



COMMUNITY ONCOLOGY ALLIANCE

Innovating and Advocating for Community Cancer Care

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May 30, 2018

The Honorable Alex M. Azar II
Secretary, Department of Health and Human Services
Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Azar:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), we are writing to provide a summary explanation to the following:

- Why COA is filing an action to seek an injunction to stop the 2% sequester cut from being applied to Medicare Part B (“Part B”) reimbursement for cancer drugs;
- Why community oncology is alarmed by proposed changes to Part B in the President’s blueprint to lower drug prices; and
- What we believe are viable, truly patient-centric solutions to lowering the increasing costs of cancer drugs and related aspects of cancer treatment.

Community oncology practices are on the front lines of treating cancer and certainly understand the increasing costs of cancer care. Oncology medical providers and support staff spend an incredible amount of time, which seems to be increasing daily, dealing with escalating drug prices and related cancer treatment costs. The toxicity of chemotherapy is something medical providers contend with daily and now the same holds true for the “financial toxicity” of cancer care.

Let us be very clear: Drug prices are unsustainable. Certainly, pharmaceutical manufacturers bear a primary burden of dealing with the increasing prices of cancer drugs. However, in this country’s overly complex system of drug pricing-to-delivery, there are many participants who share the burden of responding to the issues of escalating cancer drug prices and increasing costs of delivering cancer care. Those participants include private insurers, pharmacy benefit managers (“PBMs”), hospital administrators and their oncologists, federal and state governments, and community oncologists. Speaking only for community oncologists, we have taken that responsibility very seriously in not just talking about oncology payment reform, but in actually enacting it by designing and participating in numerous Medicare and private insurer alternative payment models.

What follows is our summary explanation of the three points bulleted above followed by a more detailed discussion.

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Summary on Sequester Legal Action, Proposed Part B Changes, and Drug Price/Cost Solutions

Sequester Legal Action

We are filing to seek an injunction against the United States Department of Health and Human Services (“HHS”) and the Office of Management and Budget (“OMB”) because we have exhausted all possibilities in stopping what is an unconstitutional application of the 2% sequester cut to Part B drug reimbursement. Simply put, applying the sequester cut to Part B drug payments impermissibly bypasses Congress and attempts to amend the Medicare Part B reimbursement rate set forth in statute (the Medicare Modernization Act of 2003 (“MMA”)) as average sales price (“ASP”) plus 6%. Today, Part B providers are not being reimbursed by the Centers for Medicare & Medicaid Services (“CMS”) at ASP plus 6% as mandated by the MMA, but instead at ASP plus 4.3% due to CMS’ wrongful application of the sequester cut to Part B drug payments.¹

Nothing in the law mandating the application of the sequester cut to Medicare payments specifically amended the MMA, which defines the Part B drug reimbursement rate as ASP plus 6%. Furthermore, OMB specifically instructed all federal agencies applying sequestration to budgets and payments to “*use any available flexibility to reduce operational risks and minimize impacts on the agency’s core mission in service of the American people.*”²

We have met and talked with numerous HHS and OMB staff in the current Administration, including CMS personnel, to explain why the sequester cut applied to Part B drug reimbursement is unconstitutional, and *most importantly*, how it is harming cancer patients – especially senior Medicare beneficiaries – and significantly increasing costs to them and Medicare. There has certainly been an adverse impact on HHS’ mission of serving American seniors covered by Medicare as a result of the CMS application of the sequester cut to Part B drug reimbursement.

Disconcertingly, the response we have received at HHS and OMB reflects more on the current Administration’s views on the policy of Medicare Part B drug reimbursement and not on correcting the prior Administration’s unconstitutional application of the sequester. Bad policy has followed more bad policy with Part B as documented by how policy changes made in Washington are demonstrably adversely impacting cancer patients across the country. As a result, we are left with no other option but to pursue legal action, something we have clearly communicated to both HHS and OMB on several occasions, as a last resort.

Proposed Part B Changes

The Part B law continues to be under attack. We are now *deeply concerned* with how the current Administration might effectively bypass Congress again in changing Part B drug reimbursement by, for example, “moving” Part B under Medicare Part D (“Part D”). It is an understatement to say that we are alarmed with conceptual proposals to “move” Medicare Part B under Part D and to revive the Competitive Acquisition Program (“CAP”). We say that because both involve increasing the power and prevalence of middlemen to “negotiate” drug prices. Examining what is now happening with Part D, as well as with private insurer pharmacy benefit plans being implemented by PBMs and other middlemen, will show you the end result of these proposals: PBMs and other middlemen involved will profit; costs will increase for

¹ The 2% sequester cut applies to only the 80% that Medicare pays for and not the 20% patient coinsurance. Thus, the 2% applied to the portion paid for by Medicare produces an effective reduced payment rate of ASP plus 4.3%.

² OMB M-13-03, “Memorandum for the Heads of Executive Departments and Agencies,” January 14, 2013.

Medicare and its senior beneficiaries; and patients will face high hurdles in getting their chemotherapy and other cancer therapies.

A recent study by the health policy firm Avalere Health shows problems with Part D, as it is currently causing seniors to pay significantly more out-of-pocket for generic drugs. Avalere found that “*some patients who take generic drugs have seen their cost sharing for the same generic drugs nearly double over a 5-year period despite the price of those drugs remaining flat over time.*”³ It appears that the Administration has some work to do in fixing Part D before even considering the fundamentally-flawed move of Part B under Part D.

Although there are no details yet on the implementation specifics of the Administration’s Part B proposals, the public discussions about them to date show some basic misunderstandings about Part B and the economic flaws in these proposals — especially the fact, supported by data, how ***shifting cancer drugs from Part B to Part D will actually increase out-of-pocket costs for seniors.*** For example, looking at patients’ costs in Part B and Part D, a recent analysis from Avalere shows that in 2016, seniors’ out-of-pocket costs “*were about 33% higher for Part D-covered new cancer therapies (\$3,200) than for those covered in Part B (\$2,400).*”⁴ Additionally, Avalere notes that, “*Another factor to consider is that shifting Part B drugs into Part D could put upward pressure on Part D premiums, which may not be fully offset by a decrease in Part B premiums, because the Part B program pays for both drugs and physician services.*”⁵

Regarding CAP, introducing middlemen into Part B drug distribution and administration will surely do the exact same thing that PBMs are doing now in Part D – unduly complicating drug procurement, delaying and denying patients treatment, and driving up costs. Allowing middlemen to “negotiate” drug prices, especially in cancer care where there are few true therapeutic and generic-to-brand substitutes, is extremely dangerous because it will result in middlemen dictating treatment choices through “negotiated” formularies, thus interfering with the oncologist, in concert with the patient, deciding on the optimal treatment. CAP will drive treatment based on what “negotiated” drugs are most profitable to the middlemen, not what are optimal for cancer patients.

Without very careful, thoughtful analysis and consultation with providers and other experts on the front lines of cancer care, the Administration’s Part B-to-D and CAP proposals are simply more government policy “experiments” on the lives of cancer patients. We urge strong caution and consideration of unintended (although completely obvious) consequences of any policy changes being considered.

Drug Price/Cost Solutions

We agree with several of the President’s blueprint proposals to reduce drug prices, spending, and patients’ out-of-pocket costs. Those include very important reforms and initiatives at the Food & Drug Administration (“FDA”) to increase drug competition in order to drive down prices of brand name and generic drugs; fixing the out-of-control 340B drug discount program in hospitals, which is increasing costs to seniors and Medicare, as well as fueling drug prices; and moving to site payment parity for identical medical services, among other initiatives. In addition to wanting to work with the Administration on the introduction, acceptance, and utilization of biosimilar cancer drugs, we believe that new, specialized (and very expensive) cancer therapies, such as CAR-T, need a modified payment mechanism.

³ Avalere Health, “Generic Drugs in Medicare Part D. Trends in Tier Structure and Placement,” May 22, 2018.

⁴ Avalere Health, “Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D,” May 21, 2018.

⁵ Ibid.

Fundamentally, COA and community oncology practices have been working for years on Medicare (COME HOME, Oncology Care Model) and private insurer (UnitedHealthcare, Aetna, BCBS, PriorityHealth, among others) alternative payment models for cancer care. For the past year, COA has been working on the Oncology Care Model (“OCM”) version 2.0 (“OCM 2.0”), which includes paying for cancer drugs based on value, just as community oncologists are being paid for services provided based on value.

We are very focused on solutions to the increasing costs of cancer care, including the drug price/cost component. We are dismayed that the Administration did not consult with community oncologists to understand what is, and is not, working with the payment for cancer drugs and services before making grand pronouncements. Patients’ lives are at stake with policy changes and practicing medical professionals on the front lines must be involved. COA is working very diligently on several important initiatives aimed at payment reform for cancer drugs and services, but feel that the proverbial rug is being pulled out from under us with some of the Administration’s proposals, starting with moving Medicare Part B cancer drugs to Part D.

What follows is a more detailed explanation on our legal action, concerns, and solutions.

Injunction Sought to Stop the Sequester Cut from Being Applied to Part B Drugs

Attached is a letter from August 2, 2017 that we sent to former Secretary Price and CMS Administrator Verma requesting that HHS/OMB stop the application of the sequester cut to Part B drug reimbursement, with the legal justification supporting this request. As part of that letter, we attached supporting documentation, including a letter from Congress questioning the sequester cut to Part B drug reimbursement signed by then Congressmen (former HHS Secretary) Price and (now OMB Director) Mulvaney and 122 other members of Congress.

The argument and logic are very simple: Congress passed legislation (the MMA), which subsequently was signed into law, that specifically establishes Part B drug reimbursement to independent (non-hospital) physicians at ASP plus 6%. When the sequester cut to Medicare went into effect in April 2013, the prior Administration applied the sequester cut to Part B drug reimbursement. What this did was to impermissibly bypass Congress and attempt to amend without new legislation the Part B reimbursement rate set forth in statute of ASP plus 6% and thus establishes a new, effective rate of ASP plus 4.3%.⁶ For all the reasons detailed in the attachments, this is unconstitutional.

By continuing to apply the sequester cut to Part B drug reimbursement, the current Administration has persisted in fueling the consolidation of cancer care into the much more expensive hospital setting, which has led to cancer clinic closings and has increased costs for seniors and Medicare.

- Since CMS applied the sequester cut to cancer drugs:
 - One-hundred and thirty-five (135) cancer treatment clinics have closed through February 2018 – a 46.9% increase in treatment site closings.⁷
 - One-hundred and eighty-nine (189) independent community cancer clinics, typically comprised of multiple treatment clinics, have been merged into hospitals – a 40.3% increase in consolidation of independent practices into the more expensive hospital setting.⁸

⁶ The 2% sequester cut applies to only the 80% that Medicare pays for and not the 20% patient coinsurance. Thus, the 2% applied to the portion paid for by Medicare produces an effective reduced payment rate of ASP plus 4.3%.

⁷ Community Oncology Alliance, “2018 Practice Impact Report,” April 20, 2018.

- From 2013 through 2016, the percentage of chemotherapy administered in the physician office setting versus the outpatient hospital setting has declined from close to 65% to a little over 50%.⁹
- Shifting cancer care to the outpatient hospital setting costs all taxpayers, not just Medicare beneficiaries. The actuarial firm Milliman estimated the shift from 2004 to 2014 to have cost Medicare \$2 billion in just one year (2014)¹⁰ and, as a result, an estimated \$500 million in the same year to senior beneficiaries responsible for the 20% coinsurance.
- One recent study found that over 25% of the hospitals analyzed provide cancer services that are more than 5 times the Medicare allowable amount, and in some cases are charging more than 15 times the Medicare allowable amount.

Additionally, CMS does have flexibility to stop applying the sequester to Part B drug reimbursement. Per a March 1, 2013 OMB memorandum notifying all federal departments and agencies of the sequestration order, “*Agencies should operate in a manner that is consistent with guidance provided by OMB in Memorandum 13-03...*”¹¹

That memorandum references an earlier January 14, 2013 OMB memorandum that states, “*Agencies should generally adhere to the following guiding principles, to the extent practicable and appropriate, in preparing plans to operate with reduced budgetary resources in the event that sequestration occurs:*”

- “*use any available flexibility to reduce operational risks and minimize impacts on the agency’s core mission in service of the American people;*”
- “*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...*”¹²

Enacting the sequester cut specifically to Part B drug reimbursement instead of using any available flexibility to direct the cuts away from patients certainly has had a profoundly harmful effect on the core mission of HHS. As documented, community cancer clinics have closed and both Medicare and its beneficiaries have been subject to higher treatment costs in the outpatient hospital setting. The purpose of the spending cuts under sequestration is to reduce and slow the growth of federal spending – not to cause both seniors battling cancer and Medicare to ultimately *spend even more* than they already are on cancer treatment.

Furthermore, there is precedent for stopping the sequester to federal programs.

The Balanced Budget and Emergency Deficit Control Act explicitly exempts from sequestration¹³, under Sections 255¹⁴ and 256¹⁵ thereof, numerous listed federal programs and activities and imposes certain

⁸ Ibid.

⁹ Berkeley Research Group data on file analyzed for COA.

¹⁰ Milliman, “Cost Drivers of Cancer Care,” April 2016.

¹¹ OMB M-13-06, “Issuance of the Sequestration Order Pursuant to Section 251A of the Balanced Budget and Emergency Deficit Control Act of 1985, as Amended,” March 1, 2013.

¹² OMB M-13-03, “Memorandum for the Heads of Executive Departments and Agencies,” January 14, 2013.

¹³ 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).

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.¹⁶

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 (the "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 that 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.¹⁷

There is no 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 sequester's effects.

As we previously related in this letter, COA representatives have had numerous discussions with HHS and OMB personnel on these points, in addition to the August 2, 2017 letter to former HHS Secretary Price and CMS Administrator Verma.

It is now disturbingly clear that, regardless of the constitutional and legal merits of this situation, the policy behind the recent Administration's proposals to fundamentally change Part B drug reimbursement overrides any constitutional and legal arguments. Additionally, and even more disturbing, in addition to the current Administration maintaining the effective cut to Part B drug reimbursement despite clear constitutional and legal violations, as well as the adverse impact on seniors and the Medicare program, *we are very concerned with how the current Administration could attempt to end-run Congress once again in fundamentally changing Part B.*

As a result of these reasons, COA has no recourse but to pursue legal action against HHS and OMB.

Problems with Proposed Changes to Part B

Medicare Part B was created by a prior Administration and Congress; not oncologists. The unintended negative consequences of policy changes to Part B have been clear and destructive:

- In 2004, 84% of cancer care was delivered in independent community cancer clinics, with the remainder in the more expensive outpatient hospital setting. That has now fallen to a little over 50%.¹⁸ This shift was further fueled by the sequester cut to Part B drug reimbursement in 2013.

¹⁴ 2 U.S.C. § 905. (West 2016).

¹⁵ 2 U.S.C. § 906. (West 2016).

¹⁶ 2 U.S.C. § 905. (West 2016).

¹⁷ 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.").

¹⁸ Milliman, "Cost Drivers of Cancer Care," April 2016.

- The change in Part B drug reimbursement in the MMA gave birth to the modern-day 340B drug discount program. Over 50% of hospitals now have 340B drug discounts, with discounts typically 50% on brand name drugs and now over 67% of cancer drugs in hospitals are discounted by 340B.¹⁹

The consolidation of cancer care – both clinic closings and mergers of independent practices into the more expensive hospital setting – has continued unabated as a result of bad public policy, starting with the sequester. Just in the past week, a practice in North Carolina, a state that has experienced massive consolidation in cancer care, has announced it will close its doors by August 1, 2018. Another practice in Pennsylvania has just announced a merger into a large 340B health system.

As the site of cancer care has shifted into the more expensive hospital setting, cancer drug prices have clearly increased. As a result, assertions that independent oncologists have fueled those increases are simply nonsensical. *Simply put, if independent community oncologists were “profiting” so much from cancer drugs under the current system, why has the site of cancer care shifted so profoundly into the hospital?* To the contrary, the Government Accountability Office (“GAO”) has found that 340B hospitals are profiting off of cancer drugs and, in fact, 340B hospitals use “*more drugs or more expensive drugs.*”²⁰ The exploding breadth of 340B discounts among hospitals, coupled with increasing magnitude of 340B discounts, is fueling increased prices of cancer drugs as pharmaceutical manufacturers account for the discounts, which they are forced to provide to 340B hospitals, in their drug prices. And even with the reduction of drug payments to 340B hospitals that CMS enacted in 2018, 340B remains a very lucrative profit center for hospitals because they still realize close to 30% margins on cancer drugs.

As we previously stated, the proposals to shift Part B into Part D, revive CAP, and generally have middlemen “negotiate” drug prices are fundamentally flawed in that they will increase costs to seniors and Medicare and, most importantly, will place additional hurdles in front of seniors to getting treated.

Drug prices have risen dramatically in Part D. Why? Because in large part, PBMs now control an estimated 85% of all prescription drugs and have a vested interest in high list drug prices due to percentage-based rebates they receive from drug manufacturers and direct and indirect remuneration fees (“DIR Fees”) they extract from pharmacy providers. DIR Fees are based on a percentage of drug list prices — the higher the list price, the higher the DIR Fee to the PBM. Giving PBMs and other middlemen more power, especially by allowing them to “negotiate” drug prices, will accrue only to their benefit. History teaches that drug prices will only continue to increase until the PBMs are stopped.

To make matters worse, community oncology practices face a virtual nightmare in fighting through prior authorizations and delivery delays in getting cancer patients their medications. COA has produced three volumes detailing actual patient horror stories of how middlemen place incredible and unnecessary obstacles in front of cancer patients obtaining their oral cancer drugs and how these bureaucratic nightmares have dangerous, and sometimes deadly, results.²¹

The data clearly shows that moving Part B under Part D will increase the cost of cancer care, especially out-of-pocket costs, to seniors.

- A new analysis from Avalere finds that Medicare patients’ out-of-pocket (“OOP”) costs for new cancer therapies can vary substantially based on whether a drug is covered by Part B or Part D due to differing benefit designs and use of supplemental health coverage. In 2016, average OOP costs

¹⁹ Berkeley Research Group, “The Oncology Drug Marketplace: Trends in Discounting and Site of Care,” December 2017.

²⁰ GAO GAO-15-442, “Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals,” June 5, 2015.

²¹ Community Oncology Alliance, “Pharmacy Benefit Manager Horror Stories,” Volumes 1-3. April 2017.

were about 33% higher for Part D-covered new cancer therapies (\$3,200) than for those covered in Part B (\$2,400).²²

- Among Part D beneficiaries who do not qualify for low-income cost-sharing subsidies (about 72% of enrollees), average OOP costs were even higher – \$4,400, on average.
- For Medicare fee-for-service (“FFS”) enrollees in Part B without supplemental drug coverage, OOP costs averaged \$9,700. However, according to the latest data by Medicare Payment Advisory Commission (“MedPAC”), 86.1% of Part B beneficiaries have some form of secondary or supplemental insurance that generally covers most of these OOP expenses. Supplemental insurance coverage is not permissible under the Part D benefit.
- In Part B FFS, beneficiaries pay a 20% coinsurance on all medical services, including drugs. In Part D, CMS caps coinsurance for specialty tiers at 33%, but cost sharing for non-preferred drug tiers can be close to 50%. An Avalere analysis of benefit design data found that average coinsurance amounts on non-preferred tier for prescription drug plans range from 35% to 41% in 2018.²³
- Cost sharing for Part B drugs is determined as 20% of a product’s ASP, which in turn is calculated by CMS as the manufacturer’s average selling price weighed per unit based on total sales volume. The ASP is net of rebates, volume discounts, and other price concessions to all classes of trade in a given quarter.²⁴ Meanwhile, under Part D, beneficiary cost sharing is based on the list price at the point of sale, which doesn’t account for discounts and rebates.
- Avalere estimates that about 27% of current Part B beneficiaries do not have Part D coverage.

Giving middlemen more power, especially in “negotiating” drug prices, and shifting Part B to Part D could truly have catastrophic results. With few real therapeutic and generic-to-brand substitutes in cancer treatment, giving middlemen the power to “negotiate” means that middlemen will be dictating treatment decisions or, at best, restricting treatment choices for oncologists and their patients, especially if cancer is eliminated as a “protected” class. This is unacceptable and a dangerous experiment with the lives of cancer patients and disrupts the sacrosanct doctor-patient relationship.

It is important to clarify that whereas Part D involves oral medications, Part B, for the most part, involves injectable drugs, such as chemotherapy, that must be administered under close physician supervision due to potential toxicities and serious side effects. As a result, it is essential that oncologists have these drugs stored at the site-of-care for administration to patients by trained oncology nurses.

Introducing yet additional middlemen with CAP will surely place more obstacles in front of patients getting their cancer treatments. Will CAP vendors be given authority to create formularies or simply exclude cancer drugs from being available? Will CAP vendors provide special CAP inventories to practices or require brown-bagging whereby patients pick up their chemotherapy at a specialty pharmacy owned by the CAP vendor and transport their drug(s) to their oncologist? Will practices have to order each patient’s chemotherapy for delivery vial by vial to the practice? What do you expect CAP vendors to charge for the procurement, inventory, storage, delivery, cost-of-money, and reimbursement filing for participating in the program? Who has the liability if a patient does not get a prescribed drug, or at least

²² Avalere Health, “Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D,” May 21, 2018.

²³ Avalere Health Analysis of 2018 Part D Formularies, November 2017.

²⁴ ASP is not a “list” price, as it has been incorrectly characterized. It is a true “net” price, including all discounts and rebates.

does not get it on time? How can the oncologist and patient be assured of the drug chain of custody? How will community oncology practices get reimbursed for the costs associated with drug procurement and preparation, as well as special CAP inventory and management? Will CAP operate just for independent medical practices or also for hospitals, including 340B hospitals?

In referencing CAP, we want to correct a common misconception that the “plus 6%” add-on to ASP is a “margin” or “mark-up.” That add-on was intended to cover the facility and human resource costs associated with drug procurement, storage, inventory, preparation, and waste disposal. Additionally, it acts as a buffer when practices purchase at prices above ASP. The fact, *supported by data*, is that manufacturer-to-wholesaler “prompt pay” discounts (not available to providers) included in ASP and the two-quarter perpetual lag in ASP²⁵ – exacerbated by the application of the sequester – *cause many drugs to be reimbursed by Medicare at less than their cost!*

- Twenty-one percent (21%) of all Part B drugs analyzed by Avalere have a negative estimated difference between drug acquisition cost and the Medicare allowable payment amount, which combines the government’s 80% portion and beneficiary cost-sharing of 20%.²⁶
 - On average, the difference is minus 10% per drug; meaning, every time these Part B drugs are prescribed providers are effectively paying the government.²⁷
- Pure losses on some Part B drugs that providers are experiencing (i.e., not breaking even on just the drug acquisition cost) are due to drug price increases not timely reflective in ASP-based Part B drug reimbursement rates.
 - The ASP for 21% of Part B drugs associated with a negative estimated difference between drug acquisition cost and Medicare allowable payment amount increased on average by 14% between Q1 and Q3 of 2017, which demonstrates the impact of the 2-quarter lag in setting the Medicare allowable payment amount.²⁸
- Among the top 10 highest cost cancer drugs that account for 72% of all cancer drugs and 23% of all Part B drug spending in 2016:
 - The average estimated difference between drug acquisition cost and Medicare allowable payment amount is 2.4% or \$2.50.²⁹
 - If the average level of beneficiary bad-debt (i.e., uncollected cost-sharing) is 11%, then the drug acquisition cost and Medicare payment are at breakeven.³⁰

We finally note that these proposed changes to Part B would totally invalidate the OCM program, which CMS has invested in through its Center for Medicare & Medicaid Innovation (“CMMI”). When so much is riding on the OCM as an oncology alternative payment model, which CMMI has invested heavily in and the participants in the model have committed to making a success, Part B changes will effectively void OCM results with CAP and/or a move to Part B to Part D.

²⁵ There is a two (2) quarter lag between the time the drug manufacturer reports their ASP for each drug and the time that CMS publishes Part B drug reimbursement rates based on those ASPs. Therefore, manufacturer price increases are not reflective in ASP-based Part B drug reimbursement rates for two (2) quarters.

²⁶ Avalere Health data on file analyzed for COA.

²⁷ Ibid.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid.

We wait for additional details on both these Part B proposals but are alarmed by the adverse impact they would likely have on the treatment of cancer patients.

Solutions on Reducing Cancer Drug Prices/Costs

We will comment formally on the President's blueprint request for information, but for now want to summarize several important considerations to lowering cancer drug prices and overall cancer treatment costs. These are as follows:

- *Competition is an essential first step in lowering drug prices.* We applaud the initiatives of FDA Commissioner Dr. Scott Gottlieb in reforming the FDA approval process for new cancer drugs, and notably generics and biosimilars. Competition is the first step to reducing drug prices, relating to therapeutically equivalent brand name drugs, as well as generics and biosimilars. In cancer treatment, there are currently very few situations where there are lower-priced therapeutic brand name or generic-to-brand substitutes, where there are no side effect considerations or other issues that dictate drug choice. Decreasing research and FDA filing costs, time, regulations, and other impediments, including roadblocks by brand name drug manufacturers, in getting competitive brand name, generic, and biosimilar competitors to market, is a necessary first step to lowering drug prices.
- *Biosimilars need to be a focus, from approval through physician acceptance.* As we noted, biosimilars are an important factor in fostering increased competition to lower drug prices. We have several plans to educate oncologists on biosimilars and to spur their acceptance when these less expensive, but therapeutically equivalent, drugs are available. We applaud the decision by the FDA to focus on biosimilar approvals and to individually name these products so that an orderly, sustainable biosimilar market can be created, not a race to the bottom. Additionally, we believe that incentives can be utilized to speed acceptance and adoption of biosimilars.
- *The scope and magnitude of discounts and rebates need to be reduced.* The drug distribution system is overwhelmed with excessive mandatory discounts and rebates that are fueling drug prices, as these discounts and rebates are increasing in scope and magnitude. These include 340B discounts and PBM-related rebates. We are not suggesting that fixing and changing these discounts and rebates let pharmaceutical companies off the hook in setting high base drug prices; however, these discounts and rebates are now so pervasive and large that they are fueling drug prices. Manufacturers clearly factor in discounts and rebates in pricing their products. We applaud the actions of HHS/CMS to date to fix 340B in hospitals and the proposal to tie 340B discounts to charity care provided by hospitals. Additionally, we agree with the proposals to limit, or even eliminate, after-sale rebates and to ensure that patients are paying off of “net” prices, not inflated “list” prices.
- *Universal site payment parity is essential, including with dedicated cancer hospitals with special Medicare exemptions.* Hospitals cost Medicare and private insurers, and their beneficiaries, more for treating cancer patients. There needs to be site payment parity whereby the same services are paid at identical rates, regardless of the site-of-care – hospital or independent oncology practice. Additionally, the special Medicare exemptions to the 11 dedicated cancer hospitals need to be stopped. According to the GAO, in 2012, the special Medicare exemptions available to these hospitals cost Medicare close to half a billion dollars in 2012 alone, versus if the treatment was

provided in comparable teaching hospitals.³¹ These dedicated cancer hospitals spend millions and millions of dollars advertising for cancer patients, essentially paid for by the federal government's special Medicare exemptions. There should be no special Medicare exemptions that give dedicated cancer hospitals license to charge highly inflated rates for common cancer care services.

- *New, highly expensive immunotherapies, such as CAR-T, require a different, more appropriate reimbursement mechanism.* Given the very specialized nature of these treatments, there needs to be a new payment mechanism reflective of how these therapies are provided and administered.
- *COA is developing a universal payment model for cancer care, including value-based payment for services and drugs.* This model – referred to as the OCM 2.0 – will inject value-based payments into cancer treatment for both services and drugs. This is a truly patient-centric approach to reforming the payment system by focusing first on the quality of cancer care delivered, and then on associated costs. We believe that value-based pricing for drugs – e.g., outcomes and indication pricing – combined with value-based pricing for services can enhance the quality of cancer care while decreasing costs. Community oncologists only have partial control over the cost of drug therapy; pricing is in the hands of the manufacturers. However, by integrating drugs and services in a model based on value-based insurance design (“VBID”), we believe that we can positively impact both prices and utilization.

We welcome the opportunity of meeting with you, having already put in a request through the White House to do so. Additionally, we invite you to tour one or several community oncology practices to see how cancer care is delivered on the frontlines, including better understanding the complexities of procurement, selection, and administration of cancer drugs.

While we support several of the President’s initiatives on lowering drug prices – and already have expressed so publicly – we are very concerned about proposals dealing with Part B because of the potential for serious adverse impact on cancer patients, especially seniors covered by Medicare.

Sincerely,



Jeff Vacirca, MD
President



Ted Okon
Executive Director

CC:

The Honorable Greg Walden, Chairman, Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, Energy and Commerce Committee
The Honorable Kevin Brady, Chairman, Ways and Means Committee
The Honorable Richard E. Neal, Ranking Member, Ways and Means Committee
The Honorable Orin G. Hatch, Chairman, Senate Finance Committee
The Honorable Ron Wyden, Ranking Member, Senate Finance Committee
The Honorable Mick Mulvaney, Director, Office of Management and Budget

³¹ GAO-15-199 “Payment Methods for Certain Cancer Hospitals Should Be Revised to Promote Efficiency,” February 2015.



COMMUNITY ONCOLOGY ALLIANCE

Innovating and Advocating for Community Cancer Care

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August 2, 2017

The Honorable Tom Price, MD
Secretary, Department of Health and Human Services
Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Price and Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), I am writing to request that the Centers for Medicare & Medicaid Services (CMS) stop the application of the sequester cut to Medicare Part B drug reimbursement. As I will relate in this letter and the attached documents, based on extensive legal work we believe that the **application of the sequester cut specifically to Part B drug reimbursement is both illegal and unconstitutional** and was erroneously implemented by the Obama Administration (*See the attached document for a thorough explanation of the legal and constitutional arguments.*). The sequester cut is fueling the consolidation of cancer care from independent community oncology practices into the much more expensive hospital setting, costing both Medicare and beneficiaries more.

As you will recall, Secretary Price, you and one hundred and twenty-three (123) other Representatives sent a letter (attached) on April 19, 2013, to Marilyn Tavenner, then Acting Administrator of CMS, inquiring about the statutory authority of CMS to apply the sequester cut to Part B drug reimbursement. There was never a satisfactory response to that letter, which prompted another letter (attached) on June 27, 2013, to the CMS Administrator. Additionally, during Energy and Commerce hearings in 2013, then HHS Secretary Kathleen Sebelius was asked by several members of Congress about the authority of the Obama Administration to apply the sequester cut specifically to Part B drug payments.

These communications never produced any satisfactory responses supporting the statutory authority of the Executive Branch of the Obama Administration to effectively make an end-run around Congress in lowering Medicare Part B drug reimbursement, which is defined in statute – i.e., the Medicare Modernization Act (MMA) – as Average Sales Price (ASP) plus 6%. The 2% sequester cut lowers Part B reimbursement to ASP + 4.3% (considering the sequester cut does not apply to beneficiaries' 20% copayment), thus effectively changing a law passed by Congress. This is a terrible and dangerous precedent to let stand – not to mention the profound adverse impact on cancer care.

The Obama Administration used the sequester to achieve the cut in Medicare Part B drug reimbursement that it had included in proposed budgets for years but were not acted on by Congress. Then, in 2016, there was an attempt to further cut reimbursement by using the Center for Medicare & Medicaid Innovation (CMMI) to implement the Medicare *Part B Drug Purchasing Model*. Secretary Price, as you noted in the letter you authored (with one hundred and seventy-eight (178) House members cosigning) on September 19, 2016 to then CMS Acting Administrator Andrew Slavitt (attached), using CMMI was an attempt by the Obama Administration to effectively bypass Congress:

“CMS’ Part B proposal, for example, would rewrite Medicare Part B payment law in 75 percent of the country without going through the Constitutional procedures where legislation is debated and approved in both chambers of the Congress, and subsequently signed by the President. These most basic tenets of our government, intended by our Founding Fathers to preserve and maintain balance of power, have clearly been neglected.”

You further emphasized this, Secretary Price, during your opening chairman remarks at a House Budget Committee hearing on September 7, 2016, regarding the Part B model:

“This assumption of lawmaking authority by the Executive Branch takes such powers out of the hands of the legislature. No matter which political party controls which branch of government at any given time, such a precedent is unhealthy for our democracy.”

As you know, Secretary Price, I testified to your Budget Committee at that hearing and shared the considerable legal work COA did that produced the legal and constitutional arguments against using CMMI in a “demonstration project” to effectively decrease Part B drug reimbursement for 75% of the country. Those same legal arguments are even stronger with the sequester, where the Obama Administration has decreased Part B drug reimbursement from ASP + 6% written in the statute to an effective lower rate of ASP + 4.3% for the entire country.

It is clear the application of the sequester cut to Part B drug reimbursement is illegal and unconstitutional. Additionally, the impact of this cut has been the “straw breaking the camel’s back” in terms of expediting the consolidation of cancer care into the more expensive hospital setting. Over the past 10 years, there have been over 600 independent community oncology practices, comprised of multiple clinic locations, acquired by hospitals, with over 25% of those occurring after the sequester cut was implemented. The actuarial firm Milliman calculated that this shift in the site of cancer care cost Medicare an extra \$2 billion in 2014 alone. It is noteworthy that an analysis of recent merger activity found that 75% of those hospitals had 340B drug discount status prior to acquiring community oncology practices, although many of the hospitals without 340B status at the time of acquisition subsequently acquired it.

COA applauds the proposals by CMS to lower perverse profit incentives in the 340B drug discount program and to move to greater site payment parity in all hospitals. The sequester cut, which is severe to independent community oncology practices – as opposed to 340B hospitals operating on 80-100% profit margins on brand drugs – has made these practices very vulnerable to 340B hospitals. Hospitals have become increasingly aggressive in cutting off primary care referrals of cancer patients to practices, and even stopping provider privileges at their hospitals, because of the profits inherent with 340B discounts. This is not only increasing costs for Medicare and its beneficiaries, but is also creating patient access to care issues

We have provided all of this information, and more, to HHS and CMS staff. Additionally, we have shared it with the three congressional committees of jurisdiction, which are supportive of stopping the application of the sequester cut to Part B drugs. (It should be noted that this would not exempt Part B providers from the sequester cut being applied to services, as those rates are not defined in statute as with drugs, but are determined in annual fee schedules set by the HHS Secretary.) Finally, we have shared this with the Office of Management & Budget (OMB) Director Mulvaney and his staff. For the record, there is a precedent for OMB stopping the application of the sequester cut in specific areas, as OMB did with stopping the application of the sequester cut to Affordable Care Act exchange cost-sharing subsidies.

Based on the legal and constitutional reasons laid out here and in the attached document, we request that CMS stop the application of the sequester cut to Part B drugs. Although the sequester cut to Part B drug reimbursement has already done considerable damage to community cancer care, we believe that stopping it, coupled with curbing 340B excesses and moving towards greater site payment parity, will help stem the tide of further consolidation of cancer care into the more expensive hospital setting.

Finally, I want to emphasize that COA is completely committed to addressing Part B drug pricing and spending in the context of oncology payment reform. This includes our considerable efforts supporting participants in the CMMI Oncology Care Model (OCM) and our evolution of this model to what we are calling “OCM 2.0,” which will feature value-based drug payments. However, it is difficult to successfully move forward without a reversal of the sequester cut, which never should have been applied to Part B drug reimbursement in the first place.

I am available to explain any of this in greater detail. We look forward to working with HHS and CMS on advancing quality, affordable cancer care for generations of Medicare beneficiaries to come.

Sincerely,

A handwritten signature in black ink, appearing to read "Ted Okon".

Ted Okon
Executive Director

CC:

The Honorable Kevin Brady, Chairman, Ways and Means Committee
The Honorable Orin Hatch, Chairman, Senate Finance Committee
The Honorable Greg Walden, Chairman, Energy and Commerce Committee
The Honorable Mick Mulvaney, Director, Office of Management and Budget



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 sequester's 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.

Congress of the United States
Washington, DC 20515

April 19, 2013

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Tavenner:

We write regarding the two percent sequestration reduction to Medicare payments to providers – particularly those caring for cancer patients – effective April 1, 2013. We are concerned about how this cut will be implemented and if there is any flexibility available to your agency in how the cut is applied to the payments. Unencumbered 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.

As you know, the Medicare Modernization Act of 2003 (MMA) changed the pricing for cancer drugs covered under Medicare Part B to Average Sale Price (ASP) plus six percent. The intent was to reimburse cancer clinics and other providers for their drug acquisition costs at average market rates and to include an additional services payment (i.e., 6%) to cover inventory, facilities, storage, handling and waste disposal costs.

Our concerns are two-fold. First, it is unclear to us if the Centers for Medicare and Medicaid Services (CMS) has the statutory authority to reduce Medicare Part B drug reimbursement since the amount is specified in the MMA. Second, concerning sequestration, the Office of Management and Budget (OMB) has issued guidance instructing federal agencies and departments to, “[u]se any available flexibility to reduce operational risks and minimize impacts on the agency’s core mission in service of the American people...”^[1] Per a March 1, 2013, OMB memorandum notifying all federal departments and agencies of the sequestration order, “Agencies should operate in a manner that is consistent with guidance provided by OMB in Memorandum 13-03...”^[2] We would like to see CMS use any flexibility that exists to implement the cuts in such a way that the core mission of the agency – to provide care to beneficiaries – is retained and protected.

¹ OMB M-13-03, “Memorandum for the Heads of Executive Departments and Agencies,” Office of Management and Budget (OMB) website, <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-03.pdf>, January 14, 2013

² OMB M-13-06, “Memorandum for the Heads of Executive Departments and Agencies,” OMB website, <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-06.pdf>, March 1, 2013

It was reported in the news that cancer clinics across the country are already turning away thousands of Medicare patients advising them to seek treatment elsewhere, citing the Medicare sequester cuts that took effect April 1.¹ Our hope is that there is a solution that neither diminishes the access of beneficiaries to the treatments they need nor their ability to seek needed treatment in the setting of their choice. We would like more information on this issue from CMS and request your help in addressing the following:

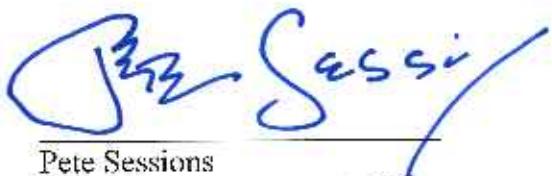
- 1) Are Medicare Part B drug reimbursement rates set in statute?
- 2) Does CMS have, and if so, intend to use the authority to reduce Medicare Part B drug reimbursements?
- 3) Will CMS be monitoring access to care for Medicare beneficiaries once the sequester takes effect – particularly for services where interruption or delay could mean success or failure of treatment, such as cancer care? What steps has CMS taken to avoid negatively affecting Medicare beneficiaries receiving chemotherapy and other specialty infusible drugs?
- 4) Does CMS believe any flexibility exists to modify cuts in areas where access barriers become present?
- 5) How will CMS calculate the reduction required under the sequester? Will it apply to the entire payment for the drug (ASP+6%) or only the base ASP amount, or only to the +6%?
- 6) Has CMS reviewed the potential program costs and impact on Medicare beneficiaries that the reduction required by the sequester may cause? For example, will reduced access to cancer clinics cause beneficiaries to seek services in higher-cost sites of care?
- 7) Have you received or collected any information about Medicare beneficiaries, to date, being turned away from their healthcare provider due to uncertainty about the future reimbursement rates for their Part B drugs?

We ask that you answer the questions posed and if ultimately this cut is applied, use any and all flexibility available to you to ensure a potential sequester cut is applied to just the 6 percent service payment and not to the underlying fixed drug cost (ASP). We are asking, therefore, that any available flexibility be used to direct the cuts away from patients. Our hope is that there is a solution that protects patients' access to their healthcare professionals. We look forward to working with you to implement impending spending reductions in a way that does not threaten needed access to care for Medicare beneficiaries.

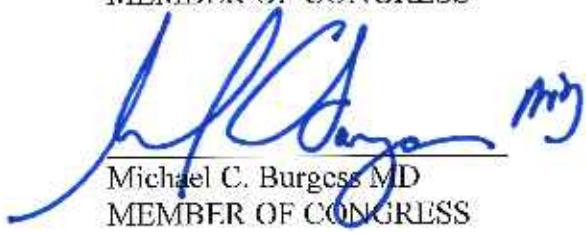
Thank you again for your attention to this important matter. In light of the sequester implementation on April 1, we kindly request that you provide a response to this letter on or before April 29, 2013.

Sincerely,

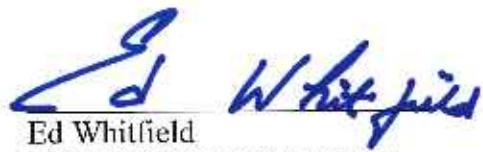
¹ Sarah Kliff, "Cancer clinics are turning away thousands of Medicare patients. Blame the sequester," *The Washington Post's WonkBlog*, <http://www.washingtonpost.com/blogs/wonkblog/wp/2013/04/03/cancer-clinics-are-turning-away-thousands-of-medicare-patients-blame-the-sequester/>, April 3, 2013.



Pete Sessions
MEMBER OF CONGRESS



Michael C. Burgess MD
MEMBER OF CONGRESS



Ed Whitfield
MEMBER OF CONGRESS



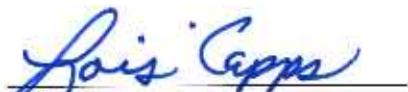
John Barrow
MEMBER OF CONGRESS



Sanford D. Bishop, Jr.
MEMBER OF CONGRESS



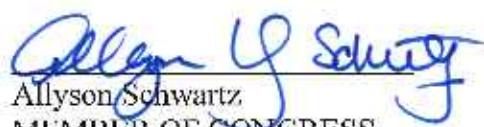
Corrine Brown
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Lois Capps
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Joyce Beatty
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Ami Bera

Ami Bera, MD
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Richard B. Nugent
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Alan Nunnelee

Alan Nunnelee
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Bill Pascrell, Jr.

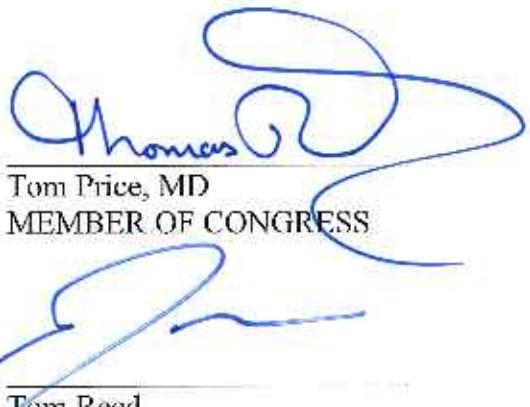
Bill Pascrell, Jr.
MEMBER OF CONGRESS

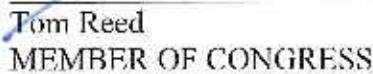
Gary C. Peters

Gary C. Peters
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Bill Posey

Bill Posey
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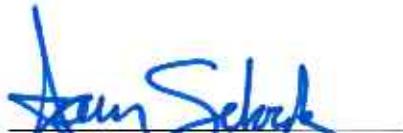

Tom Price, MD
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Tom Reed
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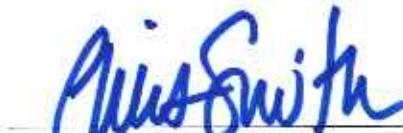

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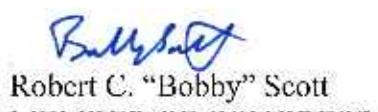

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FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
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ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

June 27, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner:

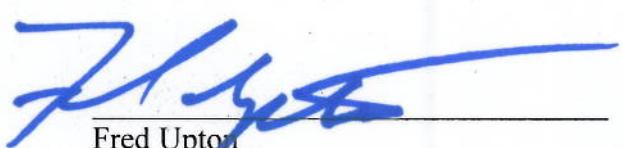
We write to request that you supplement your response to the bipartisan letter sent by 124 members of the House of Representatives, including 31 members of the Energy and Commerce Committee, related to sequestration and the Medicare program (copy attached).

On April 19, 2013, 31 members of the Committee – 22 Republicans and 9 Democrats – signed a letter with their House colleagues requesting information on how the Centers for Medicare and Medicaid Services (CMS) plans to apply sequestration to Medicare Part B drugs. Their request related in part to what flexibility CMS has to implement sequestration considering the unique circumstances that surround the purchase and reimbursement of Part B drugs by medical providers. In our opinion, the response sent by CMS, dated June 3, 2013, did not fully address their request, including the seven questions posed in the letter.

By this letter, we reiterate the request made, and questions asked, by the 31 members of the Committee. Further, we ask that you provide all documents related to any assessment by CMS on how sequestration has or will be applied to Part B Medicare drug and service reimbursement. Finally, we ask that you provide all documents provided to CMS by the Office of Management and Budget and Department of Health and Human Services regarding this sequestration issue.

Please respond to this request by July 3, 2013. If you have any questions regarding this letter, please contact Robert Horne with the Committee staff at (202) 225-2927.

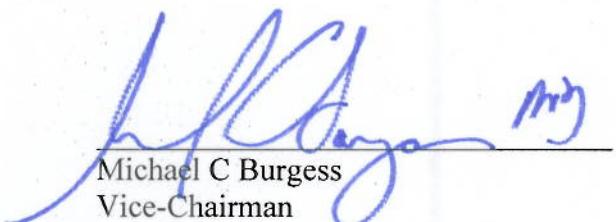
Sincerely,



Fred Upton
Chairman



Joseph R. Pitts
Chairman
Subcommittee on Health



mj

Michael C Burgess
Vice-Chairman
Subcommittee on Health

cc: The Honorable Henry Waxman, Ranking Member

The Honorable Frank Pallone, Ranking Member
Subcommittee on Health

Congress of the United States
Washington, DC 20515

September 29, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Patrick Conway, M.D., MSc
Deputy Administrator, Innovation & Quality
Chief Medical Officer
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Slavitt and Dr. Conway,

The Center for Medicare and Medicaid Innovation (CMMI) is charged with testing and evaluating voluntary healthcare payment and service delivery models with the intent of increasing quality and efficiency while reducing program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).¹ However, as evidenced by three recently proposed mandatory models, CMMI has exceeded its authority, failed to engage stakeholders, and has upset the balance of power between the legislative and executive branches.² What makes these proposals even more disconcerting is their potentially negative effects on patients, especially our vulnerable seniors. Policies that have the potential to create access issues for beneficiaries, further provider consolidation, and reduce provider participation in Medicare can drastically deteriorate quality of care our seniors rely on. This would be a step backwards in our unified effort to move to higher quality, more value-based care for our nation's seniors. We ask that you cease all current and future planned mandatory initiatives under the CMMI.

Until recently, the tests and models developed by CMMI were implemented, as intended, on a voluntary, limited-scale basis where no state, healthcare provider, or health insurer had any obligation to participate. However, on November 24th, 2015, the Centers for Medicare and Medicaid Services (CMS) published a final rule requiring at least 800 hospitals in 67 geographical areas selected by CMS to participate in a new bundled payment model for hip and knee replacements, the Comprehensive Care Joint Replacement (CJR) Model.³ Furthermore, on March 8th, 2016, CMS released a proposed rule that requires thousands of providers across the country to comply with a new drug payment model under Part B of Medicare.^{4,5} The proposed Part B Drug Payment Model is a clear example of the CMMI's overstep of authority, given the mandatory participation required of thousands of providers and millions of patients with serious conditions and rare diseases on a

¹ Social Security Act Sec. 1115A(a).

² CMS bases its authority for the Part B Proposal on Section 1115A, which can be viewed as an unconstitutional delegation of legislative power. Article I, Section 1 of the Constitution prohibits Congress from delegating its legislative powers to other bodies, including executive agencies like CMS. See *Whitman v. Am. Trucking Assn's*, 531 U.S. 457, 472 (2001).

³ 80 Federal Register 73274, November 24, 2015.

⁴ 81 Federal Register 13230, March 11, 2016.

⁵ The Demonstration Program would change reimbursement practices for 75 percent of the country.

near-nationwide scale. Most recently, on July 25th, 2016, CMS announced the Cardiac Bundled Payment Model (Cardiac Models) that forces one quarter of all metropolitan areas across the nation into bundled payments for certain severe cardiac conditions and expands the controversial CJR Model to include more hip services.⁶ In contravention of the statute, these CMMI models were developed absent input from impacted stakeholders and fail to include safeguards to protect the delicate balance of quality, cost, and access to care for beneficiaries. These mandatory models overhaul major payment systems, commandeer clinical decision-making, and dramatically alter the delivery of care.

By focusing solely on cost-savings without adequate regard to the detrimental effects that the CJR Model, Part B Drug Payment Model, and Cardiac Models may potentially have, CMS at best has heeded only part of its statutory duty—“reduc[ing] program expenditures”—at the expense of its other duties—“preserving or enhancing the quality of care.”⁷ However, a 2015 blog post by the Congressional Budget Office would suggest that CMMI’s demonstrations do not in fact reduce costs, stating that they have “not yet yielded noticeable savings.”^{8,9} In addition to failing to cut costs, mandating participation in large scale demonstrations could have the opposite effect of “preserving or enhancing the quality of care.”¹⁰ We are aware that some models tested under demonstration programs fail to produce quality improvements and anticipated cost savings. This is why the statute authorized the Secretary to “test innovative payment and service delivery models”¹¹—not *mandate* them for all providers in designated geographical areas. CMMI’s mandatory models “experiment” with thousands of patient lives without prior testing on a smaller scale or even a basic indication that they will actually achieve improved quality or, at the very least, maintain present quality.

CMMI has failed to meet its statutory requirements for implementing models, including starting with a limited, “Phase I” test, engaging stakeholders in model development, and describing the “defined population” and “deficits in care”¹² the model seeks to address. As a result, Medicare providers and their patients are blindly being forced into high-risk government-dictated reforms with unknown impacts. Any true medical experiment requires patient consent. However, patients residing in an affected geographical area will have no choice about their participation.

As elected Representatives of our constituents and patients who will be directly impacted by these CMMI models or “experiments,” we are limited in our rightful ability to act on behalf of our constituencies to alter, delay or upend these mandatory demonstration programs. CMS’ Part B proposal, for example, would rewrite Medicare Part B payment law in 75 percent of the country without going through the Constitutional procedures where legislation is debated and approved in

⁶See proposal on July 25, 2016 at <https://innovation.cms.gov/Files/x/advancing-care-coordination-nprm.pdf>

⁷ 42 U.S.C. § 1315a(a).

⁸ *Estimating the Budgetary Effects of Legislation Involving the Center for Medicare and Medicaid Innovation*, Congressional Budget Office

⁹ CBO reiterated the contents of the blogpost in testimony before the House Budget Committee on September 7th, 2016. (Mark P. Hadley, *CBO’s Estimates of the Budgetary Effects of the Center for Medicare & Medicaid Innovation*, testimony before the Committee on the Budget, U.S. House of Representatives, 7 September 2016)

¹⁰ As Justice Scalia cautioned, “*Chevron* allows agencies to choose among competing reasonable interpretations of a statute; it does not license interpretive gerrymanders under which an agency keeps parts of statutory context it likes while throwing away parts it does not.” *Michigan v. EPA*, 576 U.S. __ (2015), slip op. 9 (citing *Chevron v. NRDC*, 467 U.S. 837 (1984)).

¹¹ 42 U.S.C. § 1315a(a)(1) (emphasis added).

¹² Social Security Act Sec. 1115A(b)(2)(A).

both chambers of Congress, and subsequently signed by the President. These most basic tenets of our government, intended by our Founding Fathers to preserve and maintain balance of power, have clearly been neglected. CMMI interprets their authority to “test” innovative models on a limited basis as a means to substantially alter both the delivery and reimbursement of care without any input or approval from Congress and the constituents we represent.

Accordingly, we insist CMMI stop experimenting with Americans’ health, and cease all current and future planned mandatory initiatives within the CMMI. Additionally, we ask that you commit to ensuring future CMMI models fully comply with current law, including: limiting the size and scope of CMMI demonstrations so they represent true tests rather than wholesale changes to statute; seeking Congressional approval if expansion of test models require changes to the underlying statute; and establishing an open, transparent process that supports clear and consistent communication with physicians, patients and other relevant stakeholders in the development of new CMMI models.

We look forward to your response detailing next steps as to how the agency plans to ensure that the CMMI will cease current mandatory initiatives and refrain from pursuing any future initiatives that exceed CMMI’s scope of authority.

Sincerely,

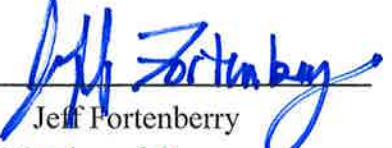


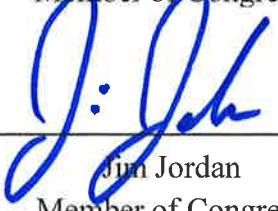
Tom Price, M.D.
Member of Congress



Charles W. Boustany, Jr., M.D.
Member of Congress

Erik Paulsen
Member of Congress


Jeff Fortenberry
Member of Congress


Jim Jordan
Member of Congress



Joe Wilson
Member of Congress



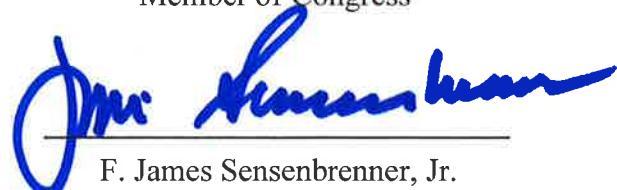
Mike Simpson
Member of Congress



Mike G. Fitzpatrick
Member of Congress



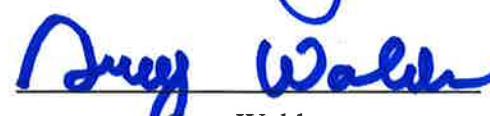
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F. James Sensenbrenner, Jr.
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Mike Kelly
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Greg Walden
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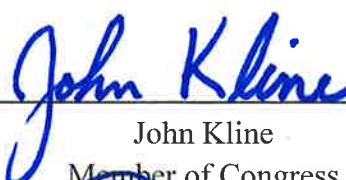
Louie Gohmert
Member of Congress



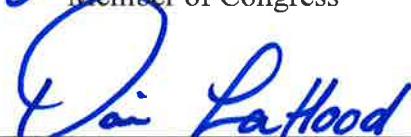
Steve Scalise
Member of Congress



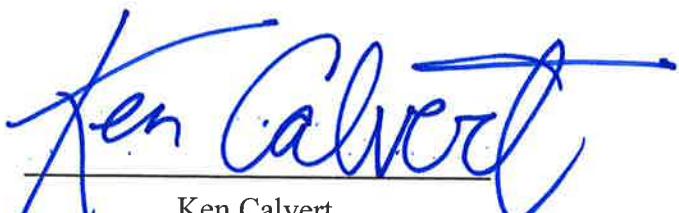
Harold Rogers
Member of Congress



John Kline
Member of Congress



Darin LaHood
Member of Congress



Ken Calvert
Member of Congress



Vicky Hartzler
Member of Congress



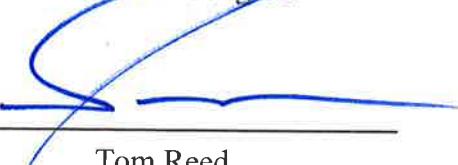
Peter Roskam
Member of Congress



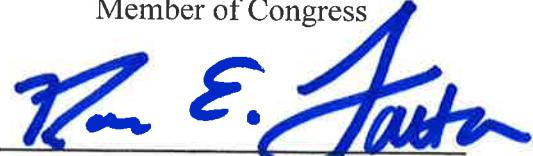
Matt Salmon
Member of Congress



Brett Guthrie
Member of Congress



Tom Reed
Member of Congress



Robert Latta
Member of Congress



Charles W. Dent
Member of Congress



Jason Chaffetz
Member of Congress



Kenny Marchant
Member of Congress



Leonard Lance
Member of Congress



Trent Franks
Member of Congress



Tom Graves
Member of Congress



Tom Cole
Member of Congress

Glenn GT Thompson

Glenn "GT" Thompson
Member of Congress

Robert B. Aderholt

Robert B. Aderholt
Member of Congress

Chris Stewart

Chris Stewart
Member of Congress

Ryan Costello

Ryan A. Costello
Member of Congress

Glenn Grothman

Glenn Grothman
Member of Congress

Dan Benishek

Dan Benishek, M.D.
Member of Congress

Randy Forbes

Randy Forbes
Member of Congress

Joe Heck

Joe Heck, D.O.
Member of Congress

Doug LaMalfa

Doug LaMalfa
Member of Congress

Ralph Abraham

Ralph Abraham, M.D.
Member of Congress

Richard Hudson

Richard Hudson
Member of Congress

Ted S. Yoho

Ted S. Yoho
Member of Congress

Walter B. Jones

Walter B. Jones
Member of Congress

Mark Sanford

Mark Sanford
Member of Congress

Billy Long

Billy Long
Member of Congress

Todd Rokita

Todd Rokita
Member of Congress

Vern Buchanan

Vern Buchanan
Member of Congress

Gus Bilirakis

Gus Bilirakis
Member of Congress

John J. Duncan Jr.

John J. Duncan, Jr.
Member of Congress

Mac Thornberry

Mac Thornberry
Member of Congress

Jeb Hensarling

Jeb Hensarling
Member of Congress

Pete Sessions

Pete Sessions
Member of Congress

Adrian Smith

Adrian Smith
Member of Congress

Marsha Blackburn

Marsha Blackburn
Member of Congress

Sam Johnson

Sam Johnson
Member of Congress

Tom McClinton

Tom McClinton
Member of Congress

Tim Murphy

Tim Murphy, Ph.D.
Member of Congress

Michael C. Burgess

Michael C. Burgess, M.D.
Member of Congress

S. Holts

George Holding
Member of Congress

D. Nunes

Devin Nunes
Member of Congress

C. Collins

Chris Collins
Member of Congress

A. Kinzinger

Adam Kinzinger
Member of Congress

B. Wenstrup

Brad Wenstrup, D.P.M.
Member of Congress

S. Brooks

Susan W. Brooks
Member of Congress

A. Harris, M.D.

Andy Harris, M.D.
Member of Congress

Rick W. Allen

Rick Allen
Member of Congress

B. Flores

Bill Flores
Member of Congress

P. Tiberi

Patrick Tiberi
Member of Congress

F. Hill

French Hill
Member of Congress

A. Barr

Andy Barr
Member of Congress

L. Jenkins

Lynn Jenkins
Member of Congress

R. Ellmers

Renee Ellmers
Member of Congress

Brad Ashford

Brad Ashford

Member of Congress

John Moolenaar

John Moolenaar

Member of Congress

Bruce Westerman

Bruce Westerman

Member of Congress

Rod Blum

Rod Blum

Member of Congress

Robert Pittenger

Robert Pittenger

Member of Congress

Chuck Fleischmann

Chuck Fleischmann

Member of Congress

Gregg Harper

Gregg Harper

Member of Congress

Lou Barletta

Lou Barletta

Member of Congress

Bradley Byrne

Bradley Byrne

Member of Congress

Gary Palmer

Gary Palmer

Member of Congress

Robert J. Dold

Robert J. Dold

Member of Congress

Barbara Comstock

Barbara Comstock

Member of Congress

Mimi Walters

Mimi Walters

Member of Congress

Brian Babin

Brian Babin, D.D.S.

Member of Congress



Mike D. Rogers
Member of Congress



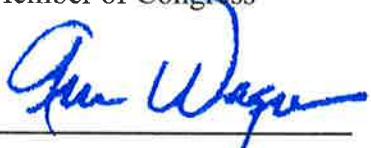
Jim Renacci
Member of Congress



Jackie Walorski
Member of Congress



Earl L. "Buddy" Carter
Member of Congress



Ann Wagner
Member of Congress



David P. Roe, M.D.
Member of Congress



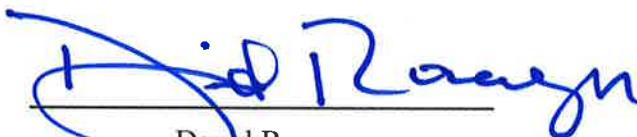
Evan Jenkins
Member of Congress



Frank Guinta
Member of Congress



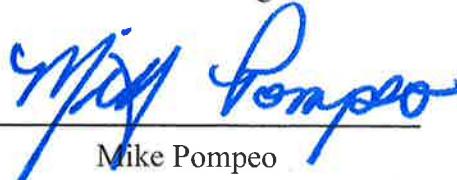
Ken Buck
Member of Congress



David Rouzer
Member of Congress



Patrick Meehan
Member of Congress



Mike Pompeo
Member of Congress



Martha Roby
Member of Congress



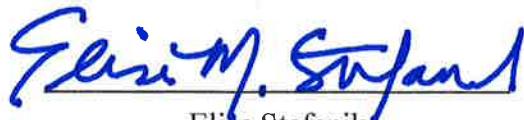
Paul Gosar, D.D.S.
Member of Congress



Ron DeSantis
Member of Congress



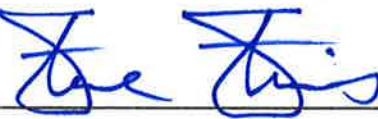
Mark Walker
Member of Congress



Elise Stefanik
Member of Congress



David G. Valadao
Member of Congress



Steve Stivers
Member of Congress



Mark Meadows
Member of Congress



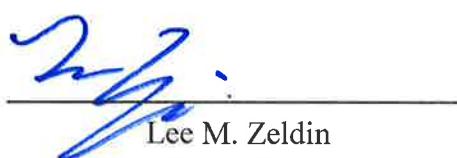
H. Morgan Griffith
Member of Congress



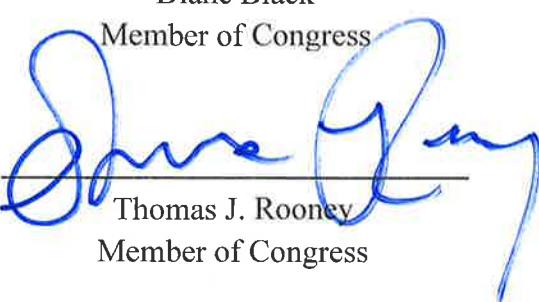
David Joyce
Member of Congress



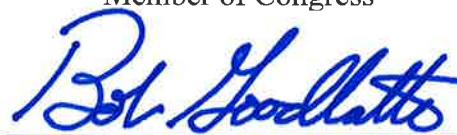
Diane Black
Member of Congress



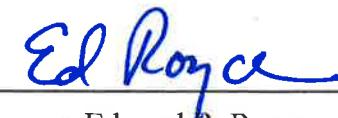
Lee M. Zeldin
Member of Congress



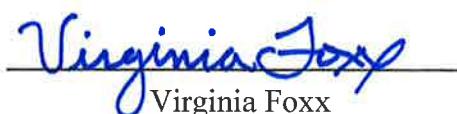
Thomas J. Rooney
Member of Congress



Bob Goodlatte
Member of Congress



Edward R. Royce
Member of Congress



Virginia Foxx
Member of Congress

Randy Neugebauer

Randy Neugebauer
Member of Congress

Carlos Curbelo

Carlos Curbelo
Member of Congress

Mike Bost

Mike Bost
Member of Congress

Reid Ribble

Reid Ribble
Member of Congress

Jody Hice

Jody Hice
Member of Congress

Dave Trott

Dave Trott
Member of Congress

Rodney Davis

Rodney Davis
Member of Congress

Pete Olson

Pete Olson
Member of Congress

Scott Garrett

Scott Garrett
Member of Congress

Bill Shuster

Bill Shuster
Member of Congress

Patrick McHenry

Patrick McHenry
Member of Congress

John Culberson

John Culberson
Member of Congress

Austin Scott

Austin Scott
Member of Congress

Tim Walberg

Tim Walberg
Member of Congress

Kevin Cramer

Kevin Cramer
Member of Congress

D. A. Ross

Dennis A. Ross
Member of Congress

S. DesJarlais

Scott DesJarlais, M.D.
Member of Congress

Martha McSally

Martha McSally
Member of Congress

J. Smith

Jason Smith
Member of Congress

K. Katko

John Katko
Member of Congress

S. Duffy

Sean Duffy
Member of Congress

Tom Rice

Tom Rice
Member of Congress

T. Marino

Tom Marino
Member of Congress

T. Young

Todd Young
Member of Congress

M. Mullin

Markwayne Mullin
Member of Congress

S. Womack

Steve Womack
Member of Congress

K. Rothfus

Keith Rothfus
Member of Congress

M. Brooks

Mo Brooks
Member of Congress

Mike Bishop

Mike Bishop
Member of Congress

David Young

David Young
Member of Congress

Bill Huizenga

Bill Huizenga
Member of Congress

Bill Johnson

Bill Johnson
Member of Congress

Lynn Westmoreland

Lynn Westmoreland
Member of Congress

Darrell Issa

Darrell Issa
Member of Congress

Blaine Luettkemeyer

Blaine Luettkemeyer
Member of Congress

Crescent Hardy

Crescent Hardy
Member of Congress

Warren Davidson

Warren Davidson
Member of Congress

Chris Gibson

Chris Gibson
Member of Congress

John Fleming, M.D.

John Fleming, M.D.
Member of Congress

Steve King

Steve King
Member of Congress

Ted Poe

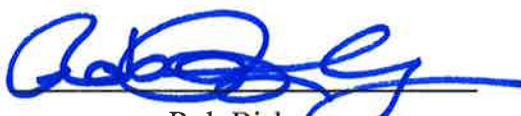
Ted Poe
Member of Congress

Randy Hultgren

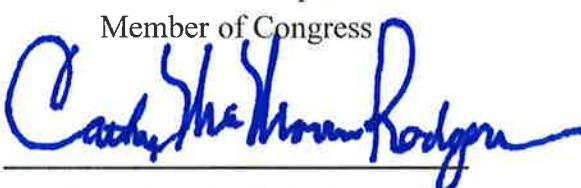
Randy Hultgren
Member of Congress



Jeff Duncan
Member of Congress



Rob Bishop
Member of Congress



Cathy McMorris Rodgers
Member of Congress



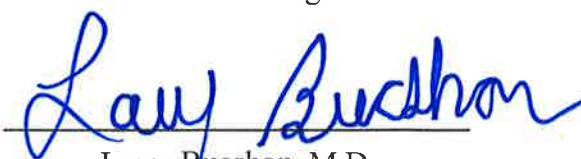
Mia Love
Member of Congress



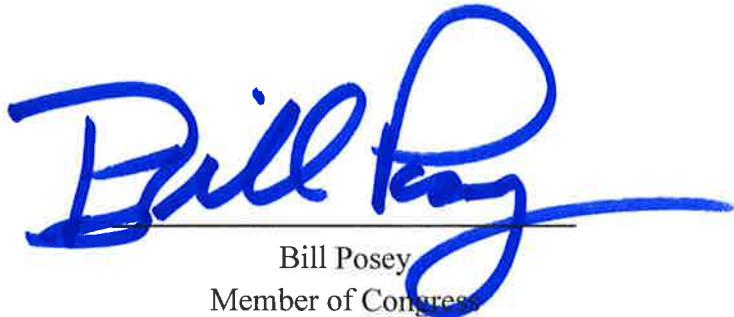
Thomas Massie
Member of Congress



David B. McKinley
Member of Congress



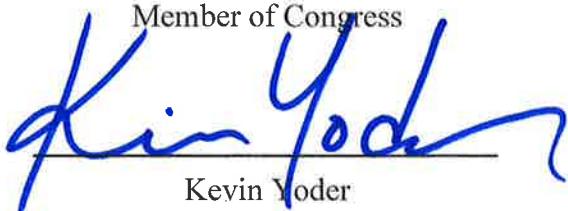
Larry Bucshon, M.D.
Member of Congress



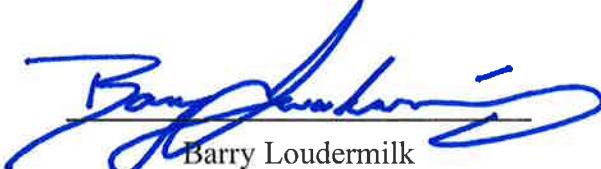
Bill Posey
Member of Congress



Michael T. McCaul
Member of Congress



Kevin Yoder
Member of Congress



Barry Loudermilk
Member of Congress



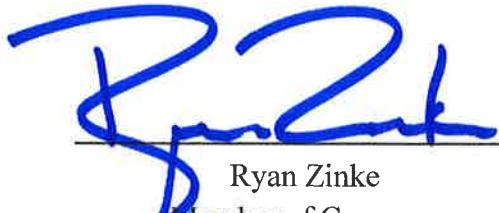
Dave Brat
Member of Congress



Tom Emmer
Member of Congress



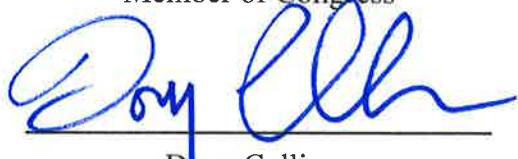
Paul Cook
Member of Congress



Ryan Zinke
Member of Congress



Tom MacArthur
Member of Congress



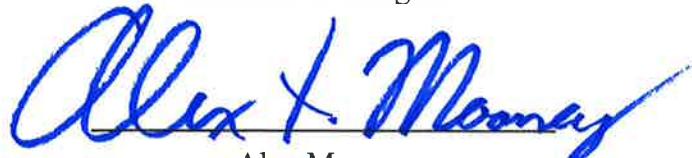
Doug Collins
Member of Congress



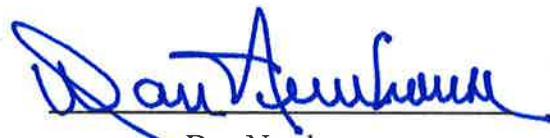
Rob Woodall
Member of Congress



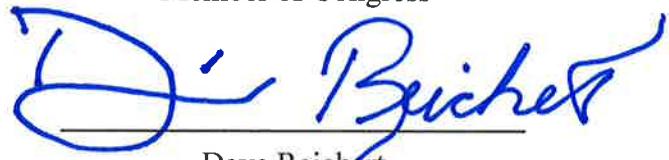
Scott Tipton
Member of Congress



Alex Mooney
Member of Congress



Dan Newhouse
Member of Congress



Dave Reichert
Member of Congress