



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.¹

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)² 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;

¹ 42 U.S.C. § 1395u (o). (West 2016). *Emphasis added*.

² Paragraph 3 defines the methodology for determining average sales prices for multiple source drugs.

(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)...³

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.⁴

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))...⁵

³ 42 U.S.C. § 1395w-3a (West 2016).

⁴ 2 U.S.C. § 901a (West 2016).

⁵ 2 U.S.C. § 906 (West 2016). *Emphasis added.*

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 sequestration⁶, under Sections 255⁷ and 256⁸ 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.⁹

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.¹⁰

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:

“... 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.”¹¹

Like the payment rates for Part B drugs in the MMA, these student loan fees are set by statutory

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

(6) ...When implementing the sequestration of direct spending pursuant to this paragraph, OMB shall follow the procedures specified in section 6 of the Statutory Pay-As-You-Go Act of 2010, *the exemptions specified in section 255, and the special rules specified in section 256*, except that the percentage reduction for the Medicare programs specified in section 256(d) shall not be more than 2 percent for a fiscal year. (emphasis added).

⁷ 2 U.S.C. § 905. (West 2016).

⁸ 2 U.S.C. § 906. (West 2016).

⁹ 2 U.S.C. § 905. (West 2016).

¹⁰ 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 fiscal year 2016 without further Congressional action.”).

¹¹ 2 U.S.C. § 906. (West 2016).

formulas.¹² 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 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.¹³ 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.¹⁴

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

¹² 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).

¹³ 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.

¹⁴ See *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 472 (2001).

guide the agency’s decision-making, with the requisite specificity of the “intelligible principle” increasing with the amount of power that Congress is delegating.¹⁵ In other words, the more power Congress delegates, the more specific guidance it must give.¹⁶

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 Act¹⁷, which the Supreme Court found unconstitutional in *Clinton v. City of New York*.¹⁸

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.”¹⁹ In *Clinton*, 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 1997.²⁰ 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.”²¹

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.”^{22 23} 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 1890.²⁴

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:

¹⁵ *Id.* at 472, 475. (West 2016).

¹⁶ *Id.* at 475. (West 2016).

¹⁷ Line Item Veto Act of 1996, Pub. L. 104–13, formerly codified at 2 U.S.C. § 691 *et seq.*

¹⁸ 524 U.S. 417 (1998).

¹⁹ *Id.* at 436. (West 2016).

²⁰ *Id.* at 421. (West 2016).

²¹ *Id.* at 437-38. (West 2016).

²² *Id.* at 438-39. (West 2016).

²³ 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.”

²⁴ *Id.* at 442. (West 2016).

“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.”²⁵

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.

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.²⁶

²⁵ *Id.* at 448-49. (West 2016).

²⁶ “Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014.” Milliman. April, 2016.