Melissa C. Brown (State Bar No. 110292)
COMMUNITY LEGAL SERVICES
McGEORGE SCHOOL OF LAW
3200 Fifth Ave.
Sacramento, CA 95817
(916) 739-7378
mbrown1@pacific.edu

Alice Bers *(pro hac vice)*
Justin Lalor *(pro hac vice)*
CENTER FOR MEDICARE ADVOCACY
P.O. Box 350
Willimantic, CT 06226
(860) 456-7790
abers@medicareadvocacy.org
jlalor@medicareadvocacy.org

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

GEORGE BEITZEL, K.K., and SHARON GOLDSTEIN, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

XAVIER BECERRA, Secretary of Health and Human Services,

Defendant.

Case No. 2:23-cv-01932-WBS-DB

**FIRST AMENDED CLASS ACTION COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

## INTRODUCTION

1. This is an action against the Secretary of the Department of Health and Human Services ("Secretary") as the official charged with administering the Medicare program.

2. Plaintiffs are Medicare beneficiaries who require an injectable drug that – for years – was administered to them by health care professionals in an outpatient clinical setting. The drug, ustekinumab (brand name Stelara), was covered by Medicare Part B as a medication furnished "incident to" a physician's or other allowed practitioner's service. Plaintiff George

Beitzel requires the drug to control symptoms of Crohn's disease. He also has Parkinson's disease and cannot administer Stelara himself due to his disability. He requires administration of Stelara by a qualified health care professional for safe management of his symptoms. Plaintiff K.K. requires Stelara to treat symptoms of psoriasis and a rare, severe form of psoriatic arthritis that are otherwise debilitating. Plaintiff Sharon Goldstein requires Stelara to treat symptoms of Crohn's disease.

3. The Secretary, in his official capacity, decided that as of October 15, 2021, Stelara would no longer be covered by Medicare Part B as incident to a practitioner's service, because the agency had determined that the drug is "usually self-administered by the patient." The Secretary provided no notice to Plaintiffs of this change in coverage terms, nor did he require notice to be issued by providers. The Secretary's policy and practice is not to require notice in this situation.

4. Only after Plaintiffs had received multiple scheduled injections from their providers did they learn through the quarterly statement they receive from Medicare that Stelara was not covered by Part B and that they were responsible for the full cost of the drug. Mr. Beitzel received four injections with listed costs of over $40,000 each. Ms. K. received two injections with listed costs of approximately $58,000 each. Ms. Goldstein received two injections with listed costs of $18,000 each. Moreover, since Mr. Beitzel cannot self-administer Stelara due to his disability, he has been forced to rely on a friend to administer the medication.

5. Plaintiffs challenge the Secretary's policy of failing to ensure that beneficiaries who have been furnished a Part B drug incident to a practitioner's service are provided with timely, adequate notice when that drug is added to the "self-administered drug list" ("SAD List"), thereby changing its coverage terms. They seek to require the Secretary to ensure provision of such notice so that—consistent with Medicare law and constitutional due process—beneficiaries can make an informed decision about whether and how to receive the medication, and can be shielded from financial liability if they do not receive proper, timely notice. For beneficiaries who, due to a disability, cannot self-administer the medication in question, they seek to require the Secretary to make a reasonable modification to the program to ensure that

these beneficiaries do not face greater barriers to accessing the drug on account of their disabilities.

## JURISDICTION AND VENUE

6. Jurisdiction is conferred on this Court pursuant to 42 U.S.C. § 405(g), which is incorporated into the Medicare statute by 42 U.S.C. §§ 1395ff(b)(1)(A) and 1395w-22(g)(5), and also pursuant to 28 U.S.C. §§ 1331 and 1361.

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

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

## PARTIES

9. Plaintiff GEORGE BEITZEL is 85 years old and lives in Elk Grove, California. He is and has been a Medicare beneficiary at all relevant times.

10. Plaintiff K.K. is a 73-year-old woman residing in Darien, Connecticut. She is and has been a Medicare beneficiary at all relevant times. She previously submitted a motion to proceed with partial anonymity (ECF No. 4).

11. Plaintiff SHARON GOLDSTEIN is 80 years old and lives in Poway, California. She is and has been a Medicare beneficiary at all relevant times.

12. Defendant XAVIER BECERRA is the Secretary of the Department of Health and Human Services ("HHS"). In that capacity he is responsible for the conduct and policies of HHS, including for the Centers for Medicare and Medicaid Services ("CMS"), which administers the Medicare program. He is sued in his official capacity.

## CLASS ACTION ALLEGATIONS

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

> All Medicare beneficiaries who have received or receive coverage of a "Part B drug" that has been or will be added to the SAD List by the Medicare Administrative Contractor responsible for administering their claims, and who

have been or will be denied coverage of the drug on the grounds that it is self-administered.

"Part B drug" is defined as a drug covered by Medicare Part B as "incident to" an allowed practitioner's services.

14. Plaintiff George Beitzel also seeks to represent a subclass defined as:

Members of the class who cannot self-administer the Part B medication they require because of a disability, as defined by Section 504 of the Rehabilitation Act.

15. Joinder is impractical due to the numerosity of class members, and for other reasons, including but not limited to their geographic diversity, their ages and/or disabilities, their ill health, and their limited incomes. Plaintiffs estimate the class to include at least thousands of Medicare beneficiaries nationwide. According to a Government Accountability Office ("GAO") report, 1,155 traditional Medicare beneficiaries had Part B claims for Stelara in 2015. GAO, *Medicare Part B: Medicare Represented at Least Half of the Market for 22 of the 84 Most Expensive Drugs in 2015* at 20 (Dec. 2017).[1] That number did not include Medicare Advantage enrollees, and by the time Stelara was added to the SAD List in 2021, the number of beneficiaries relying on Part B "incident to" coverage of the drug had likely grown higher.[2] That represents information on only one Part B drug. Reports suggest that in addition to drugs like Stelara that have already been added to the SAD List, other drugs currently covered by Part B are likely to be added to the SAD List pursuant to the Secretary's policy and practice, affecting more beneficiaries. *See infra* ¶¶ 128-132.

16. There are questions of law and fact common to the class, including the following:

a. Whether the Secretary's failure to ensure that class members receive timely, adequate notice of the change in Medicare coverage terms of a drug when it is added to the SAD List violates the Fifth Amendment Due Process Clause.

b. Whether the Secretary's failure to waive liability for class members who are furnished a drug incident to a practitioner's services without timely, adequate notice that it is no longer covered by Part B because it has been added to the

[1] https://www.gao.gov/assets/690/689275.pdf.
[2] *Inter alia*, Crohn's disease was approved as an additional indication for Stelara in 2016.

SAD List violates the Medicare Act and the Fifth Amendment Due Process Clause.

c. Whether the Secretary's failure to ensure that disabled subclass members can continue to receive Medicare-covered administration, by qualified health care professionals, of drugs that are added to the SAD List violates Section 504 of the Rehabilitation Act.

17. The named Plaintiffs are members of the class and their claims are typical of the claims of the class, as each class members' claim arises from the same course of events, and each class member would make similar legal arguments to prove the Secretary's liability. Plaintiff Beitzel is a member of the subclass and his claims are typical of those of the subclass, as each subclass members' claim arises from the same course of events, and each subclass member would make similar legal arguments to prove the Secretary's liability. The remedies sought by the named Plaintiffs are the same remedies that would benefit the class and subclass. The named Plaintiffs, like the class and subclass members, are harmed by the lack of notice and reasonable modifications caused by the policies, actions, and inactions of the Secretary.

18. The named Plaintiffs are adequate class representatives because they seek the same relief for themselves as for the class and subclass members and have no conflict with the class or subclass. They are represented by qualified counsel who have extensive experience representing classes in cases involving Medicare, disability law, and due process rights.

19. Plaintiffs seek certification under Rule 23(b)(2) of the Federal Rules of Civil Procedure. The Secretary has acted or refused to act on grounds generally applicable to the class and subclass, thereby making appropriate final injunctive and corresponding declaratory relief with respect to the class and subclass as a whole. Because Plaintiffs challenge systemic policies, practices, and failures of the Secretary, they seek declaratory and injunctive relief making class certification appropriate under Rule 23(b)(2).

## LEGAL FRAMEWORK

20. Enacted in 1965 as Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq*., Medicare is the federal program that provides health insurance to approximately 65 million individuals who are at least age 65, or who are under 65 and have significant disabilities.

21. For an item or service to be covered by Medicare, it must be defined as a covered item or service and be "reasonable and necessary" for the beneficiary. 42 U.S.C. § 1395y(a)(1)(A).

22. Medicare Part A (also called "hospital" insurance) covers, *inter alia*, inpatient hospital services, skilled nursing facility care, and home health services. Medicare Part B (also called "medical" insurance) generally covers outpatient items and services such as physician office visits and durable medical equipment.

23. Under Part C (the "Medicare Advantage" program), beneficiaries opt to receive Medicare coverage through privately-administered Medicare Advantage managed care plans instead of directly from the traditional Medicare program (Parts A and B). With few exceptions, Medicare Advantage plans must cover all items and services for which benefits are available under Medicare Parts A and B. 42 U.S.C. § 1395w-22(a)(1)(A); 42 C.F.R. §§ 422.100(a), 422.100(c)(1).

**Medicare Drug Coverage**

24. In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act established Part D of Medicare to provide coverage of outpatient prescription drugs. 42 U.S.C. §§ 1395w-101 *et seq*. Beginning in 2006, the Part D benefit authorized Medicare beneficiaries to purchase optional drug coverage from stand-alone private prescription drug plans (PDPs) or through Medicare Advantage plans (MA-PDs).

25. These Part D plans provide coverage of medically necessary drugs and are reimbursed by the federal government pursuant to contract. 42 U.S.C. §§ 1395w-111-112.

26. Each Medicare Part D plan also has its own "formulary," or list of covered prescription drugs. To obtain a Part D drug that is not included on a plan's formulary, enrollees must follow a procedure to request an "exception."

27. Part D plans also have networks of approved pharmacies. If enrollees receive a Part D drug from an out-of-network pharmacy, they must submit an out-of-network claim to their plan for reimbursement. Part D plans review such claims to determine if the drug is on the formulary and whether the situation falls into the limited circumstances when out-of-network coverage is allowed.

28. While Part D covers many outpatient prescription drugs, certain outpatient drugs and biologicals—typically those that are injected or infused in physicians' offices or other outpatient clinical settings—have long been covered, and continue to be covered, by Medicare Part B.

29. Part B pays for drugs and biologicals furnished "incident to the service of a physician (or other practitioner)." 42 C.F.R. § 410.26(b); *see also* 42 U.S.C. § 1395x(s)(2)(A); Medicare Benefit Policy Manual ("MBPM"), Pub. # 100-02, Ch. 15 § 50.[3]

30. When Part B covers outpatient drugs that are furnished incident to a practitioner's services, traditional Medicare pays for 80% of the Medicare-approved amount and beneficiary is responsible for a 20% coinsurance amount. Many beneficiaries in traditional Medicare also have a private supplemental plan (commonly called a "Medigap" plan) that helps insure against the 20% coinsurance amount. Medicare Advantage plans must provide coverage of Part B drugs that is actuarially equivalent to the coverage provided by traditional Medicare. 42 U.S.C. § 1395w-22(a)(1)(B)(i); Medicare Managed Care Manual ("MMCM"), Pub. #100-16, Ch. 4 §§ 10.3 and 10.8 (drugs covered under Medicare Part B are governed by original Medicare regulations and local coverage decisions).[4]

31. Coverage of Part B drugs under the "incident to" provision requires, *inter alia*, that the drug be furnished in a noninstitutional setting; that any charge for the drug is included in the bill of the practitioner and must represent an expense to the practitioner; and that the drug is furnished by, or under the direct supervision of the practitioner, or by auxiliary personnel with

[3] Available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.
[4] Available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf.

whom the practitioner has an employment or contract relationship. *See* 42 U.S.C. § 1395x(s)(2)(A); 42 C.F.R. § 410.26(b); MBPM Ch. 15 § 50.3.

**"Self-Administered" Drugs**

32. Part B coverage of a drug furnished incident to a practitioner's service also requires that the drug is "not usually self-administered by the patient." 42 U.S.C. § 1395x(s)(2)(A).

33. CMS interprets "usually" to mean "more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded" from Part B coverage. MBPM Ch. 15 § 50.2.C.

34. In determining whether a drug is "usually" self-administered for a particular indication, CMS directs its regional Medicare Administrative Contractors ("MACs") that handle Part B claims to use either "[r]eliable statistical information on the extent of self-administration" or to use certain presumptions depending on factors such as how the drug is delivered or the nature of the condition for which the drug is administered. MBPM Ch. 15 § 50.2.C; *see also id.* § 50.2.A.

35. CMS interprets "by the patient" to mean "Medicare beneficiaries as a collective whole." MBPM Ch. 15 § 50.2.E. It directs MACs to:

> make[] this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was needed. *Id.*

36. MACs must report to CMS the complete list of drugs they have determined are excluded from Part B coverage when furnished incident to a practitioner's service on the grounds that the drugs are "usually self-administered." MBPM Ch. 15 § 50.2.L. CMS expects MACs to review injectable drugs on a rolling basis and update their SAD Lists at least annually.

*Id*. Under a provision titled "Provider Notice of Noncovered Drugs," CMS also directs MACs to publish a list of the injectable drugs that are subject to the self-administered drug exclusion on their website, at least 45 days prior to the date the drugs will not be covered by Part B. MBPM Ch. 15 § 50.2.G.

37. There are currently 12 MAC jurisdictions for Part B claims, and each MAC maintains its own version of a SAD List that is applicable to that MAC's area of jurisdiction. The lists are often similar, but not identical. 88 Fed. Reg. 52262, 52387 (Aug. 7, 2023). The SAD Lists are published as "Local Coverage Articles" on CMS's website. An example of a SAD List maintained by a MAC is Local Coverage Article A53032, available at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53032.

38. Drugs that Medicare does not cover under Part B due to the self-administered exclusion are generally covered by Part D, subject to Part D's coverage requirements and the individual requirements of Part D plans such as formularies, pharmacy networks, prior authorization requirements, and beneficiary cost-sharing obligations. *See also* 88 Fed. Reg. 52387 (drugs put on a SAD List are excluded from Part B coverage, "but in those situations, they are almost always covered by Medicare Part D prescription drug coverage.").

39. In guidance to beneficiaries about what to do if they are billed for drugs they received that are deemed "self-administered" in an outpatient setting such as a clinic or hospital, CMS advises that "[s]ince most hospital pharmacies don't participate in Part D, you may need to pay up front and out-of-pocket for these drugs and submit the claim to your Medicare drug plan for a refund." The guidance also states that 1) if the drug is not on the plan's formulary the beneficiary will need to request an exception; 2) if the drug *is* covered by the beneficiary's Part D plan, the plan "might only reimburse you the in-network cost for the drug" minus any applicable cost-sharing amounts, leaving the beneficiary responsible for the difference; 3) if the beneficiary's plan does not cover the drug, the beneficiary needs to pay what the provider charges for the drug." CMS, *How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings* (Rev. Jun. 2020).[5]

[5] https://www.medicare.gov/Pubs/pdf/11333-Outpatient-Self-Administered-Drugs.pdf.

40. In 2015 the Secretary issued a policy statement to "assure hospitals that they will not be subject to Office of Inspector General (OIG) administrative sanctions for discounting or waiving amounts Medicare beneficiaries may owe for self-administered drugs (SADs) they receive in outpatient settings when those drugs are not covered by Medicare Part B," subject to certain conditions. OIG, *OIG Policy Statement Regarding Hospitals that Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings* (Oct. 29, 2015).[6] While this memo stated that hospitals would not risk penalties related to anti-kickback statutes if they uniformly apply policies regarding beneficiary discounts or waivers for SAD costs, it emphasized that "*[n]othing in this Policy Statement requires hospitals to discount or waive amounts owed by Medicare beneficiaries for Noncovered SADs that the beneficiaries receive in outpatient settings*" (emphasis in original).

**Medicare Beneficiary Protections**

41. Beneficiaries with traditional Medicare receive a Medicare Summary Notice ("MSN") showing items and services that providers billed to Medicare during the past 3-month period (if the notice is sent by mail), or the past month (if the notice is sent electronically). The MSN shows what Medicare paid (if anything) for each item or service, and the amount the provider may bill the beneficiary. Medicare Advantage enrollees receive an Explanation of Benefits ("EOB") from their plan periodically, listing the same payment information for all claims processed during the reporting period.

42. If Medicare does not pay for items or services listed on an MSN or EOB, beneficiaries may appeal those denials of coverage using the administrative appeal system established by statute and regulation. 42 U.S.C. §§ 1395ff(b), 1395w-22(g); 42 C.F.R. § 405.904(a)(2). The notice and appeal thus occur after the beneficiary receives the non-covered item or service.

43. The Medicare Act contains "limitation on liability" provisions that shield beneficiaries from the cost of non-covered care in certain circumstances. Financial liability is generally waived when 1) coverage is denied because the care was not reasonable and necessary

[6] https://oig.hhs.gov/documents/other-guidance/901/policy-10302015.pdf.

or the care was custodial, and 2) the beneficiary did not know, and could not reasonably have been expected to know, that Medicare would not cover the service in question. 42 U.S.C. § 1395pp(a) (also referred to as § 1879 of the Social Security Act); *see also* Medicare Claims Processing Manual ("MCPM"), Pub. # 100-04, Ch. 30 § 20[7]; MMCM Ch. 4 § 160.

44. If neither the provider nor the beneficiary knew, nor could reasonably have been expected to know, that services subject to liability protection would not be covered, liability rests with the Medicare program. 42 U.S.C. § 1395pp(a); 42 C.F.R. § 411.400(a). If the provider knew, or could reasonably have been expected to know, that the services would not be covered, Medicare indemnifies the beneficiary for any amounts the beneficiary paid to the provider, and the provider bears financial liability. 42 U.S.C. § 1395pp(b); 42 C.F.R. § 411.402.

45. CMS considers beneficiaries to know that services subject to liability protection are not covered if they receive a "written notice" that the services are "not covered because they [do] not meet Medicare coverage guidelines." 42 C.F.R. § 411.404. Once a beneficiary receives such a notice, she is presumed to know that there is no Medicare payment for subsequent receipt of the services in question. *Id.* § 411.404(b)(3). The notice can be given by Medicare contractors or by medical providers. *Id.* § 411.404(c); MCPM Ch. 30 § 40.1.

46. As explained by CMS, "written notice allows the beneficiary to…make an informed decision whether or not to receive the item and/or service, and…better participate in his/her own health care treatment decisions." MCPM Ch. 30 § 40. CMS provides specifications for written notice, including a "timeliness" requirement. *Id.* §§ 40.2, 40.2.1. Written notice "[m]ust be delivered far enough in advance of an event (e.g., receiving a medical service) so that the beneficiary can make a rational, informed decision without undue pressure." *Id.* § 40.2.1.A.

47. Thus, under the limitation on liability provision, providers can avoid financial liability for non-covered services and shift liability to beneficiaries in traditional Medicare by timely issuing an Advance Beneficiary Notice of Non-Coverage ("ABN"). MCPM Ch. 30 § 50.A. CMS has issued a model ABN for providers to use (Form CMS-R-131).

[7] Available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c30.pdf.

48. Medicare Advantage enrollees have similar protections. If a contracted provider furnishes a service that the enrollee reasonably believes is covered by her Medicare Advantage plan, "the enrollee cannot be financially liable for more than the applicable cost-sharing for that service." MMCM Ch. 4 § 160.

49. Legislative history indicates that Congress did not intend the limitation on liability provisions to apply to "clearly noncovered services such as…eyeglasses…hearing aids…[or] routine dental services." S. Rep. No. 92-1230, 92d Cong., 2d Sess. 295 (1972). In other words, protections were not intended to apply to items and services that Medicare has *never* covered. In these situations, a presumption can be made "that the beneficiary and/or the provider was aware, or should have been aware, of the fact that the services were not covered." *Id.*

50. For these types of denials, beneficiaries may be responsible for the cost of a non-covered service even if they did *not* receive a specific written notice informing them of non-coverage before receiving the item or service. MCPM Ch. 30 § 20.2.

51. A CMS manual lists examples of items and services for which no notice of non-coverage is required and beneficiaries still bear financial responsibility. These include most forms of dental care and dentures, cosmetic surgery, and health care received outside of the United States. MCPM Ch. 30 §§ 20.2, 20.2.1; *see also* MMCM Ch. 4 § 160 (if a service is never covered by a Medicare Advantage plan, the plan is not required to hold the enrollee harmless from the full cost of the service.) Again, these are services that Medicare *never* covers.

52. In its manuals, CMS also lists drugs that are "usually self-administered by the patient" as denials to which the limitation on liability provisions do not apply. MBPM Ch. 15 § 50.2.I; MCPM Ch. 30 § 20.2. CMS interprets the denial of Part B coverage for a drug subject to the "self-administered" exclusion to be a "'benefit category' denial and not a denial based on medical necessity." MBPM Ch. 15 § 50.2.I. CMS's position is that an ABN is therefore "not required" when a beneficiary is to receive a drug as incident to a practitioner's service that is not covered because it has been determined to be "usually self-administered." *Id.*

53. CMS goes on to state: "A 'benefit category' denial (i.e. a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the

financial liability protection provisions of Limitation on Liability (under § 1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug." *Id*.

54. As illustrated by the situations of the named Plaintiffs described below, the Secretary maintains that no advance beneficiary notice or liability protections apply, even when a drug that Part B has *previously covered* for a beneficiary is added to the SAD List and is thereby abruptly excluded from Part B coverage. The Secretary's policy is that beneficiaries are not entitled to any warning of non-coverage by Medicare Part B or potential coverage by Medicare Part D. The Secretary's policy is also not to apply the limitation on liability provisions when beneficiaries receive a medication that has been determined to be "usually self-administered" as incident to a practitioner's service. This is the case even if they have received prior Part B coverage of the same medication, have received no notice of the change in coverage terms, and even if they cannot in fact self-administer the drug.

55. Although hospitals may discount or waive SAD costs for beneficiaries without risking penalties under anti-kickback statutes, the Secretary does not require them to do so, and they are not likely to do so for costly medications that they have had to purchase under the "incident to" coverage provision. *See supra* ¶¶ 31, 40.

**The Rehabilitation Act**

56. Section 504 of the Rehabilitation Act , 29 U.S.C. § 794 ("Rehabilitation Act"), prohibits discrimination against individuals with disabilities by any program or activity conducted by any executive agency. 29 U.S.C. § 794(a); *see also* 45 C.F.R. §§ 85.1-85.2, 85.21(a)-(b). 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(1); 45 C.F.R. § 85.3.

57. Regulations implementing the Rehabilitation Act 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).

58. The Rehabilitation Act 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.

## FACTUAL STATEMENT

### George Beitzel

59. Plaintiff George Beitzel is an 85-year-old army veteran. He is widowed and lives by himself in an assisted living facility in Elk Grove, California. He is enrolled in traditional Medicare with a Medigap plan and a Part D plan. He is a qualified individual with a disability, with impairments that substantially affect one or more major life activity.

60. In or around 2000 Mr. Beitzel was diagnosed with Crohn's disease, which causes chronic inflammation of the GI tract. Crohn's disease has caused Mr. Beitzel stomach pain and gastrointestinal symptoms. Parts of Mr. Beitzel's intestines have been removed due to his Crohn's disease. In 2017 he was prescribed Stelara (ustekinumab), to be injected subcutaneously (under the skin) every eight weeks to treat his symptoms of Crohn's. There is no dispute that Stelara was and remains medically necessary for Mr. Beitzel.

61. Mr. Beitzel was also diagnosed with Parkinson's disease approximately eight years ago with resulting progressive symptoms. His fine motor dexterity and coordination are markedly impaired, as is his gross motor coordination. He has hand and arm tremors, and generally reduced movement capabilities. He also has memory deficits. Because of these symptoms he cannot administer Stelara injections to himself. Mr. Beitzel's facial muscles and speech are also impaired by Parkinson's. He is also diagnosed with non-Hodgkin's lymphoma.

62. For approximately four to five years, Mr. Beitzel had Stelara administered by health care professionals at an outpatient infusion center operated by a hospital. The drug was covered by Medicare Part B and his Medigap plan.

63. The MAC covering Mr. Beitzel's geographic area, acting at the direction of CMS and applying CMS policy, then determined that Stelara is "usually self-administered by the

patient." It updated its SAD List stating that effective October 15, 2021, Stelara would not qualify for Part B coverage. Local Coverage Article A53032.

64. Mr. Beitzel received no notice that Stelara would no longer be covered by Part B and was unaware that there had been a change in coverage terms. He received additional Stelara injections at the infusion center on October 21, 2021, December 16, 2021, February 10, 2022, and April 8, 2022. The infusion center submitted claims for Part B reimbursement for those dates of service, which Medicare denied.

65. Mr. Beitzel was first apprised of a coverage issue via an MSN dated March 1, 2022, which listed his October 21, 2021 and December 16, 2021 Stelara injections as non-covered. The MSN stated that Mr. Beitzel may be billed $43,543.47 for each of the two injections. The MSN provided no explanation for the non-coverage of Stelara other than: "Medicare does not pay for this item or service." Around this time he spoke to the infusion center's billing department, which told him there was a paperwork error with Medicare and that he should not worry about it.

66. At this point Mr. Beitzel had received three injections of Stelara since Medicare had added it to the SAD List, and he was still unaware that there had been a change in coverage policy. His gastroenterologist had made no changes in his prescription practices or advice, and the infusion center scheduled another injection appointment and sent reminders for the appointment. Mr. Beitzel received one more injection of Stelara from the infusion center on April 8, 2022.

67. Mr. Beitzel received an MSN dated June 10, 2022 stating that he could be billed $43,543.57 for his February 10, 2022 Stelara injection, and $45,894.81 for his April 8, 2022 Stelara injection.

68. Meanwhile, the infusion center had started the administrative appeal process, challenging Medicare's initial determinations of non-coverage. It requested redetermination (Medicare's first level of appeal) of the October 2021 injection in February 2022, and it did so for the other three dates of service as well, requesting redetermination of the last, April 2022 injection in September 2022.

69. According to CMS records, the provider argued that Mr. Beitzel required administration of Stelara at the infusion center for medical reasons. CMS Referral for Own Motion Review by DAB/MAC at 3 (ECAPE No. 3-11492272572, Apr. 17, 2023) (describing provider's appeal argument). It is not clear whether the provider understood the status of Stelara as a drug that had been determined to be "usually self-administered" or the ramifications of that determination. In its appeal of the December 2021 injection, for example, the infusion center argued that "it was medically necessary for [Mr. Beitzel] to receive Stelara subcutaneously every eight weeks at the outpatient facility because he was hypersensitivity reactions protocol, thereby making it necessary for a nurse to administer the medication." *Id.*

70. Medicare denied all four of the provider's redetermination requests. The decisions stated that Stelara could not be covered, and that the beneficiary – Mr. Beitzel – was responsible for payment. Mr. Beitzel received copies of these denials. These redetermination decisions also, for the first time in any correspondence from Medicare regarding these injections, made reference to the "self-administered drug" issue. For instance, a May 5, 2022 redetermination decision denying coverage of the October 2021 injection stated: "We find that the above services are deemed self-administered drugs. Therefore, based on the policies noted above, no payment can be made" Appeal No. 1-10930816787 at 3 (citing to MBPM Ch. 15 § 50.2 and Local Coverage Article A53032). It also stated: "The provider or supplier may bill the beneficiary for the denied item or service." *Id.*

71. In or about May 2022, Mr. Beitzel's prescribing gastroenterologist advised him to stop going to the infusion center for administration of the drug because of the coverage issue. Mr. Beitzel started to obtain the drug from a mail-order pharmacy which billed his Medicare Part D plan. He had to ask a friend, who is a retired podiatrist, to inject the drug for him since he cannot administer it himself.

72. Mr. Beitzel also sought assistance from a law school clinic, and appealed to the subsequent levels of Medicare's administrative review system. In support of his appeals, Mr. Beitzel's treating neurologist confirmed by letter that Mr. Beitzel cannot self-administer Stelara because of his tremors and memory lapses associated with Parkinson's disease. His inability to

self-administer was also confirmed by his treating gastroenterologist, who wrote that it is "medically necessary for Mr. Beitzel to have the injections provided by a qualified party such as the [infusion center] due to a medical condition that prevents him from self-administering medication. Over the past 4 years Mr. Beitzel has been approved for medication to be administered" at the infusion center. The doctor also stated that administration at the infusion center was appropriate as "the best and safest management" of Mr. Beitzel's Crohn's disease.

73. Mr. Beitzel received denials of coverage from the next level of review (reconsideration) regarding the October and December 2021 injections. These decisions also stated that he was financially liable for the drug.

74. The reconsideration decision regarding the October 21, 2021 injection, for example, stated that the relevant Local Coverage Article indicated that "effective October 15, 2021, ustekinumab (Stelara) is considered a self-administered drug. Payment of the claim remains denied." Under a section titled "Who is Responsible for the Bill?" it stated:

> You should have been aware that the services were not payable by Medicare. This information is in the Medicare & You handbook. This handbook gives advance notice to beneficiaries of items and services not covered by Medicare. A beneficiary's liability cannot be waived for charges associated with excluded services. The services are not payable by Medicare, and, therefore, you are responsible for the payment of the bill….
>
> Medicare Appeal No. 1-11462826047 (Sept. 20, 2022) at 3.

75. While the *Medicare & You* handbook issued every fall generally states that Part B does not cover self-administered drugs, this was no help to Mr. Beitzel, who had received Part B coverage of Stelara for years. Mr. Beitzel's October 21, 2021 injection was administered about one week after the MAC's determination that Stelara is "usually self-administered by the patient" had taken effect, with no notice about the change in coverage terms.

76. Mr. Beitzel appealed to the next level and a hearing with an Administrative Law Judge ("ALJ") was held on February 7, 2023. The ALJ issued a fully favorable decision, granting payment for his December 16, 2021 injection.[8] Office of Medicare Hearings and Appeals ("OMHA") Appeal No.: 3-11492272572 (Feb. 16, 2022).

[8] The ALJ claimed she could only address the December 16, 2021 date of service. However, the request for ALJ hearing included the Medicare Appeal number for the reconsideration of the October 21, 2021 date of service (1-

77. The ALJ wrote that "the circumstances in this case are unfortunate because Medicare has covered the Beneficiary's prescription for at least five years and because Stelara was still covered by Medicare just two months before the date of service at issue…. Additionally,…this drug is medically necessary to treat Crohn's disease and [the] Beneficiary's conditions prevent him from self-administering this medication." Feb. 16, 2022 ALJ Decision at 4.

78. The ALJ declined to follow the MAC's Local Coverage Article excluding Part B coverage of Stelara, "due to the Beneficiary's unique circumstances." *Id*.

79. The Medicare Appeals Council then, on its own motion, reviewed the ALJ decision and reversed it. Appeals Council Docket No. M-23-3565 (Jul. 11, 2023). It found that under Medicare's SAD policy and Local Coverage Article A53032, "the Stelara injection administered to the appellant does not fit within a defined benefit category." Appeals Council Decision at 4. The Council "recognize[d] the appellant's medical history and limitations," but found "no reason not to afford…substantial deference" to Medicare's policy manual and the Local Coverage Article. It claimed that CMS had considered the situation in which the beneficiary "may have been unable" to administer the drug and deemed it non-covered in those circumstances. *Id*.

80. The Appeals Council also found that Mr. Beitzel "is financially liable for the non-covered services," because the denial was based on the drug's exclusion from a "covered benefit category," rather than the drug not being reasonable and necessary. Jul. 11, 2023 Appeals Council Decision at 5.

81. The Council's opinion of July 11, 2023 is the Secretary's final decision. Mr. Beitzel exhausted administrative remedies, and under the final decision has been denied coverage of Stelara and remains financially liable for it, even though he had previously and repeatedly received Part B coverage of Stelara, and even though he cannot self-administer Stelara due to a disability.

1146826047), which should also have been addressed.

82. Mr. Beitzel has received conflicting information about his last two dates of service at the infusion center. A reconsideration decision denied coverage of the April 2022 injection and found that Mr. Beitzel remains financially liable for the drug. Medicare Appeal No. 1-11979655407R1 (July 18, 2023). Mr. Beitzel timely appealed that denial and an ALJ Hearing was held on November 15, 2023, from which he awaits a decision. For unknown reasons, he also received a new MSN, dated September 8, 2023, listing the same date of service (April 8, 2022) and stating he can be billed over $45,000 for the Stelara. The ALJ at the November 15, 2023 hearing would not consider the claim listed on this MSN, though it is for the same service that was at issue in the hearing, so Mr. Beitzel has submitted an appeal of that MSN as well.

83. A May 25, 2023 reconsideration decision granted coverage of the February 2022 injection on the grounds that the beneficiary was unable to self-administer the drug due to symptoms of Parkinson's disease. Medicare Appeal No. 1-12320296060R1.

84. While the precise extent of his financial liability thus remains undetermined, according to the administrative appeal decisions he has received, Mr. Beitzel is at least responsible for the cost of the October 21, 2021, and December 16, 2021 injections, and he will be responsible for the cost of the April 8, 2022 injection under a straightforward application of the Secretary's challenged policies and practices. He remains harmed by the Secretary's policies and practices, including lack of timely, adequate notice explaining the change in coverage terms for these injections.

85. In a September 2022 letter to a Medicare appeal contractor challenging non-coverage of one of his injections, Mr. Beitzel stated that he was "devastated" by the denial. He noted that he was directed to have the drug administered at the infusion center because of Parkinson's symptoms that make it "unsafe for me to self administer the injection." He also said: "I had no intent of doing anything wrong. That is the truth of the matter. The technical requirements cited are beyond the scope and knowledge of Medicare beneficiaries."

86. Mr. Beitzel is concerned about the cost of his ongoing care, and he watches his budget closely. With coverage of Stelara from his Part D plan, Mr. Beitzel now pays approximately $1,390 in cost-sharing amounts every other month for Stelara.

87. Mr. Beitzel also lost his safe access to Stelara when it was added to the SAD List. As noted by his treating physician, Mr. Beitzel's disabling medical condition requires that Stelara be administered in a clinical setting by a qualified practitioner for the "best and safest" management of his Crohn's disease. In his administrative appeals, Mr. Beitzel requested ongoing covered administration of Stelara by a qualified medical professional on account of his disability. He requires this reasonable modification to mitigate the ongoing discriminatory harm imposed on him by the Secretary's policies and practices.

**K.K.**

88. Plaintiff K.K. is 73 years old and resides independently in Darien, Connecticut. She is enrolled in traditional Medicare with a Medigap plan and a Part D plan.

89. Ms. K. has severe psoriasis and psoriatic arthritis. Specifically, she has a rare, destructive type of psoriatic arthritis called arthritis mutilans with "pencil in cup" deformity. This disease destroys the small bones and joints in the hands and feet, causing the bones to wear away at nearby surfaces and bringing intense pain. Psoriasis and arthritis mutilans have caused Ms. K. severe symptoms, including debilitating pain, in her day-to-day life. She applied for and received Social Security Disability benefits prior to age 65 based on the arthritis mutlians.

90. Ms. K. received Stelara (ustekinumab) via subcutaneous injection in a hospital outpatient setting to treat her severe psoriasis, psoriatic arthritis, and arthritis mutilans since September 2016. The injections were covered by Medicare Part B as a drug furnished incident to a practitioner's service. She requires Stelara every three months to manage her conditions and alleviate the associated symptoms. There is no dispute that Stelara is medically necessary for Ms. K.

91. The MAC covering Ms. K's geographic area, acting at the direction of CMS and applying CMS policy, then determined that Stelara is "usually self-administered by the patient." It updated its SAD List stating that effective October 15, 2021, Stelara would not qualify for Part B coverage. Local Coverage Article A53021.

92. Ms. K. received no notice that Stelara would no longer be covered by Part B. She received additional Stelara injections at the hospital on December 21, 2021 and March 22, 2022, unaware that there had been a change in coverage terms.

93. Ms. K first became aware of non-coverage when she received a quarterly MSN dated April 7, 2022, listing the Stelara injection she received on December 21, 2021 as not covered by Part B and stating that the she may be billed $58,299.90 for it. She also received an MSN dated July 7, 2022, stating that the March 22, 2022 Stelara was not covered by Part B and the hospital may bill her $58,314.91 for it. The MSNs provide no explanation for the non-coverage of Stelara other than: "Medicare does not pay for this item or service."

94. The hospital appealed the initial coverage denials, and Ms. K. received copies of the redeterminations. The redetermination decisions, dated June 22, 2022 and September 9, 2022, denied coverage and, for the first time in Medicare correspondence she had received, cited Local Coverage Article A53021 and mentioned the self-administration issue. *E.g.*, "Stelara is a self-administered drug that is not covered by Medicare. This was effective on October 15, 2021." Appeal # 1-11164544191 at 3 (Jun. 22, 2022). The decisions also stated that Ms. K. was responsible for the bill. *E.g.*, "Medicare payment cannot be made and the beneficiary is responsible for the non-covered Stelara…The provider may bill the beneficiary for the service." *Id*.

95. Ms. K. appealed to the next level (reconsideration) from the two denials and received denials that relied on essentially the same reasoning. Citing MBPM Ch. 15 § 50 and Local Coverage Article A53021, the decisions stated that Stelara could not be covered because it is self-administered, and that Ms. K is liable for the charges.

96. A hearing with an ALJ was then held at Ms. K.'s request on June 7, 2023. During the hearing the ALJ stated on the record that Ms. K. would not be responsible for the cost of the Stelara injections. However, the ALJ then issued unfavorable decisions for both dates of service. OMHA Appeal Nos. 3-12641863296 and 3-12048471799 (June 15, 2023).

97. The ALJ wrote that:

> [t]he Beneficiary had no reason to believe that the injection would not be covered or considered 'self-administered.' In this instance, the Appellant/Beneficiary followed the guidance of her provider [but] the Policy Article in effect at the date of service, and the Medicare Policy, do not include any protections for the Beneficiary. Currently the policy excludes the medication at issue and does not require an Advanced Beneficiary Notice of Non-Coverage that would put the Beneficiary on notice of changes in the coverage requirements. Both Medicare and the Provider are not liable, and the Beneficiary was left without any means of protection.
>
> June 15, 2023 ALJ Decision at 6.

98. The ALJ went on to note:

> At first blush and upon hearing the Beneficiary's testimony, this ALJ logically assumed that a Provider needed to advise the Beneficiary that the injection could not be covered. During the hearing, this ALJ indicated that she was able to waive liability, and while I feel that it is a logical requirement in this case, as an Administrative Law Judge, I am bound to give substantial deference to the CMS guidance, though in this case I believe an equitable remedy necessary….While the facts of this case present a substantial argument for an equitable finding, I am not able to ignore Medicare policy and guidance. Because of this, the Beneficiary remains liable. This ALJ is sympathetic to the Beneficiary's condition and the difficult financial situation, as well as mental stress, this has caused, however the record does not support payment or waiver of financial of liability for the injection.
>
> *Id*.

99. Ms. K timely appealed the ALJ's decisions to the Medicare Appeals Council on August 10, 2023, where they are currently pending. Docket Nos. M-23-5340 and M-23-5341. Under the Secretary's challenged policies and practices, her pending claims will be denied.

100. Ms. K. experienced and continues to experience distress, anxiety, and outrage about the termination of Part B coverage for Stelara without notice and Medicare's decisions finding that she is financially liable for the cost of the injections she received at the hospital. Ms. K. has paid the hospital just under $5,000, which she believes was a heavily discounted rate for the Stelara. Before the drug was added to the SAD List it was covered in full by Medicare Part B and her Medigap plan. Ms. K remains harmed by the Secretary's policies of lack of timely, adequate notice explaining the change in coverage terms and failure to waive liability when such notice is not provided.

101. Ms. K. would never have gone to the hospital to receive the Stelara injections after October 15, 2021 if she had been informed that it would no longer be covered by Medicare Part

B and that she would have to pay thousands of dollars for it if she received it at the hospital.

102. In a December 2022 letter to a Medicare appeal contractor, Ms. K. wrote that she had stopped taking Stelara after she received the denials of Part B coverage because of the drug's high cost to her under Part D. She noted that she now had pain and a serious rash that "looks like a third degree burn, especially on my back." The rash covered approximately 50% of her body and tormented her with itching with no relief. She wrote that her doctor was concerned about her health and that she "very much want[ed] to receive Stelara again as my two autoimmune diseases make me very sick when I am not on the medicine." Ms. K. has since enrolled in the drug manufacturer's patient assistance program, through which she receives Stelara at no cost for calendar year 2023, and she may need to apply other sources such as charitable foundations for assistance after this year.

103. In the same December 2022 letter Ms. K wrote: "Surely, my rights as a beneficiary of Medicare were violated when Medicare did not inform me that my benefit to receive Stelara under Medicare Part B was taken away from me on October 15, 2021."

**Sharon Goldstein**

104. Plaintiff Sharon Goldstein is 80 years old and lives with her husband in Poway, California. She is enrolled in traditional Medicare with a Medigap plan and a Part D plan.

105. Ms. Goldstein has Crohn's disease and started taking Stelara to treat and alleviate her symptoms in early 2020. She received subcutaneous injections administered by a health care professional at an outpatient clinic every eight weeks. Medicare Part B covered the medically necessary Stelara injections as a service furnished incident to a practitioner's service.

106. The MAC covering Ms. Goldstein's geographic area, acting at the direction of CMS and applying CMS policy, then determined that Stelara is "usually self-administered by the patient." It updated its SAD List stating that effective October 15, 2021, Stelara would not qualify for Part B Coverage. Local Coverage Article A53032.

107. Ms. Goldstein received no notice that Stelara would no longer be covered by Part B. She received additional Stelara injections at the clinic on October 26, 2021 and on December 16, 2021, unaware that there had been a change in coverage terms.

108. Ms. Goldstein first became aware of non-coverage when she received a quarterly MSN dated January 27, 2022, listing the October and December injections as not covered by Part B and stating that she may be billed $18,000 for each dose of Stelara ($36,000 total).

109. Ms. Goldstein's husband, Gerald Goldstein, is a volunteer counselor with California's Health Insurance Counseling and Advocacy Program ("HICAP"). HICAP provides free information and counseling about Medicare. HICAP counselors are trained to help Medicare beneficiaries understand their rights and options under the program. Mr. Goldstein is well-informed on Medicare coverage and beneficiary rights. Both Mr. and Ms. Goldstein were shocked by the non-coverage of Stelara.

110. Ms. Goldstein was scheduled for another injection with the clinic on or about February 10, 2022, but since she had received the MSN earlier that week indicating that Stelara was not covered she did not know what to do. As she later stated in her appeal to Medicare, "This left me in a bad situation, with my health in trouble without this medication." After her husband contacted the provider to find out what was happening with coverage of Stelara, the clinic informed the Goldsteins that the February appointment was cancelled, just days before it was supposed to occur. Ms. Goldstein still did not understand why there had been a change in coverage or why she had not been informed.

111. With help from her husband, Ms. Goldstein submitted an appeal to Medicare of the denied claims, arguing that she had never been notified of a change in coverage. The provider clinic appealed as well. The denials from the first level of appeal (redetermination), dated April 12, 2022, stated that "the drug is determined to be self-administered and therefore not covered by the Medicare program." They also stated that the beneficiary (Ms. Goldstein) was responsible for the bill. At some point after the redetermination denials were issued, Ms. Goldstein retained the assistance of an attorney to represent her in her appeals to Medicare. Ms. Goldstein received similar denials from the second level of appeal (reconsideration).

112. Ms. Goldstein received a bill from the clinic dated April 20, 2022, that showed a patient balance of over $31,800. The bulk of the balance came from the two Stelara injections, which were adjusted from $18,000 each to just under $16,000. Knowing that beneficiaries are

normally protected from liability for services they could not have known were non-covered, Mr. Goldstein later asked the clinic for a copy of any ABN that Ms. Goldstein had signed prior to receiving these services. He was told there was no ABN for either of the two injections.

113. Ms. Goldstein later received a notice from a debt collector dated July 11, 2022, attempting to collect over $31,800, plus interest of around $26 for the debt owed to the clinic. The notice warned that because of interest, late charges, and other charges, the balance could increase. Later that month, another letter from the collection agency listed interest of around $148 and the balance had grown close to $32,000. It was not until August 2022 that Ms. Goldstein learned that the collection agency had closed her account, apparently because the claims for the two Stelara injections were under appeal to Medicare so her liability had not yet been finally decided.

114. Ms. Goldstein received a favorable ALJ decision on the October 26, 2021 injection. It was based on the ALJ's premise that claims could not be denied until a 45-day period had elapsed from the effective date of Stelara being considered self-administered (October 21, 2021). OMHA Appeal No. 3-11162760267 (Oct. 31, 2022).

115. On February 14, 2023, an ALJ hearing was held on the December 16, 2021 injection. According to the ALJ's decision, the provider submitted internal emails during the hearing showing that it did not learn of Stelara's addition to the SAD List until around February 2022. The provider requested that the ALJ "reconsider denial of payment for [date of service] 12/16/2021, as my office was not notified in writing by either Medicare, or the Stelara manufacturer, of this new policy." OMHA Appeal No. 3-11763105517 at 8 (Mar. 7, 2023) (quoting provider's position paper). According to the decision, the provider also failed to submit documentation actually showing the administration of Stelara on the date of service. *Id*. at 9.

116. The ALJ denied coverage, explaining that even if proper supporting documentation had been submitted, Part B coverage of Stelara was excluded as of October 15, 2021 under the MAC's Local Coverage Article. The decision also states, "While there is no ABN in the record, this ALJ finds that the Beneficiary is liable for the denied charges." *Id*.

117. Ms. Goldstein and her attorney did not appear at the February 14, 2023 hearing because neither of them had received notice of it, even though her attorney submitted a timely request for an ALJ hearing. Upon information and belief, this was due to error by the Office of Medicare Hearings and Appeals.

118. Ms. Goldstein's attorney submitted a timely request for reopening of the ALJ hearing to the Medicare Appeals Council in April 2023, explaining that neither he nor Ms. Goldstein had received notice of the hearing and thus did not have the opportunity to provide argument or testimony. That request is currently pending.

119. Since the denials of her injections, Ms. Goldstein has received coverage of Stelara from her Medicare Part D plan.

120. Ms. Goldstein is financially liable for the December 16, 2021 injection. She remains harmed by the Secretary's policies of lack of timely, adequate notice explaining the change in coverage terms and failure to waive liability when such notice is not provided.

121. Ms. Goldstein would not have gone to the outpatient clinic to receive Stelara after October 15, 2021 if she had been informed that it would no longer be covered by Medicare Part B and that she would be responsible for thousands of dollars for its cost.

122. Ms. Goldstein remains disturbed by the communications she received from the clinic's billing office and the collection agency, which are likely to pursue the debt again once her appeal becomes final. Her pending claim will be denied under an application of the Secretary's challenged policies and practices. She is distressed about the enormous liability she faces.

**Ongoing Concerns Regarding SAD List Policy**

123. In 2020, when most of the MACs announced plans to add Stelara to their SAD Lists, the American College of Rheumatology ("ACR"), the Coalition of State Rheumatology Organizations ("CSRO"), and the Arthritis Foundation, sent a letter to CMS requesting that it review the MACs' decision. The organizations wrote: "Keeping Stelara off the list is important

to ensure continued access for patients who can't self-administer." ACR, *Joint Letter to CMS Advocates Against Adding Stelara to Self-Administered Drug List* (Jul. 6 2020).[9]

124. An April 2021 letter to CMS from CSRO summarized concerns with Medicare's SAD List, including "a recent challenge with beneficiary access to a key medication used in auto-immune diseases (Ustekinumab)." Letter from the President and Federal Advocacy Chair of CSRO to Tamara Syrek-Jansen, JD, Director, Coverage and Analysis Group, CMS (Apr. 26, 2021).[10]

125. The letter noted that while

> [a]ccording to CMS' claims data, ustekinumab is usually self-administered…in clinical practice, we note that patients with psoriatic arthritis are unable to inject the drug themselves due to joint pain and swelling caused by the disease. These patients seek the assistance of their rheumatologist, another health care professional, or caregiver/friend, to administer their medication. In fact, a recent survey by the Global Healthy Living Foundation (GHLF) found that, of Medicare beneficiary respondents taking a treatment that requires an injection, 35.7% are unable to self-inject and have a family member/friend/acquaintance administer or a health care provider administer the injection.
>
> *Id.*

126. CSRO's letter also noted that they had discussed the issue with medical directors of the MACs, but the medical directors "had been unable to meaningfully address the issue or find a pathway for patients to access an infused formulation of a SAD List drug, even when medically necessary….CMS' Sad List policies have not kept pace with the real-world use of medicines that have multiple indications and formulations. Specifically, they have the unintended consequence of discriminating against patients who are unable to self-administer certain medications based on their disease." *Id.*

127. While the effective date of Stelara's addition to the SAD List was postponed due to the ongoing public health emergency, its exclusion from Part B coverage eventually took effect on October 15, 2021 for MACs responsible for Plaintiffs' claims, despite the above-noted advocacy. Local Coverage Articles A53032 & A53021.

[9] https://www.the-rheumatologist.org/article/joint-letter-to-cms-advocates-against-adding-stelara-to-self-administered-drug-list/.

[10] https://csro.info/UserFiles/file/CSRO_Letter_to_CMS.pdf.

128. Controversy over the Secretary's SAD List policies has been occurring for years and continues to occur as more drugs that have been covered by Part B are deemed to be "usually self-administered by the patient." For instance, in 2013, after ACR intervened, CMS ordered Part B coverage to resume for three drugs that some MACs had moved to the SAD List (brand names Cimzia, Orencia, and Simponi). The president of ACR at the time noted: "These bad decisions would have kept many of our patients from accessing or staying on medications that offer them significant improvement in their conditions at more affordable prices….There was no forewarning given by Medicare carriers to rheumatologists, rheumatology health professionals, or patients about the termination of coverage…." The ACR president urged rheumatologists "to be vigilant in ensuring that carriers do not again attempt to remove drugs from coverage. 'The battle isn't over.'" Richard Quinn, ACR, *American College of Rheumatology Helps Keep Three Biologics Off the SAD List* (Nov. 19, 2013).[11]

129. The president of ACR was correct, since as of August 2023, two of the three drugs the organization had advocated to keep off the SAD List are now on the list. *See, e.g.*, Local Coverage Article A53127 listing Simponi effective Oct. 24, 2016, Orencia effective Aug. 28, 2017).[12]

130. More recently, the American College of Allergy, Asthma & Immunology ("ACAAI") successfully advocated to prevent a drug – tezepelumab-ekko (brand name Tezspire) from being placed on the SAD List by several MACs. The organization noted in July 2022 that Teszpire, a biologic used to treat severe asthma, is intended to be administered by a health care provider, and that requiring patients to self-administer would present many challenges, including jeopardizing correct utilization and stability of the drug, as well as its effectiveness.

131. In response to advocacy efforts, CMS directed the MACs to delay the addition of Tezspire to the SAD List "until a thorough review could be completed." ACAAI , *Tezspire – Advocacy Thwarts Move to SAD List* (Jul. 25, 2022)[13]; *see also* Letter from the President of

[11] https://www.the-rheumatologist.org/article/the-american-college-of-rheumatology-helps-keep-three-biologics-off-the-sad-list/.
[12] https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53127&ver=130&=
[13] https://college.acaai.org/tezspire-advocacy-thwarts-move-to-sad-list/.

ACAAI to CMS Administrator Chiquita Brooks-LaSure and Tamara Syrek-Jansen, JD, Director, Coverage and Analysis Group, CMS (Jun. 23, 2022).[14] For now the drug remains covered by Part B, but the threat of the addition of this drug to the SAD List still looms and is likely to harm class and subclass members unless the requested relief is granted.

132. More drugs that are currently covered by Part B as incident to a practitioner's service will be deemed to be "usually self-administered by the patient" and added to the SAD List. 42 U.S.C. § 1395x(s)(2). As this occurs, under the Secretary's policies of no required notice to beneficiaries who have had the drugs covered by Part B, no protection from financial liability if they receive the drug again without timely, adequate notice, and no reasonable modification for beneficiaries who cannot self-administer the drugs due to disabilities, class and subclass members will continue to be harmed unless and until the requested relief is granted. Given their age and multiple, chronic medical conditions, there is a likelihood that the named Plaintiffs will also require additional medications that are furnished incident to a practitioner's service, and that will be added to the SAD List.

133. As illustrated by the situations of the named Plaintiffs, beneficiaries who have previously received coverage of a medication under Part B have absolutely no reason to think Medicare's coverage rules have changed when that drug is added to the SAD List. And since the Secretary does not require a written notice to be provided, they may simply proceed to receive the medication thinking it is covered by Part B until they get a claim denial weeks or even months after the fact.

134. At that point, the Secretary's policy is not to apply financial liability protections for beneficiaries, who are told in Medicare correspondence that providers may charge them for the full cost of the drug in question. That cost may be exorbitant. Beneficiaries are then at the mercy of providers opting to discount costs, which can still leave them with very high and unexpected out-of-pocket expenses. Even if beneficiaries with Part D manage to self-submit a claim to their plan for the non-covered drug after the fact, they are still likely to be left financially responsible for a large portion or full cost of the drug (and more than they would

[14] https://college.acaai.org/wp-content/uploads/2022/07/ACAAI-Request-RE-Tezspire_2022-06-23.pdf.

have been responsible for under Part B). That is because Part D plans' in-network payment rates are likely lower than outpatient providers' rates, and because plans may decide that they cannot cover a particular out-of-network or non-formulary claim.

135. But for the Secretary's failure to ensure that class members receive timely, adequate notice, they could avail themselves of other means of obtaining the drugs in question and avoid potentially devastating financial liability.

136. If the Secretary required advance notice of the change in coverage terms (*i.e.* non-coverage by Part B and coverage by Part D) to be provided to class members, they could make the "informed decision" contemplated by CMS, and required by due process. MCPM Ch. 30 § 40. Beneficiaries could have sufficient time to determine whether their Part D plan covers the drug in question, and request a formulary exception if it does not. They could also make sure to obtain the drug at a network pharmacy, rather than from a hospital or clinic pharmacy – most of which do not participate in Part D plan networks – and have time to request prior authorization if needed. This is important because in 2023, for example, only 66% of Part D enrollees have formulary coverage of Stelara (the drug required by the named Plaintiffs), and 100% of those with coverage must obtain prior authorization before their plan will pay for Stelara. *See* Juliette Cubanski *et al*., KFF, *How Medicare's New Drug Price Negotiation Program Could Expand Access to Selected Drugs* (Sept. 26, 2023).[15] Beneficiaries may also invoke rights to change Part D plans if necessary, or enroll in a Part D plan if they are eligible. But under the Secretary's policy of failing to require timely, adequate notice, class members are virtually certain to be wrongly denied Part D coverage and lower financial liability that they could have otherwise obtained. They are denied an opportunity to prevent those deprivations or to make an informed decision about how to proceed.

137. Adequate, timely notice would also allow class members to make other arrangements to receive the drug, such as through a manufacturer's patient assistance program (as Ms. K. did, only *after* she incurred significant financial liability), or they could discuss

[15] https://www.kff.org/medicare/issue-brief/how-medicares-new-drug-price-negotiation-program-could-expand-access-to-selected-drugs/#.

alternative medications with their prescribing physician. *Cf. Gray Panthers v. Schweiker*, 652 F.2d 146, 172 n.55 (D.C. Cir. 1980) ("[W]e suspect that if a more helpful and thorough notice of the basis for denial were provided, many disputes could be resolved at an earlier stage."). Advance notice would also allow disabled subclass members to invoke their rights under the Rehabilitation Act.

138. Plaintiffs and class members have an interest in Medicare coverage of their required medications that is subject to due process protection under the Fifth Amendment.

139. "It is universally agreed that adequate notice lies at the heart of due process." *Gray Panthers*, 652 F.2d at 168. Due process requires that notice be granted "at a meaningful time and in a meaningful manner." *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)). Under the Secretary's policy and practices, class members receive neither timely nor meaningful notice.

140. Individuals facing the deprivation of a property interest must be timely informed of the government's reason for the denial so that they can determine how to respond. *Gray Panthers*, 652 F.2d at 168-69. In this case, Plaintiffs and class members are not even aware of the existence of a denial, let alone the reason for it, until it is too late for them to adjust their actions and responses accordingly.

**INADEQUACY OF REMEDY AT LAW AND PROPRIETY OF ISSUANCE OF A WRIT OF MANDAMUS**

141. Plaintiffs and class members are suffering irreparable injury by reason of the Secretary's actions complained of herein. They are deprived of adequate, timely notice of changes in the Medicare coverage terms of drugs they require, and Medicare holds them financially liable for receiving those drugs as incident to a practitioner's service once Medicare determines that the drugs are "usually self-administered by the patient," even when they have received no notice of the change in coverage terms. Disabled subclass members face greater barriers to accessing required drugs on account of their disabilities and are deprived of a reasonable modification that would offer continued coverage of administration of their required

medications by a qualified health care professional. Plaintiffs' and class members' mental and physical health, their safety, and their finances are harmed by the policies and practices of the Secretary.

142. Plaintiffs and 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 class members.

143. Plaintiffs and 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 Medicare. The Secretary has a plainly defined and nondiscretionary duty to provide the relief that Plaintiffs and class members seek.

**FIRST CAUSE OF ACTION**
**Violation of Due Process**

144. Plaintiffs re-allege and incorporate herein by reference each and every allegation and paragraph set forth previously.

145. The Secretary's failure to ensure that timely, adequate notice is provided to Plaintiffs' and class members when a Part B medication they have been furnished is added to the SAD List, and failure to waive Plaintiffs' and class members' liability for any such medications they receive prior to receiving adequate notice, violates rights guaranteed by the Fifth Amendment Due Process Clause.

**SECOND CAUSE OF ACTION**
**Violation of Medicare Act and Regulations: Waiver of Liability**

146. Plaintiffs re-allege and incorporate herein by reference each and every allegation and paragraph set forth previously.

147. The Secretary's failure to waive Plaintiffs' and class members' liability for Part B drugs that were or are added to the SAD List, when they did not know and could not reasonably have been expected to know that Part B would not cover the drugs, violates 42 U.S.C. § 1395pp and 42 C.F.R. §§ 411.400-411.402.

**THIRD CAUSE OF ACTION:**
**Violation of Section 504 of the Rehabilitation Act and Regulations**

148. Plaintiffs re-allege and incorporate herein by reference each and every allegation and paragraph set forth previously.

149. Plaintiff Beitzel and subclass members are qualified individuals with disabilities within the meaning of the Rehabilitation Act. 29 U.S.C. § 794(a); 45 C.F.R. § 85.21(a). The Medicare program is carried out by federal executive agency.

150. The Secretary's policies, practices, and methods of administration described herein subject Plaintiff Beitzel and subclass members to discrimination on the basis of disability in violation of the Rehabilitation Act and its implementing regulations. They are deprived of meaningful access to their Medicare benefits. 29 U.S.C. § 794(a); 45 C.F.R. §§ 85.21(a), 85.21(b)(1), 85.21(b)(3).

**REQUEST FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request that this Court:

1. Assume jurisdiction over this action;
2. Certify at an appropriate time that this case may proceed as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(2).
3. Declare that the Secretary's policies, practices, and procedures alleged herein, including failure to ensure provision of timely, adequate notice to Plaintiffs and class members when a Part B medication they receive is added to the SAD List, failure to waive their liability for any such medications they receive prior to receiving adequate notice, and failure to clarify and reasonably modify the program to ensure that disabled subclass members can continue to receive Medicare-covered administration of their required drugs by qualified health care professionals violates their rights under the Fifth Amendment Due Process Clause, the Medicare Act, and Section 504 of the Rehabilitation Act.

4. Issue a permanent injunction requiring the Secretary to comply with the Fifth Amendment Due Process Clause, the Medicare Act, and Section 504 of the Rehabilitation Act by:

   a. Ensuring that timely, adequate notice is provided when a Part B is added to the SAD List;

   b. Waiving the liability of Plaintiffs and class members for Part B medications they received or receive as incident to a practitioner's service after the drug was added to the SAD List but before they received adequate notice of the change in coverage terms; and,

   c. Clarifying and reasonably modifying the Medicare program to ensure that Plaintiff Beitzel and subclass members can continue to receive Medicare-covered administration of SAD List drugs they require by a qualified health care professional.

5. Award reasonable attorneys' fees and costs;

6. Grant such other and further relief as the Court deems to be just and equitable.

DATED: December 26, 2023

Respectfully submitted,

By: */s/Alice Bers*

Alice Bers *(pro hac vice)*
Justin Lalor *(pro hac vice)*
CENTER FOR MEDICARE ADVOCACY
P.O. Box 350
Willimantic, CT 06226
(860) 456-7790
abers@medicareadvocacy.org
jlalor@medicareadvocacy.org

Melissa C. Brown (State Bar No. 110292)
COMMUNITY LEGAL SERVICES
McGEORGE SCHOOL OF LAW
3200 Fifth Ave.
Sacramento, CA 95817
(916) 739-7378
mbrown1@pacific.edu

*Attorneys for Plaintiffs*

**CERTIFICATE OF SERVICE**

I hereby certify that on December 26, 2023, I electronically filed the foregoing First Amended Class Action Complaint for Declaratory and Injunctive Relief with the Clerk of Court by using the CM/ECF system, which will send a notification of electronic filing to all parties.

*/s/Alice Bers*
Alice Bers
Center for Medicare Advocacy