



**American Hospital
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October 27, 2015

Krista Pedley, PharmD, MS
Captain, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
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RE: 340B Drug Pricing Program Omnibus Guidance – HRSA RIN 0906-AB08, (Vol. 80, No. 167, August 28, 2015)

Dear Captain Pedley:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including nearly 2,000 hospitals that participate in the 340B Drug Pricing Program (340B program), the American Hospital Association (AHA) welcomes the opportunity to comment on the Health Resources and Services Administration's (HRSA) proposed omnibus guidance for the 340B program. The AHA appreciates HRSA's long stewardship of the 340B program and its efforts to provide guidance to fulfill the program's original intent – to stretch scarce federal resources to expand and improve access to comprehensive health care services for our nation's most vulnerable patients.

While we support certain proposals in the guidance, such as those related to telemedicine and group purchasing organization (GPO) exceptions, we have serious concerns about others, many of which are proposed without basis or justification. Overall, the proposed guidance does nothing to help patients – the biggest beneficiary would be the pharmaceutical industry. **We are particularly concerned about the agency's patient eligibility proposals, which move away from defining an eligible 340B patient in terms of his or her relationship with the hospital.** For example, HRSA's proposal that a prescription must be the result of a billable outpatient event in order to qualify for 340B drug discount pricing appears to exclude observation and emergency department (ED) visits when they lead to an inpatient admission. In addition, patients receiving "only" infusion services would not be eligible for 340B drug discounts.

Taken together, HRSA's proposals would significantly reduce the volume of drugs eligible for 340B drug discount pricing, jeopardizing hospitals' ability to serve the most disadvantaged patients in our society, including low-income patients, uninsured patients and patients receiving cancer treatments. As such, the AHA urges HRSA to revise significantly its proposed guidance to allow hospitals to continue their work advancing the health of individuals and communities, even in the face of the skyrocketing cost of pharmaceuticals.



The rapidly increasing drug prices are presenting hospitals and their patients with remarkable challenges. The Centers for Medicare & Medicaid Services says drug spending is projected to have accelerated from 2.5 percent in 2013 to 12.6 percent in 2014¹. Meanwhile, an analysis by *Forbes* notes that pharmaceutical companies averaged an 18 percent profit in 2013 – with the largest company posting a 42 percent profit.² Compare that to 340B hospitals, which had an average operating margin of 3.9 percent in 2013, and one out of three 340B hospitals had a negative margin.³ **We are concerned that HRSA’s proposals would only exacerbate these disparities, and we urge the agency to modify its guidance so that it strikes a much more appropriate balance between requirements imposed on hospitals and those imposed on the pharmaceutical industry.**

PATIENT DEFINITION

The AHA appreciates HRSA’s efforts in the proposed guidance to provide 340B hospitals and other covered entities with greater clarity around HRSA’s view of the definition of an eligible 340B patient. **However, we are concerned that, rather than providing clarity, HRSA has instead redefined patient eligibility in a way that would narrow inappropriately the number of drugs that qualify for 340B pricing. Given that 340B hospitals serve many of the nation’s poorest patients and underserved communities, such a contraction would threaten access to care for patients who need care the most.**

Infusion Services. The AHA strongly opposes HRSA’s proposal that a patient receiving “only” infusion services would not be an eligible 340B patient. We recommend withdrawing this proposal so that patients receiving infusion services provided at 340B hospitals or their outpatient sites continue to qualify for 340B drug discount pricing. HRSA’s current guidance, as communicated by its 340B Prime Vendor Program, allows 340B eligibility for infusion services provided by a hospital if all other aspects of the current patient definition are met.⁴ However, the agency’s proposals would reverse the current guidance by stating that a patient receiving “only” infusion services would not be an eligible 340B patient. Even more troubling is that HRSA proposes this guidance without any explanation or justification – it appears to be completely arbitrary.

Again, we are extremely concerned about the harmful effect this proposal would have on patients’ access to care. For example, critical oncology drugs have undergone extraordinary price increases. A recent study found that the average launch price of oncology drugs, adjusted for inflation and health benefits, *increased by 10 percent annually, or an average of \$8,500 per year, for almost 20 consecutive years* – from 1995 to 2013.⁵ 340B hospitals that provide cancer and other costly infusion services for underserved communities depend on 340B drug discount pricing to provide these vital services. Without the availability of such pricing, patients may lose access to these critical services. For example, patients in rural areas may be unable, due to their medical condition, age, or other factors, to travel to urban areas to receive these services;

¹ Sean Keehan, Gigi Cuckler, Andrea Sisko, Andrew Madison, Sheila Smith, Devin Stone, John Poisal, Christian Wolfe, and Joseph Lizonitz “National Health Expenditure Projections, 2014–24: Spending Growth Faster Than Recent Trends Health Affairs,” vol. 34 no. 8 1407-1417, (August 2015)

² *Forbes* <http://www.bbc.com/news/business-28212223>. November 6, 2014

³ American Hospital Association 2013 Annual Survey.

⁴ 340B Prime Vendor Program Frequently Asked Question Infusion Services 11/20/2014

www.340bpvp.com/resourceCenter/faqSearch.html?category=content&Ntt=infusion+services.

⁵ David Howard, Peter Bach, Ernst Berndt, and Rena Conti, “Pricing in the Market for Anticancer Drugs,” *Journal of Economic Perspectives*, vol. 29, no. 1 (Winter 2015): 139-162.

availability near their home vastly improves their quality of care and quality of life. About half of 340B hospitals are located in rural areas, and almost half of them offer vital chemotherapy services to their patient populations⁶ – this access point would be severely endangered under HRSA’s proposal.

Further, the proposed change seems to reflect a misunderstanding of the nature of infusion services and whether they can be provided in isolation. Typically, infusion patients have a close relationship with the providing hospital – the hospital assumes a clinical and legal responsibility for that patient and also provides them with other health care services, such as laboratory, nursing and monitoring services. In fact, in many cases, these other services are required by state licensure or Medicare policies, such as the conditions of participation. Again, it is clear that patients receiving infusion services at a hospital or hospital-based outpatient site are patients of the hospital; therefore, they should be defined as eligible 340B patients.

Billable Outpatient Event. The proposed guidance would limit 340B pricing to drugs ordered or prescribed to the patient when the patient has an outpatient billable event. **The AHA strongly opposes this proposal, which, again, was set forth without justification or basis. We believe that all outpatient drugs should be considered as such for purposes of the 340B program, regardless of the method under which these drugs or their associated services are billed or reimbursed. Therefore, rather than implementing its overly restrictive proposal, we recommend that HRSA avail itself of existing methods, which are discussed below, for ensuring that 340B drug discount pricing applies only for drugs that are for outpatient use.**

Under the proposed guidance, it appears that inpatients discharged from hospitals with prescriptions would not qualify as 340B eligible patients for purposes of getting their prescriptions filled by the hospital pharmacy or in a retail pharmacy setting. Yet, current guidance allows for 340B drug discount pricing to apply to discharge prescriptions to the extent that the drugs are for outpatient use.⁷ It also provides for a method to ensure that these drugs are for outpatient use, requiring 340B hospitals to be able to document that these discharge prescriptions are for outpatient use and are not used in the inpatient setting. Indeed, many 340B hospitals have relied on HRSA’s existing policy as they develop programs to reduce avoidable readmissions for their low-income patients. The ability to use 340B drug pricing for these discharge prescriptions is consistent with the objectives of the 340B program to provide access to pharmaceuticals to low-income populations.⁸ It also is consistent with the national health care objective to reduce avoidable readmissions.

In addition, under HRSA’s proposed guidance, it appears that patients receiving treatment in outpatient observation or the ED that leads to an inpatient admission would no longer qualify as an eligible patient, even if that patient receives drugs while in the outpatient observation or ED setting. We acknowledge that Medicare’s 72-hour billing rules require that all diagnostic or outpatient services furnished to a Medicare patient in the three days prior to an inpatient admission be bundled in the inpatient bill for reimbursement.⁹ However, hospitals typically

⁶ American Hospital Association 2013 Annual Survey.

⁷ 340B Prime Vendor Program Frequently Asked Question Infusion Services 09/15/2014
www.340bpvp.com/resourceCenter/faqSearch.html?category=content&Ntt=discharge+prescriptions.

⁸ U.S. House, Committee on Veterans Affairs, “Establishment of Limits on Prices of Drugs Procured by the Department of Veterans Affairs (to accompany H.R. 2890),” H. Rept. 102-384, Pt. 2, 1992.

⁹ Centers for Medicare & Medicaid Services Frequently Asked Questions 6/14/2014
www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/downloads/cr7502-faq.pdf.

document in a patient's medical record whether a drug is administered in the outpatient or inpatient setting. Therefore, there is a documentation mechanism available to ensure that these drugs are for outpatient use.

Provider Employed or Independent Contractor. The AHA recommends that HRSA remove from the proposed patient definition the requirement that a patient receive health care services from a provider who is either an employee or independent contractor of a hospital, such that the hospital may bill for services on their behalf. The proposed change is a clear and troubling departure from HRSA's current guidance, which defines a health care provider for purposes of the patient definition as a health care professional who is either employed by or provides health care under contractual or other arrangements (e.g., referral for consultation) for the covered entity, such that responsibility for the care provided remains with the covered entity.¹⁰ HRSA's proposed change fails to reflect the many types of relationship hospitals have with their physicians and ignores the complex health care environment. For example, many states, including California, New Jersey, Tennessee and Texas have strict corporate practice of medicine laws that both prohibit a hospital from employing physicians and limit their ability to contract directly with physicians. In addition, many 340B hospitals, particularly those located in vulnerable rural and inner city communities, face substantial challenges attracting physicians willing to enter into an employment or independent contractor relationship. For certain hospitals, the proposed guidance looks to preclude bona fide faculty practice plan relationships that do not necessarily include an employment relationship. Moreover, the proposal is inconsistent with payer coverage rules, including Medicare's, that do not condition coverage or payment on whether or not a written prescription order is from a hospital employee or independent contractor.

In addition, HRSA's proposal adds another degree of confusion with the phrase "may bill for services on behalf of the provider." Specifically, it is not clear whether this phrase refers to the services hospitals bill in connection with services furnished by a provider (such as the facility fee), or to the professional services furnished by the provider. **However, what remains clear and unambiguous is that a patient receiving health care services in a hospital or hospital-based outpatient facility is a patient of the hospital. HRSA should continue to base its definition on the relationship between the patient and the hospital – not on arbitrary provider billing, employment or contractual statuses.**

Telemedicine. The AHA is pleased that HRSA, in its proposed revision to the patient definition, recognizes the increasing use of telemedicine and telepharmacy to improve patient access to needed services, particularly for geographically remote areas. **The AHA urges HRSA to continue to include use of telemedicine in the definition of eligible 340B patient.**

Information System Changes. We are concerned that HRSA's proposed changes in the patient definition would require information tracking systems and software that do not currently exist. For example, a hospital would need to determine if a patient is eligible for a 340B drug at the time the prescription is written, rather than at the time the 340B drug is dispensed. **HRSA must consider not only the added burden these new information systems would represent for 340B hospitals that are already faced with many demands to expand their health information systems, but also the time that any change of this magnitude would require to implement.**

¹⁰ 61 Fed. Reg. 55156 (October 24, 1996).

COVERED OUTPATIENT DRUGS

The AHA opposes HRSA’s proposal to exclude from 340B drug discount pricing outpatient drugs that are reimbursed as part of a bundled Medicaid payment. The 340B statute defines “covered outpatient drug” by referencing the Medicaid rebate statute. In the proposed guidance, HRSA has elected to apply an aspect of the Medicaid rebate statutory definition referred to as the “limiting definition.”¹¹ The effect of applying this “limiting definition” to Medicaid outpatient drugs is that any Medicaid drug reimbursed as part of a bundled payment is excluded from the definition of a covered outpatient drug and is not eligible for the 340B drug discount.

For 340B hospitals that serve a large Medicaid patient population, this new interpretation of “covered outpatient drug” would strain already tight financial budgets. Moreover, these 340B hospitals would be faced with the added burden of tracking these drugs in terms of whether they are in the reimbursement bundle or not. Finally, in many states the Medicaid program is undergoing significant transformation, moving from volume-based reimbursement to value-based reimbursement, in which bundled payments are often used. **HRSA’s recommendation seems to contradict the health care field’s efforts to move from volume to value, since the only way to obtain a 340B drug discount for drugs provided to Medicaid patients would be to unbundle payments.**

In addition, the guidance also suggests that hospitals affected by the Medicaid bundled payment provision would possibly be able to use their GPO in purchasing outpatient Medicaid drugs. The AHA asks HRSA to provide greater clarity and assurance on this provision given the threat of expulsion from the 340B program for GPO violations.

HOSPITAL ELIGIBILITY AND OFF-SITE OUTPATIENT CLINICS

Nonprofit 340B Hospital Eligibility. The AHA recommends that HRSA clarify its proposed criterion that private nonprofit 340B hospitals’ contracts with state or local governments “...should create enforceable expectations for the hospital for the provision of health care services, including the provision of direct medical care.” The discussion in the proposed guidance neither defines what constitutes an ‘enforceable expectation’ nor elaborates on how exactly HRSA intends to apply this new criterion. Absent such clarity, affected 340B hospitals are unclear if this criteria would be applied during the recertification process or added to the audit criteria.

Off-Site Outpatient Clinics. The proposed guidance reiterates current HRSA policy stating that to qualify for the 340B program, hospital outpatient facilities must be listed on their hospital’s Medicare cost report. However, the AHA appreciates HRSA’s willingness to consider an alternative approach. **The AHA recommends HRSA consider CMS’s Medicare enrollment process for determining eligibility for off-site outpatient clinics.** Specifically, hospitals can enroll off-site outpatient clinics in Medicare through CMS’s Internet-based form CMS-855. Using Medicare’s enrollment process to determine eligibility would allow greater flexibility in determining the eligibility of off-site clinics that may not appear as reimbursable on the 340B hospital’s Medicare cost report. Further, the use of Medicare’s enrollment process also would allow the hospital outpatient off-site clinic to enter into the 340B program at an earlier date instead of having to wait until the off-site clinic appears on the filed Medicare cost report.

¹¹ 80 Fed. Reg. 52305 (August 28, 2015).

Accordingly, the AHA also recommends that HRSA remove the requirement from the proposed guidance that hospital off-site clinics must have associated outpatient Medicare costs and charges. This new requirement would jeopardize a number of hospital outpatient off-site clinics that serve indigent, pediatric or obstetric patient populations that typically do not include Medicare outpatients. Such clinics are pervasive in hospitals – nearly a quarter of all 340B AHA member hospitals reported having a dedicated indigent care clinic in 2013.

GPO PROHIBITION FOR CERTAIN 340B HOSPITALS

GPO Exceptions. The AHA supports HRSA’s proposed exceptions to its current GPO prohibition policy. Specifically, the proposed guidance would allow exceptions to the GPO prohibition for:

- Hospital off-site outpatient facilities not registered in the 340B program;
- Inpatients reclassified as outpatients by a third-party insurer, Medicare Recovery Audit Contractor or hospital review, as long as the patients’ status is documented; and
- Situations where patient care would be disrupted if the hospital could not access a drug at 340B prices or wholesale acquisition cost.

In addition, the AHA recommends another exception to the GPO prohibition policy: to allow a clinic within the four walls of a hospital to opt-out of the 340B program with appropriate documentation. Current HRSA policy requires hospital clinics within the four walls of the hospital to purchase outpatient drugs at the higher Wholesale Acquisition Cost rather than the discounted GPO price if that clinic serves a patient population that may not meet the definition of eligible 340B patient. **We also recommend that HRSA implement a monetary “materiality standard” (threshold) that any GPO violation would be required to meet before program expulsion would be considered.** HRSA could look to the materiality standards it uses in its 340B hospital recertification process. In the case that erroneous GPO purchases do not exceed the materiality threshold, HRSA should permit a corrective action, such as a credit or payment adjust of GPO purchases, instead of expulsion.

CONTRACT PHARMACY ARRANGEMENTS

Contract Pharmacy Review and Audits. The AHA recommends that HRSA provide further clarification of the proposed requirement that 340B hospitals with contract pharmacy arrangements conduct an annual independent audit and quarterly reviews. We have encouraged our 340B member hospitals with contract pharmacy arrangements to conduct self-audits on a regular basis. However, because HRSA holds 340B hospitals ultimately responsible for whether their contract arrangements are compliant with program requirements, it would be helpful if HRSA could provide more information on what specific compliance elements should be included in the reviews and annual audits. In addition, HRSA should consider tailoring these additional review and audit requirements to the size of the hospital’s contract pharmacy program. This may minimize the added burden for small and rural 340B hospitals with limited resources.

DUPLICATE DISCOUNTS

The AHA supports HRSA’s general direction with regard to allowing 340B hospitals to determine whether Medicaid patients are included or not included in the 340B drug discount pricing program for both Medicaid fee-for-service and managed care patients. However, we are concerned that the burden to prevent duplicate discounts has historically been

placed on the hospitals. Indeed, duplicate discounts occur when a *manufacturer* provides a 340B drug to a Medicaid patient for which the state Medicaid program will seek a rebate on that same drug. Therefore, the AHA recommends that HRSA engage with state Medicaid programs and Medicaid managed care plans to find ways to identify more easily Medicaid managed care patients to avoid a duplicate discount scenario.

PROGRAM INTEGRITY

Inventory Management. The AHA recommends that HRSA clarify that improper accumulations that occur in a 340B hospital's inventory management system prior to the hospital placing a GPO or 340B purchase order should not be considered drug diversion. HRSA should allow 340B hospitals the opportunity to address problems with their inventory management systems that utilize inventory replenishment models where the drug accumulator makes a mistake and the hospital can step in prior to the purchase of a drug.

Hearings and Appeals. The AHA supports HRSA's recommendation to establish a notice and hearings process to give all covered entities a formal opportunity to respond to adverse findings. The process, as proposed in the guidance, would be initiated by a written notice that would specify a 30-day response deadline by the covered entity. Hospitals and other covered entities found to be out of compliance would have an opportunity to submit a corrective action plan subject to review and approval by HRSA. The AHA further recommends that HRSA provide greater structure to the hearings and appeals process and look to other models, such as CMS's Administrative Law Judge system.

Hospital Record Keeping Requirements. HRSA proposes to require that hospitals maintain five years of auditable records. The AHA recommends that the agency also institute a parallel policy to limit audits to a five year look-back period. Further, the AHA is supportive of HRSA's effort to manage and limit the number of audits that can be conducted at a time at any given hospital, "child site" or contract pharmacy. This proposed audit limitation would include drug manufacturer audits.

DRUG MANUFACTURER PROGRAM INTEGRITY REQUIREMENTS

Recertification. The AHA supports HRSA's proposal to require that drug manufacturers submit to an annual recertification process similar to the recertification process required for hospitals and health clinics. Specifically, manufacturers would be required to attest that they are compliant with 340B program pricing requirements, and HRSA would list all certified manufactures on its public 340B database.

Hospital Audits by Drug Manufacturers. The AHA supports HRSA's proposals to require that drug manufacturers follow government auditing standards when conducting audits of 340B hospitals. Additionally, the proposed guidance further requires that drug manufactures provide 340B hospitals adequate notice of when the audit will take place and an opportunity to submit a corrective action plan.

Limited distribution. The AHA urges HRSA to apply greater oversight to drug manufacturers that choose to limit the distribution of a drug. HRSA stipulates in the proposed guidance that drug manufacturers can choose a limited distribution if the following conditions are met:

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- if required by a Food and Drug Administration risk evaluation and mitigation strategy;
- if there are special handling requirements for certain drugs; or
- if there is a limited supply of certain drugs.

While the proposed guidance expresses concern that limited distribution agreements for drug manufacturers should not result in limiting drug supplies in a discriminatory fashion or to discourage covered entities from participating in the program, we urge HRSA to exert greater oversight. As it stands, the proposed guidance would only require drug manufactures to provide written notification when choosing a limited drug distribution. HRSA should investigate when drug manufactures frequently resort to limited distribution of drugs as possible circumvention of 340B drug pricing.

EFFECTIVE DATE OF GUIDANCE

The AHA recommends that the effective date of the 340B omnibus guidance be no less than 12 months after the date the final guidance is published in the Federal Register. In the proposed guidance, HRSA makes no mention of an effective date. An explicit effective date as recommended above would clarify when the guidance would apply, and it also would allow 340B hospitals sufficient time to make the appropriate internal policy and health information technology changes.

The AHA and our 340B member hospitals appreciate the opportunity to share with you our concerns and questions. We share the common goal of ensuring that the 340B program can continue to help fulfill its original intent of helping hospitals stretch limited resources to expand and improve access to comprehensive health care services to low-income patients. The increasingly high cost of pharmaceuticals has continued to underscore the importance of the 340B program in helping achieve this goal. To that end, we encourage you to continue to strive for the right balance between requirements imposed on hospitals and those imposed on pharmaceutical manufacturers.

The AHA looks forward to working with you, your staff and all stakeholders. If you have any questions, please contact me or Molly Collins Offner, AHA director of policy, at (202) 626-2324 or mcollins@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President