



December 31, 2018

Seema Verma, Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5528-ANPRM  
7500 Security Boulevard  
Baltimore, MD 21244

RE: CMS-5528-ANPRM – Medicare Program; International Pricing Index Model for Medicare Part B Drugs; Submitted electronically via <http://www.regulations.gov>

Dear Administrator Verma,

Trinity Health appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) regarding the Center for Medicare and Medicaid Innovation (CMMI) potential International Pricing Index (IPI) Model issued in the advance notice of proposed rulemaking (ANPRM) 5528. **Trinity Health shares the Administration's interest in addressing the rising cost of drugs but has significant concerns with the immediate and unintended ramifications that this proposed IPI Model would have on the safety-net currently provided to vulnerable Medicare, Medicaid and uninsured patients by hospitals.**

Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns \$1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 23 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models (APMs). Trinity Health participates in the Next Generation ACO, Medicare Shared Savings Program (MSSP) Tracks 1, 1+ and 3, the Comprehensive Primary Care Plus (CPC+) program, and the Bundle Payment for Care Improvement (BPCI) and BPCI Advanced programs.

Trinity Health shares the agency's deep concerns over the rising cost of drugs and applauds the agency's attention to addressing this pervasive problem. We also share and appreciate the agency's concern for the financial stability of the Medicare program and the quality of care provided to Medicare beneficiaries. Lastly, we appreciate the need to be innovative in approach and look forward to better understanding the role that an organization like Trinity Health might play in ensuring success of a potential Model to address the rising and unsustainable cost of drugs. As a large, mission-driven, multi-state health system serving a diverse socio-economic population, Trinity Health is all too well aware of the challenges facing beneficiaries and health care providers by sustained year-over-year growth in drug spending. We share CMS' desire to find a comprehensive solution. We likewise share the agency's belief that evidence-based policies that encourage cost-effective, high-quality care will help bring about the important changes that will address rising costs and enhance quality of care.

While Trinity Health supports the intent of this proposal, we have significant concerns with the impact of the current proposal on safety-net hospitals—including those across Trinity Health. **There is significant concern for the impact this would have on the important role that 340B hospitals play in today's ecosystem, and we therefore urge CMS to exempt 340B hospitals from the Model.** Of Trinity Health's 94 hospitals, 33 participate in the 340B Program today. Including 340B hospitals in this Model and thereby eliminating the financial benefit of 340B would immediately put those hospitals and communities at-risk. The 340B Program allows our hospitals to continue to offer the most comprehensive patient services to the most vulnerable uninsured and underinsured patients to improve health in those communities. 340B savings are essential to ensuring our safety-net hospitals are able to care for all patients regardless of their ability to pay and keep service lines open that we would otherwise not be able to offer our communities. 340B savings support increased access to essential—non-reimbursed and under-reimbursed—services such as anticoagulation, heart failure, cancer and obstetrics services. If the 340B Program were to be scaled back or eliminated in this way, it would quite literally threaten the ability of many of our 340B hospitals to continue to sustain safety-net hospital operations that our patients and communities rely upon to meet their urgent and ongoing health care needs.

Trinity Health's concern expands more broadly to access to care provided to vulnerable patients and communities, similar to the significant access concerns that existed under the Obama Administration's proposed Part B demonstration, which was revoked by the Trump Administration. These same access to care ramifications, for many important therapies, will exist under this potential IPI Model. Trinity Health believes any modification to the current program to address cost concerns should be balanced with protecting access. We are concerned, first, that this proposal may threaten patient access to certain drugs. Oncology patients, for example, can be especially vulnerable because these patients may not have the luxury of choosing a less expensive option because one does not exist or they have tried the other options and these were either not effective or the side effects were too debilitating to continue with the treatment. It will also threaten access to care in certain settings. We anticipate that physician office practices, especially those furnishing medical oncology services, are likely to react to this model by discontinuing some or all of their infusion service. The same response might result from other medical specialties too. Faced with the prospect of financial loss, many physician practices will shift infusion volume and other drug administration services to the hospital setting. As a mission-driven system, we are committed to meeting the needs of our patients. Trinity Health will continue to provide patient access to these treatments, but the result of a policy such as this will be to shift the already-excessive burden of absorbing un--or under-compensated costs onto hospitals within Trinity Health and other mission-driven institutions that are committed to maintaining access to care to underserved and hard-to-reach populations. **We urge CMS to more completely study the impact of this proposal on beneficiaries and safety-net hospitals before implementing such wide-ranging and significant changes. These unintended consequences further support our recommendation for ensuring appropriate, additional administration payments, particularly for the hospital outpatient setting.**

Trinity Health views the movement to value-based care and payment as essential to advancing high-quality care, improving outcomes for Medicare beneficiaries and reducing costs for the program. Today, approximately 25 percent or \$8.5 billion of Trinity Health's business operates through total cost of care models, and we have set a goal of having 75 percent of our billings in value-based payment models. We share CMS' goals of transforming the health care delivery system through person-centered and market-driven approaches that empower beneficiaries as consumers and increase choices and competition to drive quality, reduce costs, and improve outcomes. Success in this movement to value includes managing the costs of these populations—including managing the significant level of spending on drugs. Trinity Health looks forward to working with the agency to ensure that any new models, including the potential IPI model, help to facilitate the further success of existing models and programs—including ACOs—that are driving value-based care, promoting population health and engaging beneficiaries.

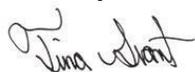
Trinity Health's goal is to advance public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all. While Trinity Health more

generally supports the adoption of mandatory CMMI models, the structure and design of this potential IPI Model is suggesting too much, too fast and has significant ramifications for today's safety-net providers and beneficiaries as articulated above. The creation of these new Model Vendors or intermediaries will have many expected and unexpected impacts on the entire distribution channel of drugs – for all populations. Therefore, we recommend that CMS/CMMI test this as a pilot in a few places first, rather than such a broad-scale mandatory model. It will take time to understand all of the impacts that these changes will have on the system. The proposed timing of 2020 to begin implementation is also concerning. Given the significant requirements to implement the potential Model, including selection of Model Vendors with capability to administer the program on a national basis, negotiation of contracts with manufacturers, negotiation of contracts with providers, development of distribution channels, Model Vendors' development of billing systems, and coordination of provider billing systems and electronic health records, **we recommend that CMS/CMMI pursue a more reasonable time frame for any such implementation, should the Model move forward.** The scope – for selected geographic areas to include 50 percent of Medicare Part B spending on separately payable Part B drugs based on Core Based Statistical Areas – is concerning as well. **We recommend that CMS/CMMI scale back the proposed scope and size of the demonstration to instead include a few smaller pilots rather than a broad mandatory model.**

Trinity Health has also identified the following, additional recommendations, concerns, questions and operational challenges for the agency to consider as it assesses future advancement of this potential IPI Model. Trinity Health strongly believes that these issues, particularly the implications for safety-net hospitals, need to be assuredly addressed before any model such as this moves forward. **We also believe that CMS needs to set forth a clear plan to evaluate the proposed Model with specific outcome measures, timelines for analysis and methods of analysis, all of which are basic standards for good research practices.** Absent this evaluation component, it is not clear that CMS will have the relevant and necessary information needed to determine the success of the program or identify components of the program that need to be modified or altogether abandoned.

Thank you, again, for the opportunity to respond on this important issue. Trinity Health is committed to identifying solutions that address the rising costs of drugs, and looks forward to working with the agency on this potential IPI Model. If you have questions on our comments, please feel free to contact me at [granttw@trinity-health.org](mailto:granttw@trinity-health.org) or 734-343-1375.

Sincerely,



Tina Weatherwax Grant, JD  
Vice President, Public Policy and Advocacy  
Trinity Health

***Trinity Health urges CMS to exempt 340B hospitals from the potential IPI Model.***

Trinity Health strongly encourages CMS to consider exempting 340B hospitals from the potential IPI Model because including these hospitals is inconsistent with Congress' intent when creating the 340B Program. Furthermore, including 340B hospitals in the potential Model would not further the stated goals of the potential IPI Model. Congress enacted the 340B Program to provide safety net providers with lower prices on certain outpatient drugs to allow these providers to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive care.”<sup>1</sup>

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<sup>1</sup> H.R. Rep. 102-384, pt. 2, at 12 (1992).

Because the potential IPI Model eliminates the ability of hospitals to buy drugs for Medicare Part B patients, manufacturers would no longer be required to reduce their prices. The potential IPI Model would, thereby, deny 340B hospitals the ability to access drug discounts and receive any financial benefit from 340B drugs dispensed to Medicare beneficiaries, as is the stated intent of the program. Removing this payment structure would not only directly oppose Congress' clear intent in creating the 340B Program, but it would also end a critical stream of revenue for 340B hospitals that are providing safety net functions to Medicare beneficiaries. Nonetheless, the ANPRM indicates that 340B hospitals located in the selected Model geographic areas would be included in the Model and would be supplied drugs for included beneficiaries through a Model Vendor, outside of the 340B Program.

Moreover, Trinity Health is deeply concerned about how the implementation and operation of the potential IPI Model may affect 340B Program compliance and participation. If CMS opts to include 340B hospitals in the potential IPI Model, Trinity Health urges CMS to coordinate with the Health Resources and Services Administration (HRSA) to avoid undermining the integrity of the 340B Program and minimize 340B Program compliance risks and administrative burdens for hospitals that are participating in both the IPI Model and the 340B Program. Trinity Health is particularly concerned about increased compliance challenges associated with managing both IPI and 340B inventories, as well as risks that the IPI Model purchasing requirements may pose to compliance with the 340B Program prohibition on purchasing covered outpatient drugs through group purchasing arrangements. If CMS determines to move forward with the Model, Trinity Health strongly encourages CMS to make clear that the Model Vendors would not constitute group purchasing arrangements for 340B purposes. Since many 340B hospitals are prohibited from using such arrangements, failure to clarify this issue could eliminate the ability of our 340B hospitals to obtain 340B discounts for drugs purchased outside the Model, thereby terminating our ability to access 340B discounts for any drugs we purchase, even those outside the Model and outside of Medicare.

***Trinity Health urges CMS to consider exploring its authority to implement a capping mechanism for drug price increases with respect to drugs purchased by Participants.***

Trinity Health is deeply concerned that as a result of the IPI Model's dramatic reductions in reimbursement for Part B drugs, manufacturers will raise the prices of their drugs sold outside of the IPI Model in order to counterbalance the revenue lost from the IPI Model. If manufacturers raise drug prices for non-IPI model drugs and providers are unable to negotiate higher reimbursement rates from payors, Participants are likely to suffer significant financial losses. Even if Participants are able to negotiate more favorable payments, the system is no better off if the IPI model merely results in a cost shift from Medicare to other payors. Therefore, it is critical for CMS to address this concern preemptively. For example, CMMI might create rebate obligations for manufacturers that dramatically raise prices of drugs purchased by Participants, such that raising prices above an appropriate threshold would be revenue neutral for the manufacturer. Such a capping mechanism would be a necessary component of the IPI Model to the extent the Model would be expected to shift drug costs from the Medicare program directly to Participants, who may be unable to recover those additional costs from commercial third-party payors.

***Trinity Health strongly encourages CMS to consider additional payments to Participants for administrative and operational burdens associated with the potential IPI Model participation.***

Trinity Health also asks CMS to consider the administrative and operational burdens that the IPI Model would impose when Participants would be required to establish new distribution relationships with Model Vendors. Such burdens could include coordination of distribution channels, establishment of new reporting systems to Medicare contractors and Model Vendors, modification of electronic health record and billing systems and implementation of new accounting models to address changes in inventory and funds flow.

It is important to note that these administrative and operational burdens would not replace the administrative and operational burdens that hospitals currently bear with respect to purchasing and

billing for physician-administered drugs. Rather, the new burdens imposed by the potential IPI Model would be in addition to existing purchasing and billing burdens, where Participants will continue to purchase and bill for drugs not included in the IPI Model. Despite the IPI Model's minimal increase in the participant add-on payment, this minimal increase presumably would not adequately reimburse hospital participants for distribution fees charged by Model Vendors, let alone the additional administrative and operating costs incurred to participate in the Model.

A further anticipated additional cost under the IPI Model as currently described is related to maintaining two drug inventories. Specifically, Participants would be required to isolate their drug inventories into two categories: (1) IPI Model drugs distributed through a Model Vendor and to which the Model Vendor holds title; and (2) non-IPI Model drugs purchased by the Participant and to which the Participant holds title. In Trinity Health's experience as a participant in the 340B Program, which requires similar inventory management controls, the complexity of these virtual inventory models pose costly administrative and logistical challenges for Participants and Model Vendors. The IPI Model would even further complicate inventory management, particularly for large national systems, which could conceivably be charged with maintaining four separate inventories: IPI, 340B, GPO, non-340B/GPO.

To address the additional administrative and operational burdens, Trinity Health believes that CMS should provide additional payment to IPI Model Participations. These payments would help to offset the direct and indirect costs incurred by Participants as a result of participating in the Model. For example, for hospital outpatient departments, CMS could reimburse hospitals for these costs on a "reasonable cost" basis via the cost reporting mechanism, and CMS could create a Relative Value Unit ("RVU") adjustment factor in the Physician Fee Schedule tied to services performed by physicians required to participate in the IPI Model. Absent this additional participation payment, Participants will be forced to incur substantial administrative and operational costs that would reduce the resources available at Participants for patient care activities.

***Trinity Health strongly urges CMS to limit Model Vendors' allowable charges to Participants to a percentage of the IPI Index of distributed drugs or another appropriate limiting factor.***

Another particular area of concern for Trinity Health is cost relating to working with Model Vendors to establish and maintain distribution channels. The ANPRM contemplates that Model Vendors would establish agreements with Participants for the distribution of included drugs, and in exchange for distribution services, Participants would make payments to Model Vendors. While the ANPRM suggests these agreements would include appropriate guardrails "to protect all parties," it does not clarify whether the rates Model Vendors would charge for distribution services would be limited in any manner. Absent such protection, the small number of Model Vendors (CMS contemplates three in the ANPRM)—as the only distributors of drugs subject to the IPI Model—could ostensibly charge excessive rates for distribution services to make up potential losses from the difference between the IPI Index rate and rates charged to the Model Vendors by drug manufacturers or offset other costs to the Model Vendors for participating in the IPI Model.

Therefore, Trinity Health strongly urges CMS to limit charges from Model Vendors to Participants to ensure Model Vendors do not use their exclusive distribution position to charge Participants unreasonable rates for distribution services. Trinity Health would further suggest CMS require these limitations to be fixed, as opposed to based on a percentage price (e.g., ASP or AWP), which would create financial incentives for Model Vendors to distribute higher cost drugs if the IPI Model is expanded to multi-source drugs.

***Trinity Health encourages CMS to establish Model Vendor rules that require Model Vendors to maintain a reliable supply chain of drugs included in the Model.***

Trinity Health stresses that it is critical for the IPI Model and Model Vendors to ensure distribution channels are consistent and reliable. Earlier this year, Trinity Health, along with other nationally prominent health systems, announced the creation of Civica Rx, a pro-competitive, not-for-profit

company dedicated to addressing critical generic drug shortages caused by market failures. Civica Rx intends to stabilize the supply of essential medications and promote market competition by partnering with health systems, like Trinity Health, to purchase “minimum viable volumes” of supplied drugs, which Civica Rx aims to price at least 35% below the current or anticipated market price.

Individual Participants may contract with Vendors for high-quality distribution services, and if multiple Model Vendors participate in the IPI Model, competitive forces may also foster high quality services from Model Vendors. However, these forces may be inadequate to ensure that Model Vendors provide high quality services and reliable distribution for smaller Participants with less negotiating power, or in the event only a few Model Vendors participate in the Model, such that competitive forces are inadequate to motivate strong Model Vendor performance. Moreover, it will be critical to motivate Model Vendors to negotiate a reliable supply chain from manufacturers in order to ensure Vendors can provide consistent distribution of Part B drugs to Participants. Market failures in existing drug distribution channels abound, and cause many of the drug pricing problems the Administration is trying to combat with this potential Model. As such, it is imperative that CMS establish Model Vendor rules as a condition of payment to the Model Vendors to provide necessary leverage to ensure Model Vendors negotiate a consistent supply of Part B drugs from manufacturers, which in turn can be distributed to Participants for administration to Medicare beneficiaries at all times.

***Trinity Health requests that CMS ensure that the IPI Model Proposed Rule provide detailed information regarding the proposed “add-on” payment.***

Trinity Health appreciates that CMS is considering continuing to pay Participants for the costs of drug ordering, storage and handling, and other administrative and overhead costs at roughly six percent of the Average Sales Price (“ASP”) of the drugs administered by Participants. However, the ANPRM proposes setting the payment amount based on the revenue that Participants would have garnered (without sequestration) in the most recent year of claims data. The ANPRM also suggests that payment amounts may be set per encounter or per month, as well as by class of drug, physician specialty, or physician practice (or hospital). These relatively unclear and open-ended statements make it difficult to understand or meaningfully comment on the ANPRM’s suggested approach to the add-on payment. Trinity Health encourages CMS to recognize that administrative and overhead costs for dispensing Part B drugs necessarily increase year-over-year as a result of inflation and the rising cost of administrative and overhead services and, as discussed above, Trinity Health anticipates that it would incur significant additional costs associated with implementation and operationalizing the IPI Model that would not be off-set by the proposed “add on” payment.