COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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Submitted electronically to: http://www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-ANPRM
P.O. Box 8016
Baltimore, MD 21244-8013

Re: *Medicare Program; International Pricing Index Model for Medicare Part B Drugs; CMS-5528-ANPRM*

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are submitting this comment letter regarding the *Medicare Program; International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM)* (the "IPI Model").

As you know, COA is an organization that is dedicated to advocating for the complex care and access needs of cancer patients and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA's mission is to ensure that cancer patients receive quality, affordable, and accessible cancer care in their own communities where they live and work. For more than 15 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support cancer patients.

First, we want to say that we appreciate your openness and interest in understanding our position on this important topic of the cost of prescription drugs in the Medicare Part B program ("Part B"), as well as the overall total cost of cancer care, which is comprised of drugs and services, both hospital and physician related. We thank you for meeting with us on two occasions leading up to the preparation and submission of this comment letter, as well as the opportunity to submit this letter. Although we are very concerned about escalating drug prices/costs and the high total cost of cancer care, as we have expressed to you, **COA does not support the IPI Model as proposed** in the pre-proposed rule published by the Centers for Medicare & Medicaid Services ("CMS") because we have serious concerns about its impact on cancer patient care and even its legality. That said, we are actively working on solutions to high drug costs and the total cost of cancer care and, as we outline in this comment letter, are developing and analyzing alternatives to the model.

COA is sincerely committed to oncology payment reform that makes cancer care more affordable, as witnessed by our commitment and involvement in the Oncology Care Model ("OCM"); our ongoing development of the OCM 2.0, a next-generation, more universal oncology payment model; the numerous summits and meetings we have held with payers, employers, stakeholders, and providers; and the involvement of community practices, like ours, in an incredible number of private insurance payment models and programs. Community oncologists are concerned about the escalating prices and costs of cancer drugs, as well as high hospital-related costs, all of which contribute to the overall increasing total cost of cancer care. As leaders in the delivery of cancer care, we are mindful of our

responsibility to be good stewards of costs we can control, including the utilization of drugs and services.

In this letter, we will detail our problems and concerns regarding the IPI Model as proposed, even though we have summarized these with you, leadership, and staff from CMS and the CMS Innovation Center ("CMMI") in previous exchanges. We understand and appreciate that CMS appears to be already considering changes to its proposed model, and implementation of it, based on input from COA and providers. However, we believe it is important to detail our concerns with the IPI Model as proposed, for both the sake of memorializing our comments and as understanding the basis for our alternative suggestions.

In this comment letter, we will also outline alternatives to the IPI Model, which we are currently working on in greater detail. Some of that detail will not be available in this comment letter, given the submission deadline of 12/31 and the holiday season, coupled with the fact that we have much more analytical work to do on these alternatives.

We hope to continue the dialogue with CMS post submission of this comment letter, as we continue our analytical process and CMS moves towards a proposed rule on the IPI Model.

Summary Comments

COA does not support the IPI Model, and we strongly urge CMS *not to move forward with it as proposed.* We are greatly concerned that the IPI Model, which would conduct nothing short of a mandatory national *experiment* on Medicare Part B beneficiaries, could disrupt access to the innovative therapies and care that vulnerable seniors with cancer and other serious diseases need and are guaranteed under Medicare. The reasons for COA's position are summarized as follows:

- Given that the three major wholesalers that provide over 95% of the cancer drugs to community cancer clinics will not participate in the Competitive Acquisition Program ("CAP") portion of the IPI Model, the only possible participants are pharmacy benefit manager ("PBM") middlemen, and their related specialty and mail order pharmacies, who will insert themselves between oncologists and their patients. As with Medicare Part D ("Part D") and commercial pharmacy benefit plans, these PBMs and related middlemen have seriously adversely impacted cancer care by delaying treatment, delivering incorrect dosages of drugs, and in some cases, denying necessary treatment.

- The only possible way to implement CAP is for these middlemen to "white bag" chemotherapy and related cancer treatment drugs to community oncology clinics; meaning, provide those drugs on an ordered, patient-by-patient basis. This will totally upend the current "just in time" Part B drug delivery system, which provides seniors and other Medicare beneficiaries with the most immediate, effective, and efficient access to cancer treatment.

- The IPI Model as proposed is a mandatory national CMMI *experiment* that would radically change how Medicare beneficiaries receive their cancer therapies. Because it is mandatory for an estimated 50% of oncology providers, it will force their patients (approximately 50% of all Medicare fee-for-service beneficiaries) to participate. Yet, there is no informed consent for patients; no ability for patients to opt-out (other than finding another oncology provider not being forced to participate); and no other meaningful research safeguards protecting patients in what is effectively forced clinical research.

We also note, for the record, that COA is adamantly against any mandatory demonstration projects conducted by CMMI. As we detail in the attached legal analysis (Attachment A: *Legal and Constitutional Problems with a Mandatory International Pricing Index Model*), mandatory demonstration projects are clearly not in the charter of CMMI as written into law by Congress. If CMS believes that CMMI has the power via statute to effectively amend Medicare law – in this case the Part B drug reimbursement rate for at least 50% of Part B providers – it (CMS representing the Executive branch) either has overstepped its constitutional boundaries separating the powers of government branches or Congress

has effectively handed over its powers to the Executive branch. That would either be illegal or unconstitutional, with the latter case invalidating the section of the law that created and funded CMMI.

By their nature, "mandatory" demonstrations are such because they force providers to participate and do not have stakeholder input or buy-in. This was the case with the attempt by the previous administration to force 75% of Part B providers to participate in the failed Medicare Part B Purchasing Model in late 2016.

Finally, we note two other concerns with the IPI Model as proposed. First, we have concerns about operationalizing an international pricing index as Part B drug reimbursement and about the adverse impact on commercial reimbursement, as further detailed in the aforementioned attached document (Attachment A). Second, we have several concerns about a "flat" average sales price ("ASP") add-on, or any type of "capitated" fee payment, which we will also touch on later in this comment letter.

In summary, COA is very concerned that the IPI Model as proposed will totally upend how cancer care is delivered under Part B given the proposed mandatory national scope. The introduction of middlemen to Part B will seriously threaten the access of seniors and other Medicare beneficiaries to cancer treatment currently being delivered on an immediate "just in time" basis and close to home. Additionally, we are concerned with how such widespread changes (impacting 50% of Part B providers) to Part B reimbursement will impact the viability of community cancer clinics to continue providing care.

COA's concerns about the IPI Model as proposed are based not on supposition or unfounded threats but on two clear facts. First, as we have documented in four volumes of actual patient cases[1], PBMs and related middlemen are having an increasingly adverse effect on the treatment of cancer patients under Medicare Part D and commercial pharmacy benefit plans providing oral cancer drugs. Second, as we have documented along with others, there has been a marked shift of cancer care from physician-run community sites into large hospital systems due to declining reimbursement, especially in Part B, and clinic closings in rural areas. Data on this shift can be clearly seen in the annual COA Practice Impact Report, which tracks the changing landscape of community cancer care in the U.S. In the 2018 report, we note that 1,653 community oncology clinics and/or practices have closed, been acquired by hospitals, undergone corporate mergers, or reported that they are struggling financially. An average of 3.5 community oncology practices have closed per month, a rate that remains unchanged since the last report issued in 2016. Overall, 13.8 practices per month have closed, been acquired by hospitals, or undergone mergers since 2008.[2] A recent feature in the Houston Chronicle newspaper makes this trend of closures real, telling the story of the anticipated closing of the Rio Bravo Cancer and Blood Clinic, which is currently providing cancer care to patients from over a 10,000 square mile area in rural Texas. As related in the story, *"Most patients are seniors and dependent on Medicare…. But the clinic has been in the red for about 18 months because of a series of Medicare cuts for cancer drugs…."*[3]

Radically changing Medicare reimbursement on a national basis, without studying its impact, could accelerate the shift in the site of cancer care from independent community cancer clinics to much more expensive hospital systems, resulting in higher costs for Medicare, commercial insurers, and beneficiaries, as well as in serious cancer care access issues, especially in rural or underserved areas.

As we have stated, COA appreciates that CMS is actively soliciting stakeholder input on what is a proposed model in a pre-proposed rule. Also, we are encouraged that CMS is listening to alternatives and other approaches.

In terms of specific alternatives that we are considering and analyzing, they include:

- Tiering ASP-Based Reimbursement
- Employing Clinically Appropriate Utilization Management in Part B

[1] https://www.communityoncology.org/category/horror-stories

[2] https://www.communityoncology.org/2018-community-oncology-practice-impact-report/

[3] www.houstonchronicle.com/news/local/article/Border-cancer-clinic-faces-closure-13399898.php

- Addressing High Out-of-Pocket Costs
- Lowering Drug Prices Without Artificial International Price Indexing

Comments on Concerns with the IPI Model as Proposed

Opposition to the Mandatory National Scope of the IPI Model as Proposed

The IPI Model as proposed is one of the largest and most complex CMMI demonstrations developed to date, with a broad geographic reach and strong potential to disrupt both the drug supply chain and the care delivery system. COA is **staunchly opposed** to mandatory models, especially of the scale and complexity outlined as part of the IPI Model. As previously expressed, we are against using mandatory demonstrations as a vehicle for the Executive branch to effectively bypass Congress by making sweeping changes to Medicare law. The IPI Model establishes a "demonstration" of the size and scope that far exceeds anything that can be reasonably considered a "test."

COA's legal and constitutional reasons for our opposition to mandatory CMMI demonstration projects are summarized as follows:

- *The IPI Model as Proposed Exceeds CMS' Statutory Authority.* In mandating a model, CMS will undoubtedly rely on Section 1115A of the Patient Protection and Affordable Care Act ("ACA"). The IPI Model as proposed exceeds CMS' authority because, among other reasons: (A) the IPI Model is inconsistent with the express mandate of Section 1115A; (B) the IPI Model – by being mandatory in scope and affecting 50% of the nation – is not a test or model; and (C) the IPI Model appears not to be based upon a model developed by CMMI, but rather one developed outside of CMMI.

- *The Secretary[4] Has No Authority to Waive Medicare Provisions Under the IPI Model*. As the IPI Model fails to meet the requirements for "testing," the Secretary has no authority to waive any requirements of the Medicare statute, especially the Part B drug reimbursement provisions.

- *The IPI Model Raises Constitutional Concerns.* Section 1115A would raise several constitutional concerns if the Secretary or CMS were allowed to modify or amend the Medicare statute, especially in view of the proposal's direct effect on 50% of the country and likely effect on the rest of the country resulting from modifications to ASP.

- *The IPI Model Contravenes Other Applicable Laws.* The IPI Model violates Section 3601 of the ACA, as the implementation of the model would affect guaranteed Medicare benefits and other provisions.

Attached (Attachment A) is a detailed overview of the legal and constitutional problems with the IPI Model as proposed.

COA is also very concerned that the mandatory nature of the IPI Model and the completely randomized process to divide the country into experimental and control groups would create insurmountable operational changes and would disadvantage patients based on geography. We do not believe that the agency can arbitrarily select geographies without creating significant disparities in access to care for seniors and other Medicare beneficiaries with cancer. Further, *because the entire supply chain for oncology products would be disrupted*, the IPI Model will impact providers both inside and outside the demonstration. As such, the IPI Model will impact not only 50% of Part B, but also Medicare Advantage ("MA") and commercial plans and beneficiaries – in effect, the entire country. Additionally, this will present serious treatment dilemmas for practices, providers, and patients, and does not represent a solid experimental design. Any wholesale changes to Part B, especially impacting care delivery, should first be carefully *tested* on a limited scale, through programs that are voluntary for both patients and providers, in order to avoid creating

[4] For purposes of the statute, "Secretary" is defined as the Secretary of Health and Human Services, *"except when the context otherwise requires."* 42 U.S.C. § 1301(6).

operational complexities, increasing administrative burdens, and potentially even adding more costs to Medicare and its beneficiaries.

We believe that the IPI Model would hurt independent community oncology providers, who, ironically, do not represent significant cost burdens to the Part B program. According to the Medicare Payment Advisory Commission ("MedPAC"), Part B spending has been growing more rapidly for hospital outpatient departments ("HOPDs") than for physicians and suppliers. Between 2009 and 2015, Part B drug spending grew at an average of roughly 16% for HOPDs and about 7% for physicians.[5] Similarly, a recent peer-reviewed study found that both the mean total cost of care and the mean chemotherapy costs per patient per month were significantly lower for patients treated in a community-based practice compared with those treated in a hospital-based outpatient facility.[6]

We understand that the administration sees the increase in spending on oncology therapies as a challenge for patients and the federal budget. However, we do not agree that it is appropriate to address Part B cost growth by targeting community practices and independent physicians and endangering their ability to practice, especially given their proven role in driving value and efficiency in cancer care. Furthermore, cancer is a complex and sensitive therapeutic area and it does not lend itself well to models that seek to interfere with evidence-based clinical decision-making. Oncologists should not be punished for embracing medical innovation in the form of immunotherapies, targeted therapies, and personalized medicines that have transformed care and given patients with cancer a fighting chance.

Concerns about CAP and Middlemen as CAP Vendors in the IPI Model as Proposed

Under the IPI Model as proposed, CMS is looking to leverage its dormant authority under the previous failed CAP to contract with private-sector "vendors" to act as middlemen between manufacturers, physicians, HOPDs, and other providers for the drugs and biologic products included in the IPI Model.

COA strongly opposes any proposal to incorporate middlemen into the Part B program and empowering those entities to wield influence on cancer treatment. We firmly believe that all Medicare seniors, especially those facing life-threatening diagnoses like cancer, should have timely and unhindered access to the therapies that their physicians believe to be most effective for them. We do not believe that allowing corporate middlemen – who do not have in-depth clinical oncology experience – into Part B under CAP will improve patient care or outcomes. In fact, experience documents that it will do the exact opposite.

Under the IPI Model, physicians would be limited in their ability to treat patients to the best of their medical knowledge and experience, as CAP vendors would be able to directly or indirectly dictate the choice of therapies in the model. As cancer treatment becomes more precise and individualized, introducing an additional layer between patients and life-saving medicines is not only inappropriate, it could be very dangerous for seniors facing life-threatening diagnoses.

Furthermore, we are concerned that **adding middlemen to Part B through the IPI Model would introduce the same cancer treatment access challenges experienced by cancer patients today in Part D.** COA is befuddled by the administration's interest in increasing the power and prevalence of middlemen at a time when both policymakers and the public have a heightened awareness of the business model and distorted incentives that have allowed PBMs to consolidate and grow their influence without reducing costs. In Medicare Part D, PBMs have increasingly sought to control costs by using a variety of mechanisms to steer patients toward less expensive therapies, but ultimately unduly complicating drug procurement, delaying and denying patients' treatment, and driving up costs.

COA believes that the IPI Model could repeat past reform mistakes. The original CAP program, which ran for 18 months between 2006 and 2008, has been suspended for the last decade for good reasons. The original program presented a host of issues for Medicare, including negative impacts on access and supply chain dynamics and limited

[5] Medicare Payment Advisory Commission (MedPAC), "June 2017 Report to Congress," June 2017.

[6] Lucio Gordan et al. "Cost Differences Associated With Oncology Care Delivered in a Community Setting Versus a Hospital Setting: A Matched-Claims Analysis of Patients With Breast, Colorectal, and Lung Cancers," October 2018 https://www.communityoncology.org/wp-content/uploads/sites/20/2018/11/Gordan-2018_JOP_Site-of-Care-article.pdf

participation from both physicians and vendors. The original CAP program, we note, did not effectively lower costs for Medicare or for patients, and added significant complexities to drug negotiations and procurements. If CMS decides to reimpose CAP on the Medicare program, it will force the creation of individual patient inventories, increase the likelihood of treatment errors and delays, and place new and unreimbursed administrative burdens on clinicians. While the agency technically has the statutory authority to bring back CAP, COA strongly urges the administration to reconsider this proposal. CAP was not the answer to increasing competition in Part B in 2008, and it is not the answer in 2018.

Concerns About Included Drugs and Biologicals in the IPI Model as Proposed

It is unclear which drugs or therapeutic classes would ultimately be included under the proposed demonstration, but CMS has indicated its interest in including the "top spending" Part B drugs in the IPI Model. The agency has stated that it would likely start with an initial set of drugs in the early model years before expanding to a broader set of therapies.

COA believes that the IPI Model proposal should be withdrawn, but at a minimum cancer drugs should be excluded. Cancer treatment is a complex and sensitive therapeutic area, and it is inappropriate to subject patients with cancer and the providers that treat them to large-scale experimentation that could threaten patient outcomes.

Since the Secretary has the authority to exclude any drugs and biologicals whose inclusion is unlikely to result in cost savings or whose inclusion would have an adverse effect on access, we would like to flag some issues related to access to cancer drugs under the original CAP[7] to point to the need to carve oncology out of any new CAP demonstration, regardless of how it is modified:

- On average, among the Top 30 CAP drugs in 2007, CAP payment for cancer drugs was higher than ASP plus 6%.

- Between 20-30% of CAP claim line items for cancer drugs were billed under the "emergency restocking" provision to account for point-of-care changes to previously ordered drugs based on patients' clinical presentation at the time of the visit. This means that CAP-participating oncology practices had to maintain a stock of drugs for emergency use at some financial risk *for about 1 of every 4 drugs they administered*.

- Provider surveys on overall satisfaction with CAP among participants showed that oncology specialists reported being less satisfied than other providers surveyed, likely due to the complexity of the therapeutic area, the types of drugs that they administered, and the types of Medicare beneficiaries who they treated.

All Medicare seniors should have access to all therapies available, and the IPI Model as proposed would severely restrict the use of both new and standard-of-care cancer treatments. Cancer patients rely heavily on innovation in treatments and COA is concerned that every element of this model seriously challenges access to therapies and innovation. As the newest and innovative therapeutic products are, by definition, single-source, this proposal could limit the availability of the best available options in cancer treatment for seniors and other Medicare beneficiaries in the Part B program. Furthermore, CMS' proposal could disincentivize lifesaving innovations.

COA believes the current Part B system offers the flexibility to use and administer the most clinically appropriate therapies based on clinical considerations, without delays or disruptions in cancer care.

Concerns About Flawed Notions of Part B Prescribing in the IPI Model as Proposed

The focus on changing the provider payment for drugs is grounded in the *flawed* notion that providers choose treatments based on financial considerations, rather than clinical ones. This is both incorrect and *incredibly*

[7] Evaluation of the Competitive Acquisition Program for Part B Drugs, December 2009 https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf

offensive. Independent, peer-reviewed research has found that modifying payment for cancer care ***does not*** impact clinical decision making for providers, but rather that the factors that *actually* impact prescribing patterns are the introduction of new drugs, new clinical evidence, and identifying new best-practices for treatment.[8] In short, medical professionals make medical decisions using clinical evidence, not for financial gain. Providers already face the burdens associated with identifying and educating themselves on innovative techniques and therapies that can help their patients. Employing bureaucratic barriers to accessing these therapies is inappropriate.

Attached is a just completed meta-analysis on the subject of oncologist prescribing (Attachment B: "*The Myth of Perverse Physician Incentives: Examining Research and Accusations in the Medicare Part B ASP Reimbursement System for Oncology*"). It thoroughly debunks the false narrative that oncologists' decision-making is driven by financial factors, much of which is based on extremely outdated and/or fundamentally flawed research. In fact, a number of studies on physician prescribing under the Part B reimbursement system have been published in recent years, all of which reach dramatically differing conclusions on physician prescribing patterns. They identify the following as drivers of drug selection by oncologists:

- Highest-quality patient care;
- Most effective treatment options;
- Best expected outcome;
- Best tolerated, least toxicity or permanent ill effects;
- Care regimen least disruptive to daily life;
- Most cost-effective option for the patient;
- Financial cost to the patient; and
- Changing physician and patient expectations about cancer care.

Concerns About the IPI Model as Proposed and Interactions with Other Models and Federal Programs

CMS requested comments on how to avoid unintended consequences of the interaction between the IPI Model as proposed and other federal programs, as well as the potential impact of the inclusion of manufacturer sales to model vendors on "best price" and average manufacturer price ("AMP"), and whether CMS should exempt prices offered under the model from AMP and "best price" calculations.

It is important that any Part B measures *not* disrupt or further complicate existing value-based care initiatives. While COA is totally committed to increasing the quality of cancer care and decreasing costs, as well as supporting value-based models that can positively impact prices and utilization, the IPI Model as proposed is not value-based. The IPI Model appears to be designed to target only costs and gives no consideration to how it will impact quality of care, access to treatment, or the utilization of those treatments.

COA is already working to spearhead innovative payment reforms aimed at lowering costs and improving the quality of cancer care, notably including the OCM. Both COA *and* CMS have invested heavily in the OCM and **we urge CMS to consider the impact that the IPI Model as proposed would have on patients that are already benefitting from the OCM and other ongoing commercial value-based payment models.** We believe that the threats to the OCM presented by the IPI Model could represent an unfortunate loss of years of effort, resources, and funds if the IPI Model as proposed is implemented.

Concerns with the Indexing of Part B Drug Reimbursement to International Prices

To reiterate, we are very concerned about the increasing cost of Part B drugs based on increasing prices. However, we do not believe that the international indexing component of the IPI Model is a realistic solution to decreasing Part B drug costs. We are concerned about the feasibility of indexing drugs to international prices, about the impact on all

[8] Hornbrook, M., Malin, J., Weeks, J., Makgoeng, S., Keating, N., Potosky, A., "Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing?" *Journal of Clinical Oncology,* 20 December 2014.

cancer drug reimbursement (Medicare fee-for-service, MA, and commercial), and about the operational implementation of index pricing.

In terms of the feasibility of indexing cancer drug prices to international prices, we are concerned about the consistent availability of cancer drugs across all countries to arrive at consistent pricing. In a number of the countries that would be involved in the indexing basket of drugs, the same drugs available in the U.S. are not available in those countries – or are available for a limited set of indications or are available under different names. Additionally, manufacturers may possibly increase international "list" prices while using rebates and discounts to bring down the true "net" price of a drug in other countries. As it is, we believe that U.S. "list" drug prices are forced higher by the increasing scope and magnitude of required rebates and discounts, the latter notably including discounts required under the 340B Drug Pricing Program ("340B"). The increasing scope and magnitude of 340B drug discounts are fueling "list" prices of Part B drugs. **Equating U.S. "net" drug prices (i.e., ASP) with other countries, where the "list" price may not be reflective of rebates and discounts, creates "apples and oranges" pricing.**

The problems just discussed may create a situation wherein the arrived at IPI Model index price is artificially and unrealistically low. Although at first blush this appears to benefit Medicare and its beneficiaries by lowering prices, this is a house of cards that is not realistic and sustainable. There is no way a CAP middleman vendor, or even a provider, will be able to use an artificially low international price to leverage that price, or lower, from a manufacturer, given that most oncology drugs do not have competitive substitutes (either generic, biosimilar, or brand therapeutic substitutes). What happens then? Will CMS reimburse the CAP vendor (or the provider, if not CAP vendor) for a drug at the index price, even though the vendor, or the provider, cannot purchase the drug anywhere close to that price? No CAP "vendor" will participate in the program under that scenario and forcing a provider to accept drug reimbursement for less than what a drug can be purchased for is simply not financially feasible.

Additionally, we note that any models involving ASP-based reimbursement must be exempted from manufacturers' calculation of ASP so as to not inappropriately bring down the ASP calculation for those not participating in the proposed IPI Model, or other models. And CMS must not apply the 2% Medicare sequestration payment cut to any drug reimbursement models that are tested.

Finally, we note that "price fixing" of any goods and services has never worked in the long-term in the history of the world and typically leads to shortages, which already is a problem with low-priced generics. There are more effective and sustainable ways of lowering drug prices/costs through competition and market reform.

Comments on Alternatives to the IPI Model Components

As we have discussed, community oncologists are very concerned about access to and affordability of treatment for our patients, as well as the viability of our practices to continue providing the highest quality, most affordable, and most accessible cancer care. These concerns have guided us in analyzing the proposals in the IPI Model and in developing and analyzing possible alternatives. As we referenced earlier in this letter, COA is working on possible alternatives including the following:

- **Tiering ASP-Based Reimbursement:** COA highly supports the drug reimbursement formula established in the MMA under careful deliberations between Congress and stakeholders. We believe that an add-on percentage versus a flat fee (for example, based on some historical ASP, as proposed in the IPI Model) is important to preserve for two reasons. First, as we will explain, we are analyzing a modification to the percentage-based fee that is tiered as opposed to the current add-on fee of plus 6% (which, it should be noted, is really 4.3% after application of the 2% Medicare sequester cut) that we believe will be more appropriate to account for escalating drug prices and the emerging biosimilar market. Second, any type of flat fee will never keep up with medical inflation and the costs relating to the increasing complexity of Part B drug procurement, storage, and handing.

We note, as COA has done on numerous occasions, that the add-on to ASP is not "profit," as some falsely assert. It has to cover the very real *increasing* costs of human resources and infrastructure required to procure, handle, store, inventory, and dispose of chemotherapy and other cancer-related Part B drugs. What is left over covers operating expenses and bad debt. As it is, in the Medicare Physician Fee Schedule for 2019, community oncology practices will be reimbursed 3% less for administering chemotherapy. This is nonsensical and illustrates the problems of flat fees determined by Medicare formulas updated annually.

What COA is considering and analyzing, and recommends that CMS considers, is an alternative to a flat fee – a tiered percentage on ASP. More specifically, we are analyzing the following tiers of ASP add-on payments:

- A very high percentage add-on for generics;
- A higher than 6% add-on for biosimilars; and
- A tiered structure for brands whereby higher priced brands have a *lower* add-on payment and the add-on payment increases as the brand price is lower.

Note that we are not suggesting in any way that finances dictate oncologists' choices in making treatment decisions in consultation with their patients. However, given both the escalating cost of brand drugs and what will be the introduction of more biosimilars in oncology, a tiered add-on will create a more appropriate reimbursement structure for what the add-on to ASP covers. Additionally, with biosimilars the goal is to create a robust and healthy market. With generics, increasing reimbursement will substantially help mitigate the constant shortages plaguing the market, as FDA Commissioner Scott Gottlieb, MD recently suggested.[9]

We also note that a tiered add-on to ASP, coupled with the clinically appropriate utilization management concept outlined below, will impact manufacturers' pricing decisions for newly launched therapies depending on their degree of innovativeness. COA wants to maintain and reward drug therapy innovation and to continue to have access to new innovative therapies for our patients, but while controlling the costs of new therapies.

Our goals in considering this tiered ASP percentage add-on, in conjunction with employing clinically appropriate utilization management (as described below), are as follows:

- Maintain access to innovative new cancer therapies and incentivize manufacturers to continue to introduce those therapies;
- Enhance oncologists' clinically appropriate decision making;
- Control the pricing and costs of cancer drug therapies for patients and Medicare (and the taxpayers who fund the program);
- Create a robust and healthy biosimilar market; and
- Maintain a more healthy, competitive generic market not plagued by constant shortages.

We realize that more detail is needed in this proposal, but the timing of this comment letter submission deadline only allows us to detail this proposal as much as we can at this point.

- **Employing Clinically Appropriate Utilization Management ("CAUM") in Part B:** If the administration is determined to find ways to steer prescribing toward the highest value therapies in Part B, it should do so by giving the right tools and incentives to physicians themselves, instead of PBMs and other middlemen CAP vendors. A potential CAUM program that incentivizes the use of pathways and clinical protocols developed by physicians would protect evidence-based care much more effectively than other entities whose decisions are purely based on cost. COA has been engaging with other stakeholders and we see a great opportunity to empower providers to ensure the most appropriate and value-based prescribing, without jeopardizing patient access or timely care. Furthermore, this would also help community oncology practices to more easily move toward sophisticated, performance-based alternative payment models.

[9] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613346.htm

We believe that a CAUM provider-led model would be patient-centric, but at the same time, it would provide CMS an opportunity for savings by ensuring that Part B drug utilization best reflects value and efficacy, while encouraging more competition between manufacturers. Coupled with a tiered ASP add-on percentage, as outlined above, CAUM would create an environment that drives both manufacturer research and development, as well as oncologist decision making, in collaboration with patients, towards high value (a function of both quality and cost). Manufacturers would be driven by value in research and development, both in terms of therapy innovation and pricing. Oncologists and other Part B providers would be driven by the same value in adhering to provider-developed pathways, with Part B drug reimbursement equitable for generics, biosimilars, and brands. Finally, this would be in an environment devoid of any PBMs and related middlemen dictating treatment decisions based on rebates and other financial incentives *feeding their bottom line profits* rather than on what is clinically appropriate and in patients' best interests.

- **Addressing High Out-of-Pocket ("OOP") Costs:** As providers, we are well aware that cancer patients and survivors face serious hardships and anxiety related to the affordability of their cancer treatments. COA is very supportive of efforts to reduce OOP costs for Medicare beneficiaries by reducing the coinsurance amount, introducing an out-of-pocket maximum, or shifting to fixed copays for drugs. Part B fee-for-service beneficiaries pay a 20% coinsurance on all medical services, including drugs. Even though most patients have some type of supplemental medical insurance (e.g., Medigap, employer plans), those Part B beneficiaries without supplementary coverage face the greatest exposure to drug costs under Medicare. Seniors with pre-existing conditions, such as those who get diagnosed with cancer, can be denied Medigap coverage in many cases when they apply for supplemental insurance policies, leaving them exposed to the full burden of coinsurance on very costly therapies. We understand that in this fiscal environment this policy could increase Medicare costs, but we believe that there are multi-stakeholder solutions with support from manufacturers that can produce rebate passthrough or additional copay assistance mechanisms for low-income beneficiaries or for those who were denied supplemental insurance due to health status.

- **Lowering Drug Prices Without Artificial International Price Indexing:** We have serious concerns about the indexing of Part B drug reimbursement to international prices, as explained earlier in this letter. For close to a year (well before the IPI Model was proposed), COA has been in discussions with well over 20 manufacturers on the concept and execution of performance-based pricing arrangements (e.g., indication and outcomes pricing models) as part of our development of the OCM 2.0. Although these types of arrangements (which CMS has referenced in relation to CAP vendors in the IPI Model) show real promise in addressing payment for drugs based on value, they would require waivers from Medicaid best pricing, ASP, etc. to be implemented in the Medicare system. We welcome the opportunity to discuss this further with CMS. Additionally, since the release of the IPI Model proposal, COA has been in discussions with several manufacturers on alternatives to international indexing, which involve rebating and other creative approaches. We are not at liberty to disclose the specifics of those alternatives at this time in this letter, but we are hoping you will hear directly from manufacturers.

Conclusion

As we have detailed very extensively in this letter and the supporting attachment, COA cannot support any mandatory experiment on patient care using CMMI as the IPI Model proposes. Rather, we hope to be able to continue working with CMS on constructing a patient-centric, value-driven, *voluntary* demonstration project with appropriate patient safeguards. COA would enthusiastically support this and help drive large-scale participation by community oncology practices across the country. The OCM provides the perfect model of collaboration whereby CMMI and providers have been working together to develop, implement, and refine a *voluntary* model of oncology payment reform.

Although COA has serious concerns with the IPI Model as proposed, we are very actively developing and analyzing alternative approaches. This should be demonstrated by our meetings and calls with CMS leadership and staff, as well

as the comments provided in this letter. If you examine COA's work over the past eight years, and the specific programs implemented by practices, community oncology has done more to advance payment reform in general and very specifically in cancer care. This dedication to doing what is right has come at a time when community oncology practices have faced declining Medicare reimbursement; enormous obstacles to providing clinically appropriate care, such as increasing inappropriate prior authorizations by insurers and other middlemen; and the destructive and harmful behavior of PBMs in obstructing cancer patients from getting timely and appropriate cancer care.

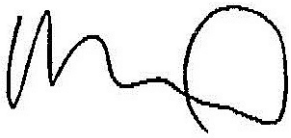
COA's unwavering commitment and steadfast determination to continually improve our cancer care system is driven by a mission to ensure that patients with cancer, the majority of which are seniors who are Medicare beneficiaries, continue to have access to the highest quality, most affordable, and most accessible cancer care in the communities where they live and work.

COA looks forward to working closely with CMS to advance meaningful, patient-centered, and value-driven policies relating to cancer care. We are available to discuss any of our concerns and recommendations provided in this letter.

We thank you for your consideration.

Sincerely,

Jeff Vacirca, MD
President



Michael Diaz, MD
President Elect

Ted Okon
Executive Director

Attachment A

Legal and Constitutional Problems with a Mandatory International Pricing Index Model

If the Centers for Medicare and Medicaid Services ("CMS") implements a mandatory International Pricing Index Model ("IPI Model") through the CMS Innovation Center ("CMMI"), CMS will rely on Section 1115A for authority to do so.[1] However, according to Section 1115A, the Department of Health and Human Services Secretary ("the Secretary") cannot select for testing *any* model it chooses. Rather, the Secretary is permitted to select for testing only *"models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."*[2] In addition to these criteria, in phase 1 of a test, the Secretary is required to undertake an evaluation of each model involving the *"quality of care furnished under the model, including measurement of patient-level outcomes . . . ,"* and changes in spending.[3] While the Secretary may waive specified statutory requirements in phase 1, such waiver is limited. The waiver applies only *"as may be necessary solely for purposes of carrying out"* (emphasis added) the testing in phase 1.[4]

If the Secretary elects to proceed to phase 2, Section 1115A expressly requires the Secretary to conduct rulemaking, and the Secretary may undertake phase 2 expansion only if the Secretary determines that such expansion is expected to reduce spending under Medicare without reducing the quality of care or improve the quality of patient care without increasing spending.[5] The Secretary cannot waive statutory requirements in phase 2 because the statute permits waivers *"solely for the purposes of testing."*[6]

Section 1115A was designed to encourage innovation in payment and service delivery models. However, this innovation is limited. For several reasons explained below, the IPI Model exceeds the statutory limits on phase 1 testing.

1. The IPI Model Exceeds CMS' Statutory Authority.

a. The IPI Model is inconsistent with the express mandate of Section 1115A.

As discussed above, the Secretary cannot select for testing any model it chooses. The Secretary is permitted to select models for testing only where it determines *"deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."* This determination is to be made before selecting the models for testing, not during or after model testing. Having reviewed the IPI Model, we do not find evidence to suggest that the Secretary has made a determination of any deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.

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[1] In the Summary of the IPI Model, CMS states *"[t]his proposed rule discusses the implementation of a new Medicare payment model under section 1115A of the Social Security Act (the Act)."* 81 FR 48, 13230.

[2] Section 1115A(b)(2)(A).

[3] Section 1115A(b)(4)(A)(i) and (ii).

[4] Section 1115A(d)(1) (*"The Secretary may waive [specified statutory requirements] as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)."*).

[5] Section 1115A(c).

[6] Section 1115A(d)(1).

Moreover, Section 1115A expressly requires that a phase 1 testing model address a *"defined population for which there are deficits in care."*[7] While the IPI Model establishes a test area—providers in approximately 50% of the country who prescribe a Part B drug—this does not address the requirements of Section 1115A. Specifically, Section 1115A does not permit the selection or designation of any test area. Rather, the Secretary must have determined in advance that the group to be tested has deficits in care. Merely statistically selecting areas without regard to this determination fails to meet the statutory requirements. This IPI Model ignores the statutory requirements, as it would cover beneficiaries in approximately 50% of the country who take a Part B drug regardless of whether any of these beneficiaries has a "deficit in care." This is a random selection made without regard to the Secretary's statutory charge to select a "defined population" with "deficits in care."

More importantly, the IPI Model focuses on cost aspects of care, not the quality, sufficiency, or effect on care. The IPI Model is devoid of any significant reference to the effects on care, let alone the provision of findings with regard to existing deficits of care.

b. The IPI Model—by being mandatory in scope and affecting most of the nation—is not a test or model.

CMS proposes to subject 50% of the country to the IPI Model, which by its proposed design will likely impact the rest of the country – not just the fee-for-service Medicare population but also Medicare Advantage ("MA") and commercial insurance plans. This proposal goes well beyond what could reasonably be considered a "test." A test is the essence of phase 1. Section 1115A contemplates a two-step process. A smaller test in phase 1, expanded through rulemaking if the following requirements are met:

> (1) *the Secretary determines that such expansion is expected to—*
>
> (A) *reduce spending under applicable title without reducing the quality of care; or*
>
> (B) *improve the quality of patient care without increasing spending;*
>
> (2) *the Chief Actuary of the Centers for Medicare and Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and*
>
> (3) *the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable titles for applicable individuals.*[8]

Despite the statutory mandate of Section 1115A, the Secretary has opted to bypass a controlled "test" geography, making this an "expansive" experiment affecting 50% of the country, without addressing the requirements set forth above. It is clear that by reading Section 1115A as a whole these requirements are expressly imposed upon the Secretary before it can make a test expansive, and these requirements cannot be ignored.[9]

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[7] Section 1115A(b)(2)(A).

[8] Section 1115A(c)(1)-(3).

[9] "It is, however, a cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute." Williams v. Taylor, 529 U.S. 362, 404 (2000) (internal quotations and citations omitted).

CMS should focus on a 2012 MedPAC report, which discussed a concern about the scope of a test related to Medicare-Medicaid dual eligible models. Even though the planned scope of the dual eligible models was much smaller than the IPI Model—about 1/3 of dual eligibles—MedPAC expressed concern with the sample size as follows:

> *Most states pursuing the capitated model are proposing to enroll most or all dual-eligible beneficiaries in a state or entire subgroups of beneficiaries (such as disabled individuals under the age of 65) in a state into a* [demonstration] *health plan. However, the varied and complex needs of many of these individuals leads us to question whether care management models should be tested on large numbers of dual-eligible beneficiaries or entire subgroups within a state. In addition, the large scope also makes the demonstrations appear to be large-scale program changes rather than true demonstrations*.[10] (emphasis added)

Beyond the MedPAC report expressing alarm with regard to large test populations, courts have also stressed the need for tests to be of a controlled size and duration.[11]

The IPI Model goes well beyond a geography of limited duration and is exactly the type of test arrangement with respect to which MedPAC and the courts have expressed concern. Accordingly, the mandatory nature of a test constituting of 50% of the county is well beyond what the courts, MedPAC, and others have considered acceptable for testing and thus cannot constitute a test.

c. *The IPI Model appears not to be based upon a model developed by CMMI, but rather initiated outside of CMMI.*

Section 1115A provides for the creation of CMMI within CMS. CMS itself has explicitly recognized the mandate for CMMI to develop models:[12] *"[p]ayment and service delivery models are developed by CMMI in accordance with the requirements of section 1115A of the Act. During the development of new models, CMMI builds on the ideas received from internal and external stakeholders and consults with clinical and analytical experts."*[13]

Despite the requirement that CMMI develop the models, it is very clear that the Secretary has referenced the IPI Model as a product directly of President Trump's initiatives to bring down drug prices — *"President Trump promised that he would bring down drug prices and put American patients first," said HHS Secretary Alex Azar. "With this innovative approach, he is now proposing historic changes to how Medicare pays for some of the most expensive prescription drugs, securing for the American people a share of the price concessions that drug makers voluntarily give to other countries."*[14]

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[10] MedPAC, Report to the Congress: Medicare and the Health Care Delivery System (June 2012) at 64 (emphasis added).

[11] See Bay Ridge Diagnostic Laboratory, Inc. v. Dumpson, 400 F. Supp. 1104 (E.D.N.Y. 1975) (implementation of the program in limited locality under Section 1115); Am. Acad. Of Ophthalmology, Inc. v. Sullivan, 998 F.2d 377, 384 (6th Cir. 1993) (finding that "[t]he Demonstration does not alter or modify the whole Medicare program, it does not affect Medicare's coverage of all medical services, medical items, and health care provides. Instead, the Demonstration touches only cataract surgeries and, in fact, only specified varieties of cataract surgeries. Further, patient as well as health care provider participation is strictly voluntary in the Demonstration.") (emphasis added).

[12] Section 1115A further provides that *"[i]n carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums or other mechanisms to seek input from interested parties."* Section 1115A(a)(3).

[13] 80 FR 132, 39869.

[14] https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html

This and other statements by the Secretary clearly show that CMMI did not develop this model. Accordingly, the IPI Model would not constitute a "model" under Section 1115A. We also note that the statement just referenced by the Secretary points to the IPI Model as much more than a "test" of a concept.

2. The Secretary Has No Authority to Waive Medicare Provisions under the IPI Model.

In order for the Secretary to have the authority to "waive" requirements of Medicare, the Secretary must be doing so "*solely for the purpose of carrying out this Section with respect to testing models described in subsection (b).*" (emphasis added).[15] The Secretary has opted to bypass a limited test phase, instead implementing what amounts to a program change affecting, on a mandatory basis, 50% of the country, if not in effect the entire country.

Section 1115A (b) (4) is clear that any waiver authority of the Secretary applies solely with respect to testing. As we have earlier discussed, the IPI Model is not a phase 1 "test," and, accordingly, the Secretary cannot use any waiver authority for this model. Thus, any attempt to change the reimbursement method for Part B drugs does not apply.

3. The IPI Model Raises Constitutional Concerns.

For the reasons described above, the Secretary cannot use the waiver authority in Section 1115A in the manner proposed. Assuming for the sake of argument that the Section 1115A waiver provision did apply to the IPI Model and permitted the Secretary to waive the applicable Medicare provisions—which we dispute—the attempted exercise of any such authority would raise serious constitutional concerns.

a. The waiver provision violates Article I of the Constitution.

The Secretary's proposal to waive the statutory payment mechanism for Part B drugs and substitute a new payment methodology through the IPI Model is effectively a repeal of a statutory provision of the Medicare statute and enactment of what amounts to new statutory language. This raises significant constitutional concerns. The Supreme Court has recognized that *"repeal of statutes, no less than enactment, must conform to Art. I."*[16] Under the Constitution, legislation must be passed by both the House and Senate and signed by the President absent the override of a veto.[17] These constitutional requirements also apply to repealing existing legislation.[18] Following this constitutional principle, the Supreme Court struck down the Line Item Veto Act, which permitted the President to cancel certain provisions of duly enacted statutes.[19]

If Section 1115A were interpreted to permit the waivers in the IPI Model, Section 1115A would have the same constitutional concerns as the Line Item Veto Act. Also, it would present the added issue of CMS attempting to enact new statutory language to replace the provisions of the Medicare statute that the Secretary or CMS proposed to "waive" (*i.e.,* repeal).

b. The IPI Model raises additional constitutional concerns.

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[15] Section 1115A(d)(1).

[16] INS. v. Chadha, 462 U.S. 919, 954 (1983).

[17] U.S. Const., art. I, § 7.

[18] Chadha, 462 U.S. at 954.

[19] Clinton v. City of New York, 524 U.S. 417 (1998).

CMS will base its authority for the IPI Model 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.[20] Given this constitutional constraint, if Congress seeks to delegate its legislative power to an executive agency like CMS, the legislation must contain an "intelligible principle" to guide the agency's decision-making.[21] The requisite specificity of the "intelligible principle" depends on the amount of power that Congress is delegating.[22] In other words, the more power Congress is delegating, the more specific its guidance must be.[23] If the interpretation CMS will likely propose to give to Section 1115A is correct, then, in drafting Section 1115A, Congress failed to provide a sufficiently specific intelligible principle to CMS and CMMI to guide its decision making (including with regard to the waiver authority), and, consequently, Section 1115A as interpreted by CMS and the IPI Model would be unconstitutional.

Further, the IPI Model denies those beneficiaries and others who are forced to participate in the IPI Model the potential right to equal protection of the laws in violation of the Due Process Clause of the Fifth Amendment to the Constitution. The beneficiaries and others who are forced to participate in the model are not treated equally with those who are not required to participate. As explained above, among other things, the beneficiaries forced to participate will run the risk of receiving less favorable care than those beneficiaries who are not compelled to participate. Even assuming that the IPI Model is authorized by Congress, it is one situation to have a congressionally authorized, limited "test" of a new payment methodology. It is quite another situation to propose a scheme that treats 50% of the country disparately from the other 50%. The latter is, at a minimum, an abuse of discretion; and, more importantly, a direct violation of the right to equal protection of the laws.

Moreover, courts have long recognized the need to narrowly construe statutes to avoid constitutional challenge. CMS' interpretation of the statute to permit a large-scale application of the IPI Model to 50% of the country and implementation on a mandatory basis is inconsistent with the concept of a "test," and the language of the statute would need to be construed narrowly to avoid a violation of the Constitution.

4. The IPI Model Contravenes Other Applicable Laws.

a. The IPI Model contravenes Section 3601 of the ACA.

Even if CMS could be found to have the authority to implement the IPI Model and Section 1115A could be found to pass Constitutional muster, neither of which we believe, the IPI Model would violate Section 3601 of the ACA ("Section 3601"), as the implementation of the IPI Model would affect "guaranteed" Medicare benefits. Section 3601 prohibits another provision of the ACA from reducing "guaranteed benefits" under Medicare. Specifically, Section 3601 states:

> *Protecting Guaranteed Medicare Benefits. Nothing in the provisions of, or amendments made by, this Act shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act*.[24]

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[20] Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001) (internal quotation omitted).

[21] Id.

[22] Id. at 475.

[23] Id.

[24] Pub. L. No. 111-148 (2010).

The Medicare statute expressly covers the provision of drugs under Part B of the Medicare law. While the term "guaranteed benefits" is not defined by Section 3601, beneficiaries are entitled to coverage for Part B drugs by Medicare and, as such, these benefits are "guaranteed" to beneficiaries.[25] Moreover, this provision embodies the assurance that the ACA would not reduce "guaranteed benefits" as advanced by the legislative members and the President when the passage of the ACA was being considered. Effectively, through the IPI Model, CMS is creating a mechanism for it to influence clinical decision-making and direct patients away from a guaranteed benefit. The consequences of CMS' proposal would be a violation of Section 3601.

b. The IPI Model likely contravenes other laws.

Beyond the contravention of Section 3601, the IPI Model contravenes other laws. Among other things, the IPI Model likely impairs a Medicare beneficiary's right to select health care services as guaranteed under the Medicare Act. Specifically, 42 U.S.C. § 1395a provides:

> *Any individual entitled to insurance benefits under this subchapter may obtain health services from any institution, agency, or person qualified to participate under this subchapter if such institution, agency, or person undertakes to provide him such services*.[26]

The IPI Model would likely result in impediments to Medicare beneficiaries' access to certain drugs based on reimbursement changes in the IPI Model. Beneficiaries desiring those drugs from a particular physician may not be able to obtain them because of financial penalties imposed by the IPI Model upon the prescribing physician and, thus, the IPI Model impairs the beneficiary's selection right.

[25] See 42 U.S.C. §§ 1832 and 1842.

[26] 42 U.S.C. § 1395a(a).

Attachment B

The Myth of Perverse Physician Incentives:

Examining Research and Accusations in the Medicare Part B ASP Reimbursement System for Oncology

A frequent accusation aimed at physicians who prescribe and administer medications within the Medicare Part B system is that they are motivated by a perverse incentive of higher reimbursement to prescribe expensive drugs. For oncologists, who utilize potentially life-saving, but increasingly very expensive drugs in treating some of the nation's sickest patients, this is a baseless charge, often made without any evidence to support it.

Cancer drugs are amongst the costliest medications available today. For many patients, the cost of a full course of treatment in the United States can be financially toxic and catastrophic. The country currently sits on the precipice of proposed drug system changes of considerable magnitude and scope. Several proposals under consideration take aim at Part B reimbursement as a means of forcing changes to drug prices and pricing methodologies. These are, ironically, occurring just as the adoption of value-based cancer care programs, such as the Centers for Medicare and Medicaid Services (CMS) Oncology Care Program (OCM), are being increasingly implemented.

To help inform policymakers and stakeholders working to reform our health care system and reduce the total cost of cancer care, the Community Oncology Alliance (COA) has conducted this critical analysis of research studies that are often cited as "evidence" that oncologists prescribing in the Part B system are financially driven, rather than driven to provide the highest-quality cancer care. Evidence and recent studies proving that those assertions are misguided are provided in this paper.

To properly review the studies most commonly cited as "proof" of a perverse physician prescribing incentive, an expert review panel of six medical oncologists with literally decades of clinical and research experience, was assembled. They evaluated the studies, methodology, and data sources for all relevant findings. Their critical insight into the health care history and medical developments that drive prescribing patterns and behavior were critical to this paper. The conclusions included here represent their collective meta-analysis of relevant data.

ASP + 6%: A Brief History and Background

In 2003, Congress enacted the largest single overhaul of Medicare in the public health program's history with the Medicare Prescription Drug, Improvement and Modernization Act, also commonly called the Medicare Modernization Act or MMA. This legislation changed the reimbursement rate for Medicare Part B drugs, which are typically injectable medications such as chemotherapy, administered under a medical provider's supervision. The new reimbursement rate became Average Sales Price (ASP) of the drug plus 6%.

Critics presume the 6% represents "profit" and serves as the driver of prescribing habits. In fact, the 6% add-on was intended to cover the costs associated with the procurement, storage, inventory, preparation, and waste disposal for these volatile and highly toxic drugs. The reimbursement rate was deliberately set to be revenue neutral with the stated intent to eliminate "profit" through drug selection bias.

Since the 2005 adoption of ASP + 6% as the Medicare drug reimbursement formula, a subsequent and quite significant change in Part B drug reimbursement later became part of Medicare policy. Specifically, the Budget Control Act of 2011 (BCA) mandated a 2% sequestration cut to Medicare reimbursement, which CMS applied, COA believes inappropriately, to Part B drug payments, serving to decrease actual reimbursement for chemotherapy drugs to ASP + 4.3%. The drug costs and administrative fees associated with dispensing cancer drugs remained unchanged as reimbursement declined, resulting in physicians being under-reimbursed on many chemotherapy drugs.

In fact, analyses have verified that many community oncology practices actually lose money on key infusion services and select drugs due to low Medicare reimbursements.[1] A 2018 analysis of reimbursement data by Avalere Health found that practices lose money for 21% of all Part B drugs.[2] That is, for those drugs, the cost of acquisition is less than the reimbursement rate. On average, the difference is 10% per drug; meaning, every time these Part B drugs are prescribed, providers are under-reimbursed. Among the top 10 highest cost cancer drugs, which account for 72% of all cancer drugs and 23% of all Part B drugs in terms of total Medicare spending in 2016, the average estimated difference between drug acquisition cost and Medicare allowable payment amount is 2.4%, or $2.50.

Commonly Cited Studies – and Their Shortcomings

Critics that claim a perverse incentive exists affecting which Part B drugs patients are prescribed have consistently referenced the same five studies to support their argument. Additionally, a new study that reaches the same suspect conclusions was recently published. The studies are as follows:

1. "Practice Patterns for Older Adult Patients with Advanced Cancer: Physician Office versus Hospital Outpatient Setting." Allison Lipitz-Snyderman; Coral L. Atoria; Stephen M. Schleicher; Peter B. Bach; Katherine S. Panageas.[3]
2. "How Medicare's Payment Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment." Mireille Jacobson; Craig C. Earle; Mary Price; Joseph P. Newhouse.[4]
3. "Physician Response to Financial Incentives When Choosing Drugs to Treat Breast Cancer." Andrew. J. Epstein; Scott J. Johnson.[5]
4. "Reduction in Physician Reimbursement and Use of Hormone Therapy in Prostate Cancer." Sean P. Elliott; Stephanie L. Jarosek; Timothy J. Wilt; Beth A. Virnig.[6]
5. "Infused Chemotherapy Use in the Elderly After Patent Expiration." R.M. Conti; M.B. Rosenthal; B.N. Polite; P.B. Bach; Y.C. Shih.[7]
6. "Impact of Payment Reform on Chemotherapy at the End of Life." Carrie H. Colla; Nancy E. Morden; Jonathan S. Skinner; J. Russell Hoverman; Ellen Meara.[8]

The studies have been cited in pseudo-analyses and quoted as evidence by those seeking to influence health care policy, presenting presumptions and conclusions about physician prescribing as fact while ignoring contributing factors beyond drug prices. In many cases, study authors – most of whom are neither practicing physicians nor oncologists – demonstrate a lack of clinical knowledge and judgement that influence the treatment decisions oncologists and their patients make in determining optimal cancer treatment. This leads the studies to confuse or conflate correlation with causation in prescribing where none exists.

Another problem with some of these studies is the "cherry picking" of items and data to focus on without explaining sources of potential bias that can confound complex results. For example, excluding confounding factors, such as major reimbursement changes, i.e., the MMA, the introduction of groundbreaking new therapeutic treatment options, or even changes in clinical guidelines.

A majority of the most commonly cited studies are more than a decade old and/or utilize data as much as two decades old. Drawing on data for any patient prior to implementation of key MMA provisions in 2005, which fundamentally and radically changed Part B drug reimbursement, means the authors are drawing conclusions about prescribing patterns based on a reimbursement system completely different from the current ASP system of today. Additionally, since the two decades on which the older studies draw, treatment protocols have often dramatically changed and/or advanced so substantially that the study conclusions may no longer be applicable to current cancer care decision-making and prescribing.

Finally, the studies collectively often ignore contributing factors in drug selection. These include criteria such as patient status, drug toxicity, drug efficacy, changes in treatment protocols, and the development of newer, better drugs; all of which can be part of the process of drug selection and utilization. Again, this demonstrates a lack of clinical oncology knowledge when casting aspersion on physician behavior that is actually driven by guidelines and best practices at the time of treatment.

In the following sections, we will specifically examine what each of these studies purports, whether any evidence truly exists of a perverse financial incentive in Part B prescribing, and what additional or contributing factors must be considered.

1. Practice Patterns for Older Adult Patients with Advanced Cancer: Physician Office versus Hospital Outpatient Setting

What the study says:

> *"Compared with patients treated in a hospital outpatient department, those treated in a physician's office setting were more likely to receive erythropoiesis-stimulating agents (odds ratio, 1.72; 95% CI, 1.53 to 1.94) and granulocyte colony–stimulating factors (odds ratio, 1.28; 95% CI, 1.18 to 1.38). For combination chemotherapy and nanoparticle albumin-bound–paclitaxel in patients with breast cancer, there was a trend toward higher use in physicians' offices, although this was not statistically significant. Chemotherapy-related hospitalizations and hospice did not vary by setting. "*

> *"We found somewhat higher use of several drugs for patients with advanced cancer in physicians' office settings compared with hospital outpatient departments. Findings support research to dissect the mechanisms through which setting might influence physicians' behavior… Although the reasons for differences in physicians' behavior by oncology practice setting are unclear, research has shown that physician behavior is influenced by payment incentives."*

This study though just recently released, relies on old data from 2004 – 2011, which is an eternity in modern-day cancer treatment. Standards of care, site of care, and attitudes on low-value care in older adults who often present with co-morbidities that increase the occurrence of complications necessitating multi-drug combination treatment, have changed profoundly since that period.

Since 2011, there have been many changes within the reimbursement landscape, including changes in Erythropoiesis-Stimulating Agents' (ESA) coverage, MMA, sequestration, the introduction of oral oncolytic therapies, and more rapid adoption of new therapies that impact supportive care. The availability of immuno-oncology therapies has significantly reduced the quantity of supportive care medications required due to a reduction in drug-related side effects. The use of such old data results in an examination of prescribing and treatment patterns long since supplanted and taints the study conclusions.

The authors claim that there is a "trend" towards greater use of combination chemotherapy in patients treated in the physician office setting versus the hospital outpatient department. However, this cannot be called a "trend" because the results are not statistically significantly different.

The study's stated intent was to determine if patients treated in the physician office setting versus the hospital outpatient department setting were more likely to receive what the authors deemed to be "low-value" erythropoiesis-stimulating agents and granulocyte colony-stimulating factors. However, the authors make no mention of important clinical information that would have driven these treatments, such as the incidence of admissions for neutropenic fever or the issue of red blood cell transfusions. The analysis also fails to adjust for line-of-therapy where the cancer patient could be represented more than once in cases where higher-cost therapies may be administered after the failure of lower-cost options.

The authors also fail to mention that within the 2004 – 2011 study time frame, the standard of care for patients with stage IV breast carcinoma requiring chemotherapy, often correctly utilized combination therapeutic approaches. In fact, a 2009 peer-reviewed study concluded and confirmed that multi-drug combinations were the often-favored standard of care and were not reflective of a therapeutic choice influenced by profit-motivated care.[9]

The authors also cite the American Society of Clinical Oncology (ASCO) "Choosing Wisely" campaign list as "long standing" evidence that the drugs were low-value. However, they fail to note that the ASCO list came out in 2013, well after the study time period of 2004 – 2011.

Reflecting on guideline-driven, physician prescribing patterns well after new consensus has emerged is nonsensical.[10]

It is also disconcerting that the authors appear to "cherry pick" data sets and periods to evaluate without reason or explanation. While stating that they will evaluate treatment interventions by site of service, the authors then only report on a selected few and make sweeping generalizations in the conclusions and discussions sections. Similarly, with SEER-Medicare claims data available through 2016, raises the question of why the authors did not extend their study period to include more years of recent data.[11]

In addition, while the authors' application of a mixed effects model is appropriate, their attribution to bias is substantially limited. Other confounders that could have been assessed that would have influenced supportive care utilization, such as transfusion burden, febrile neutropenia, or other infectious illnesses, were not evaluated. All of these would have been available in the data set. The authors also failed to evaluate the conditions that would necessitate supportive care and alternative outcomes that patients may have faced, such as transfusion or infectious complications.

Finally, the Charlson Comorbidity Index (CCI) used by the authors to reach their conclusions may have been incorrectly modified in some way, resulting in skewed results. When using online tools, every patient in the study should have had a score of at least 8 (+2 for age greater than 60 and +6 for metastatic cancer). If the score for age was omitted, then patients treated in the physician office setting would have had a higher CCI and, therefore, would have likely benefited from higher levels of supportive care with G-CFS and ESA to reduce the risk of complications resulting in hospitalizations and/or emergency room visits. This latter benefit was identified by the authors' findings.

2. How Medicare's Payment Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment

What the study says:

> *". . . the Medicare reform law aimed to lower Medicare spending by reducing reimbursements for specific drugs. It also aimed to reduce the incentive to prescribe certain drugs that afforded particularly higher margins for the doctors and clinics but did not offer any clear clinical advantage for patients."*

This is an old study, first published in 2005. The study focuses heavily on the increased use of docetaxel, a successor drug more expensive than its predecessor, paclitaxel, as substantiation of a perverse incentive.[12] The increased use more correctly reflected the change in the clinical standard of treatment since 2005.[13] The study conflicts with itself as it asserts both that the premise of the MMA was that ASP + 6% was designed to cover costs and result in a "break even," no matter the cost of the drug and that there is a perverse incentive to make drug selections that garner a higher profit.

3. Physician Response to Financial Incentives When Choosing Drugs to Treat Breast Cancer

What the study says:

> *"Physicians have explicit financial incentives attached to each potential drug treatment, with profit margins ranging more than a hundred-fold."*
>
> *"We find that increasing physician margin by 10% yields between an 11 and 177% increase in the likelihood of drug choice on average across drugs. Physicians were more likely to use drugs with which they had experience, had more citations, and were FDA-approved to treat breast cancer. Oncologists are susceptible to financial incentives when choosing drugs, though other factors play a large role in their choice of drug."*

This again, is an old study examining even older data from 1992 - 2002. No treatment domain has changed more in the last 20 years than breast cancer care, making most of the study conclusions obsolete. Additionally, reimbursement, the standards of care, and pathways have also changed dramatically since this study was published. Simultaneously, a substantial increase in treatment options offering newer, better drugs serves as the true driver of prescriber preferences, despite the drugs being costlier. To presume that drug choice is based on a perverse incentive ignores other important drug selection factors such as patient status, drug toxicity, and efficacy.

4. Reduction in Physician Reimbursement and Use of Hormone Therapy in Prostate Cancer

What the study says:

> *"In this example of hormone therapy for prostate cancer, decreased physician reimbursement was associated with a reduction in overtreatment without a reduction in needed services."*

This 2010 study is yet another old study reviewing data collected from 1992 - 2005. Again, as with breast cancer, dramatic changes in prostate cancer treatment have evolved since the study period. The conclusions reached in this study are suspect because patient results from Prostate-Specific Antigen (PSA) testing were not included in the examined data.

Additionally, this study is another instance where toxicity as a basis for drug choice was not considered in the study conclusions. The current earlier detection of prostate cancer, resulting in stage migration, thus increasing the number of patients eligible for treatment, was also not considered.

5. Infused Chemotherapy Use in the Elderly After Patent Expiration

What the study says:

> *"The generic entry of irinotecan resulted in a 17% to 19% decrease ($P < .001$) in use among elderly patients with MCRC compared with oxaliplatin."*
>
> *"This study provides novel and robust estimates of the decline in use of a chemotherapy to treat a common cancer in the elderly after patent expiration. The results suggest estimates from a previous Office of the Inspector General report of the potential savings derived from the generic entry of irinotecan for*

public payers are an overestimate, likely confounded by oncologists' response to financial incentives, changes in scientific evidence, and promotional activities."

The study authors readily admitted that a drug option, the widespread use of oxaliplatin, was frequently preferred because of lower toxicity with similar efficacy.[14] Oxaliplatin became available concurrent with the patent expiration of irinotecan. The two concurrent events, a patent expiration and the availability of a costlier new drug, were not related. Physician drug preference was based on lower toxicity and the widespread clinical pattern of utilization of oxaliplatin and did not focus on financial motivations.

6. Impact of Payment Reform on Chemotherapy at the End of Life

What the study says:

"In physician offices, where drugs generate the majority of revenue and prescribing patterns can determine physician income, use of chemotherapy at the end of life fell significantly after reimbursement reductions; no concurrent change occurred in hospital outpatient departments. These results suggest that payment reform may be used to better align appropriate financial incentives with better quality of care."

This study, published in 2012, addresses the impact of post-MMA reimbursement on chemotherapy utilization during the last 14 days of life. The study authors immediately confuse high drug revenues with high drug profits. The study references evidence showing no decline in chemotherapy services or access to chemotherapy consequent to the implementation of MMA.

Pathway changes have evolved since this study leading to a now greater emphasis on end-of-life palliative care and the associated deployment of earlier integration of palliative care and hospice into end-of-life care planning. Because of these treatment changes, as well as changes in physician and patient attitudes about end-of-life care management, it is reasonable to conclude that physicians may currently approach treatments during the last few weeks of life quite differently than in the past. Finally, the authors readily admit that *"the simultaneous cultural shift in the oncology community driven by end-of-life cost/benefit concerns and emerging models addressing the demands for better physician and patient communication"* were not fully implemented during the study period.

This study raises the question of whether a physician might be incentivized to prescribe a more toxic, less effective drug because it is cheaper. Based on this study alone, the answer would appear to be "yes". However, no thoughtful physician would use an older, more toxic, less effective drug when a newer, less toxic, and more effective one is available.

Often Overlooked – or Omitted – Contrasting Studies

A number of studies on physician prescribing under the Medicare Part B reimbursement system have been published in recent years, all of which reach dramatically differing conclusions on

physician prescribing patterns. To help inform policymakers, COA has compiled the following summary and analysis of recent evidence on the issue.

1. "Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount?" Xcenda
2. "Providing High Quality Care in Community Oncology Practices/An Assessment of Infusion Services and Their Associated Costs." Avalere Health
3. "Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model." Lee N. Newcomer, MD; Bruce Gould, MD; Ray D. Page, DO, PhD; Sheila A. Donelan, MS; Monica Perkins, PhD
4. "Unintended Consequences in Cancer Care Delivery Created by the Medicare Part B Proposal: Is the Clinical Rationale for the Experiment Flawed?" Lucio Gordan, MD; Amy Grogg; Marlo Blazer; Barry Fortner
5. "Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing?" Mark C. Hornbrook; Jennifer Malin; Jane C. Weeks; Solomon B. Makgoeng; Nancy L. Keating; Arnold L. Potosky

1. Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount? [15]

What the study says:

> *"Overall, treatment choice does not appear to be driven by the margin physicians are paid on a drug, indicating that the ASP+6% payment rate does not drive high-cost drug utilization."*
>
> *"These findings call into question claims made by some that the ASP+6% add-on payment rate for prescription drug reimbursement in Medicare Part B distorts prescribing decisions."*

This 2018 study researched the very premise that physicians select more expensive drugs because with Part B drug reimbursement of ASP + 6% they can financially benefit. The study conclusions were clear, *"findings indicate that there is no meaningful correlation between drug payment and utilization, challenging the theory that physicians significantly favor drugs with high add-on payments."*

2. Providing High Quality Care in Community Oncology Practices/An Assessment of Infusion Services and Their Associated Costs [16]

What the study says:

> *"The services required to deliver quality oncology care to patients exceed simply administering chemotherapy and other therapeutics. The comprehensive suite of services involves patient and family counseling, nutrition advice, care coordination with other healthcare providers, palliative care, telephone support, financial counseling, and other services that assist patients through their treatment regimen"*

Avalere Health worked with COA to design and administer a survey to identify the complete suite of infusion-related services available at community oncology practices and to capture detailed costs associated with delivering high-quality cancer care. The survey looked specifically at the resources needed to deliver infusion services, beyond the task of administering chemotherapy and other medications, and counseling patients during evaluation and management visits.

When comparing the difference in current Medicare payments to practice costs collected in this survey, Avalere found that the sampled practices would receive payment equivalent to only 56.53% of the costs incurred to provide infusion services. Thus, they are actually losing money on the drug reimbursement.

3. Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model [17]

What the peer-reviewed study says:

> *"This program had two objectives. The primary objective was to decrease the total medical cost by using aligned financial incentives supported by actionable use and quality information. This goal was met, as demonstrated by a 34% reduction of the predicted total medical cost. The secondary objective was to remove the linkage between drug selection and medical oncology income. Without this linkage, it was expected that CDC [chemotherapy drug cost] trends would decrease. Paradoxically, the pilot resulted in 179% more CDC than predicted when compared with the controls. Despite the additional $13 million for chemotherapy drugs, the total medical costs were reduced by $33 million."*

The importance of this study, which served to demonstrate that when any link between drug choice and physician profit was removed, chemotherapy drug utilization (and costs) went up, not down. Even the study authors conclude *"modifying the current fee-for-service payment system for cancer therapy with feedback data and financial incentives that reward outcomes and cost efficiency resulted in a significant total cost reduction. Eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy* [emphasis added]*."*

4. Unintended Consequences in Cancer Care Delivery Created by the Medicare Part B Proposal: Is the Clinical Rationale for the Experiment Flawed? [18]

What the peer-reviewed study says:

> *"For the largest Medicare oncology drug expenditures, there is not a lower-cost option with equal efficacy for their primary indications. Without lower-cost alternatives, the unintended consequence of this CMS experiment may include curtailing access to care or an increase in patient/program costs. The CMS proposal, by simply lowering reimbursement for drugs, does not acknowledge the value of these agents and could unintentionally reduce quality of care. Alternative approaches to value-based care, such as the Oncology Care Model and similar frameworks, should be explored."*

The premise that the current ASP + 4.3% reimbursement model has encouraged the use of higher-priced drugs is not supported by existing evidence. An examination of the study conclusions suggests the driving force in product selection is clinical effectiveness and that the current ASP payment methodology has not stimulated use of higher-priced drugs.

5. Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing? [19]

What the peer-reviewed study says:

> *"Changes in reimbursement after the passage of the MMA appear to have had less of an impact on prescribing patterns in Fee for Service (FFS) settings than the introduction of new drugs and clinical evidence as well as other factors driving adoption of new practice patterns."*

The main driver of prescribing is the introduction of new drugs and clinical evidence in such areas as toxicity, as well as other factors that are driving adoption of new practice patterns.

Summary

There is no compelling evidence of a perverse incentive in oncology prescribing within the Medicare Part B reimbursement system. If finances are not the primary driver of drug selection, then other factors must be. It is important to recognize those variables in order to develop a correct working hypothesis as to the reasons why physicians prescribe what they prescribe, before there can be any real payment reform that avoids unintended consequences. For example, federal reimbursement policy must be examined holistically, including profit incentives created in the federal 340B Drug Pricing program or the utilization of middlemen like pharmacy benefit managers (PBMs).

The following have been identified by oncologists as drivers of drug selection:

- Highest-quality patient care;
- Most effective treatment options;
- Best expected outcome;
- Best tolerated, least toxicity or permanent ill effects;
- Care regimen least disruptive to daily life;
- Most cost-effective option for the patient;
- Financial cost to the patient; and
- Changing physician and patient expectations about cancer care.

Many of the newest cancer drugs, which currently have no alternatives, have achieved unprecedented survival rates and have advanced the state of cancer care. Inevitably, these new drugs are almost always more expensive than existing therapies. However, to presume that new drugs that are proven to save lives and/or improve quality of life are prescribed because the oncologists benefit financially is simply unproven and not true. In fact, as referenced in this paper, multiple studies have proven the exact opposite.

Cancer care costs and drug prices are too high, by any standard. Change is necessary, and COA is leading the way towards a solution that ensures patients have access to the highest-quality, most accessible, and most affordable cancer care. If we are to make progress, all stakeholder parties must understand and discuss how drug pricing and patient costs, including non-drug costs of hospital-related costs, factor into cancer treatment planning and joint decision-making with patients.

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