Biotechnology Industry Organization

January 31, 2014

***VIA ELECTRONIC SUBMISSION***

Vendor Drug Program
Medicaid/CHIP Division
4900 N. Lamar
Austin, Texas 78751

**RE: TX Health and Human Services Commission Proposed Rule: 340B Program Reimbursement**

Dear Ms. Gibson:

To Whom It May Concern:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Texas Health and Human Services Commission (HHSC) proposed rule regarding 340B program reimbursement (the "Proposed Rule"). BIO is the largest trade association to serve and represent the biotechnology industry in the United States and around the globe. Indeed, BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

In Texas, BIO works with the Texas Healthcare & Bioscience Institute (THBI), which is the leading voice of the Texas Healthcare Bioscience Industry and the only provider of statewide resources to our members and the industry. With a focus on using advocacy as a tool to create a more favorable environment for the life sciences, THBI works with government and industry leaders to attract new participants in the life sciences to Texas and to promote effective government legislation on the behalf of the industry.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we support the 340B program as a way to improve access to therapies for needy patients. We have become aware, however, that oversight of the program has been inadequate, including with respect to the federal prohibition on duplicate discounts (i.e., the prohibition on obtaining both a Medicaid rebate and a 340B discount for a drug).[1] For instance, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) has found that approximately half of the states do not yet have systems in place and/or access to the necessary pricing

[1] See 42 U.S.C. § 256b(a)(5)(A) (" . . . [a] covered entity shall not request payment under [the Medicaid program] . . . with respect to a drug that is subject to an agreement under [the 340B program] if the drug is subject to the payment of a rebate to the State under [the Medicaid drug rebate statute].")

data to ensure that duplicate discounts do not occur.[2] BIO therefore supports the efforts by the state of Texas to prevent duplicate discounts in accordance with federal law. We are concerned, however, that the reimbursement methodology contemplated under the Proposed Rule would not be feasible and may result in increased costs for the Texas Medicaid program. We also believe that certain aspects of the rule could benefit from further clarification.

## I. The Proposed Reimbursement Methodology is Not Feasible and May Result in Increased Costs to the Texas Medicaid Program

As noted above, BIO is very supportive of Texas's efforts to eliminate duplicate discounts in accordance with federal law. BIO is very concerned, however, that the Proposed Rule lacks critical detail with respect to how the Medicaid program will actually reimburse covered entities for 340B drugs and adopts a reimbursement methodology that may far exceed the actual 340B ceiling prices obtained by covered entities.

As proposed, the term "340B price" is defined to mean "[t]he maximum price that the United States Health Resources and Services Administration will allow a drug manufacturer to charge a 340B covered entity for a 340B covered outpatient drug purchased through the 340B program. The 340B price is also known as the 'ceiling price.'"[3] Reimbursement to "a 340B covered entity for a 340B covered outpatient drug dispensed to a patient of a 340B covered entity" would then be determined on the basis of either: (1) HHSC's estimate of the "340B price" (defined above); or (2) the maximum allowable cost (TMAC), as defined under section 355.8545 of the state's Medicaid regulations.[4] Notably, the Proposed Rule does not specify the basis for relying on the estimated 340B price versus TMAC, and vice versa.

As an initial matter, it is important to note that the state will not have access to the 340B ceiling prices, which are not released by the Health Resources and Services Administration (HRSA)—the federal agency charged with administering the 340B program. Therefore, the state will not be able to derive a "340B price" that necessarily aligns with actual 340B ceiling prices. It is also not clear from the text of the Proposed Rule how HHSC intends to "estimate" the 340B price, particularly given that the agency will not necessarily have access to the underlying information.[5] Consequently, it is difficult for stakeholders

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[2] HHS Office of the Inspector General. 2011. *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*. Washington, DC: HHS/OIG, http://www.hrsa.gov/opa/programrequirements/reports/medicaidpoliciesandoversities062011.pdf.

[3] 1 TAC § 355.8548(b)(3) (proposed).

[4] 1 TAC § 355.8548(c) (proposed).

[5] As you may be aware, the 340B ceiling price is calculated by subtracting the Unit Rebate Amount (URA) from the Average Manufacturer Price (AMP) for the smallest unit of measure, and then multiplying by the drug package size. These AMP data are reported by manufacturers to the Centers for Medicare and Medicaid Services (CMS) pursuant to the Medicaid Drug Rebate statute. CMS then uses these data, together with other data reported by manufacturers, to calculate the URA. While CMS provides states with URA data in order to bill manufacturers for Medicaid Drug Rebates, AMP data are not automatically shared with the states. Moreover,

to provide meaningful input on the state's proposal. Nonetheless, even based on the limited information provided, we are very concerned that the state's proposal would undermine manufacturers' efforts to identify potential duplicate discounts, and also may create improper incentives to the extent the estimated ceiling price differs from covered entities' actual acquisition cost for different drugs.

With respect to this first point, one way in which manufacturers attempt to identify duplicate Medicaid and 340B discounts is by reviewing rebate invoices for utilization billed at or near the 340B ceiling price. Texas's current policy of requiring covered entities to bill Medicaid based on actual acquisition cost facilitates this process. However, to the extent the amount covered entities bill Medicaid for 340B products were to be based on an amount other than actual acquisition cost, manufacturers may no longer be able to identify these claims. This is particularly true where, as here, the amount would be established by the state through what appears to be a non-transparent process.

As to the latter point, as noted above, Texas proposes to reimburse covered entities for 340B product based on either: (1) the state's estimated "340B price"; or (2) TMAC. Both of these either are, or have the potential to be, higher than the rates covered entities pay for drugs under the 340B program. As a result, we believe this proposal has the potential to create improper incentives with respect to the 340B Program.

First, we believe that the state will find it exceedingly difficult to estimate the 340B price given the wide variability in 340B ceiling prices, which are subject to quarterly fluctuations, restatements, and, in some instances, penny pricing.[6] Indeed, to ensure calculation of an accurate 340B ceiling price, the state would have to perform its estimate on an ongoing basis (i.e., each quarter, the state would have to pair average manufacturer price (AMP) data with the unit rebate amount (URA) from two quarters prior to develop that quarter's ceiling price). Even if the state were somehow able to accurately estimate the 340B ceiling price each quarter, covered entities may obtain sub-ceiling prices which would reduce their costs even further, yet which would not be reflected in the AMP and URA.

By way of background, under the 340B program, manufacturers are permitted, but not required, to offer covered entities "sub-ceiling prices" (i.e., prices below the mandatory 340B ceiling price) on covered outpatient drugs.[7] The 340B program has developed a mechanism, through the Prime Vendor Program (PVP), to negotiate sub-ceiling prices on behalf of 340B covered entities: Apexus, the government's awarded 340B Prime Vendor, is responsible for securing sub-ceiling discounts on outpatient drug purchases for covered entities participating in the PVP.[8] Given that covered entities can—and often

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even were the state to obtain AMP data, it is not clear that the URA and AMP data would be provided in a form that would facilitate the development of the ceiling price.

[6] HRSA, 340B Drug Pricing Program Notice, Release No. 2011-2 – Clarification of Penny Pricing Policy (Nov. 21, 2011), available at: http://www.hrsa.gov/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf.

[7] 42 U.S.C. § 256b(a)(10).

[8] HRSA, 340B Implementation, http://www.hrsa.gov/opa/implementation/ (last visited Jan. 29, 2014).

do—secure these sub-ceiling prices, Texas should revise the Proposed Rule to ensure these discounts are passed on to the state. Specifically, BIO urges Texas to continue to require covered entities to bill Medicaid at the 340B drug acquisition cost as reflected on the invoice, plus a dispensing fee, which would more accurately capture the applicable price of drugs (including sub-ceiling prices) than the proposed "estimated 340B price."

Second, we are concerned that the use of TMAC may substantially overpay covered entities for 340B drugs. Under Texas Medicaid regulations, TMAC is determined using the wholesale estimated acquisition cost (WEAC), which, in our experience is generally substantially higher than the 340B ceiling price. Particularly because the Proposed Rule does not specify when the state will use the TMAC price (as opposed to the 340B price), Texas Medicaid may end up using this pricing methodology and thus greatly overpaying covered entities for 340B-purchased drugs. To prevent this result, BIO urges the state to revise the Proposed Rule to specify that the lesser of the two pricing methodologies applies. This will help ensure that Texas realizes maximum savings, and is typically the approach taken by states in their Medicaid state plans with respect to reimbursement for commercial products.

To summarize, BIO urges Texas to revise the proposed 340B reimbursement methodology such that covered entities would be paid the lesser of: (1) the 340B drug acquisition cost, as reflected on the invoice, plus a dispensing fee; or (2) TMAC. While we appreciate that using acquisition costs may be more administratively challenging for covered entities to implement than a uniform estimated amount, we believe it is the only way for Texas to accurately determine the 340B price and thus ensure that 340B discounts obtained by covered entities are passed on to the state. Moreover, the use of actual acquisition costs for this purpose has been successfully adopted in other states, and thus would not be unique to Texas. Not to mention that this approach will further the state's efforts with respect to 340B program integrity by preserving the ability of manufacturers to identify potential duplicate discounts.

In the event that Texas nonetheless proceeds with its proposed reimbursement methodology, we strongly urge the state to provide stakeholders with an opportunity for meaningful comment with respect to how the "340B price" will be estimated by HHSC before the proposal is submitted to CMS in the form of a State Plan Amendment.

## II. HHSC Should Clarify its Intent With Respect to "Carve In"

BIO also believes that certain aspects of the Proposed Rule require further clarification. As you are aware, in accordance with federal guidance, covered entities must determine whether they will use 340B drugs for their Medicaid patients (i.e., "carve-in") or whether they will purchase drugs for their Medicaid patients through other mechanisms (i.e., "carve-out").[9] We believe that Texas should explicitly state that proposed subsection (c), which applies where a 340B drug is used for a Medicaid

[9] HRSA, 340B Drug Pricing Program Notice, Release No. 2013-2 (Feb. 7, 2013), available at: http://www.hrsa.gov/opa/programrequirements/policyreleases/medicaidexclusionclarification020713.pdf.

patient, does not mandate "carve in" for purposes of the Texas Medicaid program, but rather applies only where the election to use 340B drugs for Medicaid patients is made by the covered entity.

## III. HHSC Should Add Claims Processing Requirements for Physician-Administered Drugs

Finally, we note that the Proposed Rule fails to address the unique claims-processing requirements applicable to drugs purchased under the 340B program. While we appreciate that the state has issued guidance, effective January 1, 2014, outlining requirements for reporting Medicaid claims filled with 340B products,[10] we believe that the agency should also issue regulations specifically addressing how the agency will ensure compliance with these obligations. Merely stating that "[i]t is the responsibility of the provider to correctly report claims filled with 340B stock for 340B-eligible patients to ensure rebates are not collected for these drugs" is not sufficient, as providers' failure to comply with this requirement will have real implications for the state. Indeed, to the extent providers' fail to report these claims, it would be impossible for the state to identify those claims filled with 340B drugs—a necessary part of complying with the federal duplicate discount prohibition.

We also believe that the state should revisit its sole reliance on the Medicaid Exclusion File for purposes of identifying claims for physician-administered drugs. As you may be aware, in 2011, the OIG issued a report regarding the 340B program, which noted that the majority of states use alternatives to the Medicaid Exclusion file, in many cases because the file contains inaccurate data.[11] As the OIG noted, "[s]tates need accurate data to identify 340B claims so they do not subject manufacturers to duplicate discounts by including 340B claims in utilization data submitted for Medicaid rebates."

As an additional safeguard, we urge the state to require covered entities to employ the industry standard, under which providers add a "UD" modifier, in addition to the National Drug Code (NDC), to their claims forms to identify physician-administered 340B products. Notably, without the inclusion of this modifier, it would be impossible to identify which physician-administered drugs were purchased under 340B (and are thus barred from obtaining Medicaid drug rebates) where the Medicaid Exclusion File is inaccurate.

## IV. Conclusion

BIO appreciates the opportunity to comment on HHSC's Proposed Rule regarding 340B program reimbursement. We very much support the state's efforts to eliminate duplicate discounts and hope that our comments will be a useful tool as the state refines its proposed regulations. Please feel free to

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[10] HHSC, Vendor Drug Program – 340B Rebate Procedures Manual for Texas Medicaid Providers Participating in the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program (Effective Jan. 1, 2014), available at: http://www.txvendordrug.com/downloads/formulary/Rebate-Procedures-Manual.pdf.

[11] Levinson, Daniel R. *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs.* Washington, DC: U.S. Department of Health and Human Services; 2011. Page 13.

contact me at (202) 962-9200 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

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