UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COMMUNITY ONCOLOGY ALLIANCE, INC., 1634 I Street NW, Suite 1200 Washington, DC 20006 Plaintiff, v. OFFICE OF MANAGEMENT AND BUDGET, 725 17th Street, NW Washington, DC 20503; MICK MULVANEY, Director of the Office of Management and Budget, in his representative capacity, 725 17th Street, NW Washington, DC 20503; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W. Washington, DC 20201; and ALEX M. AZAR II, Secretary of the U.S. Department of Health and Human Services, in his representative capacity, 200 Independence Avenue, S.W. Washington, DC 20201 Defendants.	Civil Action No.

COMPLAINT

Plaintiff Community Oncology Alliance, Inc. ("COA"), hereby files this Complaint against Defendants Office of Management and Budget ("OMB"), Mick Mulvaney, in his representative capacity ("Director Mulvaney"), United States Department of Health and Human Services

("HHS"), and Alex M. Azar II, in his representative capacity ("Secretary Azar") (OMB, Director Mulvaney, HHS, and Secretary Azar collectively referred to herein as "Defendants"), seeking declaratory and injunctive relief for constitutional violations pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, 2 U.S.C. § 922(a)(2) ("Balanced Budget Act").

PRELIMINARY STATEMENT

This Complaint seeks a declaratory judgment and injunctive relief to stop Defendants' ongoing constitutional violations. Beginning on April 1, 2013, Defendants (through actions commenced during the predecessor administration) have applied a 2% capped cut to the reimbursement or payment for drugs, including oncology drugs ("Part B drugs"), payable under Part B of Title XVIII of the Social Security Act of 1935, as amended ("Medicare Part B"), ostensibly pursuant to the sequestration trigger contained in the Budget Control Act of 2011 ("BCA"), which amended the Balanced Budget Act. The sequestration has been extended multiple times, with the recent Bipartisan Budget Act of 2018 (the "2018 Budget Act") extending the sequestration another two years, which will now last through 2027.

In applying the sequestration to Part B drugs, Defendants violated, and are continuing to violate, the separation-of-powers doctrine essential to our government's constitutional structure. The Medicare Modernization Act of 2003 ("MMA") provides an express statutory formula by which Medicare Part B outpatient providers or suppliers (not including hospitals) are to be paid or reimbursed for Part B drugs. By applying the sequestration to Part B drugs, Defendants have invaded the legislative sphere by effectively amending the MMA. Irrespective of whether Congress intended to give the Executive Branch that authority, it is a clear constitutional violation of the Presentment Clause (Article I, Sec. 7), which provides, in essence, that the Executive Branch cannot alter duly enacted legislation under the guise of executing the laws. Putting that aside, the

Balanced Budget Act provides for the ability of the Executive Branch to sequester up to 2% of funds for a BCA sequestration for Medicare Part B "services," but it does not provide the same authority for Part B drugs and does not contain any express language indicating an intent that a sequestration can be applied to alter the MMA's statutory formula.

Defendants' acts jeopardize cancer patients, as well as their community oncology healthcare providers, because these patients are being forced to receive their treatment in more expensive hospital settings rather than in more affordable independent community oncology practices. These wrongful acts also compromise access to cancer care for patients who cannot find or afford treatment when their local community oncology practice is forced to shut down or combine with or join a more expensive hospital. And these dire consequences, which are being felt now, are being extended yet again. The sequestration has been extended four times already (and there is no telling whether these ad hoc extensions will be continued indefinitely). This unconstitutional practice must be stopped or else community and rural oncology practices will continue to close and cancer patients will continue to suffer.

THE PARTIES

1. COA is a non-profit corporation incorporated under the laws of Tennessee and has a principal place of business located at 1634 I Street NW, Suite 1200, Washington, DC 20006.

2. OMB is an Executive Branch agency tasked with implementing Executive Branch policies and orders and has a principal place of business located at 725 17th Street, NW, Washington, DC 20503.

3. Director Mulvaney is the current OMB Director and has a principal place of business located at 725 17th Street, NW, Washington, DC 20503.

4. HHS is an Executive Branch agency that oversees federal programs affecting essential health and human services and has a principal place of business located at 200 Independence Avenue, S.W., Washington, DC 20201.

5. Secretary Azar is the current HHS Secretary and has a principal place of business located at 200 Independence Avenue, S.W., Washington, DC 20201.

JURISDICTION, VENUE, AND STANDING

6. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 because the suit arises under both the Constitution and the laws of the United States.

7. Venue is proper in the United States District Court for the District of Columbia pursuant to 28 U.S.C. § 1391, because this is the judicial district in which Defendants reside and/or the judicial district in which a substantial part of the events giving rise to the claims occurred. Venue is also proper under 2 U.S.C. § 922(a) (2), because this is a constitutional challenge.

8. COA has standing to bring this suit through the doctrine of associational standing because its members are "person[s] adversely affected" by Defendants' actions taken under Balanced Budget Act, and COA seeks declaratory and injunctive relief "concerning the constitutionality" of those actions. *See* 2 U.S.C. § 922(a)(2).

9. First, COA's members would otherwise have standing to sue in their own right. COA represents more than 5,000 healthcare providers who are independent, community-based oncologists. *See* Affidavit from COA Executive Director Ted Okon ("Okon Affidavit") ¶ 3, attached hereto as **Exhibit "A"**; *see also* COA, *Membership*, available at https://www.communityoncology.org/home/coa-membership/membership-information.

10. Second, COA seeks to protect interests that are germane to COA's purpose, which is to "ensure that cancer patients receive quality, affordable, and accessible cancer care in their

own communities." COA, *Who We Are*, available at *https://www.communityoncology.org/home/about-us*; *see also* Okon Affidavit at ¶¶ 4-6; Leavitt Partners, *Cancer Treatment Costs Are Consistently Lower in the Community Setting Versus the Hospital Outpatient Department: A Systematic Review of the Evidence* ("Leavitt Report"), a true and correct copy of which is attached hereto as **Exhibit "B."** COA brings this suit to stop the impermissible reduction in reimbursement for Part B drugs and the consequent destructive effects that threaten cancer patients from being able to obtain affordable cancer care in their own communities. *See* Ex. A, Okon Affidavit, at ¶¶ 7-12; *see also* April 19, 2013 Letter from Congress to Centers for Medicare and Medicaid Services ("4/19/13 Letter from Congress"), a true and correct copy of which is attached hereto as **Exhibit "C."** Defendants' actions in reducing reimbursement for Part B drugs through the sequestration process are having a deleterious effect on community-based oncology practices and driving oncology treatment to the more expensive hospital setting, which injures both cancer patients and their community-based practitioners. *See* Ex. A, Okon Affidavit, at ¶ 7; *see also* Ex. C, 4/19/13 Letter from Congress; August 2, 2017 Letter from COA to Hon. Tom Price, MD ("COA-Price Letter"), a true and correct copy of which is attached hereto as **Exhibit "D"**; October 4, 2016 COA Practice Impact Report ("COA 2016 Impact Report"), a true and correct copy of which is attached hereto as **Exhibit "E."** Stopping the impermissible sequestration cuts for Part B drugs would limit the flight of oncology treatment to more expensive hospital settings. Ex. A, Okon Affidavit, at ¶ 12; Ex. D, COA-Price Letter, at 2.

11. Third, this action seeks declaratory and injunctive relief only, which the Circuit Court for the District of Columbia recognizes is the type of relief that does not require the participation of individual members in the lawsuit.

FACTUAL BACKGROUND

A. *Medicare Part B Provides Separate Reimbursement Methods for Physician Services and Drugs*

12. Medicare Part B governs reimbursement or payment for certain physician services and supplies considered medically necessary to treat a disease or condition. *See* Medicare.gov, *What Part B Covers*, available at https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html.

13. Professional medical services rendered by physicians participating in Medicare are reimbursed at the lesser of either: (a) the actual service charge; or (b) the fee schedule established by the Centers for Medicare and Medicaid Services ("CMS") under the authority provided in 42 U.S.C. § 1395W-4 (subject to exceptions). *See* COA, *The Medicare Sequester Cut to Part B Cancer Drugs* ("COA Sequestration Summary"), a true and correct copy of which is attached hereto as **Exhibit "F".**

14. In addition, under the Medicare Part B program, patients are entitled to receive certain prescription drugs as a covered benefit pursuant to 42 U.S.C. § 1395k, and participating providers are entitled to bill for these drugs pursuant to 42 U.S.C. § 1395u(o)(1). In the community-based oncology setting, they are typically infusible drugs and other drugs administered in a physician-office setting to treat cancer patients. *See* Anna Azvolinsky, *U.S. Cancer Organizations Say Medicare Cuts Will Negatively Impact Cancer Patients*, Apr. 29, 2013, available at http://www.physicianspractice.com/practice-management/us-cancer-organizations-say-medicare-cuts-will-negatively-impact-cancer-patients.

15. Medicare Part B drugs are reimbursed through a different method than professional medical services. As opposed to the reimbursement for professional medical services, the

reimbursement method for Medicare Part B drugs is fixed by the express formula contained in the MMA. *See* Ex. F, COA Sequestration Summary. Under 42 U.S.C. § 1395u(o)(1), the amount payable for such drugs furnished on or after January 1, 2005, is determined pursuant to, among other sections, 42 U.S.C. § 1395w-3a (b), which provides in pertinent part:

> (b) PAYMENT AMOUNT
>
> (1) IN GENERAL
>
> Subject to paragraph (7) and subsections (d)(3)(C) and (e) of this section, the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—
>
> (A) in the case of a multiple source drug (as defined in subsection (c)(6)(C) of this section), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;
>
> (B) in the case of a single source drug or biological (as defined in subsection (c) (6) (D) of this section), 106 percent of the amount determined under paragraph (4); or
>
> (C) in the case of a biosimilar biological product (as defined in subsection (c) (6) (H)), the amount determined under paragraph (8).

16. Under this statutory formula, payment for Part B drugs, such as oncological drugs, is equal to the "average sale price" ("ASP") for the drugs plus 6%. 42 U.S.C. § 1395w-3a (b); *see also* 4/19/13 Letter from Congress.

B. *Balanced Budget Act and BCA Sequestration Provisions*

17. The Balanced Budget Act was created to cut the federal budget deficit, with the aim of balancing the budget by 1991. To help achieve the intended goal, the Balanced Budget Act created the sequestration device in the event that certain spending exceeded the established thresholds for the fiscal year.

18. A sequestration calls for automatic spending cuts for certain budgetary items and is defined in the statute as a permanent "cancellation of budgetary resources provided by discretionary appropriations or direct spending law." *See* 2 U.S.C. §§ 900(c) (2), 906(k).

19. The BCA amended the Balanced Budget Act and provided for additional debt reduction procedures, including sequestration, to extend until 2021, with the goal of achieving a $1.2 trillion deficit reduction. 2 U.S.C. § 901a(1). The BCA provides the Executive Branch the ability to sequester both non-exempt defense and non-defense discretionary or direct spending funds. 2 U.S.C. § 901a (3)-(4). The recent 2018 Budget Act extends sequestration for an extra term, which now expires in 2027 (which is the fourth extension enacted thus far).

20. Under the BCA, OMB calculates and prepares the proposed sequestration for the President to then order. *See* 2 U.S.C. § 901a (5)-(6). The sequestration is then applied through the various Executive Branch agencies. *See* January 14, 2013, OMB Memorandum for the Heads of Executive Departments and Agencies ("1/14/13 OMB Memo"), a true and correct copy of which is attached hereto as **Exhibit "G."**

21. As originally drafted, the Balanced Budget Act capped the potential sequestration cut amount at 4% for any Medicare sequestration. *See* 2 U.S.C. § 906(d)(2). The BCA amended this limitation for cuts made pursuant to the BCA so that sequestration for non-exempt Medicare programs cannot exceed 2%. *See* 2 U.S.C. § 901a(6)(A).

22. The Balanced Budget Act, as amended by the BCA, provides for "Special rules for Medicare Program." 2 U.S.C. § 906(d), that states in relevant part:

(d) Special rules for Medicare program.

(1) Calculation of reduction in payment amounts.

To achieve the total percentage reduction in those programs required by sections 252 or 253 [2 U.S.C. § 902 or 903], subject to paragraph

> (2), and notwithstanding section 710 of the Social Security Act [42 U.S.C. § 911], OMB shall determine, and the applicable Presidential order under section 254 [2 U.S.C. § 904] shall implement, the percentage reduction that shall apply, with respect to the health insurance programs under title XVIII of the Social Security [42 U.S.C. §§ 1395.] –
>
> > (A) ***in the case of parts A and B of such title*** [42 U.S.C. §§ 1395c *et seq*. and 1395j *et seq*.], to individuals payments ***for services*** furnished during the one-year period beginning on the first day of the first month beginning after the date the order is issued (or, if later, the date specified in paragraph (4)); . . . .

42 U.S.C. 906(d)(1)(A) (emphasis added).

23. While the Balanced Budget Act provides for limitations or caps on the amount of any reduction in payment for Medicare services, it does not mandate or specify any specific percentage cut to the Medicare services. The specific amount is determined by the Executive Branch through recommendations by the OMB, not by Congress.

24. Moreover, pursuant to 42 U.S.C. 906(d)(1)(A), the Balanced Budget Act expressly permits a reduction only in payment "for services". There is no express mention of Part B drug reimbursement in this section. This exhibits Congress' intent not to interfere with the statutory reimbursement formula of ASP plus 6% for Part B drugs. *See* 42 U.S.C. § 1395w-3a(b).

25. In other sections of the Balanced Budget Act, such as those covering federally-funded student loans, Congress expressly provided guidance to the Executive Branch for applying sequestration to payment schemes set by a separate statute. *See* 2 U.S.C. § 906(b). But Congress did not do the same for Part B drugs and there is nothing suggesting that the sequestration applies to alter the ASP plus 6% formula contained in the MMA.

26. This intent not to apply the sequestration to Medicare Part B drugs is further evidenced by subsequent correspondence from Congressional members to CMS, which is

discussed below. CMS, which is an agency within HHS, is the implementing agency for the Medicare sequestration.

C. *March 1, 2013 Sequestration Order and Unconstitutional Application as to Part B Drugs*

27. On March 1, 2013, after Congress failed to reach a budget agreement, OMB issued a report on the sequestration calculations to be ordered.

28. OMB determined that "[t]he sequestration . . . requires reductions of 2.0 percent to Medicare . . . ." *See* March 1, 2013 OMB Letter to House Speaker John A. Boehner, a true and correct copy of which is attached hereto as **Exhibit "H."** Thus, OMB applied the maximum 2% sequestration allowed under Section 901a(6)(A).

29. OMB was critical of the sequestration cuts, noting that "sequestration is a blunt and indiscriminate instrument . . . and does not represent a responsible way for our Nation to achieve deficit reduction." *Id.* Even prior to March 1, 2013, OMB issued a memorandum to Executive Department Agency Heads directing the agencies to (1) "use any available flexibility to reduce operational risks and minimize impacts on the agency's core mission in service of the American people"; and (2) "identify and address operational challenges that could potentially have a significant deleterious effect on the agency's mission or otherwise raise life, safety, or health concerns." *See* Ex. G, 1/14/13 OMB Memo.

30. The cuts for Medicare payments commenced for claims with dates of services on or after April 1, 2013. *See* Ex. C, 4/19/13 Letter from Congress.

31. OMB -- through HHS/CMS -- applied the sequestration cut to Part B drugs and thereby reduced the pertinent Part B drug statutory reimbursement formula from ASP plus 6% to ASP plus 4.3%. *See* Sequestration Update: The Process and its Impact on Federal Health Programs, available at http://www.kimbell-associates.com/sequestration-update-the-process-and-

its-impact-on-federal-health-programs/. Thus, despite OMB's recognition of the dangers of sequestration and its urging to have agencies -- such as HHS/CMS -- use their discretion to minimize the dangers to the American people, the sequestration was applied indiscriminately to Part B drugs. In other words, HHS/CMS failed to use its available flexibility to direct that cuts not be applied to Part B drugs, thereby harming vulnerable cancer patients and ignoring the core mission of HHS/CMS.

32. Almost immediately after the sequestration effective date, 124 members of Congress wrote CMS to demonstrate that cutting the ASP plus 6% formula on Medicare Part B drugs was not an intended side effect of sequestration. *See* Ex. C, 4/19/13 Letter from Congress. The Congressional members -- ***including then Congressmen Mulvaney*** and Tom Price (former HHS Secretary) -- implored CMS to find "any flexibility available" to not apply the cuts to the reimbursement formula for Medicare Part B drugs. *Id.* They further stressed that "[u]nencumbered access to critical cancer medicines for Medicare beneficiaries is a top priority for us and we would like to work with you to find a path forward that does not result in cancer patients being turned away by their oncologists." *Id.*

33. After receiving an insufficient response from CMS, the Congressional members wrote to CMS seeking to address "what flexibility CMS has to implement sequestration considering the unique circumstances that surround the purchase and reimbursement of Part B drugs by medical providers." June 27, 2013 Letter from Congress to Centers for Medicare and Medicaid Services ("6/27/13 Letter from Congress"), a true and correct copy of which is attached hereto as **Exhibit "I."** No satisfactory response was provided to that letter either. *See* Ex. D, COA-Price Letter.

34. OMB or HHS does not have the authority to effectively amend through sequestration the legislatively sanctioned formula by which providers or suppliers are paid or reimbursed for Part B Drugs. The application of the 2% sequestration cut against Part B drugs is a constitutional violation of the separation-of-powers doctrine. Specifically, using the BCA's sequestration tool to reduce spending for Part B drugs constitutes a de facto amendment to the MMA's statutory formula and thereby violates the Constitution's Presentment Clause (Article I, Section 7).

35. The Presentment Clause provides that before becoming a law, a bill must pass through both the House and Senate and "be presented to the President," and "[i]f he approve he shall sign it, but if not he shall return it . . . ." U.S. Const. Art. I, § 7. The presentment requirement was considered so important to the Founders that they took effort to make sure the requirements could not be circumvented. As a result, the President is entrusted with only the limited authority in the lawmaking process to nullify ***proposed*** legislation. Under the Presentment Clause's mandate, the President (or other parts of the Executive Branch) has no authority to nullify, alter, or amend existing legislation.

36. Applied here, the Executive Branch could not alter the MMA's statutory ASP plus 6% formula even if Congress intended it to do so. It is clear, though, Congress did not intend to do so, because the BCA does not contain any express language indicating that the sequestration applied to the MMA's statutory formula. Moreover, the letters from Congress to CMS immediately after the sequestration effective date further corroborate that the statutory formula was not intended to be altered. In other words, even if reimbursement for Medicare Part B drugs could somehow be considered "services," that still does not demonstrate that the MMA's statutory ASP plus 6% formula was meant to be altered. The Balanced Budget Act does not specifically

amend or modify the separate statutory ASP plus 6% reimbursement formula contained in the MMA.

37. OMB's recommendation to the President to make the 2% cut to Medicare (and HHS/CMS' implementation), including the cut to Part B drug reimbursement, is analogous to an Executive Branch line-item veto, which has been ruled an unconstitutional invasion into the legislative sphere. By reducing the payment formula contained in the MMA, Defendants effectively amended the Medicare Part B payment provisions.

38. The MMA's statutory formula can only be amended or repealed through a duly approved bill in Congress that the President then signs into law. It cannot be amended or repealed through OMB's (or HHS/CMS') purported execution of the separate BCA, especially where the BCA itself does not address the MMA's statutory formula, and Congressional members specifically urged CMS not to apply the sequestration cut to Medicare Part B drugs.

39. Federal reimbursement payments made for Part B drugs that are calculated in a manner inconsistent with the MMA's existing ASP plus 6% formula effectively amends or alters the MMA after the effective date of the law. Congress has established a separate framework for the Medicare Part B drug payment methodology, and those provisions must not be interfered with by OMB's use of sequestration.[1]

[1] In addition, in multiple subsequent budget negotiations, other lawmakers made actual proposals to cut the MMA's statutory formula to ASP plus 3%. *See* Alex Brill, *Sequestration's Uniform Medicare Cut Will Yield Disparate Impacts Across Providers*, The Health Lawyer (June 11, 2013), available at http://www.aei.org/publication/sequestrations-uniform-medicare-cut-will-yield-disparate-impacts-across-providers. These efforts stalled. But this nonetheless evidences that Congress understands that a reduction to the statutory MMA rate can only be achieved through new legislation, and not by actions of the Executive Branch. Sequestration, therefore, is being used as an impermissible end-run around the proper legislative process.

40. In 2015, the 2% cap on sequestration reductions to Medicare were extended until 2025 through the Bipartisan Budget Act. On February 9, 2018, the sequestration was extended (for the fourth time) another two years through the Bipartisan Budget Act of 2018, which means the sequestration will be applied against Part B drugs through 2027 unless stopped.[2]

D. ***Sequestration Cuts to Medicare Part B Drug Reimbursement Causes Irreparable Harm***

41. Applying the BCA sequestration cut to Medicare Part B drug reimbursement has had a harmful and expensive impact on cancer patients, the Medicare program, and all taxpayers. *See* COA-Price Letter; *see also* COA 2016 Impact Report; 2018 Community Oncology Alliance Practice Impact Report ("COA 2018 Impact Report"), attached hereto as **Exhibit "J**." Certain Congressional members themselves -- including then Congressman Mulvaney -- recognized immediately that OMB's 2% sequestration cut to Medicare Part B drugs endangered Medicare cancer patients. *See* Ex. C, 4/19/13 Letter. That prediction was accurate.

42. More than 60% of cancer patients in the United States rely solely on Medicare, and, prior to the sequestration, more than 80% of cancer patients overall were treated in community-based settings. *See* April 1, 2013 Letter from American Society of Clinical Oncology to U.S. Dep't of Health and Human Services ("ASCO Letter"), attached hereto as **Exhibit "K."**

[2] In addition, the Statutory Pay-As-You-Go Act of 2010 was nearly triggered when Congress passed its tax bill in December 2017. The projected deficit increase threatened to cause Defendants to issue a PAYGO sequestration order. The PAYGO sequestration was ultimately avoided. But the point being further cuts loom over community oncology practices and their patients due to the current fiscal climate. Further proof of that is the President's new policy proposal to cut the premium above average wholesale price for new Part B drugs. The declaration that COA seeks here is necessary to prevent all potential encroachments on the explicit MMA reimbursement framework through general application of spending restraints contained in various budget acts.

43. Community oncology clinics provide a more cost-efficient model than institutional sites of care for delivering high-quality cancer services to elderly Americans. *Id.*; *see also* Ex. B, Leavitt Report, at 6-7.

44. The lower reimbursements for cancer drugs are causing a shift from the primary treatment of cancer being in local, independent community practices to the more expensive institutional or hospital setting, which increases costs to both Medicare and beneficiaries. *See* Ex. E, COA 2016 Impact Report; Ex. J, COA 2018 Impact Report.

45. These cuts are also causing community cancer practices to close in alarming numbers. *See* Ex. J, COA 2018 Impact Report. Since the effective date of the sequestration, approximately 135 community cancer clinics have been forced to close their doors and approximately 190 clinics have been acquired by hospitals. *Id.* Hospitals continue to acquire physician-owned clinics and shut down the least profitable, particularly in rural areas. *Id*. Oncology practice closures have occurred in numerous states, including Florida, Texas, and Michigan. *Id.*

46. Based upon the COA 2018 Impact Report, over the last decade, 1,653 community oncology clinics and/or practices have closed, been acquired by hospitals, undergone corporate mergers, or reported that they are struggling financially. An average of 3.5 community oncology practices have closed per month, a rate that remains unchanged since the last report issued in 2016. Overall, based upon this report, 13.8 practices per month have closed, been acquired by hospitals, or undergone mergers since 2008. *See* Ex. J, COA 2018 Impact Report.

47. To make matters worse, these negative impacts combine with negative impacts to community oncology practices that are felt through Part B's 340B program. That is another program that favors hospitals over independent oncology clinics, which combines with the

sequestration order to create a double whammy for community oncology. *See* Ex. A, Okon Affidavit.

48. This dramatic shift in cancer treatment threatens to compromise care for all Medicare cancer patients, and threatens most acutely the vulnerable population of elderly cancer patients (as well as those in low-income urban and rural areas). *See id.*; *see also* B.J. Drye, *Ellmers Reintroduces Bill to Care for Cancer Patients*, Mar. 18, 2015, available at http://www.thesnaponline.com/news/ellmers-reintroduces-bill-to-care-for-cancer-patients/article_66b628c4-cdb0-11e4-93bd-8f865f2d6535.html. ("According to the report, 'for more than 59 million Americans living in rural areas, a diagnosis of cancer can present unique challenges to obtaining high-quality care for their disease, including long travel distances and decreased access to specialist, and state-of-the-art diagnostics, treatments and technologies.'").

49. It also threatens to further destabilize the already strained Medicare reimbursement system. *See* Ex. K, ASCO Letter. An actuarial firm has conducted a study that estimates that the consolidation of community oncology practices into the more expensive hospital setting cost Medicare at least $2 billion in 2014 alone. *See* Ex. F, COA Sequestration Summary (citing Milliman, *Cost Drivers of Cancer Care*). Extrapolating from that estimate, it also cost Medicare beneficiaries an increased $500 million in co-pay payments.

50. The longer this unconstitutional practice is allowed to continue, the greater the harm will become for cancer patients, the ability of oncologists to provide such patient care in a community setting and to the Medicare program as a whole.

COUNT I – DECLARATORY RELIEF

51. COA incorporates its allegations in Paragraphs 1-50 as if set forth at length herein.

52. COA is entitled to bring this action pursuant to the Balanced Budget Act, 2 U.S.C. § 922(a) (2), on behalf of its members, who are adversely affected by Defendants' application of the 2% sequestration cut on Part B drugs.

53. Section 922(a)(2) allows an aggrieved plaintiff to bring an action for a declaratory judgment concerning the constitutionality of actions taken under the Balanced Budget Act.

54. Defendants' use of the sequestration order to amend the MMA's express statutory reimbursement formula for Part B drugs violates the Constitution's Presentment Clause (Article I, Section 7). The Presentment Clause provides that before becoming a law, a bill must pass through both the House and Senate and "be presented to the President," and "[i]f he approve he shall sign it, but if not he shall return it . . . ." U.S. Const. Art. I, § 7.

55. Defendants' application of the sequestration order to Medicare Part B drugs has effectively amended or altered the separate statutory reimbursement formula contained in the MMA. Defendants, in other words, caused an existing statute to be amended and altered outside of the normal lawmaking process.

56. The sequestration order as applied to Medicare Part B drugs, which is tantamount to an executive legislation drafting, represents a separation-of-powers violation by the Executive Branch, providing for Defendants' intrusion into Congress' legislative sphere.

WHEREFORE, COA respectfully requests a declaratory judgment be entered declaring Defendants' conduct to be unconstitutional and declaring that the application of the sequestration to Medicare Part B drugs that was made effective April 1, 2013, is invalid and that the sequestration cannot be applied to alter the MMA's statutory ASP plus 6% formula for reimbursement of Medicare Part B drugs.

COUNT II – PERMANENT INJUNCTION

57. COA incorporates its allegations in Paragraphs 1-56 as if set forth at length herein.

58. COA is entitled to bring this action pursuant to the Balanced Budget Act, 2 U.S.C. § 922(a) (2), on behalf of its members, who are adversely affected by Defendants' application of the 2% sequestration reduction on Part B drugs.

59. Section 922(a)(2) allows an aggrieved plaintiff to bring an action for injunctive relief concerning the constitutionality of actions taken under the Balanced Budget Act.

60. COA's members have experienced irreparable harm and will continue to do so until Defendants' unconstitutional actions are stopped. Cancer patients are losing their access to affordable oncological treatment in a community setting and, instead, are being forced to shift to the more expensive hospital-based setting. And community-based cancer practices are jeopardized by the application of the sequestration.

61. Monetary damages are inadequate to compensate for the loss (or potential loss) of community-based oncology practices.

62. The balance of hardships favors COA, especially considering that sequestration has resulted in movement of cancer care into the hospital setting, which is estimated to cost the Medicare program billions of dollars more.

63. The public interest would be served by a permanent injunction.

WHEREFORE, COA respectfully requests a permanent injunction ordering Defendants to immediately cease application of any sequestration to Part B drugs.

Respectfully submitted,

BLANK ROME LLP

Alan M. Freeman (Bar ID No. 454693)
Negar M. Kordestani (Bar ID No. 1028627)
1825 Eye Street NW
Washington, D.C. 20006
(202) 772-5925/420-2579 (phone)
(202) 572-8370/379-9126 (fax)
freeman@blankrome.com
nkordestani@blankrome.com

-and-

Laurence S. Shtasel (to be admitted *pro hac*)
William E. Gramlich (to be admitted *pro hac*)
Jaret N. Gronczewski (to be admitted *pro hac*)
One Logan Square
Philadelphia, Pennsylvania 19103
(215) 569-5691 (phone)
(215) 832-5691 (fax)
shtasel@blankrome.com
gramlich@blankrome.com
gronczewski@blankrome.com

Attorneys for Plaintiff Community Oncology Alliance, Inc.

Dated: May 30, 2018