March 31, 2014

Dr. Mary Wakefield
Administrator, Health Resources and Services Administration
5600 Fishers Lane
Room 14-05 Parklawn Building
Rockville, MD 20857

Re: Issues for Consideration Related to Forthcoming Comprehensive 340B Regulations

Dear Dr. Wakefield:

The undersigned organizations respectfully submit comments regarding the Health Resources and Services Administration’s (HRSA) forthcoming proposed regulations intended to address a variety of issues regarding the 340B federal drug discount program. We urge HRSA to draw upon the experience and input we have gathered from working with our members, who are critical participants in the 340B program.

Since its enactment in 1992, the 340B drug discount program has successfully lowered the costs of outpatient drugs for safety net providers, as Congress intended. The original legislation applied the discount program to certain disproportionate share hospitals that treat large numbers of uninsured, underinsured, and other vulnerable Americans. Congress has recognized the value of the 340B program and has permitted other safety net hospitals to participate, including free-standing children’s hospitals, rural referral centers, stand-alone cancer hospitals, sole community hospitals, and critical access hospitals. The program requires drug manufacturers, as a condition of having their drugs covered and reimbursed by Medicare and Medicaid, to reduce their prices on covered outpatient drugs for safety net providers. The discounts help reduce the costs of these providers’ operations which, in turn, allow them to stretch their scarce resources so that they can serve more needy patients and provide more needed services within their communities. Government and other studies have confirmed many times that 340B providers use their program savings to benefit vulnerable patients by providing medications free of charge or at lower cost, serving more patients, and providing more services to vulnerable patients.

The hospital organizations listed below represent more than half of the hospitals that participate in the 340B program. We believe that HRSA, which is charged with administering the 340B program, should exercise robust program oversight to ensure that the program is fulfilling its intended purpose on behalf of the vulnerable patients served by 340B covered entities. We are pleased that HRSA has already announced its plan to reissue its current 340B guidances as binding regulations using formal rulemaking procedures with notice and comment. We believe that this will help to avoid confusion and differing interpretations among stakeholders about important program requirements, as was demonstrated by the recent HHS Office of the Inspector General (OIG) report. We also strongly support the issuance of 340B rules by regulation. We believe regulations will provide more comprehensive guidance and more clarity than the informal guidance that has been relied upon over the past twenty plus years. Further, much of the 340B guidance has been issued on an ad hoc basis in the form of answers to frequently asked questions,
which were not subject to public comment. Technical support is critical in a program as complex as the 340B program, but HRSA should no longer rely on such informal guidance as a tool for policy making.

This document summarizes our recommendations and provides specific suggestions on areas that we believe should be addressed in HRSA’s comprehensive 340B regulation. A recent update from HRSA announced that “[t]he regulation currently under development will address the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities.” We strongly support HRSA’s intention to clarify the definition of a 340B-eligible patient in the comprehensive regulation, and we urge HRSA to also address the agency’s policy on documentation needed to register offsite outpatient facilities. We also request that HRSA include in the comprehensive regulation provisions to implement the manufacturer accountability and compliance provisions included in paragraph (d) of the 340B statute, address specific issues that have arisen around preventing Medicaid duplicate discounts involving Medicaid managed care claims, and modify the policy on the use of group purchasing organizations (GPOs).

I. Recommendations Relating to Manufacturer Compliance

To achieve program integrity, both covered entities and manufacturers must be held accountable for their 340B compliance status. We applaud HRSA for devoting more resources to overseeing compliance in the program. As we requested in the 340B Coalition’s recent letter to you, we believe HRSA should continue its efforts to improve manufacturer compliance with the funding Congress recently appropriated to HRSA. We understand that HRSA is currently auditing a manufacturer and has suggested plans to audit more, which is an important step to ensuring manufacturer compliance.1 We welcome HRSA’s goal of conducting more manufacturer audits, because although manufacturers have the right to audit covered entities, covered entities have no right to audit manufacturers. Covered entities also have no right to seek damages if they discover that they have been harmed by a manufacturer’s misconduct. The U.S. Supreme Court ruled two years ago that there is no 340B private right of action against manufacturers.

It is well established that manufacturers overcharge covered entities when selling outpatient drugs subject to discounts under the 340B program. In July 2006, the OIG issued a report – entitled “Review of 340B Prices” – documenting the 340B overcharge problem. The OIG sampled pricing over the course of a month and found that 14 percent of total 340B purchases by covered entities resulted in overcharges. The 2011 GAO report also included a discussion of how manufacturers may be “charging covered entities more than the 340B price for drugs which would limit the benefit of the program for these entities.” Our members have long complained about manufacturer overcharging, and the complaints continue today. For these reasons, we welcome HRSA’s commitment to increased oversight in the area of overcharging.

The Affordable Care Act (ACA) added program integrity improvements intended to protect covered entities from overcharges. HRSA was instructed by Congress to “provide for improvements in compliance by manufacturers with the requirements of [section 340B] in order to prevent overcharges and

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other violations of the discounted pricing requirements specified in this section.” The specific improvements enumerated by Congress include information sharing between covered entities and manufacturers, price calculation verification, spot checks of transactions, and selective auditing of manufacturers.

We understand that HRSA is working to improve its information technology systems, which would include “reconstituting” HRSA’s pricing database “to allow manufacturer price reporting, price validation, and covered entity access to pricing.”

Further, HRSA has stated it plans to issue separate proposed regulations to implement civil monetary penalties for manufacturers that violate the law. We ask that HRSA move forward with these plans expeditiously – if not as part of the proposed comprehensive regulation, in other proposed regulations this year – to help maintain the integrity of the program. Without full implementation of the ACA’s manufacturer integrity measures, manufacturer overcharges will continue without formal procedures in place to process refunds. For example, Genentech recently announced that it had recalculated its “average manufacturer price” and “best price” for many of its products used by 340B hospitals for the period 2008 through 2010, potentially owing millions of dollars in refunds to these entities. Not only is there no formal HRSA process in place to assure that manufacturers pay these refunds, but there is also no formal process to resolve disputes should one arise between a hospital and manufacturer regarding the refunds. Accordingly, we encourage HRSA to include measures aimed at improving manufacturer compliance in its proposed regulations.

A. Implement ACA Manufacturer Integrity Provisions

We urge HRSA to implement as part of the comprehensive regulation, or through separate regulations to be published this year, provisions in the ACA that are designed to ensure manufacturer pricing transparency and integrity in the 340B program. The specific improvements enumerated by Congress in the ACA, which have yet to be implemented, include:

- Requiring that covered entities have password-protected access, through the Internet website of the Department of Health and Human Services (HHS), to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the HHS Secretary, and providing adequate security and protection of privileged pricing data from unauthorized re-disclosure;

- Developing a system to enable the HHS Secretary to verify the accuracy of ceiling prices calculated by manufacturers and charged to covered entities;

- Establishing procedures that would require manufacturers to engage in a dispute resolution process with covered entities relating to overcharges;

- Establishing procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers;

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3 Id.
• Auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section;

• Imposing sanctions on manufacturers in the form of civil monetary penalties.

We also urge HRSA to devote more resources to ensuring that manufacturer registration information on the HRSA database is accurate and up-to-date. Covered entities are subject to annual recertification and potential penalties if their database entries are inaccurate. Manufacturers should be subject to the same requirements.

Recommendations

• HRSA should implement and enforce the 340B manufacturer integrity requirements established under the ACA as part of its upcoming comprehensive regulation or through separate regulations to be published this year.

B. Prohibit Discrimination Against Covered Entities

As part of its proposed regulation, we urge HRSA to clarify and strengthen the guidance it developed to protect covered entities from discriminatory practices by manufacturers. In its 2011 report, the GAO found that HRSA’s non-discrimination guidance was “not specific in the practices that manufacturers should follow to ensure the drugs are equitably distributed to covered entities.” The GAO reported on concerns raised by stakeholders about the way manufacturers of intravenous immunoglobulin (IVIG) have interpreted and complied with HRSA guidance because covered entities have sometimes had to purchase IVIG at higher, non-340B prices. The GAO was sufficiently concerned about this response that it included in its list of recommendations that HRSA “further specify its 340B non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturer’s plans to restrict distribution of drugs at 340B prices.”

More recently, Amgen has made it more difficult for 340B hospitals to obtain Neulasta, an important drug used to prevent infection in patients receiving chemotherapy. Amgen will only permit 340B hospitals to purchase the drug through specialty distributors. Non-340B hospitals, by contrast, are free to purchase Neulasta through their traditional wholesalers. This discriminatory practice increases the costs incurred by 340B hospitals of both obtaining Neulasta and complying with 340B program record keeping requirements.

We appreciate HRSA following up on individual reports of discrimination. However, we still believe this issue needs to be addressed in a more comprehensive manner. The 2012 HRSA republication of its 340B non-discrimination policy did not provide any more detail or specificity regarding what constitutes discrimination. This is problematic because the release does not address several key areas in which discrimination may be an issue. For example, the release does not address manufacturers’ reliance on allocation plans in non-shortage situations (such as for IVIG), drugs sold through specialty distributors, participation criteria for specialty pharmacy networks, and covered entities entering into contract
pharmacy arrangements with specialty pharmacies. HRSA’s lack of guidance in this area leaves manufacturers uncertain of their obligations and covered entities unclear on their rights. We therefore believe that HRSA should strengthen its non-discrimination policy by adopting more specific guidance in these areas.

**Recommendations**

- In its proposed regulation, HRSA should further clarify and expand its non-discrimination policy as follows:
  - Prior to implementing an allocation plan for producing and selling outpatient drugs (including IVIG), manufacturers should submit their plans to HRSA for review and approval, even in non-shortage situations.
  - A manufacturer must ensure that its participation criteria for specialty pharmacy networks are 340B-neutral.
  - A manufacturer must ensure that its drugs sold to covered entities through specialty distributors are available at 340B prices.
  - A manufacturer must allow (1) a pharmacy participating in a specialty pharmacy network to serve as a 340B contract pharmacy for covered entities and (2) covered entities to purchase at 340B prices the drugs dispensed by contract pharmacies participating in specialty pharmacy networks.

- HRSA should make clear in its proposed regulation that it will audit manufacturers to ensure compliance with the above non-discrimination policies.

**II. Recommendations Relating to Policies Intended to Support a Successful 340B Program**

**A. Create Clear, Concise Definition of Patient**

The 340B statute is clear that 340B drugs may only be resold or otherwise transferred to covered entity patients, but the law does not provide a definition of “patient.” HRSA’s efforts to define patient eligibility in 1996 left many questions unanswered and there is an inherent conflict of interest between covered entities and manufacturers over how broadly HRSA’s 1996 definition should be applied. Given this conflict of interest, the federal government has a special responsibility to be clearer in defining a covered entity “patient.” All 340B stakeholders, not just covered entities and manufacturers, would benefit from a clear and concise regulatory framework for applying the definition of patient. That way, all parties can be confident about appropriate use of 340B drugs.

Patient definition issues are more complex in hospitals than in other provider groups by virtue of the nature of the health care services that hospitals provide. For example, whereas non-hospital 340B entities provide only outpatient care, hospitals provide both inpatient and outpatient services. Identifying when a drug is provided in an "outpatient" setting versus an "inpatient" setting is complicated, such as when a patient is being transferred from outpatient status to an inpatient unit or when a patient is in observational status, which is an outpatient status, but the patient’s bed is located in an inpatient setting.
Further, hospitals provide a wide range of services that go beyond primary care, often requiring the involvement of non-hospital specialists, post-hospitalization treatment plans, and care coordination. Hospitals are encouraged to create relationships with providers in the area to form a continuum of care for their patients. In fact, under the constructs of the ACA, there is an implied assumption that the hospitals will have responsibility for the continuum of care for their patient populations along with financial responsibility. Hospitals maintain responsibility for their patients’ care in these situations. Many safety net hospitals provide home care, hospice, behavioral health, and other services outside their walls, further complicating application of the definition of patient.

Recommendations

- Recognizing that HRSA is planning to address the definition of patient in the expected regulations, we urge HRSA to create a clear, implementable definition that does not unduly burden covered entities or restrict the benefit of the program for their patients. In 2007, HRSA proposed new patient definition rules that were overly bureaucratic and too burdensome for providers to implement. In an effort to help HRSA, many 340B provider groups submitted in April 2008 a detailed patient definition alternative that would have provided more clarity than the current HRSA guidance and a more user-friendly solution than the 2007 proposal. HRSA should issue a new patient definition regulation, through formal rulemaking with notice and comment, taking the April 2008 proposal into consideration. The new regulations must be clear enough so that covered entities, manufacturers, and regulators understand what they mean and how they can be applied in a meaningful and measurable way.

- We recommend that a HRSA regulation on patient definition address the use of 340B drugs when an outpatient is admitted into the hospital as an inpatient. This will help clarify at what point a 340B-priced drug may no longer be used. In providing such guidance, it is imperative that HRSA recognize the practical realities of patient admissions, such as delays in movement of patients when beds are unavailable, and other complicating factors in admitting patients (e.g., orders for admission can occur prior to actual admissions). In addition, HRSA should avoid any overly prescriptive framework that may inadvertently impede patient care. There should be flexibility, for example, to allow patients to continue receiving intravenous 340B drugs provided in the emergency department while they are being transferred to an inpatient unit. Interrupting treatment to replace the intravenous bag with a non-340B solution could jeopardize patient safety and quality of care.

- We recommend that HRSA provide greater clarification regarding what “contractual and other arrangements” means in a manner that will promote and not impede continuity of care. For example, we believe that the patient definition should recognize legitimate referrals and other arrangements in which a patient of the covered entity receives treatment or consultation from a health care professional (not otherwise employed or under a contractual arrangement) as part of a single continuum of care for health care services that are proximate to the services provided by the covered entity to the patient.
• We recommend that HRSA provide greater clarity around the term “responsibility,” especially in connection with using 340B to fill prescriptions that originate outside the walls of a hospital. Safety net hospitals often provide home care services or supply medical staff for school-based clinics, mental health departments, free or indigent care clinics, correctional institutions, etc. Prescriptions written by hospital professionals, whether employed or contracted by the hospital, in non-hospital settings should be 340B eligible if the hospital maintains the relevant health care records, is responsible for the care provided, and the costs are reimbursable on the hospital’s cost report.

• We recommend that HRSA continue to permit use of 340B for physician-administered drugs that are administered to the patient by the 340B hospital even when the order for the drugs originates outside the hospital. As we wrote in a recent letter to the Office of Pharmacy Affairs (OPA), which we have attached, in this situation, the hospital registers the patient and provides the service of administering the drugs, making it responsible for the care delivered through that service. For example, a patient living in a rural community may seek oncology treatment from a teaching hospital several hours away, from which the patient receives an order for chemotherapy. The patient may bring the order to her local rural hospital to receive infusion services close to home, and the hospital would administer the chemotherapy to her. Comments made at Apexus’s 340B University have suggested that 340B may not be used in this instance. HRSA should make clear that 340B may be used in situations where the hospital is providing an actual service to its patients.

B. Prevent Duplicate Discounts

When Congress established the 340B program in 1992, it recognized that, due to the potential overlap of drugs subject to both 340B discounts and Medicaid rebates, it was creating a risk that manufacturers would be asked to give two discounts on the same drug. Congress included specific language in both the 340B and Medicaid statutes to avoid this duplicate discount problem. This is just one of the numerous areas in which the 340B program intersects with Medicaid. For that reason, CMS should have a more formal role in administering the program. Both HRSA and CMS have important roles to play in ensuring that the 340B program runs smoothly.

The duplicate discount provisions enacted by Congress in 1992 only apply to 340B drugs billed and reimbursed by Medicaid on a fee-for-service basis because, at the time, manufacturers were only obligated to pay rebates on Medicaid fee-for-service drugs. Under the ACA, Congress expanded the Medicaid rebate program to managed care drugs but chose to address the duplicate discount risk in a different way. Congress simply clarified that managed care drugs purchased through the 340B program are not subject to Medicaid rebates, thereby extinguishing a state’s right to collect rebates for such drugs. Thus, states are prohibited from seeking rebates on 340B Medicaid managed care drugs. Though the statute clearly places the burden on states to ensure that they do not request rebates on such drugs, some stakeholders, including certain state Medicaid agencies, are under the misconception that the fee-for-service rules apply to managed care drugs and that covered entities are responsible if states inadvertently collect rebates on 340B Medicaid managed care drugs. There also appears to be a misconception in some states that the HRSA exclusion file applies to both fee-for-service and managed care claims. However, the exclusion file was created to address duplicate discounts with respect to fee-for-service claims, not managed care. Applying
the existing exclusion file to managed care claims would require covered entities to have the same carve-out or carve-in decision for both fee-for-service and managed care claims. This would be a significant departure from past practice, and there is no evidence that Congress intended for that to be the outcome when it excluded 340B Medicaid managed care claims from being subject to Medicaid rebates. The OIG also found confusion on this point in its recent report on 340B contract pharmacies, reporting that conflicting strategies are being used to address this issue.

Recommendations

- HRSA and CMS should work together to develop regulatory language that would clarify that states, not covered entities, are responsible for preventing the collection of rebates on 340B Medicaid managed care drugs.

- HRSA and CMS should work together to develop regulatory language that would identify and promote effective strategies that states and their Medicaid managed care plans can use to exclude 340B Medicaid managed care claims from their rebate requests.

C. Modify GPO Exclusion Policy

HRSA issued a policy in February 2013 related to the program requirements that DSH and free-standing children’s and cancer hospitals may not purchase covered outpatient drugs through a GPO or other similar group purchasing arrangements, known as the “GPO exclusion.” We appreciate that HRSA extended the deadline for complying with one of the more challenging aspects of the February notice, namely, how to operate a virtual inventory split-billing replenishment system. But we also feel strongly that, before adopting a notice involving a key eligibility requirement, HRSA should have requested comments so it could gather information on the implications of its proposal, including the compliance challenges, significant costs posed by its policy, and the length of time needed to implement the policy. Now that we have eight months of experience, it is clear that the February 2013 policy release has created significant complexity in supply chain procurement and significantly increased the costs of participating in the 340B program.

HRSA needs to clarify the definition of “covered outpatient drug” as that term applies to the 340B program so that hospitals can know when they can use a GPO to purchase non-340B medications. The 340B statute defines that term by referencing the term’s definition in the Medicaid statute. That definition was written for the purpose of implementing the Medicaid rebate program, not the 340B program, and does not take into account many aspects of the 340B program. We believe that HRSA has the authority and obligation to interpret the term “covered outpatient drug” in a manner that is appropriate for the 340B program. Specifically, we believe that the term should: (1) exclude drugs furnished to individuals who do not qualify for 340B; and (2) interpret the second part of the definition (42 USC §1396r-8(k)(3)), referred to as the “limiting definition,” in a manner that minimizes its impact on the 340B program. This is because the language of the limiting definition only makes sense when applied to the Medicaid program, whereas the 340B program applies to all payers, both private and public.
In addition, we believe that HRSA should create exceptions to the GPO exclusion to allow hospitals to purchase covered outpatient drugs through a GPO under limited, policy-based circumstances, including when they are (1) sold by a manufacturer that does not participate in 340B; (2) an intravenous saline solution, contrast agent, anesthesia gas, or other product as determined by the HHS Secretary; (3) not available at the 340B price; or (4) purchased for a clinic that is not provider-based, including when the clinic is within the four walls of the hospital. There are other situations as well in which allowing a 340B hospital to purchase through a GPO would help reduce the costs of medications for these entities, thereby giving them the necessary resources to meet the needs of their vulnerable patients.

Recommendation

• HRSA should withdraw the February 2013 GPO exclusion policy guidance and reissue it through notice-and-comment rulemaking as part of the comprehensive regulation. This will allow the agency to understand and more fully address the circumstances under which it would make sense for 340B hospitals to be able to purchase pharmaceuticals through a GPO to lower their costs, consistent with the intent of the program, so they can better serve their patients and maintain program compliance without employing unreasonable or unnecessary administrative burdens.

D. Modify Offsite Facility Documentation Policy

In order to improve access to affordable hospital services within a community, a hospital can dispense or administer 340B drugs in hospital outpatient facilities outside the four walls of the hospital, provided that the facilities are listed as reimbursable on the hospital’s Medicare cost report. However, existing HRSA policy delays hospitals’ access to 340B drugs in offsite outpatient facilities. HRSA should issue clarifications to this policy reducing the waiting period for hospital enrollment of offsite outpatient facilities without sacrificing compliance or diminishing program integrity.

HRSA’s current policy is that it will not enroll an offsite outpatient facility until the hospital can provide a copy of the hospital’s most recently filed Medicare cost report, showing the costs of the facility on a reimbursable line. However, this policy causes significant delays in the sites’ access to 340B drugs, in some cases by as much as 20 months. Because hospitals only file cost reports once a year, it can take up to five months to file a cost report, and hospitals may only register outpatient facilities once a quarter.

There are at least two documents other than the filed cost report that demonstrate a facility is reimbursable for Medicare cost reporting purposes. These documents include the CMS 855A enrollment application, which must be completed for provider-based facilities, and the attestation that providers may make to the federal government indicating they are provider-based for Medicare payment purposes. Allowing hospitals to demonstrate 340B eligibility for their outpatient facilities with these forms would improve access to the 340B benefit for hospitals and their patients without sacrificing compliance. Both of these forms are submitted to the federal government with consequences for including false information, so their use would not be a sacrifice to program integrity. And, indeed, accepting these alternative forms of documentation would not preclude HRSA from requiring the submission of additional documentation, as it becomes available—including the next cost report when filed—as a condition of continued enrollment. Acceptance of these forms would dramatically reduce
the wait time for enrollment, resulting in significant savings to hospitals and increased access to drugs for vulnerable populations.

**Recommendation**

- HRSA should make clear in its proposed regulation that the agency will accept documents other than a filed Medicare cost report that are equally or even more reliable in demonstrating that an offsite facility of a hospital is eligible to participate in 340B by virtue of being an integral part of the hospital.

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If you have any questions, please feel free to contact us. Thank you for considering our comments.

Sincerely,

America’s Essential Hospitals
Children’s Hospital Association
Safety Net Hospitals for Pharmaceutical Access

cc:

Cheryl Dammons, Associate Administrator, Healthcare Systems Bureau, HRSA
CDR Krista Pedley, Director, Office of Pharmacy Affairs, HRSA

Enclosure
Re: Application of the 340B Definition of Patient to the Administration of Chemotherapy

Dear Cdr. Pedley:

Thank you for meeting with Safety Net Hospitals for Pharmaceutical Access (SNHPA) on June 26. I write to follow up on our discussion regarding the use of 340B drugs when the drugs are administered at a 340B hospital by a health professional with an employment, contractual, or other arrangement with the hospital, but were ordered by a physician unrelated to the 340B hospital. I would also like to express SNHPA’s strong concerns regarding a Frequently Asked Question (FAQ) on this matter that we understand was recently published by Apexus and request that it be removed or revised immediately.

Background

As we discussed during our meeting, SNHPA was contacted not long ago by a rural hospital that had recently attended Apexus’s 340B University and believed it received guidance that seemed contrary to the definition of patient set forth by the Health Resources and Services Administration (HRSA) in the Federal Register on October 24, 1996.\(^1\) The rural hospital had administered chemotherapy to a patient who had been diagnosed with cancer by a physician located at a teaching hospital in a large city several hours away by car. The physician at that teaching hospital prescribed a regimen of chemotherapy for the patient to receive at a location closer to her home. The physician did not have any relationship with the rural hospital located in the patient’s hometown. The patient took the order for chemotherapy to the rural hospital in her town and was administered chemotherapy drugs by a health professional (either a physician or a member of the nursing staff) who was employed by the hospital. The hospital is registered with HRSA as a 340B hospital, and purchased at the 340B price the chemotherapy drugs administered to this patient. In accordance with routine billing practices, the hospital billed the payer separately for (1) the health care services associated with administering the chemotherapy drug, and (2) the drug itself. Subsequently, an employee of the rural hospital thought that it had been suggested at a 340B University session that a 340B hospital may not use the 340B program to

purchase chemotherapy drugs unless the hospital had an employment, contractual, or other arrangement with the physician who prescribed the drugs. The rural hospital did not believe that advice was accurate, since HRSA’s current definition requires only that the hospital have a relationship with the health care professional who furnishes a service to the individual, and does not require the hospital to have a relationship with the physician who writes the order for administration of the drug.

We raised this matter with you in our meeting, and you invited us to send additional information to support why 340B drugs should be used in the situation described above. You noted that the definition of patient prohibits an individual from being considered a “patient” of the hospital if the only health care service received is the dispensing of drugs for self-administration. You also noted that, under the definition of patient, hospitals must retain responsibility for the care provided.

Since then, Apexus published an FAQ that appears to address the same issues. The FAQ states the following:

**Q:** May a 340B covered entity site, registered on the 340B Database and listed as reimbursable on a 340B registered hospital's most recently filed cost report, utilize 340B drugs for patients that meet all of the following:

1. A patient was discharged from the 340B registered hospital
2. A drug for infusion was written by a private physician, with no relationship with the covered entity
3. The private physician does not practice in a clinic on the hospital's most recently filed cost report

**A:** The individual is not a patient of the covered entity if the individual is discharged from the covered entity and subsequently receives care from a private physician with no relationship with the covered entity. HRSA's patient definition guidance states the individual must receive 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 (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity (61 Fed. Reg. 55156 (October 24, 1996)). The covered entity is not responsible for the health care services of a discharged patient that have been provided by a physician with no relationship with the covered entity. HRSA's patient definition guidance also states that an individual will not be considered a 'patient' of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug (61 Fed. Reg. 55156, 55158 Oct. 24, 1996).²

The FAQ is available to the general public, not just to participants of the 304B Prime Vendor Program.

As discussed below, SNHPA is concerned with the guidance imparted at the 340B University to the rural hospital mentioned above. It is SNHPA’s strong belief that, under the existing definition of patient, hospitals are permitted to use 340B drugs when administering chemotherapy drugs within their facilities. SNHPA is also concerned with the new FAQ on the Apexus website. SNHPA finds the FAQ to be both confusing and misleading and therefore recommends that it be removed or clarified immediately.

**Definition of Patient for 340B**

Both the 340B University guidance provided to the rural hospital and the recent Apexus FAQ described above involve interpretations of the 340B definition of “patient.” Under HRSA’s 1996 patient definition guidelines, individuals qualify as “patients” of a 340B hospital if two criteria are met:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care; and

2. 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 (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.³

The current definition of patient also notes that an individual will not qualify as a patient if the only health service received is the dispensing of a drug for subsequent self-administration.⁴

**Application of Definition of Patient**

An individual becomes a patient of a 340B hospital by virtue of receiving infusion and related professional services in connection with his or her chemotherapy visit. That the order originates from a physician who has no pre-existing relationship with the hospital should not matter. Both prongs of the patient definition are satisfied.

The first part of the definition is met because, when administering chemotherapy to a patient, a hospital must maintain a record of delivery of that health care service. Thus, the hospital has a relationship with the individual such that it has registered the patient as an outpatient of the hospital and maintains a record of the patient’s health care. This issue does not appear to be in dispute.

³ *Id.*
⁴ *Id.* at 55158.
The second part of the definition is also met. In the fact pattern described above, the hospital employed the health care professionals who administered the chemotherapy to the patient. Further, that health care professional provided an actual health care service, which is separate from the purchasing and preparation of the chemotherapy drugs that were administered. As is discussed in detail below, administration of chemotherapy is a highly complex service, requiring skill and direct attention, and may only be performed by trained health care professionals. Failure to administer chemotherapy appropriately can result in severe consequences for the patient, for which the hospital is responsible.

To understand the nature of this service, it is helpful to look at the description of chemotherapy administration services that is used by the American Medical Association’s Current Procedural Terminology (CPT) Codebook. The CPT Codebook serves as the worldwide standard for describing and reporting medical services and procedures, and is required to be used when billing government and private payers. The CPT Codebook includes a section that contains codes describing the administration of chemotherapy:

Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration: Intravenous or intra-arterial push is defined as: (a) an injection in which the healthcare professional who administers the substance/drug is continuously present to administer the injection and observe the patient, or (b) an infusion of 15 minutes or less.\(^5\)

Chemotherapy administration codes … apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses … or to substances such as certain monoclonal antibody agents, and other biologic response modifiers. The highly complex infusion of chemotherapy or other drug or biologic agents requires physician work and/or clinical staff monitoring … because the incidence of severe adverse patient reactions are typically greater. … Chemotherapy services are typically highly complex and require direct physician supervision for any or all purposes of patient assessment, provision of consent, safety oversight and intraservice supervision of staff. … [T]hese services entail significant patient risk and frequent monitoring. Examples are frequent changes in the infusion rate, prolonged presence of the nurse administering the solution for patient monitoring and infusion adjustments, and frequent conferring with the physician about these issues.\(^6\)

The excerpt above (especially the italicized portion) clearly demonstrates that the administration of chemotherapy is a highly complex health care service that requires advanced training of the health professionals involved, as well as significant involvement of health professionals to monitor and oversee the administration. In addition to requiring highly skilled

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\(^6\) Id. at 520-521 (emphasis added).
individuals, the service entails significant patient risk and frequent monitoring, all of which falls under the hospital’s patient care responsibility. Thus, administration of chemotherapy is very different from the mere dispensing of a drug for self-administration, as there is considerably more involvement by skilled health care professionals, separate from preparation of the drug, and the hospital undertakes significant responsibility for the care provided, as the administration presents substantial risk to the patient.

Further, chemotherapy administration is its own health care service that can be billed separately from the charge for chemotherapy drugs. The status of chemotherapy administration as a separate health care service has been recognized by the Office of the Inspector General (OIG) in a report focused on billing and payment of chemotherapy administration under Medicare Part B. According to the OIG report, there is a charge for the administration of chemotherapy, which is a professional service, and a separate charge for the chemotherapy drugs used. Indeed, these two items may be billed by separate providers if, for example, a physician administers a drug that was purchased separately by the patient. Thus, chemotherapy administration fits squarely within the requirement that an individual “receives services from a health care professional.” The service provided is the administration of chemotherapy, as described in the CPT Codebook, and the health care professional is the individual who provides that skilled service, who, in the fact pattern above, is a hospital employee.

The CPT Codebook’s description of the involvement by health care professionals in the administration of chemotherapy is also built into payers’ coverage and reimbursement policies for hospitals. Medicare, for example, explicitly requires that, in order to bill for the administration of chemotherapy, physicians must maintain certain levels of supervisory responsibility for care provided in a hospital’s provider-based outpatient clinic. The Medicare Benefits Policy Manual (BPM) states that a physician must be involved in the course of treatment for an outpatient in order for Medicare to reimburse the hospital for those services. For infusion services, physicians must provide some level of supervision, with some services even requiring especially intensive supervision at the initiation of the services. Moreover, Medicare’s provider-based rules, with which hospital clinics must comply in order to be listed on a reimbursable line of the cost report and participate in the 340B program, also require extensive involvement by hospital health professionals in all aspects of care and directly impose liability on the hospital. Medicare’s provider-based regulations require significant clinical integration between the hospital and the provider-based clinic, which includes, among other things, that the main provider maintains the same monitoring and oversight of the clinic as it does any of its other departments, that the reporting relationships and level of accountability between the

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7 See Medicare Part B Chemotherapy Administration: Payment and Policy, Office of the Inspector General, OEI-09-08-00190 (June 2009).
8 Id. at 3.
9 Specifically, Medicare Part B pays for therapeutic outpatient services, including infusion therapy, furnished incident to physicians’ or non-physicians practitioners’ services, and requires direct supervision of those services by the physicians or practitioners. 42 C.F.R. § 410.27.
10 Medicare Benefit Policy Manual, ch. 6, § 20.5.2.
11 Id.
medical director of the clinic and the hospital be the same as those between the medical director of other hospital departments, that medical staff committees or similar committees at the main provider be responsible for medical activities in the outpatient clinic, and integration of the hospital and inpatient/outpatient services of the clinic. 12 Off-campus clinics have additional requirements to show their clinical integration with the main hospital. 13

Nothing in the 1996 definition of patient requires the hospital to have a relationship with the physician who wrote the order for infusion of chemotherapy. Indeed, HRSA proposed modifying the existing definition of patient by specifically including that requirement in guidance proposed in 2007. 14 However, since that proposed guidance was never finalized, the requirement may not be enforced. 15 To make the FAQ’s change in policy enforceable, HRSA would first have to issue the requirement in proposed form, provide the public with notice and an opportunity for comment and publish a final rule based on the comments received. 16 We are aware that HRSA is currently developing a revised definition of patient that it intends to propose in the coming year. We urge HRSA to continue to make the distinction that is made in the current definition between use of 340B for drugs dispensed for subsequent self-administration and drugs dispensed for administration in the hospital setting.

Not only is infusion of chemotherapy its own distinct health care service that is separate from preparation of the drug itself, but provision of the infusion service imposes a legal responsibility on the hospital for the care provided. Even if the hospital were not responsible for the care that gave rise to the chemotherapy order or for follow-up care, these facts do not diminish the level of responsibility exercised by the hospital during the chemotherapy visits themselves. Nothing in the 1996 patient definition suggests that the "responsibility" test applies to services rendered before or after the services accompanying the administration of 340B drugs.

12 42 C.F.R. § 413.65(d)(2).
13 Id.
15 The 2007 notice states multiple times that the new patient definition guidelines were merely "proposed." Id. The notice also states that HRSA would issue “final guidelines” after it considered comments on the proposed guidance and that the “[f]inal guidelines [would] replace all previous 340B Program guidance addressing the definition of a patient,” including the 1996 patient definition. Id. However, the agency never issued a final notice. Since HRSA never finalized new patient definition guidelines, the 1996 patient definition never was replaced and still governs who is a 340B-eligible patient.
16 Substantive rules, also called legislative rules, have the force and effect of law and must generally be issued through notice-and-comment rulemaking. 5 U.S.C. § 553. The leading case on determining whether a rule is legislative is the D.C. Circuit’s opinion in American Mining Congress v. Mine Safety & Health Administration. Am. Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106 (D.C. Cir. 1993). The American Mining court held that a rule is legislative only if the agency intends to exercise its authority to issue a rule with the force of law. Id. at 1109. The D.C. Circuit established a three-part test for determining whether an agency has intended to exercise its lawmaking authority in a substantive rule: “(1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties; (2) whether the agency has explicitly invoked its general legislative authority; or (3) whether the rule effectively amends a prior legislative rule.” Id. at 1112. A rule is a substantive rule if any one of the three factors is met. Since the FAQ’s change in policy amends a prior legislative rule, HRSA’s 1996 patient definition guidance, it too is a legislative rule that must go through notice and comment before it can be enforced.
To the contrary, the test only applies to "the care provided" by the covered entity, which in this case means the care provided by the hospital while administering chemotherapy drugs.

In addition, applicable state tort law clearly holds hospitals responsible for the care provided to patients in the hospital. It would not make sense for a hospital to be held responsible in a court of law for the provision of the health care service of administering chemotherapy, but not be deemed to be responsible for this service for purposes of meeting the 340B definition of patient. How can OPA maintain that a hospital is not sufficiently responsible for its chemotherapy patients to qualify it for 340B pricing if, at the same time, the hospital can be ordered to compensate such patients for damages in the event it fails to exercise such responsibility with reasonable care? Safety net hospitals rely on 340B savings to meet the standard of care expected of them, including the standards applicable to proper administration of chemotherapy agents.

Thus, it seems clear that under the current definition of patient, it is appropriate for hospitals to use 340B for their chemotherapy patients, even if ordered by an unrelated physician, because, by performing the health care service of chemotherapy administration, the hospital furnishes "a health care service from a professional employed by the [hospital] … such that responsibility for the care provided remains with the [hospital]."

Moreover, the fact pattern described above, where individuals in rural areas seek cancer services in a more populated area several hours away and then receive chemotherapy in their home town, is not uncommon. By virtue of having their outpatient chemotherapy administered by the rural hospital, the individual becomes a patient of the hospital for 340B purposes. There is no rational reason to exclude this type of service from those health care services that permit use of 340B pricing. Indeed, if the hospital were not permitted to use 340B pricing, the hospital would be required to purchase the chemotherapy drugs through their wholesale acquisition account at an extremely high price, potentially making it cost prohibitive to furnish the care. This would defeat a key purpose of the 340B program of providing access to care to these vulnerable populations.

We are also concerned that defining patient to exclude services ordered by physicians who have no relationship to the hospital would establish a dangerous precedent for other kinds of hospital services rendered outside the chemotherapy area. Hospitals provide many services upon direction of physicians who may have no relationship to the hospital. For example, physicians routinely advise their patients to go to hospital emergency rooms after hours and on weekends because the doctor’s office is not open at that time. Physicians also refer patients to hospitals for

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surgery and other types of routine procedures. A hospital’s right to use 340B drugs in these situations could be challenged if OPA finds that chemotherapy patients are not entitled to 340B drugs when ordered by an unrelated physician. Requiring that hospitals provide an actual health care service as a prerequisite to establishing responsibility for patient care is a workable standard for hospitals to use. If the actual provision of a health care service is not sufficient to demonstrate responsibility for 340B purposes, there is no clear standard for hospitals to apply.

**The Apexus FAQ Should Be Clarified**

In addition to confirming with you that 340B priced drugs may be used in the fact pattern set forth above, we would also like to express our strong concerns regarding the FAQ that we understand was recently published by Apexus. As an initial matter, it is not clear to us that the FAQ is intended to address the administration of chemotherapy by the hospital, as described in the fact pattern above. It is possibly intended to make clear that mere provision of a drug, absent administration of the drug by the hospital, would not meet the definition of patient. We would agree that 340B hospitals may not supply 340B priced drugs to other providers for that separate provider to administer to the patient and bill to a payer. In such a situation, the hospital would not have provided the health care service to the patient of administering the chemotherapy. If, however, the hospital has actually registered the individual as an outpatient, and provided the health care service of administering this chemotherapy in a location that is reimbursable on the provider’s cost report, then the hospital has met the second criterion in the currently applicable definition of patient set forth by HRSA in 1996.

Even if the FAQ is not intended to address the fact pattern described above, we note that the last sentence of the answer in the FAQ is inaccurate because it is written to apply to all types of drugs. In fact, the existing definition of patient applies this rule only to drugs that are dispensed for subsequent self-administration or administration in the home setting. The federal Administrative Procedure Act forbids enforcement of a policy that was not subject to notice and comment when that policy directly conflicts with prior policy that was adopted after being subject to notice and comment. 19

To address any ambiguity, we request that HRSA require that this FAQ be revised, and respectfully suggest the italicized language below:

**Q: May a 340B covered entity site, registered on the 340B Database and listed as reimbursable on a 340B registered hospital’s most recently filed cost report, utilize 340B drugs for patients that meet all of the following:**

1. A patient was discharged from the 340B registered hospital
2. A drug for infusion was written by a private physician, with no relationship with the covered entity
3. The private physician does infusion drugs are not practice furnished in

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19 See footnote #16.
a clinic that is listed as reimbursable on the hospital's most recently filed cost report

A: The individual is not a patient of the covered entity if the individual is discharged from the covered entity, subsequently receives care from a private physician with no relationship with the covered entity, and does not receive further health care services from the hospital, such as administration of an infusion drug. HRSA's patient definition guidance states the individual must receive 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 (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity (61 Fed. Reg. 55156 (October 24, 1996)). The covered entity is not responsible for the health care services of a discharged patient that have been provided by a physician with no relationship with the covered entity. HRSA's patient definition guidance also states that an individual will not be considered a 'patient' of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug for subsequent self-administration or administration in the home setting. (61 Fed. Reg. 55156, 55158 Oct. 24, 1996.)

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Thank you again for meeting with us and for your attention to this matter. I would be happy to answer any questions you may have.

Very truly yours,

Maureen Testoni
General Counsel