



July 16, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 600E
Washington, DC 20201

Re: RIN 0991–ZA49; HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Submitted electronically via <http://www.regulations.gov>

Dear Secretary Azar,

Trinity Health appreciates the opportunity to respond to the Department's request for information (RFI) on lowering drug prices and reducing out-of-pocket costs. Our comments and recommendations to HHS reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all. In this letter, we are responding to the questions related to the 340B Drug Pricing Program (340B Program) in support of continued access to 340B drug pricing to enable 340B-participating covered entities to stretch scarce federal resources and to preserve the integrity of the 340B Program.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. 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. 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 that are accountable for 1.4 million lives across the country.

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. Our hospitals use savings from the purchases of 340B drugs consistent with the purpose of the 340B Program: to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Most importantly, the 340B Program allows us to continue to offer the most comprehensive patient services to the most vulnerable uninsured and underinsured patients to improve health in our 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—often non-reimbursed and under-reimbursed—services such as anticoagulation, heart failure, cancer and obstetrics services. This also includes operating clinics dedicated to the provision of care to the poor and underserved, including free dental clinics in the hospital for example, and ensuring strong physician participation in state Medicaid programs. 340B savings allow our 340B hospitals to provide medical care in convenient primary care practice settings in order to expand access to care, particularly for the most vulnerable in our communities.

Our hospitals also support important programs through 340B savings. This includes, for example, Prescription Access Programs where the hospital is able to fill prescriptions with no cost to patients who are 200 percent of the Federal Poverty Level with no insurance or with insurance and co-payments that are unaffordable. In one community this includes over 25 percent of the population served in their county, and the hospital is on track to fill over 20,000 prescriptions annually helping more than 550 patients each month at no cost to the patient.

At Trinity Health ministries across the country, the 340B Program is supporting improved patient care, increased patient medication access and adherence, and decreased hospital readmissions. A decrease in medication adherence by patients, will lead to increased readmissions and emergency care thereby increasing costs to Medicare and Medicaid. If the 340B Program were to be scaled back or eliminated, our hospitals would be forced to eliminate many of the important programs supported today by 340B savings and considerable reductions and restructuring would be required to many of the critical subsidized services offered to the community. In many cases, it would quite literally threaten the ability of our covered entity to continue to sustain safety-net hospital operations that our patients and communities rely upon to meet their urgent and ongoing health care needs.

The focus on 340B as an avenue to reduce drug prices is misplaced and misguided, as 340B discounts are such a small share of the overall drug market and there is no evidence that reducing the level of discounts that manufacturers provide to hospitals would result in manufacturers voluntarily lowering list prices rather than simply returning those amounts to their respective companies and shareholders. Proposed changes to shrink the 340B Program would not reduce list prices for drugs but would instead serve to limit the extent to which hospitals like ours are currently able to provide more comprehensive care to underserved patients. We urge the department to instead redirect efforts toward direct action to halt the unchecked, unsustainable increases in the cost of drugs.

Program Growth

Does the Group Purchasing Organization (GPO) exclusion, the establishment of the Prime Vendor Program, and the current inventory models for tracking 340B drugs increase or decrease prices?

Trinity Health appreciates that HHS is seeking information on the impact of certain 340B Program requirements on the cost of drugs purchased by 340B-participating entities. Under the current requirements of the GPO prohibition, hospitals that are subject to the GPO prohibition must pay significantly more for outpatient drugs that are not eligible for 340B pricing. Specifically, if a hospital subject to the GPO prohibition needs to provide a drug to a patient who is not eligible for 340B pricing or at a location that is not eligible for 340B pricing, the hospital must purchase the drug at "Wholesale Acquisition Cost", which is often the highest market price for the drug, and which is often much higher than other prices that would be available if the hospital were not subject to the GPO prohibition. As a result, the GPO prohibition (and the associated compliance costs) increases drug costs incurred by hospitals subject to the GPO prohibition. Additionally, the Health Resources and Services Administration's (HRSA's) 2013 GPO guidance was a significant departure from previous guidance regarding the statutory GPO prohibition and this has resulted in added burden and cost on our 340B hospitals. Trinity Health encourages HHS to conduct further evaluation of the impact of the GPO prohibition on access to and cost of drugs and to explore opportunities for modifications to or elimination of the GPO prohibition that might reduce administrative and regulatory burden on hospitals and better ensure access. We urge HRSA to ensure important exceptions and flexibilities to its GPO prohibition policy are put in place, for example, in situations where patient care would be disrupted if the hospital could not access a drug at 340B or wholesale acquisition cost, such as during a drug shortage or another disruption in availability. Furthermore, exceptions should also be put in place for inpatients that are reclassified as outpatients by a third-party insurer, Medicare Recovery Audit Contractor (RAC) or hospital review, as long as the patients' status is documented.

While the GPO prohibition increases costs to 340B hospitals, the Prime Vendor Program (PVP) provides some relief. The PVP allows 340B-participating entities to benefit from reduced drug prices, in some cases below the 340B ceiling prices. Further, the PVP provides enhanced opportunities for 340B-participating entities to access discounts on other items and services, as well as free training resources on 340B Program compliance. Trinity Health urges HHS to support the PVP and access to PVP pricing and resources for all 340B-participating entities, including those subject to the GPO prohibition.

What are the unintended consequences of this program?

Congress created the 340B Program to enable entities participating in the 340B Program to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”.¹ As noted by the House Committee on Energy and Commerce in its January 2018 review of the program: “The 340B program is an important program that helps reduce the prices of covered drugs for certain participating entities who, in turn, provide care for patients.”²

340B-participating entities are required to expend significant resources in compliance monitoring and evaluating potential future program changes. These program changes often occur with limited warning and are increasingly inconsistent with the stated purpose of the 340B Program. It is important for HHS to understand that a requirement of 340B Program participation is that the participating-entities meet statutorily defined criteria that limit participation to *safety-net* providers—providers that, by definition, serve low-income and under-resourced populations and communities. 340B payment cuts and increased administrative costs and regulatory burdens may result in 340B-participating entities, like Trinity Health, reducing services and programs supported by savings generated by participation in the 340B Program. This includes access to essential—often non-reimbursed—services, as articulated earlier in our letter, and would undermine population health in these communities.

Of significant concern is the proposal included in the President's fiscal year 2019 budget that would change Medicare outpatient payments for 340B hospitals to be based, in part, on the hospital providing a minimum amount of uncompensated care. By cutting Medicare outpatient payments for 340B, the Centers for Medicare and Medicaid Services (CMS) have not saved beneficiaries any out-of-pocket costs for Part B services but have essentially eliminated a significant portion of savings for safety-net hospitals to “stretch scarce federal resources” as Congress intended in order to provide more comprehensive services to our communities. Such proposals to redistribute 340B savings for other non-340B purposes is a violation of the statute and significantly undermines the 340B Program.

Program Eligibility

Would changing the definition of “patient” or changing the requirements governing covered entities contracting with pharmacies or registering off-site outpatient facilities (i.e., child sites) help refocus the program towards its intended purpose?

Trinity Health strongly believes that 340B participating entities are uniformly committed to the stated purpose of the 340B Program to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”³

¹ See Health Resources and Services Administration, 340B Drug Pricing Program, <https://www.hrsa.gov/opa/index.html>.

² See Review of the 340B Drug Pricing Program, https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

³ See Health Resources and Services Administration, 340B Drug Pricing Program, <https://www.hrsa.gov/opa/index.html>.

Trinity Health recognizes the need for a definition of “patient” that provides for a clear and consistent approach to identifying patients of a covered entity who are eligible to receive 340B drugs. Trinity Health strongly encourages HRSA, however, not to narrow the definition of patient as this would do significant harm to 340B hospitals and the patients we serve. The definition of patient must recognize the varying arrangements between an individual and a covered entity that may create a provider-to-patient relationship. Trinity Health recommends a definition of patient that ensures covered outpatient drugs are eligible for 340B pricing whenever dispensed to an individual when receiving drugs as a part of outpatient services delivered by the covered entity, or filling outpatient prescriptions that were written in conjunction with care delivered by the covered entity.

Regarding covered entities contracting with pharmacies, Trinity Health recognizes the need for close oversight of contract pharmacy arrangements to ensure compliance with 340B Program requirements and appreciates HRSA’s efforts to-date to ensure that program integrity is maintained under such arrangements. Trinity Health encourages HHS to ensure that any future requirements imposed on such arrangements do not result in increased costs to 340B-participating entities. Trinity Health reminds HHS that current HRSA guidance already requires annual independent audits of contract pharmacy arrangements.⁴ We do, however, encourage HHS to evaluate the need for additional oversight of the contracted pharmacies’ participating in the 340B Program, including limits on dispensing and administrative fees that could be charged by contract pharmacies and regulations that impose accountability on contract pharmacies for ensuring compliance with 340B Program requirements.

Regarding alternative approaches to determining eligibility for off-site outpatient hospital locations, consistent with the 340B statute, Trinity Health recommends that HRSA deem as 340B-eligible those locations of a hospital that are determined by CMS to be part of the hospital for purposes of the hospital’s Medicare certification. It is our understanding that CMS views all locations of a hospital that may furnish services to Medicare or Medicaid patients to be part of the hospital, even if a location does not furnish services to Medicare or Medicaid patients in a given cost report year. Further, CMS does not postpone determination of whether a location is part of a hospital until after it appears on a filed Medicare cost report. HRSA’s current and proposed policy of delaying 340B eligibility until a location appears on a filed Medicare cost report is not required by the 340B statute, is inconsistent with CMS practice and does little to protect the integrity of the 340B Program. Trinity Health strongly encourages HHS to adopt a definition of “child site” that provides for 340B eligibility of all locations of a hospital as soon as the hospital commences delivery of clinical services at the location.

Duplicate Discounts

What should be considered to improve the management and the integrity of claims for drugs provided to 340B patients in the overall insured market?

With limited exceptions imposed by certain state Medicaid programs, 340B-participating entities are eligible to access discounted 340B prices on drugs dispensed to eligible patients of such entities, regardless of the patients’ insurance status. The Congressional intent in establishing the 340B Program was to ensure that the 340B-participating entities could then use the revenue generated from the 340B discounts to provide more care to more patients. With the exception of claims to state Medicaid programs, the 340B Program does not contemplate a scenario where there would be a need for “management” or “integrity” of claims for 340B drugs that are provided in the “overall insured market.” The benefit of 340B discounts is clearly intended to accrue to the 340B-participating entities, not to any other third-party. Therefore, whether or not a drug dispensed in the “overall

⁴ See Health Resources and Services Administration, Office of Pharmacy Affairs Update, Contract Pharmacies, June 2015, <http://www.hrsa.gov/opa/updates/2015/june.html> (last accessed 6/18/2018).

insured market” was purchased at a 340B discount should be irrelevant to a non-Medicaid payer. HHS should not be devoting resources to establishing policies or rules relating to claims for 340B drugs in the “overall insured market.”

What additional oversight or claims standards are necessary to prevent duplicate discounts in Medicaid and other programs?

Trinity Health appreciates HHS’ interest in addressing current challenges experienced by 340B-participating entities in complying with the statutory prohibition on duplicate discounts. In particular, Trinity Health believes that 340B-participating entities would benefit from HHS clarifying covered entity responsibilities regarding prevention of duplicate discounts and Medicaid managed care organization (MCO) patients. Trinity Health is particularly supportive of efforts to permit covered entities to select different “carve in/out” policies for Medicaid fee-for-service and MCO enrollees.

340B-participating entities are currently challenged to accurately and efficiently identify Medicaid MCO patients, making it extremely difficult to ensure that all Medicaid MCO patients are identified. Trinity Health would welcome HHS intervention to establish a uniform system across all states and Medicaid MCOs to identify Medicaid MCOs at the time drugs are dispensed to enrollees in such plans. We do not believe that reliable mechanisms currently exist to identify Medicaid MCO patients at the time of dispensing, particularly in the retail pharmacy setting. We note that while HRSA asserted in the proposed “mega guidance” that there are existing data elements that can be used to identify Medicaid MCO patients, we do not agree with HRSA’s understanding of the use of these data elements. For example, as recognized in the proposed guidance, Bank Identification Number (BIN) is one method that could potentially be used to identify Medicaid MCO patients. In practice, however, MCOs often use the same BIN for both commercial and Medicaid plans, making it impossible to rely on the BIN to identify Medicaid MCO patients.

Until such time as HHS is able to develop and implement a system for identification of Medicaid MCO patients at the time of drug dispensing, we ask that HHS impose the obligation for the prevention of duplicate discounts as to Medicaid MCO patients on states and Medicaid MCOs, and that such obligation continue at least until such time as the states and Medicaid MCOs develop and implement a uniform and reliable mechanism for identification of Medicaid MCO patients and pharmacy claims.

Thank you for the opportunity to respond to this RFI. If you have questions on any of our comments, please feel free to contact me at wellstk@trinity-health.org or 734-343-0824.

Sincerely,



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