HRSA’S PROPOSED OMNIBUS GUIDANCE WOULD JEOPARDIZE 340B HOSPITALS:
RESULTS FROM A SURVEY OF 340B HEALTH MEMBERS

The Health Resources and Services Administration’s 2015 proposed guidance on the 340B Drug Pricing Program may have intended to cut through previous confusion in the administration of the program, but a survey of 340B Hospitals indicates the proposed guidance would cause significant harm to hospitals that rely on 340B to provide critical care in their communities.

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ABOUT THE 340B DRUG PRICING PROGRAM
The 340B Drug Pricing Program was signed into law in 1992 to ensure safety-net providers could afford to continue to provide a wide range of services to the patients who need them. In the decades since, the number of covered entities in 340B has changed but its mission has not. In order to participate in the Medicaid and Medicare Part B markets, pharmaceutical companies must agree to provide outpatient drugs to safety-net providers at a discounted rate. Safety-net providers use these savings to ensure they are able to provide care to any patient that walks through their doors.

ABOUT 340B HEALTH
340B Health is an association of more than 1,100 hospitals. We are the leading advocate and resource for those providers who serve their communities through participation in the 340B drug pricing program. For more information about us and the 340B program, visit www.340bhealth.org.
EXECUTIVE SUMMARY

INTRODUCTION

The 340B Drug Pricing Program has been integral to the survival of America’s safety net since it was signed into law by President George H.W. Bush in 1992. The program has always served to bolster safety-net providers, allowing them to stretch scarce resources so they can better serve the patients and communities who need them.

In August 2015, the Health Resources and Services Administration (HRSA) released proposed omnibus guidance intending to clarify rules governing the 340B program. The proposed guidance was understood to be an attempt to balance the interests of drug manufacturers and the various categories of covered entities eligible for the program while recognizing the program’s intent to assist covered entities. It was also understood that HRSA hoped to develop “bright line” guidelines to provide clarity on the many compliance issues related to this program, particularly with regard to use of 340B drugs for individuals treated outside participating hospitals. However, a number of provisions proposed in the guidance would prohibit the use of 340B in scenarios where 340B has been used for many years for individuals who are clearly patients of an eligible hospital and are treated on the premises of the hospital. Regardless of intent, some attributes of the proposed guidance could hurt the program, and by extension safety-net providers and patients.

Following the proposed guidance’s release, 340B Health asked its members to complete a survey describing how the proposed guidance would affect their use of the 340B program. Five hundred and twenty-three hospitals responded to the survey, including Disproportionate Share Hospitals (DSH), Critical Access Hospitals, Rural Referral Centers, Sole Community Hospitals, Freestanding Cancer Hospitals, and Freestanding Children’s Hospitals.

KEY FINDINGS

Instead of clarifying 340B’s administration, the survey found five parts of HRSA’s proposed guidance would vastly complicate it. The survey concluded that some of the proposals are poorly defined, incompatible with state law, and have the potential to negate any positive impact these discounts are supposed to have on the safety net and patient care. The cumulative impact of these aspects of the proposed guidance could force many hospitals, especially rural hospitals, to drop 340B and therefore cut back services to the poor.
Overall, 76 percent of respondents indicated that the cumulative impact of HRSA’s proposed guidance would be harmful to their hospital, with 28 percent indicating these changes would force them to consider dropping 340B. Though this problem presented itself across the hospital types, it was particularly acute with rural hospitals, for which dropping out of 340B would force many patients to travel hours for care.

Of the problems respondents had with the new proposed guidance, the issues that stood out as being particularly harmful are as follows:

**A ban on using 340B for discharge prescriptions would increase readmission rates**

- **Summary:**
  - 340B is commonly used for prescriptions written at the end of an inpatient stay to be filled on an outpatient basis to ensure patients have access to affordable medication and do not suffer gaps in care. HRSA’s proposal would end this practice.

- **Expected impact:**
  - 81 percent of respondents would lose discounts if this measure were enacted
  - 11 percent say they could be forced to drop 340B altogether due to this measure. This number is 22 percent if DSH and free-standing children’s and cancer hospitals are required to use wholesale acquisition cost (WAC) pricing instead of GPO.
  - 57 percent of respondents would struggle without 340B for discharge prescriptions
  - 59 percent of respondents would struggle to implement these changes
  - 24 percent find implementation of these changes to be “not feasible”

* All figures presume hospitals subject to the group purchasing organization (GPO) prohibition are able to use GPO pricing for drugs ineligible for 340B, unless indicated otherwise.
HRSA’s Proposed Omnibus Guidance Would Jeopardize 340B Hospitals

Requiring infusion orders to be written from the administering hospital to qualify for 340B discounts would leave some patients without affordable care nearby

- **Summary:**
  - It is common practice for patients to seek diagnosis for conditions that require infusion care (like cancer) in a location far from home and pursue treatment close to home. HRSA’s proposal would end discounts for infusion orders written under this scenario, which has the potential to shut down infusion centers

- **Expected impact:**
  - 85 percent of respondents would lose 340B discounts if this measure were enacted
  - 21 percent say they could be forced to drop 340B altogether due to this measure
  - 53 percent of respondents would struggle without 340B for outside infusion orders
  - 57 percent of respondents would struggle greatly to implement these changes
  - 26 percent find implementation of these changes to be “not feasible”

Classifying any patient who received care within 72 hours of admittance as inpatient, and any drugs they received before admittance, as inpatient would raise the cost of care and create an administrative minefield

- **Summary:**
  - The 72-hour Medicare reimbursement rule (also known as the three-day rule) requires outpatient services within three days of hospital admissions to be billed as part of inpatient services. The rule does not retroactively change a patient’s outpatient status. Because these patients are outpatients at the time of care, most 340B hospitals use 340B for their medication. The proposed guidance would end this practice and add major administrative hurdles to the provision of emergency care

- **Expected impact:**
  - 81 percent of respondents would lose discounts if this measure were enacted
  - 17 percent would consider dropping 340B if this provision were enacted. This number is 20 percent if DSH and free-standing children’s and cancer hospitals are required to use WAC pricing
  - 49 percent would struggle without 340B for patients admitted within 72 hours of outpatient care
  - 68 percent of respondents would struggle to implement these changes
  - 28 percent find these changes to be “not feasible.” This number is higher, 33 percent, if DSH and free-standing children’s and cancer hospitals are required to use WAC pricing

Requiring scripts to be written by hospital employees or independent contractors such that the hospital may bill for services on behalf of the provider ignores the realities of the hospital setting

- **Summary:**
  - Hospital staff is usually cobbled together from hospital employees, independent contractors, privileged and credentialed providers, and others. HRSA’s proposed guidance would require that for scripts to be filled with 340B, they must be written by an employee or independent contractor of the hospital such that the hospital may bill for services on behalf of the provider. This proposal would render 340B useless or operationally impossible for many hospitals. And because HRSA’s definition of eligible providers is exceedingly vague, it is difficult to fully gauge how badly this provision would impact hospitals.

- **Expected impact:**
  - Every 340B hospital has the potential to lose discounts if this provision were enacted
The cumulative burden of the HRSA proposed guidance would devastate the majority of 340B hospitals

- **Summary:**
  - A recurring theme was that although these proposed provisions would be damaging on their own, the cumulative impact of the provisions in the proposed guidance is what would really threaten safety-net hospitals. Most respondents would have the capacity to deal with one or two of the proposed limitations, but together they have the potential to cripple a program designed to help providers better serve low-income and vulnerable patients.

- **Expected impact:**
  - 97 percent of respondents find the combined impact of this proposed guidance to be problematic to their administration of the 340B program
  - 28 percent would consider dropping out of the program due to these changes
  - Many respondents stated that the proposed changes would create a significant operational burden in which software would have to be completely revamped, staff retrained, and practices re-examined

Restrictions on using 340B discounts for many drugs paid for by Medicaid would also be problematic, though this issue was not included in the member survey. The 340B program is intended for hospitals that treat high percentages of Medicaid patients, so this proposed provision would significantly limit the scope of the program.

**CONCLUSION**

Although the proposed guidance may have been intended to clarify the 340B program rules, particularly with regard to use of 340B for individuals treated outside a participating hospital, the proposed guidance would instead make the drug discount program much harder to implement and threatens to strip the intended benefit from the safety-net providers that need it. For many hospital respondents, the cost of accommodating the proposed guidance’s demands would vastly limit their use of the 340B program or defeat the purpose of participating in the program altogether. These problems are stark, but not unfixable. Many other parts of the proposed guidance were welcome changes.

To protect hospitals that participate in the program, HRSA should reevaluate the problematic rules outlined in this survey. When finalizing the proposed guidance, HRSA should make clear whether it is intending to replace or merely supplement current policy. HRSA should also include a transition period that would allow hospitals at least a year to implement the new provisions, as many of these proposed new policies would require significant changes to hospital tracking systems for drugs, orders, scripts, location of services, and relationship of providers. One year would be the minimum amount of time for hospitals to make these changes and develop new software systems.

Kept as-is, the proposed guidance would reduce patient access to affordable care, force a reduction in uncompensated care and drive some hospitals out of the program altogether – a result that could jeopardize the provision of critical care in their communities.
SECTION 1: HRSA’S PROPOSED RESTRICTIONS ON USE OF 340B FOR DISCHARGE PRESCRIPTIONS WOULD DISRUPT PATIENT CARE AND SPUR READMISSIONS

Discharge prescriptions play an incredibly important role in terms of hospital patient care. As explained by the U. S. Supreme Court, hospital participation in the transition from hospital to home is “real” and serves “as a continuation of, or supplement to, the treatment that was administered at the hospital to the patient who needed, and now continues to need that treatment.” Many studies have shown that adherence to the medication regimen prescribed by a physician during an inpatient stay is a significant factor in improving patient outcomes and reducing readmissions.

Currently, it is common for 340B hospitals to use the program to send inpatients home with the prescriptions they need. Discharge prescriptions are used on an outpatient basis (i.e., after the patient has been discharged from an inpatient unit), they are dispensed to outpatients and are treated by hospitals and the government as outpatient drugs. Thanks in part to 340B, many hospitals have programs to provide pharmacist counseling at discharges, which has been shown to lead to better patient outcomes, fewer adverse drug events and a reduction in preventable emergency department visits and readmissions.

PROPOSED CHANGE IN THE GUIDANCE

The proposed guidance states that the script or order must be written as a result of a service billed as outpatient for 340B to be used, meaning hospitals could no longer use 340B for discharge prescriptions written as the result of an inpatient stay.

THE ANTICIPATED IMPACT

Removing discharge prescriptions from the 340B program would have a devastating effect on hospitals and patients. Eighty-one percent of respondents would be impacted by this proposal, with 46 percent...
saying that the provision would be highly problematic and another 11 percent reporting that if the provision is finalized they may have to stop participating in the 340B program.

For example, Einstein Medical Center Philadelphia, a 772-bed tertiary-care teaching hospital located in North Philadelphia that treats a significant volume of vulnerable patients, has found the use of 340B for discharge prescriptions to be instrumental in its efforts to address readmissions.

Einstein’s “Medication REACH” program ensures patients have a face-to-face meeting with a pharmacist before being discharged and that a pharmacist has a follow-up call with patients after discharge. Einstein has achieved a 50 percent reduction in the likelihood of patient readmission as a result of the REACH program. Not being able to use 340B for discharge prescriptions would jeopardize this effort and Einstein’s ability to help connect patients with sustained services.

In addition to cutting hospital savings, the survey indicated that respondents find this measure operationally difficult to implement, with 24 percent describing the provision as “not feasible.” This feeling is likely because of the switch from patient definition to billing as the measure for whether or not 340B pricing can be used for a given prescription. Though this change is simpler than the others, it would still require retraining and rewriting of 340B software.

The survey included an open-response section in which safety-net hospital representatives were asked to provide details on guidance implementation, operational hurdles, the overall impact of the proposed guidance and how the proposed guidance would affect their mission of providing services to vulnerable patient populations. One of the most concerning impacts of this provision is the potential for the patient readmission rate to surge due to gaps in prescription care. When hospitals cannot reliably pass on discounts to patients who need them, those patients are more likely to forego care because of the expense.
“Our hospital is focused on minimizing readmissions. Part of our plan for this is making sure that our patients leave the hospital with their prescriptions filled and with an understanding of their medications. Without 340B for discharged inpatients, this would be significantly more costly.”
—DSH Hospital near Philadelphia, PA

“Currently we provide free care, medication when discharged from hospital so that patients will not be readmitted....we have multiple care vans picking up patients to receive care ... we have a home health nursing agency that goes to patient homes. We would not be able to support these services if the proposed changes go into effect.”
—DSH Hospital near Schererville, IN

“Right now, our policy is that all patients who are discharged from an inpatient stay can have all prescriptions filled (up to 30 day) at our hospital pharmacy. If they have insurance, insurance is billed. If there’s no insurance, the prescriptions are filled anyway and the patients receive their medication for free. Our hospital is able to do this because of our 340B savings. If we are unable to fill these prescriptions at 340B prices, we would likely not be able to continue this program.”
—DSH Hospital near Philadelphia, PA

“We serve a large percentage of indigent patients. The program helps many after they are discharged from the hospital and if discharge prescriptions were to not be allowed under 340B, many may just skip the medication. This would cause them to go without their medication and have a higher chance of being readmitted.”
—DSH Hospital near Louisville, KY

SECTION 2: PAYING FULL PRICE FOR OUTSIDE INFUSION ORDERS WOULD THREATEN PATIENT ACCESS TO CARE, ESPECIALLY IN RURAL COMMUNITIES

Though it differs from hospital to hospital, infusion orders are often written in one place and administered in another. Currently, 340B pricing is used for these infusions to defray the cost of administration for the hospital and the cost of treatment for the patient. For example, patients from rural areas might seek an expert diagnosis and treatment plan at a city hospital and return home for treatment at the local provider where there might not even be an oncologist on staff. Additionally, private oncologists often only administer infusions for commercially-insured patients themselves and write orders for Medicaid and other low-income patients to be filled at a safety-net hospital.

PROPOSED CHANGE IN THE GUIDANCE

The proposed guidance states that an infusion order must be written as a result of services provided in the hospital or a registered clinic to be filled with 340B and appears to permit 340B only for drugs that are ordered or prescribed during a service provided on the premises of the hospital.
THE ANTICIPATED IMPACT

Many respondents have grave concerns about this provision, as it would prohibit 340B for infusions administered on the premises of the hospital if the order for the infusion were written pursuant to a service provided outside the hospital.

Almost one third of respondents get more than half of their 340B savings from infusions orders written outside the hospital. Eighty-five percent of the respondents reported being impacted by this prohibition, with 32 percent identifying this restriction as highly problematic and another 21 percent saying that they would consider dropping out of the program if this provision were finalized.

This restriction ignores the reality of the infusion process. Hospitals are unquestionably responsible for infusions they provide to their patients even if the order is written outside the hospital. Because many hospitals, particularly rural hospitals, fill infusion orders that were not written on-site, the prohibition of 340B pricing for these orders would necessitate a drastic cut in discounted services and may lead to an end to infusion services in some cases. For patients in rural areas, that would mean regularly traveling hours to another facility to receive chemotherapy or other infusion treatments.

WITHOUT DISCOUNTS FOR OUTSIDE INFUSION ORDERS, MOST 340B HOSPITALS WOULD STRUGGLE

[Bar chart showing the impact of without discounts for outside infusion orders, with the majority indicating a negative impact, especially on whether the hospital would consider dropping out of the program.]
For example, Southern Ohio Medical Center (SOMC), a disproportionate share hospital (DSH) located in Portsmouth, Ohio, currently accesses $1.4 million in 340B savings for outpatient infusions, which represents 18 percent of their total 340B savings. One third of the orders filled at the hospital’s cancer and non-cancer infusion centers are written by providers in non-340B locations. SOMC anticipates a ban on 340B for infusion orders written outside of the hospital would result in reduced oncology services provided to low-income patients. Currently, SOMC provides approximately $70,000 in charity care for the infusion clinics alone. The patients they serve would also suffer given that there are no other viable treatment options in their five county service area.

In addition to drastically reducing savings for many hospitals, which would lead to many providers dropping services to reduce costs, this policy would also impose significant and expensive operational challenges. Fifty-seven percent of respondents found the operational implications worrisome, with 26 percent describing this provision of the HRSA proposed guidance as “not feasible.” For example, hospitals do not currently have systems to track whether an order was written at the hospital or outside the hospital. As a result, this proposal would require the development of entirely new software and processes.

Moreover, this proposal conflicts with every health insurer coverage rule under which payers do not limit coverage based on where an order is written. As-is, the proposed guidance creates a brand new 340B-only coverage rule that would add another layer of burden on hospitals who would be required to develop new tracking systems and software.

**IN THEIR OWN WORDS**

Many hospital administrators shared that the expense involved in providing infusion services without 340B pricing would mean they would likely not be able to provide it, forcing many patients to travel significant distances to obtain care, especially the uninsured. In other cases, the loss of 340B savings related to infusion services would require hospitals to reduce other forms of discounted services they provide to their low-income patients.
“[The proposed guidance] would drastically reduce access to drugs for patients that are referred to our infusion clinic by other providers. For a majority of these patients they have nowhere else to receive these drugs, as doctor’s offices are not willing to accept the financial risks of treating these under or non-insured patients.”

--DSH Hospital near Flint, MI

“As a critical access hospital, we are staffed by primary care providers - we don’t have specialists ... After a patient’s initial visit with a specialist, we often provide outpatient infusions at our hospital. If we were unable to utilize 340B pricing for our infusions, this could impact our ability to provide infusion services. For example, one Medicaid patient receives infusions every 2 months for rheumatoid arthritis. We carve out Medicaid, so we end up purchasing this on our GPO account. With Medicaid reimbursement, every infusion for this patient results in a $2000 loss for the hospital. Over the course of one year, that comes out to $12,000 for ONE patient. The 340B savings that we receive on our non-Medicaid population helps us to provide these much needed medications to vulnerable patients.”

—Critical Access Hospital near Fargo, ND

“[Under the proposed guidance], patients will no longer have access to chemotherapy and antibiotic infusion treatments close to their homes. Patients will have to travel one or more hours away for treatment.”

—DSH Hospital near Mobile, AL

SECTION 3: CONFLATING BILLING AND PATIENT STATUS FOR OUTPATIENT DRUGS BILLED AS INPATIENT SERVICE CREATES AN ADMINISTRATIVE NIGHTMARE IN THE EMERGENCY ROOM

Often, patients receive outpatient care and are admitted as inpatients shortly after. As it stands, 340B is used to pay for drugs administered during outpatient care, but the billing for those drugs is sometimes bundled with inpatient care. This happens most commonly with emergency room patients who are initially treated as outpatients and later admitted. For example, stroke victims will usually receive Activase in the emergency room or stroke center before they are admitted as inpatients. Under current guidance, how the medication is billed is irrelevant; the patient’s status at the time drugs are administered is the qualifying factor.
PROPOSED CHANGE IN THE GUIDANCE

HRSA has proposed that for 340B to be used the script or order must be written as a result of a service billed as outpatient.

THE ANTICIPATED IMPACT

Because of the proposed guidance’s focus on billing, administering 340B drugs in emergency rooms and stroke units could become an administrative nightmare. Nearly half of survey respondents indicated this measure would be highly problematic to their administration of the 340B program, with 17 percent indicating that they would be motivated to consider dropping out of the 340B program altogether. The impact on 340B hospitals required to use WAC pricing would be even more severe.

Under HRSA’s proposed guidance, many drugs provided in the emergency department or as part of observation services prior to an inpatient stay would be ineligible for 340B discounts due to operation of Medicare’s 72-hour reimbursement rule. This three-day bundling rule states that charges for outpatient services provided in the three days before or on the day of admission to a general acute care hospital must be included in the inpatient charges. For children’s and cancer hospitals, the rule applies to charges for outpatient services provided the day before or the day of admission.
An Office of Inspector General (OIG) report examining the three-day payment window states that its purpose is to “prevent separate reimbursement for preadmission services.” Therefore the three-day bundling rule is a reimbursement rule and does not change the status of the patient who receives preadmission services.

Medicare defines an outpatient as “a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.” Notably, the Medicare bundling rule does not change the status of an individual who is receiving preadmission services from an outpatient to an inpatient. The bundling rule merely dictates how those preadmission services are billed. Thus, there is an inherent conflict between insurance rules, which are designed to control costs, and the 340B statute, which is intended to help covered entities stretch their scarce resources to serve more patients and provide more comprehensive services.

Having inpatient or outpatient status determined through billing is inherently contradictory. The proposed HRSA guidance focuses on the patient’s status when the drug is ordered or prescribed, but also states that HRSA will follow billing rules with respect to the individual’s health care services to determine whether the individual is an outpatient or inpatient. There is no explanation given for why HRSA would focus on how the healthcare services are billed rather than how the patient’s status at the time the drug is used. Individuals who received drugs and services in the three days before an inpatient stay are outpatients “when the drug is ordered or prescribed.” A subsequent admission does not change the individual’s status, and only affects how the hospital bills.

HRSA’s proposed provision linking patient status with billing status presents numerous administrative obstacles for hospitals. This includes requiring them to track hundreds of payer policies, which the hospital may only be aware of after the insurer is billed. For drugs associated with therapeutic services, the hospital would also have to track whether it submitted a certification that the services were not related to the inpatient stay for billing purposes.
Because of this proposal, all settings that are currently 100 percent outpatient, including both clinics and retail pharmacies, would become mixed-use settings because a hospital would not know at the time a drug is dispensed whether the individual would become an inpatient. Under HRSA’s proposed guidance, if a patient develops complications during the infusion and has to be admitted to the hospital, the patient would no longer be eligible to receive 340B drugs. Similarly, if a patient leaves the emergency room and is readmitted as an inpatient within three days, drugs used or prescribed in the emergency room would no longer be 340B-eligible. Given these challenges, 68 percent of respondents felt this measure would be operationally challenging, with 28 percent describing this provision as “not feasible.”

**IN THEIR OWN WORDS**

The survey found that this proposed guidance change, along with other billing requirements, is almost impossible to accommodate with current software and would require such significant changes that many members would consider dropping out of the program altogether.

“**Our system is set up to identify drugs as outpatient based on the patient’s admission time. Medicare doesn’t bundle preadmission services because they don’t think the patient was really an outpatient, but strictly to save Medicare dollars. The patient is still an outpatient until time of admission.**”

—DSH Hospital near Bolivar, MO

“**Reversing and rebilling 340B accumulations for ER patients that get admitted would be an operational challenge, especially if the drug were already replenished on 340B before the patient was admitted...**”

—DSH Hospital near Daytona Beach, FL

“**The requirement to only qualify medications dispensed to patients who were billed as an outpatient status would be so burdensome to our billing department we would re-evaluate the benefits of the 340B program for our hospital. This would also increase the time delay between dispensing a medication and accumulating that medication for repurchase due to the outpatient billing requirement.**”

—Freestanding Children’s Hospital near San Diego, CA

**SECTION 4: A VAGUE DEFINITION OF “INDEPENDENT CONTRACTOR” AND “MAY BILL FOR” SHAPES A PROPOSED GUIDANCE CONTRARY TO STATE LAW AND COMMON HOSPITAL PRACTICE**

Statutes and policies regarding the definition of hospital employees and independent contractors vary wildly from state to state and hospital to hospital. 340B hospitals are currently expected to have an employment, contractual, or some other arrangement with a provider to be able to use 340B for a prescription or order written by that provider, which allows 340B use for prescriptions or orders written by privileged providers. While privileged providers constitute independent contractors in most states, not all states follow that rule.
PROPOSED CHANGE IN THE GUIDANCE

The proposed guidance would require that for a health care professional to write a prescription for a 340B drug, the individual must be an employee or “independent contractor” of the hospital, “such that the covered entity may bill for services on behalf of the provider.” The proposed guidance does not define the term “independent contractor,” but states that “simply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by the privileged provider is a patient of the covered entity for 340B Program purposes.” It is unclear what HRSA intends the term “independent contractor” to mean, nor is it clear what “may bill” should indicate.

THE ANTICIPATED IMPACT

It is especially unclear what HRSA means by the phrase “such that the covered entity may bill for services on behalf of the provider.” This language could be interpreted in several ways including the following:

- The service has been furnished by a provider who has a relationship with the hospital such that the hospital could bill for at least one service rendered by the provider
- The arrangement qualifies for an exception under the Medicare reassignment rules such that the hospital could bill Medicare for the provider’s service. (See 42 C.F.R. § 424.80 and Section 1842(b)(6) of the Social Security Act.)
- The hospital must bill for the provider’s service that resulted in the script for 340B drugs. In other words “may bill” actually means “must bill”
- The provider must furnish a service for which the hospital bills a facility fee
- The hospital “provider” is in a professional category for which his or her services are separately billable (e.g., a nurse practitioner but not a registered nurse)
- It is legal, under state law, for the hospital to bill for the physician’s service

It is unclear which, if any, of these possible meanings was intended by HRSA.
We are concerned that this proposal could mean that a hospital must bill for a provider’s services for the hospital to use 340B for prescriptions or orders written by that provider. Most hospitals cannot bill for their privileged providers, either due to legal restrictions or due to accepted practices in the community.

According to the survey, the majority of respondents directly employ fewer than half of their providers. Seventy-two percent of respondents indicated that they would be unable to bill for the services of physicians they do not directly employ. In fact, a whopping 25 percent reported that they would consider dropping out of the 340B program if this were required. Put simply, if HRSA intends to require such billing, many hospitals could no longer participate in 340B.

Especially disconcerting, HRSA’s proposed requirement ignores state corporate practice of medicine laws, such as those in California and Texas that restrict the right of hospitals to bill for physicians. In strict corporate practice states, corporate entities, including hospitals, are generally prohibited from employing and billing for services of physicians, and physicians who engage in such practices risk loss of their license to practice.

In California, for example, hospitals are prohibited from employing physicians and even billing for their services without a specific employment arrangement, with some narrow exceptions. Instead, physicians providing services in a hospital in California must bill for their own professional services, either directly or through their group practice or foundation.

Like California, Texas physicians are prohibited from entering into employment agreements with corporations, including hospitals, unless a specific exception applies. The corporate practice prohibition also restricts billing and collection arrangements between licensed physicians and corporate entities such as hospitals. Although some county or district-owned hospitals would qualify for an exception, most 340B hospitals would find it impossible to meet this criterion. In states with these restrictions, it would be impossible for 340B hospitals to meet the “may bill for” test. This requirement would create an uneven playing field in which hospitals in some states could access 340B drugs while similarly situated hospitals in other states could not.

In Illinois, on the other hand, courts view billing by hospitals for their providers’ services as a likely indicator that the provider is actually a hospital employee, rather than an independent contractor. There are a series of tax and other obligations that would be placed on hospitals forced to treat their independent contractors as employees. It does not make sense that hospitals would have to incur such obligations as a consequence of participating in the 340B program.

Another possible interpretation of this proposed provision is that HRSA is confirming its existing policy that use of 340B does not extend to prescriptions written in connection with care furnished at non-hospital sites simply because they are prescribed by a provider with hospital privileges. If this is HRSA’s meaning, then scripts related to services provided at the hospital by providers with hospital privileges would permit use of 340B and the condition should be revised to make that clear.

The vast majority of provider-hospital relationships involve only privileging agreements. This interpretation would be consistent with the fact that most case law interpreting provider-hospital relationships conclude providers with privileges are either employees or independent contractors of the hospital. However, there is no universal test to determine whether a provider is an independent contractor of a hospital. Whether an individual can be properly categorized as an employee or an independent contractor for federal tax purposes is a fact-specific analysis, which focuses on the degree of control over the individual providing the service.
Additionally, the many state tort law cases distinguishing between independent contractors and employees do not identify the minimum criteria necessary for a provider to qualify as an independent contractor. Instead, courts generally engage in a variety of multifactor balancing tests to discern whether a person constitutes an employee rather than an independent contractor. There are even occasional cases that place privileged providers in categories other than employee or independent contractor.

**IN THEIR OWN WORDS**

Many respondents expressed concerns that they cannot bill for all of the doctors credentialed with their hospital.

“The in-house pharmacy savings would decrease dramatically due to the fact that the hospital does not bill for the professional services of 80 percent of the doctors currently credentialed with us.”

—DSH Hospital

“[Infusion center] providers are privileged/credentialed but not employed. We may be able to place a contract, but likely unable to bill for their services. Exiting the program for this reason would cost the hospital approximately $4.5 million annually in lost savings.”

—DSH Hospital near Chicago, IL

“We are still responsible for the patient care regardless of who bills for the doctor’s services. If we were to get in a fight with our largest independent physicians saying we have to take over their billing, we would risk losing their services.”

—DSH Hospital near Marshfield, MO

“Since most of our providers only have privileges, our 340B savings would be drastically decreased. Existing programs that have been put in place to help our most vulnerable patients would have to be scaled back or even cut.”

—DSH Hospital near Rapid City, SD

**RECOMMENDATIONS**

The 340B Drug Pricing Program was conceived to help keep safety-net providers running and able to serve vulnerable patients. The parts of HRSA’s proposed guidance highlighted here have the potential to effectively negate that purpose. Instead of streamlining the law’s practice, it complicates how hospitals might administer the 340B program and could force many safety-net hospitals to opt out of the program, hurting patients and communities in the process. Especially worrisome is the cumulative impact of these proposals, which could jeopardize the use of 340B and role of 340B hospitals.

To protect the original intent of the 340B program, HRSA should revise the problematic provisions outlined in this survey and consider other changes to provide further clarity to covered entities.
HRSA SHOULD ALLOW DISCHARGE PRESCRIPTIONS TO QUALIFY FOR 340B TO CUT DOWN ON READMISSIONS

HRSA should continue its policy of permitting 340B pricing to be used for prescriptions issued upon discharge of an inpatient for the patient’s use outside the hospital. Discharge prescriptions are essential to limiting gaps in patient care and readmissions. There is no danger of 340B being used for drugs actually used on an inpatient basis because of the statutory requirement that 340B apply only to covered outpatient drugs. Additionally, HRSA should specifically permit registration of hospitals’ provider-based offsite inpatient locations in some manner so that discharge prescriptions issued to those patients may be filled with 340B priced drugs.

HRSA SHOULD ALLOW OUTSIDE INFUSION ORDERS TO QUALIFY FOR 340B TO KEEP CARE CLOSE TO HOME

HRSA should add “or administered during” after “as a result of” in the text of the proposed guidance to ensure that hospitals are not prohibited from using 340B pricing for outpatient drugs that they administer to their patients. All efforts should be made to allow hospitals to continue administering infusion orders written off-site. Without discounted infusion care close to home, many patients would expend more time and money getting their care. Others would forego care altogether.

340B POLICIES SHOULD NOT BE BASED ON A SINGLE INSURER

HRSA should re-evaluate or rescind the 72-hour restriction. In addition to putting billing above patient status, the nature of the 72-hour rule varies across hospital type. Acute care hospitals are subject to a three-day bundling rule, children’s and cancer hospitals are subject to a one day bundling rule and CAHs are not subject to preadmission bundling rules. This distinction makes sense in a Medicare reimbursement context because these categories of hospitals are each paid under different reimbursement systems. Treating patients of these hospitals differently for 340B purposes, however, is arbitrary and capricious.

These rules are also likely to change soon. The OIG has recommended that the Centers for Medicare and Medicaid Services propose legislation to extend the three-day bundling rule to 14 days. If it does so, prescriptions that are currently eligible to be filled with 340B drugs would no longer be eligible. HRSA should not allow the definition of patient to be dependent on the policies of a government or private insurer.

HRSA NEEDS TO CLEARLY DEFINE WHAT IT MEANS BY “INDEPENDENT CONTRACTOR” AND “MAY BILL FOR”

Given the vagueness surrounding the definition of both “independent contractor” and the “may bill for” test, the variability of state law and the lack of any clear 340B policy being served, HRSA should eliminate this criterion from the proposed guidance. Alternatively, HRSA could revise this condition so that it is consistent with current policy. This proposal would replace the “independent contractor” language with language requiring that the provider have hospital privileges and drop the “may bill” language. If HRSA is unwilling to do this, then HRSA should re-issue this provision for comment with additional clarification as to its interpretation.

WE NEED 340B TO KEEP THE SAFETY NET RUNNING
340B was designed to keep America’s safety net strong, but HRSA’s proposed guidance does the opposite of that. Instead of clarifying implementation of this program, the proposed omnibus guidance further confuses it and would make the guidance governing 340B so convoluted as to make the program useless for many participating hospitals. Without these savings, many discounted services would have to be cut. Some hospital administrators fear they would have to close infusion centers that treat patients close to home or discharge prescription programs that bridge gaps in care to keep patients healthy. This survey shows that if HRSA shares 340B’s initial mission, its proposed changes to the program need to be seriously reconsidered.