October 27, 2015

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

Regulatory Information Number: 0906-AB08

Dear Captain Pedley,

On behalf of over 220 children’s hospitals across the country, the Children’s Hospital Association (CHA) appreciates the opportunity to provide comments on the proposed 340B Drug Pricing Omnibus Guidance (the guidance) published by the Health Resources and Services Administration (HRSA). Since 44 freestanding children’s hospitals and a significant number of children’s hospitals within hospital systems participate in the 340B program, the proposed guidance has implications for children’s health and children’s hospitals.

Though children’s hospitals account for only 5 percent of hospitals in the United States, they provide 47 percent of the hospital care required by children covered by Medicaid. Children’s hospitals are regional centers for children’s health, providing care across large geographic areas and serving Medicaid children across state lines. Children’s hospitals serve the majority of children with serious illnesses and complex chronic conditions and most children in need of major surgical services. On average, 52 percent of the patients treated at children’s hospitals are covered by Medicaid, which on average pays approximately 30 percent less compared to Medicare; therefore, children’s hospital rely on the savings from the 340B program to stretch scarce federal resources as far as possible. The savings are critical to reaching more eligible patients and providing more comprehensive services.

CHA shares HRSA’s goal of ensuring that the 340B Drug Pricing Program remains strong and that covered entities are good stewards of the program. Since becoming eligible covered entities six years ago, freestanding children’s hospitals have upheld high standards of 340B program integrity and remain fully committed to improving the program by supporting the administration’s ongoing audits and annual recertification process. As HRSA works to finalize the guidance, we urge the agency to consider the challenges that children’s hospitals face in caring for the pediatric population and their unique health care needs.

Before we provide specific comments on the proposed guidance, CHA would like to highlight that there are sections of the guidance that seem to contradict the Department of Health and Human Services’ (HHS) trend of promoting care coordination to ensure that patients and their families get
the right care, at the right time, at the right place. Therefore, as HRSA finalizes the guidance, we urge the agency to think broadly about how today’s health care delivery system functions and to work to ensure that the proposed changes to 340B align with how HHS is encouraging covered entities to provide care.

CHA also recognizes that HRSA had a difficult task in providing greater clarity to the 340B program. Unfortunately, this proposed guidance leads to more questions than answers. As HRSA finalizes the guidance, we strongly urge the agency to ensure consistency in language and provide greater detail in many of the key areas. In addition, while all stakeholders need clarity, program guidance must accommodate the various kinds of covered entities and the unique needs of the vulnerable patients being served.

Most importantly, the program guidance must reflect the original purpose of the 340B program – enabling safety net providers and other covered entities to care for more patients and provide more services. Unfortunately, the proposed guidance fails to do this and will ultimately limit services for some of the neediest patients.

**Patient Definition**

HRSA proposes to expand the current three-part definition to six parts. Unfortunately, this new six-prong approach does not provide greater clarity. Instead the proposed definition increases complexity and leads to more questions than answers. The proposed definition is very problematic for children’s hospitals and will greatly limit the scope of the program. CHA will focus our comments on the four prongs that will impact children’s hospitals most.

- **The individual receives a health care service at a covered entity site that is registered for the 340B Program and listed on the public 340B database.** (1) HRSA proposes that the patient must receive a health care service from the covered entity, and the covered entity is medically responsible for the care provided to the individual. The guidance also notes that an individual will not be considered a patient of the covered entity if the individual’s health care is provided by another health care organization.

CHA recognizes that HRSA wants to ensure that the covered entity maintains full responsibility for care. However, CHA is concerned that this provision could impact many children’s hospitals’ home care programs, which provide critical supports and services to vulnerable patients who are often too fragile to travel. For example, a children’s hospital may have a neonatologist prescribe Synagis, a drug to help prevent serious lower respiratory tract disease in children at high risk for respiratory syncytial virus disease. A nurse will then take the drug and administer it to the baby in the home. This is an important service that ensures the patient gets the right care at the right place as it keeps the baby out of the hospital or clinic where s/he would be at greater risk for illness or infection. In fact, bringing a baby to a registered site to receive this drug puts the baby at greater risk of exposure to the virus that the health care system is trying to avoid. The preamble notes that HRSA interprets the statute such that a 340B eligible patient receives health care services from the covered entity, and the covered entity is medically responsible for the care provided to the individual. In this case, the baby is discharged from the neonatal intensive-care unit and receives care at another clinic. The original referral is from the entity’s provider, but the care is now elsewhere. The service
is provided by the covered entity, but we request that HRSA clarify that this type of home care services would remain eligible under the 340B.

- The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that that the covered entity may bill for services on behalf of the provider. (2)

Under this provision, HRSA changes current guidance from an “individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the covered entity” to “the individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill (emphasis added) for services on behalf of the provider.” We believe that HRSA must provide greater details about what is meant by “may bill.” Does this refer to services that hospitals bill in connection to services furnished by a provider (e.g., the facility fee)? Or does it refer to billing for the professional services furnished by the providers? Given the extent of this change, we request that HRSA explain why this shift is necessary.

In addition, in the preamble, HRSA outlines the boundaries on what types of arrangements are sufficient (e.g., locum tenens and faculty practice arrangements) and what types of arrangements are not sufficient (e.g., maintaining hospital privileges). This is an example of how HRSA’s proposal does not align with current health care practice. A covered entity typically does not bill for the services provided by practitioners under arrangements such as locum tenens. Moreover, a number of children’s hospitals do not employ physicians, including those that are in states that have a corporate practice of medicine that bars hospitals from employing physicians. Hospitals that do not employ physicians either work with contractors or individuals that have privileges. Whether a covered entity bills for a provider’s services is often a contractual term between the covered entity and a staffing agency or physician group. Therefore, this should not be the basis for determining whether an individual treated by the covered entity is a patient. Regardless of whether a covered entity does or does not bill on behalf of these health care providers, it is furnishing services in the covered entity’s premises to many individuals who in all other respects are patients (e.g., receive care at covered entity, covered entity is responsible for care, care is consistent with scope of Federal grant/designation/project, outpatient, etc.). Under this proposed definition, covered entities would not be able to accommodate the many different types of arrangements with practitioners that covered entities rely on to serve their patients. This is particularly true for covered entities that provide care to medically complex patient populations (such as children’s hospitals). Patients with serious, chronic or complex conditions require many different services, some of which may extend beyond the hospital confines.

We urge HRSA to reconsider this provision so that providers that are furnishing care at the covered entity would qualify. We urge HRSA to remove the language “such that the covered entity may bill for services on behalf of the provider.” Removing this language will help to avoid exclusion of 340B discounts for individuals receiving care under legitimate relationships between hospitals and professionals. We also request that HRSA
provide clarity on what must be in a “faculty practice arrangement” agreement.

- **An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in 2. (3)** Under this provision, HRSA modifies the current guidance from “the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements” to “an individual receives a drug that is ordered or prescribed by the covered entity as a result of the services described in step 2.” The proposed guidance specifically mentions that an individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug.

The infusion of a drug – especially in a pediatric patient – is more complex than the proposed guidance suggests as it requires the administration of medication intravenously, under the management of a trained health care professional. These infusions play a vital role in treating neonatal and pediatric patients with different types of health conditions, including blood diseases, cancer, immune disorders, and genetic abnormalities. As a result, some pediatric patients are referred to children’s hospitals’ infusion clinics because they require specialized care, including having a trained nurse or health care provider that understands the unique physiology of children and can closely monitor, observe, and provide additional health care services as necessary. In fact, due to children’s unique health care needs, many adult based infusion sites will not accept pediatric patients. Therefore, in many cases the pediatric hospital infusion center is the only option.

Since children’s hospitals are regional providers, patients and their families are often coming from across the state or possibly from a neighboring state to receive infusion treatment. While it is important that these children receive this treatment at a children’s hospital, it may not be necessary for the patient to receive their overall care from a children’s hospital. CHA understands HRSA’s attempt to ensure that patients of a covered entity are receiving health care services and not just receiving a prescription. However, infusion treatment, regardless of where the prescription originates, requires substantial care from a health care provider. In addition, while the covered entity is administering the infusion drug, they are responsible for that person and his or her care. Therefore, it seems arbitrary to deem infusion treatment of patients from another facility as ineligible for 340B, especially when the prescription meets all other criteria under the revised patient definition. In addition, no other government program or health care payer requires infusion orders be written at the hospital as a condition of payment. HRSA is proposing a 340B-specific requirement for infusion orders that does not exist anywhere in health care policy. CHA strongly encourages HRSA to reconsider this proposal.

- **The individual is classified as an outpatient when the drug is ordered or prescribed. (5)** CHA is very concerned with HRSA’s proposal that an individual cannot be considered a patient of the entity furnishing outpatient drugs if his or her care is classified as inpatient. We seek additional clarification on this proposal. CHA understands that the 340B program should only be used to furnish covered outpatient drugs. However, we are concerned that the wording of the proposed guidance would prohibit hospitals from using 340B pricing for drugs that are billed as outpatient drugs if
the script/order was written in connection to a discharge from an inpatient stay. If this interpretation is correct, then the proposed policy goes too far and seems to contradict the purpose of the 340B program as well as the way care should be provided. For example, discharge prescription programs have been implemented by many institutions to facilitate the transition of care and improve compliance with medication therapy in an effort to improve patient outcomes and reduce hospital readmissions (one of HHS’s goals). These types of programs help educate and remove some of the challenges related to medication compliance. Finalizing this policy could jeopardize these types of discharge programs. Covered entities may instead be forced to have an individual make a second trip to the hospital solely to have the physician prescribe or order a much needed covered outpatient drug, which would waste both time and resources.

There is no requirement under the 340B statute that covered drugs that are billed as outpatient drugs must also pertain directly to an outpatient service. Therefore, the current practice of allowing discharge drugs from an inpatient stay, which are billed by pharmacies as outpatient, is consistent with the purpose of the 340B program. Moreover, tracking whether an outpatient drug is tied to an inpatient service would be operationally challenging because hospitals generally do not track in their retail pharmacies whether a prescription resulted from an outpatient encounter. Compliance with the proposed change would require significant modifications to hospital systems.

Apexus notes in a frequently asked question (FAQ ID: 1563) that “340B drugs can be used for discharge prescriptions to the extent that the drugs are for outpatient use.” This seems consistent with the intent of the program and we urge HRSA to maintain the current interpretation. We strongly encourage HRSA to continue to allow this practice.

In addition, it appears that patients receiving treatment in outpatient observation or the emergency department (ED) that leads to an inpatient admission would no longer qualify as an eligible patient, even if that patient receives drugs while in the outpatient setting. This seems to also include instances when someone goes to the ED for care (e.g., asthma attack), receives care, and is sent home. Once home, the patient experiences another asthma-related issue within 72 hours and is admitted as an inpatient in the hospital. That initial visit to the ED would no longer be eligible for 340B. Again, this proposed change seems inconsistent with the intent of the program. Hospitals should be able to use 340B for drugs administered in outpatient settings, regardless of whether the drug is billed as part of an inpatient stay. Under current direction from Apexus (FAQ 1526), covered entities may determine inpatient vs. outpatient status such that the determination is in compliance with all 340B program requirements. CHA believes that drugs provided in the ED, prior to an individual being admitted as inpatient, are consistent with the program.

This change would also create a significant operational and financial burden on covered entities. Currently, systems that determine the eligibility of the drug on the front-end and systems that generate the final bill on the back-end are disparate and not integrated. If HRSA changes the status such that eligibility is based on the patient’s bill, which may not materialize until 30 days after discharge, the entire eligibility process can no longer be based on current or real time information. Existing information systems and accounting methods would be taxed tremendously if covered entities had to wait until final billing to
determine patient status and 340B eligibility. Slowing the process requires more systems implementation and unproductive processes, and makes maintaining 340B accruals more complex. The integration of these very different systems – which do not currently exist – will be very costly and require significant time and resources to develop. For all of the reasons outlined above, we urge HRSA not to finalize this policy as proposed.

Children’s hospitals are deeply committed to the integrity of the 340B program and work hard to be in compliance. However, CHA is concerned that the changes to the patient definition are too bureaucratic and could lead to unintentional mistakes. For example, hospitals will have to ensure that they pull out all non-employed physicians who prescribe drugs, which could prove to be complicated. One mistake could accidentally lead to drug diversion. In addition, the proposed guidance notes that the replenishment model is acceptable. But the guidance warns that accumulation into a 340B account for ineligible patients, even without purchase, is considered diversion. CHA believes that a mistake caught before the purchase is made should not constitute diversion and we urge HRSA to reconsider the proposed position.

**Drugs Eligible for Purchase under 340B**

CHA has concerns with the “limiting definition” for covered outpatient drugs and the proposed requirement that a covered entity that receives a bundled payment by Medicaid and does not receive direct reimbursement for the drug would not qualify for 340B. The limiting definition is intended to apply solely to the Medicaid rebate program, and not to 340B, because section 1927(k)(3) states that it applies to covered outpatient drugs that are paid in a bundled manner “under this subchapter,” i.e., by Medicaid. The 340B program, in contrast, is not a Medicaid program. It is codified in the Public Health Service Act, not the Social Security Act, and applies to thousands of payers, both public and private, not just the Medicaid program.

As proposed, each state’s reimbursement methodology and each state’s Medicaid managed care plan’s reimbursement methodology will determine which drugs can be purchased under 340B. This will result in tremendous variability across states and within states as to which drugs a covered entity can purchase under the 340B program. Therefore, if implemented as proposed, this provision would create significant administrative challenges and require new 340B tracking systems that do not exist today. Covered entities could no longer categorically classify certain drugs as “covered outpatient drugs” because the status of such drugs will vary by the site/context of delivery and state Medicaid agency involved for border state and regional providers (as is the case with most children’s hospitals). As a result, covered entities might be unable to determine the appropriate drug purchasing account to use in procuring such drugs until after the payer is determined, which in some cases could occur well after the drug is dispensed.

This proposal also changes the economics of caring for Medicaid patients. Removing the ability to receive 340B pricing on Medicaid bundles eliminates the savings to the covered entity on the very group of patients where on average, Medicaid reimburses significantly below the cost of care. Consequently, some children’s hospitals have noted that these changes would force them to carve out the Medicaid population, which would lead to significant increases in drug purchasing costs. This would be particularly problematic since the majority of children’s hospitals patients are covered by Medicaid. It is also contrary to the purpose of the program, which was created to help safety-net providers “stretch scarce federal resources” (like Medicaid) to provide more comprehensive health care services to more patients.
Finally, health care is increasingly moving toward bundled payments (e.g., Accountable Care Organizations). We urge HRSA not to finalize a proposal that contradicts this shift.

We request that HRSA clarify that the limiting definition does not apply to its definition of “covered outpatient drug” for purposes of identifying 340B drugs in both fee-for-service (FFS) and Medicaid managed care organizations (MCOs).

**Hospital Eligibility and Recertification**

The guidance proposes a change to private, nonprofit 340B hospitals that have contracts with state or local governments by stating that the contracts “…should create enforceable expectations (emphasis added) for the hospital for the provision of health services, including the provision of direct medical care.” It is not clear from the proposed guidance what HRSA means by the addition of the phrase “contract that should create enforceable expectations,” and how it would affect nonprofit hospitals’ eligibility. CHA requests that HRSA provider greater clarity in this area. Specifically, how will HRSA evaluate the contract when hospitals apply or recertify for the program? Or how will the new language be used in HRSA’s audit criteria for those nonprofit 340B hospitals?

CHA also requests clarification on how children’s hospitals should handle registering off-site outpatient facilities and clinics (e.g., child sites). The proposed guidance notes that child sites not located at the same physical address as the parent hospital covered entity will be listed on the public 340B database, and are able to purchase and use 340B drugs for eligible patients, if the hospital covered entity provides its most recently filed Medicare cost report demonstrating that: 1) each of the facilities or clinics listed on a line of the cost report is reimbursable under Medicare; and 2) the services provided at each of the facilities or clinics have associated outpatient Medicare costs and charges. A number of children’s hospitals have off-site outpatient facilities, and very few of them see Medicare patients (on average, Medicare represents less than 1 percent of children’s hospitals’ payer mix since the only pediatric population covered by Medicare is patients with End Stage Renal Disease). Consequently, this proposal could unintentionally eliminate child sites for children’s hospitals. Therefore, we believe that HRSA should clarify that off-site clinic eligibility does not require treating Medicare patients. We recommend that the guidance on page 52317 should read “2) Would be correctly included on a reimbursable line with associated outpatient costs and charges on a Medicare cost report, if filed.”

**Group Purchasing Organization Prohibition**

CHA appreciates HRSA’s attempt to clarify when a covered entity has not violated the group purchasing organization (GPO) prohibition. Specifically, we appreciate the recognition that there are times when a covered entity cannot access a drug through 340B or wholesale acquisition cost, such as when children’s hospitals have not been able to access intravenous immunoglobulin (IVIG). Being able to use a GPO would help in these limited situations. We support the proposal to allow covered entities to use their GPO to prevent disruptions in patient care.

CHA urges HRSA to consider additional exceptions to the GPO prohibition. HRSA should not require hospitals subject to the GPO prohibition to use wholesale acquisition cost pricing when 340B use is not permitted, such as when a hospital:

- Is treating an outpatient who is not eligible to receive 340B drug (e.g., walk-in patient or ineligible employee)
- Carves out and must provide non-340B drugs to Medicaid patients
• Is unable to track a drug appropriately to justify 340B use, such as intravenous saline solutions, contrast agents, anesthesia gases, and other similar products.

We also have concerns with the 30 day timeframe for credit and rebill transactions. We do not think this is reasonable given the complexity of 340B transactions and the timeframe required to process these transactions. A minimum of 90 days is needed; however, 180 days would be preferred.

**Contract Pharmacy Arrangements**

The guidance states that “any” 340B program “violation” (emphasis added) detected through quarterly reviews or annual audits of contract pharmacies should be disclosed to HRSA. The terms “any” and “violation” are not defined and we seek further explanation. The explanation should include language that is measurable and applicable to audits with contract pharmacies or other audits within 340B. HRSA should also define “violation,” and clarify whether it is the same as discrepancy.

Given the large numbers of transactions, “any” violation could be interpreted to include any single transaction, which is neither reasonable nor practical and will create significant operational and financial burdens for covered entities. It would also be a burden on HRSA if it must receive reports for each of these violations.

Most children’s hospitals that have contract pharmacies already conduct internal audits or reviews. HRSA’s proposal to require covered entities to audit each and every site is overly burdensome and an unnecessary drain on resources that provides no added assurance of compliance. Instead a covered entity should be able to conduct a single annual independent audit or quarterly review for each contract it has with a contract pharmacy provider, rather than at each site. Typically all of the sites subject to a single agreement use the same processes and software, which is usually maintained at a central location.

**Duplicate Discount**

The guidance outlines the standard that 340B prohibits duplicate discounts whereby a state obtains a rebate on a drug provided to a Medicaid patient when the same drug was discounted under the 340B program. Under the proposed guidance, a covered entity will be listed on the public 340B database if it notifies HRSA at the time of registration whether it will purchase and dispense 340B drugs to its Medicaid FFS patients (carve-in) and bill the state, or whether it will purchase drugs for these patients through other mechanisms (carve-out).

For managed care, HRSA has proposed that the covered entity may make a different determination regarding carve-in or carve-out status for MCO patients than it does for FFS patients. The guidance notes that an entity can make different decisions by covered entity site and by MCO, but must provide HRSA with identifying information of the covered entity site, the associated MCO, and the decision to carve-in or carve-out. CHA is concerned that this proposal places too much of the burden on covered entities. The Medicaid rebate statute maintains that states, not 340B covered entities, are legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. The Centers for Medicare and Medicaid Services recently reaffirmed this interpretation in the proposed managed care regulations. As such, covered entities have the right to choose whether or not to use 340B drugs for Medicaid MCO patients. CHA urges HRSA to issue guidance that protects the covered entity’s right to choose whether or not to use 340B drugs for Medicaid MCO patients. HRSA should clarify that MCO and states should not require covered entities to carve out for Medicaid managed care. In addition, HRSA
should clarify that it is the responsibility of the MCOs and states to develop retrospective 340B claim identification methods for instances when a 340B Medicaid MCO claims cannot be identified at the point of sale.

However, if HRSA maintains that the responsibility of protecting the manufacturer from paying both a 340B discount and a Medicaid rebate on a Medicaid MCO claim falls on the covered entity, we support HRSA’s position that a covered entity may choose to use 340B drugs for Medicaid MCO patients, including making different selections for each of its sites and each MCO with which it contracts. Any exclusion file or other mechanism developed by HRSA for Medicaid managed care should accommodate these choices.

**Self-Disclosure**

Current HRSA policy requires that covered entities report material noncompliance to HRSA. The proposed guidance suggests that all such instances must be reported, even if they are not material. The annual recertification process would require notification of “any 340B program requirement, subject to HHS audit,” while other sections would require the reporting of “all corrective actions” relating to diversion and duplicate discounts. HRSA should limit disclosures to those that rise to the level of being “material.” Notifying HRSA of all program violations, no matter how minor, would be too burdensome for both HRSA and providers, and fail to provide significant program integrity value.

**Transition Period**

Children’s hospitals are deeply concerned with this proposed guidance. We strongly urge HRSA to seriously reconsider a number of the proposals. However, if HRSA does finalize these policies, HRSA will have to provide greater clarity on expectations. In addition, HRSA must give covered entities an appropriate amount of time to make these changes. HRSA needs to consider that many of these proposals will require vendors to create new technologies for covered entities. Covered entities also will need time to purchase and start using the technologies. Minimally, HRSA should give covered entities 12 months to implement these changes.

In general, covered entities are good stewards of the program. However, many of these proposals will only make an already complicated program much more complex. Children’s hospitals will do their best to be in compliance with the changes. But given the complexity of these changes, inevitably mistakes will occur. Therefore, HRSA should consider a grace period for covered entities as they develop and implement these new systems and work to ensure that staff is properly trained with the new policies and procedures.

We appreciate the opportunity to provide comments on the proposed guidance. We look forward to working with HRSA to advance the needs of children, particularly as HRSA looks to finalize and implement the guidance. If you have questions or need additional information, please contact Liz Parry at (202) 753-5392 or liz.parry@childrenshospitals.org.

Sincerely,

M. James Kaufman, PhD
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