AMERICA'S ESSENTIAL HOSPITALS

Statement for the Record
Committee on Energy and Commerce
Subcommittee on Health

Opportunities to Improve the 340B Drug Pricing Program
July 11, 2018

America's Essential Hospitals appreciates the opportunity to submit a statement for today's hearing on the recent Government Accountability Office (GAO) report on the 340B Drug Pricing Program and 340B-related legislation under the committee's consideration. The 340B program is among our association's top legislative priorities because our hospitals depend on the savings it provides. This program not only helps essential hospitals across the country keep their doors open, it also helps them meet their mission of caring for the nation's most vulnerable patients and underserved communities.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to providing high-quality care to all. While our membership represents 325 hospitals out of more than 5,500 nationally, they provide 20 percent of all charity care nationwide and 14.4 percent of all uncompensated care, or about $5.5 billion. In the communities our hospitals serve, three out of four patients have no insurance or rely on Medicaid or Medicare, 10.1 million people face food insecurity, 25.3 million live below the federal poverty line, and 350,000 are homeless. Essential hospitals account for more than a third of the nation's level I trauma centers and nearly 40 percent of burn care beds. Our members train nearly three times as many physician residents as other U.S. teaching hospitals.

Essential hospitals anchor health care and economic activity in their communities. To meet this commitment, they operate with margins about half that of other U.S. hospitals, on average. Many essential hospitals operate at even lower margins. It is because of their commitment to providing high-quality care for all that our hospitals rely on the 340B program and other sources of support. Since its inception, this program has helped ease the burden of high drug prices so hospitals can direct more resources to patient care and service to the community, helping those who have nowhere else to turn.

Below, America's Essential Hospitals provides feedback on the GAO report and on legislative proposals the committee will discuss at today's hearing.

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GAO Report: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

America's Essential Hospitals strongly supports continuing to allow contract pharmacy arrangements, which are vital to ensuring access to affordable drugs for vulnerable patients. Essential hospitals are known for establishing accessible clinics in neighborhoods across their service areas to make it easier for individuals to obtain care. To that end, they have leveraged the ability to dispense 340B drugs through contract pharmacies to ensure patients can readily fill and refill prescriptions vital to maintaining health and holding down the cost of care. Any limitation on the flexibility to use contract pharmacies in this way would reduce patient access to drugs and, in turn, jeopardize patient health.

Covered entities' use of contract pharmacies allows patients to more easily access medications within their communities. The ability to enter into arrangements with contract pharmacies enables patients to fill their prescriptions closer to home and without having to return to an in-house pharmacy at the main hospital. This is particularly critical for rural patients, for whom it would be time-consuming and difficult to return to the hospital to fill a prescription. The usefulness of contract pharmacies in fulfilling the original intent of the 340B program has been fully endorsed by the Health Resources and Services Administration (HRSA), which first allowed covered entities to enter into contract pharmacy arrangements in 1996 guidance.[1] Since then, HRSA has expanded the use of contract pharmacies through a demonstration project in 2001. HRSA then formally allowed for the use of multiple contract pharmacy arrangements in 2010 guidance, recognizing that these arrangements "allow covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served."[2] Rolling back contract pharmacy arrangements would run counter to the program's original intent and severely limit patient access to lifesaving, affordable drugs in their communities.

In its June 2018 report, the GAO published its findings on covered entity contract pharmacy arrangements and made seven recommendations to HRSA. Two of these recommendations are limited to the contract pharmacy context, including recommending that HRSA require covered entities to register contract pharmacy arrangements for each child site of the covered entity and directing HRSA to provide more guidance on contract pharmacy oversight. The remaining recommendations focus on preventing duplicate discounts in Medicaid managed care and, more generally, on covered entity audits. HRSA disagreed with three of the seven recommendations, noting that some would be administratively burdensome or unnecessary, given existing audit practices and procedures. We agree there are certain areas in which HRSA can provide additional direction to covered entities in complying with program requirements. For example, it is important HRSA work with the Centers for Medicare & Medicaid Services (CMS) on developing guidance for states and covered entities on identifying 340B drugs in the managed care context.

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[1] 61 Fed. Reg. 43,549 (August 23, 1996).
[2] 75 Fed. Reg. 10,272 (March 5, 2010).

But we disagree with GAO's assessment that HRSA should go beyond clarifying guidance to impose additional compliance requirements on hospitals related to audits. Hospitals readily comply with audits and respond to adverse audit findings. In fact, hospitals and other 340B covered entities have complied with nearly 900 federal audits since fiscal year (FY) 2012, while drug companies have faced only 11 audits since FY 2015, when manufacturer audits began.

As some of the 340B program's original participants, essential hospitals have a vested interest in ensuring program integrity. They invest substantial time and resources into internal processes to verify compliance with program requirements, including with prohibitions against diversion and duplicate discounts. Participation in the 340B program creates significant administrative and compliance-related costs, including to hire appropriate staff, such as a program manager, pharmacists, and pharmacy technicians to ensure the hospital follows the program's highly technical and evolving requirements. Also, 340B hospitals must invest in appropriate billing software and allocate resources to comply with the program and respond to audits. Additional requirements, such as mandating that covered entities register contract pharmacies at the child site level, would be extremely burdensome for hospitals already navigating complex regulatory and compliance requirements.

Legislative Proposals

H.R. 2889, CLOSING LOOPHOLES FOR ORPHAN DRUGS ACT

Under current law, orphan drugs are excluded from 340B discounts. In 2013, HRSA issued a rule to limit the orphan drug exclusion to apply only when a drug is used for the rare condition or disease for which it was designated. However, a court ruling stated that HRSA did not have the authority to issue the rule, and it was rescinded. H.R. 2889 would put the intent of HRSA's 2013 rule into statute. This legislation would expand access to 340B discounts for more patients, particularly those who need covered drugs to treat more common or chronic conditions for which the medication was approved, while maintaining the higher cost of the drug when used for rare orphan indications.

H.R. 4392, TO PROVIDE THAT THE PROVISION OF THE MEDICARE PROGRAM: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS FINAL REGULATION RELATING TO CHANGES IN THE PAYMENT AMOUNT FOR CERTAIN DRUGS AND BIOLOGICALS PURCHASED UNDER THE 340B DRUG DISCOUNT PROGRAM SHALL HAVE NO FORCE OR EFFECT, AND FOR OTHER PURPOSES.

H.R. 4392 would impose a permanent moratorium on the 2018 Outpatient Prospective Payment System (OPPS) rule provision that cut by more than 27 percent reimbursement for Medicare Part B drugs prescribed at 340B hospitals. This damaging cut hits essential hospitals hard, given their high levels of uncompensated care and narrow margins. Some will be forced to scale back services made possible by 340B and others might consider leaving the program entirely. H.R. 4392 would put a permanent stop to this harmful policy.

H.R. 4710, 340B PROTECTING ACCESS FOR THE UNDERSERVED AND SAFETY-NET ENTITIES (340B PAUSE) ACT

H.R. 4710 would impose an excessive administrative burden on 340B hospitals through unneeded new reporting requirements. Further, the proposed moratorium on enrollment of new

child sites and new covered entities will jeopardize patient access to care in our most underserved communities.

H.R. 5598, 340B OPTIMIZATION ACT

H.R. 5598 would burden hospitals with new administrative requirements by requiring reporting at the child site level under a metric not currently collected. This requirement yields nothing relevant to HRSA's oversight role and would not usefully increase program transparency. The bill also would widen the disparity in 340B program accountability for hospitals versus that for drug companies, putting hospitals and their vulnerable patients at a disadvantage and undermining the program's value as a hedge against high drug prices.

H.R. 6071, STRETCHING ENTITY RESOURCES FOR VULNERABLE (SERV) COMMUNITIES ACT

This legislation would affirm Congress' intent for the 340B program, increase manufacturer transparency and accountability, and stop the deeply damaging OPPS payment cuts. H.R. 6071 is a step in the right direction to create parity between 340B covered entities and drugmakers.

H.R. 6240, DRUG DISCOUNT ACCOUNTABILITY ACT

This legislation would require hospitals to pay a 0.1 percent user fee to the program and report their total 340B purchases. An industry user fee program is not necessary, as HRSA has the authority to oversee the program and Congress has the authority, should it choose, to fund stronger program oversight.

H.R. 6273, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO ENSURE APPROPRIATE CARE BY CERTAIN 340B COVERED ENTITIES FOR VICTIMS OF SEXUAL ASSAULT, AND FOR OTHER PURPOSES.

This legislation could limit access to 340B program participation and impose additional financial burden on essential hospitals to comply with the bill's requirements. H.R. 6273 is inconsistent with Congress' intent for the 340B program and conflates unrelated—albeit, important—issues.

H.R. ____, PROTECTING SAFETY-NET 340B HOSPITALS ACT

This legislation would exclude a significant group of essential hospitals currently participating in the 340B program by increasing the Medicare disproportionate share hospital (DSH) threshold from 11.75 to 18 percent. There should be thoughtful consideration and review of the potential impact when considering any change in threshold.

H.R. ____, BETTERING OPERATIONS AND OVERSIGHT THROUGH SENATE PROCESS TRANSPARENCY (BOOST) IN 340B ACT

This legislation would impose an additional layer of regulatory burden on the 340B program, putting it at odds with the administration's goal of reducing regulatory complexity and burden.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO DEFINE THE TERM PATIENT FOR PURPOSES OF THE 340B DRUG DISCOUNT PROGRAM

This bill significantly restricts the definition of a patient under the 340B program in a way that would drastically reduce access to discounted drugs and services made possible by 340B savings. It also fails to recognize the way hospitals, particularly DSH hospitals, deliver care.

H.R. ____, TO REQUIRE THE SECRETARY OF HEALTH AND HUMAN SERVICES TO IMPLEMENT THE GOVERNMENT ACCOUNTABILITY OFFICE RECOMMENDATIONS

This legislation would require HHS to implement all seven recommendation in the GAO's June report. But HRSA disagreed with three of the seven recommendations, noting they were burdensome or unnecessary given current safeguards in place. Further, the analysis used a nongeneralizable sample, and broad conclusions about all covered entities cannot be made from a small, non-representative sample.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REQUIRE UNDER THE 340B DRUG DISCOUNT PROGRAM REPORTS BY COVERED ENTITIES

This legislation does not demonstrate a benefit to 340B program oversight or administration that would justify the additional burden it would place on providers. This proposal overlooks how 340B covered entities use their savings. It also imposes burdensome administrative and reporting requirements, based on patient payer mix and charity care, which do not accurately determine hospitals' care for low-income patients.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REQUIRE THE SECRETARY OF HEALTH AND HUMAN SERVICES TO CONDUCT AUDITS

Although HRSA is not required to comply with the standards proposed under this legislation, we believe that using accepted government auditing standards issued by the comptroller general would provide a more streamlined audit process. Additionally, it would apply to both covered entities and manufacturers, ensuring parity in auditing standards.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REQUIRE CERTAIN COVERED ENTITIES UNDER THE 340B DRUG DISCOUNT PROGRAM

This legislation would prohibit hospitals from charging low-income patients more than the ceiling price for 340B drugs. While we support the intent of the proposal, essential hospitals already have financial assistance and charity care policies in place to ensure low-income patients are not overcharged. Additionally, there is a public reporting process in place under IRS 501(r) rules for nonprofit institutions requiring that these policies be publicly available.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO ALLOW THE SECRETARY OF HEATH AND HUMAN SERVICES TO PRESCRIBE REGULATION

We support granting HRSA authority to oversee the 340B program within its original statutory intent: to help covered entities "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." But we have concerns with HRSA having discretion to regulate the program's scope beyond this original congressional intent.

Again, America's Essential Hospitals thanks the committee for the opportunity to provide feedback on the recent 340B program-related GAO report and legislative proposals under consideration. Our association looks forward to working with the committee and its leadership to strengthen the 340B program and to ensure it continues to help covered entities stretch their scarce resources to meet their mission of caring for the nation's most vulnerable people.