340B UPDATE: AHA PROPOSES VOLUNTARY 340B PROGRAM TRANSPARENCY EFFORTS

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Health Care Alert

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On September 18, 2018, leaders from the American Hospital Association ("AHA") formally announced a new initiative called the "Commitment to Good Stewardship Principles," which requests certain voluntary public reporting of eligible hospitals related to the 340B Drug Discount Program ("340B Program" or "340B"). This grassroots initiative comes on the heels of recent debate in Washington, D.C., regarding policy changes to promote greater transparency in the 340B Program.

AHA GOOD STEWARDSHIP PRINCIPLES

Earlier this year, AHA issued a call to action asking all 340B hospitals to sign a commitment to publicly disclose certain information related to their 340B participation. The Commitment to Good Stewardship Principles follows up on this call to action, stating that 340B hospitals should demonstrate their commitment to the 340B Program by "sharing publicly how 340B savings are used to benefit the community." [1]

To align with this commitment, each 340B hospital would specifically:

> 1. Communicate the Value of the 340B Program: Each hospital would publish a narrative annually that describes how it uses 340B savings to benefit the community, including programs/services funded in whole or in part by 340B savings. AHA expects these summaries would describe services to support access to care that could not be provided by the hospital without the support of 340B savings, such as expansion of access to drugs for vulnerable populations, preventative care, emergency services, and cancer treatment. 2. Disclose the Hospital's Estimated 340B Savings: Each hospital would also publish its estimated 340B savings annually. AHA suggests that hospitals calculate 340B savings by comparing the 340B acquisition cost to group purchasing organization ("GPO") pricing or other acceptable pricing sources. Specifically, AHA recommends that the 340B estimated savings may be calculated by: (a) establishing applicable GPO or other estimated acquisition costs (such as wholesale acquisition cost) for drugs purchased through the 340B Program, (b) subtracting the actual 340B acquisition cost, and (c) adding benefits realized from contract pharmacy arrangements, if any, which may be calculated as the total reimbursement for 340B drugs dispensed through the contract pharmacy less any dispensing or administrative fees. AHA also recommends providing a comparison of 340B savings to the hospital's total drug expenditures, as well as examples of the hospital's top 340B drugs. 3. Continue Rigorous Internal Oversight: Finally, each hospital would be expected to conduct internal reviews to ensure all 340B requirements are met, as well as regular and periodic training for the hospital's interdisciplinary 340B

> teams, including the hospital's corporate executives and applicable pharmacy, legal, financial assistance, community outreach, and government relations staff.

PENDING LEGISLATION

The AHA principles come as policymakers continue to push for greater drug pricing transparency both on 340B and on drug pricing more broadly. On 340B in particular, legislation introduced this Congress includes S. 2453, Ensuring the Value of the 340B Program Act of 2018, and S. 2312, Helping Ensure Low-income Patients have Access to Care and Treatment Act. These bills are aimed at requiring additional reporting by 340B hospitals, including reporting of aggregate acquisition costs and revenue derived from dispensing of 340B drugs to hospital patients. Although those bills have not yet gained traction — and Congress has not yet adopted specific transparency requirements for 340B hospitals — there continues to be much interest in the Congress on 340B. In this regard, the bipartisan leaders of the House Energy and Commerce Committee and the Senate Health, Education, Labor and Pensions Committee recently wrote a joint letter urging the Health Regulation and Service Administration ("HRSA") to promulgate regulations to clarify and update requirements of the 340B Program. [2] In speaking with the media about this proposal, Rick Pollard, president and CEO of the AHA, has stated, "Legislation in our view is not necessary as long as we have these kinds of principles in place to achieve the objectives that legislation might want to achieve… And I think we can probably do it quicker than relying on the legislative process." [3]

NEXT STEPS

While the AHA initiative is voluntary, covered entities may face increasing pressure to make such numbers available, particularly to the extent the AHA's Good Stewardship Principles are widely adopted by peer institutions. Accordingly, covered entities should assess their current readiness to do public reporting as contemplated by AHA, and particularly given that similar requirements are endorsed by HRSA and/or Congress and may become a 340B Program requirement. Likewise, covered entities will need to assess whether and when to participate in any voluntary reporting regimes.

K&L Gates' health care practice can assist stakeholders in addressing how to respond to the new voluntary public disclosure landscape. We regularly advise clients on 340B Program implementation and compliance matters and facilitate stakeholder engagement with Congress and the Administration through our public policy and law practice.

Notes:

[1] AM. HOSP. ASS'N, 340B HOSPITAL COMMITMENT TO GOOD STEWARDSHIP PRINCIPLES, https://www.aha.org/system/files/2018-09/Final-Stewardship-Principles_Sept-2018_0_1.pdf.
[2] Letter from Rep. Greg Walden et al. to Krista Pedley, Health Regulation and Service Administration (Aug. 27,

2018), https://energycommerce.house.gov/wp-content/uploads/2018/08/20180827HRSA.pdf.
[3] Lauren Clason, Health, Hospitals Commit to Transparency Under Drug Discount Program, CQ (Sept. 18, 2018), http://www.cq.com/doc/hbnews-5390384?0.

