December 27, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted electronically via https://www.regulations.gov

RE: (CMS–5528–ANPRM) Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

The National Association of ACOs (NAACOS) is pleased to submit comments in response to the Advanced Notice of Proposed Rulemaking (ANPRM), *Medicare Program; International Pricing Index Model for Medicare Part B Drugs*, as published in the October 30, 2018 Federal Register.[1] We appreciate the efforts of the Centers for Medicare & Medicaid Services (CMS) to lower drug prices. Medicare Part B drug spending has increased about 10 percent each year since 2011, accounting for $28 billion in 2016. The United States spends about 80 percent more for the same physician-administered drugs compared to other industrialized nations.[2]

Since accountable care organizations (ACOs) are held responsible for all of Medicare Part A and B costs, including Part B drugs, our interest in controlling Part B drug spending aligns with CMS's. Part B drugs make up about 5 percent of spending in the Medicare Shared Savings Program (MSSP), a not-inconsequential amount. Some NAACOS members have said their Part B drug spending is unmanageable, and they would welcome a mechanism to better control spending.

The ACO model is a market-based solution to fragmented and costly care that empowers local physicians, hospitals, and other providers to work together and take responsibility for improving quality, enhancing patient experience, and reducing waste. Importantly, the ACO model also maintains patient choice of clinicians. While the origin of Medicare ACOs dates back to the George W. Bush administration, the MSSP has grown considerably in recent years and now includes 561 ACOs, covering 10.5 million beneficiaries. ACOs have been instrumental in the shift to value-based care and a central part of the ACO concept is to transform health care through meaningful clinical and operational changes to put patients first by improving their care and reducing unnecessary expenditures.

But CMS's ANPRM contains a number of unanswered questions about how its proposed International Pricing Index (IPI) Model affects ACOs, which must be addressed before moving forward. Our following

[1] https://www.govinfo.gov/content/pkg/FR-2018-10-30/pdf/2018-23688.pdf
[2] https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf

comments reflect how CMS can address Part B drug costs, a problematic area for ACOs, while working in concert with the MSSP and other Medicare ACO programs, which have quickly become successful in controlling spending. A recent analysis of Medicare data shows the MSSP netted more than $660 million to the Medicare Trust Fund between 2013 and 2016 after accounting for shared savings payments, comparing ACO spending to similar non-ACO providers.[3] The MSSP netted Medicare $314 million in 2017, using the more conservative standard of ACO benchmarks, as a reference.[4]

NAACOS is the largest association of ACOs, representing more than 5 million beneficiary lives through 330 MSSP, Next Generation, and commercial ACOs. NAACOS is an ACO member-led and member-owned nonprofit organization that works on behalf of ACOs across the nation to improve the quality of Medicare, population health and outcomes, and healthcare cost efficiency. Our members, more than many other healthcare organizations, want to see an effective, coordinated, patient-centric care process.

Summary of Key Recommendations

- **NAACOS requests more information on the overlap between ACOs and their work to reduce drug costs and the proposed IPI Model. Furthermore, we ask for ACO programs to take precedence.**
- **NAACOS encourages CMS to examine alternatives to mandatory participation for roughly half of the country's Part B drug spending.**
- **NAACOS appreciates the commitment by CMS to hold providers harmless to revenue changes to the greatest extent possible but requests further clarification on CMS's plans to execute this.**
- **The IPI Model's new vendor system should be transparent and simple, allowing ACOs the opportunity to fairly purchase needed drugs without unnecessary costs or burdens.**
- **CMS should not count bonuses to incentivize quality, low-cost care as ACO expenditures as it has in some other Medicare value-based care programs.**
- **CMS should include quality measures calculated directly by CMS or not require submission of additional data by providers to the extent possible.**

Overlap with Other CMS Models

Proposal: The IPI Model would potentially overlap with other Center for Medicare and Medicaid Innovation (CMMI) models that operate in the same geographic areas and include Part B drug spending in the calculation of model payments, incentive payments or shared savings, and the MSSP.

NAACOS requests more information on the overlap between ACOs and their work to reduce drug costs and the proposed IPI Model. Furthermore, we ask for ACO programs to take precedence.
NAACOS appreciates that CMS recognizes in the ANPRM the potential overlap between the proposed IPI Model and other Medicare alternative payment models, including the MSSP and other CMMI programs that hold providers accountable for the total cost of care. CMS's commitment to exploring these potential overlaps follows a September 2017 letter NAACOS sent Administrator Verma on a series of issues arising from an apparent lack of attention to how ACOs interact with CMMI's work.[5] A lack of coordination of models creates confusion for providers over program rules and leads to policies that potentially undermine CMS's efforts.

That being said, there are questions arising over how the proposed IPI Model would intersect with the MSSP, other ACO models, and ACO-like models. Most notable, what will happen to ACOs that span large geographic areas and have providers both in and outside of the selected geographic areas? Some ACOs

[3] https://www.naacos.com/mssp-savings-2012-2016-full-report
[4] https://www.naacos.com/press-release--more-medicare-acos-achieve-quality-and-cost-goals-in-2017
[5] https://www.naacos.com/naacos-letter-to-cms-on-amp-overlap-issues

extend beyond a single Core Based Statistical Area, which CMS considers as the primary unit of analysis in the model. How would CMS handle ACOs that include some practices granted an exclusion from IPI Model participation? What happens to ACOs' benchmarks if ACOs are not in the IPI Model and manufacturers raise prices for non-IPI Model drugs?

CMS should also consider making available information on providers included in the IPI Model or granted exceptions from participation. Such information could affect referral patterns if ACOs are aware of the financial incentives of providers their assigned beneficiaries might seek care from.

Without further details on how CMS plans to select IPI model participants, how add-on payments for providers will be calculated, or what drugs will be included in the IPI Model, it is difficult to determine the impact on ACOs. **NAACOS requests more information on the overlap between ACOs and their work to reduce drug costs and the proposed IPI Model. Furthermore, we ask for ACO programs to take precedence.** The success of ACOs —which incentivizes appropriate and lower-cost care — shouldn't be jeopardized by additional, well-meaning CMS programs.

Mandatory Participation

Proposal: Model participation would be mandatory for the physician practices, hospital outpatient departments, and potentially other providers and suppliers, in each of the selected geographic areas.

- **NAACOS encourages CMS to examine alternatives to mandatory participation for roughly half of the country's Part B drug spending.**

NAACOS strongly opposes mandatory CMMI demonstrations while supporting the movement to value-based care. In the past, CMMI has released a number of models that intersect with the MSSP and other CMS programs that have unfortunately created negative unintended consequences and undermine ACOs' ability to succeed.[6] The IPI could create more of those unintended consequences if CMS chooses to pursue mandatory participation.

While understanding the need to ensure the IPI Model captures the experience of various types of provider practices in different geographic areas, NAACOS encourages CMS to examine alternatives to mandatory participation for roughly half of the country's Part B drug spending. If CMS is successful in creating policies that address the concerns of doctors and hospitals, the agency will create a program that's attractive enough for robust voluntary participation. After that, there should be ample opportunity to find comparable practices by which to measure the success of the IPI Model.

NAACOS is a member of the Healthcare Leaders for Accountable Innovation in Medicare and Medicaid (AIM), a coalition that includes nearly 50 organizations representing patients and providers. AIM submitted a letter in May 2017 calling for several guiding principles for CMMI's work to follow.[7] Those principles included small-scale testing of models before expansion and providing sufficient safeguards for beneficiaries. The IPI Model does not adhere to either of those principles and lacks evidence on the impact on the healthcare system. The potential negative unintended consequences on patients and providers must be fully considered before moving ahead with any proposed CMMI model.

[6] https://naacos.memberclicks.net/naacos-policy-recommendations
[7] https://www.hlc.org/app/uploads/download.php?dl=app/uploads/2017/05/FINAL-AIM-Principles-Letter-to-Price.pdf

Add-On Payments

Proposal: Do away with compensating providers for Part B drugs at the average sales price plus 6 percent and instead pay an add-on payment based on a yet-unspecified structure. CMS says add-on payments would be paid per encounter or per month, set by classes of drugs, physician specialty or practice.

- **NAACOS appreciates the commitment by CMS to hold providers harmless to revenue changes to the greatest extent possible but requests further clarification on CMS's plans to execute this.**

HHS Secretary Alex Azar has stated publicly that the IPI Model will "keep providers whole while replacing the system with compensation that's independent of prices."[8] Azar is also right to say that for the IPI Model to be successful it is imperative that provider compensation remain steady. Doctors need to be able to recoup the costs of providing drugs. Without that assurance, their ability to treat patients is compromised and those patients need to be assured they'll have timely access to drugs.

NAACOS appreciates the commitment by CMS to hold providers harmless to revenue changes to the greatest extent possible but requests further clarification on CMS's plans to keep its promise. It's unclear from the ANPRM how this would happen. Administrator Verma explained during a November 14 speech that the pool of funds for add-on payments would be six percent of the prior year spending on Part B drugs.[9] If this is the case, it's hard to see how provider compensation would remain steady. If Medicare pays $17 billion less for Part B drugs, as the agency estimates,[10] then doctors would be paid less since the pool of add-on payment funds would shrink by a corresponding amount.

However, CMS chooses to determine the payment amount — whether by class of drug, physical specialty, or physician practice — it should be in a manner that holds true to HHS's promise to "keep providers whole." Also, any transition to an alternative percentage-based add-on payment should produce the least disruptive path possible for patients and providers.

Model Vendors

Proposal: Allow private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business.

- **The IPI Model's new vendor system should be transparent and simple, allowing ACOs the opportunity to fairly purchase needed drugs without unnecessary costs or burdens.**

NAACOS appreciates CMS's effort to rid providers of the risk and burden of "buy and bill" by considering private vendors to supply physicians, hospital outpatient departments, and other providers with drugs in the IPI Model. But the concept could introduce more uncertainty than help it provides.

While the ANPRM notes several key differences the proposed IPI Model offers over the failed Competitive Acquisition Program (CAP) of the mid-2000s, CAP had just one vendor that participated. CMS's move to the IPI Model must provide assurance that vendor participation will be as robust as options outside the IPI Model while protecting timely, cost-effective avenues of drug supplies. Today's doctors and hospitals have well-established supply channels and relationships built with third parties like group purchasing

[8] https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-at-brookings-on-drug-pricing.html
[9] https://www.cms.gov/newsroom/press-releases/remarks-administrator-seema-verma-biopharma-congress
[10] https://www.hhs.gov/blog/2018/10/30/answering-your-questions-about-the-ipi-drug-pricing-model.html

organizations. But CMS should make clear what opportunities ACOs might have to participate as eligible vendors as alternatives to today's wholesalers, distributors and specialty pharmacies.

CMS's proposed vendor program raises questions about what costs will be to providers who will be forced to purchase drugs through these vendors. As we have seen in the growth of pharmacy benefit managers, a network of arrangements has introduced convoluted deals into an already complex system. **The IPI Model's new vendor system should be transparent and simple, allowing ACOs the opportunity to fairly purchase needed drugs without unnecessary costs or burdens.** NAACOS encourages CMS to examine these possible consequences of moving to the proposed private vendors and institute appropriate guardrails to protect patients and providers.

Bonus Pool

Proposal: To incentivize reduced utilization where appropriate, CMS is considering creating a bonus pool, where model participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization.

- **CMS should not count bonuses to incentivize quality, low-cost care as ACO expenditures as it has in other Medicare value-based care programs.**

The proposal to offer bonus payments to providers as an incentive for prescribing lower-cost drugs or practicing evidence-based prescribing is noble, but several points must be considered or answered before moving ahead. CMS's use of extra incentives has not always been fair to ACOs.

For example, payments under the Comprehensive Primary Care Plus (CPC+) model — namely the care management fee and comprehensive primary care payments — for ACO-aligned beneficiaries are counted as an ACO's expenditures.[11] The addition of these payments, which are substantial, make it challenging for ACOs electing to also participate in CPC+ to succeed in an ACO model. NAACOS continues to ask that these payments not be counted as ACO expenditures. Exceptional performance bonuses under the Merit-based Incentive Payment System (MIPS) also count against the ACO when expenditures are calculated for purposes of MSSP calculations, and NAACOS has advocated for those to be excluded from MIPS payment adjustments.[12] Therefore, the better an ACO and its clinicians perform in MIPS, the greater they will be penalized when calculating shared savings/losses for the ACO.

CMS should avoid counterproductive policies by creating bonuses to incentivize quality, low-cost care then have those bonuses hurt ACOs, the very providers practicing the behavior CMS seeks to incentivize. Should CMS elect to create a bonus pool for prescribing lower-cost drugs or practicing evidence-based prescribing, those bonuses should not penalize ACOs by counting against their benchmark. ACOs are already held accountable to lower their costs relative to a pre-determined benchmark, and they shouldn't be hurt by the creation of a bonus to reduce the cost of care.

Quality Measures

Proposal: CMS intends to identify quality measures to be collected as part of the IPI Model that reflect national priorities for quality improvement and patient-centered care.

- **Either CMS should include quality measures calculated directly by CMS, or the agency should not require submission of additional data by providers to the extent possible.**

[11] https://innovation.cms.gov/Files/x/cpcplus-practiceapplicationfaq.pdf
[12] https://www.naacos.com/naacos-comments-on-final-2018-qpp-rule

NAACOS appreciates and is supportive of CMS's commitment to reduce administrative burden in the IPI Model. Participation should not come with an extra layer of bureaucracy around tasks like data collection and quality reporting. However, participants across the spectrum of CMS's and CMMI's work should be held to the same quality standards. **To the extent that the IPI Model can follow other models that include quality measures calculated directly by CMS or do not require submission of additional data by providers.** This approach would create the less burdensome approach possible.

Conclusion

Like patients, ACOs have at times struggled with uncontrollable Part B drug costs. Since there are often times when few alternatives to certain treatments are available, ACOs are forced to administer sometimes very pricey drugs for which they have no control over the costs. At times, this has caused ACOs to miss their CMS-set benchmark. If alternatives can be created to help stabilize or control drug costs, many ACOs would welcome that. But CMS's outline of a proposed IPI Model creates more unanswered questions than assurances. NAACOS appreciates CMS's work to address this issue and hopes future iterations of this proposal will help value-based care models, including ACOs, to further reach their goals, which align with CMS's. Should you have any questions about this letter or the ACO program, please contact David Pittman at dpittman@naacos.com.

Sincerely,

Clif Gaus
President and CEO