October 27, 2015

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Health Resources and Services Administration  
5600 Fishers Lane, Mail Stop 08W05A  
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Ref: RIN 0906–AB08: 340B Drug Pricing Program Omnibus Guidance

Dear Captain Pedley,

Thank you for the opportunity to submit comments on the above-captioned guidance. America’s Essential Hospitals appreciates the Health Resources and Services Administration’s (HRSA’s) desire to provide clarity on the parameters of the 340B Drug Pricing Program. However, many elements in the proposed guidance fall short of this desired purpose. While there are sections of the guidance that could prove helpful, any gains in clarity are dwarfed by the harm caused through an unprecedented narrowing of the program Congress enacted more than two decades ago. If implemented as is, the proposed reductions in the scope of patients for whom hospitals may use 340B discounted drugs and the drugs for which such discounts are available will restrict patients’ access to critical drugs and undermine quality of care.

As HRSA works to finalize this guidance, we ask the agency to consider the unique challenges essential hospitals face in caring for our nation’s most vulnerable patient populations. Filling a safety net role in their communities, essential hospitals use their scarce resources efficiently to provide cutting-edge care to patients in their communities, regardless of income or insurance status. The 340B Program was intended to support this very purpose, and any guidance finalized by HRSA should preserve essential hospitals’ ability to fulfill their critical missions. Our association was integral to the creation of the program and, thus, we have always seen program stewardship and integrity as vital elements for ensuring the future of the program.

America’s Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Our more than 275 member hospitals provide access to high-quality health care for all patients, predominantly

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1H.R. Rep. No. 102-384, pt. 2 (1992) (noting that Congress intended for the 340B Program to enable safety net providers to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”).
serving patients covered by public programs and the uninsured. Of the outpatient services provided by our members, 21 percent are to Medicare beneficiaries, another 27 percent are to Medicaid recipients, and 24 percent are to uninsured patients. Our members provide this care while operating on margins substantially lower than the rest of the hospital field—with an aggregate operating margin of negative 3.2 percent, compared to positive 5.7 percent for all hospitals nationwide.

Essential hospitals play a vital role in providing ambulatory care to their communities. The average member operates a network of 20 or more ambulatory care sites. And in 2013, our average member saw nearly four times as many non-emergency outpatient visits as other acute care hospitals nationwide. Our members also offer more comprehensive ambulatory care than many other providers and create medical homes for community residents through networks of provider-based ambulatory health clinics.

Due to the high percentage of low-income patients served by essential hospitals, many qualify to participate in the 340B Program, which has been critical to ensuring that low-income and vulnerable individuals have access to affordable health care. Through their integrated health systems, essential hospitals offer the full range of primary through quaternary care, including trauma care, public health services, mental health services, substance abuse services, and wraparound services critical to vulnerable patients. Many of the specialized inpatient and emergency services they provide are not available elsewhere in their communities. Essential hospitals are able to use savings from the 340B Program to reach more patients—many of whom are uninsured and low-income—and continue to offer these vital services. Because of the challenges uninsured and low-income patients face, managing their care with limited resources is a difficult undertaking. Essential hospitals are able to reinvest 340B savings into programs targeted at coordinating care and improving outcomes for these vulnerable patient populations, including initiatives aimed at reducing readmissions, ensuring medication compliance, and identifying high-risk patients in need of ancillary services.

The 340B Program has been instrumental in the drive toward a more integrated and coordinated health care delivery system, which has been a key priority of this administration. If these proposals are implemented, the loss of crucial savings would jeopardize the innovative developments in care coordination and delivery system reform providers have made. The guidance runs counter to the direction in which the health care delivery system is moving—toward integrated and coordinated care through alternative payment models and value-based payment. While government initiatives in other programs encourage care coordination across different settings, many components of the guidance, such as the prohibition on the use of 340B discounts for discharge medications, push the delivery system in the opposite direction. Not only does the proposed guidance threaten to limit access and quality but it will also raise overall health care costs by increasing avoidable admissions—ultimately undermining the Triple Aim.

The proposed guidance threatens 340B providers’ ability to continue to offer critical services to vulnerable patients by potentially restricting the definition of a patient, adding

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3Ibid.

4Ibid.
requirements for hospital outpatient facility eligibility, and narrowing the interpretation of which drugs qualify as covered outpatient drugs. If finalized, these revisions would also restrict patient access to lifesaving drugs. To ensure essential hospitals are able to implement innovative and efficient strategies for providing high-quality, complex care to their patients and are not unfairly disadvantaged for serving the most vulnerable among us, it is imperative that HRSA understand the impact of its proposals.

In our attached detailed comments, we also provide suggestions to ensure the standards for enforcement are proportionate and consistent with HRSA’s statutory authority, the opportunity for an appeal of findings is robust, and the new reporting requirements and standards for self-reporting potential program violations support compliance and are not overly burdensome. In addition, we urge HRSA to provide needed clarifications on what is being proposed and to delineate which aspects of the guidance are existing policy and which are new proposals to avoid creating additional confusion. Furthermore, should any of the proposals that would make significant program changes be implemented in the final guidance, HRSA must afford the field adequate time to comply with these provisions.

We refer you to the attached document for our more detailed comments on the issues of most importance to our members and respectfully request and appreciate your thoughtful consideration when finalizing the above-mentioned guidance.

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America’s Essential Hospitals appreciates the opportunity to submit these comments. If you have any questions, please contact Erin O’Malley, director of policy, at 202-585-0127.
Attachment

Detailed Comments on the Proposed 340B Drug Pricing Program Omnibus Guidance

Patient Definition

I. The proposed patient definition would impossibly and dramatically restrict the scope and benefit of the 340B Program and introduce unreasonable complexity and regulatory burden.

HRSA must pull back its proposal to dramatically narrow the definition of a patient to whom a covered entity may provide 340B discounted drugs. The new definition does not provide clarity, but rather exponentially increases complexity and the potential for confusion. It does not improve program integrity, as it sets up extensive and complicated legal requirements that will be exceedingly difficult for even the most well-intentioned providers to meet. Ultimately, the new definition appears to simply restrict the program’s scope, a move that has been urged by many of the program’s opponents.5

HRSA proposes to expand the current three-part definition to six parts. In combination with requirements related to covered outpatient drugs and duplicate discounts, the guidance would require every prescription to pass at least 10 requirements to qualify for 340B discounts. The test must be applied to each prescription written and depends on where an individual patient sought care for a particular medical condition, which clinician wrote the prescription, and what type of insurance, if any, the patient has. The proposal distorts what had been a straightforward use of the word “patients” in the statute into a complex, multipart legal concept that would be utterly unrecognizable to any practicing health care professional, let alone patients themselves. This would be disastrous for patients and providers.

The proposed changes are contrary to the clear directives providers are receiving from other U.S. Department of Health and Human Services (HHS) programs and commercial payers to reform health care delivery. The changes also ignore the basic realities of how patients are served in evolving systems of care. The 340B Program does not exist in a vacuum, and one agency within HHS should not define the concept of “patient” in a way that undermines the department’s policies in every other context.

Furthermore, the complexity of the proposal would result in significant new practical burdens on covered entities, from both an administrative and a compliance perspective. This new burden does not just impact the hospitals intended to benefit from the program but may also place a significant burden on patients. If hospitals were required to comply with the definition as

5Letter from Maye J. Bermingham, Senior Assistant General Counsel and Lori M. Reilly, Executive V.P., Policy and Research, PhRMA, to Commander Krista Pedley, Director, HRSA, June 28, 2013, re: 340B Patient Definition and Hospital Outpatient Facility Status (proposing that “A 340B covered entity’s ‘patients’ are: (1) uninsured individuals, (2) who receive outpatient medical care on an ongoing basis at the covered entity’s facilities from a physician who is an employee or independent contractor who is subject to oversight or control by the covered entity. For example, a ‘patient’ would not include an individual who only receives case management services from the 340B entity, who is prescribed a drug by someone who is not an employee or independent contractor of the covered entity, or who visits the covered entity once and then is referred to another provider for subsequent care.”).
proposed, it would result in senseless distinctions between patients for whom hospitals can and
cannot use 340B discounts, as well as associated administrative/compliance mechanisms to
educate providers and track and audit patients based on such distinctions.

The definition of a patient created by HRSA’s Office of Pharmacy Affairs (OPA) in 1996 set forth
a set of principles for covered entities that reasonably captures the commonly understood
elements of a provider-patient relationship. Under this current definition for disproportionate
share hospitals (DSH) hospitals, an individual is considered a patient if

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...

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 or drugs for subsequent self-administration or administration in the home
setting.”

This basic structure remains a reasonable and implementable standard. To the extent that
HRSA has identified specific concerns with implementation of the definition, it should
identify them and propose direct and narrow revisions in these discrete areas. Instead,
HRSA’s approach would fundamentally change the definition as it has been implemented
for years, even though the agency has offered little policy rationale for these changes. The
proposed changes could add a huge administrative cost and burden to hospitals, while at
the same time materially narrowing the benefit of the program. Such a disruptive
approach is well beyond the appropriate scope of HRSA’s interpretive authority.

A. HRSA’s proposed patient definition exceeds the agency’s statutory authority and sets a
standard that is arbitrary, capricious, and otherwise inconsistent with the statute.

The proposed definition of a patient is so far removed from the understanding of a patient-
provider relationship in any other context and is so inconsistent with the framework of the 340B
Program that it cannot withstand scrutiny as a persuasive interpretation of the 340B statute. The
U.S. District Court of the District of Columbia recently overturned HRSA guidance on another
provision of the 340B statute, ruling that HRSA impermissibly imposed narrowing conditions on
what it deemed to be a plain language statutory reference.7 HRSA’s proposed definition of a
patient clearly adds additional narrowing conditions into the plain language reference to a
“patient” in the statute.

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7Pharm. Research & Mfrs. of Am. v. U.S. Dep’t of Health & Human Services, No. 14-1685, slip op. (D.D.C. Oct. 15, 2015) (hereinafter “PhRMA”). (HRSA impermissibly interpreted a statutory exclusion from 340B pricing for drugs designated for orphan to include only those orphan drugs actually used to treat rare diseases or conditions).
The fundamental statutory structure of the 340B Program is that covered entities are given discounts on covered outpatient drugs to “enable these entities to stretch scarce federal resources as far as possible.” The sole reference to a “patient of the entity” appears in the statute as a requirement that a covered entity “shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.”

This requirement is reasonably intended to ensure eligible providers are not mere distributors of discounted covered outpatient drugs to any third party. Many of HRSA’s proposals in the guidance, however, would prohibit the use of 340B drugs for individuals who would be considered patients of the hospital in any other context. The statutory language simply cannot support many of the restrictions included in HRSA’s proposed definition.

In a fundamental change to the current definition of a patient, which has been in place since 1996, HRSA now proposes that a patient relationship between an individual and a covered entity be defined on a prescription-by-prescription basis. This is far more restrictive than the statutory language indicates. The statute does not limit covered entities to only providing 340B drugs to individuals who are “patients of the covered entity for a particular prescription” or “for a particular service”; it simply requires dispensing to “patient[s] of the covered entity.”

Nor is the term “covered entity” restricted or limited in the statute to certain units or sites of the hospital. HRSA proposes to limit the dispensing of 340B drugs to individuals who are patients of the outpatient department of the covered entity. But the statute refers to DSH hospitals in their entirety, as defined as “subsection (d) hospital[s]” in the inpatient hospital reimbursement section of the Medicare statute. The “covered entity” is not statutorily limited to the outpatient department of a subsection (d) hospital, and HRSA therefore does not have the authority, through subregulatory guidance, to narrow the reading of “patients of the covered entity” to “patients of the outpatient department of the covered entity.”

HRSA’s reliance on the fact that the program is limited to “outpatient covered drugs” cannot compensate for this fundamental lack of underlying legal authority. A patient relationship can be established with a hospital based on the provision of inpatient services, outpatient services, and services in a variety of locations.

The recent decision in *Pharmaceutical Research and Manufacturers of America v. U.S. Department of Health and Human Services (PhRMA)* only serves to underscore the very tenuous legal basis for the patient definition. In that case, the court struck down HRSA’s interpretation of a statutory provision that excludes, for certain covered entities, 340B coverage of any “drug designated . . . for a rare disease or condition.” HRSA (reasonably, in our view) determined that this language did not exclude orphan drugs when not used for a rare disease or condition. But the court disagreed, holding that the statute refers only to the “designation” of an orphan drug and not its use.

In defining a patient, HRSA has strayed much further from the statutory language than it did for the orphan drug exclusion. The statute simply prohibits transferring 340B drugs to an individual

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8Public Health Service Act (PHSA) § 340B(a)(1).
10PHSA § 340B(5)(B).
who is not “a patient of the entity.” HRSA, however, has superimposed several additional layers of restrictions—prohibiting transfers to several categories of individuals who, for every other purpose, are deemed to be “patients” of the covered entity. For example, HRSA has, without statutory support, excluded

- patients of the covered entity who receive services at the covered entity but whose physicians do their own billing;
- patients of the covered entity receiving services from a professional who does not have the precise employment or contractual relationship with the covered entity as prescribed by HRSA;
- patients of the covered entity who receive infusion services at the covered entity but ordered by a provider outside of the covered entity;
- patients of the covered entity who receive services from a hospital-based clinic that does not serve Medicare patients;
- patients of the covered entity who receive hospital care in the inpatient department;
- patients of the covered entity who receive follow up care outside of the covered entity; and
- patients of the covered entity who are referred to specialists outside of the covered entity.

And even those “patients” who do pass HRSA’s multipronged patient test may only be considered a patient in connection with certain prescriptions and not others.

The district court found in the PhRMA case that HRSA had impermissibly focused on the use of orphan drugs rather than the designation. In this new guidance, HRSA has even more radically focused on a series of extraneous factors rather than the simple relationship between an individual and a covered entity.\(^2\) The interpretation, therefore, is “contrary to the plain language” of the statute,\(^3\) and cannot be sustained.\(^4\)

**HRSA should withdraw the proposed patient definition as inconsistent with the 340B statute and impermissibly arbitrary and capricious.**

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\(^2\)The Merriam Webster dictionary, for example, simply defines a patient as “an individual awaiting or under medical care and treatment.”

\(^3\)PhRMA at 29.

\(^4\)Even if HRSA’s proposed interpretation were not inconsistent with the plain language of the 340B statute, it is a far from “persuasive” interpretation (PhRMA, “the Court will ‘follow [the] agency’s rule only to the extent it is persuasive’”, citing Gonzales v Oregon, 546 US 243 (2006)). As described in detail in this section of our letter, the agency’s apparent failure to consider the application of the proposal in a number of common circumstances in hospital care delivery, the resulting arbitrary distinctions among covered entity hospitals in their ability to use 340B discounted drugs, the discord between HRSA’s interpretation and other HHS rules (e.g., the acknowledgment of the services provided in administering infusion drugs), and the significant departure from prior policies (e.g. the treatment of discharge prescriptions), all undermine the proposed patient definition’s “power to persuade.” See Gonzales (“The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade.”).
B. HRSA should consider the following specific feedback on each of the proposed conditions for patient status.

While America’s Essential Hospitals urges HRSA to withdraw the proposed definition, we nonetheless provide comment on each of HRSA’s proposed elements (referred to as “prongs”) for individuals to be considered patients of eligible DSH covered entities. Of particular importance, if HRSA chooses to move forward with the proposed six-pronged structure (five of which pertain to DSH hospitals), the agency should revise its proposal such that any patient definition

- permits the use of 340B discounted drugs for discharge prescriptions;
- does not limit use of the program for infusion medications in a way that threatens access to lifesaving care for poor and uninsured patients;
- does not hinge on whether the entity does or may bill for services of a treating or prescribing provider; and
- generally ensures the program enables hospitals to use their scarce resources to treat the uninsured, pediatric, and other vulnerable populations as Congress intended.

Below, we provide detailed comments on each of the five prongs of HRSA’s proposed patient definition that pertain to DSH hospitals.

i. Comments on Proposed Prong 1: “The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database.”

We agree in concept that if an individual receives a health care service at a covered entity site, he or she is a “patient” of the covered entity. However, this concept becomes more complex in practice especially in reference to the complicated structure proposed in the guidance. HRSA should return to the existing definition and delete the unnecessary burden added in the guidance.

With regard to the first prong, HRSA mentions telemedicine and specifically provides that “[t]he use of telemedicine involving the issuance of a prescription by a covered entity provider is permitted, as long as the practice is authorized under state or federal law and the drug purchase otherwise complies with the 340B Program.” We support HRSA’s acknowledgment of the important role of telemedicine and that care delivered through a range of technologies creates patient relationships sufficient for the 340B Program. We note, however, that the description of telemedicine outlined in prong 1 is different from and narrower than the range of telemedicine and other remote service arrangements outlined in prong 3.

We suggest that the agency develop a consistent policy throughout the guidance on the service arrangements sufficient to create a patient relationship. And, we believe that the broader language used in prong 3 including “telemedicine, telepharmacy, remote, and other health care service arrangements” should be the common definition. This flexibility will allow HRSA to work with covered entities as technological solutions evolve. In addition, telehealth policies differ across programs and payers, and there has been considerable recent discussion of reforming such policies in particular for the Medicare Program. We further encourage HRSA to provide

14For example, this Congress has introduced a number of bills to broaden Medicare payment for telehealth (see, e.g., The TELEmedicine for MEDicare (TELE-MED) Act, S. 1778/H.R. 3081; Furthering Access to Stroke Telemedicine (FAST) Act, H.R. 2799; The Medicare Telehealth Parity Act of 2015, H.R.2948; Telehealth Enhancement Act of 2015,
additional clarification on the role the hospital covered entity must play in a telehealth arrangement and to create a broad policy in the interests of expanding patient access.\textsuperscript{17} iii. Comments on Proposed Prong 2: “The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider.”

The proposed guidance would limit the types of relationships between covered entities and prescribing providers that are sufficient to make the individual receiving care a “patient” of the covered entity. This requirement is not a persuasive interpretation of Congress’ statutory language and as implemented would arbitrarily exclude certain common hospital/provider relationships without explanation and on a basis that has nothing to do with demonstrating responsibility for the patient’s care. Two aspects of this proposal in particular would newly and potentially very significantly end the use of 340B discounted drugs for patients of hospitals who have entered into certain common arrangements with clinicians.

a. HRSA’s categorical exclusion of the use of 340B drugs for prescriptions from referring providers is a reversal of its existing policy.

First, compared to the existing patient definition, HRSA proposes to remove the explicit acknowledgment that a covered entity may have responsibility for an individual’s care even if that individual also receives care and prescriptions as a result of “referral for consultation” or “other arrangements.” The categorical exclusion of prescriptions written as a result of referrals is a total reversal of existing policy. Yet, HRSA does not explain the basis of its reversal.\textsuperscript{18} HRSA should retain its standard as reaffirmed in a recently modified response to a frequently asked question (FAQ).

A covered entity may refer an individual for consultation to an outside clinic not registered for the 340B Program and consider that patient 340B eligible only if the individual receives health care 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)). If the covered entity can document that it retained responsibility for the health

\textsuperscript{17} See additional comments on telemedicine in response to prong 3.

\textsuperscript{18} The rule’s reversal of prior HRSA policy undermines the persuasiveness of the interpretation. (See Gonzales v Oregon, 546 US 243 (2006) (in applying Skidmore deference to interpretive rules, the Supreme Court provided that, among other factors, “The weight of such a judgment in a particular case will depend upon...its consistency with earlier and later pronouncements.”)). Furthermore, failure to provide an explanation for the new policy and the reason for the change in policy is itself a basis for an agency action to be deemed “arbitrary and capricious.” See, e.g., Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co., 463 U. S. 29 (1983); FCC v. Fox Television Stations, 129 S. Ct. 1800 (2009); Smiley v. Citibank (South Dakota), N. A., 517 U.S. 735 (1996).” Indeed, such a change in the interpretation of the definition of patient may require a more detailed justification where there has been significant reliance on the prior interpretation, as is the case with covered entities that have structured their programs in some cases for nearly 20 years based on the existing definition. See, e.g., FCC v. Fox Television Stations, Smiley v. Citibank.
care services provided to the referred individual, then that individual may be eligible to receive 340B drugs from the covered entity. How a covered entity counts referrals under the 340B Program should be addressed in their written policies and procedures (emphasis added).\textsuperscript{15}

If HRSA’s concern is that a covered entity must demonstrate responsibility for the individual’s overall health care in order for a sufficient patient-provider relationship to exist, then that should be the standard and “referral arrangements” and “other arrangements” that meet this standard should be permitted. Otherwise, the proposal will unnecessarily disrupt the coordination of patient care between providers within a system and within a larger community. For these reasons, **HRSA should add referrals and other arrangements back into this prong and require documentation or demonstration of responsibility for the individual’s care without completely eliminating the appropriateness of any and all such arrangements.**

b. **HRSA should remove its new requirement that a hospital “may bill” for contracted providers.**

Second, HRSA proposes to add the condition that for contracted providers, the “covered entity may bill for services on behalf of the provider” (emphasis added). However, the agency is unclear as to how it would interpret and enforce the phrase “may bill”; therefore, it is difficult for us to fully evaluate and provide comment on the potential impact of this proposal. In order to determine its full impact, we ask that HRSA address the following questions:

- Does this mean the covered entity could bill for the services or actually does bill for the services?
- Does HRSA mean that the provider must have the ability to assign payments to the covered entity or some other standard?
- If assignment is the standard, under whose assignment rules? Medicare, Medicaid, and commercial payers often differ.

More fundamentally, HRSA does not explain why a covered entity’s capacity to bill for a service is a determinative factor of whether the individual receiving the service is a patient of the covered entity. HRSA’s failure to provide such explanation or to fully consider the examples below—especially in light of the significant disruption in hospital delivery models and loss of 340B discounts—would, in and of itself, amount to an arbitrary and capricious interpretation of the statute.

Certain existing hospital-provider relationships would be particularly challenged under HRSA’s proposal.

- The proposal would be devastating to academic medical centers, whose providers are often employed by or under contract with affiliated faculty practice plans, not the hospital itself. The preamble says that HRSA intends the definition to include faculty practice arrangements, but not all such plans are set up in a way that the hospital bills for or even “may bill” for the services. The conflict between HRSA’s professed intention to include faculty practice plans and the requirements of the guidance that would preclude their

participation suggest a misunderstanding either of how academic medical centers operate or of the significant reach of the proposed patient definition.

- HRSA's proposed guidance also completely fails to consider the circumstances of covered entities in states prohibiting the corporate practice of medicine. State laws vary, but in some cases these laws prohibit the ownership or control of medical practices or employment of professionals by nonprofessionals, including hospital corporations. While it may or may not be possible for physicians in such states to enter into independent contracts with a hospital covered entity, it may be difficult or impossible for a hospital to bill for the services provided by those professionals. It would be arbitrary and capricious for HRSA to exclude hospitals from the ability to participate in the 340B program simply based on their location in a state with corporate practice of medicine laws.

The arbitrariness of the billing requirement becomes particularly apparent when considering the impact on services provided in a covered entity facility. If a service is provided in a covered entity facility then there can be no doubt of the covered entity's responsibility for that individual's care. The individual should qualify as a patient under any reasonable definition, regardless of who bills for the provider's component of the hospital services provided. The addition of this new requirement does not improve program integrity and only serves to exclude patient/physician relationships that Congress intended to permit. See the following examples:

- Some hospitals have to contract with independent consulting physicians to ensure sufficient emergency department (ED) coverage. There is no question that when an individual is receiving services in the ED the hospital is responsible for that person's care. Yet HRSA's proposed definition would result in such an individual not being a patient and prevent use of 340B drugs in delivering or as a result of those services.

- Many hospitals rely entirely on community physicians with privileges or credentials to provide services rather than employed physicians, based on the market dynamics in their service area. Such independent physicians or physician groups typically do their own billing and certainly do not assign their payments to the hospital. But there is no rational basis for categorically excluding from the patient definition individuals who receive care from the covered entity through such community physicians.

- At the same time, the preamble states that “volunteer health care provider programs” would meet the standard. These programs are by their nature set up to provide free care to indigent patients, so it is unclear how billing for services is even a relevant requirement or how volunteer provider relationships could meet it. Furthermore, volunteer providers might not have the employee or contractual relationship with a covered entity that HRSA intends to apply to other provider-hospital relationships. For example, volunteer providers may be considered employees of the state, not the covered entity, for purposes of tort liability protection.20

Even if hospitals could comply with the proposed requirements for certain services through corporate restructuring, HRSA would be forcing hospitals to change relationships with their professionals solely for the 340B Program with no corresponding benefit to patient care or program integrity and potentially significant administrative cost. In its broader efforts to reform health care delivery, HHS is pushing to decrease regulatory barriers and increase efficiency in the delivery of care; this proposal moves us in the opposite direction.

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HRSA should remove the language “such that the covered entity may bill for services on behalf of the provider” to avoid the unjustified exclusion of 340B discounts for individuals receiving care under legitimate relationships between hospitals and professionals and to avoid the arbitrary impact, which is inconsistent with HRSA’s statutory authority.

iii. Comments on Prong 3: “An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). 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.”

HRSA proposes in this third prong that a patient is only eligible for 340B discounted drugs if a particular prescription is written as a result of a health care service than fulfills prong 2. In practice, this standard could produce situations in which an individual receiving health care services from a covered entity hospital could present two prescriptions at a hospital pharmacy for covered outpatient drugs and qualify for 340B discounted drugs for one but not for the other prescription. This would result if the patient’s provider wrote one prescription in the hospital outpatient department and the other in a follow-up visit at a private office. That a patient’s status could be negated on a prescription-by-prescription basis is inconsistent with the concept of being a patient for whom the covered entity has demonstrated responsibility for care. This prong in particular undermines HHS’ substantial efforts to encourage coordination and integration on the part of providers collectively treating patients and instead erects additional silos of care based on individual prescriptions.

a. HRSA should remove the reference to infusion services and chemotherapy.

HRSA specifically states in prong 3 that “infusion of a drug” does not qualify as an outpatient service with respect to prong 2. It is unclear why the agency has taken this position and entirely disregarded the substantial services involved in administering infusion medications and the significant responsibility for care the covered entity retains during the infusion. As a result, HRSA’s proposal would exclude life-saving outpatient covered drugs from 340B discounts. We believe this arbitrary reading of the statute is beyond HRSA’s authority and more importantly, could have devastating consequences for low-income patients.

HRSA does not provide any explanation as to why infusion of a drug does not involve health care services that make an individual a patient for whom the covered entity is responsible. Infusion of chemotherapy involves distinct health care services that are separate from preparation of the drug itself and billable as separate professional and/or hospital services.21 Because the

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21See, e.g., CMS Internet Only Manual (IOM) Publication 100-04, Medicare Claims Processing Manual, Chapter 12, Section 30.5; Office of the Inspector General, Medicare Part B Chemotherapy Administration: Payment and Policy, OEI-09-08-00190 (June 2009); Medicare Contractor Noridian Healthcare Solutions at https://med.noridianmedicare.com/web/jca/policies/coverage-articles/chemotherapy-administration (quoting the Current Procedural Terminology CPT® 2014 Professional Edition, page 595, “The highly complex infusion of chemotherapy or other drug or biologic agents requires physician or other qualified health care professional work and/or clinical staff monitoring well beyond that of therapeutic drug agents...because the incidence of severe adverse patient reactions are typically greater...Chemotherapy services are typically highly complex and require direct supervision for any or all purposes of patient assessment, provision of consent, safety oversight, and intraservice supervision of staff. Typically, such chemotherapy services require advanced practice training and competency for staff who provide these services; special considerations for preparation, dosage, or disposal; and commonly, these services entail significant patient risk and frequent monitoring...”).
administration of chemotherapy is a highly complex service with potentially severe consequences if inappropriately delivered, it must be performed and supervised by trained health care professionals. Patients receive these services in the hospital outpatient setting and the hospital maintains a record of that care. There is no sound reason why HRSA should exclude infusion therapy patients from meeting the definition of a 340B patient. The agency’s proposal to do so, and without sufficient explanation, is arbitrary and capricious and inconsistent with the statutory reference to “patient of the covered entity.”

Furthermore, HRSA’s proposal threatens to undermine access to lifesaving services for low-income patients. Medicaid and uninsured patients often cannot access ongoing chemotherapy or other infusion services at clinics that are not supported by a larger health care entity or system dedicated to serving vulnerable patients. Even with 340B discounts, such services result in significant uncompensated costs that community physician practices often cannot sustain. In addition, essential hospitals have particular experience addressing the socioeconomic factors that must be dealt with to ensure meaningful access to care. In practice, many patients get treatment prescriptions elsewhere and receive chemotherapy at a hospital clinic where they can access the social services and extended support that hospital clinics offer, such as non-emergency transportation, nutrition counseling, and interpretation services. DSH hospitals such as members of America’s Essential Hospitals have provided lifesaving access to services for cancer patients with no other options. HRSA’s policy would effectively foreclose those options. For these reasons, HRSA should remove the reference to infusion services and confirm that infusion involves outpatient services that create a patient relationship with the covered entity, regardless of where the order or prescription is written.

b. HRSA should recognize an array of telehealth arrangements as creating covered entity patient relationships under the 340B Program.

As in the first prong, HRSA explicitly proposes a role for telehealth in providing services that create a patient relationship. Specifically, HRSA proposes that “The use of telemedicine, telepharmacy, remote, and other health care service arrangements (e.g., medication therapy management) involving the issuance of a prescription by a covered entity is permitted, as long as the practice is authorized under State or Federal law and otherwise complies with the 340B Program.”22 America’s Essential Hospitals supports HRSA’s proposed acknowledgement of the delivery of services through evolving telehealth means. However, we request clarification as to how the 340B rules apply to particular telehealth models and the role the covered entity must play.

Currently, Medicare coverage of telehealth services is limited to a list of specified services and is subject to geographical limitations on where the patient receiving the telehealth service must be located for the provider to be reimbursed under Medicare. The payment and policy landscape around telehealth is still evolving, and recent legislative efforts in Congress have focused on expanding the scope of reimbursable telehealth services. Because the scope of telehealth coverage under Medicare is limited, HRSA should not limit the types of telehealth services covered under the 340B Program to those covered by Medicare.

As a general matter, given that HRSA is appropriately willing to recognize that covered entities can establish patient relationships through a range of telehealth and remote arrangements, we urge HRSA to apply similar reasoning and acknowledge that an array of arrangements involving face-to-face encounters with providers outside a registered covered entity site can still involve sufficient covered entity responsibility for the care to create a patient relationship.

iv. Comments on Prong 5: “The individual is classified as an outpatient when the drug is ordered or prescribed. The patient’s classification status is determined by how the services for the patient are billed to the insurer (e.g., Medicare, Medicaid, private insurance). An individual who is selfpay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently.”

HRSA newly proposes that an individual is a 340B-eligible patient only if the patient is receiving outpatient services when the prescription is written. This interpretation has no basis in the 340B statute and thus is beyond HRSA’s statutory authority. Furthermore, HRSA’s proposal is contradictory, as it specifies that the patient must be an outpatient at the time the prescription is written and yet also bases eligibility on the patient’s final billing status, ignoring the fact that a patient’s status may change from the time the prescription is written to the time that the hospital submits the final bill for that patient encounter and the insurer pays the claim.

a. HRSA’s proposed prong 5 is inconsistent with the 340B statute.

As explained above, the 340B statute limits the program’s scope only to outpatient covered drugs. The statute contains no limitation on discounts to drugs prescribed as a result of outpatient hospital services. Furthermore, the 340B statute defines DSH eligibility as the “subsection (d) hospital”—again not limiting eligibility to a particular location of the hospital or service provided by it. And the reference to “patient of a covered entity” does not say “outpatient of a covered entity” or “patient of a covered entity receiving outpatient services.” If anything, the plain language of the statute explicitly contemplates inclusion of drugs “used in connection with an inpatient or outpatient service provided by a hospital.”

For this reason, HRSA should remove prong 5 in its entirety, as it is contrary to the 340B statute.

b. HRSA’s proposal is a damaging reversal of its existing policy on discharge prescriptions.

One of the most concerning elements of the proposed patient definition for our members is the complete reversal of current policy on the use of 340B drugs for discharge prescriptions. This is based on prong 5’s requirement that the underlying service resulting in the prescription cannot be an inpatient service. This reversal in policy is a significant narrowing of the program—a narrowing for which HRSA provides no policy rationale in the proposed guidance. It is contrary to HRSA’s prior interpretation that discharge prescriptions may permissibly be filled using 340B

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20PHSA § 340B(b)(2).
drugs under the statute.\textsuperscript{24} And it is contrary to HHS’ incentives for reducing hospital readmissions and improving care management.

HRSA’s current guidance on its website reflects that the defining statutory criterion is whether the discharge medication is for outpatient use.

“The 340B Program is an outpatient drug program. Enrolled covered entities have the responsibility to ensure that drugs purchased under the 340B Program be limited to outpatient use and provided to individuals who meet the requirements of the current patient definition. 340B drugs can be used for discharge prescriptions to the extent that the drugs are for outpatient use. Whether a drug qualifies as outpatient and the individual meets the definition of patient depends upon the factual circumstances surrounding the care of that particular individual. If a covered entity uses 340B drugs, it should be able to explain why the covered entity is responsible for the use of the drugs on an outpatient basis and have auditable records that demonstrate compliance with 340B Program requirements.”\textsuperscript{25}

The reversal of this reasonable policy not only is unsubstantiated by the language of the statute, but undermines hospitals’ and HHS’ significant efforts to keep patients healthy after discharge and prevent readmissions. Discharge prescriptions are a key component of a patient’s ability to subsequently manage any ongoing illness or disease without returning for further inpatient hospital care. Noncompliance with medication plans is particularly problematic among patient populations who face socioeconomic challenges that impede access to needed drugs. If patients cannot fill prescriptions upon discharge and take them home with them but instead must have an intervening outpatient service or travel to a community pharmacy, there is an increased likelihood that they will not fill their prescriptions during a critical period. This could result in patients returning to the hospital for further inpatient admissions. This is particularly true, for example, for transplant patients who, without strict adherence to discharge medications, could wind up with life-threatening complications.

HRSA’s policy reversal would create a distinction between a patient who receives a discharge prescription while in the hospital and another patient with the same condition and same discharge instructions who receives a prescription at an outpatient follow-up visit the next day. There is no discernible difference between the patients, especially no difference that would further the goal of 340B compliance.

Again, HRSA should remove prong 5 in its entirety, or at least find a way to retain its existing policy permitting the use of 340B drugs for discharge prescriptions.

\begin{enumerate}
\item[c.] HRSA’s proposed classification of “outpatient” based on billing status does not offer a complete window into a patient’s experience or status.
\end{enumerate}

\textsuperscript{24}The agency’s reversal of its prior position undermines the persuasiveness of the interpretation. Additionally, failure to provide an explanation for the new policy and the reason for the change in policy is itself a basis for an agency action to be deemed “arbitrary and capricious.” See \textit{supra} note 18.

America’s Essential Hospitals believes that HRSA has exceeded its statutory authority by limiting the use of 340B drugs to prescriptions or orders resulting from outpatient hospital services. However, if HRSA continues to apply this concept rather than maintain its existing standard, it will be necessary to revise the discordant guidance that the patient must be classified as an outpatient when the drug is prescribed and when the hospital submits its final bill for that patient encounter.

HRSA proposes that an individual must be “classified as an outpatient when the drug is ordered or prescribed” (emphasis added). To document the classification, however, HRSA proposes that classification status be determined by how the services are “billed to the insurer.” Our concern is that in certain important instances, the patient’s status when the bill is submitted may not be the same as when the drug is actually ordered or prescribed, which may create potential liability issues.

A potentially significant example is that of covered outpatient drugs administered to a patient in the ED or in observation status (i.e., outpatient status) who is later admitted as an inpatient. In such an instance, the payer might require that the services in the ED and/or observation setting be billed as part of the inpatient stay. The insurer could also later change the classification of a patient’s stay upon review.

In the context of exceptions to the group purchasing organization (GPO) prohibition, HRSA proposes that covered entities not be penalized if an insurer later changes a patient’s classification for payment purposes. Such a principle should apply here as well.

For these reasons, HRSA should remove prong 5, but in the event it does not, the agency should delete the second sentence of the prong defining classification based on how the services are ultimately billed. HRSA should give covered entities the option to rely upon the patient record to demonstrate the drug was appropriately classified as outpatient when ordered or prescribed. At the very least, HRSA should incorporate language that avoids penalizing the use of 340B when an insurer later changes payment for a drug to part of an inpatient service.

\textit{v. Comments on Prong 6: “The individual’s patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.”}

Without the complexity introduced by the requirements of the other prongs, the plain language of this prong is a reasonable requirement of a provider-patient relationship. This requirement is captured in the current 1996 definition and we support its retention.

\textit{vi. Comment on introductory requirement to apply for 340B on a prescription-by-prescription basis}

HRSA proposes that covered entities can provide discounted drugs to individuals only if they meet each of the prongs described above “on a prescription-by-prescription or order-by-order basis.” As described above, this proposal is not warranted by the plain language of the 340B statute, which does not limit covered entities to only providing 340B drugs to individuals who are “patients of the covered entity for a particular prescription” or “for a particular service”; it simply requires dispensing to “patient[s] of the covered entity.”
Furthermore, requiring covered entities to apply each prong for each prescription exponentially increases the complexity of the proposed patient definition and magnifies the concerns with the individual components expressed above. Indeed, as we continue to absorb the complexities of the proposal, we may find that it is impossible for all hospitals to implement the proposed requirements.

**Hospital Outpatient Facility Eligibility**

II. HRSA should remove arbitrary barriers from the proposed hospital outpatient facility eligibility standards so DSH hospitals can make full, intended use of the program.

The proposed guidance would place the following conditions on the 340B eligibility of offsite outpatient hospital facilities or clinics:

- the listing of such facilities on a reimbursable line on the hospital’s most recently filed Medicare cost report
- a demonstration that the services provided at the facility have associated outpatient Medicare costs and charges

**America’s Essential Hospitals strongly objects to both prongs of this eligibility requirement.**

A. The proposed requirement that facilities be listed on the most recently filed Medicare cost report does not align with existing Medicare regulations.

The 340B statute defines a “covered entity” to include, at subsection (a)(4)(L), “A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act)” that meets certain other listed requirements. The reference to a subsection (d) hospital is a Medicare reimbursement reference. HRSA is correct, therefore, to look to Medicare requirements for determining whether an offsite facility is reimbursable as part of the 340B hospital. But HRSA has imposed a requirement not found in Medicare regulations that the facility actually be listed on the most recently filed cost report before it can be considered part of the hospital. This is narrowing the definition of a subsection (d) hospital such that it no longer comports with the Medicare reference contained in the statute. As such, HRSA has exceeded its statutory authority in imposing this unnecessary requirement.

Under Medicare requirements, an offsite facility is considered to be part of the subsection (d) hospital if it is “provider-based.” Provider-based status triggers eligibility for Medicare outpatient hospital reimbursement. The regulation includes detailed requirements intended to ensure that a provider-based facility is clinically, financially, and operationally integrated with the main hospital.

Since October 1, 2002, the Centers for Medicare & Medicaid Services (CMS) has not required subsection (d) hospitals to obtain an actual determination from the agency that their offsite facilities meet the provider-based requirements. However, hospitals may still request a determination from CMS that a clinic or facility is provider-based by submitting an attestation.

26 42 C.F.R. § 413.65.
27 42 C.F.R. § 413.65(d)(e).
certifying compliance with the requirements (and acknowledgment of potentially significant penalties for false certification) and accompanying documentation.\textsuperscript{28}

Regardless of whether the hospital submits an attestation and obtains a CMS determination, it may begin billing Medicare as an outpatient hospital facility as of the date it meets all of the provider-based requirements. \textit{Thus, under Medicare reimbursement rules, hospitals do not need to wait until they have filed a cost report listing the offsite facility as reimbursable in order to bill Medicare as a subsection (d) hospital.} If CMS later determines the offsite facility does not, in fact, meet the provider-based requirements, the hospital must refund CMS the incrementally higher reimbursement it erroneously received as a result of billing as an outpatient hospital.\textsuperscript{29}

Despite Medicare’s treatment of an offsite facility as a part of the hospital as of the date the facility meets the provider-based requirements, HRSA has inexplicably decided that Medicare’s standards are insufficient to protect the integrity of the 340B Program.

HRSA appears to be more concerned with avoiding the possibility of potentially erroneous discounts by pharmaceutical manufacturers than CMS is with the possibility of erroneously paying incrementally higher reimbursement rates for ineligible provider-based clinics. Asserting without explanation that there would be “difficulty in verifying whether outpatient facilities and clinics meet provider-based standards,” HRSA has rejected its own prior proposal issued in 2007\textsuperscript{30} to rely on provider-based attestations until a cost report is filed listing the facility as reimbursable. What is more, if the attestations are sufficient to establish eligibility as part of the subsection (d) hospital for Medicare purposes, HRSA’s determination to impose a higher standard on the 340B definition of a subsection (d) hospital, without any statutory basis for a distinction, is arbitrary and capricious.

The arbitrary nature of this unnecessary obstacle to eligibility is further underscored by HRSA’s willingness to accept a signed certification from children’s hospitals (which generally do not file Medicare cost reports) that they meet the eligibility requirements as sufficient to establish 340B eligibility. If a signed certification is sufficient for children’s hospitals, there is no plausible rationale for HRSA’s refusal to allow a similar (and in fact more robust) attestation from DSH hospitals—even more so if the DSH hospital attestation is a temporary mechanism that can be confirmed upon the actual filing of the cost report. Indeed, given HRSA’s proposal related to children’s hospitals, the agency should accept either documentation of submission of a provider-based attestation to CMS or a certification from the hospital to HRSA that it meets the requirements.

HRSA points to the fact that “many hospitals choose not to seek provider-based designation for their departments or facilities for unrelated reasons even though these facilities may qualify for the designation,” seemingly as an explanation for why the agency should not accept voluntary provider-based attestations to CMS as temporary documentation.\textsuperscript{31} If HRSA is referring to the fact that hospitals might not choose to submit provider-based attestations to CMS, this fact is not surprising because CMS no longer requires submission of an attestation to bill as a provider-

\textsuperscript{28}42 C.F.R. § 413.65(b)(3)(ii).
\textsuperscript{29}42 C.F.R. § 413.65(j)(ii).
\textsuperscript{31}Guidance, 80 Fed. Reg. at 52302.
based site. The fact that some hospitals choose not to submit attestations is not a reason to prevent those that choose to do so from using the attestation to establish 340B eligibility pending filing of a cost report.

HRSA has failed to provide a reasoned explanation for why it should not apply the same standard to DSH hospitals as it proposes to apply for children’s hospitals regarding new outpatient facility eligibility. And if HRSA will not treat hospitals alike, the agency certainly has not provided a reasoned justification for why a more robust attestation submitted to CMS, which carries a far greater risk of false certification with Medicare payments, should not be sufficient documentation. For these reasons, HRSA should permit offsite facilities and clinics to participate in 340B as of the date of submission of a voluntary provider-based status attestation to OPA or documentation of submission of such an attestation to CMS.

B. HRSA’s proposed requirement that the services provided at the facility have associated outpatient Medicare costs and charges will deny access to the 340B Program for the most vulnerable patients.

In a newly added second prong to the offsite facility eligibility criteria, HRSA proposes to require the hospital to “demonstrate[] that the services provided at the facility or clinic have associated outpatient Medicare costs and charges.” HRSA provides no explanation of why an offsite facility would need to demonstrate Medicare costs and charges. Essentially, HRSA has transformed the requirement that the clinic services be “reimbursable” under Medicare—a requirement captured by prong 1 described above—into a requirement that the services are actually reimbursed by Medicare.

Essential hospitals are leaders in providing community-based and accessible offsite clinic services in neighborhoods where their patients live and work. Many of these clinics tailor their services to the needs of unique populations. Some clinics, for example, are pediatric clinics geared to the unique needs of children, who generally are not Medicare eligible. It would not be unusual for such a clinic to have no Medicare costs or charges. Similarly, some essential hospitals operate provider-based clinics geared to indigent populations or Medicaid and uninsured populations who also are not Medicare eligible. Provider-based clinics serving prisoners are another example. HRSA has proposed to eliminate all of these clinics from the 340B Program, even though these are exactly the types of vulnerable populations that the 340B Program was intended to help hospitals benefit.

The lack of any rational policy basis for HRSA’s proposal is compounded by the absence of any statutory basis. As noted above, the 340B statute provides eligibility for subsection (d) hospitals, and offsite clinics are part of a subsection (d) hospital if they meet the provider-based requirements. The provider-based regulations require clinical, financial, and other indices of integration among the main provider and the clinic. They do not require the clinic to incur Medicare costs and charges to be considered part of the hospital. A clinic’s services become “reimbursable” as outpatient hospital services when the clinic meets the provider-based status. And facilities have already had to demonstrate this fact under the requirement that the clinic be listed on a reimbursable line of the Medicare cost report. HRSA is now suggesting that the clinic’s services must not only be “reimbursable,” but also must actually be “reimbursed” by Medicare, incurring costs and charges for Medicare patients. HRSA has conflated the concept of a “reimbursable” provider-based clinic with a Medicare—“reimbursed” clinic. There is no basis under the 340B statute to so narrow the eligibility requirements for subsection (d) hospitals. This
second prong of HRSA’s proposal is, therefore, arbitrary and capricious and beyond its statutory authority.

For these reasons, HRSA should eliminate the requirement that hospitals demonstrate their offsite facilities have associated outpatient Medicare costs and charges to be eligible for 340B.

**Definition of Outpatient Covered Drugs**

III. HRSA should not apply the Medicaid limiting definition to the definition of 340B covered outpatient drugs.

HRSA’s proposed guidance would limit the scope of drugs that are eligible for 340B pricing based on a limiting provision in the Medicaid rebate statute. HRSA proposes that “drugs bundled for and receiving such bundled reimbursement under [Medicaid] will be considered excluded from the definition of covered outpatient drug.” In the preamble, HRSA further states that “the limiting definition in section 1927(k)(3) to exclude covered outpatient drugs for purposes of the 340B Program only applies when the drug is bundled for payment under Medicaid as part of a service in the settings described in the limiting definition. In contrast, a drug provided as part of a hospital outpatient service that is billed to any other third party or directly billed to Medicaid would still qualify as a covered outpatient drug.”

**HRSA should define covered outpatient drugs without regard to the limiting definition on Medicaid rebates at 1927(k)(3).**

America’s Essential Hospitals urges HRSA to revise its proposal and adopt a reasonable reading of the 340B statute that does not apply the limiting definition at 1927(k)(3), consistent with legislative history and sound policy. The limiting definition was intended to apply to Medicaid rebates, not to the 340B Program. In the Medicaid rebate program, the limiting definition precludes rebates for drugs that are included in a bundled Medicaid payment by excluding these drugs from the definition of “covered outpatient drug.” 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 many payers, both public and private, not just to the Medicaid Program.

The legislative history of the 340B statute also makes clear that the limiting definition does not apply to the 340B Program. Congress specifically clarified that the 340B law was not intended to prevent a provider from using a 340B drug in situations where a state Medicaid program pays for the drug in a bundled manner. The House report accompanying the 340B statute states the following: “[T]he Committee emphasizes that the bill does not prohibit the entity from dispensing a [340B] drug ... in connection with a clinic visit and including the drug in the cost of the clinic visit for which the clinic bills the State Medicaid program.”

Therefore, although a state might not be able to collect a rebate on a drug that falls under the limiting definition because the state pays for the drug in a bundled manner, the drug is still a

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covered outpatient drug for purposes of the 340B Program. Covered entities may use 340B pricing in circumstances in which the manufacturer would not be required to pay the state a Medicaid rebate. Thus, the 340B statute’s legislative history confirms that the limiting definition does not apply to the 340B Program.

Application of the limiting definition would result in negative unintended consequences. It would exclude from the program any number of drugs that are critical to effectively preventing and managing conditions, as well as avoiding hospitalization. The specific drugs will vary by state Medicaid program, but examples from our members’ states range from certain chemotherapy drugs to tissue plasminogen activator for immediate treatment of heart attack and stroke, to the contrast media used in medical imaging.

To avoid this consequence, states would be incentivized to unbundle their Medicaid payments for outpatient drugs to protect discounts for their essential providers—contrary to the incentives from HHS and other payers to move toward alternative payment methodologies intended to improve the delivery of care.

If HRSA nonetheless applies the limiting definition to the definition of a 340B covered outpatient drug, America’s Essential Hospitals requires clarification as to HRSA’s actual proposal in order to have a meaningful opportunity to comment. There are a number of questions left unanswered in the proposal because HRSA does not clearly state how the agency itself would interpret this language. We ask that HRSA address the following questions:

- Is HRSA suggesting that covered entities cannot receive 340B discounts for drugs reimbursed on a bundled basis by Medicaid for any Medicaid patient or only for Medicaid patients for whom the covered entity is actually reimbursed on a bundled basis?
- Does HRSA intend for this proposal to cover all patients, regardless of their coverage status?
- Is bundled reimbursement based only on payments from the Medicaid state agency to providers, and therefore excludes Medicaid managed care plan payments to providers?

HRSA should draft a clarification and provide additional opportunity for comment on this issue. At a minimum, if HRSA applies the limiting definition to the definition of a 340B covered outpatient drug in its final guidance, it should only apply it to drugs actually reimbursed by Medicaid in a bundled payment for Medicaid patients, and the limitation should not apply to Medicaid managed care drugs. If 1927(k)(3) applies at all, it references payment “under this Title,” which is Title XIX, or Medicaid. There is no reasonable basis to apply the limiting definition more broadly. HRSA should exclude managed care drugs because the state does not pay providers directly for any services or drugs, bundled or separate, in this instance. 1927(k)(3) references payment under Title XIX, and such payment in the managed care context is simply the capitated payment from the state to the managed care organization (MCO). It is the decision of the individual plans whether to pay providers on a bundled basis for outpatient drugs. Furthermore, it would be administratively impossible to track how each MCO is paying for a particular drug at a particular time, especially as payment policies are currently undergoing significant change.
Group Purchasing Organizations

IV. HRSA should interpret and enforce the Group Purchasing Organization prohibition in a manner that accounts for the complexity of hospital inventory management.

The Group Purchasing Organization (GPO) prohibition requires, as a condition of eligibility, that DSH hospitals not purchase covered outpatient drugs through a GPO. The proposed guidance clarifies certain situations in which the use of a GPO would not violate this requirement, and we appreciate the clarifications.

We believe, however, that HRSA must interpret the eligibility requirement in a manner that accounts for the enormous complexity of pharmaceutical inventory management in modern-day hospitals, particularly hospitals participating in 340B. Adhering to the GPO prohibition is not simply a matter of putting 340B drugs on one shelf and GPO drugs on another so that the pharmacist can pull the drug from the proper shelf at point of sale. The purchasing, dispensing, billing, and replenishing process is now highly automated. Covered entities are using complex systems developed by outside vendors to help manage it. And they are working with these vendors to connect the pharmacy systems with electronic health record systems being implemented and updated throughout the hospital. As with any complex technological system, there may be system bugs, flaws, and breakdowns at certain points, which could result in inadvertent technical violations of the GPO prohibition. HRSA’s policy should support, and not discourage, hospitals from implementing ongoing system improvements, even with the knowledge that prior errors may be revealed as part of that process. The proposed guidance should recognize this reality and allow covered entities to repay manufacturers for unintentional violations due to system errors without terminating them from the program.

In fact, termination should be reserved only for the most egregious and intentional violations of the GPO prohibition. The proposed guidance states that, unless the GPO violation is an “isolated error” as opposed to a “systematic violation,” the covered entity will be deemed ineligible for 340B as of the date of the violation and be required to repay affected manufacturers for all 340B drugs purchased after that date.

Yet HRSA does not adequately explain what it considers an “isolated error.” It cannot be that any error using a replenishment system is necessarily “systematic” or necessarily warrants termination. The scope of repayment obligation should also be tailored to the seriousness of the violation. As drafted, a violation on the purchases of a handful of drugs deemed to be a “systematic violation” could subject a covered entity to repayment for all of its drug purchases dating back multiple years, including for drugs that were not purchased through a GPO. Such a disproportionate penalty is not mandated by the statute. While it is true that the GPO prohibition is a condition of eligibility, corrective action in the form of repayment for those drugs actually purchased in violation of the GPO prohibition would sufficiently rectify the violation so the covered entity could retain its eligibility.33 We therefore urge HRSA to reserve a retroactive

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33HRSA has not, for example, concluded that manufacturers’ Pharmaceutical Pricing Agreements (PPAs) are void if they violate the requirement to offer all of their covered outpatient drugs to all covered entities at the 340B price, even though that requirement is a condition of receiving payment through the Medicaid and Medicare programs. Requiring retroactive termination and repayment for covered entities would be akin to requiring retroactive termination of the
termination and repayment obligation for only the most egregious and deliberate violations of the GPO prohibition and to provide clarity on what constitutes such violations.

The preamble to the proposed guidance acknowledges informal collaboration among manufacturers and covered entities to correct errors in GPO purchasing through a credit and rebill process within the first 30 days of the purchase. America’s Essential Hospitals recommends that such a grace period be extended to at least 90 days (as proposed for repayment related to diversion) but preferably 120 days of the date of purchase (allowing for detection and correction based on errors discovered in OPA’s proposed quarterly reviews), and incorporated into the guidance as a protected period in which additional sanctions can be avoided.

Audits and Compliance

V. HRSA should reconsider certain proposals that erect excessive regulatory barriers and compliance risks that do not serve the interests of the 340B Program.

As described above in the context of enforcing the GPO prohibition, HRSA’s proposed guidance includes a number of provisions that, particularly when combined with the complexity of the proposed patient definition, make hospital compliance with the program excessively burdensome and nearly impossible to achieve at the level seemingly expected. Congress intended hospitals to benefit from the program; thus, while we agree that program integrity is of utmost importance, program rules should be designed to acknowledge such complexities and should avoid regulatory barriers to hospital participation. The following are a few examples of particular concern.

A. HRSA’s proposal that failure to maintain auditable records is a violation of a condition of eligibility and grounds for termination exceeds its statutory authority and would result in disproportionately severe consequences for covered entities.

Section 340B(a)(5)(C) of the Public Health Service Act (PHSA) requires a covered entity to permit HHS and manufacturers to audit records pertaining to compliance with the prohibitions on duplicate discounts and diversion. Based on that authority, HRSA proposes a requirement that covered entities maintain records related to 340B compliance. To the extent that a covered entity must permit audits, it is reasonable that there must be something to audit. However, HRSA has overstepped its statutory authority in attempting to tie the sufficiency of record-keeping or the production of records for HHS or manufacturer audits to grounds for termination from the 340B Program and past repayment obligations.

HRSA should correct its misstatement that “a covered entity’s failure to provide required records is grounds for termination from the 340B Program.” 34 U.S.C. 340B(a)(5)(C) requires covered entities to permit audits by HHS and manufacturers related to compliance with diversion and duplicate discounts. There is no statutory requirement specifically relating to record retention. Nor does HRSA propose a reasonable threshold for when records are so insufficient as to constitute denying HHS or a manufacturer the opportunity to audit.

PPA and repayment of all Medicaid and Medicare reimbursement received back to the date of any “systemic” 340B violation by a manufacturer.

34 Guidance, 80 Fed. Reg. at 52309.
HRSA further proposes that “If a covered entity cannot produce records pertaining to compliance with any specific 340B Program requirement during an audit or pursuant to a request from HHS, the covered entity could be presumed to be out of compliance with that 340B Program requirement and subject to the penalty applicable to the requirement.” Again, HRSA does not define when records are so insufficient that lack of compliance with a particular requirement must be presumed.

Even assuming that failure to produce records could constitute a violation of the program requirement to which the absent records pertain, HRSA overstates its statutory authority to terminate a covered entity from the program. HRSA proposes that

“If a covered entity systematically fails to maintain auditable records...or fails to provide them as requested by HHS or a manufacturer authorized to conduct an audit, the covered entity will be removed from the 340B Program...”

But Congress has limited HRSA’s authority to terminate a covered entity to violations of the actual eligibility requirements defined for each covered entity under statute or to cases of diversion “where the Secretary determines a violation...was systematic and egregious as well as knowing and intentional.” Thus, HRSA does not have the authority it proposes to terminate an entity for “systematically” failing to maintain auditable records—an appropriate limit given that much of hospital compliance is based on software systems in which a single error in programming by the entity or the vendor could be automatically repeated until caught. Nor would HRSA’s proposed exception from termination for non-systematic violations be sufficient even if HRSA had such termination authority. HRSA proposes that

“A non-systematic recordkeeping violation would occur if the covered entity generally has available records but cannot produce a certain specific record demonstrating compliance with a 340B Program requirement. For example, if a covered entity can generally produce 340B records for patient eligibility, but cannot produce a record for a particular patient who received a 340B drug, the drug purchase would be presumed to be in violation of section 340B(a)(5)(B) of the PHS Act diversion and the entity may be liable for repayment to the manufacturer; however, the covered entity would not be removed from the 340B Program.”

We agree that the example above should not be considered a systematic violation and that the appropriate remedy is repaying the manufacturer for the specific instance of diversion. However, the threshold for records to be so poorly maintained as to merit termination and repayment should be substantial given the benefit being stripped from the covered entity. Does the preamble above mean that if a covered entity was unable to produce “a certain specific record” for more than one “particular patient” the violation would be systematic?

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30For DSH hospitals, the 340B statute defines eligibility criteria as 1) owned or operated by a unit of state or local government, or granted governmental powers, or a nonprofit hospital with a contract with such a government; 2) having a disproportionate share adjustment percentage of at least 11.75%, and 3) complying with the GPO prohibition.
The termination of a covered entity from the program even for a quarter can have severe consequences for its financial stability. It is unreasonable, then, for HRSA to propose that “A covered entity deemed ineligible and removed from the 340B Program for failure to maintain auditable records would be liable for repayment to manufacturers for periods of ineligibility.” This is not an eligibility requirement and does not deserve such draconian penalties. Repayment for insufficient records for certain purchases or prescriptions might be fair. But to suggest that the covered entity would have been ineligible for those periods and thus repay 340B discounts on all drugs is a significant overreach and not a proportionate penalty for the underlying compliance issue.

HRSA proposes to also potentially terminate the covered entity from the program if the entity “fails to provide [records] as requested by HHS or a manufacturer authorized to conduct an audit.” The audit procedures should clearly define what constitutes “failure to provide” records and clearly outline the requirements for the scope, timing, etc., of providing records under an audit.

For these reasons, HRSA should rewrite the auditable records provision of the guidance to 1) comport with its actual statutory authority, 2) provide clear and reasonable standards for when records are so insufficient as to result in violation of the requirement they are intended to demonstrate and what constitutes a failure to produce records to HRSA or a manufacturer, and 3) replace the proposed draconian penalties with proportionate standards.

B. It is unreasonable to propose that a hospital can violate the prohibition on diversion before it even places an order for drugs at the 340B discounted price.

According to the preamble of the proposed guidance, a hospital using a replenishment system to track 340B and non-340B orders can commit diversion (i.e., providing 340B discounted drugs to individuals who are not “patients”) if there are errors in accumulation even before any drugs are actually ordered at a 340B discounted price.

“If the covered entity improperly accumulates or tallies 340B drug inventory, even if it is prior to placing an order, the covered entity has effectively sold or transferred drugs to a person who is not a patient, in violation of section 340B(a)(5)(B) of the PHS Act. A similar violation would occur if the recorded number of 340B drugs does not match the actual number of 340B drugs in inventory, if the covered entity maintains a virtual or separate physical inventory.”

If a hospital has not yet purchased drugs then it cannot have inappropriately received a 340B discount and has not committed diversion. HRSA’s proposal is an unnecessary construct with nonetheless real consequences for covered entities that could result in self-disclosure, publicly available audit findings, and even termination from the program. Yet, under this scenario, the manufacturers whose drugs are at issue would not even be owed a repayment because they would not yet have sold the drugs to the hospital for the lower 340B price.

40Guidance, 80 Fed. Reg. at 52308.
HRSA goes on to acknowledge that manufacturers and covered entities often “work together to identify and correct errors in purchasing within 30 days of the initial purchase” and “encourages manufacturers and covered entities to continue this practice.” We support this approach of treating such errors as correctible purchasing errors and encouraging collaborative efforts on program compliance. HRSA should treat accumulation errors similarly and not as diversion. HRSA should also include this safe harbor-like concept in the language of the guidance itself and include at least a 90-day grace period (as discussed in the context of working with manufacturers to correct diversion after ordering) or preferably a 120 day grace period that would allow for correction of errors identified during HRSA’s proposed quarterly reviews.

C. HRSA should modify its excessive increase in proposed covered entity reporting obligations to include a materiality requirement for self-disclosures and reduce other unnecessary administrative burdens.

HRSA proposes to require self-reporting of effectively any program violation or corrective action, regardless of whether the violation is material and whether the covered entity has fixed the issue directly with the manufacturer. The following are several examples of instances in the guidance where HRSA excessively increases the expectations for self-disclosure:

- During the required annual recertification, HRSA proposes that “By certifying compliance with all 340B Program requirements, a covered entity attests that it ... notifies HHS in the event the entity ... has violated any 340B Program requirement.”\(^{41}\)
- In the context of the proposed new requirements for quarterly reviews and independent annual audits of contract pharmacy relationships, “any 340B Program violation detected ...should be disclosed to HHS,” and if the covered entity has corrected any discovered errors, it should “report corrective action to HHS.”\(^{42}\)
- The covered entity “should notify HHS of its corrective actions regarding diversion, including any manufacturer agreements on repayment,” the reporting of which should include “a summary of its corrective actions taken.”\(^{43}\)

HRSA’s current requirements for self-disclosure and recertification, which were revised only last year, include a materiality test that is strikingly missing in the current proposal. In issuing additional guidance on the self-disclosure process in September 2014, HRSA stated that a covered entity has the responsibility “to contact HRSA as soon as reasonably possible if there is any ...material breach by the covered entity of any of the foregoing [points of 340B compliance].”\(^{44}\) HRSA should revise the proposed guidance so that self-reporting in any context is required only when there is a material breach of a program requirement.

Without such a standard, covered entities would be required to report even minor technical violations of the program, even when easily resolved and documented. This does not improve program compliance, but simply creates excessive administrative burdens for the entities and for

\(^{41}\)Guidance, 80 Fed. Reg. at 52304.
\(^{42}\)Guidance, 80 Fed. Reg. at 52321, 52331.
\(^{43}\)Guidance, 80 Fed. Reg. at 52319, 52338.
HRSA and makes it more difficult for the agency to identify more problematic and significant compliance problems. If anything, the requirement provides a perverse incentive for covered entities to be less thorough in compliance review so that only the biggest errors are identified and trigger the reporting requirement.

In addition, HRSA proposes more extensive explanations than necessary for compliance related to a covered entity’s voluntary decision to terminate a pharmacy or outpatient site from the program. Upon termination and annual recertification, a covered entity is expected to provide explanation and documentation of the reason for the voluntary termination—a requirement that becomes more burdensome when dealing with large systems with numerous sites and pharmacies. It is unclear why HRSA would require this information specifically for sites that, by definition of the termination, are no longer part of the 340B program. This is one area where burden can be easily reduced without affecting program integrity. HRSA should reduce the reporting burden when covered entities voluntarily terminate sites or pharmacies from the program.

**Appeals Process**

VI. HRSA should strengthen and finalize its proposed notice and hearing process.

The proposed guidance sets out a notice and hearing process for covered entities (and manufacturers) to contest adverse findings by HRSA. The guidance specifically refers to the process in connection with adverse audit findings on duplicate discounts, diversion, and eligibility, as well as determinations that a covered entity has violated the GPO exclusion in a systematic fashion or has failed to maintain auditable records for the requisite five-year period. The consequences of these adverse findings can potentially include repayment to manufacturers of hundreds of thousands or millions of dollars and termination from the program, including consequent loss of access to discounted drug prices.

Given the potential enormity of the consequences of adverse findings, the proposed notice and hearing process is wholly inadequate, lacking in fundamental principles of fairness. America’s Essential Hospitals urges HRSA to adopt a much more formal and robust appeals process that includes, at a minimum, the following elements:

- **Detailed Written Findings:** The text of the guidance itself is silent on the form and content of HRSA’s notice to a covered entity about any findings of noncompliance or ineligibility, other than noting that it may make audit findings public. The preamble to the guidance mentions that HHS will provide “written notice to a covered entity of a proposed finding of noncompliance” but does not elaborate. The guidance should be revised to state explicitly that HRSA will issue a detailed notice to a covered entity of any adverse findings, including a description of the underlying facts and the legal basis for the findings and the specific provision(s) of law (statute, regulation, or formal guidance) violated. Only such a detailed description will permit the covered entity a full opportunity to respond.

- **Oral Hearing Opportunity:** In addition to responding to adverse findings in writing, covered entities should be afforded the opportunity to have an in-person or telephonic

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hearing. In the Medicare Program, for example, providers have the right to a telephonic or in-person hearing whenever the amount in controversy exceeds $150.\textsuperscript{46} The potential consequences for covered entities far exceed the amount-in-controversy threshold for Medicare, yet the proposed guidance provides no opportunity for an oral hearing.

- **Independent Decision-Maker**: The guidance is silent with respect to who will be reviewing the covered entity’s response to the adverse findings. It should guarantee the availability of an independent decision-maker who was not involved in the original findings of noncompliance or ineligibility. Ideally, given the stakes, the hearing should be before an administrative law judge or other trained, impartial decision-maker.

- **Detailed Written Final Decision**: The proposed guidance states that, after the covered entity has had the opportunity to respond to the adverse findings, HRSA will issue a “final written notice with its final determination regarding noncompliance” and that where applicable it will include the audit report. The guidance should clarify that this notice will include a detailed decision with findings of fact, a response to each point raised by the covered entity, and the legal basis for the decision (including reference to the specific provisions of statute, regulation, or formal guidance on which the decision is based).

- **Final Agency Action**: The guidance should clearly specify that the decision issued at the conclusion of the notice and hearing process constitutes final agency action so that the covered entity may proceed to challenge the decision in District Court.

### Manufacturer Audits

VII. HRSA should finalize clear guidelines for manufacturer audits of covered entities and modify some guidelines to ensure its goals of minimizing burden while supporting compliance.

We appreciate HRSA’s intent to adopt clear guidelines and an approval process to govern manufacturer audits of covered entities and to reduce the burden on covered entities by, for example, prohibiting more than one audit at a time and confining the scope of the audit to the statutorily authorized areas of diversion and duplicate discounts. Nonetheless, we recommend that HRSA strengthen the guidance further by limiting not only the length of a manufacturer audit (proposed to be no more than one year) but also the frequency. We recommend that a manufacturer not audit a covered entity more than once every five years. Otherwise, the covered entity could be under perpetual sequential audits from a manufacturer.

We also suggest that the guidance clearly state that a manufacturer may not audit a covered entity unless the reasonable cause basis, audit scope, audit procedures, and work plan have been affirmatively approved by HRSA. Further, the guidance should be clear that HRSA has the authority to withhold such approval or to require changes in any of these aspects of the audit. The proposed guidance is currently lacking in such clarity.

We have heard from members that some manufacturers have started working with a third party contractor that specializes in requesting 340B-related records from pharmacies and hospitals and for all intents and purposes is performing audits without initiating any request or process with HRSA. This entity has been known to make multiple concurrent requests of hospitals at the same time.

\textsuperscript{46}42 C.F.R. § 430.1006(b); 80 Fed. Reg. 57827 (Sept. 25, 2015).
time. These efforts create the burden of an audit but avoid HRSA’s rules around process and scope. It is imperative that HRSA’s proposals prevent such activity moving forward. Furthermore, HRSA should ensure that if a covered entity does not respond in detail or provide all requested records in response to manufacturers or contractors that do not follow HRSA’s process, this should not constitute a “refusal to respond” that may be “construed as reasonable cause” for a manufacturer audit under the proposed guidance.

Finally, the proposed guidance provides no process to request or receive an extension to the 30-day deadline for responding to the manufacturer’s audit report and instead deems a failure to respond within the deadline an agreement with the findings. Given the potential large scope and range of a year-long audit, the potential complexity of the findings, and the potential significant consequences of the findings, there should be a process for a covered entity to request a good-cause extension of the deadline to respond and to appeal to HHS if the manufacturer refuses to grant such a request.

America’s Essential Hospitals recommends that HRSA revise the proposed guidance to clarify that a) manufacturers may not audit any individual covered entity more than once every five years, b) affirmative HRSA approval of the audit is required before the manufacturer may proceed with the audit, c) HRSA may withhold such approval, and d) covered entities may request a good-cause extension of the deadline to respond to manufacturer audits.

**Contract Pharmacies**

VIII. We strongly endorse HRSA’s continued allowance of contract pharmacy arrangements and suggest flexibility to demonstrate sufficient compliance with program requirements to minimize new regulatory burdens.

The proposed guidance preserves the ability of covered entities to contract with multiple licensed pharmacies to dispense 340B drugs to covered entity patients. We strongly endorse the continued allowance of such multiple contract pharmacy arrangements, which are essential to ensuring access to affordable drugs for vulnerable patients. Essential hospitals are known for establishing accessible clinics in neighborhoods across their service areas to make it easier for individuals to obtain care. On that same philosophy, they have leveraged the ability to dispense 340B drugs through contract pharmacies to ensure patients can readily fill and refill prescriptions that often are critical to maintaining their health and holding down the cost of care. Any rolling back of the flexibility to use contract pharmacies in this way would have had a direct impact on patient access to drugs and, as a result, patient health. We applaud HRSA for retaining this important option.

We also understand the additional complexity of ensuring compliance when drugs are being dispensed through multiple locations not directly owned by the covered entity. Our members are acutely aware that they are subject to audit at any time, both by HRSA and by manufacturers, and that the consequences of being found in violation of program requirements are severe. As a result, we have witnessed a rapid spread in the adoption of comprehensive compliance programs among our members and ongoing work with software vendors and their contract pharmacy
partners to prevent violations before they occur and root out any vulnerabilities in their policies, procedures, and systems.

However, the proposed guidance mandates certain compliance processes with respect to contract pharmacies that are unnecessarily prescriptive to achieve HRSA’s desire for a regular opportunity for compliance review. In particular, the guidance would effectively require, rather than “expect,” covered entities to obtain an independent annual audit of each contract pharmacy location. HRSA describes an “expectation” to perform such an audit under current guidance, but for the first time in the proposed guidance states that “the results of these reviews are included in the records’ requirements of section 340B(a)(5)(C) of the PHSA.” The proposal also requires the covered entity to conduct quarterly reviews comparing its prescribing records with the contract pharmacy’s dispensing records.

We propose that the annual independent audit continue to be a recommended but not mandatory procedure and that covered entities be allowed flexibility to adopt other compliance procedures as they deem necessary. Because the consequences of program violations are so significant, covered entities are already sufficiently motivated to ensure compliance, and they do not need HRSA to prescribe the precise procedures to be followed. We recommend that HRSA provide discretion to covered entities and allow them to choose their own methods to ensure they remain compliant with all 340B requirements.

We also urge HRSA to maintain sufficient flexibility in determining whether a hospital has satisfied the requirement to audit each location, such that compliance can be confirmed with the minimum increase in administrative burden, particularly in light of the many other new requirements under this guidance. For example, if a hospital uses a centralized system and/or vendor for tracking compliance at multiple pharmacy locations, the hospital could demonstrate that the central system could be sufficient without using a process that would entail the pulling and auditing of a large number of prescriptions by an independent auditor.

Duplicate Discounts

IX. We support HRSA’s proposed flexibility in use of 340B drugs for Medicaid managed care patients and urge further clarification of covered entity, state, and managed care plan roles in preventing duplicate discounts.

Essential hospitals are significant providers of care to Medicaid beneficiaries. We support HRSA’s position that covered entities have flexibility to make different decisions regarding whether to use 340B drugs (i.e., “carve in” or “carve out”) for Medicaid fee-for-service versus Medicaid managed care populations. This also applies when making decisions within managed care populations and by MCOs.

We encourage HRSA to clarify the responsibilities of the state and managed care organizations in ensuring duplicate discounts do not occur under Medicaid managed care. The Medicaid rebate statute clearly makes states legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. The 340B statute, in turn, imposes liability on covered entities that bill Medicaid for 340B drugs that are subject to a Medicaid rebate. The relevant provision states that a provider shall not request
Medicaid reimbursement for a 340B drug that is “subject to the payment of a rebate to the state.”

While the Affordable Care Act (ACA) amended the Medicaid rebate statute by requiring manufacturers to provide rebates for drugs dispensed to individuals enrolled in MCOs it specifically excluded 340B MCO drugs from the rebate requirements. Because 340B MCO drugs are not subject to rebates, the provision in the 340B statute imposing liability on covered entities for creation of duplicate discounts does not apply when the underlying drug is an MCO drug.

It also makes sense from an operations standpoint that Congress did not assign providers responsibility for protecting manufacturers from paying rebates on 340B Medicaid MCO drugs because billing for such drugs is substantially more complex than billing for 340B fee-for-service (FFS) Medicaid drugs. As compared to FFS Medicaid, in which a covered entity submits claims directly to the state, billing for 340B MCO drugs involves submitting claims to various pharmacy benefit managers (PBM)s acting on behalf of health plans that contract with the state. With so many state contractors and subcontractors participating in the billing process, states and their agents are in a better position than covered entities to protect manufacturers from paying rebates on 340B MCO drugs. We urge HRSA to explicitly clarify the responsibilities of the state and MCOs in ensuring the duplicate discounts do not occur under Medicaid managed care when finalizing its guidance.

**Clarifications in Final Guidance**

X. HRSA’s final guidance should systematically clarify the status of existing and new policies, or the agency will not succeed in providing the clarity it intended.

America’s Essential Hospitals supports the issuance of omnibus guidance covering the full range of 340B Program policies through a notice and comment process. To date, program requirements have been decentralized across multiple informal policies, issuances, letters, and FAQs, which are often implemented without advance notice or opportunity to respond. The complexity of the 340B Program requires a more systemized and transparent process for policy development, and we support HRSA in this effort.

That said, we believe that the proposed guidance should go further in ensuring the consolidation of all 340B Program requirements in one set of policies. As it is, the proposed guidance does not always treat existing policy consistently. It sometimes explicitly incorporates or modifies existing policies and in other areas it is silent on existing policies, leaving stakeholders to wonder whether the existing policy is being replaced or left intact. For example, it is unclear whether the provisions on the GPO prohibition replace or add to the guidance issued on the topic in 2013. If the proposed guidance does not completely supersede the 2013 guidance, which provisions from 2013 would remain in effect? It would be very helpful to have those remaining effective portions of the 2013 guidance incorporated into the omnibus guidance so there is more clarity as to what the requirements are with respect to GPOs. We therefore recommend that the final guidance incorporate any existing guidance that HRSA intends to retain so that it may explicitly supersede all previous issuances.

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4PHSA § 340B(a)(5)(B).
Transition Period

XI. HRSA should provide a transition period for significant changes made effective in the final guidance.

Certain policies proposed by HRSA would, if implemented, represent significant changes to current policy, requiring covered entities to implement massive new policies, procedures, and systems to ensure compliance. The proposed patient definition, implementing no fewer than 10 separate criteria for covered entities to confirm prior to dispensing a 340B drug, will, as described above, be particularly challenging to implement. Given the level of reliance on electronic systems for managing 340B compliance, software vendors will need time to create and make available the systems necessary to implement certain changes, and hospitals will need time for testing once they are able to acquire them. HRSA should also be sensitive to the fact that inventory management systems are just part of the larger electronic health record systems being implemented and updated on an ongoing basis in hospitals, so changes in such systems take time.

Typically, major regulations become effective no earlier than 60 days after final publication. Acknowledging that the proposed guidance is not a regulation, we nonetheless believe that even 60 days would be an insufficient amount of time for covered entities to come into compliance with some of the major changes proposed in the guidance, such as those regarding patient definition. For example, if the proposed patient definition were finalized as is, covered entities would need at least one year to implement system changes to ensure compliance. While we remain adamantly opposed to the new patient definition, we nonetheless urge HRSA to adopt a sufficient transition period to account for any major changes to the patient definition, the definition of covered outpatient drugs, the eligibility of offsite facilities, or other major program aspects that are incorporated in the final guidance. We also strongly encourage HRSA to work with hospitals as unexpected challenges arise (as they did, for example, in implementation of the 2013 GPO guidance).