

October 26, 2015

Captain Krista Pedley, Director
Office of Pharmacy Affairs
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Attention: RIN 0906-AB08

RE: 340B Drug Pricing Program Omnibus Guidance

Dear Captain Pedley:

Saint Thomas Hickman Hospital appreciates the opportunity to provide comments on omnibus guidance issued by the Health Resources and Services Administration (HRSA) regarding the 340B drug pricing program. Since 1964, Saint Thomas Hickman Hospital, a 25-bed, critical-access hospital has provided person-centered care to the people of Centerville and Hickman County. The hospital, which was the first in Tennessee to qualify as a critical-access hospital, serves more than 10,000 patients annually, 50 to 60 percent of whom are uninsured. Saint Thomas Hickman Hospital is a member of Saint Thomas Health, a faith-based ministry of Ascension Health.

Saint Thomas Hickman Hospital supports HRSA's efforts to assist covered entities to help ensure that they are in compliance with the statute. We especially appreciate that some of the changes in this proposed guidance would level the playing field, helping to provide for a fairer regulatory and oversight structure. Under existing regulations and guidance, eligible entities are subject to oversight from both HRSA and prescription drug manufacturers whereas manufacturers are subject only to HRSA oversight. Most important to Saint Thomas Hickman Hospital is that the revised final guidance be consistent with the original intent of the statute – to stretch limited resources and to reach more eligible patients with more comprehensive services. The guidance should not impede access to prescription drugs or reduce the ability of hospitals and other health care providers to provide charitable care, especially in the low-income and underserved communities that are by definition served (in many cases exclusively) by the safety net providers eligible to participate in the 340B Program.



Program Eligibility and Registration

HRSA proposes that the eligibility of off-site outpatient facilities or clinics as 340B “child sites” be based on their listing on a Medicare cost report. Our experience is that this approach causes a long delay before those sites are incorporated onto Medicare cost reports, even though it provides no additional certainty that a facility is an integral part of a 340B covered entity. That delay means that eligible individuals are unable to access 340B drugs at those “child sites” for periods that can be as long as 18 months, which functions primarily as a benefit to drug manufacturers while serving to limit access to reasonably priced drugs for safety net hospitals.

We therefore recommend that HRSA use an alternate method of registering child sites of hospital entities to ensure that all eligible individuals are able to access 340B medications at 340B eligible sites. One reasonable approach would be to allow parent sites to submit their CMS Form 855A enrollment application listing the child site location. Our covered entities already have robust 855A validation processes given that the accuracy of those submissions are assured by a certification statement that the signor affirmatively acknowledges the accuracy of the information, and by the potential application of civil money penalties and False Claims Act protections as well. HRSA may also consider requiring, in addition to the Form 855A, an attestation that the child site *could* submit a UB-04 institutional claim form (again attaching/acknowledging criminal and civil penalties for intentional falsification). In addition to improving the timeliness of child site registration, this approach would address the concern that some provider-based departments, such as free-clinics, do not charge for services – and as a result would not be included as a reimbursable cost center on a Medicare cost report.

Definition of covered drugs

We support HRSA’s proposed guidance clarifying that drugs reimbursed under Medicaid as part of a bundle are excluded from the definition of covered outpatient drug. We note, however, that entities have an array of existing methods to identify those purchases. We recommend that HRSA identify best practices for tracking drugs based on whether or not they are bundled for the purpose of Medicaid reimbursement.

Individuals eligible to receive 340B drugs

Saint Thomas Hickman Hospital has a number of concerns with proposed changes to the definition of individuals eligible to receive 340B drugs. Overall, we expect that the proposed changes will significantly restrict access to affordable medications for vulnerable patients and will undermine the program's objectives to stretch scarce resources as far as possible to reach more eligible patients and to provide more comprehensive services. Specifically:

- HRSA proposes that an individual eligible for 340B drugs receive a health care service and have a prescription written at a facility or clinic site which is registered for the 340B Program and is listed on the public 340B website. This condition would put the care of individuals who are appropriately being treated by hospital covered entities at great risk. Under current practice, 340B prescriptions may be written in the non-child site setting when hospital covered entities are able to demonstrate that they referred the patient to the outside provider and that referral was documented in the record. We strongly recommend that HRSA clarify, consistent with current practice, that if a patient is referred by the hospital to a non-hospital provider from whom the patient receives the prescription, then a 340B drug may be dispensed.

More specifically, the proposed change would eliminate the ability of a physician to dispense 340B drugs in his or her private practice which is not listed on the public 340B database even when providing follow-up for care initiated at a registered site. A patient who is discharged from the hospital with a referral to see a specialist on the medical staff who then sees the patient off-site continues to be a patient of the covered entity. That entity would remain responsible if the referral were insufficient or inappropriate and would in all likelihood return to the hospital if the issues were not resolved. As a result, we again recommend that HRSA clarify that this limitation is not intended to apply to patients for whom there exists a documented direct referral for follow-up care in the covered entity's medical record related to the condition for which the covered entity is responsible.

Without the recommended clarifications, the changes proposed would increase the cost of follow-up treatment related to cancer care, chronic conditions and other public health issues for many low-income patients, and could force patients to have to travel greater distances for medical treatments, particularly those in rural areas.

They could also reduce the quality of care as providers struggle to find more affordable treatment options for patients, potentially substituting less effective products that could be self-administered thereby effectively limiting patients' treatment alternatives.

As noted above, we recommend that HRSA clarify that this limitation is not intended to apply to patients: i) for whom there exists a documented direct referral for follow-up care in the covered entity's medical record related to the condition for which the covered entity is responsible; or ii) who are treated in provider-based hospital space where the covered entity is indisputably responsible for patient care irrespective of where the prescription may have originated.

- We recommend that HRSA not finalize a proposal to require that individuals receive their treatment from physicians who are employed (or under contract) by a covered entity so that the covered entity "may" bill for services on behalf of the providers. We believe the requirement is inconsistent with the very Medicare program rules which HRSA references for establishing covered entity status in requiring that those entities be listed on the Medicare cost report. For that program, to be eligible for Medicare payment, beneficiaries must simply be registered on hospital records as outpatients. (42 CFR 419.1(a)).

The provision would have the effect of forcing contractual relationships between covered entities and providers who practice at those facilities -- relationships that would not further the intent of the program and are not likely to be trackable because laws defining who is an independent contractor vary from state to state. In addition to understanding how HRSA would track such a requirement, we request additional clarity on what is meant by "may bill." Does this mean that the provider has to have provided services in a hospital such that the covered entity could bill, or does it require that an actual bill be submitted? Since this is not a common practice and has no effect on covered entity responsibility for the patient, we assume not.

As the provision seems to require hospitals to employ or have written contracts with providers practicing at covered entities, it would potentially require major restructuring of provider relationships. New arrangements would be required with physician services organizations (where a separate corporate entity employs health care providers who staff covered entities without a contract), with rural providers, and between academic medical centers and faculty practice groups.

This could have a significant impact on our operations given that we employ only 35% and have contracts with only 35% of our providers (out of 17 providers). We urge HRSA to carefully consider the unnecessary costs in time and personnel that would be necessary to meet this standard – and not finalize this proposal. We recommend, as an alternative that HRSA establish that a covered entity must simply maintain responsibility for a patient provided care in a space for which a Medicare payment under 42 CFR Part 419 could have been claimed if the patient were a Medicare beneficiary, irrespective of where the prescription originated. That standard would be consistent with the standard that HRSA proposes for child sites of hospitals that do not file a cost report, such as children’s hospitals.

- The guidance would require that drugs are provided to an individual who is classified as an outpatient when the drug is ordered or prescribed as determined by how the services are ultimately billed. This misguided provision would have major unintended consequences on patient care, patient outcomes, and access to services. It would eliminate the ability of hospitals to use 340B drugs in an emergency room for patients who are later admitted to the hospital and for patients in Medicare’s 3-day payment window. Eliminating the ability of covered entities to use 340B prices in those situations will have the effect of raising costs – limiting the resources available to provide charity care and low cost services for uninsured and underinsured individuals.

The provision would also raise the price of prescriptions provided at discharge for people who are leaving an inpatient stay – an important tool that hospitals use to make sure patients follow-through with their care and avoid unnecessary re-hospitalizations. For our covered entities, this could implicate over 40% of discharge prescriptions. As such, this change would have a direct negative impact on the resources we have available to provide reduced or no-cost drugs to patients, thereby having a material impact on public health. A recently admitted patient at our facility with diabetes was able to obtain an insulin prescription post-discharge for around \$16 under the 340B program. By excluding this patient’s discharge prescription as eligible, the patient would be paying around \$288 dollars making the medication unaffordable and increasing the risk this patient would return to the Emergency Room or be readmitted to the hospital.



We are very concerned about the unintended consequences of these limitations on continuity of care and access to services and therefore recommend that HRSA not finalize this condition. Instead, we recommend that a patient's outpatient status be determined at the time of administration, as is currently widely practiced.

- Saint Thomas Hickman Hospital supports HRSA's clarification that covered entity providers may use telemedicine services to issue a 340B prescription. Telemedicine services are increasingly being used to enhance access to services especially for safety net providers struggling to meet the needs of underserved communities. We request, however, that HRSA clarify the circumstances where the use of telemedicine can result in 340B pricing. It is clear that telemedicine could be used to provide a patient who is at a covered entity site with a 340B-eligible prescription issued by a provider in another location as well as to provide a patient not at a covered entity site with a 340B-eligible prescription provided the prescriber is located at a covered entity. We urge HRSA to consider that the benefit of telemedicine services is to improve access to health care services for people in rural and health shortage areas – objectives that are consistent with those of the 340B program. As a result, the 340B guidance should support the use of telemedicine by allowing for maximum availability of 340B drugs through telemedicine services.

Covered Entity Responsibilities

Saint Thomas Hickman Hospital supports HRSA's proposal to require that covered entities retain auditable records for a period of five years. It is reasonably consistent with Medicare's False Claims Act record retention requirement of 6 years. In addition, we support HRSA's proposed changes to allow HRSA to exercise discretion regarding terminating an entity from the program when a violation is not systemic and providing a notice and hearing process prior to being removed from the program for violations.

The proposed guidance would require additional complicated accounting and audit trails for entities that use drug replenishment models if the patient status is to be based on payor status. In many cases, entities already need to use multiple accumulators to separately identify inpatient versus 340B purchases while also tracking Medicaid purchases and GPO purchases.



Saint Thomas Hickman Hospital is concerned about the growing administrative complexity of participating in the 340B Program and urges HRSA to finalize only those procedures that are consistent with the objective of the program to stretch scarce resources, as opposed to adding increasingly complex operational challenges.

Limited Distribution of Covered Outpatient Drugs

Saint Thomas Hickman Hospital recommends that HRSA affirmatively state that it *shall* (rather than may) publish all limited distribution plans so that covered entities can audit and validate covered outpatient drug availability.

Program Integrity

Finally, HRSA proposes that “Covered entities are expected to work with manufacturers regarding repayment within 90 days of *identifying* the violation.” (emphasis added). The standard that applies to manufacturers who charge a covered entity more than the 340B ceiling price is: “This refund or credit is expected to occur within 90 days of the determination by the manufacturer or HHS that an overcharge occurred.” This standard could be interpreted to require a covered entity to disclose findings of potential diversion while manufacturers would only be required to make refunds on their own final determinations, which could be months (or even years) after an actual occurrence. We recommend that HRSA implement an “actual knowledge” requirement with an obligation to diligently identify and monitor potential diversion. Whatever standard is adopted, however, HRSA should apply the same standard to both covered entities and manufacturers.

Likewise, HRSA states that “If a covered entity fails to act to accept a direct repayment (e.g., cash a check) within 90 days of a manufacturer’s refund and the repayment amount is undisputed by the covered entity, the covered entity has waived its right to repayment.” We recommend that manufacturers be held to the same standard and be required to act on a covered entities’ self-disclosure within the same period of time or similarly waive its own right to repayment.

Timeline for Implementation

Saint Thomas Hickman Hospital recommends that HRSA, in the final notice, establish a realistic timeline for implementing the provisions in the guidance. The final notice should affirmatively state that its provisions are to apply prospectively following publication of the notice and



Saint Thomas
HICKMAN HOSPITAL

should include sufficient time for covered entities to change their operations in response to the finalized provisions. If an insufficient timeline is established, or if the provisions were to apply retrospectively, we would anticipate major difficulties with compliance that could result in many entities losing their eligibility for the 340B program at least on a temporary basis – an outcome whose affects would largely be borne by the low-income, under- and uninsured patients the program was intended to benefit. We recommend that HRSA require implementation no sooner than one year after the publication of the final notice.

In closing, Saint Thomas Hickman Hospital thanks you for the opportunity to provide comments to the omnibus guidance for entities enrolled in the 340B program and drug manufacturers. If you have any questions about these comments or need more information, please do not hesitate to contact me at jack.keller@sth.org.

Sincerely,

Jack Keller, CEO
Saint Thomas Hickman Hospital
135 E Swan St
Centerville, TN 37033
931-729-6782
Jack.keller@sth.org