr. Engler, many Medicare beneficiaries find it difficult to distinguish inpatient and outpatient hospital services that are rendered in similar hospital environments for comparable periods. "Neither CMS regulations nor payment codes require that outpatient hospital services be delivered in a specific setting." Christopher W. Baugh & Jeremiah D. Schuur, *Observation Care—High-Value Care or Cost-Shifting Loophole?*, 369 N. Engl. J. Med. 302, 303 (2013) (hereinafter "Cost-Shifting Loophole"); *cf.* Ctrs. for Medicare and Medicaid Servs., *Medicare*

Benefit Policy Manual, Pub. 100-02, Rev. 10541, Ch. 6, § 20.6. Outpatient observation services may be – and are – delivered through "protocolized care in dedicated observation units" and "care on a traditional hospital ward." Baugh & Schurr, *Cost-Shifting Loophole*, *supra*, at 303; *cf. Alexander v. Azar*, No. 3:11-cv-1703, 2020 WL 1430089, *15-17 (describing observation services in outpatient units and other settings). Moreover, with long observation stays increasing despite CMS' adoption of the "two-midnight rule" for inpatient admission, neither the duration of hospital stays nor patient classifications reliably reflect the nature or amount of services needed by hospitalized older adults and people with disabilities. *Cf.* U.S. Dep't of Health and Hum. Servs., Off. of Inspector Gen. ("OIG"), OEI-02-15-00020, *Vulnerabilities Remain Under Medicare's 2-Midnight Hospital Policy* 3, 10, 12 (2016) https://bit.ly/2OoKTTP (acknowledging "hospitals continue to bill for a large number of long outpatient stays") (hereinafter "Vulnerabilities Remain"); Jennifer N. Goldstein et al., *Observation Status, Poverty, and High Financial Liability Among Medicare Beneficiaries*, 131 Am. J. Med. 101.e09, 101.e09 (2018) ("Since this rule was enacted, hospitalizations under observation status have increased by 8%, and inpatient admissions have decreased by 2.8%.") (internal citations omitted).

C. Hospitalized Patients with Cognitive Impairments or Other Disabilities Might Be Unable to Distinguish Inpatient from Outpatient Care Despite Observation Status Notices.

While differentiating inpatient from outpatient hospital care is challenging for most patients, for those who enter the hospital with cognitive impairments or other disabilities it is nearly impossible. Patients entering hospitals for emergent care in a compromised medical state often cannot comprehend outpatient status notices that contradict all observable aspects of their hospital stays. Hospitals are required to provide Medicare beneficiaries receiving observation services for more than twenty-four hours a Medicare Outpatient Observation Notice ("MOON"). 42 U.S.C. § 1395cc(a)(1)(Y). Yet many hospitalized older adults and patients with disabilities cannot comprehend this notice without accommodations and instructions regarding what the patient can do with this information. *Cf.* Bakerjian, *Hospital Care and Older Adults*, *supra* ("About 30 to 40% of older [emergency department] patients [] are cognitively impaired but do not have a [dementia] diagnosis[.]"). For patients with disabilities, MOON notices might be wholly incomprehensible without interpretation services, assistive technology, or other accommodations. *Cf.* 28 C.F.R. §§ 35.104 (auxiliary aids and services defined), 36.303(c) ("A public accommodation shall furnish appropriate auxiliary aids and services where necessary to ensure effective communication with individuals with disabilities."); *Pabon v. Wright*, 459 F.3d 241, 246, 249 (2d Cir. 2006) (right to refuse medical

treatment "carries with it a concomitant right to such information as a reasonable patient would deem necessary to make an informed decision regarding medical treatment"); *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 314-15 (1950) (notices must be reasonably calculated to convey requisite information in a manner that enables the recipient to act upon it).

D. Post-Acute Skilled Nursing Facility Services Can Prevent Re-Hospitalization and Speed Recovery from Acute Illnesses.

Older adults and people with disabilities frequently require post-hospital SNF care for rehabilitation, to recover from the deterioration of an illness that precipitated the hospitalization, and to avoid hospital re-admission. Nearly twenty percent of Medicare fee-for-service patients receive post-acute care in SNF after hospitalization. K. Lucy Kim et al., *Changes in Hospital Referral Patterns to Skilled Nursing Facilities Under the Hospital Readmissions Reduction Program*, 57 Medical Care 695, 695 (2019).

Post-hospital SNF care is particularly important for older adults because the "outcome of hospitalization appears to be poorer with increasing age." Bakerjian, *Hospital Care and Older Adults*, *supra*. "About 75% of patients who are [] 75 [or older] and functionally independent at admission are not functionally independent when they are discharged; 15% of patients [] 75 [or older] are discharged to SNFs. The trend toward abbreviated acute hospital stays followed by subacute care and rehabilitation in a SNF may partially explain why these percentages are high." *Id*.

Medicare beneficiaries often need post-hospital SNF care to recover functionality and avoid hospital re-admission. Even among "marginal" hospital patients discharged to SNFs versus home health care – those for whom home health versus SNF is borderline and either setting would be reasonable – discharge to home health care has been associated with a 5.6 percentage point higher rate of hospital readmission at thirty days. Rachel M. Werner et al., *Patient Outcomes After Hospital Discharge to Home with Home Health Care vs to a Skilled Nursing Facility*, 179 JAMA Intern. Med. 617, 620-22 (2019). Yet hospital and SNF providers find "patients discharged to SNFs to be medically and socially complicated." Meredith Campbell Britton et al., *Care Transitions Between Hospitals and Skilled Nursing Facilities: Perspectives of Sending and Receiving Providers*, 43 Jt. Comm. J. Qual. Patient. Safety 565, 569 (2017). "What's come out of the hospital now was always treated in the hospital years ago . . . People are coming out quicker . . . [and] sicker," according to one SNF medical director. *Id.* Sending hospital providers and receiving SNF providers commonly report "caring for patients with multiple co-morbidities whose conditions often require[] numerous medications and the use of specialized medical equipment." *Id.* Post-hospital SFN care can be vital for older adults and people with disabilities who also have higher rates of co-morbidities during and after their hospital stay and who often require

extensive pharmacological and specialized equipment. *Cf.* Kaiser Family Found., *Overview of Medicare, supra*, at 1-2; Adams, 12 Prev. Chron. Dis. at 1607, 1609.

While many older adults and people with disabilities critically need post-hospital SNF care, fewer Medicare beneficiaries receive it because their classification as outpatients while hospitalized deprives them of the Part A coverage needed to fund it. *See* Section II.C below. Where they do receive SNF care, they bear its costs in ways that adversely affect their financial security, health, and, at times, their ability to continue to live independently in their communities.

II. Medicare Beneficiaries Can Suffer Catastrophic Financial and Health-Related Consequences When They Are Not Covered by Medicare Part A Due to Their Classification as Outpatients Under Observation While Hospitalized.

The number of Medicare beneficiaries has grown significantly in recent years and the number without supplemental insurance remains high. Medicare enrollment for people age 65 and over grew to 54.1 million in 2020; up from 52.4 million in 2019, and 50.7 million in 2018. U.S. Dep't of Health and Hum. Servs., *Putting America's Health First,* 76 (2020), https://bit.ly/3uY4FWP. "Nearly one in five beneficiaries in traditional Medicare (19%)—6.1 million beneficiaries overall—had no source of supplemental coverage in 2016, which places them at greater risk of incurring high medical expenses or foregoing medical care due to costs." Juliette Cubanski et al., *Sources of Supplemental Coverage Among Medicare Beneficiaries in 2016* (Kaiser Family Found. 2018), https://bit.ly/2MT8BXW.

A. The Out-of-Pocket Expenses for Medicare Beneficiaries Who Are Not Covered by Part A Can Be Financially Hazardous.

The costs of hospital and subsequent SNF care for which Medicare beneficiaries designated as outpatients under observation are responsible vary and can be significant. Medicare beneficiaries who receive hospital services as outpatients under observation are responsible for a portion of the outpatient hospital services they receive and self-administered drugs taken during their outpatient stay, if they have Medicare Part B coverage. *See* Ctrs. For Medicare and Medicaid Servs., *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 4, §§ 10, 30; OIG, *Vulnerabilities Remain*, *supra*, at 6. If Medicare beneficiaries are hospitalized under outpatient observation and do not have Medicare Part B or other supplemental insurance coverage, they often must pay for hospital services and drug charges out of pocket.

Medicare beneficiaries classified as outpatients during their hospital stays can and have paid more for those hospital services and post-hospital SNF services. In Fiscal Year 2014, Medicare beneficiaries in 352,940 outpatient stays paid more than the inpatient deductible of $1,216. OIG, *Vulnerabilities Remain*, *supra*, at 13; Soc'y for Hosp. Med., *The Observation Status Problem: Impact and Recommendations for Change* 4 (July 2014), https://bit.ly/3riKFMw (hereinafter "Observation Status

Problem").[2] In the same year, 1,628,628 outpatient stays had charges for self-administered drugs, an increase of 13 percent over FY2013. OIG, *Vulnerabilities Remain*, *supra*, at 13. Medicare beneficiaries in 2014 also faced substantial medical costs after leaving the hospital. In Fiscal Year 2014, Medicare beneficiaries had 633,148 hospital stays that lasted at least three nights but did not include three inpatient nights; these stays did not qualify beneficiaries for Part A coverage of subsequent SNF care. *Id*. This figure represents an increase from Fiscal Year 2012, in which Medicare beneficiaries had over 600,000 hospital stays that lasted three nights or more but did not qualify them for coverage of SNF services. OIG, *Hospitals' Use of Observation Stays*, *supra* note 2, at 14. In Fiscal Year 2012, Medicare beneficiaries with 2,097 hospital stays received SNF services following their discharge that Medicare did not cover; these beneficiaries were fully liable for SNF service charges totaling $22 million, for an average of $10,503. OIG, *Hospitals' Use of Observation Stays*, *supra* note 2, at 15.

[2] The Society of Hospital Medicine's 2014 report questioned the OIG's earlier suggestion that "observation patients may pay less out of pocket than inpatients." Soc'y of Hosp. Med., *Observation Status Problem*, *supra*, at 4 (noting the observation Part B dollar amounts in the OIG's 2013 report were estimates, the report lacked information on services delivered, and the "only head-to-head comparison of a specific service was for coronary stent insertion, where observation patients paid $817 *more* out of pocket than inpatients"); *cf*. U.S. Dep't of Health and Hum. Servs. Off. of Inspector Gen., OEI-01-12-00040, *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries* 12 (2013), https://bit.ly/2O6cGIC (hereinafter "Hospitals' Use of Observation Stays").

An AARP Public Policy Institute study of Fiscal Year 2009 Medicare claims found that approximately 2.2 million fee-for-service Medicare beneficiaries were placed under observation. Keith D. Lind *et al*., *Observation Status: Financial Implications for Medicare Beneficiaries* 6 (AARP Public Policy Institute April 2015), https://bit.ly/3e9BhXD (hereinafter "Financial Implications of Observation Status"). Nearly seventy-eight percent of these patients received only outpatient services. *Id*. "One in ten observation patients (167,358) paid more for hospital services than the deductible owed by post-observation inpatients ($1,068 in 2009)." *Id*. "The one percent of observation patients who spent the most (16,736) paid at least $2,283—more than twice what they would have owed had they later been admitted." *Id*.

Medicare beneficiaries requiring frequent observation hospitalizations often bear an increased financial burden because there is no benefit period for outpatient observation services.[3] Ann M. Sheehy et al., *Thirty-Day Re-Observation, Chronic Re-Observation, and Neighborhood Disadvantage*, 95 Mayo Clin. Proc. 2644, 2645 (2020); *see also* Shreya Kangovi et al., *Patient Financial Liability for Observation Care*, 10 J. Hosp. Med. 718, 720-21 (2015) (finding beneficiaries with more than one observation stay in sixty days incurred significantly higher out-of-pocket costs).

[3] The absence of a benefit period for outpatient observation services means that Medicare beneficiaries' cost-sharing is not limited in the way that inpatient deductibles fund coverage for care spanning an episode of illness.

Given that Medicare beneficiaries in the most disadvantaged neighborhoods have had a materially higher thirty-day reobservation rate than those in the least disadvantaged neighborhoods, the costs of frequent observation stays have considerable implications for healthcare equity. *See* Sheehy, *Thirty-Day Re-Observation*, 95 Mayo Clin. Proc. at 2644. Growing evidence of income and racial disparities in the use of outpatient observation is also cause for alarm. *See* Goldstein, *Observation Status, Poverty, and High Financial Liability Among Medicare Beneficiaries*, 131 Am. J. Med. at 101.e11-12 (finding low-income Medicare beneficiaries at risk of high use of observation care and higher out-of-pocket costs for that care); Brad Wright et al., *Evidence of Racial and Geographic Disparities in the Use of Medicare Observation Stays and Subsequent Patient Outcomes Relative to Short-Stay Hospitalizations*, 2 Health Equity 45, 45 (2018) (finding "blacks 3.9% points more likely than whites, rural 5.4% points less likely than urban" to have observation hospital stays).

The cost of outpatient observation services to Medicare beneficiaries is likely to grow with increasing use of observation and longer outpatient hospital stays. *See* OIG, *Vulnerabilities Remain*, *supra*, at 9-10 (reporting increase in longer outpatient hospital stays); Keith D. Lind et al., *Increasing Trends in the Use of Hospital Observation Services for Older Medicare Advantage and Privately Insured Patients*, 76 Med. Care Research and Rev. 229, 230 (2019) (finding patients with Medicare

Advantage plans experienced similar increases in frequency of observation use as those in government-run health care plans). Historically, the duration of hospital observation stays has had a pronounced impact on Medicare patients' out-of-pocket costs. A 2014 study of Healthcare Cost and Utilization Project data for 2009 found that among Medicare patients, "[s]tays of 25-48 hours increased cost by 22 percent, 49-72 hours increased costs by 41 percent, and stays of greater than 72 hours increases costs by 61 percent." Jason M. Hockenberry *et al.*, *Factors Associated with Prolonged Observation Services Stays and the Impact of Long Stays on Patient Cost*, 49 Health Serv. Res. 893, 901 (2014). While recent changes to Medicare billing for outpatient services might mitigate the sharpest increases in costs over longer outpatient stays, it is unclear how much bundling will ultimately reduce patients' financial burden for outpatient observation stays.

B. Medicare Beneficiaries Can Face Mounting Medical Debt as a Direct and Insurmountable Consequence of Being Classified as Outpatients Under Observation While Hospitalized.

The financial consequences of outpatient observation classifications can be catastrophic for Medicare beneficiaries who can face staggering, and often surprising, bills for hospital stays and subsequent SNF stays not covered by Medicare Part A. The experience of one Medicare beneficiary, Betty Goodman, illustrates the challenges faced by many older adults who require hospital and post-hospital SNF care not covered by Medicare Part A. Ms. Goodman, a former high

school teacher from Rhode Island, incurred $7,000 for the nursing facility stay that she needed to recover from knee replacement surgery. Susan Jaffe, *Class-Action Lawsuit Seeks to Let Medicare Patients Appeal Gap in Nursing Home Coverage*, Kaiser Health News, Aug. 12, 2019, https://bit.ly/3sOwRJZ. Although Ms. Goodman, who lives with hypoglycemia and an immune deficiency disorder, was hospitalized for three days, she was classified as an outpatient. *Id*. Consequently, Ms. Goodman had to borrow money to pay for necessary SNF care that Medicare did not cover. This result "d[id]n't seem fair" to her "after paying for Medicare all these years." *Id*.

Many Medicare beneficiaries cannot afford to pay the higher variable costs of outpatient observation services or the costs of SNF care not covered by Medicare Part A. Not only do many Medicare beneficiaries have low annual incomes, they often have relatively small savings from which to pay medical bills. *See, e.g.*, Gretchen Jacobson et al., *Income and Assets of Medicare Beneficiaries, 2016-2035*, (Kaiser Family Found. Apr. 21, 2017), https://bit.ly/38abTgN ("In 2016, half of all people on Medicare had incomes below $26,200 per person and savings below $74,450."). In 2015, roughly one-fourth of adults ages 18-64 reported that they or someone in their household had difficulty paying medical bills. Liz Hamel et al., *The Burden of Medical Debt: Results from the Kaiser Family Foundation/New York*

Times Medical Bill Survey, 1 (Kaiser Family Found. Jan. 5, 2016), https://bit.ly/2OlRi1V.

Medical debt can have wide-ranging and long-term consequences for older adults and people with disabilities who face collections actions, lowered credit ratings, and even bankruptcy when they are unable to pay hospital and skilled nursing facility charges not covered by Medicare. *See* David U. Himmelstein et al., *Medical Bankruptcy: Still Common Despite the Affordable Care Act*, 109 Am. J. Pub. Health 431, 432 (2019) (66.5 percent of bankruptcies studied resulted from medical debt whether due to costs of care or time out of work). Medical debt service, for Medicare beneficiaries with limited incomes already stretched to cover housing, essential prescription drugs, and food, can lead to grave financial insecurity and persistent poverty.

C. Older Adults and People with Disabilities Unable to Obtain Medicare Part A Coverage for Post-Hospital Skilled Nursing Facility Care May Face Unnecessary Institutionalization or Inescapable Poverty.

Older adults and people with disabilities hospitalized as outpatients are vulnerable to deteriorating health and, ultimately, unnecessary institutionalization when they forego post-hospital SNF care not covered by Medicare Part A. They also face a significant risk that they will have to spend down their assets to become eligible for Medicaid.

Fewer Medicare beneficiaries classified as outpatients under observation during their hospital stay receive post-hospital inpatient rehabilitation than need it. A 2017 study of Medicare beneficiaries hospitalized as observation patients found that 4.4% were evaluated as medically qualifying for and potentially benefitting from post-acute inpatient rehabilitation ("PAIR"). Jennifer N. Goldstein et al., *The Unmet Need for Postacute Rehabilitation Among Medicare Observation Patients: A Single-Center Study*, 12 J. Hosp. Med. 168, 170 (2017). While 4.4% represents a minority of hospitalized patients, the figure "is 5- to 6-fold higher" than the number of patients discharged from the hospital to PAIR. *Id*. at 170. The study revealed cases in which "patients clearly could have benefited from PAIR and would have gone had it been covered by Medicare. The gap suggests an unmet need for PAIR among a substantial proportion of Medicare beneficiaries for whom the therapy is recommended and wanted." *Id*. The study also found that "[a]lmost 25% of our observation patients returned to the hospital within 30 days." *Id*. at 171. Critically, "[t]here was a significant trend toward increased rehospitalization among patients recommended for PAIR than among patients with no PT needs." *Id*.; *see also* Soc'y of Hosp. Med., *Hospital Observation Care Problem*, *supra*, at 3 (reporting that beneficiaries who would benefit from post-hospital care but do not meet the three-day requirement "will often forgo or truncate recommended SNF care to avoid out-of-pocket expense, which [they] may not be able to afford.").

Older adults and people with disabilities denied Medicare Part A coverage for necessary post-hospital SNF care might suffer ongoing illness requiring rehospitalization, or fail to fully recover and experience serious physical impairments that place them at greater risk of requiring long-term institutionalization in nursing facilities. Amber Willink et al., *Risks for Nursing Home Placement and Medicaid Entry Among Older Medicare Beneficiaries with Physical or Cognitive Impairment* 7 (Commonwealth Fund Oct. 2016), https://bit.ly/3sTyZjs (hereinafter "Risks for Nursing Home Placement"); Soc'y of Hosp. Med., *Hospital Observation Care Problem*, *supra*, at 3 ("[F]orgone [post-hospital] care can lead to otherwise preventable complications (i.e., dehydration, falls, etc.), degradation of health status and a readmission to the hospital.").

Older adults and people with disabilities who require post-hospital care not covered by Medicare Part A also face heightened risk of requiring Medicaid entry, a financial situation from which they might not recover. "Individuals with [physical and cognitive impairments ("PCI")] have high out-of-pocket spending, defined as spending more than 10 percent of one's income on health care costs." Willink, *Risks for Nursing Home Placement*, *supra*, at 7. "Forty-six percent of individuals with PCI with incomes below 200 percent of poverty and not covered by Medicaid have high out-of-pocket spending[.]" *Id*. "This may indicate that people with PCI are going without necessary services or at high risk of spending down to Medicaid." *Id*.

As such, "[i]ndividuals with PCI are at a much higher risk of entering Medicaid than are those who do not have PCI." Willink, *Risks for Nursing Home Placement*, *supra*, at 9.

Older adults and people with disabilities who need hospital services can face a heightened risk of avoidable institutionalization in unskilled nursing facilities due to observation stays that provide acute care but not the more robust rehabilitation under Part A that would allow them to return to and remain in their communities. Yet when older adults and people with disabilities need post-hospital rehabilitative care to avoid medical deterioration that can result in longer term institutionalization, and Part A does not cover that care, they might have no alternative to spending their limited resources on care that leaves them impoverished.

III. CMS Regulations Unfairly Result in Hospitals' Overuse of Outpatient Observation While Denying Medicare Beneficiaries the Right to Timely Challenge Potentially Erroneous Classifications.

CMS' regulations governing inpatient admission and its aggressive overpayment recovery practices drive hospitals to classify patients whose inpatient admission might be challenged by CMS' auditors[4] as outpatients. CMS'

[4] The roles of Medicare contractors responsible for post-payment reviews of Part A hospital claims throughout the class period, including Medicare Administrative Contractors ("MACs"), Recovery Audit Contractors ("RACs"), and Beneficiary and Family Center Care – Quality Improvement Organizations ("QIOs"), are set forth in Section III.B (CMS Enforcement of Part A Eligibility Requirements) of the lower court's decision. *See generally Alexander*, 2020 WL 1430089, at *10-15.

overpayment recovery system results in hospitals shifting the risk of admission errors onto the Medicare beneficiaries who lack the ability to challenge classification decisions while they are still in the hospital. Medicare beneficiaries thus frequently suffer the erroneous deprivation of their Medicare Part A coverage as a result of hospital utilization review committees ("URC") rationally erring in favor of coverage-denying outpatient classifications.

CMS created and has sustained this admission error bias on the part of hospitals through its system of overpayment recovery audits. Medicare requires hospitals to carefully manage utilization for Medicare beneficiaries, *see* 42 U.S.C. § 1395x(k) (utilization review plan requirement); 42 C.F.R. § 482.30, and hospital URCs attempt to balance the risk of overpayment claims with good-faith efforts to comply with "muddled" admission rules. Soc'y of Hosp. Med., *Hospital Observation Care Problem*, *supra*, at 2 (observation care often "muddles the line between inpatient services and outpatient care"); Lisa Bragg & Amanda Koroly, *Utilization Review: 5 Reasons Hospitals Lose Revenue* 3 (Healthcare Fin. Mgmt. Ass'n Apr. 1 2019), https://bit.ly/2PoWIcX ("Realistically, to uphold a hospital's true mission of providing high-quality care, it's rarely enough to simply follow the rules of insurer evidence-based medical necessity guidelines, which often are ill-defined with room for interpretation.").

Hospital URCs aggressively managing risk because CMS's overpayment recovery auditors, particularly RACs, are themselves incentivized to overturn hospital billing determinations. "The RAC program pays independent contractors on a contingency basis for the amount they recover for Medicare. Thus, RACs are incentivized to overturn hospital inpatient claims and deny reimbursement for services rendered." Soc'y of Hosp. Med., *Observation Status Problem*, *supra*, at 6. "In response" to the work of RAC auditors, "virtually all hospitals adopted systems to prospectively evaluate whether admissions meet those inpatient criteria and, if they don't, to assign patients to observation status." Baugh & Schuur, *Cost-Shifting Loophole*, *supra*, at 303.

While the RACs' role has shifted since the adoption of the "two-midnight rule," hospitals advisors acknowledge that the risk of auditor scrutiny cannot reliably be avoided simply by following guidelines; it requires impenetrable documentation. Bragg & Karoly, *Utilization Review*, *supra*, at 3. As the Society of Hospital Medicine observed in 2017, "[i]n recent years, CMS has made several programmatic improvements to the audit and appeals process, and has replaced [its] RACs with Q[IOs] as first-line auditors, but the long-term impact of these changes remains unclear." Soc'y of Hosp. Med., *Hospital Observation Problem*, *supra*, at 3.

Moreover, recent calls for the restoration of the RAC's role in patient status claims audits are likely to reinforce hospitals' risk-aversion in classification

decisions. *See, e.g.*, Karen Matarazzo, *The Need to "Recover" Recovery Auditing*, 45 J. Health Care Fin. 1, 23 (2019), https://bit.ly/3ealN5H (urging restoration of patient status claim audits to RACs tasked with finding and recovering overpayments rather than QIOs "more focused on patient safety and quality of care"). Given the continued role of CMS auditors – RACs and QIOs – in the review of hospital patient status classifications, the admission-error bias pervading hospital billing classifications perpetuates the risk of erroneous coverage deprivations borne by Medicare beneficiaries.

Absent Medicare beneficiaries' ability to timely challenge hospital observation classifications, and, through expedited due process hearings, participate in the development of a record that allays hospitals' fear of overpayment actions, Medicare beneficiaries will continue to bear the burden of a perverse regulatory regime.

CONCLUSION

For the foregoing reasons, Amici respectfully request that the Court affirm the lower court's decision.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A) AND LOCAL RULE 29

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and Local Rule 29.1(c) because it contains 5,959 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

I hereby certify that I filed a copy of the foregoing *Brief of AARP, AARP Foundation, National Disability Rights Network, and Disability Rights Connecticut as Amici Curiae in Support of Intervenor-Plaintiffs-Appellees* with the Clerk of Court via the CM/ECF electronic filing system, which will provide notice and a copy of this document to all counsel of record.

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