TEACHING HOSPITALS of TEXAS

THOT Members

AUSTIN
Central Health
Seton Healthcare Family

CORPUS CHRISTI
CHRISTUS Spohn Health System
Nueces County Hospital District

DALLAS
Children's Health System of Texas
Parkland Health & Hospital System
The University of Texas Southwestern Medical Center

EL PASO
University Medical Center of El Paso

FORT WORTH
JPS Health Network

GALVESTON
The University of Texas Medical Branch

HOUSTON
Harris Health System
The University of Texas MD Anderson Cancer Center

LUBBOCK
UMC Health System of Lubbock

MIDLAND
Midland Memorial Hospital

ODESSA
Medical Center Health System

SAN ANTONIO
University Health System

TYLER
UT Health Northeast

VICTORIA
Citizens Medical Center

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
RIN 0906-AB08
340B Drug Pricing Program Omnibus Guidance

October 27, 2015

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Rockville, MD 20857

By E-mail to: 340BGuidelines@hrsa.gov.
Subject: RIN 0906-AB08
Vol. 80, No. 167, August 28, 2015
Comments on 340B Drug Pricing Program Omnibus Guidance

Dear Captain Pedley:

Thank you for the opportunity to provide comments on HRSA's proposed 340B Omnibus Guidance. Members of the Teaching Hospitals of Texas (THOT) include the state's largest providers of Medicaid and health care for the uninsured. Our members are brought together by shared commitments to: support access to care for all in our communities with a special focus on vulnerable populations; to provide and coordinate essential community health services such as trauma and disaster management; and to train tomorrow's healthcare providers while supporting research and healthcare transformation. We are committed to investing our resources to support our bottom line of improved health in our communities.

We believe the proposed guidance will have a **significant negative impact** on the health of our patients and the health of our communities by reducing access to affordable prescriptions, and through related cost increases, by reducing access to outpatient primary, specialty and chronic care services. Much of the outpatient primary, specialty and chronic care healthcare services our members provide operate at full capacity. Because of our mission, our high uninsured and

Medicaid patient populations, and our limited local funding, reduced access to 340B discounts **will result in contraction of services and reduced access to care for our patient populations.**

Furthermore, several of HRSA's proposed changes have no documented policy basis yet have a significant detrimental impact to patient care and are contrary to the original and consistent intent of the program. As such, these proposed changes are arbitrary and capricious. In addition, THOT concurs with America's Essential Hospitals' argument that the proposed sweeping changes are beyond HRSA's statutory authority to make. We would look forward to discussing these comments with you and having you speak with one of our many committed health system and 340B providers.

The comments below express our general concerns and recommendations followed by specific concerns and related recommendations.

General Impact:

HRSA is faced with growing demand for 340B access, the pharmaceutical companies' concerns about the related financial impact, and a need for increased clarity in the 340B program requirements. At the same time, HHS is committed to investing in and supporting the Triple Aim[1] as a core principle of its health mission, and maintaining the original[2] and amended (by e.g., the Affordable Care Act[3]) intent of the 340B legislation.

HRSA's attempt to resolve these tensions with the proposed Guidance has the unintended effect of shifting the health system's focus away from the access and care provided **through a patient-centered perspective** (what is best for the care of each patient over time) and away from the Triple Aim, to a discrete, disruptive prescription by prescription perspective. This shift and this guidance will result in outcomes contrary to the Triple Aim. **As proposed, the Omnibus Guidance does not best serve the program intent, our low income patients, or larger health care goals.**

Access to discounted 340B drugs makes possible care to low income populations that would not otherwise be available to them. Our members are already facing a double-digit[4] annual growth rate in pharmaceutical costs. Compounding that rate of cost growth, reduced access to 340B drugs (in particular for providers such as THOT's essential safety net providers), will result in one or more of the following, each of which will reduce access to care for low-income vulnerable populations:

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[1] The Triple Aim is defined as: improving the individual experience of care; improving the health of populations; and reducing the per capita costs of care for population. http://content.healthaffairs.org/content/27/3/759.full

[2] The intent of the 340B Program is to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Ryan White clinics for care of HIV patients are among those originally included.

[3] The ACA added children's and freestanding cancer hospitals.

[4] Harris Health in Houston for example reports a 15.4% annual cost growth for pharmaceuticals. Depending on utilization patterns, different providers' rates may vary.

- Health systems will need to increase cost sharing for indigent populations to make up for reductions in 340B. With low income patients expected to pay more for the costs of their drugs, our experience is that, in many cases, patients will go without.
- Health systems will reduce coverage levels for indigent care programs, leaving individuals who currently have access to indigent healthcare with no access to healthcare services and no access to affordable drugs.
- Health systems will reduce health care services, programs and access to new drug treatments provided to vulnerable populations in the community to adapt to financial losses related to lost 340B discounts.

As access to health care and affordable prescriptions contracts, health systems will see avoidable reductions in individual and population health, increased and more expensive visits to emergency departments, increased avoidable disease and related costs such as Potentially Preventable Readmissions (PPRs) and other preventable health events. To have the Department of Health and Human Services penalize hospitals for PPRs while at the same time providing guidance that will increase PPRs sends a mixed message and hinders providers' ability to manage care to reduce avoidable PPRs.

One of our members with a 1.1% margin representing about $10 million, a payer mix that includes 34% Medicaid, and nearly half a billion dollars in uncompensated care annually, would, as a result of proposed guidance lose nearly $31 million. For a health system so clearly committed to providing care to vulnerable populations, the proposed guidance would directly result in reduced access to care and reduced community health.

In addition to reducing access, key program changes included in the proposed guidance are ambiguous (e.g., the "may bill" criterion). This leads to increased complexity and more costs to program operations, administration and oversight.

THOT strongly recommends that:

1. HRSA withdraw its proposed patient definition.

2. Failing that, we recommend that any changes made be made in alignment with the Triple Aim; and more specifically:

3. Any changes made ensure that those providers with a documented commitment to caring for a significant and disproportionate share of low income individuals have a continued ability to access 340B drugs for eligible patients' care across the spectrum of coordinated care services including for discharge prescriptions, referrals for care, infusion services in outpatient settings and other services in settings where Medicare need not be provided.

Ideally, in its guidance, HRSA would be able to create guidelines that provide clarification and protections against abuse without impairing patient care, access and broader HHS program goals such as the triple aim. In addition to providing its own comments, THOT supports the comments submitted by

America's Essential Hospitals as well as our individual member organizations including Harris Health in Houston, Texas.

Key issues with the proposed 340B mega-guidance, as well as recommended changes are identified below.

Key Issues:

1. Issue: Drugs provided to a patient upon discharge from the hospital would no longer qualify for 340B pricing.
    a. Reason: Under the proposed new definition of a qualifying patient, this guidance would exclude prescriptions provided at the time of discharge from an inpatient hospital stay. .

    b. Implications for care, access and cost: Being able to provide 340B drugs at discharge ensures that patients get prescriptions they need to follow treatment plans, to recover, and to avoid a hospital readmission. This proposed limitation of 340B drugs would create an unnecessary obstacle to care for patients at discharge. By requiring another stop, and a greater expense, patients most at need would be less likely to obtain and take required prescriptions. This new requirement/exclusion will reduce the quality of care while increasing the likelihood of readmissions and related avoidable costs of care for the patient, provider and health system. In addition, information system and policy changes to support the "may bill" criterion will increase administrative costs and program complexity and divert program focus and resources available for patient care.

    c. Reference to Guidance: HRSA Proposed Patient Definition Prong #5: The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.

    d. Recommended changes:

        i. Do not change the patient definition.
        ii. Include in any new patient definition an exception to allow for 340B pricing for discharge prescriptions subsequent to an inpatient hospital stay.

    e. Data:
        i. One of our members, University Health System in San Antonio, estimates cost increases of nearly $1 million per year ($950,000) related to increased costs for discharge pharmacy acquisition costs.
        ii. Harris Health, one of our larger members estimated costs of $800,000 up to $1.8 million if all discharge prescriptions are affected.
        iii. In addition to data from specific, typically larger members, we've created a smaller composite hospital based on member data to show the impacts to an illustrative smaller health system. This composite system is in a community with 40% uninsured and a higher than average poverty rate (23% compared to 17.6% statewide[5]). It has positive net assets of

[5] http://quickfacts.census.gov/qfd/states/48/48141.html

$3 million. The overall impact of the guidance would be a loss of $5 million in increased costs annually; bringing this system to a negative margin. The specific impact of excluding 340B pricing for discharges would increase costs by almost one-half million dollars or over 16% of the hospital's net margin.

2. Issues: Access to prescriptions related to referrals for care including critical specialty care and to chemotherapy and other infusion services would be reduced under the proposed guidance. Drugs prescribed by outpatient providers including specialists as well as drugs used for services such as outpatient chemotherapy could be ineligible for 340B pricing. In systems of care committed to low income populations, reductions in discounts will lead directly to health service contraction and reduced access, especially for access to cost-effective outpatient clinics and care.

    a. Reason: The guidance includes as a criterion for use of 340B drugs that a covered entity's patients must receive services from a provider that is employed by the covered entity or that is a contractor for the entity such that the covered entity "may bill" on behalf of the provider. In addition, because infusion services may be provided in outpatient settings with providers who may not meet the "may bill" criteria, access to 340B infusion services under the proposed guidance will also threaten infusion services. (See Issue #4 for another component of the proposed guidance that directly prohibits 340B for outpatient infusion services.)

    Providers with a commitment to care for low income populations may use contracted providers including referral specialists for access to specialty services that augment the care provided directly by a hospital system's outpatient clinics. In addition, hospital and care systems provide care such as chemotherapy and other infusion services on an outpatient basis where possible to increase access while reducing costs.

    In some states such as Texas, hospitals are generally prohibited from employing physicians, with some exceptions. The impact of this requirement therefor has a disproportionate impact on states like Texas.

    In addition, the guidance's "may bill" test for determining whether prescriptions by certain outpatient providers are or are not 340B eligible is unclear. What "may bill" means, how it would be assessed and how it could be put into operation and documented for compliance and audit, are all unclear leaving access to outpatient specialists and infusion centers and related prescriptions at risk.

    b. Implications for care, access and cost: Referrals to those affiliated and referral providers and specialist providers are critical to provide continuity of care and needed services. If the covered entity is not able to bill for those providers, or if the "may bill" criterion is required, access to 340B will be denied and care compromised. Reduced access to affordable drugs

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For the period 2009 – 2013 see census document above.

prescribed by specialists as part of their care plans for patients will result in poorer health, poorer outcomes and avoidable recurring care needs and/or incomplete treatments.

Our members provide Graduate Medical Education (GME); a mission which generates net financial costs to our members. Some patient care is provided by medical school faculty and residents at our health systems, including in outpatient clinics. However, the "may bill" requirements put at risk the ability of affiliated providers including GME providers, to provide 340B pricing to our patients. The "may bill" requirement has the unintended effect of penalizing hospital and health systems like ours for providing GME, and makes the care provided more expensive. In a system at full capacity, a reduction in access to discounts will lead to reduced access to care, including the primary and specialty care our medical school partners and GME residents provide.

In addition to putting specialty and referral care at risk, this guidance also puts at risk chemotherapy and other infusion services. Without access to infusion services, indigent care populations would do without; while their cancer progresses untreated and unabated.

The guidance would also require documentation of the ambiguous "may bill" authority for multiple providers in a team responsible for providing coordinated care for patients in covered entities. This will make program administration and compliance documentation unnecessarily complex and expensive.

The consequences of reducing access to 340B pricing include reduced access to care as well as increased program costs, emergency department use and costs and increased readmissions.

c. Reference to Guidance: Prong 3 of the proposed patient definition -- An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in ([Prong] 2). Prong (2) – The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity such that the covered entity may bill for services on behalf of the provider.

d. Recommended Changes: 1) Withdraw the proposed changes to the patient definition. 2) Delete the "may bill" requirement related to the covered entity. Explicitly clarify that when a patient of record at a covered entity has received a referral for care, that prescriptions directly related to that referral are eligible for 340B pricing. 3) Explicitly allow use of 340B pricing for teaching affiliates providing patient care as part of an affiliation agreement with a 340B DSH-qualified covered entity.

e. Data: Our composite public hospital with positive net assets of $3 million would face an additional $2 million in costs (a 66% reduction in margin) related to this new requirement, making continued access to services at the same level untenable.

3. Issue: New guidance would reduce access to pediatric clinics, obstetrics/gynecology care, dental care, and would hobble innovative approaches to provide health care to patients where it is needed. It would increase costs of correctional institutions; and increase public health risks.

    a. Reason: The guidance includes new requirements that in order to be considered part of a Covered Entity (and therefore eligible for 340B pricing), an offsite clinic must be listed as reimbursable on the most recent Medicare report. Furthermore, the services provided must generate Medicare cost and charges. In other words, unless a clinic provides care to Medicare eligibles, the clinic is ineligible for 340B. Many clinics and programs target low income populations that would not typically include Medicare patients (who by definition, have insurance and some different health needs). Special pediatric clinics, clinics to improve birth outcomes such as OB/GYN clinics, and clinics offering dental care could be ineligible for 340B pricing. Furthermore, the targeted services some of our members offer (such as physician visits at the home); while consistent with the Triple Aim and the Center for Innovation goals, do not necessarily include Medicare patients. This requirement will hinder our ability to stretch scarce resources to provide care and our ability to provide access through targeted programs and clinic sites.

        This same program requirement would disqualify correctional programs that now access 340B drugs since health care provided within correctional institutions is not billed to Medicare.

    b. Implications: For no clear policy reason, this guidance would reduce access to 340B drugs to patients seeking care in pediatric and/or OB/GYN clinics, correctional settings and other settings that don't generate Medicare costs. Medicaid and indigent care costs would increase for federal, state and local taxpayers and access to care would be impeded.

        Additional implications and considerations for correctional care include the following: Many of the patients within correctional facilities would, if not incarcerated, be eligible to access care from an essential safety net provider such as our members. Providing access to 340B drugs within correctional care helps to ensure that: health conditions are managed, that patients learn about their conditions and how to manage their own care in the community, and that contagious conditions are consistently treated and kept in check within institutions and out in the community. A high proportion of 340B drugs used in correctional care, for example, is provided to care for costly HIV treatments made possible with discounts up to 50 percent which would be lost under the proposed guidance.

        In addition, behavioral health and related prescriptions are provided to a high proportion of individuals in correctional settings. Elimination of 340B pricing for behavioral health prescriptions would have similar negative consequences for individual health and the health of our communities.

        Furthermore, many local taxing authorities are responsible both for correctional care and for care for low income populations in their communities. With both types of healthcare

funded by the same source, changes that result in increased costs at one location will affect the ability to maintain the same level of access to health care in both settings. Without a clear policy reason for doing, the guidance will significantly increase costs of care at correctional facilities and impact the broader community's health and related care access.

c. Reference to Guidance: See the section titled: "Eligibility of off-site outpatient facilities and clinics (child sites)."

d. Recommended Changes: Eliminate the Medicare-related criteria.

e. Data: Related to Correctional Care, the guidance will result statewide in increased costs over funding of more than $50 million per year. Per institution costs vary from under $1 million per year to up to $10 million per year. University Health System, for example, estimates $3.52 million in additional acquisition costs related to the loss of 340B in correctional settings.

4. Issue: New requirements would eliminate access to care provided at hospital districts and other outpatient chemotherapy and infusion centers.
   a. Reason: The guidance disallows use of 340B when the services provided are solely for administration of the product alone. In addition to the "may bill" issue discussed above, this change prohibits use of 340B for infusion services, including chemotherapy.

   b. Implications for care, access and cost: The ACA added freestanding cancer care as a site eligible for 340B, and mapped out program intent for 340B eligibility for chemotherapy and implied support for outpatient cancer care. The proposed guidance would not only run counter to the ACA intent on cancer care, it would reduce access to care for low income patients depended on the discounts which make possible the services they receive.

      Our members' infusion centers are already at capacity, meaning any reduction in discounts will result in contraction of services and reduced access to care. Just one of our health systems provides pediatric and adult infusion services to between 240 – 326 unique patients per month and 3,462 unique patients per year. If access to 340B infusion services are prohibited as the guidance proposes, nearly 3500 unique individuals per year from just one of our members per year would be unable to access potentially life- saving care. Furthermore, these patients would access the system, including emergency departments and hospital inpatient settings, when they reach crisis stage, receive care and return to the community in an uncontrolled cycle of expensive care.

   c. Reference to Guidance: Prong 3 of the proposed patient definition -- An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in ([Prong] 2). Prong (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.

d. Recommended Changes: Specifically include 340B eligibility for infusion services when a patient is a patient of record of a covered entity.

e. Data: Our composite hospital's infusion costs increased by over $750,000 or 25% of margin. As noted above, loss of 340B infusion pricing will affect almost 3,500 unique patients annually in just one of our member's programs. Low income patients largely served by those programs are unlikely to be able to afford these ongoing services, and the health system is unlikely to be able to afford the additional costs without reducing health care services.

5. Issue: New annual external audit and contract pharmacy audit requirements would increase administrative load, program costs, and could limit contract pharmacy participation and patient access to 340B drugs with no basis to support the value of more audits. Additionally, the guidance sets an unrealistic standard of perfection in audits which may also limit contract pharmacy participation and patient access.

a. Reasons: New contract pharmacy audit guidelines require that the existing annual audit be performed by an external auditor and, in addition, requires that the covered entity conduct quarterly reviews and annual independent audits of each contract pharmacy location. Additionally, the guidance requires that all findings – not just material findings – be reported.

b. Implications for care, access and cost: Contract pharmacies are needed to augment covered entities' ability to provide 340B drugs to patients in communities, increasing access and compliance. Most of our members use a significant number of contract pharmacies to increase access to 340B prescriptions for their patients. Costs for an annual external audit with sampling of contract pharmacies ranges from $100,000 to $200,000 per year per covered entity. A requirement to have quarterly reviews and annual audits for all contract pharmacies will significantly increase covered entity audit staffing as well as external audit costs. This will take additional funding from patient care. This also will pose significant administrative loads on contract pharmacies which could limit their participation and access to 340B drugs that help make prescriptions more affordable for vulnerable populations who might otherwise do without them. Finally, setting an unrealistic standard of perfection for program performance (by requiring reporting of even immaterial findings) may also limit contract pharmacy participation and related access to affordable 340B pricing.

c. Reference to Guidance: Part E – Contract Pharmacy arrangements section (3) Contract pharmacy oversight.

d. Recommended Changes: Require annual external audits of contract pharmacies only based on risk assessments and prior significant material findings. Require reporting only of material audit findings of contract pharmacies. Use risk approaches and require quarterly audits only after two or more annual audits with material audit findings. Eliminate the "may bill" requirement.

e. Data: Based on RFP responses from one of our members, one external Annual Audit of a 340B program that includes random samples of contract pharmacies ranges from $100,000 to $200,000. Required annual external audits of all contract pharmacy locations will result in significant cost increases, especially for providers with many contract pharmacy locations.

Other Recommendations

HRSA should use this opportunity to remove the current delay for use of 340B pricing at covered entity new clinic sites.

HRSA currently does not allow otherwise qualifying new clinic sites to receive 340B pricing until after cost reports are submitted and sites are authorized. This typically takes over one year during which covered entity clinics' and their eligible patients' access to 340B pricing is delayed. During this time, programs must sustain higher costs. HRSA should use this guidance to document a process by which covered entities can begin accessing 340B pricing for eligible patients at new clinics as or soon after the clinics open. HRSA should apply to all new public hospital sites the same standard utilized for children's hospitals. 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. Doing so will allow for lower operational costs and lower new clinic costs which will reduce the costs for expanding access to care for low income populations being served by covered entities and their qualifying sites.

Conclusion

As explained and detailed above, the proposed guidance **will have a significant negative impact** on access to health care for at-need low income populations. These impacts are specifically related to discontinued eligibility of 340B drugs for: prescriptions provided at discharge; care provided in settings without Medicare cost reports or payments; care provided through affiliation agreements including residency and GME programs; and infusion provided within a larger context of comprehensive care. In addition, increased audit requirements will increase program costs and administrative burden without a commensurate increase in program benefit.

These changes will affect the ability of all our members to continue their current level of service for low income populations. Harris Health, one of the largest providers of care, estimates losses of $17 million annually related to proposed changes. These losses will increase its current projected deficit for 2016 from $14 million to $31 million.

Our smaller composite system is pushed from a small but positive margin to a negative margin based on the estimated impact for these changes. This composite system started with positive net assets of $3 million. The overall impact of the guidance would be a loss of $5 million from increased costs, bringing this system to a negative $2 million margin.

Our assessment and experience indicates that the proposed guidance will negatively impact the health of our patients and the health of our communities by:

- reducing access to affordable prescriptions;
- reducing access to outpatient primary, specialty and chronic care services;
- resulting in a contraction of services and/or increased costs and reduced affordability for low income at need populations;
- providing financial disincentives to provide comprehensive, patient-centered, coordinated care;
- negatively affecting GME programs and related affiliation agreements;
- increasing rates of Potentially Preventable Readmissions, Emergency Department visits, and hospital admissions; and
- inhibiting our ability to provide care consistent with the Triple Aim.

Thank you for the opportunity to provide input. We would look forward to the opportunity to discuss our concerns and data with you, as well as to discuss alternative approaches to achieve your goals. Please feel free to contact me.

Sincerely,

Maureen Milligan
President & CEO
Teaching Hospitals of Texas