



A Passionate Voice for Compassionate Care

October 27, 2015

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

Attention: RIN 0906-AB08

RE: 340B Drug Pricing Program Omnibus Guidance

Dear Captain Pedley:

The Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic health care systems, hospitals, long-term care facilities, sponsors, and related organizations, appreciates the opportunity to comment on the referenced omnibus guidance issued by the Health Resources and Services Administration (HRSA) regarding the 340B drug pricing program.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers that participate in the Medicaid program to provide covered outpatient drugs at a discounted rate to safety net health care facilities serving vulnerable populations. Six types of hospitals are eligible to participate in the 340B program: disproportionate share hospitals (DSHs), children's hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals (CAHs). To be eligible a hospital must be nonprofit, be owned or operated by or under contract with state or local governments and, except for CAHs, comply with payer-mix criteria related to the Medicare DSH program. Several kinds of non-hospital entities that receive federal funding are also eligible for the program, including federally qualified health centers (FQHCs) and "look-alikes" and programs under the Ryan White CARE Act. The significant pharmacy discounts available under the program allow safety net hospitals to continue to provide and expand services to low-income, vulnerable patients.

Overall, we support HRSA's efforts to assist covered entities to help ensure that they are in compliance with the statute. CHA especially appreciates that some of the changes in this proposed guidance would level the playing field, providing for a fairer regulatory/oversight

structure. Under existing regulations and guidance, eligible entities are subject to oversight and control from both HRSA and prescription drug manufacturers whereas manufacturers are subject only to HRSA oversight. It is essential that HRSA's final guidance be consistent with the original intent of the statute, "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services,"¹ and not create barriers to prescription drugs access for low-income and underserved communities. However, we do have deep concerns about several aspects of the proposal, as detailed below.

As a general matter, we note that the proposed guidance would require covered entities to implement new systems for tracking drug purchases based on the use of the drug, the prescriber, the ultimate disposition of a patient, and their Medicaid status. It would also require increasing oversight of contract pharmacies and GPO purchasing violations and would potentially require changes to organizations' relationships with their medical staff. CHA is concerned about the growing administrative complexity of participating in the 340B Program and reminds HRSA that the objective of the program is to stretch scarce resources, not to add layers of increasingly complex operational challenges that diminish those resources.

Program Eligibility and Registration

HRSA proposes to add specifications for hospitals eligible for the 340B program on the basis of having a contract with a state or local government. Under the proposed guidance, to be eligible via this pathway, the contract must have "enforceable expectations." CHA requests additional clarification about what "enforceable expectations" entails, including whether contracts will need to include specific language and how enforceability will be determined.

Eligibility of Off-Site Outpatient Facilities and Clinics (Child Sites)

HRSA proposes to continue its current practice of requiring that child sites be listed as separate entities on a Medicare cost report. In several of our members' experience, however, the current process of HRSA using the Medicare cost reports to limit child sites to those listed on those reports has raised problems because a long time lag often occurs before those sites are incorporated into the Medicare cost reports. This has become a particular problem for bringing infusion centers onto the 340B program. In communities in which an infusion center is the sole provider of infusion services, the delay can impede access to cancer treatment. Another concern is that our members' pediatric or obstetric outpatient clinics would be excluded from the program if they did not treat Medicare patients in the prior year, which is not unlikely given the services they provide. To mitigate these problems, we recommend that HRSA use an alternate method of registering child

¹ H.R. Rep. No. 102-384(II), at 12 (1992).

sites of hospital entities, including using a new service listed on a hospital's state license or certification, or through the hospital's billing system. One alternative would be to include all of those entities that are listed under a state license of a covered hospital. Another possibility would be to determine 340B-eligible locations based on their inclusion on the Medicare Enrollment Application for Institutional Providers (Medicare Form 855A.) While HRSA notes that it found the form to be "insufficient as an accurate indicator of the facilities' reimbursement under Medicare for purposes of 340B Program administration," its accuracy is ensured by both a certification by the signor attesting to the accuracy of its contents and the application of civil money penalties or criminal consequences if falsification leads to billing Medicare incorrectly.

Group Purchasing Organization Prohibition

CHA supports the additional flexibility that HRSA is proposing in allowing for certain exemptions to the statutory prohibition on using group purchasing organizations (GPOs) for entities affected by that prohibition. We support HRSA formalizing a provision that would allow GPO purchases when covered entities are unable to access certain drugs either at the 340B price or at wholesale acquisition cost. We note, however, that the proposed guidance retains the administratively burdensome requirement that entities must repeatedly file for exemptions for drugs that they are unable to access at the 340B price. We recommend that HRSA compile and make those filings available, perhaps quarterly or annually, to identify when covered entities have repeated problems with accessing particular drugs, with an objective to identify if there are patterns of lack of availability. HRSA could then use such findings as part of its oversight of manufacturers to address problematic access patterns and to relieve the burden on covered entities that are repeatedly unable to access products at 340B prices.

CHA also supports HRSA's proposal to distinguish between systemic and isolated violations of the GPO prohibition, so that an isolated violation would not result in elimination of the entity from the program, upon submission of a corrective action plan. We request that HRSA provide more guidance as to how it will distinguish isolated from systemic non-compliance, and urge HRSA to include errors of *de minimis* value in the category of "isolated" errors that may be addressed through a corrective action plan.

Under the proposed guidance, "a covered entity found in violation" of the GPO prohibition would have to "repay affected manufacturers for any 340B drug purchase made after the date of the first GPO violation." As written, this would appear to apply to all violations, even isolated violations which do not result in removal from the program. However, in the preamble HRSA states that this repayment requirement would be imposed on a covered entity whose violation had been found not to be isolated, and had therefore been deemed ineligible for the 340B program as of the date of the violation and removed from program. HRSA's current enforcement policy requires hospitals with isolated violations to make repayments only for those 340B purchases that violated the GPO prohibition. CHA

strongly urges HRSA to continue this policy and to clarify in the proposed guidance that the broader repayment policy applies only to covered entities deemed ineligible for and removed from the program due to non-isolated violations.

Drugs Eligible for Purchase under 340B

HRSA proposes to exclude drugs that are billed and paid for as part of a Medicaid bundled payment from the definition “covered outpatient drugs,” making them ineligible for 340B pricing. CHA is concerned that this requirement could be difficult to administer. For example, it could be difficult to determine at the time it is dispensed whether or not a drug will be reimbursed as part of a Medicaid bundled payment. Our members tell us that as states have moved aggressively to shift the provision of Medicaid services to managed care organizations, it has become difficult for covered entities to identify the 340B drugs. Identifying bundled drugs can be very complicated. CHA recommends that HRSA continue its current policy of permitting each covered entity to determine which drugs satisfy the definition of “covered outpatient drug,” so long as the interpretation is defensible, consistently applied, documented and auditable. If HRSA decides to implement this proposal, it should first determine whether adequate software solutions exist and are available to covered entities to allow them to identify drugs ineligible for 340B by virtue of their inclusion in a Medicaid bundle.

Individuals Eligible to Receive 340B Drugs

CHA shares HRSA’s goal of ensuring that 340B drugs are not diverted to ineligible patients or to uncovered entities. We have a number of concerns, however, regarding proposed changes to the definition of individuals eligible to receive 340B drugs. Overall, we believe these changes to the definition of individuals eligible for 340B drugs will result in restricting access to affordable medications, undermining the program’s objectives to stretch scarce resources as far as possible for safety net hospitals and impeding our members’ efforts to provide comprehensive services to more low-income patients.

Relationship between covered entities and providers. CHA opposes the proposal to limit individual eligibility for 340B drugs to those patients receiving their treatment from health care providers who are employed by or are an independent contractor of a covered entity such that the covered entity “may” bill for services on behalf of the providers. The relationship between a hospital and a doctor who provides services in the hospital is irrelevant to determining the relationship between the hospital and the patient receiving those services. The statutory question is whether the individual is a patient of the covered entity. HRSA states in the proposal that “[s]imply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B purposes.” If HRSA believes there is a specific problem or abuse that this rule is intended to address, it should identify the problem and propose a narrowly tailored solution. However, applying this rule generally is

inappropriate. There are many models of relationships between hospitals and the physicians practicing therein in which the physicians are not employees or contractors of the hospital, and the hospital does not bill for the physicians' services. For example, a separate corporate entity bills for providers who are in a physician services organization (PSO), and academic medical centers can have complex and varying relationships with faculty practice groups.

For services provided outside of the hospital, HRSA should maintain existing practice which allows for 340B discounts when care is referred by the covered entity, that referral is documented in the patient's record, and the off-site provider reports back to the covered entity on the outcome. Under those conditions, it is clear that the patient remains in the care of the covered entity.

In addition, the proposal would pose complex challenges for covered entities in states like California, where hospital-physician alignment is governed by a strong corporate practice of medicine prohibition. Unlike other states with a similar ban, in California the doctrine mandates the separation of business models, restricting hospitals' ability to bill for physician services that occur within its walls. If this proposal is finalized, hospitals could face the possibility of having to discontinue their participation in the 340B program.

CHA strongly urges HRSA not to limit individual eligibility for 340B drugs to those patients receiving their treatment from health care providers who are employed by, or are an independent contractor of, a covered entity such that the covered entity "may" bill for services on behalf of the providers. If HRSA does finalize this proposal, we request that it clarify what is meant by an entity that "may" bill on behalf of a provider. HRSA should also clarify how this provision, if finalized, would apply in states that do not allow hospitals to employ physicians under "corporate practice of medicine" laws.² The proposal as drafted would appear to have the effect of barring hospitals in those states from the 340B program.

Infusion services. Related to the proposed requirement that health care providers be employees or independent contractors of the covered entity hospital in order for patients to be eligible to receive 340B drugs, HRSA proposes to limit the availability of 340B drugs at infusion centers. HRSA has given no justification for categorically excluding patients receiving infusion services from the definition of eligible individual. Patients receiving infusion services from a covered entity must be registered outpatients and receive a range of health care services in connection with infusion services. The covered entity is

² While many states that prohibit the corporate practice of medicine carve some or all hospitals out of that prohibition, not all do. California, Iowa and Texas are three examples of states that prohibit some or all hospitals from employing physicians. (See <https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Corporate%20Practice%20of%20Medicine.aspx>).

responsible for and must document all aspects of drug administration, patient assessment, monitoring, instruction, management of adverse events, and all other elements consistent with the care of a patient.

CHA is deeply concerned that the proposed policy would mean patients would lose access to the infusion services they need, especially rural and low-income patients. In many communities, a local infusion center allows patients who must travel long distances to receive care from specialists such as oncologists to receive infusion services close to their home instead of having to make many long trips back and forth. These services are of particular importance to vulnerable populations that may find it physically or financially challenging to travel long distances to receive care. Furthermore, this proposed policy could harm low-income patients whose ability to receive affordable cancer treatment depends on the infusion centers they attend participating in the 340B program. CHA urges you not to finalize the proposal on infusion centers.

Patient status at time of prescription. Another proposed condition of eligibility would require that drugs be provided to an individual who is classified as an outpatient when the drug is ordered or prescribed, as determined by how the services are billed. This proposal would appear to limit the ability of hospitals to use 340B drugs to fill outpatient prescriptions for patients who are being discharged from inpatient status. Currently, HRSA allows 340B drugs to be used for discharge prescriptions if the drugs are for outpatient use if other program requirements are met, which is determined on a case by case basis. We are very concerned about the unintended consequences of this limitation, particularly on our ability to improve the likelihood that individuals will follow through with the necessary medications prescribed for them upon discharge from an inpatient stay. Hospitals that are able to provide low-income patients with free or discounted drugs at discharge thanks to the 340B program may no longer be able to do so. If a covered entity is unable to provide a patient with their prescribed medications upon discharge from the hospital, the likelihood that those medications are not obtained rises considerably. We are concerned that forbidding the use of 340B drugs for discharge prescriptions will result in some patients not filling their necessary prescriptions because of prohibitive cost. Patients who fail to take medications prescribed at discharge are more likely to relapse and require readmission to the hospital. This outcome would be in direct contradiction to the goals of other existing federal efforts to reduce unnecessary hospitalizations.

We are also concerned about how this provision would apply in other areas where 340B drugs are now available -- for example, when a patient is prescribed a 340B drug during treatment in the emergency department and is subsequently admitted to the hospital, or when a patient is within Medicare's 72 hour payment window. If the costs of drugs provided during those periods rises to wholesale acquisition cost, then that would have the effect of limiting the funds available for charity care -- the opposite of the intent of the program.

CHA urges HRSA not to finalize its proposed guidance on individual eligibility. HRSA should either maintain the current requirements or propose a new approach, with an additional comment period. Any new proposal to redefine individual eligibility must take into consideration the changing nature of how health care is delivered and the increased focus on clinical integration and care coordination delivery models. More and more, hospital-managed care is provided in non-hospital locations, including patients' homes or by telemedicine, and involves many types of providers with different relationships to the hospital directing the care. HRSA's guidance of the 340B program should reflect this new reality.

Covered Entity Requirements

We appreciate and support HRSA's proposed changes to allow HRSA to exercise discretion regarding terminating an entity from the program if a violation of the record retention requirement is not systemic and establishing a notice and hearing process for those entities prior to being removed from the program for violations.

Contract Pharmacy Arrangements

HRSA proposes to establish as a default that contract pharmacies utilize Medicaid rebates, instead of 340B pricing for dispensing to Medicaid patients, unless there is a written agreement approved by HRSA to dispense 340B products. CHA requests that HRSA provide additional guidance to enable covered entities to have a clearer understanding of what is necessary for contract pharmacies to dispense 340B products to Medicaid patients. What must contract pharmacies or parent entities provide to HRSA, what is the timeline for such a filing, and when and how will HRSA communicate whether or not the contract pharmacy arrangement has been approved?

Program Integrity

CHA supports HRSA's establishment of a notice and hearing process for covered entities to respond to adverse audit findings or charges of noncompliance. As part of that process, entities would be required to respond to any proposed finding of noncompliance within a 30-day response deadline. We recommend that HRSA allow entities to request and obtain HRSA approval of an extension of the 30-day response deadline under extenuating circumstances.

CHA also supports proposed changes to manufacturer audit procedures, including a requirement that manufacturer audits establish, to HRSA's satisfaction, that there is reasonable cause for an audit; that audits be limited to the 5-year record retention period' and that they take no more than one year to conduct. CHA recommends, however, that HRSA require all drug manufacturers to provide HRSA with pricing files to support

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pricing transparency. A recent Health Affairs Policy Brief reports that more than one hundred manufacturers voluntarily do so today.³ Better transparency would make HRSA's oversight more effective and would increase protections for covered entities from manufacturer overcharges.

In closing, thank 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 Kathy Curran, Senior Director, Public Policy at 202-296-3993.

Sincerely,

A handwritten signature in black ink, reading "Michael Rodgers". The signature is fluid and cursive, with a long horizontal stroke at the end.

Michael Rodgers
Senior Vice President
Public Policy and Advocacy

³Health Policy Brief: *The 340B Drug Discount Program*, Health Affairs, November 17, 2014, http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_130.pdf.