The Community Oncology Alliance (COA) is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to community oncology where the majority of Americans with cancer are treated. The mission of COA is to ensure that cancer patients receive quality, affordable, and accessible cancer care in their own communities. For more than 15 years, COA has built a national grassroots network of community oncology practices to advocate for public policies that benefit patients.

As the front-line providers for the majority of Americans with cancer, we understand better than anyone the realities and problems of the increasing cost of cancer care. For five years, COA has been working with Medicare and private insurers in advancing real payment reform in cancer care. Seven community oncology clinics participated in the Centers for Medicare & Medicaid Innovation (CMMI) COME HOME project based on the patient-centered Oncology Medical Home (OMH) model that community oncologists created and continue to advance. We also currently host close to eighty percent (80%) of the CMMI Oncology Care Model (OCM) participants in a network cooperative to ensure the success of that model. This is helping shape our work on what we call the “OCM 2.0,” an advanced model with single-sided and double-sided risk, which will incorporate concepts related to testing value-based drug payment models.

Additionally, many community oncology practices also engage in numerous payment reform projects with private payers, including Aetna, Anthem, Cigna, Horizon, Humana, Priority, and UnitedHealthcare, to name a few. These projects are producing impressive results in both enhancing the quality of cancer care and reducing costs. During the past three years, we have also held major summits where literally thousands of providers, payers, and industry representatives have come together to discuss oncology payment reform projects in the field and to share ideas in an open, cooperative, information exchange forum.
As can be clearly seen, community oncology and COA are leading progress in tackling the increasing costs of cancer care. In doing so, we are using data, market facts, and the real-world medical experience of physicians, nurses, administrators, and others on the front lines of cancer care to craft viable, patient-centric solutions.

As the Centers for Medicare & Medicaid Services (CMS) is looking to finalize policies for calendar year 2018, the second performance year of the Quality Payment Program (QPP), we have some concerns and seek clarification on select items delineated in the QPP Proposed Rule. Generally, COA is interested in:

- How best to navigate flexibility in QPP, especially for those currently in a Merit-based Incentive Payment System (MIPS) model or an Alternative Payment Model (APM), such as the OCM.
- How community oncology practices, not currently a part of an APM or an Advanced Alternative Payment Model (AAPM), are able to adjust to the MIPS requirements for CY 2019, including cost and resource measures.
- The potential inclusion of Medicare Part B drug costs into the MIPS adjustment.

Our specific comments on the QPP Proposed Rule follow.

I. Potential Inclusion of Part B Drug Costs to MIPS Adjustment Based on the Performance Period or for Eligibility Determinations

a. **Issue:** CMS notes that, “for Part B items and services furnished by a MIPS eligible clinician such as purchasing and administering Part B drugs that are billed by the MIPS eligible clinician, such items and services may be subject to MIPS adjustment based on the MIPS eligible clinician’s performance during the applicable performance period or included for eligibility determinations. For those billed Medicare Part B allowable charges relating to the purchasing or administration of Part B drugs that we are able to associate with a MIPS eligible clinician at an NPI level, such items and services furnished by the MIPS eligible clinician would be included for purposes of applying the MIPS payment adjustment or making eligibility determinations.”

**Concern:** COA is extremely concerned by what appears to be a change in previous policy around adjustments to physician payments for MIPS. In prior communication, CMS has indicated that while drug cost could be included in various MIPS measures, payment adjustments would be applied only to professional services, not Part B drugs or DME. COA has serious concerns about the application of payment adjustments to Part B drug costs, counter to CMS’s previously stated position on the issue, and the potential impact on providers and patient access to therapy. This is additionally concerning given that CMS notes areas where this is not operationally feasible, and therefore the potential of including Part B drug costs in the provider adjustment may disproportionately impact certain providers as compared to others.

To assess the potential impact of this policy change, COA queried data provided in the CY 2015 Physician and Other Supplier NPI Aggregate File. This revealed that hematology/oncology would be disproportionately affected by this policy, as their drug reimbursement may constitute seventy-one percent (71%) (aggregate) of their part B payments.

Most fundamentally, based on extensive legal research, COA contends that any change to Medicare Part B reimbursement is illegal and unconstitutional. This is because Medicare Part B drug reimbursement is specifically fixed in statute as Average Sales Price (ASP) plus six percent (6%). We cite the attached document we previously sent to you and Health and Human Services Secretary Price on why the Obama Administration’s application of the sequester cut to Part B drug reimbursement was illegal and unconstitutional.

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1 P. 37.
unconstitutional, and still remains so today. If Medicare Part B reimbursement is to be changed from the current statutorily-defined ASP + six percent (6%), then Congress must pass legislation amending the current statute – the Medicare Modernization Act of 2003 – and the President must sign it into law. Until such time, Medicare Part B reimbursement must remain at ASP + six percent (6%), which prohibits CMS from changing it per the QPP Proposed Rule. Additionally, we note for the record, that CMS must stop the application of the sequester cut to Part B drug reimbursement.

b. Issue: CMS states that “there may be circumstances in which it is not operationally feasible for us to attribute those items or services to a MIPS eligible clinician at an NPI level in order to include them for purposes of applying the MIPS payment adjustment or making eligibility determinations.”

Concern: COA is concerned that this inability to operationally attribute items and services to an eligible clinician National Provider Identifier (NPI) speaks to situations where the Part B drug is dispensed, administered, or billed by a different provider. It creates an arbitrary situation where a MIPS-eligible clinician has no idea whether his/her items or services will be included in the MIPS calculation, the relationship between the quality of the care provided, its cost, and the merit increase or decrease. This is bad enough with potential reimbursement cuts to services but will be devastating to community oncology practices experiencing reimbursement cuts to drugs.

We note that Part B drug reimbursement cuts have already led to the consolidation of cancer care from independent community cancer clinics into the more expensive hospital setting. Indeed, the shift in cancer care that has already taken place has been documented as increasing costs to Medicare. In 2014 alone – just one year – Milliman found that this shift cost Medicare $2 billion more than it would have had the site-of-service remained in the community practice setting. Obviously, an increased cost to Medicare has a corresponding increase to Medicare beneficiaries, who are responsible for a twenty percent (20%) copayment of Medicare’s cost.

II. Small Practices: Low Volume Threshold and Hardship Exemptions

a. Issue: CMS notes in the QPP Proposed Rule that they have heard from many small practices that challenges still exist in their ability to participate in the program and, therefore, are proposing additional flexibilities including: implementing the virtual groups provision; increasing the low-volume threshold to less than or equal to $90,000 in Medicare Part B allowable charges or less than or equal to two hundred (200) Medicare Part B patients (previously, set at $30,000 in allowable charges and less than or equal to one hundred (100) Medicare Part B patients); adding a significant hardship exception for the advancing care information performance category; and providing bonus points that are added to the final score of MIPS eligible clinicians who are in small practices.

Concern: COA appreciates that CMS updated the threshold to meet physician needs, but we recommend that the agency provide more transparency in the assessment process and how the threshold will be viewed in future years.

III. Modification of the Definition of a Hospital-Based MIPS Eligible Clinician

a. Issue: CMS is proposing to modify the policy around hospital-based MIPS eligible clinicians. Under the CY 2017 final rule, CMS defined a hospital-based MIPS eligible clinician as a “MIPS eligible clinician who furnishes seventy-five percent (75%) or more of his or her covered professional services in sites-of-service identified by the Place of Service codes used in the HIPAA standard transaction as an inpatient.

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2 P. 36-37.
3 Cost Drivers of Cancer Care: A Retrospective Analyses of Medicare and Commercially Insured Population Claim Data 2004-2014, Milliman, April 2016.
4 P. 15.
hospital, on campus outpatient hospital, or emergency room setting based on claims for a period prior to
the performance period as specified.” For the CY 2018 rule, CMS is proposing to modify the policy to
include covered professional services furnished by MIPS eligible clinicians in an off-campus-outpatient
hospital in the definition of a MIPS eligible clinician.⁵

**Concern:** We are supportive of these efforts to be inclusive in defining a MIPS eligible clinician. However, we express concerns regarding the potential for such actions to unintentionally encourage consolidation and further drive physicians to practice in the higher cost hospital settings.

### IV. Weight of the Cost Performance Measure

a. **Issue:** For CY 2018, CMS is proposing no changes to the weights (Quality, ACI, IA, Cost) from 2017, with cost performance weighted at zero percent (0%) again, even though statute requires a weight of thirty percent (30%) for the cost performance category by the 2021 payment year, which cannot be waived. CMS is seeking feedback on alternative approaches to weighting cost for 2018 to avoid such a large shift in the 2019 performance period, including weighting the cost category at ten percent (10%) in 2018.⁶

b. **Recommendation:** We are very concerned about cost performance and therefore, its weighting. Our concern is with the **accurate** attribution of costs to individual providers. As such, we believe that CMS needs to more carefully analyze cost performance and its accuracy, leaving the cost performance weighting at zero percent (0%) for 2018. That said, we are also concerned about a sharp shift of zero to thirty percent (0-30%) and would support a move to a ten percent (10%) weight for CY 2018. We highly recommend more frequent cost measure information be made available, potentially on a quarterly or even monthly basis. We believe this information needs to be transparent and readily available for all clinicians, even those who are reporting as a group.

### V. Feedback on Cost Performance Category

a. **Issue:** In the proposed rule, CMS is collecting feedback on whether it would be helpful to provide more frequent feedback on the cost performance category using rolling 12-month periods or quarterly snapshots of the most recent 12-month period, how frequent the feedback should be, and the format in which we should make it available to clinicians and groups.⁷

**Recommendation:** We agree that the feedback should be provided more frequently and encourage the agency to do so in a transparent manner.

### VI. Quality Performance Category and Quality Measures

a. **Issue:** In the QPP Proposed Rule, CMS asks for feedback on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS patient satisfaction measures, specifically around expanding the patient experience data available, as well as modifying existing reporting mechanisms and streamlining survey vendor notification.

**Recommendation:** Options for obtaining patient satisfaction in order to qualify for MIPS should be expanded to include surveys for specialists. COA has developed and has fielded a patient satisfaction survey for the last four (4) years, with more than 100,000 completed surveys to date. This survey is very

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⁵ P. 228.
⁶ P. 24.
⁷ P. 467.
helpful in improving the patient experience in cancer care. Approximately twelve percent (12%) of all oncologists are registered and using this survey, which is available in five (5) languages, and is specifically designed to minimize the administrative and financial burden of gathering this feedback. Over fifty percent (50%) of the responses received are in an electronic format and readily available for real-time benchmarking at the physician level. In addition, one of the final requirements for an approved CMS CAHPS survey vendor is the ability to conduct calls by telephone.

We request that the agency re-review this requirement and consider a pilot period for specialty-related CAHPS measures that does not require a telephone capacity for survey vendors. Relaxing such a requirement will allow for more specialists to use the satisfaction measure which we feel is well suited for specialties, like oncology, that comprehensively care for patients. It should also be noted that retention of the telephone requirement would cause cancer patients to receive numerous calls relative to feedback as a cancer patient and is often seen by multiple providers.

In addition, CMS should refine and further strengthen the quality measure reporting requirements under MIPS and should ensure that data on the quality of care furnished by a MIPS-eligible provider is reliable, accurate, and comparable. CMS also should ensure that measures are appropriate to the MIPS-eligible providers who will be required to report them.

VII. APM Quality Measure Benchmarks and Nominal Risk Threshold for Advanced Alternative Payment Models

a. Issue: CMS is proposing to use a benchmark score for the quality measure as the benchmark used by the MIPS APM for calculation of the performance-based payments within the APM if possible, to align the measure performance outcomes between the MIPS and APM programs. If there is no benchmark score for a reportable measure, the benchmark used for the MIPS quality performance category generally for that performance year will be used.8

In addition, CMS is proposing to align all categories for MIPS across APMs (versus a different standard for ACOs). This is illustrated in the table below:

<table>
<thead>
<tr>
<th>Domain</th>
<th>SSP &amp; Next Generation ACOs</th>
<th>Another MIPS APMs</th>
<th>All MIPS APMs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
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<td>50%</td>
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<tr>
<td>Cost</td>
<td>0%</td>
<td>0%</td>
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<td>20%</td>
</tr>
<tr>
<td>Advancing Care Information</td>
<td>30%</td>
<td>75%</td>
<td>30%</td>
</tr>
</tbody>
</table>

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8 P. 254.

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**Recommendation:** We are very supportive of alignment between the various alternative payment models; however, we encourage CMS to retain flexibility in alignment that also balances each payment model’s requirements. Participants in the OCM have significant technology requirements and there is significant overlap with the Advancing Care Information (ACI) requirement. We request that for those participants, the ACI requirement would be considered fulfilled if the practice requirements are met. Below are the Practice Requirements related to health IT:

1. Attestation to the use of Certified Electronic Health Record (EHR) technology
2. Provide and attest to 24 hours a day, 7 days a week patient access to an appropriate clinician who has real-time access to practice’s medical records
3. Closing the Referral Loop: Receipt of Specialist Report
4. Documentation of Current Medications in the Medical Record
5. Significant EMR requirements for capturing clinical staging

**Concern:** An additional area of concern for the MIPS-APM category is the critical issue of overlap of a majority of the NPIs within a Tax Identification Number (TIN) and the APM entity. For example, if there are NPIs within a TIN who are not prescribing chemotherapy, they are technically not allowed to be participating providers in the OCM, and are thus subject to either reporting on MIPS as individuals or the entire TIN has to report as a group and then get MIPS scoring credit for the portions of MIPS which are dictated by the APM. For small practices this is highly inefficient and it is concerning that there is an expectation of dual reporting mechanisms.

We strongly encourage CMS to continue their theme of flexibility and consider allowing for the APM entity (which, in the case of the OCM, is the entire TIN) to be deemed out of MIPS requirements for quality and clinical improvement activities if a plurality of providers are also reporting under the MIPS-APM requirements. This will allow for administrators and practitioners to concentrate on practice transformation and better patient care rather than setting up two systems to collect MIPS requirements.

b. **Issue:** CMS is proposing to continue to use nominal risk thresholds for AAPMs eight (8%) of the average estimated Parts A and B revenue of the participating AAPM Entities through performance year 2020.

**Concern & Recommendation:** We are concerned that there is significant misalignment between the risk thresholds for nominal risk under the Medicare Access and CHIP Reauthorization Act (MACRA) and for OCM, which has a twenty percent (20%) risk threshold for the two-sided risk model and is the APM that is available for oncologists. We highly recommend that the risk thresholds be aligned for new AND existing APMs and to change the two-sided risk threshold to eight percent (8%) for the OCM. To date, not a single oncology practice has entered into two-sided risk in the OCM, which we believe is due to the abnormally high-risk threshold that is completely an outlier for any CMMI model.

VIII. Health IT Support of Feedback Related to Participation in the Quality Payment Program

a. **Issue:** CMS is seeking comment on how health IT (either EHR or as a supplemental module) could better support feedback related to QPP participation, including:

- Are there specific health IT functionalities that could contribute significantly to quality improvement?

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9 P. 469.
- Are there specific health IT functionalities that could be part of a certified EHR technology in order to support the feedback loop?
- In what other ways can health IT support clinicians seeking to leverage quality data reports to inform clinical improvement efforts?
- Are there opportunities to expand existing tracking and reporting for use by clinicians? For example, expanding the feedback loop for patient engagement tools that support remote monitoring of patient status and access to educational materials.

**Concern:** We are actively involved in the support and encouragement of cancer care teams that are involved in the OCM. We continue to hear of the high level of anxiety fed by the challenges of the model and associated expenses required to develop, enter, and extract data seemingly irrelevant to improving quality and lowering costs in cancer care. We request that considerable thought and discussion occur with leading EHR vendors before requiring new data points.

IX. **Conclusion**

COA appreciates the opportunity to comment on the QPP Proposed Rule. We look forward to continuing to work with CMS to refine the program and address the issues raised in this letter.

Sincerely,

Jeffrey Vacirca, MD

President
Why CMS Did Not Have the Authority to Apply the Sequester Cut to Medicare Part B Drug Reimbursement

The Legal and Constitutional Case

For years, the budget of the Obama Administration included a reimbursement payment cut to Medicare Part B drugs, which are generally infusible drugs to treat cancer and other complex, potentially life-threatening diseases administered in a clinical setting. However, Congress has fixed Medicare Part B drug reimbursement in statute with the Medicare Modernization Act of 2003 (the “MMA”) – and the Obama budget cut to the reimbursement of these drugs was never acted upon legislatively by Congress.

In 2013, the Obama Administration made an end-run around Congress to cut reimbursement for cancer drugs and other Part B therapies by applying the sequester cut, even though the payment rate for these drugs is legislatively fixed in statute by Congress in the MMA. This was done in much the same way that the Centers for Medicare & Medicaid Services (“CMS”) innovation center (“CMMI”) attempted to cut Part B drug reimbursement in 2016 under the guise of a national, mandatory payment “model.” That attempt failed as the outgoing Obama Administration decided to not proceed with the proposal.

During the Community Oncology Alliance’s (COA) work to stop the Obama Administration from using CMMI to end-run Congress to cut Part B drug reimbursement, it is now clear CMS did not have the legal or constitutional authority to cut Part B drug reimbursement using the sequester. As we elaborate in this paper, COA believes that applying the sequester to cut Part B drug reimbursement is not legal or constitutional and must be stopped.

A. Summary: Why CMS Does Not Have the Authority to Cut Part B Drug Reimbursement

The application of the sequestration to the provisions of the MMA that set forth the specific statutory payment methodology for Part B drugs raises several constitutional concerns. Specifically:

1) The MMA establishes, by statute, a formula for the payment of Medicare Part B drugs. In the case of most Medicare Part B drugs, the rate is the average sales price (ASP) of the drug plus six (6) percent.

2) The Budget Control Act of 2011 (the “Budget Control Act”), which amended the Balanced Budget and Emergency Deficit Control Act of 1985, establishes a mechanism for making payment reductions through a sequestration order issued by the President and prepared by the Office of Management and Budget (“OMB”). While the Budget Control Act lists specific spending programs and activities that are exempt from sequestration and provides special rules for applying sequestration to other specified programs, including federally-funded student loans and certain Medicare programs, the exemptions do not expressly apply to the Part B drug payment provisions of the MMA.

3) Congress has not chosen in the sequestration law to expressly amend the Part B drug payment provisions of the MMA. However, by applying the sequestration reductions to Medicare Part B drug reimbursement, the Executive Branch, not Congress, has effectively amended the statutory drug payment formula of the MMA from “average sales price plus six (6) percent” to “average sales price plus a factor of less than six (6) percent.”

4) The US Supreme Court, in Clinton v. City of New York (524 U.S. 417, the line item veto case), found the President’s exercise of the legislative function in amending line items in budgets and another law, unconstitutional as a violation of the Presentment Clause (of Article I of the US Constitution).
5) Thus, reducing the amount payable under the statutory formula of the MMA through sequestration is, in effect, a unilateral “amendment” of the statute by the Executive Branch, not by Congress. This is contrary to constitutional constraints of the Presentment Clause.

6) Additionally, there is precedent for OMB exercising discretion and excluding programs from sequestration that are not expressly exempt in the sequestration law. For example, OMB originally held that sequestration applied to cost-sharing subsidies of the Patient Protection and Affordable Care Act of 2010 (“ACA”). However, despite there being no specific exemption in the sequestration law, OMB changed its position and exempted these subsidies a year later. Similarly, the US Department of Health and Human Services (“HHS”) adopted a rule that delays sequestration cuts in funding for the ACA’s reinsurance and risk payments. Therefore, OMB’s precedent of creating exemptions despite the lack of clear statutory support, in addition to the potential constitutional concerns of the statutory conflict with the MMA, means that OMB can, and should, exempt Part B drug payments from sequestration.

B. Background

1) The Medicare Modernization Act

Payment under Medicare for Part B drugs is set by statute. The pertinent provisions of the MMA outline the payment mechanism for drugs covered by Medicare Part B, as follows:

(1) If a physician's supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to the following…

(C) In the case of a drug or biological that is not described in subparagraph (A) (iv), (D) (i), or (F) furnished on or after January 1, 2005, the amount provided under section 1395w-3 of this title, section 1395w-3a of this title, section 1395w-3b of this title, or section 1395rr (b) (13) of this title, as the case may be for the drug or biological.\footnote{42 U.S.C. § 1395u (o). (West 2016). \textit{Emphasis added.}}

The statutorily prescribed payment formula is set forth in Section 1395w-3a. Specifically, Section 1395w-3a 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)\footnote{Paragraph 3 defines the methodology for determining average sales prices for multiple source drugs.} 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)…\footnote{42 U.S.C. § 1395w-3a (West 2016).}
Essentially, the “amount determined” for use in the formula for such drugs, subject to special rules, is the average sales price; thus, the MMA generally sets the payment rate for such Part B drugs as the average sales price of the drug plus six (6) percent.

The Secretary of HHS has the statutory authority to adjust the method of calculating the payment rate in certain situations, such as when the Inspector General finds that the average sales price of a drug exceeds a widely available market price or average manufacturer price for the drug (42 U.S.C. § 1395w-3a (d)(3)(c)) or during public health emergencies (42 U.S.C. § 1395w-3a (e)). However, these situations apply only in limited circumstances, not generally to the statutory formula for payment.

2) Budget Control Act

The Budget Control Act amended the Balanced Budget and Emergency Deficit Control Act of 1985, 2 U.S.C. § 900 et seq. The Budget Control Act defines the authority of the Executive Branch through OMB to reduce direct spending programs, including Medicare, in the event of sequestration. Among other things, it outlines procedures for OMB (and caps reduction in Medicare programs at two (2) percent, as provided below) as follows:

(6) Implementing direct spending reductions

(A) On the date specified in paragraph (2) during each applicable year, OMB shall prepare and the President shall order a sequestration, effective upon issuance, of nonexempt direct spending to achieve the direct spending reduction calculated pursuant to paragraphs (3) and (4). When implementing the sequestration of direct spending pursuant to this paragraph, OMB shall follow the procedures specified in section 935 of this title, the exemptions specified in section 905 of this title, and the special rules specified in section 906 of this title, except that the percentage reduction for the Medicare programs specified in section 906(d) of this title shall not be more than 2 percent for a fiscal year.13

Section 906 describes the calculation of a reduction in Medicare reimbursements and grants OMB discretion to fix the exact percentage:

(d) Special rules for Medicare program

(1) Calculation of reduction in payment amounts

To achieve the total percentage reduction in those programs required by section 902 or 903 of this title, subject to paragraph (2), and notwithstanding section 710 of the Social Security Act [42 U.S.C.A. § 911], OMB shall determine, and the applicable Presidential order under section 904 of this title shall implement, the percentage reduction that shall apply, with respect to the health insurance programs under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.]—

(A) in the case of parts A and B of such title [42 U.S.C.A. §§ 1395c et seq., 1395j et seq.], to individual 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))….14

Thus, despite the fact that the MMA sets the payment rate for specified Part B drugs and does not give CMS authority to alter it, it appears that the Budget Control Act could be read to give OMB discretion to set a percentage reduction in Medicare spending.

The Balanced Budget and Emergency Deficit Control Act explicitly exempts from sequestration15, under

15 Section 251A(6) thereof provides in pertinent part:

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Sections 255\textsuperscript{16} and 256\textsuperscript{17} thereof, numerous listed federal programs and activities and imposes certain special rules as to the application of sequestration. Exempt programs include, among others, Social Security benefits, programs administered by the Department of Veterans Affairs, payments to individuals in the form of refundable tax credits, and certain designated low income programs.\textsuperscript{18}

Despite the statute’s explicit list of exemptions, OMB changed its mind at least once, as to whether sequestration applies to the ACA’s cost-sharing. In the Sequestration Preview Report, OMB initially included the ACA cost-sharing subsidies in its list of programs to be affected by the sequester, with a line in the Report showing the planned reduction in those subsidies. However, in a later Report to Congress for Fiscal Year 2015, it appears that OMB ultimately excluded the cost-sharing subsidies from the effects of the sequester, as the Report does not list the line for the applicable cost-sharing subsidies.

Additionally, agency regulations have limited the application of the sequester to the ACA’s reinsurance and cost-reduction programs. While these are subject to sequestration, a 2014 rule from HHS and CMS provides that any funds sequestered and withheld from these programs will not be cut outright, but instead will be delayed and made available for payment to issuers in the following fiscal year.\textsuperscript{19}

COA has not found any express statutory support for these exemptions or a clear rationale given by the agencies for the deferrals or exemptions. Thus, these reports show that there is, in fact, a precedent established administratively for the discretionary exclusion of certain programs from the sequesters effects.

In addition to exemptions for specific programs, Section 256 of the Balanced Budget and Emergency Deficit Control Act provides special rules for applying the sequester in the case of certain programs, including certain subsidies under Medicare Part D and federally-funded student loans. Specifically, with respect to student loan fees, the rules provide that in the event of sequestration:

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“… loan processing and issuance fees under [the Higher Education Act of 1965] shall each be increased by the uniform percentage specified in that sequestration order, and, for student loans originated during the period of the sequestration, special allowance payments under section 438(b) of that Act accruing during the period of the sequestration shall be reduced by the uniform percentage specified in that sequestration order.”\textsuperscript{20}
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Like the payment rates for Part B drugs in the MMA, these student loan fees are set by statutory formulas.\textsuperscript{21} In this case, Congress provides specific guidance to agencies for applying sequestration to payment schemes set by statute.

The special rules under Section 256 of the Balanced Budget and Emergency Deficit Control Act, also contain a provision relating to Medicare Part B. Specifically, Section 256(d)(5) of the Balanced Budget and Emergency

\textsuperscript{17}2 U.S.C. § 906. (West 2016).
\textsuperscript{18}2 U.S.C. § 905. (West 2016).
\textsuperscript{19}Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, 79 Fed. Reg. 30,240, 30,257 (May 27, 2014) (“[F]unds that are sequestered in fiscal year 2015 from the reinsurance and risk adjustment programs will become available for payment to issuers in 2016 without further Congressional action.”).
\textsuperscript{21}The provisions of the Higher Education Act of 1965 limit origination fees charged by lenders to three (3) percent of the loan principal. See 20 U.S.C.A. § 1087-1(c) (2) (A) (“each eligible lender under this part is authorized to charge the borrower an origination fee in an amount not to exceed 3.0 percent of the principal amount of the loan”); 20 U.S.C.A. § 1087-1(c) (6) (for SLS and PLUS loans, “each eligible lender under this part charge (sic) the borrower an origination fee of 3.0 percent”). The statute sets origination fees charged by the Secretary of Education at four percent of the principal amount of the loan. 20 U.S.C. § 1087e(c)(1). The Higher Education Act sets the special allowance payment paid by the Secretary of Education to guaranty agencies to reduce student interest costs at 0.40 percent of the total principal insured for loans originated on or after October 1, 2003 and first disbursed before July 1, 2010. 20 U.S.C. § 1078(f)(1)(A)(ii).
Deficit Control Act, provides that a physician’s acceptance of a reduced payment amount calculated pursuant to a sequestration order will qualify as acceptance of payment in full in cases of payment by assignment under Medicare Part B. This section further shows that Congress contemplated the sequestration of funds for Medicare Part B services. **However, these special rules refer only to Part B’s coverage of “services” – they are silent on sequestration of payments for Part B drugs.**

These provisions create conflicting issues as to possible Congressional intent. The special student loan provisions exhibit Congress’ willingness to provide specific procedures to be used in applying sequestration to a statutorily-defined payment scheme. The student loan rules’ specific alternative procedures could support the argument that Congress, by not creating a similar alternative procedure for the Medicare Part B formula, intended the standard sequestration procedures to apply to other statutory formula.

However, even if this argument can be made, the further issue is whether the Executive Branch has the Constitutional authority to apply sequestration to amend the drug payment provisions of the MMA, even if Congress intended to give the Executive Branch the authority.

C. **Constitutional Challenges**

There are two constitutional challenges presented by the sequestration statute: (i) impermissible delegation of legislative authority; and (ii) improper exercise of legislative authority – line item veto analysis.

1) **Impermissible Delegation of Legislative Authority**

CMS bases its two (2) percent reduction in payments for Part B drugs on Congress’ granting of authority through the Balanced Budget Act, allowing OMB to make budget cuts pursuant to a sequestration order. This grant of authority to OMB is an unconstitutional delegation of legislative power. Specifically, Article I, Section 1 of the Constitution, prohibits Congress from delegating its legislative powers to other bodies, including executive agencies – like CMS and OMB.

Given this constitutional constraint, if Congress seeks to delegate its legislative power to an executive agency like CMS or OMB, the legislation must contain an “intelligible principle” to guide the agency’s decision-making, with the requisite specificity of the “intelligible principle” increasing with the amount of power that Congress is delegating. In other words, the more power Congress delegates, the more specific guidance it must give.

Congress failed to provide to CMS and OMB a sufficiently specific intelligible principle to guide its decision making with regard to the application of sequestration, specifically to the Medicare Part B statute, and consequently, the application of the Balanced Budget Act to the Part B drug payment provisions of the MMA as interpreted by CMS would be unconstitutional.

2) **Improper Exercise of Legislative Authority - The Line Item Veto Act: Clinton v. City of New York**

The interaction of the Budget Control Act and Part B payment provisions of the MMA implicate “Presentment” Clause (Article I of the Constitution) issues similar to the Line Item Veto Act, which the

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22 The statutory text reads: (5) No increase in beneficiary charges in assignment-related cases: If a reduction in payment amounts is made under paragraph (1) for services for which payment under part B of title XVIII of the Social Security Act [42 U.S.C.A. § 1395j et seq.] is made on the basis of an assignment described in section 1842(b)(3)(B)(ii) [42 U.S.C.A. § 1395u(b)(3)(B)(ii)], in accordance with section 1842(b)(6)(B) [42 U.S.C.A. § 1395u(b)(6)(B)], or under the procedure described in section 1870(f)(1) [42 U.S.C.A § 1395gg(f)(1)], of such Act, the person furnishing the services shall be considered to have accepted payment of the reasonable charge for the services, less any reduction in payment amount made pursuant to a sequestration order, as payment in full.


24 Id. at 472, 475. (West 2016).

25 Id. at 475. (West 2016).

The Line Item Veto Act, enacted in April 1996, gave the President the power to “cancel in whole” three types of provisions that Congress had signed into law: “(1) any dollar amount of discretionary budget authority; (2) any item of new direct spending; or (3) any limited tax benefit.”

In *Clinton v. City of New York*, the Supreme Court reviewed challenges to President Clinton’s use of the line item veto power to cancel one provision in the Balanced Budget Act of 1997 and two provisions in the Taxpayer Relief Act of 1997. Under the Line Item Veto Act, such cancellations prevented the cancelled provisions “from having legal force or effect,” which the Supreme Court characterized as a presidential repeal: “[i]n both legal and practical effect, the President has amended two Acts of Congress by repealing a portion of each.”

The Supreme Court held that this “repeal” violated the Presentment Clause of Article I of the Constitution. Under the Presentment Clause, a bill that passes both houses of Congress must be presented to the President, who may either sign it or “return” it, usually described as a “veto.” However, the cancellation permitted by the Line Item Veto Act differed significantly from the President’s constitutional veto power. The Constitution grants authority to the President to exercise the veto before a bill becomes law, not after the law becomes effective. The Line Item Veto Act failed constitutional muster because the statutory cancellation power of the President was exercised after the bill became law.

The Court differentiated the Line Item Veto Act power from other legislative grants of discretion to the President in extraordinary circumstances, such as a statutory ability to alter tariffs under the Tariff Act of 1890.

The Court thus interpreted the Line Item Veto Act as an invalid attempt by Congress to grant lawmaking power to the President. The Supreme Court stated:

“If the Line Item Veto Act were valid, it would authorize the President to create a different law—one whose text was not voted on by either House of Congress or presented to the President for signature. Something that might be known as “Public Law 105–33 as modified by the President” may or may not be desirable, but it is surely not a document that may “become a law” pursuant to the procedures designed by the Framers of Article I, § 7, of the Constitution.”

The fact that Congress itself authorized the Line Item Veto Act did not move the Supreme Court, which noted that, absent a constitutional amendment, Congress may not give the President the power to amend statutes, even by passing a statute giving him that power.

Applying the Line Item Veto Act analysis, the sequestration law, as being applied by OMB through the President’s order, effectively amends the Part B payment provisions of the MMA by reducing the payment formula for Part B drugs. Payment for most Part B drugs is set forth in a formula under the MMA. Amounts paid inconsistent with the formula, determined by application of sequester, are arguably an impermissible amendment to the law made after the effective date of the law. Also, as we reviewed above, OMB has elected, with regard to ACA subsidies, to exclude these from sequestration, further evidencing Executive action under the sequestration law.

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28 Id. at 436. (West 2016).
29 Id. at 421. (West 2016).
30 Id. at 437-38. (West 2016).
31 Id. at 438-39. (West 2016).
32 Under Article I, Section 7 of the Constitution, the President has a third option, namely, to not sign the law; such Article provides in pertinent part: “[i]f any Bill shall not be returned by the President within ten Days (Sundays excepted) after it shall have been presented to him, the Same shall be a Law, in like Manner as if he had signed it, unless the Congress by their Adjournment prevent its Return, in which Case it shall not be a Law.”
33 Id. at 442. (West 2016).
34 Id. at 448-49. (West 2016).
D. Conclusion

The Obama Administration did not have the authority to apply the sequester payment cut to Medicare Part B drug reimbursement. We note that the authority exists to apply the sequester cut to Medicare services, which are not specifically set in statute but are determined annually in Medicare fee schedules. The arguments we provide are based on both legal and constitutional findings. The sequester cut must be stopped from being applied to Medicare Part B drug reimbursement based on these legal and constitutional reasons.

The application of the sequester cut to Part B drug reimbursement has had a disastrous and expensive impact on the site of cancer care treatment in the United States. Since being implemented, cancer care has shifted significantly from community cancer clinics into the much more expensive hospital settings, costing both Medicare and its beneficiaries more for cancer treatment. One research estimate found that because of the ongoing shift of cancer care out of the community setting and into hospitals, Medicare had paid an extra $2 billion dollars for chemotherapy infusions in 2014 alone.35