340B HEALTH

September 2, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Pharmaceutical Manufacturers' Requirement of Rebate Arrangements for Covered Entities to Access 340B Pricing

Dear Secretary Azar:

On behalf of our members, more than 1,400 public and nonprofit hospitals that participate in the federal 340B drug pricing program, 340B Health is writing to express our deep concern about plans of some pharmaceutical manufacturers to adopt a mandatory rebate model for drug purchases by 340B covered entities to replace the longstanding method of providing direct discounts to covered entities at the time of purchase. We have significant concerns about a rebate model and urge HHS to use its statutory authority to reject a rebate model for 340B. At the very least, the Secretary must prevent a rebate model from being implemented until guidance has been issued, subject to notice and public comment, directing how a rebate model would work, including what type of administrative dispute resolution process would be available to covered entities to challenge overcharges under a rebate model.

1. Manufacturers Cannot Unilaterally Change 340B Into a Rebate Program

The manufacturer consultant Kalderos recently announced plans to launch its 340B Pay product on September 8, 2020, through which participating manufacturers would implement a process for payment of rebates, rather than providing upfront discounts, to covered entities for some or all of the manufacturers' drugs subject to 340B pricing. Kalderos has indicated that under 340B Pay, covered entities would be required to purchase the participating manufacturers' drugs at higher non-340B prices and submit requests for rebates that would be paid at a later date.

Implementation by manufacturers of a rebate model for accessing 340B pricing would be directly contrary to longstanding program guidance, published by the Department of Health and Human Services (HHS) in the Federal Register, providing for operation of 340B as a discount program. Guidance published in 1993 and 1994 made clear that a "**discount** must be made available" to covered entities through wholesalers. [1] The guidance specifically distinguished

[1] Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994) (Final Notice on Entity Guidelines) (emphasis added); *see also* Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993) (Notice on Initial Guidance) ("discounts" must be passed through wholesalers to covered entities).

discounts from "rebates" and "retroactive discounts", permitting rebates only in the narrow case of making covered entities whole for purchases made prior to initial implementation of 340B. [2] 340B has been administered by the Health Resources & Services Administration (HRSA) exclusively as a discount program, with only one very narrow exception to accommodate one type of covered entity, which was implemented only after publishing notice in the federal register and providing the opportunity for public comment.[3]

The imposition of a rebate process on covered entities by manufacturers participating in Kalderos 340B Pay represents a fundamental departure from the manner in which the 340B program has operated since its inception. Such a change in the method by which covered entities access 340B pricing cannot be implemented unilaterally by manufacturers. Under the 340B statute, HHS must provide public notice of the proposed change and the opportunity for comment by covered entities and other stakeholders, and HHS must then decide whether to permit the rebate model after considering the public comments and must issue a final notice setting forth its determination. Public notice and comment and careful evaluation of the rebate model by HHS is essential to avoid significant disruption in the operation of the 340B program, surprise to regulated parties, and potential harm to covered entities and other stakeholders.

Inaction by HHS, or the granting of permission to operate 340B as a rebate program without public notice and comment, risks substantial harm to the 340B program and to 340B hospitals and other covered entities that are the backbone of the nation's health care safety net. 340B hospitals are currently on the front line of the battle against COVID-19, providing care to those afflicted, testing to those at risk, and educating their communities to decrease spread of the virus. HHS must take steps to stop unilateral actions by manufacturers that threaten to reduce the benefit of 340B pricing when 340B hospitals must deal with unprecedented challenges posed by the COVID-19 pandemic, including drug supply chain issues.

2. The Secretary Must Determine Whether to Provide for a Rebate Model Under 340B and Must Provide for Public Notice and Comment Before Making That Determination

The 340B statute does not permit manufacturers or their vendors to determine unilaterally how covered entities obtain 340B pricing. The statute requires that under each manufacturer's pharmaceutical pricing agreement with the Secretary, "the amount required to be paid *(taking into account any rebate or discount, as provided by the Secretary)* to the manufacturer" for a covered outpatient drug by a covered entity shall not exceed the 340B ceiling price for that drug.[4] Congress provided the Secretary with "the discretion to determine the mechanism (rebate,

[2] Final Notice on Entity Guidelines, 59 Fed. Reg. 25112; Notice on Initial Guidance, 58 Fed. Reg. 27291, 27292. The 1993 initial program guidance stated that covered entities added to updated eligibility lists would be eligible for "drug discounts" only for purchases on or after their inclusion on the eligibility list and that HHS was "notifying each covered entity of its eligibility to purchase drugs at the discounted prices."
[3] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45823 (Aug. 29, 1997) (Notice on Proposed Rebate Option); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35239 (June 29, 1998) (Final Notice on Rebate Option).
[4] 42 U.S.C. § 256b(a)(1) (emphasis added).

point-of-purchase discount, or otherwise) for assuring [the] price reduction" to covered entities and expected that the Secretary would "use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'"[5] Thus, the statute prohibits manufacturers from restricting access to 340B pricing through a mandatory rebate process unless the Secretary provides for a rebate model, after determining that doing so would be most effective for the covered entity.

The rebate process under Kalderos 340B Pay represents a major change from how practically all covered entities have obtained 340B pricing for covered outpatient drugs during the 340B program's existence. From the beginning, HRSA has operated 340B under the discount model, requiring manufacturers to provide 340B pricing to covered entities at the time of purchase. HRSA has provided for a rebate model only once, for State AIDS Drug Assistance Programs (ADAPs), as "an optional alternate means of accessing section 340B discount pricing."[6]

HRSA provided notice and the opportunity for public comment before approving the rebate model for ADAPs.[7] The rebate option for ADAPs is a limited exception to the discount process described in HRSA guidance and was "developed by HRSA in response to a clear need by certain State ADAPs which are unable to access such pricing through the direct discount option."[8] HRSA made clear that it was not extending a rebate option beyond ADAPs.[9] Because Kalderos 340B Pay would affect how all other categories of covered entities obtain 340B pricing, and because participation in the Kalderos rebate model would be mandatory for covered entities, it is even more crucial that the Secretary proceed with notice and opportunity for comment in this case, so that HHS can hear from **all** stakeholders regarding the impact of this rebate model on the 340B program.

Although Kalderos has been promoting its rebate model under 340B Pay, HHS has not issued any public notice that it is proposing to allow a rebate model for obtaining access to 340B pricing. Basic principles of administrative law require that "[r]egulated parties must know in advance the rules" by which federal agencies will evaluate their actions.[10] Under Executive Order 13892, agencies are to avoid "unfair surprise" about what is required under legal standards they administer through public notice of the applicable rules.[11] Similarly, Executive Order 13891 envisions that for significant guidance documents, agencies will provide "a period of public notice and comment of at least 30 days before issuance" and "a public response from the agency to major concerns raised in comments."[12] In a recent notice of proposed rulemaking implementing "good guidance practices" pursuant to Executive Orders 13891 and 13892, HHS

[5] H.R. Rep. No. 102–384, 102d Cong., 2d Sess., pt. 2, at 16 (1992).
[6] Final Notice on Rebate Option, 63 Fed. Reg. 35239.
[7] Notice on Proposed Rebate Option, 62 Fed. Reg. 45823; Final Notice on Rebate Option, 63 Fed. Reg. 35239.
[8] Final Notice on Rebate Option, 63 Fed. Reg. 35240. Notably, election of the rebate option rests with the ADAP—the covered entity—and not the manufacturer. HRSA expressly stated that manufacturers were required "to provide a rebate that meets or exceeds the 340B discount" to an ADAP "participating in the section 340B rebate program. Final Notice on Rebate Option, 63 Fed. Reg. 35240-35241.
[9] Final Notice on Rebate Option, 63 Fed. Reg. 35241-35242.
[10] Executive Order 13892 (Oct. 9, 2019), 84 Fed. Reg. 55239 (Oct. 15, 2019).
[11] *See* 84 Fed. Reg. 55240, 55241.
[12] Executive Order 13891 (Oct. 9, 2019), 84 Fed. Reg. 55235, 55237 (Oct. 15, 2019).

has proposed that before issuance, a "significant guidance document" must be approved by the Secretary, reviewed by the Office of Management and Budget's Office of Information and Regulatory Affairs, and be subject to public notice and opportunity for comment.[13]

A "significant guidance document is a document that "may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, . . . public health or safety, or State, local, or tribal governments or communities . . . or raise novel legal or policy issues arising out of legal mandates."[14] A determination to allow a rebate model for 340B qualifies as "significant" guidance based on the financial impact and potential disruption in changing the manner in which 340B operates. Allowing manufacturers to restrict covered entities' access to 340B pricing through a rebate process would certainly affect more than $100 million in drug purchases, given the scale of the 340B program. Further, it would adversely affect the health care provider sector in a material way, because covered entities would incur significant increases in upfront costs to purchase drugs at higher non-340B prices and face delays in receiving the benefit of 340B pricing through later rebate payments. Thus, any action by HHS to allow a rebate model should be treated as significant guidance subject to approval by the Secretary and notice and comment under Executive Order 13891 and the proposed rule on HHS good guidance practices.

Furthermore, to avoid unfair surprise to regulated parties, HHS must issue a notice seeking public comment on standards for operating 340B as a rebate program to resolve important issues that are not addressed under current regulations and guidance. As one significant example, the regulations establishing civil monetary penalties for manufacturers' intentional overcharges to covered entities do not address manufacturer overcharges in the context of rebate arrangements. The regulations provide that "[a]n instance of overcharging" may occur in two situations: (1) "at the time of initial purchase" or (2) "when subsequent ceiling price recalculations due to pricing data submitted to CMS or new drug price estimations . . . result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity."[15] Both manufacturers and covered entities need to know in advance what practices would constitute overcharges under a rebate model.

The control that the Kalderos rebate model gives manufacturers over covered entities' access to 340B pricing also presents issues that should be addressed through notice and comment. The rebate model has significant potential to enable abusive practices by manufacturers, and because HHS has not issued final regulations establishing the binding administrative dispute resolution process that was mandated ten years ago by the Affordable Care Act, covered entities lack this important remedy intended by Congress to address manufacturer overcharges.[16] HHS needs to address how covered entities' access to 340B pricing will be protected under a rebate model.

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[13] Proposed Rule on Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 51396, 51398, 51400 (Aug. 20, 2020).
[14] Proposed Rule on Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 51397, 51400. *See also* Executive Order 13891, 84 Fed. Reg. 55236.
[15] Final Rule on 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017) (adopting 42 C.F.R. § 10.11(b)(4).
[16] *See* 42 U.S.C. § 256b(d)(3), added by Pub. L. 111–148, § 7102, as amended by Pub. L. 111–152, § 2302.

3. The Kalderos 340B Pay Rebate Model Poses Significant Risk of Imposing Additional Burdens and Financial Strain on Safety Net Hospitals

The rebate model being implemented by participating manufacturers poses significant risk of imposing substantial administrative burdens and financial harm on hospitals that participate in the 340B program, potentially creating a barrier to participation by covered entities. The Kalderos proposal was announced very recently, and little information has been made public. Based on what we can glean from the publicly available information, we have many concerns about this proposal, and we are continuously receiving more from our members. Some of our concerns are discussed below, but the wide-reaching impact of the proposal combined with the lack of available details further argues for a process involving public notice and comment.

340B hospitals will be required to enroll in 340B Pay and request rebates in order to eventually receive the 340B price for purchases of drugs from the participating manufacturers via the rebate process. Rather than saving on covered outpatient drug costs at the time of purchase, 340B hospitals will be forced to incur higher carrying costs for these drugs until the manufacturers remit rebate payments, reducing the hospitals' resources available for other patient care. For 340B hospitals subject to the statutory limitation on use of group purchasing organizations or arrangements, these upfront costs will be at wholesale acquisition cost pricing, which substantially exceeds 340B pricing.[17] Many smaller covered entities would be unable to meet this requirement.

In order to participate in the Kalderos 340B Pay rebate program, 340B hospitals will have to devote additional administrative resources to develop purchasing arrangements for covered outpatient drugs at non-340B prices, make appropriate rebate requests, and track and reconcile rebate payments with the 340B price for each purchased drug. Because the Kalderos 340B Pay program is voluntary for manufacturers, these administrative costs will be on top of existing operational costs associated with the current method of accessing 340B pricing through upfront discounts for purchases of covered outpatient drugs from manufacturers who do not participate in 340B Pay. For those manufacturers, hospitals will still incur costs in operating purchasing and inventory systems that are compliant with HRSA guidance for the direct discount method. As a result, hospitals will be burdened by instituting and maintaining different purchasing, inventory, and financial systems and procedures for those manufacturers choosing the rebate process, and in some cases applying different systems and procedures for the same manufacturer, if the manufacturer elects to participate in the rebate process for only some of its drugs.

The rebate model under Kalderos 340B Pay would appear to give manufacturers operative control over hospitals' access to 340B pricing, We are concerned that under the proposed rebate process manufacturers would be able essentially to audit individual rebate claims and unilaterally deny rebate payments for alleged "noncompliant" transactions. Given the lack of detailed public information about the operational rules and procedures of the Kalderos rebate model, there is no assurance that manufacturers would be prohibited from making offsets against current rebate

[17] 42 U.S.C. §§ 256b(a)(4)(L), (M).

payments owed to hospitals in order to recoup purported duplicate discounts relating to past 340B purchases. In the absence of any procedures or requirements established by HHS to govern the rebate process, manufacturers could engage in these and other practices that would effectively deny hospitals the 340B prices to which they are entitled under the statute and thwart statutory limitations and existing HRSA guidance on manufacturers' audits of covered entities.[18] Such denials or recoupments of rebates would result in further financial harm to 340B hospitals and impose the additional burden of contesting and attempting to recover the lost rebates from manufacturers.

The potential burdens and financial harm to 340B hospitals from a rebate model would come at a time when the resources and finances of these safely net providers are already severely strained. Although 340B disproportionate share (DSH) hospitals represent 43 percent of hospitals, they provide 75 percent of all hospital services to Medicaid patients,[19] who have a higher burden of illness and have payment rates below cost, thus creating special challenges for these hospitals.[20] 340B DSH hospitals are much more likely than non-340B hospitals to provide essential health care services that are vital to low-income patients, but are often under-reimbursed, including HIV/AIDS services, trauma care, and outpatient alcohol/drug abuse services.[21] 340B DSH hospitals also are more likely to serve racial and ethnic minorities.[22] The crucial role of 340B DSH hospitals in the safety net is accompanied by substantially lower—negative on average—operating margins than those of non-340B hospitals.[23] As a result of COVID-19, these hospitals are now dealing with shortages of equipment and drugs and struggling to cope with massive decreases in revenue that necessitate reductions in expenses and staffing. HHS needs to seriously examine whether now is the right time to allow manufacturers to change how safety net providers access 340B pricing.

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At a time when 340B hospitals are focused on confronting the global pandemic of COVID-19 and dealing with the continuing increase in prescription drug costs, HHS should not allow manufacturers to impose unilaterally a rebate model that would drastically reshape the 340B program. We ask that HHS exercise its statutory authority on how covered entities may obtain 340B pricing by providing notice and the opportunity for public comment on the Kalderos rebate

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[18] 42 U.S.C. § 256b(a)(5)(C); Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406 (Dec. 12, 1996).

[19] Dobson DaVanzo, Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients (2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf

[20] Medicaid and CHIP Payment and Access Commission (MACPAC) and Medicare Payment Advisory Commission (MedPAC), Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid. 2018, https://www.macpac.gov/wp-content/uploads/2020/07/Data-Book-Beneficiaries-Dually-Eligible-for-Medicare-and-Medicaid-January-2018.pdf; American Hospital Association,. Underpayment by Medicare and Medicaid Factsheets, 2016-2020, https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid

[21] Dobson DaVanzo, Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients, *supra*.

[22] L&M Policy Research, A Comparison of Characteristics of Patients Treated by 340B Hospitals (2019), https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_FINAL_04-10-19.pdf

[23] Dobson DaVanzo, Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients, *supra*.

model, assessing whether the Kalderos 340B rebate model is the most effective method for covered entities to obtain 340B pricing based on those comments, and issuing a final notice setting forth its determination. Based on our concerns about the potential burdens and financial harm to covered entities, we urge HHS to reject implementation of a rebate model for 340B.

Thank you for your consideration of our request. We would be happy to answer any questions or provide additional information. You may contact me at maureen.testoni@340bhealth.org or 202-552-5860.

Sincerely,

Maureen Testoni
President and CEO
340B Health

cc: Thomas J. Engels, Administrator, Health Resources & Services Administration

Rear Admiral Krista M. Pedley, Director, Office of Pharmacy Affairs, Health Resources & Services Administration