UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

CATHERINE JOHNSON, KATHERINE VACZI, and CARA BUNNELL, on behalf of themselves and all others similarly situated, and NATIONAL MULTIPLE SCLEROSIS SOCIETY 733 Third Ave. New York, NY 10017, and TEAM GLEASON 2021 Lakeshore Dr. #120 New Orleans, LA 70122 *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, U.S. Department of Health Human Services 200 Independence Avenue SW Washington, DC 20201, *Defendant*.	Civil Action No. **CLASS ACTION COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

I. PRELIMINARY STATEMENT

1. Plaintiffs bring this class action to challenge the Secretary of Health and Human Services' ("the Secretary's") violation of their rights under the Medicare Act and Section 504 of the Rehabilitation Act of 1973. Specifically, Plaintiffs challenge the Secretary's policies and practices that impede and restrict the availability, accessibility, and coverage of home health aide services for individuals with chronic, disabling conditions who qualify for such services under Medicare law.

2. Named Plaintiffs, described in detail below, have chronic, disabling conditions. They require and qualify for Medicare-covered home health aide services to assist with hands-on, personal care that helps reduce their risk for infections, falls, and other conditions that can lead to preventable hospitalizations and other forms of institutionalized care. They wish to remain in their homes and communities, but they are unable to secure the home health aide services they require from Medicare-certified home health agencies. They struggle to find and retain Medicare-covered aide services, and they face a pattern of misinformation, denials, and underservice from Medicare-certified home health agencies. They have been forced to cobble together costly alternatives to Medicare-covered home health aide services.

3. The Secretary's policies and practices, described below, deprive named Plaintiffs, and others similarly situated, of necessary, Medicare-covered home health aide services. The Secretary's actions harm the named Plaintiffs and the class they seek to represent, including by placing them at serious risk of entering an institutional setting to receive necessary care.

4. Home health aides, who provide hands-on, personal care to beneficiaries, are a critical component of the Medicare home health benefit and of the treatment plans for many beneficiaries. Medicare law authorizes a variety of home health aide services, including but not limited to assistance with bathing, dressing, toileting, feeding, administering certain medications, oral hygiene, walking, changing positions in bed, transfers (e.g., from bed to chair), routine care of prosthetic and orthotic devices, and assistance with maintenance exercises. These services can be essential to health and are often the very services that allow Medicare beneficiaries to remain safely in their homes, and out of hospitals and nursing homes.

5. Recognizing the importance of these services, Congress mandated that Medicare cover up to 28 hours per week, and in some circumstances 35 hours per week, of home health

aide services for beneficiaries who qualify. There is no durational limit to coverage of home health aide services as long as the beneficiary remains eligible for coverage of Medicare home health care and home health aides in accordance with Medicare criteria.

6. While the eligibility criteria for home health aide services have remained virtually unchanged since Medicare was enacted in 1965, the services actually available to beneficiaries and covered by Medicare have dropped drastically over the past 20 years. The number of aide visits per 60-day episode of home health care, for example, has declined by 90% since 1998. As a result, many beneficiaries with chronic, disabling conditions, such as Parkinson's disease, paralysis, multiple sclerosis, the effects of stroke, ALS, or other conditions that are expected to persist and generally worsen over time, cannot obtain the types, amounts, or duration of home health aide services that they require and that they are eligible to receive coverage for under the law.

7. The Secretary has adopted policies and practices that impede and restrict the availability and accessibility of Medicare-covered home health aide services for eligible beneficiaries with chronic, disabling conditions. The Secretary has effectively redefined eligibility for Medicare-covered home health aide services to exclude people who require more than very minimal aide services for a short duration of time. He thereby deprives these beneficiaries of necessary, Medicare-covered services for which they qualify and subjects them to discrimination on the basis of disability.

8. Without Medicare-covered home health aide services, named Plaintiffs and the class of beneficiaries they seek to represent are forced to forgo those services altogether, pay out of pocket for private aides, or patch together alternatives, by, for example, relying on family members or other non-professional caretakers for informal caretaking arrangements. They may

also be forced to live unsafely at home without needed services. Without reasonable and necessary, Medicare-covered home health aide services, they are at serious risk of institutionalization in a nursing home or hospital to address life-threatening infections, falls, and other preventable conditions.

9. The Secretary's policies and practices violate the plainly expressed intent of Congress to cover "part-time or intermittent" home health aide services, which is defined as fewer than 8 hours each day and 28 or fewer hours each week (or in some cases, 35 or fewer hours per week) for Medicare beneficiaries who require and qualify for such services under law.

10. The Secretary's failure to administer and operate the Medicare home health benefit so that proposed class members can reasonably access the covered aide services they require and qualify for affects a uniquely vulnerable group. Older, disabled individuals are more likely to be members of a racial or ethnic minority group, to have lower incomes, and to be in poorer overall health compared to people without disabilities. They also face greater barriers to health care (such as difficulty traveling) while having greater health care needs. As limitations in activities of daily living increase, older Medicare beneficiaries are less likely to receive recommended health care. *See* Ling Na et al., *Disability Stage and Receipt of Recommended Care Among Elderly Medicare Beneficiaries*, 10 Disability & Health J. 48, 49, 52 (Jan. 2017).

11. Plaintiffs are qualified individuals with disabilities, or organizations that serve such individuals. Named Plaintiffs have impairments that substantially limit one or more major life activities, and they require and qualify for necessary, Medicare-covered home health aide services. However, due to the Secretary's failure to properly implement and administer the home health benefit, and his administration of the benefit in a manner that discriminates against beneficiaries with chronic, disabling conditions, Plaintiffs have received and continue to receive

fewer Medicare-covered aide services than they require, or none at all. They are deprived of necessary, Medicare-covered aides services, and they have been and remain at serious risk of institutionalization without the aide services for which they qualify.

II. JURISDICTION AND VENUE

12. Jurisdiction is conferred on this Court by 42 U.S.C. § 405(g), as made applicable to and incorporated in the Medicare statute by 42 U.S.C. §§ 1395ff(b)(1)(A) and 1395w-22(g)(5), and by 28 U.S.C. §§ 1331 and 1361. The action is also brought pursuant to Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. §§ 794, 794a.

13. Plaintiffs seek a declaration of rights pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

14. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)(2) and (e)(1) and 42 U.S.C. § 405(g).

III. PARTIES

15. Plaintiff CATHERINE JOHNSON resides in Missouri and is 57 years old. She is and has been a Medicare beneficiary at all relevant times. Ms. Johnson has multiple sclerosis ("MS") and related quadriplegia, among other conditions.

16. Plaintiff KATHERINE VACZI resides in New Jersey and is 80 years old. She is and has been a Medicare beneficiary at all relevant times. Ms. Vaczi's medical conditions include paralysis from the waist down due to a spinal cord injury, and she has a chronic, severe pressure wound.

17. Plaintiff CARA BUNNELL resides in Michigan and is 51 years old. She is and has been a Medicare beneficiary at all relevant times. Ms. Bunnell has MS, resulting in quadriplegia, among other medical conditions.

18. Plaintiff NATIONAL MULTIPLE SCLEROSIS SOCIETY is a nationwide organization headquartered in New York, N.Y., that works to cure MS and empower people affected by MS to live their best lives.

19. Plaintiff TEAM GLEASON is a nationwide organization headquartered in New Orleans, Louisiana, that works to improve life for people with amyotrophic lateral sclerosis ("ALS").

20. Defendant XAVIER BECERRA is the Secretary of the United States Department of Health and Human Services ("HHS") and is responsible for the overall operation of the Medicare program through the HHS division known as the Centers for Medicare & Medicaid Services ("CMS"). He is sued in his official capacity.

IV. CLASS ACTION ALLEGATIONS

21. Named Plaintiffs bring this action on behalf of themselves and all others similarly situated, pursuant to Rules 23(a) and 23(b)(2) of the Federal Rules of Civil Procedure. The class is defined as:

> All Medicare beneficiaries with conditions that are chronic (expected to last one year or more) and disabling (substantially limit one or more major life activities); who are at serious risk for institutionalization without reasonable and necessary Medicare-covered home health aide services for which they qualify; and who are unable to obtain reasonable access to Medicare-covered home health aide services.

22. Joinder is impracticable due to the large number of class members and for other reasons, including but not limited to their geographic diversity, their ages and/or disabilities, and their relatively low incomes. Plaintiffs estimate the class to include at least tens of thousands of

members. Reports suggest the existence of many beneficiaries with chronic, disabling conditions who are not receiving Medicare-covered home health aide services they are eligible for.

23. For instance, over 13% of community-dwelling Medicare beneficiaries age 65 and older (close to 6 million people) reported having a "self-care" disability, meaning they were not able to, or had difficulty, performing ADLs: bathing/showering, dressing, eating, getting out of bed or chairs, and toileting—the same activities that home health aides assist with. CMS, *Does Disability Affect Receipt of Preventive Care Services among Older Medicare Beneficiaries?*, Data Highlight at 4, 9, 14 (Jul. 2017).[1] Thirty-three percent of community-dwelling Medicare beneficiaries age 65 and older (over 14 million people) reported having an ambulatory disability. *Id*. at 4, 14. Yet only 3.3 million people – representing 8.6% of Medicare beneficiaries - used Medicare home health care at all in 2019. Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* at 239 (Mar. 2021). And as the below figures show (¶¶ 179-80), very few aide services were provided to beneficiaries who *did* receive home health services.

24. Medicare beneficiaries are by definition older and/or disabled, and most do not have the resources to mount a legal challenge to the Secretary's policies and practices. Half of all Medicare beneficiaries had incomes below $29,650 per person in 2019. One in four had incomes below $17,000 per person. Kaiser Family Foundation, *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic* (Apr. 24, 2020).[2]

[1] Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-ADA-2017.pdf.

[2] Available at: https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/.

25. There are questions of law and fact common to the class members. Common facts include that all class members are eligible for Medicare-covered home health aide services, but are unable to obtain reasonable access to the covered services for which they qualify. The common questions of law include, *inter alia*, 1) whether the Secretary's administration of the home health benefit—and of aide services in particular—violates the Medicare statute and regulations providing for coverage of reasonable and necessary home health aide services, 2) whether the Secretary's administration of the home health benefit—and of aide services in particular—violates his duty to oversee and enforce the Medicare Conditions of Participation and requirements for Medicare-certified home health agencies, and 3) whether the Secretary violates Section 504 of the Rehabilitation Act by utilizing methods of administration that subject Plaintiffs and Plaintiff class members to discrimination on the basis of disability, and by failing to administer the home health benefit so that class members receive aide services in the most integrated setting appropriate to their needs and in a manner that avoids unnecessary institutionalization.

26. Named Plaintiffs' claims are typical of the claims of the proposed class. Named Plaintiffs and all members of the proposed class are Medicare beneficiaries with chronic, disabling conditions who qualify for Medicare-covered home health aide services, but who are unable to reasonably access necessary services as a result of the Secretary's policies and practices, and are at risk of institutionalization without the aide services.

27. Named Plaintiffs and Plaintiff class members have all experienced harm as a result of the Secretary's policies or practices, which have resulted in a deprivation of Medicare-covered home health aide services for which they qualify, discrimination on the basis of

disability, and serious risk of institutionalization. The named Plaintiffs will fairly and adequately protect the interests of the proposed class.

28. Named Plaintiffs have a personal and clearly defined interest in vindicating their rights as well as the rights of the class in order to obtain prospective injunctive relief. They seek relief that will benefit the entire class.

29. Named Plaintiffs' counsel are attorneys experienced in federal class action litigation involving the Medicare program and claims vindicating the rights of older and disabled adults.

30. Named Plaintiffs' claims satisfy the requirements of Rule 23(b)(2) of the Federal Rules of Civil Procedure because the Secretary has acted on grounds generally applicable to the Plaintiffs and each member of the proposed class, thereby making final declaratory and injunctive relief appropriate with respect to the class as a whole.

V. LEGAL FRAMEWORK

A. Medicare's Home Health Benefit and Coverage of Home Health Aides

31. Codified as Title XVIII of the Social Security Act, Medicare is the federally funded and administered program of health insurance for people who are 65 and over, people who are under 65 and entitled to Social Security Disability Insurance, and people of any age with end-stage renal disease.

32. Under Part A of Medicare, beneficiaries are entitled to coverage of, *inter alia*, inpatient hospital services, skilled nursing facility care, and home health services. Medicare Part B provides coverage for, *inter alia*, physician services, durable medical equipment, and home health services that are not covered by Part A. Under Part C (the "Medicare Advantage" program), beneficiaries may opt to receive Medicare coverage through a privately-administered managed care plan instead of directly from the traditional Medicare program (Parts A and B).

33. Medicare's home health benefit may thus be covered by Part A, B, or C. 42 U.S.C. §§ 1395d(a)(3), 1395k(a)(2)(A), 1395w-22(a)(1). For purposes of this action, the part of Medicare that covers a particular beneficiary's home health services is not relevant.

34. Since 1980, Medicare has had no limit on the number of home health visits that can be covered as long as the qualifying criteria are met. 42 C.F.R. § 409.48(a)-(b); Medicare Benefit Policy Manual ("MBPM"), Ch. 7 § 70.1; Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599 (Dec. 5, 1980) (removing home health visit limit).

35. Under the statute, a beneficiary is eligible for covered home health services if she is 1) "confined to the home" (also known as the "homebound" requirement), and 2) requires a triggering skilled service. 42 U.S.C. §§ 1395d(a)(3), 1395f(a)(2)(C), 1395n(a)(2)(A)(i), 1395n(a)(2), 1395x(m); 42 C.F.R. § 409.42(a).

36. To be considered "homebound," an individual must 1) either require the assistance of another person or of a supportive device to leave home, *or*, have a condition such that leaving home is medically contraindicated, and 2) there must be a normal inability to leave the home, and leaving home must require "considerable and taxing effort." Beneficiaries may in fact leave the home and be considered homebound if absences are attributable to the need to receive health care, or are infrequent or for relatively short periods of time. 42 U.S.C. § 1395n(a)(2); 42 C.F.R. § 409.42(a); MBPM, Ch. 7 Sec. 30.1.1.

37. To begin covered home health services, the required "triggering" skilled service can be either nursing or therapy (physical or speech). For skilled nursing to trigger coverage, the services must be required on an "intermittent" basis. Intermittent means that the nursing services are required fewer than seven days per week and at least once every 60 days. Intermittent nursing can also include daily services of fewer than eight hours per day under some circumstances. If

skilled physical or speech language pathology services are required, the triggering skilled service requirement is met. 42 U.S.C. §§ 1395f(a)(2)(C), 1395n(a)(2)(A)(i), 1395x(m); 42 C.F.R. § 409.42(c); MBPM, Ch. 7, § 40.1.3.

38. As conditions of coverage and payment, Medicare also requires 1) that home health services be furnished by, or under arrangements made by, a Medicare-certified home health agency, 2) that a physician who is caring for the beneficiary establishes a "plan of care" and certifies the patient's eligibility, and 3) that the beneficiary and the physician or an allowed practitioner have had a "face-to-face" encounter during a certain time period. 42 U.S.C. §§ 1395x(m), 1395f(a)(2)(C), 1395n(a)(2)(A); 42 C.F.R. §§ 409.42, 424.22(a)-(b); MBPM, Ch. 7, §§ 30-30.5.4.

39. If the requirements in Paragraphs 35 and 38 are met, then, in addition to coverage of qualifying skilled nursing and/or skilled therapy visits, a beneficiary is also entitled to coverage of certain "dependent" services, including home health aide services. 42 U.S.C. § 1395x(m)(4); 42 C.F.R. § 409.45(b).

40. Medicare covers "part-time or intermittent" home health aide services, which are defined as aide services furnished any number of days as long as they are furnished fewer than 8 hours each day, and 28 or fewer hours each week. On a case-by-case basis as to the need for care, the aide services may be furnished fewer than 8 hours each day and 35 or fewer hours each week. When both home health aide and skilled nursing services are provided, the two services combined may not exceed the part-time or intermittent limits. 42 U.S.C. § 1395x(m); 42 C.F.R. § 409.45(b)(2)(ii); MBPM, Ch. 7, §50.7.

41. As with any Medicare service, to be covered, home health aide services must be "reasonable and necessary" for the beneficiary, and the services must be of the type authorized

by statute, regulation, and guidance. Aide services are considered reasonable and necessary when they 1) meet the regulatory definition of home health aide services, 2) are of a type that the beneficiary cannot perform for himself or herself, and 3) are of a type that there is no able or willing caregiver to provide, or, if there is a potential caregiver, the beneficiary is unwilling to use the services of that individual. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. 409.45(b)(3); MBPM, Ch. 7, § 50.2.

42. The home health aides themselves must meet certain training and competency requirements before they can provide services. 42 U.S.C. §§ 1395x(m)(4), 1395bbb(a)(3)(A); 42 C.F.R. § 484.80. Classroom and supervised on-the-job training must total at least 75 hours, and must include instruction on certain topics that are critical to patient safety, including observation and reporting of patient status, reading and recording certain vital signs, recognition of emergencies and knowledge of instituting emergency procedures, infection prevention and control procedures, appropriate and safe techniques for bathing, toileting and other personal hygiene tasks, safe transfer techniques (*e.g.*, from bed to chair) and ambulation (walking), recognition of changes in skin condition and body functions that must be reported to a supervisor, adequate nutrition and fluid intake, and maintenance of a clean, safe, and healthy environment. 42 C.F.R. § 484.80(b). Ongoing in-service trainings are also required. *Id.* § 484.80(d).

43. To be covered by Medicare, the reason for the home health aide visits must be to provide hands-on personal care to the beneficiary, or services that are needed to maintain the beneficiary's health, or to facilitate treatment of the beneficiary's illness or injury. Orders for home health aide services are part of the beneficiary's plan of care, ordered by a doctor or other

qualified practitioner. 42 C.F.R. § 409.45(b)(1). Home health aides are thus responsible for carrying out beneficiaries' prescribed treatment plans.

44. Medicare-covered home health aide services include but are not limited to:

- Personal care services that are needed to facilitate treatment or to prevent deterioration of the beneficiary's health, such as bathing, dressing, grooming, caring for hair, nail and oral hygiene, changing the bed linens of an incontinent beneficiary, shaving, deodorant application, skin care with lotions and/or powder, foot care, ear care, feeding, assistance with elimination, walking, changing position in bed, and transfers;
- Dressing changes that do not require the skills of a licensed nurse;
- Assistance with medications that are ordinarily self-administered and that do not require the skills of a licensed nurse to be provided safely and effectively;
- Assistance with activities that are directly supportive of skilled therapy services but do not require the skills of a therapist to be safely effectively performed, such as routine maintenance exercise and repetitive practice of functional communication skills to support speech-language pathology services;
- Routine care of prosthetic and orthotic devices.

42 C.F.R. § 409.45(b)(1)(i)-(v).

45. Home health aides may also perform services that are "incidental" to a visit that was for the provision of the above-listed services, such as changing bed linens, personal laundry, or preparing a light meal. 42 C.F.R. § 409.45(b)(4).

46. When Medicare's criteria for the home health benefit are met, beneficiaries are entitled to coverage of reasonable and necessary home health services, including the part-time or

intermittent services of home health aides. 42 U.S.C. §§ 1395d(a)(3), 1395y(a)(1)(A); MBPM, Ch. 7 § 20.2.

B. Oversight and Enforcement Role of the Secretary

47. In order to enroll in the Medicare program and obtain billing privileges, medical providers, including home health agencies, "must be operational to furnish Medicare items or services." 42 C.F.R. § 424.510(d)(6). "Operational" means that the provider is, *inter alia*, "open to the public for the purposes of providing health care related services, is prepared to submit valid Medicare claims, and is properly staffed, equipped, and stocked (as applicable, based on the …services or items being rendered), to furnish these items or services." *Id*. § 424.502. CMS may deny or revoke a provider's enrollment in the Medicare program when CMS determines that the provider is not or is no longer "operational to furnish Medicare-covered items or services" or otherwise fails to satisfy any Medicare enrollment requirement. *Id*. §§ 424.530(a)(5), 424.535(a)(5); *see also* 42 CFR § 489.53(a)(1)-(3) (circumstances under which CMS may terminate agreements with providers).

48. To obtain Medicare certification, home health agencies must attest that they will comply with applicable nondiscrimination laws, including Section 504 of the Rehabilitation Act. 42 C.F.R. §489.10(b); 45 C.F.R. § 88.4(a).

49. Home health agencies must also meet certain Conditions of Participation to be in the Medicare program. "It is the duty and responsibility of the Secretary to assure that" the Conditions of Participation "and the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency and to promote the effective and efficient use of public moneys." 42 U.S.C. § 1395bbb(b); *see also id*. § 1395x(o)(6).

50. One Condition of Participation that the Secretary must enforce is that "[p]atients are accepted for treatment on the reasonable expectation that a[] [home health agency] can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence." 42 C.F.R. § 484.60.

51. Patients also "must receive an individualized, written plan of care," that specifies "the care and services necessary to meet the patient-specific needs as identified in [the patient's] comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the [home health agency] anticipates will occur as a result of implementing and coordinating the plan of care….Services must be furnished in accordance with accepted standards of practice." 42 C.F.R. § 484.60.

52. Another Condition of Participation that the Secretary must enforce states that a home health agency "must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs." 42 C.F.R. § 484.105.

53. Medicare Conditions of Participation also require home health agencies to provide accurate information to their patients about Medicare payment and coverage. Medicare patients have a right to participate in care planning and to receive all services outlined in their plan of care. 42 U.S.C. § 1395bbb(a)(1); 42 C.F.R. § 484.50(c).

54. Home health agencies must provide Medicare-covered home health services rendered to patients either directly or "under arrangement" with an outside provider that furnishes the services and then looks to the primary home health agency for payment. The primary home health agency must bill Medicare for all covered services and payment is made

only to that agency. 42 U.S.C. § 1395x(m); 42 C.F.R. § 484.105(e); MBPM, Ch. 7 § 10.10; Medicare Claims Processing Manual Ch. 10, §§ 20, 20.1.1.

55. If a home health agency that accepts a beneficiary for treatment cannot itself provide one of its patients with the reasonable and necessary covered Medicare services she has been assessed to need under her plan of care, including home health aides, the home health agency should contract with another provider to furnish the services "under arrangement," or it should refer the beneficiary to a different agency that can furnish the required services. 42 C.F.R. §§ 484.50(c)(5), 484.50(d)(1), 484.55, 484.60, 484.105.

56. In practice, due to the Secretary's failure to oversee and enforce the Conditions of Participation and requirements for Medicare-certified home health agencies, beneficiaries who require any more than minimal home health aide services for short durations can often find *no* agency that will furnish—either directly or under arrangement—the Medicare-covered aide services they are eligible for and require.

C. Medicare Payment for Home Health Services

57. CMS pays Medicare-certified home health agencies based on a prospective payment system ("PPS"). 42 U.S.C. § 1395fff. PPS was implemented in 2000 and replaced a retrospective, cost-based payment system.

58. Under PPS, home health agencies receive a "bundled" payment, periodically adjusted for various factors, that is intended to cover virtually all home health services provided, including home health aides, nursing, therapy, certain medical supplies, and medical social services. The prospective payment amount is meant to "provide[] for continued access to quality services." 42 U.S.C. § 1395fff(b)(2)(A). Each year the Secretary adjusts and updates home health payment rates and policies through administrative rulemaking.

59. PPS used to reimburse certified home health agencies based on 60-day episodes of care, and since 2020 does so based on 30-day payment periods. *See* CMS, "Home Health PPS," https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS. To receive a full periodic payment under PPS, agencies must provide the beneficiary with a minimum number of home health visits (*e.g.*, skilled nursing, physical or occupational therapy, or home health aide visits).[3] Agencies that provide more than the minimum number of visits receive no more than the full episodic or periodic payment. PPS thus created a financial incentive for home health agencies to limit the number of visits and duration of services in each period of care.

60. However, PPS did *not* alter the coverage rules for home health services. Thus, as long as Medicare beneficiaries meet the eligibility criteria for covered home health services, they can receive Medicare coverage of those services, notwithstanding any payment rules. 42 U.S.C. § 1395x(m); 42 C.F.R. § 409.48(a)-(b); MBPM, Ch. 7 § 70.1; CMS, MLN Booklet, Home Health Prospective Payment System (March 2018) ("Medicare does not limit the number of continuous episode recertifications for patients who continue to be eligible for the home health benefit.").

61. The Bipartisan Budget Act of 2018 included several provisions for home health payment reform. To implement the payment reform, CMS promulgated a new method of calculating prospective payments for home health services called the Patient-Driven Groupings Model ("PDGM"), which took effect on January 1, 2020. *See* CMS, "Home Health PPS," https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS.

[3] The minimum threshold used to be five visits and more recently is three to seven visits depending on clinical characteristics of the beneficiary.

62. Like its predecessor prospective payment methodologies, PDGM did *not* change Medicare's eligibility or coverage rules for home health services. Indeed, CMS issued a bulletin confirming that "[w]hile there has been a change to the case-mix adjustments methodology and the unit of payment beginning in CY 2020, eligibility criteria and coverage for Medicare home health services remain unchanged. That is, as long as the individual meets the criteria for home health services as described in the regulations at 42 C.F.R. § 409.42, the individual can receive Medicare home health services…." CMS, MLN Matters, *The Role of Therapy in Home Health Patient-Driven Groupings Model (PDGM)* (Feb. 10, 2020); *see also* MBPM, Ch. 7 § 10.3.

63. While home health coverage rules have not changed, changes to the payment system have thwarted access to Medicare-covered home health aide services authorized by law, and the Secretary and has failed to ensure that Plaintiffs and Plaintiff class members can access the necessary, Medicare-covered home health aide services for which they qualify.

64. The Secretary has failed to take reasonable measures to ensure that, irrespective of the home health payment system or method, Plaintiffs and Plaintiff class members have reasonable access to Medicare-covered home health aide services as Congress authorized and intended. Moreover, the Secretary has adopted policies and practices that actually impede access to and coverage of such services for Plaintiffs and Plaintiff class members.

D. Auditing Practices and Quality Measurement Policies

65. The Secretary regularly conducts audits and reviews of Medicare-certified home health agencies. As part of these audits and reviews, the Secretary frequently alleges, *inter alia*, that home health agencies have billed for services that were not reasonable and necessary. Home health agencies with adverse findings from audits or reviews may have to participate in one-on-one education with Medicare contractors, return "overpayments" to Medicare and/or appeal such overpayments, and potentially face corrective action up to revocation of Medicare billing

privileges. *See, e.g.*, Medicare Program Integrity Manual §§ 3.2.5, 3.6.4, 3.7; CMS, *Targeted Probe and Educate*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Targeted-Probe-and-EducateTPE (last modified Sept. 16, 2022).

66. The Secretary does not regularly audit, review, or monitor the discrepancy between beneficiaries' service needs and the services that are actually delivered, nor does the Secretary typically penalize home health agencies for *failing* to provide reasonable and necessary home health services, including aide services.

67. Home health agencies risk losing time and resources addressing audits and reviews, refunding significant Medicare payments, and potentially losing Medicare as a payment source, if they accept and serve patients with chronic, disabling conditions who require home health services for longer than the average length of care who may attract Medicare reviewers' attention. However they do not face these risks for failing to serve such beneficiaries.

68. The Secretary's auditing and review practices contribute to home health agencies' refusing to accept or prematurely discharging patients with chronic, disabling conditions who require and qualify for Medicare-covered home health services. This prevents class members from receiving Medicare-covered home health aide services they require and qualify for.

69. The Secretary has implemented a quality measurement or rating system based on star ratings to assist Medicare beneficiaries in choosing a home health agency. The web-based system assigns quality ratings to home health agencies ranging from one star, indicating lowest quality, to five stars, indicating highest quality. 42 U.S.C. § 1395fff(b)(3)(B)(v); 42 C.F.R. § 484.245; *see also* https://www.medicare.gov/care-compare/?providerType=HomeHealth&redirect =true#search (web-based comparison tool).

70. The "Quality of Patient Care Star Rating" is focused largely on measuring home health patients' "improvement" in certain "outcomes," including improvement in ambulation, improvement in bed transferring, improvement in bathing, improvement in breathing, and improvement in managing oral medications. CMS, *Quality of Patient Star Ratings Methodology* at 2 (Apr. 2020), https://www.cms.gov/files/document/quality-patient-care-star-ratings-methodologyapril-2020.pdf.

71. There is no requirement that a beneficiary "improve" for Medicare coverage of home health services. *See, e.g.*, 42 C.F.R. §§ 409.32(c) (incorporated by reference in 42 C.F.R. § 409.44(b)(1) and noting that services may be needed to prevent deterioration or to preserve current capabilities), 409.44(b)(3)(iii) (noting that determination of whether skilled nursing is a reasonable and necessary home health service must be based solely on the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time.); MBPM, Ch. 7 § 40.1.1; *Jimmo v. Sebelius*, No. 5:11-cv-17, Settlement Agreement (Doc. # 85-1), (D. Vt., settlement approved Jan. 24, 2013).

72. Nonetheless, the Secretary's home health quality rating system is biased toward the care of beneficiaries with conditions that can improve and are only needed on a short-term basis. It does not take into account, and thus discourages care for beneficiaries with chronic, disabling conditions, who may, for example, never show "improvement" in walking, but who still require and are eligible for Medicare-covered home health services, including aides.

73. The quality measurement system penalizes home health agencies that provide services to beneficiaries – such as Plaintiffs and Plaintiff class members – who cannot achieve the enumerated measures. Achieving a four- or five-star rating indicates that a home health agency has likely disproportionately provided care to beneficiaries who can improve and has

avoided serving beneficiaries with chronic, disabling conditions, who would not score well on the above outcome measures.

74. The Secretary's quality rating system contributes to home health agencies' refusing to accept or prematurely discharging patients with ongoing or debilitating conditions who require and qualify for Medicare-covered home health services. This prevents class members from receiving the Medicare-covered home health aide services they require and qualify for.

75. The combination of the payment system, audit and review system, and quality rating system, compounded by Medicare-certified home health agencies' selectively choosing which beneficiaries to admit and serve, creates an array of factors that are stacked against the Plaintiffs and Plaintiff class members. The Secretary has failed to counterbalance those factors and ensure that Medicare and nondiscrimination law are enforced so that Plaintiffs and Plaintiff class members can reasonably access the Medicare-covered home health aide services they require and qualify for.

E. Section 504 of the Rehabilitation Act

76. Section 504 of the Rehabilitation Act , 29 U.S.C. § 794 ("Section 504"), prohibits discrimination against individuals with disabilities by any program or activity conducted by any Executive agency. 29 U.S.C. § 794(a). "No otherwise qualified individual with a disability… shall, solely by reason of her or his disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency…." 29 U.S.C. § 794(a); 45 C.F.R. §§ 85.21(a), 85.21(b)(1); *see also* 45 C.F.R. §§ 85.1, 85.2. A disability is an impairment that substantially limits one or more major life activities. 29 U.S.C. § 794(d), 42 U.S.C. § 12102; 45 C.F.R. § 85.3.

77. Regulations implementing Section 504 also provide: "The agency [HHS] may not, directly or through contractual or other arrangements, utilize criteria or other methods of administration the purpose or effect of which would…[s]ubject qualified individuals with handicaps to discrimination on the basis of handicap; or…[d]efeat or substantially impair accomplishment of the objectives of a program or activity with respect to individuals with handicaps." 45 C.F.R. § 85.21(b)(3).

78. Section 504 and its implementing regulations prohibit the segregation of people with disabilities into institutions and provide that HHS "shall administer programs and activities in the most integrated setting appropriate to the needs of qualified individuals with handicaps." 45 C.F.R. § 85.21(d); *see also Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581, 597-98 (1999) (unnecessary institutionalization of people with disabilities is *per se* discrimination).

79. Section 504 requires reasonable modifications to programs carried out by executive agencies to avoid discrimination on the basis of disability, unless the agency can show that such modifications would constitute an undue burden. *See, e.g., American Council of the Blind v. Paulson*, 525 F.3d 1256, 1266 (D.C. Cir. 2008). On information and belief, the Secretary's implementation of the relief requested here would not be an undue burden.

VI. STATEMENT OF FACTS

80. Plaintiffs and Plaintiff class members qualify for Medicare-covered home health aide services that they have been unable to obtain. They are qualified individuals with disabilities under Section 504, with impairments that substantially limit one or more major life activity.

A. Plaintiff Catherine Johnson

81. Catherine Johnson lives in Missouri and as of the filing of this complaint is 57 years old. She lives with advanced, progressive MS.

82. Ms. Johnson has complete quadriplegia with the exception of minimal lower-left arm movement. As a result of her chronic conditions, she uses a motorized wheelchair for mobility. She requires "maximum assistance" (three or more points of contact by one or more people performing the work) or the use of a lift to transfer into or out of her wheelchair.

83. In addition to MS and quadriplegia, her significant, complex, and ongoing conditions include, *inter alia*, type 2 diabetes, venous insufficiency, centrilobular emphysema (a form of chronic obstructive pulmonary disease), a bladder disorder, recurring urinary tract infections ("UTIs"), and seizures.

84. Ms. Johnson lives with her husband, who provides care but cannot provide all of the home health services, including hands-on, personal care, that she requires. Ms. Johnson is homebound as defined by Medicare law. She requires a wheelchair to leave home and has a normal inability to leave home, and leaving home requires a considerable and taxing effort.

85. Ms. Johnson wants to remain in her home and community rather than entering a nursing facility. Without appropriate, Medicare-covered home health aide services, however, she is at serious risk of being unnecessarily institutionalized.

86. Ms. Johnson requires and receives intermittent skilled nursing services for management of her indwelling catheter. She also requires and receives skilled physical therapy for management of painful spasticity. Ms. Johnson relies on others for hands-on, personal care, including for bathing, dressing, grooming, toileting, and transfers into and out of her wheelchair.

87. Her homebound status and need for skilled services trigger her eligibility for coverage of dependent services under the Medicare home health benefit, including for home health aides.

88. A Medicare-certified home health agency terminated all of Ms. Johnson's services, including home health aides, in January 2021. The aides had been providing assistance with activities of daily living such as dressing and undressing, showering, transfers, perineal and basic catheter care, and hair and skin care. Ms. Johnson challenged the termination of services using Medicare's administrative appeal system. She submitted a required statement from her doctor stating that failure to receive home health services would place her health "at significant high risk." *See* 42 C.F.R. § 405.1202(a)(1). Nevertheless, she was denied at the lower levels of appeal. Medicare-covered home health services from that agency ended on or about January 17, 2021.

89. Ms. Johnson continued her appeal and eventually won a favorable decision from an Administrative Law Judge in May 2021. The ALJ held that the termination of home health services "was improper. The record supports that, at the time of the termination, Beneficiary still required [skilled nursing], [physical therapy], and [home health aide] services." The decision also noted that Ms. Johnson is "homebound due to paralysis from neck down requiring maximum assist to leave home" and that she "required the self-care assistance provided by the [home health aide]."

90. The favorable ALJ decision was a hollow victory. By the time it was issued, Ms. Johnson had been discharged from all home health services four months earlier. The decision did not and could not require the home health agency to readmit Ms. Johnson as a patient. Meanwhile, she and her husband had scrambled to find a different provider of home health services.

91. The Johnsons struggled to find any agency that would accept Ms. Johnson and provide her with the reasonable and necessary home health aide services she requires. They

contacted at least eight different Medicare-certified home health agencies serving their area and explained Ms. Johnson's needs. The agencies typically stated that Medicare-covered services would only last for 30 to 60 days, and some also stated that their private-pay affiliates could fulfill services after Medicare-covered services ended.

92. Starting on or around January 30, 2021, Ms. Johnson was briefly a patient of a Medicare-certified home health agency that was prepared to provide skilled nursing services. But the agency informed her that aide services would not be covered. They suggested a private-pay source of home health aides. According to agency records, when Ms. Johnson insisted that her insurance (Medicare) would cover home health aide services, a supervisor "[c]onfirmed that insurance does not cover bath aide services."

93. Ms. Johnson then started with a different Medicare-certified home health agency beginning on or around February 12, 2021. This agency provided skilled nursing, some physical and occupational therapy, and minimal home health aide services: bathing assistance once per week. According to agency records, when Ms. Johnson said her doctor ordered three baths per week, the agency informed her that "we only provide one bath per week." They suggested a private-pay aide service, which Ms. Johnson started using in March to supplement her minimal, Medicare-covered aide services.

94. Following this period of insufficient and unpredictable home health care, Ms. Johnson was admitted to Cox Hospital on April 21, 2021 for uncontrolled seizures. Her Medicare-certified home health agency discharged her on April 22, 2021.

95. Ms. Johnson was in poor condition and remained hospitalized until May 5, 2021, with much of that time spent in the ICU. While the seizures that led to her hospitalization were

an immediate threat to her safety, multiple other conditions can be linked to inadequate aide-level care in the months leading up to the admission.

96. In addition to possible pneumonia, Ms. Johnson had a UTI, a common chronic condition among MS patients and main cause of death.[4] Without adequate home health aide care, people who rely on others for personal care face a high risk of institutionalization due to UTI. In an institutional setting, such as a hospital, paradoxically their risk for severe infection with associated complications only *increases*,[5] highlighting the crucial importance of aide services related to toileting, bathing, perineal care, and non-skilled catheter care.

97. Evaluation of Ms. Johnson's skin integrity revealed pressure points over bony prominences, skin fragility, and an area of nonblanchable erythema (discoloration) – a skin injury that is predictive of the development of a stage 2 or higher pressure ulcer within 28 days. Ms. Johnson's skin condition and developing pressure injury presented a serious risk to her safety. Pressure injury is a sign of inadequate repositioning – a common home health aide task.

98. Several aspects of Ms. Johnson's condition indicated a need for aide assistance with feeding. A registered dietitian noted "moderate-severe nutrition status" and "loss of muscle mass." Her labs revealed low albumin– a protein that plays a crucial role in maintaining adequate fluid levels in blood vessels. Low albumin can lead to low intravascular fluid volume, edema (swelling), ascites (fluid accumulation in the abdomen), and hypotension (low blood pressure). Ms. Johnson had all of these conditions when she presented to the hospital on April 21. Most

[4] *See* Katharine Harding et al., *Multiple Cause of Death Analysis in Multiple Sclerosis*, 94 Neurology e820 (2020) (deaths attributed to MS were commonly caused by infection, especially respiratory and urinary tract-related).

[5] *See, e.g.*, Alessio Mancini et al., *Differences Between Community- and Hospital-Acquired Urinary Tract Infections in a Tertiary Care Hospital*, 43 New Microbiologica 17 (2020) (hospitalized patient has higher risk of contracting UTI pathogen resistant to an antimicrobial agent than patient in the community).

critically, she was suffering from hypovolemic shock, a life-threatening condition caused by extremely low blood pressure due to low circulating blood volume.

99. A hospital swallowing study identified several swallowing deficits, including gross aspiration and silent aspiration. Feeding evaluations by hospital speech and language pathologists noted that Ms. Johnson required one-on-one feeding supervision and assistance with oral intake to prevent aspiration, which can lead to aspiration pneumonia. Assistance with feeding is another home health aide task covered by Medicare.

100. After the hospitalization Ms. Johnson had to find yet another Medicare-certified home health agency. In May 2021 she again started receiving skilled nursing visits for management of her catheter. The home health agency noted that Ms. Johnson was "at high risk for hospitalization due to risk for infection, seizure." The agency also noted that a home health aide was "required to assist with hygiene and personal care due to MS." Nonetheless, the "Goal Term" for aides was listed as "short" and minimal aide services were provided for only one 60-day certification period, even though Medicare-covered skilled services have continued.

101. Ms. Johnson also continued paying out-of-pocket for additional home health aide services that should have been covered by Medicare. The privately-paid aides provided services that included assistance with dressing, exercising, transferring, showering, toileting, applying lotion, hair and nail care, and oral hygiene. Ms. Johnson could not perform these tasks for herself and they are all recognized as coverable services under Medicare law. The aide services were needed to maintain Ms. Johnson's health and to facilitate treatment of her illness.

102. Ms. Johnson attempted to request coverage for close to $5900-worth of these privately-paid home health aide services covering dates of service July 13, 2021 – March 18, 2022. A letter with supporting documentation, dated June 28, 2022, was sent to the Medicare

contractor that handles home health service claims for Missouri. At the time of this filing, she has received no response as far as she knows.

103. Recently, the agency Ms. Johnson was paying privately for aide services increased the minimum hours it requires each patient to use. Feeling that they could not afford the increase, the Johnsons stopped using the services of that agency and started to pay out-of-pocket for aide services from the Medicare-certified agency that is also providing Ms. Johnson with Medicare-covered skilled nursing services. These aide services meet the criteria for Medicare coverage and should be covered by Medicare; Ms. Johnson should not have to pay for them out of pocket.

104. Ms. Johnson wants to remain in her home and community. Her experiences with Medicare denials and barriers to necessary care have caused her significant stress, exacerbating her symptoms and leaving her demoralized about her ability to remain at home.

105. Ms. Johnson met and continues to meet the criteria for Medicare home health coverage, including home health aides. Having been forced to manage erratic, unpredictable, and insufficient aide care, she has required hospital care to save her life and stabilize her health. Due to Ms. Johnson's complex, chronic health conditions, she is likely to face hospitalizations in the future. Without necessary Medicare-covered home health aide services, her ability to remain safely in her home and community is threatened and she remains at serious risk for institutionalization.

B. Plaintiff Katherine Vaczi

106. New Jersey resident Katherine Vaczi is 80 years old. She was paralyzed from the waist down in a car accident at the age of 23. Ms. Vaczi went on to teach second grade in the public school system for 25 years, drove a modified van until 2018, and has successfully lived in the community for over 40 years. She uses a wheelchair for mobility.

107. Ms. Vaczi lives alone and wants to continue living in her own, fully-accessible home instead of having to enter a nursing facility. Without appropriate, Medicare-covered home health aide services, however, she is at serious risk of being unnecessarily institutionalized.

108. Ms. Vaczi is homebound as defined by Medicare law. She requires a wheelchair to leave home and has a normal inability to leave home, and leaving home requires a considerable and taxing effort. Ms. Vaczi also requires intermittent skilled nursing services to care for her chronic, stage 4 pressure wound. The wound involves "full-thickness" tissue loss (exposure of bone, tendon, or muscle), placing Ms. Vaczi at high risk for severe infection and sepsis. For such an individual, the significance of home health aide care, in addition to skilled wound care, cannot be overstated. Aides provide bathing, toileting, hygiene, and basic catheter care that minimize the risk of infection due to contamination. They assist patients with repositioning to offload pressure points, and assist with providing nutrition and hydration. These services are critical to reducing the risk of entering an institutional setting such as a hospital or nursing facility, where the risk of severe infection only increases.[6]

109. After a period of health complications, including a diagnosis of breast cancer, complicated UTIs, kidney disease, cardiac issues, recurrent pleural effusion ("water on the lungs"), pneumonia, cellulitis (skin infection), and numerous hospitalizations, Ms. Vaczi received hospice care services at home from September 2020 through August 2021. The Medicare hospice benefit is separate from the home health benefit, and during this period Ms. Vaczi received a robust level of service, including home health aide services five days per week. The aides assisted with hands-on, personal care that was needed to maintain Ms. Vaczi's health,

[6] *See, e.g.*, Mancini, *Differences Between Community- and Hospital-Acquired Urinary Tract Infections*, *supra* note 5.

including dressing, bathing, perineal care, managing her ostomy bag, skin care (including checking pressure areas), hair and foot care, oral hygiene, and assistance with transfers.

110. The care from the hospice agency was remarkably effective at preventing infection and further decline of Ms. Vaczi's condition. In fact, her condition improved so dramatically that she remained out of the hospital for the entire 11- month period of hospice enrollment. Eventually, it was determined that Ms. Vaczi was not terminally ill and she was discharged from hospice care in August 2021.

111. When hospice services stopped, Ms. Vaczi began a long struggle to find and retain Medicare-covered home health care services that include adequate and consistent home health aide care. Between the hospice-care agency, Ms. Vaczi's daughter, and a representative from Medicare's "conflict resolution department" (which Ms. Vaczi's daughter had contacted), more than two dozen home health agencies were contacted before one would accept Ms. Vaczi for home health services. Ms. Vaczi's daughter also contacted the Medicare Ombudsman, but that office stated it had no power to make an agency accept Ms. Vaczi as a patient and could even make things worse if it tried to intervene on her behalf.

112. Ms. Vaczi's physician tried to order the home health services she reasonably required for her health and safety. But it was only after the ordered services were reduced that a Medicare-certified home health agency eventually accepted her as a patient in August 2021 to provide skilled nursing (primarily wound care), as well as home health aides two days per week. Even when aides from the Medicare-certified agency were providing services, Ms. Vaczi had to pay out of pocket for additional aide services, as she required more than two days per week of critical assistance with activities of daily living. The aides that she paid for, and that should have been covered by Medicare, were needed to maintain Ms. Vaczi's health and facilitate treatment

of her illness. They assisted with activities such as bathing, dressing, transfers from bed to wheelchair, incontinence care, oral hygiene, hair and nail care, applying lotion, checking skin integrity, and emptying her urinary drainage bag. These are services that Ms. Vaczi could not perform herself and that are recognized as covered, Medicare home health aide services.

113. On or around February 23, 2022 Ms. Vaczi went to the emergency room and was then admitted to Inspira Hospital with cellulitis. In addition to her chronic wound, she had pressure wounds on her lower legs. She was treated with antibiotics and was ready to be discharged on or around March 4. However, no Medicare-certified home health agency would accept her as a patient. The agency that had been serving her would not resume services.

114. Ms. Vaczi's hospitalization was prolonged as her family worked with a discharge planner to find a way for her to return home safely. Ms. Vaczi's daughter also contacted the office of Ms. Vaczi's U.S. Representative. A Medicare contractor sent the Representative's office a letter stating: "Home health agencies have the option to accept or deny patients within the scope of their own operating policies." Ms. Vaczi was evaluated for hospice services but was deemed inappropriate for such care. No solution was forthcoming and no Medicare-certified home health agency was willing to accept her as a patient.

115. The hospital eventually stated that Ms. Vaczi's options were either to go home with her daughter or to enter a skilled nursing facility for institutional care. Ms. Vaczi and her daughter explained that living at the daughter's house was not an option since it was not designed and adapted for Ms. Vaczi's disability, as her own home is.

116. Ms. Vaczi resisted discharge to a residential facility. She anticipated inadequate aide care, an inability to deal with her particular needs as a person with paraplegia, and risk for

infection. Ultimately, having run out of options, Ms. Vaczi was admitted to a skilled nursing facility on or about March 14, 2022.

117. Ms. Vaczi's fears were soon realized. On or around March 25, the facility transported Ms. Vaczi to the emergency room for a suspected fistula – an abnormal opening in the lower bowels. Hospital records reveal that "when closely examined by the ED physician it turns out that there was no fistula but simply stool in the vaginal vault from recent diarrhea and inadequate cleansing." The event was more than a reflection of low-quality care; Ms. Vaczi showed signs of possible serious infections linked to contamination of the urinary tract, as well as indications of inflammation of her kidneys and ureters. She was admitted from the emergency department to the hospital where she stayed until March 27, 2022. Her situation is a stark demonstration of the potential dangers of institutional care.

118. Since returning to her home from the skilled nursing facility in April 2022, Ms. Vaczi has been unable to find a Medicare-certified home health agency willing to provide her care. Ms. Vaczi's daughter has been told by various Medicare-certified home health agencies that they provide short-term care only. Meanwhile, Ms. Vaczi has been paying privately for home health aide services.

119. In a letter to the Medicare contractor that handles home health claims for New Jersey, Ms. Vaczi requested coverage for around $3600-worth of home health aide services she paid for privately covering dates of service August 18, 2021 through February 22, 2022. While it is not clear if it is a response to that request, Ms. Vaczi received a letter from CMS dated August 8, 2022 addressing "correspondence regarding home health services you received from August 13, 2021, through February 23, 2022." The letter states that CMS "has no record of a claim for home health services provided to you" on those dates.

120. Ms. Vaczi wishes to remain in her home, but without access to reasonable and necessary Medicare-covered home health aide services, she continues to face a very high risk of deteriorating health and institutionalization. She met and continues to meet the criteria for Medicare home health coverage, including home health aides. She has required hospitalizations and a nursing facility admission. Due to Ms. Vaczi's complex, chronic health conditions, she is likely to face such institutional admissions in the future. Indeed she was recently hospitalized on or around September 19-26, 2022 and her health situation is fragile and fluctuating. Without necessary Medicare-covered home health aide services, her ability to remain safely at home and in her community is threatened.

C. Plaintiff Cara Bunnell

121. Cara Bunnell lives in Michigan and is 51 years old. She is enrolled in a Medicare Advantage plan. She has MS and related quadriplegia. She uses a power wheelchair with head controls for mobility. She taught middle school for 18 years in Michigan public schools before retiring due to her disability.

122. Ms. Bunnell has recurrent, symptomatic UTIs with related pain and dysfunction. She also has a stage 2 pressure ulcer and history of falls.

123. Ms. Bunnell lives alone and receives intermittent skilled nursing services for care of her catheter. She is homebound as defined by Medicare law. She requires a wheelchair to leave home and has a normal inability to leave home, and leaving home requires a considerable and taxing effort. Her mother provides some assistance but cannot provide all of the home health services, including aide care, that Ms. Bunnell requires. Ms. Bunnell used to receive some care from her daughter, but her daughter died in a car accident in April 2021 at 26 years old.

124. Ms. Bunnell relies on others for activities of daily living, including for hygiene, repositioning, and providing nutrition and hydration. She wishes to remain living in her home

and community. Without appropriate, Medicare-covered home health aide services, she is at serious risk of being unnecessarily institutionalized.

125. Ms. Bunnell's Medicare-certified home health agency has noted factors in addition to her chronic urinary infection and dysfunction that present an ongoing high risk of serious complications. These include immobility, skin lesions, risk of developing new pressure ulcers, and risk of future falls. All of the home health agency's evaluations identify Ms. Bunnell as requiring full assistance in all activities of daily living.

126. In December 2021, Ms. Bunnell was receiving intermittent skilled nursing and home health aide services three times per week from her Medicare-certified home health agency. The home health aides assisted Ms. Bunnell with bathing and drying, transferring and repositioning among mobility devices and other assistive equipment, taping toes to minimize overlap, applying skin protectants to pressure ulcers and her urostomy site, application of antiembolism stockings, oral hygiene, basic catheter care, providing fluids, and communicating observations to supervisors in the case of a change of mental status or skin integrity. These services provided a bulwark against infection, skin breakdown, blood clots, dental disease, dehydration, further urogenital dysfunction, and isolation.

127. Infection, especially of the urinary and respiratory systems, is a main cause of death and a major cause of hospitalizations for individuals living with MS.[7] The more an MS patient's condition impedes her ability to maintain adequate hydration and nutrition, perineal care, regular bathing, and regular repositioning – the more she is at risk for urinary, respiratory, and integumentary system (*i.e.*, skin, nails, hair) infections. Without adequate home health aide

[7] *See, e.g.*, Amit Akirov, *Urinary Tract Infection in Multiple Sclerosis: Risk, Diagnosis, and Management*, Neurology Advisor (Feb. 24th, 2021), https://www.neurologyadvisor.com/topics/multiple-sclerosis/urinary-tract-infection-in-multiple-sclerosis-risk-diagnosis-and-management/.

care, a person who depends on others for hands-on personal care activities faces a serious risk of institutionalization due to infection. In an institutional setting, paradoxically, her risk for severe infection and associated complications only increases.[8]

128. On or around December 23, 2021, Ms. Bunnell's Medicare-certified home health agency informed her by telephone that the aide visits would be discontinued.

129. The home health agency also issued two "Home Health Change of Care" notices regarding the termination of Ms. Bunnell's aide services. The first notice stated that aide services would end on January 10, 2022 because "[a]gency policy" stated that "family/caregiver must be available to participate in care" and that "[d]ue to capacity," the agency was unable to meet her personal care needs. The box indicating that "Your doctor's orders for your home care have changed" was *not* checked. The form indicated that "Your home health agency has decided to stop giving you" home health aide services, and that Ms. Bunnell could "look for care from a different agency if you have a valid order for home care and still think you need home care." The agency agreed to keep aide services in place for a time after issuing the first notice when Ms. Bunnell explained her precarious care situation and tried to convince the agency not to terminate. When those efforts were unsuccessful, Ms. Bunnell received a second notice.

130. The second Home Health Change of Care notice stated that aide services would end on March 4, 2022. The sole reason provided for the termination was "Agency policy…states family/caregiver must be available to participate in care. This means patient is required to have a teachable caregiver to provide her non-skilled care. [The home health agency] can assist with identifying available options." Again, the agency did not check the box indicating that the doctor's orders for home care had changed.

[8] *See, e.g.*, Mancini, *Differences Between Community- and Hospital-Acquired Urinary Tract Infections*, *supra* note 5.

131. Before the services stopped, Ms. Bunnell explained to the Medicare-certified home health agency how much she depends on the aide services for critical personal care services that would not otherwise be performed. After filing a complaint with the home health agency, she received a letter dated February 24, 2022 from the manager of patient relations. The letter stated: "*[I]t was determined that you did not have the necessary family/caregiver available to participate in your personal care as outlined in the policy*. It was explained that admission for home health services is based on the patient's willingness and ability to function in a non-institutional environment, and the willingness, ability, and availability of family/caregiver or significant designated caregiver to participate in the care of patient. Those home health skilled services (for example, changing the catheter once/month) can continue. However, non-skilled services, such as bathing, cannot continue indefinitely. The patient's caregiver(s) must assume the non-skilled care of the patient 7 days per week. Home care services are intended to provide skilled services of a licensed professional; ongoing non-skilled services that do not require a licensed professional must be provided by the patient's caregivers. This is the reasonable and expected procedure of home health agencies." [Italics in original.]

132. Several statements in the letter conflict with Medicare home health law. As noted above, there is no time limit on non-skilled (or skilled) services that continue to meet coverage requirements. There is no requirement that a patient have a "family/caregiver" assume non-skilled care. To the contrary, Medicare policy specifies, "Where the Medicare criteria for coverage of home health services are met, patients are entitled by law to coverage of reasonable and necessary home health services. Therefore, a patient is entitled to have the costs of reasonable and necessary services reimbursed by Medicare *without regard to whether there is someone available to furnish the services*." MBPM, Ch. 7 § 20.2 (emphasis added); *see also* 42

C.F.R. § 409.45(b)(3) (one factor in determining whether aide services are reasonable and necessary is that there is "no able or willing caregiver to provide….").

133. And of course, Ms. Bunnell is very willing to "function in a non-institutional environment." That is her goal – to remain in her home in the community. She requires the Medicare-covered home health aide services she is eligible for in order to do so.

134. Ms. Bunnell contacted the office of one of her U.S. Senators about the termination of aide services, to no avail. She also attempted to appeal the termination of the aide services to the Medicare contractor that handles beneficiary complaints and service discharge appeals for Michigan. The contractor informed her that she had no right to appeal the termination of aide services because she was still receiving skilled nursing services from the Medicare-certified home health agency.

135. Since her Medicare-covered home health aide services ended on March 4, 2022, Ms. Bunnell has paid for the same types of aide services that used to be provided by her Medicare-certified home health agency, which continues to provide intermittent skilled nursing services. The privately paid aides generally come three times per week, and provide hands-on, personal care including assistance with bathing, dressing, grooming, transferring, toileting, applying lotion, oral hygiene, hair care, and checking skin integrity. These services are needed to maintain Ms. Bunnell's health; she cannot perform them herself. They are Medicare-coverable services.

136. As her only income is from Social Security Disability Insurance and a small teacher's pension, Ms. Bunnell is very concerned about her continuing ability to afford to pay for these aide services. She has used a small charitable grant to help pay for some of the services and fears for what will happen when she is forced to rely completely on her own funds.

137. Ms. Bunnell requested coverage for over $1,000-worth of home health aide services she paid for from March through June of 2022 in a letter to her Medicare Advantage plan dated June 29, 2022. As of the date of this filing, she has received no response.

138. Ms. Bunnell met and continues to meet the criteria for home health coverage, including home health aides. Without necessary Medicare-covered home health aide services, her ability to remain safely in her home and community is threatened and she is at serious risk for institutionalization.

D. Plaintiff National Multiple Sclerosis Society

139. The National Multiple Sclerosis Society ("the Society") works to cure MS and empower people affected by MS to live their best lives. To fulfill its mission, the Society funds research, advocates for policy changes, collaborates with MS organizations around the world, and provides services designed to help people with MS address the everyday challenges of living with a complicated disease like MS. This includes helping people with MS maintain their independence and remain living in their preferred community setting, their home.

140. Multiple sclerosis is a disorder of the central nervous system ("CNS") characterized by inflammation, demyelination, and degenerative changes. Most people with MS initially experience relapses and remissions of neurological symptoms, particularly early in the disease, due to clinical events usually associated with areas of CNS inflammation. Gradual worsening, known as progressive or degenerative change, may take place early, and usually becomes more prominent over time. Those diagnosed with MS may have many fluctuating and disabling symptoms, including, but not limited to, fatigue, impaired mobility, mood and cognitive changes, pain and other sensory problems, visual disturbances, paralysis, and elimination dysfunction. This constellation of symptoms may result in significant disability greatly impacting quality of life for patients and their families.

141. Approximately 30% of people with MS experience sufficient disability to require caregiving. Caregiving may include daily assistance with hands-on tasks such as dressing, bathing, grooming, transferring, and feeding. These tasks are commonly referred to as activities of daily living ("ADLs").

142. Recent estimates of the percentage of people in the US living with MS who qualify for Medicare vary from 21% to over 35% depending on data source and type of survey, with many gaining eligibility after leaving the workforce due to disability and before turning 65.

143. The cause of MS is unknown and it is an incurable disease. Medications can help modify or slow the course of the disease. Other interventions including rehabilitation, mental health care, mobility aids, home care, durable medical equipment, and wellness strategies, can help treat relapses, manage symptoms, and improve quality of life.

144. The Society provides resources at no cost to the MS community across the United States, including information and referral on all aspects of MS-related care, as well as programs and direct services designed to help people affected by MS live better lives. The MS Navigator program, the Society's flagship service, provides expert help to members of the MS community so they can respond to the everyday challenges of living with the disease. After conducting a comprehensive service assessment, navigators offer customized information, resources, support, and financial assistance for MS-related needs on a regular basis.

145. The MS Navigator program provides services for the MS community along a continuum of support from self-directed care to personalized navigator assistance to intensive case management services. The Edward M. Dowd Personal Advocate Program is composed of contracted case mangers throughout the United States who provide intensive case management services to members of the MS community who are facing multiple, complex challenges and

whose health and safety is compromised by limited knowledge, understanding, cognitive barriers and/or ability to access programs and benefits. Contracted case managers make home visits where they assess the needs of the person with MS and their family, and then collaboratively create an individualized care plan. Care plans address immediate needs for a range of issues while also identifying longer-term needs and solutions to enhance their client's safety, independence and quality of life in conformity with the principle of community integration.

146. The average age of people with MS who reach out to the Navigator program (by phone, chat or email) is 58 years old, and many members of the MS community contacting the MS Navigator program require assistance with activities of daily living.

147. The Society has observed through their MS Navigator and case management programs that many individuals with MS are unable to obtain the Medicare-covered home health aide services they require and should be eligible for. The Society has observed that despite asking for such services from Medicare-certified home health agencies, social workers, or heath care providers, people with MS and their caretakers are often told that home health agencies cannot provide the aide services, or that Medicare will not cover the aide services they require, even when they appear to meet all eligibility criteria.

148. The Society has also observed that otherwise-qualified people with MS and their family members sometimes stop trying to obtain Medicare-covered home health aide services because the struggle is too difficult. The time demands of caring for a significantly disabled person can prevent them from having the necessary time to devote to advocacy for aide services and coverage.

149. The Society has observed its constituents having these difficulties accessing Medicare-covered home health aide services for many years and well before the onset of the

COVID-19 public health emergency. While some issues may have been exacerbated by the pandemic, they certainly pre-date it.

150. The Society has spent and continues to spend staff time and financial resources helping people with MS address their inability to access Medicare coverage of necessary home health aide services.

151. Home care is one of the most common issues MS Navigators and case managers address, and they typically spend considerable time on cases involving home health issues, especially those involving aides providing hands-on, personal care. The cases are often time-sensitive and involve individuals with complex and urgent needs that must be met in order for them to remain in their homes. This typically includes people who have recently undergone an adverse health event that has diminished their ability to function independently, or people who have experienced a change in caregiver due to circumstances such as the death, disability, or burn out of their primary caregiver, or loss of aide services coming from a different source.

152. On a regular basis, the Society pays for home health aide services to supplement the Medicare-covered home health services its constituents receive. These payments are made through the Society's Financial Assistance program, which helps people pay for MS-related expenses including home care, durable medical equipment, home modifications, assistive technologies, transportation, and limited critical short-term needs like rent or utilities.

153. The Society typically pays for home health services when a constituent returns home from the hospital after treatment for an MS-related need, such as an exacerbation requiring IV steroids, a serious urinary tract infection, a complex pressure sore, or aspirating pneumonia. Other scenarios when the Society may pay for home health services include an individual returning home from a short-term skilled nursing facility stay; an individual who is on a waitlist

for home- and community-based services from a state's Medicaid "waiver" program; or an individual who experiences the sudden loss of a caregiver.

154. In a typical scenario, the Society has observed that Medicare-certified home health agencies frequently do not provide adequate aide services to its constituents in the aftermath of an acute-care hospitalization, even when other covered home health services are being provided and even though additional aide hours could be covered by Medicare. The Society intervenes to assist MS community members in this situation by paying for additional aide hours for hands-on, personal care so that the needs of these individuals can be adequately and reasonably met during these difficult transitions from hospital to home.

155. The Society has and will continue to use its Financial Assistance resources to pay for home health aide services that should be covered by Medicare. The Society's Financial Assistance funding is limited and varies over time. If its community members could reasonably and meaningfully access Medicare-covered aides, the Society could use the funds spent on home health aides to help its community members with other critical and costly needs.

156. In 2019, the Society spent over $37,000 on home health aides providing personal care services for constituents whose primary insurance was Medicare. In 2020, the expenditure was over $20,000, and in 2021, when the Society changed its funding policies to increase the dollar amounts it spends per person on such services, the figure was over $86,000. Expenditures for the first nine months of 2022 were over $78,000.

157. The Society also pays for respite care services to provide breaks for family caregivers of people with MS. These are also personal care services for constituents who cannot perform such tasks for themselves and they are nearly always provided in the constituent's home. With meaningful access to Medicare-covered aides, many constituents who use the Society's

respite care services would have less need for those services. This would allow the Society to pay for other services and resources or help other people. In 2019, the Society spent over $55,000 on family caregiver respite services for people whose primary insurance was Medicare. In 2020, the figure was over $37,000, in 2021 it was approximately $40,000, and in the first nine months of 2022, Society has spent over $18,000.

158. It is not only Medicare beneficiaries and their family members or other helpers who contact the Society for assistance with home health issues. Periodically, Medicare-certified home health agencies themselves contact the Society and ask if the Society will pay for aide services for their patients when those services should be covered by Medicare. Usually in these situations, the home health agency is providing only minimal aide assistance for bathing. Although the agency could bill Medicare for additional hours and types of aide services, it declines to do so and asks the Society to pay for aide services instead. The Society sometimes encourages the home health agency to bill Medicare for aide services in these circumstances, but if it refuses and the individual's need is significant, the Society will pay for limited aide services to address the personal care needs of the community member.

159. The Society has observed that home health agencies often make statements along the following lines to MS Society staff or to MS community members: (1) "Medicare doesn't cover aide services;" (2) "Medicare only covers aides for a very limited period of time;" or (3) "Medicare only covers bathing aides." Agencies may make such statements even when the patient in question is receiving an ongoing skilled service, such as nursing, and is clearly homebound as defined by Medicare. MS Navigators or case managers then spend time educating the agency about proper coverage for home health aides, or, more typically, finding other ways

for the patient to obtain the aide services he or she requires. As noted, sometimes the Society pays for aide services for a short period of time in these situations.

160. By counsel, the Society sent a letter to the Secretary on or about September 9, 2022, explaining the difficulties its constituents face in in accessing Medicare-covered home health aide services, and the staff time and financial resources it has spent and continues to spend to help people with MS address their inability to access those services. The letter described specific payments the Society had made to support home health aide services for a Medicare beneficiary in Ohio who was eligible for covered services, and requested that the Secretary administer, oversee, and enforce the Medicare home health benefit to ensure that eligible beneficiaries with chronic, disabling conditions can access the aide services for which they qualify. As of the date of this filing the Society has not received a response.

161. The Society has spent and will continue to spend resources to address the severe gap in services caused by the Secretary's policies and practices that deprive class members of Medicare-covered home health aide services

E. Plaintiff Team Gleason

162. Team Gleason is a non-profit organization based in New Orleans, Louisiana, whose mission is to improve life for persons living with ALS. The organization was founded by former New Orleans Saints football player Steve Gleason, who was diagnosed with ALS in 2011. Team Gleason helps people with ALS across the United States live with continued purpose and as productively and independently as possible.

163. ALS (also known as "Lou Gehrig's disease") is a progressive nervous system disease that causes loss of muscle control, eventually affecting the muscles needed to move, speak, eat, and breathe. There is no cure, and the average survival time is three to five years.

164. The vast majority of the individuals Team Gleason serves rely on Medicare for their primary health coverage. People with ALS commonly receive Medicare based on disability, and the normal 29-month waiting period for Medicare benefits to commence has been eliminated for people with ALS. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763, § 115 (Dec. 21, 2000); ALS Disability Insurance Access Act of 2019, Pub. L. No. 116-250, 134 Stat. 1128 (Dec. 22, 2020).

165. Team Gleason's mission was originally to advocate and provide for innovative assistive technology and equipment, as well as to provide "adventures" (excursions) for people living with ALS. The organization discovered, however, that the individuals they were serving were often consumed with fighting for the care they required to remain safely at home in the community. Team Gleason found that many of the people they wanted to assist and their family members were constantly struggling to obtain home care services, including Medicare-covered home health aide services.

166. Team Gleason observed that the families it wanted to help with assistive technology or adventures were often so overwhelmed by having to appeal denials of home care and navigating benefit programs, including attempting to access Medicare-covered home health aide services, that they scarcely had the time or energy to consider other issues, such as innovative assistive technology, or to participate in a Team Gleason adventure. The organization also noticed that people with ALS and their family members would sometimes simply give up trying to obtain the home health care benefits they should have qualified for, including home health aides, because Medicare-covered services were not available from Medicare-certified home health agencies and the struggle was too difficult.

167. Around 2015, in order to respond to this lack of home health aide services affecting so many ALS families, Team Gleason added what they refer to as a "respite" care program to its services, and around 2016, it hired an additional part-time staff member as a respite care services coordinator. The organization had to shift its staff and allocation of funding to accomplish this.

168. The respite services Team Gleason funds provide personal care to individuals with ALS, allowing their family caretakers to have some time during which they are not providing such care. Team Gleason contracts with providers and programs to pay for the services of personnel who are competent to safely care for people with ALS. The majority of the care provided entails hands-on, personal care such as dressing, bathing, grooming, transfers, toileting, feeding, and assistance with medications that are normally self-administered. These are the same tasks that are performed by Medicare-covered home health aides.

169. Since 2019 Team Gleason has spent approximately $750,000 on such services for the people it serves. Two of its main partnerships in its respite care program are with ALS in the Heartland and ALS of Michigan. Through those two partnerships it serves approximately 85 people living with ALS in 12 different states on a monthly basis. In 2022, Team Gleason expects to grant a combined total of $170,000 to ALS in the Heartland and ALS of Michigan. Outside of the grants for those two partnerships, Team Gleason has used at least 18 providers since 2019 to help fund such services.

170. Around the fall of 2021 Team Gleason stopped the expansion of its respite care program any further because it could not afford to spend further funds on these services.

171. With meaningful access to Medicare-covered aides, many people with ALS who use Team Gleason's respite care services would have less need for Team Gleason to provide

those services. This would allow the organization to help additional people or to apply those resources towards the organization's other priorities and programs.

172. In assisting families to coordinate and navigate health care programs and benefits, Team Gleason also continues to devote time and resources to providing guidance, support, and education to the people it serves about Medicare coverage of home health services including home health aides. It has observed that Medicare-certified home health agencies rarely suggest providing aide services to those who qualify, and that even after Team Gleason educates families about what aide services Medicare covers, they are virtually never able to access anywhere close to the amount and types of aide services for which they qualify.

173. By counsel, Team Gleason sent a letter to the Secretary on or about September 19, 2022, explaining the difficulties its constituents face in accessing Medicare-covered home health aide services, and the staff time and financial resources it has spent and continues to spend to help people with MS address their inability to access those services. The letter described specific payments Team Gleason made to support home health aide services for a Medicare beneficiary in Texas with fully progressed ALS who qualified for Medicare-covered services. Team Gleason requested that the Secretary administer, oversee, and enforce the Medicare home health benefit to ensure that eligible beneficiaries with chronic, disabling conditions can access the aide services for which they qualify. As of the date of this filing Team Gleason has not received a response.

174. Team Gleason has been compelled to use and will continue to use its resources to address the severe gap in services caused by the Secretary's policies and practices that deprive class members of Medicare-covered home health aide services. If the individuals Team Gleason serves had meaningful access to Medicare coverage of the home health aide services they are

eligible for under law, the organization would not have to devote the amount of time and resources that it currently does, and will continue to do, to assist people with home health care benefits and respite care, and could instead apply more resources to its original core mission of assistive technology and providing adventures.

F. Additional Factual Statements

175. Named Plaintiffs and Plaintiff class members have impairments that substantially limit one or more major life activities, such as self-care, walking, and major bodily functions such as bladder and bowel functions. They are qualified to participate in the Medicare program, with or without reasonable modifications to the program's rules, policies, or practices.

176. Studies have confirmed that unmet need for assistance with ADLs such as bathing, dressing, transferring, and toileting – the very services home health aides are intended to help with – is associated with an increased risk of hospitalization. *See, e.g.*, Glen DePalma et al., *Hospital Readmission Among Older Adults Who Return Home with Unmet Need for ADL Disability*, 53 Gerontologist 454 (2013) (unmet ADL need among community-living Medicare enrollees associated with increased risk for hospital readmission); Huiping Xu et al., *Insufficient Help for Activity of Daily Living Disabilities and Risk of All-Cause Hospitalization*, 60 J. Am. Geriatrics Soc'y 927 (2012) (Medicare beneficiaries reporting insufficient help for one or more ADL were more likely to experience hospitalization); Laura P. Sands et al., *Rates of Acute Care Admissions for Frail Older People Living with Met Versus Unmet Activity of Daily Living Needs*, 54 J. Am Geriatrics Soc'y 339 (2006) (frail older people living without needed help for ADL disabilities have higher rates of hospital admissions while living with unmet ADL needs than after their needs are met).

177. For example, when Plaintiffs and Plaintiff class members do not receive coverage of the home health aide services that they need, they can suffer dangerous infections, falls,

broken bones, medication errors, and skin breakdowns, all of which are recognized contributors to the need for acute medical care in hospitals. *See Patient Safety and Quality: An Evidence-Based Handbook for Nurses* Ch. 13 at 9 (Ronda G. Hughes ed., 2008) (risk factors associated with unplanned hospitalizations for home health patients include simultaneous use of multiple medications, wound deterioration, and falling accidents). In turn, hospitalizations are likely to lead to nursing home admissions. *See* 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. 617-23 (2019) (review of over 17 million hospitalizations showed 61.2% of individuals requiring post-acute care were discharged to a skilled nursing facility, while 38.8% were discharged to home with home health care).

178. Moreover, receipt of home health services in general, and aide services in particular, has been shown to delay entry into a nursing facility. *See* Laura P. Sands et al., *Volume of Home- and Community-Based Services and Time to Nursing-Home Placement*, 2 Medicare & Medicaid Res. Rev. E1, E14 (2012) (each five-hour increase per month in personal care services addressing ADL disability reduced likelihood of nursing home placement by 5%); Yuchi Young et al., *Is Aging in Place Delaying Nursing Home Admission?*, 16 J. Am. Med. Directors Ass'n. 900.e1 (2015) (home health services delayed nursing home entry by eight months).

179. The Medicare Payment Advisory Commission ("MedPAC") reported that from 1998 to 2019, home health aide visits per 60-day episode of home health care declined by 90%, from an average of 13.4 visits per episode, to an average of 1.3 visits per episode. MedPAC, *Report to the Congress: Medicare Payment Policy* at 236 (Mar. 2021) ("MedPAC 2021 Report"); *see also* 87 Fed. Reg. 37600, 37606 (June 23, 2022) (in 2021 the average utilization of

home health aides was less than half of a visit (.47) per 30-day period of care); *id*. at 37614 (proportion of 30-day periods of care with any home health aide or social worker visits went from 16.6% to 12.2% between 2018 and 2021—a 27% drop); 86 Fed. Reg. 62240, 62351 (Nov. 9, 2021) (CMS noted 2019 MedPAC report that between 1998 and 2017 "home health aide visits declined by 88 percent.").

180. As a proportion of total home health visits from 1997 to 2019, home health aides declined from 48% of total services to 6% of total services. MedPAC, *Report to the Congress: Medicare Payment Policy* at 234 (Mar. 2019); MedPAC 2021 Report at 245.

181. Although the Medicare statute and regulations authorize coverage of home health aide services for as long as the relevant coverage criteria are met, the Secretary has nonetheless implemented and administered the home health benefit in a manner that impedes and restricts Plaintiffs' and Plaintiff class members' access to Medicare-covered home health aide services.

182. As access to Medicare-covered home health aide services has decreased, Plaintiffs and Plaintiff class members have also been unable to access the types and varieties of services they require. As reflected in the experiences of Plaintiffs described above, Medicare-certified home health agencies typically offer services limited to bathing, for short periods of time, though the law authorizes many more types of personal, hands-on care that are often critical to beneficiaries with chronic, disabling conditions, with no durational limit. 42 C.F.R. § 409.45(b)(1)(i)-(v).

VII. INADEQUACY OF REMEDY AT LAW AND PROPRIETY OF ISSUANCE OF A WRIT OF MANDAMUS

183. Plaintiffs and Plaintiff class members suffer irreparable injury by reason of the Secretary's actions complained of herein. They are deprived of Medicare-covered home health

aide services that are crucial to their health, safety, well-being, and ability to remain in their homes. They are placed at risk of institutionalization and/or harm to their health.

184. Plaintiffs and Plaintiff class members have no adequate remedy at law. Only the declaratory, injunctive, and mandamus relief that this Court can provide will fully redress the wrongs done to Plaintiffs and Plaintiff class members.

185. Plaintiffs and Plaintiff class members have a clear right to the relief sought. There is no other adequate remedy available to correct otherwise unreviewable defects in the administration of the home health benefit. The Secretary has a plainly defined and nondiscretionary duty to provide the relief that Plaintiffs and Plaintiff class members seek.

VIII. CLAIMS FOR RELIEF

First Cause of Action: Violation of the Medicare Statute and Regulations

186. Plaintiffs reallege and incorporate the allegations in Paragraphs 1 through 185 above as if fully set forth herein.

187. The Secretary's policies and practices that impede and restrict the availability and accessibility of Medicare-covered home health aide services for Plaintiffs and Plaintiff class members violate the Medicare statute and its implementing regulations, including the plainly expressed intent of Congress to cover reasonable and necessary home health aide services for qualified beneficiaries. 42 U.S.C. §§ 1395d(a)(3), 1395k(a)(2)(A), 1395w-22(a)(1), 1395x(m), 1395y(a)(1)(A); 42 C.F.R. § 409.40-48.

188. The Secretary's policies and practices that impede and restrict the availability and accessibility of Medicare-covered home health aide services for Plaintiffs and Plaintiff class members violate his duty to oversee and enforce the Medicare Conditions of Participation and requirements for home health agencies, including that patients be accepted for treatment on the reasonable expectation that the home health agency can meet the patient's medical, nursing,

rehabilitative, and social needs in his or her place of residence, that home health agencies be operational to furnish Medicare-covered services, and that home health agencies provide optimal care to achieve the goals and outcomes identified in a patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. 42 U.S.C. §§ 1395bbb(b), 1395bbb(d)-(f), 1395x(o)(6); 42 C.F.R. §§ 484.60, 484.105, 424.510(d)(6), 409.41(a)(1).

Second Cause of Action: Violation of Section 504 of the Rehabilitation Act and Regulations

189. Plaintiffs reallege and incorporate the allegations in Paragraphs 1 through 188 above as if fully set forth herein.

190. Plaintiffs and Plaintiff class members are qualified individuals with disabilities within the meaning of Section 504 of the Rehabilitation Act, 29 U.S.C. § 794(a). They are qualified to receive Medicare-covered home health aide services, require such services, and wish to receive them in a community setting.

191. Medicare is a program that is conducted by the Department of Health and Human Services, an Executive agency.

192. The Secretary's policies and practices discriminate against Plaintiffs and Plaintiff class members on the basis of disability by impeding and restricting the availability and accessibility of Medicare-covered home health aide services to them, in violation of Section 504 of the Rehabilitation Act and its implementing regulations. 29 U.S.C. § 794(a); 45 C.F.R. § 85.21.

193. The Secretary utilizes criteria and methods of administration that subject Plaintiffs and Plaintiff class members to discrimination on the basis of disability, including risk of unnecessary institutionalization, by, among other things, impeding and restricting the availability and accessibility of Medicare-covered home health aide services to them; failing to oversee and

enforce the Conditions of Participation and requirements for Medicare-certified home health agencies; and auditing, reviewing, and measuring Medicare-certified home health agencies in a manner that deprives Plaintiffs and Plaintiff class members of necessary, Medicare-covered home health aide services that they qualify for. 45 C.F.R. §§ 85.21(b)(1)(i), 85.21(b)(3).

194. The Secretary fails to administer the Medicare home health benefit so that necessary aide services are provided in the most integrated setting appropriate to the needs of Plaintiffs and Plaintiff class members. The Secretary's actions impeding and restricting the availability and accessibility of home health aide services for Plaintiffs and Plaintiff class members threatens their ability to remain in their homes and in the community, putting them at serious risk of institutionalization. The Secretary therefore violates Section 504's integration mandate, and the requirement to make reasonable modifications to avoid discrimination on the basis of disability. 45 C.F.R. § 85.21(d).

IX. REQUEST FOR RELIEF

Plaintiffs, on behalf of themselves and the Plaintiff Class, request that the Court:

1. Assume jurisdiction over this action;

2. Certify this case a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(2);

3. Declare that the Secretary's policies and practices as set forth in Paragraphs 1 through 185 above violate:

a. the Medicare statute's and regulations' guarantee of coverage for reasonable and necessary home health aide services, for as long as the beneficiary requires and qualifies for such aide services, 42 U.S.C. §§ 1395d(a)(3), 1395k(a)(2)(A), 1395w-22(a)(1), 1395x(m), 1395y(a)(1)(A); 42 C.F.R. § 409.40 *et seq*.

b. the duty to oversee and enforce the Medicare Conditions of Participation, and requirements for Medicare-certified home health agencies, including the requirement to

accept patients for treatment on the reasonable expectation that the home health agency can meet the patients' medical, nursing, rehabilitative, and social needs in his or her place of residence; to be operational to furnish Medicare-covered services; and to provide optimal care to achieve the goals and outcomes identified in a patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. 42 U.S.C. §§ 1395bbb(b), 1395bbb(d)-(f), 1395x(o)(6); 42 C.F.R. §§ 484.60, 484.105, 424.510(d)(6), 409.41(a)(1);

c. the prohibition against discrimination on the basis of disability and against utilizing methods of administration that subject class members to discrimination on the basis of disability. 29 U.S.C. § 794(a); 45 C.F.R. §§ 85.21(a), 85.21(b)(1)(i), 85.21(b)(3), 85.21(d);

d. the mandate to avoid institutionalization of people with disabilities and to provide aide services in the most integrated setting appropriate to the needs of class members. 29 U.S.C. § 794(a); 45 C.F.R. § 85.21(d).

4. Issue a permanent injunction directing the Secretary to:

a. Ensure that class members who require and qualify for Medicare-covered home health aide services have reasonable access to the home health aide services authorized by the Medicare statute and regulations;

b. Administer and implement the home health benefit in a manner that does not discriminatorily deter access to reasonable and necessary Medicare-covered home health aide services for class members, and in a manner that comports with the mandate to provide aide services in the most integrated setting appropriate to the needs of class members;

c. Meaningfully enforce:

i. Medicare-certified home health agencies' obligation to accept patients with the reasonable expectation of providing services – including home

health aide services - that meet patients' needs in their place of residence, including providing reasonable and necessary home health aide services "under arrangement" with other home health agencies when necessary;

ii. proper "operational" requirements, including staffing requirements, for Medicare-certified home health agencies with regard to home health aides;

iii. Medicare-certified home health agencies' obligation to provide optimal care to achieve the goals and outcomes identified in a patient's plan of care, for each patient's medical, nursing, and rehabilitative needs.

d. Ensure that payment methods and criteria effectuate reasonable access to necessary, Medicare-covered aide services for class members in the most integrated setting appropriate to their needs;

e. Ensure that quality measurement and/or rating criteria for Medicare-certified home health agencies effectuate reasonable access to necessary, Medicare-covered aide services for class members in the most integrated setting appropriate to their needs.

f. Train Medicare auditors and reviewers on home health coverage rules and ensure they do not use auditing and reviewing methods or criteria that subject or have the effect of subjecting class members to discrimination on the basis of disability with regard to Medicare-covered home health aide services;

g. Provide education, and training to Medicare-certified home health agencies on coverage rules for home health aide services and on their obligation not to discriminate against beneficiaries on the basis of disability or severity of disability, including in their patient selection, service, and discharge policies and practices.

5. Award reasonable attorneys' fees and costs;

6. Grant any other relief as the Court deems necessary and proper to protect the federal rights of the individual Plaintiffs and members of the class they represent.

DATED: October 6, 2022

Respectfully submitted,

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