Biotechnology Industry Organization

October 27, 2015

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BY ELECTRONIC SUBMISSION

Re: *340B Drug Pricing Program Omnibus Guidance* [RIN-0906-AB08]

Dear Secretary Burwell, Acting Administrator Macrae, and Director Captain Pedley:

The Biotechnology Industry Organization ("BIO") appreciates the opportunity to submit the following comments in response to the proposed Notice, issued by the Health Resources and Services Administration ("HRSA") and published in the *Federal Register* on August 28, 2015, entitled *340B Drug Pricing Program Omnibus Guidance* [RIN-9096-AB08] ("Proposed Notice").[1]

BIO represents an industry 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 indigent patients. We believe that compliance with 340B Program requirements by all parties—including manufacturers—is an important part of ensuring the sustainability of the 340B Program. Accordingly, we applaud HRSA's recent commitment and activities to enforce program oversight and compliance, as well as HRSA's effort to provide further program guidance by means of the Proposed Notice. Given the widely recognized need for greater programmatic guidance and oversight, we strongly urge HRSA to finalize the guidance proposed in the Proposed Notice in a timely fashion, after careful consideration of the recommendations articulated in this letter.

[1] 80 Fed. Reg. 52,300 (Aug. 28, 2015).

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BIO's Comments

I. Overview of BIO's Comments

Since its inception, the 340B Program has been implemented in a manner that presumes covered entity compliance with program requirements, which has resulted in both intentional and unintentional instances of diversion and duplicate discounts. As we have expressed in the past, BIO remains concerned that, without stronger enforcement, the 340B Program will cease to benefit the population for whom it was enacted to help. Particularly since the passage of the Affordable Care Act, which expanded 340B Program eligibility to a greater number of entity types, the program has seen exponential growth in terms of the number of participating facilities deemed eligible to receive drugs at the discounted 340B price. These changes have made it even more imperative for HRSA to properly enforce and oversee the 340B program, which has undergone significant growth and is thus increasingly at risk for abuse. HRSA cannot and should not continue to rely primarily on covered entities' self-policing of compliance. Instead, the program and its intended beneficiaries will be better served if HRSA implements comprehensive guidance with respect to the 340B Program, including mechanisms for direct oversight of compliance by all program participants.

The Proposed Notice addresses many of the factors that currently obfuscate compliance within the Program, and we urge HRSA to finalize it in a timely manner, taking into consideration the recommendations articulated here. Specifically, clearer guidance is still needed, including to assure that HRSA, manufacturers, and covered entities can appropriately work together in a manner that imposes the fewest burdens across program participants. In addition, as recognized throughout BIO's comments, there may be a need for HRSA to create limited exceptions from certain aspects of the proposed guidance in recognition of the diversity of non-hospital covered entities and the geographic areas that they serve. These entities, together with true safety-net hospitals, are a key part of our nation's public health infrastructure and it is critical that they can continue to use the 340B Program to support this important role, while the requirements of the federal grants and programs that form the basis of their 340B Program eligibility also help assure that the 340B Program is used appropriately. In the body of the letter, BIO has comprehensively responded to all aspects of the Proposed Notice, but we use the paragraphs below to highlight our primary concerns with how the Program has been implemented to date, as well as how these issues can be addressed via the timely finalization of the Proposed Notice, with the refinements articulated throughout this letter.

- **Definition of "Patient":** Given the widely recognized need for a definition of the term "patient" that is both auditable and clearly limits the scope of the 340B Program to individuals who have a true patient-to-provider relationship with a 340B covered entity, BIO strongly supports HRSA's proposals to reinforce aspects of the current "patient" definition, in particular the proposed requirement that a patient relationship must be established on a prescription-by-prescription (or order-by-order) basis, which will help address stakeholder concerns that the existing patient definition is substantially outdated, overly broad, and lacking clarity. We also strongly support HRSA's proposed clarification that referrals, and the provision of

infusions/administration alone, are insufficient for establishing a "patient" relationship for purposes of 340B, but urge HRSA to eliminate its proposed recognition of "telemedicine, telepharmacy, remote or other health care service arrangements" under the patient definition, which we believe could be subject to significant abuse. We also urge HRSA to require that private, non-profit hospitals be limited to the scope of their contract or governmental powers that form the basis of their eligibility for the 340B Program.

- **Contract Pharmacy Program:** Since the inception of the 340B Program in 1992, the 340B statute has never authorized—or even made reference to the concept of—contract pharmacies. Nevertheless, HRSA's most recent guidance permitted all covered entities to enter into an unlimited number of contract arrangements, which has substantially increased the scope of the 340B Program, as well as the risk for diversion and duplicate discounts, without necessarily benefitting the low-income or otherwise needy patients of the covered entities for whom the benefits of the program were intended. While we support many of the proposed clarifications with respect to contract pharmacy arrangements outlined in the Proposed Notice, we believe that further direction and clarity is warranted, including with respect to covered entity oversight of both contract pharmacies and other for-profit third-parties involved in contract pharmacy arrangements that are increasingly reaping substantial profit from their involvement in the 340B Program.

- **Hospital Child Site Eligibility:** Another area in which the 340B Program is experiencing substantial growth relates to the increased participation of hospital child sites. Specifically, there is evidence to suggest that hospitals are increasingly acquiring community-based practices—often in wealthier or distant locations—motivated, in part, by an interest in enabling these acquired facilities to participate in the 340B Program, with substantial financial benefits for the parent hospital. However, this practice also often results in greater out-of-pocket costs for patients, as well as disruptions in care. BIO is therefore extremely concerned that HRSA has proposed to eliminate its longstanding policy of requiring facilities to obtain Medicare "provider-based status" in order to participate as child sites in the 340B Program. Not only would this proposal contribute to the alarming trend of practice acquisitions by 340B hospitals by lowering the bar as to the degree to which acquired practices must be integrated with the parent in order to be able to participate in 340B, it also would deviate from the statutory scheme—which expressly limits 340B eligibility to certain, specified entity types—as there would be no way to establish the level of integration and ownership necessary to ensure a given child site is actually considered part of its parent hospital in the absence of the "provider-based status" requirement. We also ask that HRSA require that all facilities be wholly owned and operated by their parent hospital in order to participate as child sites in the 340B Program.

- **Covered Outpatient Drug:** BIO has significant concerns with HRSA's proposal to change its longstanding policy, in place since the inception of the Program, with respect to the "covered outpatient drug" definition in a manner that is inconsistent with the statute. We strongly urge HRSA to instead maintain its current policy,

under which all drugs reimbursed via bundled payments by any payor are excluded from this definition.

- **Duplicate Discounts:** While HRSA is now finally proposing to address the duplicate discount prohibition in the context of Medicaid managed care, the Agency's specific proposal—to allow covered entities to make unique "carve-in/out" determinations across Medicaid managed care and fee-for-service utilization, and even among Medicaid managed care plans—would be so complex as to be inoperable. We therefore urge the Agency not to finalize this proposal, and instead require that covered entities make one "carve-in/out" determination applicable across all Medicaid utilization, including both fee-for-service and managed care.

- **Manufacturer Obligations:** For the 340B Program to be successful for patients, manufacturers and covered entities must be able to work together; however, HRSA has consistently released guidance that, in our view, emphasizes the lopsided framework through which this program is structured. Several policies proposed by HRSA in the Proposed Notice continue this trend and appear to suffer from a lack of understanding with respect to the operational realities of the biopharmaceutical industry. One particular example of this can be seen in HRSA's proposal with respect to manufacturer credits and refunds in the Proposed Notice. While HRSA has not yet established a clear process for the issuance of such refunds—as required by statute—the proposals on this topic outlined in the Proposed Notice would impose undue burden on manufacturers (e.g., multiple refunds during the Medicaid Drug Rebate restatement period, no *de minimis* thresholds), and may even require manufacturers to extend sub-ceiling discounts to covered entities, contrary to the 340B statute (e.g., by discouraging netting or aggregating purchases). In addition, HRSA has proposed to require review and approval of manufacturer distribution plans, which would pose significant operational burdens and risks for manufacturers, potentially jeopardizing patient access to critical medicines, without providing any evidence of difficulties on the part of covered entities to obtain 340B drugs at the ceiling price in the absence of such a policy. We therefore urge the Agency not to finalize either policy, as proposed.

While foregoing paragraphs do not comprehensively summarize all of BIO's feedback and suggestions addressed in the body of our comment letter, we hope that this overview provides context for our recommendations, as well as an indication of BIO's key priorities. In sum, we urge HRSA to finalize the Proposed Notice, taking into consideration the manufacturer perspective articulated throughout this letter, as well as the impact of the program's considerable and heretofore unfettered growth.

II. Stated Purpose of Proposed Notice; Effective Date; Structure

HRSA describes the purpose of the Proposed Notice as follows: "The notice proposes guidance for covered entities enrolled in the 340B Program and drug manufacturers that are required by section 340B of the PHSA to make their drugs available to covered entities under the 340B program. When finalized after consideration of public comments solicited by this notice, the guidance is intended to assist 340B covered entities and drug

manufacturers in complying with the statute."[2] BIO supports this description for two important reasons.

First, we support HRSA's decision to release the Proposed Notice for public comment. A wide array of stakeholders are deeply vested in the 340B Program, all of which are likely to provide feedback regarding how the Proposed Notice, as drafted, would affect them. We further support HRSA's intent to consider these public comments, including the recommendations made in this letter, in issuing a final notice.

Second, we support HRSA's characterization of the notice as "guidance" that is "intended to assist 340B covered entities and drug manufacturers in complying with the statute." Given that the Proposed Notice addresses areas where HRSA lacks rulemaking authority, we support HRSA's decision to make clear—at the outset of the Proposed Notice—that any final notice would be guidance intended merely as a tool to assist program participants in complying with the 340B statute.[3]

We are concerned, however, with respect to certain general aspects of the guidance as proposed. For instance, the Proposed Notice covers a wide range of topics, many of which have been addressed in various documents, including *Federal Register* notices and policy releases, over the life of the 340B Program. BIO urges HRSA to state clearly in any final guidance that it supersedes all prior guidance on the topics covered, and also to ensure that the substance of all prior guidance that HRSA intends to keep applying is explicitly incorporated into the final guidance. As the Office of Management and Budget's Bulletin for Agency Good Guidance Practices emphasizes, in developing significant guidance documents "agencies should be diligent to identify for the public whether there is previous guidance on issue and, if so, to clarify whether that guidance is repealed by the new significant guidance document completely and, if not, to specify which provisions in the previous guidance document remain in effect."[4] This will be critically important to ensure that stakeholders are not left guessing as to whether certain portions of prior HRSA guidance remain in force, and will make the final guidance an "omnibus" guidance document, as intended.

We also are concerned that the Proposed Notice does not indicate when a final notice would become effective. The Proposed Notice includes an effective date only with respect to one aspect of the Agency's proposal regarding the AIDS Drug Assistance Program ("ADAP") rebate policy.[5] HRSA also does not indicate in the Proposed Notice

[2] 80 Fed. Reg. at 52,300.
[3] Am. Tort Reform Ass'n v. Occupational Health & Safety Admin., 738 F.3d 387 (D.C. Cir. 2013) (citing and quoting Nat'l Park Hospitality Ass'n v. Dep't of Interior, 538 U.S. 803, 809 (2003)). Throughout the guidance, we note that HRSA is proposing to require certain actions of covered entities that have elected to participate in the 340B Program; BIO recommends certain, additional, covered entity requirements and obligations throughout this letter. Although this guidance is non-binding, it addresses many circumstances where covered entities are effectively required to take certain actions as a condition of participating in the 340B Program and obtaining the 340B discounts in the first instance. Consequently, HRSA is not technically requiring covered entities to take action through the guidance; instead the guidance merely clarifies the conditions of participation by covered entities in the program. Any requirements on covered entities articulated by HRSA, or recommended by BIO, are thus merely conditions of receiving the 340B discount.
[4] 72 Fed. Reg. 3432, 3436 (Jan. 25, 2007).
[5] See 80 Fed. Reg. at 52,313 ("Therefore, to allow for the development of systems and any other necessary changes in order to make qualified payments on behalf of an ADAP client for those states utilizing the rebate

whether any final guidance would apply prospectively only, or retrospectively as well. As a general matter, any retrospective application would be unlawful under basic principles of administrative law, as well as HRSA's historical practice of applying policies prospectively.[6] We therefore urge HRSA to make clear that any guidance articulated in the Proposed Notice—particularly language that deviates from the Agency's current policy—would apply on a prospective basis only. Moreover, we strongly urge HRSA to provide stakeholders with a reasonable period of time—at least 12 months from publication of the final guidance, which is the time period proposed with respect to the change in the ADAP rebate policy—to consider how best to account for any such final guidance.

Finally, BIO is concerned with the manner in which the Proposed Notice is structured. As published in the *Federal Register*, the Proposed Notice includes not just the proposed guidance (under the heading "Proposed Guidance"), presented in a similar manner to regulation text (albeit without provision numbers), but also preamble text (under the heading "Summary of the Proposed Guidance"). Specifically, as we note throughout this letter, there are instances in which the preamble text and the guidance text are inconsistent. We believe that this oversight not only makes the Proposed Notice more difficult to understand, but also is likely to result in stakeholder confusion as to the Agency's policies going forward. We therefore urge HRSA to either: (1) present its guidance as a unified document that consolidates the discussion currently articulated in both the preamble and the guidance sections; or (2) at a minimum, ensure consistency between the two separate sections, taking into account the recommendations articulated in this letter.

III. Part A—340B Program Eligibility and Registration

a. Non-Hospital Eligibility

Consistent with the 340B statute and current practice, in the Proposed Notice, HRSA proposes that "[a] non-hospital entity will be listed on the public 340B database if it registers and establishes that it receives a qualifying Federal grant, Federal contract, Federal designation, or Federal project as defined in sections 340B(a)(4)(A) through (K) of the PHSA."[7] HRSA further proposes that the Agency will "assign a unique 340B identification number to represent each entity type for which a non-hospital covered entity registers and demonstrates eligibility and list the entity accordingly on the public 340B database,"[8] and that "[a] non-hospital covered entity . . . is able to purchase and use 340B drugs under each of its eligible entity types, if the covered entity registers accordingly."[9] If HRSA finalizes its patient definition (discussed below) as proposed, which would limit non-hospital covered entities' use of 340B drugs to patients receiving health care services that are consistent with the scope of the covered entity's grant, project, designation, or

option, HHS is proposing to delay the effective date of section (b) of Part G, defining qualified payment, for 12 months after the publication date of the final guidance.").

[6] See Bowen v. Georgetown University Hospital, 488 U.S. 204, 208-209 (1988) (finding that, as a general matter, statutory grants of rulemaking authority will not be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by express terms).

[7] 80 Fed. Reg. at 52,316.

[8] Id.

[9] Id. at 52,302.

contract, we understand the need to allow these non-hospital entities to participate under multiple eligibility types.

We are concerned, however, that this proposed policy could result in duplicate discounts, particularly where one of a non-hospital's eligibility pathways is as an ADAP. This is because, as discussed in section (IX) of this letter, while 340B discounts generally are provided at the front-end (either at the point-of-sale, or through replenishment models), ADAPs are permitted to obtain 340B discounts in the form of retroactive rebates. We also have identified instances in which a single entity appears in the public 340B database as a non-hospital covered entity *and* is part of a hospital covered entity and included on that hospital's Medicare cost report. This circumstance similarly could result in duplicate discounts to the extent that these entities rely on contract pharmacies, as the same prescription could be counted as 340B for the parent hospital *and* for the non-hospital covered entity. As we further discuss below, HRSA therefore should take steps to ensure that non-hospital entities enrolled under multiple eligibility types are not obtaining more than one 340B discount (i.e., an upfront discount, as well as a retroactive rebate) on the same unit of product. The same concern must be addressed where child sites associated with covered entities enrolled under multiple eligibility types are listed in the public 340B database under each eligibility type, as proposed.[10]

b. Hospital Eligibility

In accordance with the 340B statute, the Proposed Notice provides that HRSA will "list hospital covered entities on its public 340B database if the entity establishes that it meets the eligibility requirements in section 340B(a)(4)(L), (M), (N), or (O) of the PHSA"[11] and that such hospitals comply with "all 340B Program requirements for the hospital covered entity type for which it registered."[12] BIO supports these proposed clarifications.

BIO also supports HRSA's proposed clarification that "[a] hospital which qualifies for the 340B Program as more than one of the statutorily-defined hospital types may only register as one hospital covered entity type."[13] As proposed, "the hospital covered entity may change its covered entity type by registering as a different covered entity type during a regular registration period," which would become effective "as of the start date listed on the public 340B database for the new 340B identification number."[14] BIO supports this proposed requirement, as we believe that it would be confusing for hospitals to be simultaneously registered as multiple covered entity types. There also would be an

[10] In the Proposed Notice, HRSA proposes that "associated sites" of non-hospital covered entities—defined as "a health care delivery site which is not located at the same physical address as a non-hospital covered entity, but is part of and delivers outpatient services for the non-hospital covered entity"—may be eligible to participate in the 340B Program as "child sites" if the non-hospital covered entity: (1) registers the associated site; and (2) provides information demonstrating that each site is performing services under the main qualifying grant, contract, designation, or project. The Proposed Notice further states that such child sites "will be listed on the public 340B database, and can purchase and use 340B drugs, if the Departmental division which oversees such grant, project, designation, or contract verifies the eligibility." 80 Fed. Reg. at 52,302; 52,316. Notably, "HHS will list on the public 340B database all sites associated with multiple covered entities under each covered entity type." Id. at 52,316 (emphasis added).
[11] Id. at 52,317.
[12] Id.
[13] Id.
[14] Id.

increased risk for program abuse if hospitals were able to change their eligibility category other than through the quarterly registration process. We note, however, that there are instances in which the public 340B database currently shows an overlap of participation by the same location as two separate entity types. We recommend that HRSA develop controls to both flag and resolve any such inaccuracies moving forward.

We also support the proposed clarification that the hospital would have to proactively register each of its contract pharmacies upon re-enrolling as the new covered entity type.[15] However, we urge HRSA to further clarify that the start date for contract pharmacy participation would be prospective only, and that it would be the same start date as applies to all other entities that enrolled during the registration period in question.

i. Hospital Public Ownership or Contract

As a condition of eligibility for participation in the 340B Program, the 340B statute requires that *all* categories of 340B hospitals have some formalized relationship with a unit of state or local government.[16] Specifically, section 340B(a)(4)(L)(i) articulates three alternative categories of hospital eligibility:

(1) The hospital is owned or operated by a unit of state or local government;
(2) The hospital is a public or private non-profit corporation that is formally granted governmental powers by a unit of state or local government; or
(3) The hospital is a private non-profit hospital that has a contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid.

BIO appreciates HRSA's efforts to provide greater clarity with respect to each of these eligibility pathways.

We believe that further Agency guidance is particularly critical with respect to hospitals that are not publicly owned or operated (i.e., eligibility categories #2 and #3), as the lack of HRSA guidance with respect to the 340B eligibility pathways for these hospitals has been the subject of recent scrutiny.[17] Specifically, while Congress expressly stated that it did not intend for a private non-profit hospital to be eligible for the 340B Program on the sole basis of "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues,"[18] a 2011 Government Accountability Office ("GAO") report found that the lack of HRSA guidance in this area has resulted in "hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare" becoming eligible to claim 340B discounts.[19]

Below, we discuss our recommendations with respect to the Agency's proposed clarifications provided in the Proposed Notice specific to each of the three eligibility

[15] Id. at 52,304.
[16] 42 U.S.C. § 256b(a)(4)(L) – (O).
[17] Gov't Accountability Office, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, GAO-11-836 (Sept. 23, 2011) (hereinafter "2011 GAO Report").
[18] H.R. Rep. No. 102-284(II), at 15 (1992).
[19] 2011 GAO Report.

pathways in turn. In addition, as a general matter, we urge HRSA to indicate in the 340B database entry for each hospital participating in the program under section 340B(a)(4)(L)(i) which of the three pathways forms the basis for the hospital's eligibility for the 340B Program. Publishing this information would provide greater transparency and accountability for participating hospitals, which constitute a significant proportion of participating covered entities.

1. Owned or operated by a unit of state or local government.

The Proposed Notice would clarify that HRSA considers a hospital eligible for the 340B Program on the basis of being "owned or operated by a unit of State or local government" if the hospital is either: (1) wholly owned by a state or local government and recognized as such in documentation from federal agencies (e.g., Internal Revenue Service ("IRS") filings and acknowledgements, as applicable); or (2) operated through an arrangement where the state or local government is the sole operating authority of the hospital.[20] BIO supports this proposed clarification, in particular the proposed requirement that the hospital's public ownership be documented by federal agencies, such as the IRS. However, we urge the Agency to further clarify that any federal documentation used for this purpose is subject to penalty for any knowing and willful materially false representation under section 1001 of title 18 of the United States Code. We also urge HRSA to outline with precision the applicable documentation requirements to establish that a state or local government is the "sole operating authority of a hospital." Finally, we urge HRSA to clarify that establishing both ownership and operation by a public entity requires a valid signature by the relevant state or local official, also subject to penalty for false statements.[21]

2. Public or private non-profit corporation that is formally granted governmental powers by a unit of state or local government.

Under the Proposed Notice, HRSA would consider a hospital eligible for the 340B Program on the basis of having been "formally granted governmental powers by a unit of State or local government" if the Agency "receives certification that a State or local government formally delegates to the hospital a power usually exercised by the state or local government."[22] BIO supports this proposal, as well as the proposed documentation requirements,[23] but urges the Agency to clarify that this certification must be made not only by an individual legally authorized to bind the hospital, but also by the relevant state or local official, and is subject to penalty for any false statement as discussed above.

[20] 80 Fed. Reg. at 52,317.
[21] It is our impression that this is current practice, based on the hospital certification forms provided to the Office of Management and Budget with HRSA's recent proposed information collection request related to ceiling price verification and covered entity eligibility. See Office of Pharmacy Affairs (OPA) Hospital Certification of Ownership Operation by a Unit of State/Local Government.
[22] 80 Fed. Reg. at 52,317.
[23] The preamble seeks to further clarify that "HHS will list a hospital qualifying under this provision when it submits, as part of its registration: (1) The name of the government agency granting the governmental power to the hospital; and (2) a description of the governmental power granted to the hospital and a brief explanation as to why the power is considered to be governmental; and (3) a copy of any official documents issued by the State or local government to the hospital that reflect the formal grant of governmental power." Id. at 52,301.

BIO supports HRSA's proposed further clarification in the Proposed Notice that "[t]he delegation may be granted through State or local statute or regulation; a contract with a State or local government; creation of a public corporation; or development of a hospital authority or district to provide health care to a community on behalf of the government,"[24] although we urge HRSA to clarify that this is the exhaustive list in terms of how governmental powers may be delegated. We further support HRSA's explanation in the preamble text that "[e]xamples of governmental powers include, but are not limited to, the power to tax [and] issue governmental bonds," but find it odd that HRSA also proposes that "act[ing] on behalf of the government" would similarly qualify, as it is a much less defined standard as compared to "power to tax" and "issu[ing] governmental bonds," and thus could be subject to abuse, if finalized.

We also agree that a hospital would not be eligible for the 340B Program by virtue of having been granted "powers generally granted to private persons or corporations upon meeting of licensure requirements, such as a license to practice medicine or provide health care services commercially."[25] We believe that this proposed clarification is important to draw a distinction between those activities that constitute acting on the government's behalf—which could fairly be characterized as "governmental powers"—and activities that merely constitute acting with the government's permission or license—which could not. Analogously, HRSA also should distinguish between instances in which a state grants *powers* as opposed to merely imposing *duties*, as the latter similarly would not meet the statutory eligibility criterion of having been "granted governmental powers." This proposal could be strengthened by further illustrating areas in which a *hospital* (as opposed to another type of entity) could be granted governmental powers (e.g., immunization or quarantine in the case of a public health emergency), as we doubt that hospitals are often, if ever, granted the authority to tax state or local citizens, for instance.

Finally, we note that, while the statute limits eligibility under this pathway to hospitals that are either "public" or "private non-profit," HRSA's proposal does not provide clarification with respect to the documentation necessary to demonstrate a hospital's public or non-profit status. We therefore urge HRSA to articulate criteria as to what constitutes a public hospital, as well as a non-profit hospital. In particular, with respect to a hospital's non-profit status, we note that federal and state non-profit requirements may differ. Given the requirement to obtain governmental powers from a state or local government entity, as well as the federal nature of this program, it is important for covered entities to comply with both federal and state non-profit requirements, and we urge HRSA to clarify that this is so.

We also urge HRSA to take steps to improve its processes for verifying non-profit status. We understand that HRSA verifies the status of participating hospitals quarterly by matching the list of participating hospitals with the Centers for Medicare & Medicaid Services' ("CMS's") list of hospitals to ensure that ineligible private for-profit hospitals are not participating in the 340B Program. However, as HRSA is surely aware, hospitals that enroll in the 340B Program as non-profit hospitals are sometimes acquired by for-profit entities, which, under the terms of the statute, renders them ineligible for continued

[24] Id. at 52,317.
[25] Id. at 52,301.

participation in the 340B Program. To guard against violations of the statute and to protect the integrity of the 340B Program, BIO recommends that HRSA require covered entities to include a complete list of all of their parent entities, including any immediate owners, ultimate parents, and those entities in between and require this information to be included, and regularly updated on the public 340B database. We also strongly recommend that HRSA revise the annual re-certification requirement to include a statement that the covered entity, and any immediate owners, ultimate parents, or entities in between, are all non-profit entities, subject to penalty for any false statement as discussed above. We also recommend that HRSA require covered entities to further certify that all of their child sites are non-profit organizations, similarly subject to penalty.

3. Private non-profit hospital that has a contract with a state or local government.

Under the Proposed Notice, HRSA would consider a hospital eligible for the 340B Program on the basis of having a contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid if the hospital "provides a signed certification by the hospital's 340B Program authorizing official and an appropriate government official" indicating that a contract is "currently in place" between the private, non-profit hospital and the state or local government to provide such services.

While we support this proposed clarification, we note that it is effectively restating current practice, which has been the subject of criticism. Specifically, in its 2011 report, the GAO stated:

> For the second requirement, HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals. Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.[26]

To address the GAO's concerns, BIO urges HRSA to: (1) require that covered entities provide a copy of the contract at issue; and (2) review each of these contracts to ensure that the statutory eligibility criteria are met.

In addition, while we support HRSA's proposed clarification that the contract in question should "create enforceable expectations for the hospital for the provision of health care services, including the provision of direct medical care" to low-income individuals,[27] HRSA should make an effort to interpret this criterion in accordance with Congressional intent, as evidenced in the provision's legislative history. As noted above, in enacting this provision, Congress specified that it would not allow 340B participation by a private

[26] 2011 GAO Report (internal citations omitted).
[27] 80 Fed. Reg. at 52,317.

nonprofit hospital that had "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues."[28]

As early as 2006, even the Public Health Pharmacy Coalition ("PHPC") had cited concerns about the possibility of a private, non-profit hospital enrolling in the 340B Program based on inadequate indigent care contracts, and had recommended that "[HRSA] devise guidelines to ensure that hospitals provide significant levels of indigent care as a condition of participation in 340B, and further, that the guidelines be constructed in a way that jeopardizes a hospital's 340B status if it does not provide adequate levels of indigent care."[29] This request for specific standards to ensure these hospitals were providing "significant levels of indigent care as a condition of participation in 340B" was echoed by the Safety Net Hospitals for Pharmaceutical Access (SNHPA)[30] in 2007.[31]

Accordingly, HRSA should both require that activities under such contracts represent a significant portion of the hospital's operating revenues, and are not for services the hospital is otherwise obligated to provide under state or federal law (e.g., the Emergency Medical Treatment and Active Labor Act). HRSA also should require that only drugs prescribed in connection with health care services that are within the scope of the qualifying contract be eligible for 340B pricing, as described in greater detail in section (V)(a), below. We also urge HRSA to work with stakeholders to identify criteria with respect to the patient population that qualifies as "low-income" for purposes of operationalizing these recommendations (e.g., individuals at or below the Federal Poverty Level). We note that this recommendation aligns with SNHPA's 2007 position that the "government should establish more specific standards to ensure program integrity."[32]

Finally, we note that, as with the eligibility pathway for hospitals granted government powers, described above, HRSA has not addressed how a hospital's non-profit status would be verified for purposes of assessing a hospital's eligibility under this pathway. We therefore urge HRSA to establish criteria to determine and verify a hospital's non-profit status for purposes of eligibility under this pathway, as recommended in the previous section.

ii. Hospital Eligibility Under Section 340B(a)(4)(L)(ii)

In addition to the requirements that a hospital have a formalized relationship with state or local government described in the previous section, with the exception of critical access hospitals, all hospitals also are required to exceed a certain Medicare disproportionate share hospital ("DSH") adjustment percentage in order to be eligible to participate in the 340B Program.[33]

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[28] H.R. Rep. No. 102-284(II), at 15 (1992).
[29] Public Hospital Pharmacy Coalition, Indigent Care Policy for Private Non-Profits, Letter to Jimmy Mitchell, OPA, HRSA (July 13, 2006) (hereinafter "2006 PHPC Letter").
[30] Now referred to as "340B Health."
[31] SNHPA, Letter to Bradford R. Lang, Comment on Proposed Guidelines on 340B Patient Definition (March 13, 2007) (hereinafter "2007 SNHPA Letter").
[32] 2007 SNHPA Letter.
[33] As HRSA notes in the preamble text, DSH hospitals, children's hospitals, and free-standing cancer hospitals must have a Medicare disproportionate share adjustment percentage greater than 11.75 percent (or be a "Pickle hospital" described in section 1886(d)(5)(F)(i)(II) of the Social Security Act ("SSA")); rural referral

As an initial matter, BIO would like to voice its concerns with respect to the DSH metric generally. Specifically, the DSH formula as applied in the 340B Program is flawed in at least two ways. First, the DSH percentage reflects care provided to low-income Medicare and Medicaid patients but does not reflect care provided by a hospital to other uninsured, or charity-care, patients, whom the 340B Program is intended to benefit. Second, the DSH percentage is a measure of *inpatient care*, while the 340B Program is limited to *outpatient drugs*. Consequently, hospitals are permitted to enter the 340B Program on the basis of a metric that is unrelated to the scope of the 340B Program itself. Indeed, even the PHPC had noted to HRSA that tightening up the patient definition will not solve the problem of 340B hospitals enrolling in the program based on inadequate indigent care contracts, because "the real issue relates to the payer mix of a hospital's outpatient population, not how a patient is defined."[34]

Nonetheless, the 340B statute defines hospital eligibility based on the DSH percentage reported on a hospital's Medicare cost report for the most recent cost reporting period, and we generally support HRSA's proposed clarification in the Proposed Notice that the Agency would "review a hospital's most recently filed Medicare cost report to ensure that the hospital meets the statutorily required DSH percentage," although we urge HRSA to clarify that the Agency would rely on the *final* cost report that has been audited and accepted by CMS for this purpose. Pending the availability of this final cost report, we further recommend that an otherwise-eligible hospital be permitted to participate provisionally in the 340B Program if its most recently filed cost report shows a DSH percentage above the relevant threshold and the public 340B database record for that hospital signals its provisional status; however, if the hospital's final Medicare-approved cost report for the quarter involved shows a DSH percentage at or below that threshold, the hospital would be required to pay manufacturers the difference between the 340B price and the commercial price for the drugs provisionally obtained at the 340B price. The same principle should apply to the extent that a hospital appeals the DSH percentage in its final Medicare cost report, but loses. Simply put, a hospital that qualified for 340B Program participation based on an erroneously high DSH percentage cannot retain those discounts once it is determined that hospital in fact never satisfied the statutory eligibility requirement for participation in the 340B Program in the first instance.

As noted in section (III)(d), below, BIO also recommends that HRSA consider including in the public 340B database information regarding the DSH percentage upon which a hospital has based its current 340B Program eligibility, as applicable, to be updated on a regular basis, and flag those covered entities that are provisionally eligible for 340B, as recommended in the prior paragraph. This information will provide greater transparency regarding each hospital's eligibility status. We also urge HRSA to provide a historical report of each covered entity's periods of 340B Program eligibility/ineligibility, DSH status, and ownership status (e.g., non-profit vs. for-profit), which, together with information regarding each hospital's current DSH percentage, also will facilitate processing claims

centers and sole community hospitals must have a disproportionate share adjustment percentage equal to or greater than 8.0 percent. Critical access hospitals are not subject to a disproportionate share adjustment percentage requirement.

[34] 2006 PHPC Letter.

from—and resolving disputes with—hospitals with borderline DSH percentages that may fluctuate into and out of eligibility for the 304B Program.

HRSA also proposes to clarify in the Proposed Notice that those children's hospitals that are not required to file a Medicare cost report would be required to "provide, in a time frame determined by HHS, a statement from a qualified independent auditor certifying that the auditor performed an audit on the records of the children's hospital, that the auditor is familiar with Federal rules and regulations relevant to its findings, and found that the hospital would meet the criterion in section 340B(a)(4)(L)(ii) of the PHSA" (i.e., maintain a disproportionate share adjustment percentage of greater than 11.75 percent).[35] BIO generally supports this proposed requirement, in particular the proposed clarification that such statements be provided by a qualified independent auditor.

iii. Hospital Child Sites

Under the Proposed Notice, off-site outpatient facilities and clinics of hospital covered entities would be eligible to participate in the 340B Program "if the most recently filed Medicare cost report lists each facility or clinic on a line that is reimbursable under Medicare, and demonstrates that the services provided at the facility or clinic have associated outpatient Medicare costs and charges."[36] HRSA also proposes, in its "child site" definition, that any such entity also must be "enrolled in the 340B Program and listed on the public 340B database" in order to be considered a "child site" for purposes of participating in the 340B Program.[37]

As an initial matter, we agree with HRSA's acknowledgment in the Proposed Notice that a hospital child site must have "*outpatient* Medicare costs and charges" in order to be 340B eligible. Given that the 340B Program is limited to "covered *outpatient* drugs," it is important that only outpatient facilities be included in the program as child sites.

We also support HRSA's recognition that an entity must be both enrolled in the 340B Program and listed on the 340B database in order to be considered a child site.[38] These proposed requirements align with HRSA's recently proposed definition of a "covered entity,"[39] which similarly would require that a covered entity be registered and appear on the public 340B database, and would help ensure that manufacturers have a means to identify those facilities that are 340B-eligible, including child sites of covered entities. That said, we urge HRSA to provide an example—similar to the example provided in the section regarding loss of eligibility—with specific dates when the hospital would no longer be eligible to purchase 340B drugs. For example, if a child site is acquired in July of 2015 and included in the hospital's cost report for the 2015 calendar year, then that site would be eligible to begin purchasing 340B drugs, at least provisionally, when the hospital files that cost report, typically in May of 2016.

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[35] 80 Fed. Reg. at 52,317.
[36] Id. See also id. at 52,302.
[37] Id. at 52,316.
[38] Id.
[39] 80 Fed. Reg. 34,583, 34,585 (June 17, 2015) (42 C.F.R. § 10.3 [proposed]).

However, while the proposed Medicare cost report requirement outlined in the Proposed Notice generally aligns with HRSA's longstanding child site guidance—first articulated in 1994[40]—HRSA is now proposing to abandon its equally longstanding policy of requiring these facilities to also meet Medicare's provider-based status requirements (outlined at 42 C.F.R. § 414.65). The Agency is "actively seeking comment on alternatives" to this standard on the grounds that covered entities apparently do not wish to seek provider-based status determinations for their off-site facilities, even though those facilities may nonetheless qualify for the designation. HRSA also proposes that the remaining requirements would only apply to "off-site" facilities, which is similarly inconsistent with the Agency's prior guidance, under which any hospital "outpatient facility" was subject to HRSA's child site requirements.[41] We are extremely concerned with respect to both of these proposals, which likely would exacerbate the concerning growth of child-site participation in the 340B Program.

As an initial matter, we note that, over the last several years, the number of child sites have grown exponentially. To illustrate, a recent Berkeley Research Group analysis found that there were 239 oncology-related sub-entities in 2011 compared to 29 in 2004—a more than 8-fold increase.[42] This reflects an upward trend in hospital acquisitions of community-based physician practices more generally.[43] As these acquisitions increasingly occur in higher-income communities, the acquired sites often serve a different patient mix from that which formed the basis of their parent hospital's 340B eligibility.[44] While there may be other factors driving these acquisitions, the availability of deeply discounted 340B pricing allows 340B hospitals to generate higher net revenues than independent physician offices for administering the same medicine. This opportunity—never intended or foreseen by Congress—creates financial incentives for 340B hospitals to purchase independent physician practices and bring them under the 340B umbrella, and recent studies suggest that these incentives are, in fact, driving 340B hospital acquisitions of formerly independent physician practices.[45] Meanwhile, nothing in the 340B statute provides for any offsite hospital outpatient facility to participate in the 340B program, rather 340B eligibility for hospital "child sites" is a doctrine developed by HRSA alone. This doctrine cannot legitimately be used to extend 340B eligibility to offsite facilities—including formerly

[40] 59 Fed. Reg. 47,884 (Sept. 19, 1994).
[41] See id. at 47,886
[42] Aaron Vandervelde, Growth of the 340B Program: Past Trends, Future Projections, BRG White Paper (Nov. 2014), accessed at: http://www.thinkbrg.com/media/publication/524_Vandervelde_340B_GrowthDrivers_WhitePaper_20141202_FINAL.pdf.
[43] See, e.g., Aaron Vandervelde, Dr. Henry Miller, and JoAnna Younts, Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration, BRG White Paper (June 2014), accessed at: http://www.thinkbrg.com/publications-vandervelde-miller-younts-siteofcare.html; Aaron Vandervelde, 340B Covered Entity Acquisitions of Physician-based Oncology Practices, BRG white paper (April 2014), accessed at: http://www.thinkbrg.com/publications-vandervelde-340B-oncology.html.
[44] Rena M. Conti & Peter B. Bach, The 340B Drug Discount Program: Hospitals Generate Profits By Expanding to Reach More Affluent Communities, 33 Health Affairs 1786-92 (Oct. 2014).
[45] New data from Avalere Health finds that 340B hospitals are more likely than other hospitals to purchase independent physician offices that administer medicines. Avelere Health. Hospital acquisitions of physician practices and the 340B program (June 8, 2015). The study authors found that 61 percent of hospitals identified in the study as potentially acquiring physician practices participated in the 340B Program, as compared to a 45 percent 340B participation rate among all hospitals in the data set. Also, a 2014 *Health Affairs* study concluded that 340B is a "powerful contributor" to driving these hospital acquisitions of physician practices. Bradford Hirsch, Suresh Balu & Kevin Shulman, The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs. 33 Health Affairs 1714-20 (Oct. 2014).

independent physician practices—that are distinct from the covered entity hospital and serve distinct patient populations that the 340B Program was not created to assist. Yet, by proposing to loosen existing standards for child site eligibility, this is exactly what HRSA's proposal would do.

First, as noted previously, elimination of the provider-based status requirement would represent a significant departure from longstanding HRSA policy. HRSA has not provided an explanation as to why it proposed this policy change. Moreover, it is not clear from HRSA's cursory description which of the provider-based status requirements covered entities purportedly cannot—or do not wish to—satisfy with respect to their child sites, or how the facilities would demonstrate sufficient integration with the parent hospital based solely on the remaining requirements. HRSA also has not explained how the Agency would operationalize the only remaining criterion—inclusion on the hospital's cost report—in the absence of the provider-based status requirement, which we believe would be exceptionally difficult, given our understanding of the interplay between provider-based status and the Medicare cost report process generally.

Provider-based status is the standard used by Medicare for assessing that a facility in fact is an integral part of a parent hospital, such that the parent hospital may permissibly bill Medicare for services provided by that facility. To illustrate, this standard assesses, among other things, that the child is operated under the ownership of the parent; that there is full integration of clinical services, medical records, and financial operations between the parent and the child; and that the parent maintains the same monitoring and oversight over the child as it does over other provider departments.[46] As CMS has explained, the provider-based regulation is designed to "provide a high level of assurance that a facility complying with [the regulation] is, in fact, an integral and subordinate part of the facility with which it is based, and do[es] not accord provider-based status to facilities that . . . have only a nominal relationship with [the main] provider."[47] HRSA adopted this standard for purposes of assessing child site eligibility because, as the Agency explained in its 1994 guidance, it establishes "criteria that are not ambiguous" and that form "an independent and objective basis on which to determine eligibility."[48] Furthermore, if a facility does not demonstrate its integration with the parent hospital under these criteria, there is no basis for justifying the child site's participation in the 340B Program, unless that site is independently eligible for the program. Indeed, as HRSA notes in its proposed "child site" definition, a child site's 340B eligibility must be "derived from" that of an enrolled parent site.[49]

Notably, one of the criteria for obtaining provider-based status is that the facility is included on the hospital's Medicare cost report—one of the metrics of integrated financial

[46] See 42 C.F.R. § 413.65(d)-(e).
[47] 67 Fed. Reg. 49,981, 50,088 (Aug. 1, 2002).
[48] 59 Fed. Reg. at 47,885. The Agency similarly explained in 2007 that the decision to rely on provider-based status was made "because HRSA believes that the requisite integration of facilities necessary to demonstrate that the secondary facility is functioning as part of the DSH under 42 C.F.R. § 413.65, the regulation on when a facility is 'provider-based,' is appropriate for facilities eligible under the 340B program. Compliance with the rule for provider-based facilities would . . . [e]nsure that the individuals [served by a DSH hospital's outpatient facilities] are truly patients of the DSH." 72 Fed. Reg. 1543, 1545 (Jan. 12, 2007).
[49] 80 Fed. Reg. at 52,316.

operations. This is critical because, in the absence of provider-based status, it can be difficult to confirm that a particular facility is in fact included on a given hospital's Medicare cost report—the only other criterion HRSA is proposing for child site participation in the 340B Program.[50] Indeed, it is our understanding that an off-campus facility *cannot* bill as a Medicare provider (i.e., under the hospital's Medicare cost report) *unless* that facility has obtained provider-based status.

Accordingly, HRSA's proposal to abandon its longstanding provider-based status requirement has the very real potential to swallow the approach as a whole, particularly given that consolidation and conversion of physician offices into outpatient facilities of hospitals appear to be an emerging trend, and covered entities have financial incentives to adopt an aggressive interpretation of the remaining cost report requirement. Although HRSA has proposed that the Agency may review other documentation, as necessary, to verify child site eligibility, verifying that a given child site is included on a cost report in the absence of provider-based status is a near-impossible task, as described above, particularly for HRSA, an agency with limited resources. We therefore strongly recommend that HRSA continue its longstanding policy of relying on Medicare provider-based status, a binding standard that ensures that participating child sites are sufficiently integrated with an eligible covered entity in order to assess their eligibility for the 340B Program.

Provider-based status similarly should form the basis for independent auditors to assess whether a child site of a children's hospital that does not file a Medicare cost report is an integral part of the parent hospital, and would be included on the parent's Medicare cost report if one were filed. We remind HRSA that any policy purporting to permit entities to participate in the 340B Program that do not, on their own, meet 340B eligibility criteria and are only loosely affiliated with a covered entity would impermissibly expand 340B eligibility criteria beyond those outlined in the statute.

Second, we are concerned that HRSA appears to be limiting the applicability of its hospital child site policy to those facilities that are located "off-site." Yet, there are hospital covered entities that have arrangements with outpatient facilities that operate within the four walls of the hospital, but are not actually owned or operated by the hospital. For example, there are independent physician practices that rent office space from 340B hospitals. We are concerned that these entities could be considered part of the covered entity without meeting the same rigorous standards to demonstrate integration and ownership as apply to off-site facilities. Moreover, the artificial distinction that HRSA makes between on-site and off-site facilities is without merit, particularly given that HRSA has not provided a rationale for this proposed change (or even indicated that a change is being made). We therefore urge HRSA to modify its proposal such that it applies to all facilities, including those that are "on-site."

[50] Research conducted on behalf of BIO has demonstrated that using hospital cost reports to identify off-campus facilities is difficult, and that it often is necessary to infer the presence of newly acquired physician practices through increases in costs reported on Worksheet A of the parent entity's cost reports. This inference provides little information, however, in terms of the identity of the child site, nor is it even possible to perform such inferences where the off-campus facility is relatively small in size.

We also urge HRSA to require all facilities to demonstrate that they are wholly owned and operated by the parent hospital—a requirement already applicable to off-campus facilities per Medicare's provider-based status requirements.[51] Extending 340B eligibility to sites that are not wholly owned by a covered entity, and thus are at least partly owned by a non-covered entity, is inconsistent with HRSA's representations in the Proposed Notice that parent covered entities are ultimately responsible for program compliance of their child sites, and runs counter to Congress' intent that only "an entity that meets the requirements" specifically listed in the statute qualifies for participation in the program.[52]

In light of the foregoing, we therefore urge HRSA to clarify that *all* outpatient facilities—even those located on the same site as the hospital—must meet the following four criteria:

(1) be listed on the parent hospital's most recently filed Medicare cost report on a line that is reimbursable under Medicare, and demonstrates that the services provided at the facility or clinic have associated outpatient Medicare costs and charges;
(2) obtain provider-based status under the applicable Medicare regulations with respect to the parent hospital;
(3) be enrolled in the 340B Program and listed on the public 340B database;[53] and
(4) be wholly owned and operated by the parent covered-entity hospital.

We believe that all four of these requirements are critical to ensuring that a given outpatient facility is, indeed, an integral part of its parent 340B hospital such that the facility's eligibility can legitimately be "derived" from that of its parent hospital. Establishing standards to this effect are necessary not only to protect the integrity of the 340B Program, but to ensure that the Program's scope is sustainable so it can continue to benefit those who truly need it.

In terms of the specific documentation that HRSA should review to confirm compliance with these requirements, we urge HRSA to direct hospitals, as part of the child site registration process, to:

- Provide proof of ownership (i.e., non-profit, wholly owned by parent hospital) and operations status;
- Provide proof of compliance with Medicare's provider-based status requirements; and
- Identify the specific line of the Medicare cost report on which the child site appears, and to further include this information on the public 340B database.

[51] See 42 C.F.R. § 413.65(e)(1) (requiring that (1) the business enterprise that constitutes the facility is 100 percent owned by main provider; (2) the facility and main provider have same governing body; (3) the facility and main provider are operated under same organizational documents; and (4) the main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies, and final approval for medical staff appointments in the facility).
[52] See 42 U.S.C. § 256b(a)(4).
[53] While we recognize that off-site facilities are not required to independently register and appear on the public 340B database under current HRSA policy, we believe that greater transparency regarding entity participation in the program will assist both covered entities and manufacturers to better ensure program compliance.

We believe that this last requirement is essential, as we are aware of instances in which hospitals appear to be putting the drug purchases by off-campus facilities on the reimbursable portion of the Medicare cost report, while the facility itself is listed on a non-reimbursable portion. This would not appear to be permitted under HRSA's current or proposed policies regarding child site eligibility; requiring hospitals to provide this information during the registration process would help highlight these issues.

We further urge HRSA to provide additional clarification with respect to its proposal regarding reflecting the use of child sites on the public 340B database. BIO supports HRSA's proposal that each child site "will be listed individually even if they share the same physical address and/or common off-site location." We believe that this approach is necessary, given that a child site may lose 340B eligibility independent of the parent. Indeed, we strongly urge HRSA to ensure that covered entities are enrolling child sites *before* these sites begin purchasing through the 340B Program. We also urge HRSA to require covered entities to provide both a "bill-to" and a "ship-to" address for these sites.

If a hospital does not separately register its child sites with HRSA and instead uses a single "bill-to" address for drugs used at multiple sites—including drugs used by the hospital and those used by unregistered child sites—it would be impossible for manufacturers to disaggregate those purchases and distinguish between the legitimate 340B sales (going to the hospital and its registered and otherwise qualified 340B outpatient child sites) and those purchases ultimately going to child sites that do not qualify for and should not receive 340B pricing. Further, this practice would violate long-standing HRSA guidance, which clearly requires that outpatient facilities that qualify as integral parts of a 340B hospital may not obtain 340B drugs until they are registered with HRSA and added to the public 340B database.[54]

BIO strongly recommends that, when registering these child sites, the 340B hospital parent site be required to provide both the "bill-to" and the "ship-to" addresses for the child sites. This is necessary because chargeback data formats, which govern the data that manufacturers receive from wholesalers, often currently allow for the inclusion of only a single address, either "ship-to" or "bill-to." Many manufacturers elect to receive the "bill-to" address because this address provides some insight into whether the purchaser is a 340B covered entity. If the covered entity registers its child sites using the "ship-to" address, manufacturers thus may not be able to match chargebacks with a registered covered entity site because the chargeback data that manufacturers receive will not include the "ship-to" address. Requiring that outpatient facilities are listed with both their "bill-to" and "ship-to" addresses would ensure that manufacturers can adequately identify their customers and thus determine whether they are eligible for 340B discounts.

Finally, as noted in section (III)(b)(i), above, to the extent that the child site's parent hospital is 340B-eligible based, in part, on the hospital's non-profit status, HRSA should require the hospital to certify, subject to penalties for knowing and willful materially

[54] 59 Fed. Reg. at 47,886.

false statements, as to the non-profit status of each of its child sites during the registration and annual reenrollment periods.

c. Loss of 340B Eligibility

BIO supports HRSA's statement in the Proposed Notice that, "[i]n all scenarios, the covered entity must immediately notify HHS regarding any changes in eligibility for itself or a child site,"[55] as this information is critical for purposes of immediately removing those entities whose eligibility for the program has lapsed. We further support the Agency's request that covered entities provide to HRSA "the reason for the loss of eligibility, the effective date for the loss of eligibility, and the date of the last 340B purchase for a terminated"[56] entity, as we believe this information may assist HRSA in identifying not only the reasons for a particular entity's termination, but also potentially more systemic compliance issues affecting the program. However, while we support HRSA's recognition that the provision of such notifications is a condition of a covered entity appearing in the public 340B database—itself a requirement for 340B participation[57]—we urge HRSA to specify how the Agency actually will ensure covered entity compliance with this obligation. We also urge HRSA to further clarify that, in addition to relying on information regarding changes in eligibility status received from covered entities, the Agency also will take steps to proactively monitor ongoing 340B eligibility, both via the Agency's audits of covered entities and otherwise. The Agency should make clear that any changes that result in a loss of 340B eligibility take effect immediately. To illustrate, if a hospital's ownership status changed from non-profit to for-profit on October 21, 2015, that hospital's 340B eligibility ended on that day—even though it is in the middle of a 340B registration period.

In addition, BIO supports HRSA's proposed clarification that, "upon loss of eligibility of a parent site, child site, or termination of any contract pharmacy arrangement, the covered entity must immediately . . . stop purchasing and using 340B drugs at the terminated site(s),"[58] and that the entity "is liable to manufacturers for repayment for the 340B discounts on any drugs purchased for itself, any child site, or any contract pharmacy when the covered entity was ineligible for the 340B Program for any reason."[59] BIO also supports the proposed clarification that, "[i]f any non-eligible entity purchased 340B drugs after the date of loss of eligibility, it will be noted in the public 340B database,"[60] as this provides critical information to manufacturers regarding liability by entities for inappropriately claimed 340B discounts. We are concerned, however, that HRSA is inconsistent in the way in which it describes this proposed requirement. Specifically, in some instances, HRSA states that the covered entity "may" be liable for repaying discounts after losing eligibility, while in other instances, HRSA uses more mandatory language. We urge HRSA to emphasize that, in accordance with the 340B statute, such repayments are uniformly required of covered entities.

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[55] 80 Fed. Reg. at 52,302.
[56] Id. at 52,304.
[57] Id.
[58] Id.
[59] Id. at 52,302; 52,317. We note, however, that this language is missing from the hospital-specific provisions of the guidance found on page 52,317. We urge HRSA to correct this oversight in issuing its final guidance.
[60] Id. at 52,302.

Further, as BIO has articulated in prior comment letters,[61] we urge HRSA to ensure that the Agency's efforts to ensure covered entity eligibility pursuant to this proposal or otherwise do not have negative price reporting implications for manufacturers. Specifically, once a covered entity is terminated from the program, any discounts given to that entity may no longer be exempt from "best price" under the Medicaid rebate program. Discounts given to a terminated entity also may have to be included in manufacturer reporting of Average Manufacturer Price (AMP) and Average Sales Price (ASP)—and any sales to the formerly covered entity may be subject to the Medicaid rebate from the time of termination. For that reason, we also urge the Agency to establish mechanisms and processes for ensuring that the public 340B database is, in fact, updated immediately upon receiving information that a covered entity has lost its 340B eligibility. As noted in the following section, we further urge HRSA to ensure that the public 340B database includes information on historical periods of covered entity eligibility and ineligibility, which should clearly identify the date on which the covered entity lost its eligibility status. HRSA also should send out "push" notifications to manufacturers and/or entities designated by manufacturers (e.g., wholesalers) with this information, to include information regarding the effective date of covered entity ineligibility. We also urge HRSA to work with other federal agencies, including CMS, to ensure that manufacturers will be held harmless from price reporting implications when limitations in the specificity of the public 340B database records or eligibility notification procedures inadvertently allow 340B Program purchases by ineligible entities.

Finally, BIO supports HRSA's efforts in the Proposed Notice to outline the bases upon which a parent entity, child site, and contract pharmacy can lose 340B eligibility, as well as the applicable effective date.[62] BIO supports this proposed clarification, particularly with respect to the bases on which a child site may lose its eligibility for the 340B Program—due to the closure or ineligibility of the parent, or on an independent basis. We note, however, that a discussion regarding loss of eligibility due to a violation of the group purchasing organization ("GPO") prohibition appears to have been inadvertently omitted from the provision of the Proposed Notice on the parent hospital's loss of eligibility.[63] As compliance with the GPO prohibition is a condition of 340B eligibility for most hospitals, we urge HRSA to incorporate language to this effect into any final notice to avoid confusion.

d. Covered Entity Registration

As HRSA notes in the Proposed Notice, sections 340B(d)(2)(B)(i), (ii), and (iv) authorize—indeed require—HRSA to maintain a single, universal, and standardized identification system listing participating covered entities.[64] As HRSA further notes, the Agency currently lists covered entities, including any registered child sites, in its public 340B database, the purpose of which is to assist manufacturers in verifying eligibility for

[61] See, e.g., BIO comments in response to 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation [RIN 0906-AA89] Proposed Rule (Aug. 17, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20CMP%20&%20Ceiling%20Price%20Rule%208_17_15_0.pdf.
[62] See 80 Fed. Reg. at 52,302; 52,317.
[63] See id. at 52,317-18.
[64] Id. at 52,318.

340B drug purchases.[65] As described in the preamble, this database includes the following information: name, location, eligibility type, eligibility date (including for each child site), termination date (when applicable), and a 340B-specific unique identification number.[66]

While BIO strongly supports HRSA's efforts to ensure that there is a standardized system to accurately identify covered entities that are currently eligible to participate in the 340B Program, as well as HRSA's recent efforts to improve the quality of this database, there are certain ways in which this database can be further improved. First, as described in prior BIO comments,[67] we urge the Agency to consider adding certain additional information to the database, including: (1) historical information regarding covered entity eligibility/termination, DSH status, and ownership status (e.g., non-profit vs. for-profit) to assist both covered entities and manufacturers to identify periods of 340B eligibility (and ineligibility) for purposes of resolving questions and disputes regarding prices charged in prior quarters; (2) the specific DSH percentage upon which a hospital covered entity has based its eligibility for the 340B program, as applicable, which should be updated on a timely basis; (3) the specific reimbursable line on a hospital covered entity's Medicare cost report on which a given child site appears; and (4) a unique identifier for each covered entity and contract pharmacy relationship, as well as historical information regarding a covered entity's use of each contract pharmacy location. Second, in order to enable manufacturers to confidently rely on the information in HRSA's public 340B database, we urge HRSA to verify and provide a certification to manufacturers that data provided in this database are both up-to-date and accurate.

BIO also greatly supports the proposed additional clarification provided in the Proposed Notice with respect to both: (1) the Agency's verification of information provided through the registration process; and (2) the limits on 340B eligibility with respect to certain entity types. We are concerned, however, with respect to the Agency's suggestion that special eligibility criteria might apply in the event of a public health emergency, as described in greater detail below.

First, in terms of the Agency's process to verify covered entity information provided through the registration process, BIO supports HRSA's proposed clarification that the Agency lists covered entities in its public 340B database "after receiving the entity's registration from an appropriate authorizing official . . . who can legally bind the covered entity" and that, "[d]uring registration, the authorizing official attests to the covered entity meeting the eligibility criteria and its ability to comply with the 340B Program requirements."[68] We urge HRSA to also articulate the process that the Agency will use to verify such attestations; clarify that any federal documentation used for this purpose will be subject to penalty for any knowing and willful materially false representation under section 1001 of title 18 of the United States Code; and outline any other penalties that will apply in the event such attestations are found to be false or misleading.

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[65] Id.
[66] Id. at 52,304.
[67] BIO comments in response to 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation [RIN 0906-AA89] Proposed Rule (Aug. 17, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20CMP%20&%20Ceiling%20Price%20Rule%208_17_15_0.pdf.
[68] 80 Fed. Reg. at 52,303.

BIO similarly supports the proposed clarification that "HHS will not list a covered entity on the public 340B database when the information submitted pursuant to 340B Program registration does not demonstrate the entity is eligible for the 340B Program according to the statutory requirements," which can occur, for example, if the appropriate operating division of the Department of Health and Human Services ("HHS") does not verify non-hospital covered entity receipt of a grant, or the Medicare cost report does not support hospital/child site eligibility. It is reasonable for the Agency to leverage determinations already made by other Agencies within HHS related to 340B eligibility to avoid unnecessary duplication in the expenditure of HHS resources. However, we urge HRSA to take affirmative steps to improve its information-sharing capacities with other components of HHS, particularly in light of a recent report issued by the HHS Office of Inspector General ("OIG") finding that HHS's oversight of its grantees could be improved by better information sharing.[69] We also urge the Agency to establish mechanisms to independently verify the registration information provided by covered entities to ensure that 340B-specific eligibility requirements are met.

Second, in terms of providing further clarity regarding the limitations on eligibility for certain types of entities, BIO supports the proposed express clarification that "[e]ligibility for the 340B program is limited to the categories of entities specified in statute."[70] Thus, as HRSA notes in the preamble text, "[i]nclusion of a covered entity in a larger organization, such as a health system or an Accountable Care Organization does not make the entire larger organization eligible for the 340B Program or automatically qualify all of the individuals receiving services from the larger organization as patients of the covered entity for 340B Program purposes."[71] This statement is consistent with the Agency's Policy Release Number 2012-2, which reinforces the applicability of the patient definition to accountable care organization ("ACO") arrangements,[72] as well as with the statute, which clearly limits eligibility for participation in the 340B Program to the enumerated entity types.[73] We believe, however, that additional tools would be beneficial to assist both the Agency and manufacturers in monitoring potential diversion relating to ACO and health system arrangements. Specifically, BIO recommends that new fields be added to the public 340B database to identify when a covered entity is part of an ACO or health system, as well as the identifying information for that ACO or health system. Such information would enable both HRSA and manufacturers to monitor the purchasing patterns of the covered entity and those other customers that are part of the ACO or health system for signs of possible diversion.

BIO similarly supports HRSA's express recognition that a parent organization cannot obtain 340B eligibility merely through the acquisition of a 340B covered entity.[74] Specifically, the preamble states that, "if covered entity eligibility is limited to a distinct

[69] See OIG, HHS Oversight of Grantees Could Be Improved Through Better Information Sharing, OEI-07-12-00110 (Sept. 2015).
[70] 80 Fed. Reg. at 52,303.
[71] Id. See also id. at 52,318.
[72] HRSA, 340B Drug Pricing Program Notice, Release No. 2012-2, Clarification of Covered Entity Eligibility Within Accountable Care Organizations (May 23, 2012).
[73] See 42 U.S.C. § 256(a)(4).
[74] 80 Fed. Reg. at 52,303; 52,318.

part of a hospital, HHS will not list the hospital as a covered entity unless the hospital is otherwise eligible and registers for the 340B program."[75] We note that this language mirrors the statutory requirement outlined in section 340B(a)(6), which provides that "[t]he inclusion of a covered entity within a larger organization does not make the entire organization eligible for the 340B Program."[76] Relatedly, we urge HRSA to address the fact that non-hospital covered entities (e.g., hemophilia treatment centers) that are part of non-340B-elgible organizations are, we believe, in some instances, being required to remit revenue generated through the non-hospital covered entity's participation in the 340B Program to its parent organization, which is not a 340B Program participant. This is not the intent of the 340B Program; rather, these funds should be utilized for providing therapies to patients of the covered entity. We therefore recommend that HRSA further clarify that covered entities are not permitted to remit any revenue that accrues to the covered entity as a result of its participation in the 340B Program to any non-340B entity. The only permitted payments to a non-340B entity should be remuneration consistent with fair market value for items or services furnished by the non-340B entity to the covered entity.

BIO also strongly supports HRSA's proposed clarification in the Proposed Notice that pharmacies are not a 340B eligibility category recognized in the statute. We agree that the statutory eligibility criteria do not establish an independent eligibility pathway for pharmacies. We further note that this recognition underscores the fact that covered entities are ultimately responsible for the 340B Program compliance of their 340B enrolled pharmacies, including both in-house and other pharmacies, as described in greater detail in section (VIII) (relating to HRSA's contract pharmacy proposals) below.

Relatedly, HRSA proposes to clarify in the Proposed Notice that the Agency lists in-house pharmacies owned and operated by covered entities as an "authorized shipping address" (i.e., the "ship-to" field in the public 340B database) if drugs purchased by the covered entity at the 340B ceiling price will be shipped to the in-house pharmacy directly. HRSA also notes in the preamble text that "HHS also lists contract pharmacies registered by a covered entity to dispense 340B drugs to eligible patients of the covered entity."[77] We recognize that these statements conform to current HRSA policy, and we support HRSA in its efforts to ensure pharmacies are identified appropriately in the public 340B database.

BIO also believes that all covered entities should be required to list the National Provider Identifiers ("NPIs") of their contract pharmacies (and in-house pharmacies, if they are billing under different NPIs) as part of the registration and recertification processes so that HRSA and manufacturers are able to accurately identify contract pharmacies when responding to requests for drugs at the 340B price. Currently, the "Contracted Pharmacy Services Self-Certification Form for the 340B Program" requires covered entities to provide information regarding their contract pharmacies, including the pharmacy name, address, phone and fax numbers, and contact name and e-mail. The NPI should be added to this

[75] Id. at 52,303; 52,318.
[76] This provision states that, "[i]n the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection."
[77] 80 Fed. Reg. at 52,304.

form as well. That said, we strongly urge HRSA to require covered entities to direct their contract pharmacies to use the covered entity's NPI in billing for 340B-priced drugs in order to more clearly identify utilization associated with the covered entity in an effort to better prevent diversion and duplicate discounts. In addition, as articulated throughout this letter, we urge HRSA to establish a unique identification number for each contract pharmacy "ship-to" location, which could be generated by combining existing identifiers, such as the covered entity's 340B ID with the contract pharmacy's NPI. Indeed, we believe that this would be an easy way for HRSA to improve program transparency and accountability and thus we urge HRSA to move forward with this recommendation immediately.

Finally, HRSA proposes that "[s]pecial registration procedures apply in the case of a public health emergency declared by the Secretary. Information will be posted on the 340B Program Web site as to the geographic scope and duration of such registration opportunities."[78] While we appreciate that there may be the need to rely on special *procedures* to enroll covered entities in the program in the event of a public health emergency, we want to highlight that the 340B statute provides an exhaustive list of the entity types that are eligible to participate in the program; therefore, any special enrollment procedures adopted by the Agency in response to a public health emergency or otherwise should not be used to circumvent these statutory eligibility categories. Moreover, we urge HRSA to ensure—consistent with the Agency's proposed "covered entity" definition[79]—that the identity of any covered entity enrolled through this special process is immediately posted on the public 340B database or, if the database is inoperable or inaccessible as a result of the public health emergency in question, provided to manufacturers and wholesalers through some other mechanism. If no mechanism is available to publicize the identities of covered entities enrolled through this process, manufacturers should not be penalized if they fail to provide their covered outpatient drugs to such covered entities at the 340B ceiling price. We also urge HRSA to outline, for public comment, the special registration procedures that will apply in these instances, which should be limited in both time and scope in a manner commensurate with the public health emergency in question (e.g., the covered entities that may enroll through this process should not exceed the number and geographic distribution necessary to address the public health emergency, and such covered entities should be terminated and required to re-enroll through standard processes once the public health emergency is resolved), and to clarify that any plans negotiated between manufacturers and the government—whether under an agreement with the Centers for Disease Control and Prevention ("CDC"), or other local, state, or federal health agencies—for the distribution of drugs during a public health emergency should supersede any process established by HRSA. We also urge HRSA to work with other federal agencies, including CMS, to ensure that manufacturers will be held harmless from price reporting implications where the processes utilized during these emergencies inadvertently allow 340B Program participation by ineligible entities.

[78] Id. at 52,303.
[79] 80 Fed. Reg. at 34,585 (42 C.F.R. § 10.3 [proposed]).

e. Termination and Re-Enrollment

BIO supports HRSA's proposal that a covered entity removed from the 340B Program would be eligible to re-enroll during the next regular enrollment period only after it has satisfactorily demonstrated to the Agency that it: (1) will comply with all statutory requirements moving forward; and (2) has completed any repayments to affected manufacturers, or has received written notice from affected manufacturers that such manufacturers decline to accept such repayments.[80] We also agree with HRSA's clarification that failure to provide an explanation and documentation of the termination, the timing of the termination, and the date the covered entity has ceased or plans to cease purchasing and using 340B drugs should be taken into consideration in any determination as to whether a covered entity may be permitted to re-enroll in the program.[81] In response to HRSA's request for suggestions regarding the type of information a covered entity would need to submit to HRSA to demonstrate compliance with the 340B Program requirements in order to re-enroll pursuant to this proposal, we urge the Agency to consider outlining documentation requirements that are related to and based on the reason why the covered entity lost eligibility in the first instance. Some proposed documentation requirements are described here for the Agency's consideration:

- GPO Prohibition: BIO agrees with HRSA's proposal that, if a covered entity subject to the GPO prohibition is removed for a violation of the GPO prohibition, the hospital should be required to demonstrate that it has established appropriate purchasing accounts and, if applicable, implemented software programmed to allocate drug purchases to the correct purchasing accounts.[82] We also agree that the hospital should be required to submit to HRSA written policies and procedures directing proper purchase allocations, as well as a self-audit report confirming correct purchasing. In addition, as described in greater detail in section (III)(g), below, one of the common operational issues with GPOs is related to the underlying claims systems that support the accumulation of 340B-eligible and GPO-eligible purchases. Therefore, HRSA should further require such covered entities to provide an accounting of how claims from all ineligible sites (e.g., inpatient settings, mixed-use settings, ineligible outpatient settings) are designated as non-340B eligible. The same requirement should apply to Medicaid claims (including managed Medicaid) if the entity is not listed on the Medicaid Exclusion File. Finally, we urge HRSA to establish a one-year ineligibility period for covered entities terminated on the basis of a GPO violation, particularly if HRSA finalizes its proposal limiting the removal of covered entities for such violations to instances determined to be "systematic," as discussed in greater detail below.

- Diversion: BIO recommends that covered entities found to have violated the prohibition on diversion should be required to provide to HRSA documentation demonstrating that they have established policies and procedures to accurately

[80] 80 Fed. Reg. at 52,304; 52,317. See also id. at 52,318 ("A covered entity removed from the 340B Program for a GPO prohibition violation would be able to re-enroll during the next regular registration period after it has satisfactorily demonstrated to HHS that it will comply with the GPO prohibition going forward and is in the process of offering repayment to affected manufacturers.").
[81] Id. at 52,304.
[82] Id.

identify patients of the entity based on applicable HRSA guidance, and that these policies have been operationalized through formal training for employees, contractors, and agents, and have been incorporated into the algorithms used in any virtual inventory software utilized by the covered entity, child sites, and contract pharmacies. As in the GPO context, we support a requirement that the covered entity also provide to HRSA a self-audit report confirming correct purchasing.

- Duplicate Discounts: For those covered entities found to have violated the prohibition on duplicate discounts, we urge HRSA to require the provision of documentation demonstrating the establishment of policies and procedures that address: (1) accurate reporting for purposes of the Medicaid exclusion file, as well as utilization practices consistent with the covered entity's "carve-in/out" election for such purposes (including with respect to managed care utilization); and (2) compliance with applicable state and federal Medicaid policies that address the prevention, identification, and correction of duplicate discounts. We also recommend that HRSA require such covered entities to document that they have worked, in good faith, with all affected parties—including manufacturers, state Medicaid programs, and Medicaid MCOs—to identify and resolve any duplicate discounts that may have occurred. As duplicate discount issues often cover very broad periods of time, covered entities should be further required to demonstrate the specific period of time during which the duplicate discounts occurred to facilitate an assessment of the extent of the duplicate discounts by states, manufacturers, CMS, and HRSA. If the duplicate discounts occurred as the result of utilization dispensed through a contract pharmacy, the covered entity should be required to demonstrate that it has worked with state Medicaid programs, HRSA, and the applicable contract pharmacy(ies) to address the issues that led to the violation(s). We also support a requirement that the covered entity provide a self-audit report confirming that the covered entity has come into compliance with the duplicate discount prohibition (i.e., that the covered entity is providing non-340B drugs to Medicaid patients if the covered entity "carves out," or that the covered entity accurately reports the proper information to both HRSA and the state Medicaid agency if the covered entity "carves in").

- DSH Percentage: Hospitals that lost 340B eligibility due to a change in their DSH percentage should be required to document that their DSH percentage now exceeds the applicable statutory threshold, based on information reported in the most recently filed final Medicare cost report that has been audited by CMS. If, as HRSA describes, a hospital lost eligibility based on DSH percentage, but subsequently won an appeal to have the DSH percentage changed, we agree that the hospital should be required to submit documentation of the favorable resolution of that appeal. We further urge HRSA to specify the documentation that should be required if a change in eligibility occurs as a result of changes in the DSH percentage between the time the cost report was submitted to CMS, and the time the final cost report that has been audited by the agency becomes available.

- Ownership/Child Site Status: Hospitals and child sites that lost 340B eligibility due to a change in their ownership status (e.g., a change from non-profit to for-profit ownership or a covered entity's divestiture of a child site location) should be required to provide documentation indicating that their ownership status has changed again and now complies with 340B Program requirements. For hospital child sites, this would require demonstrating that the child site is reported on a reimbursable line on the parent hospital's Medicare cost report, which generally means that the child site cannot be eligible for roughly 18 months post-acquisition.[83]

We also urge HRSA to specify the types of documentation that a covered entity would be required to provide to demonstrate that the covered entity has completed repayments to affected manufacturers, or has received written notice from affected manufacturers that such manufacturers decline to accept such repayments. It should be clarified that all documentation required for purposes of re-establishing eligibility is subject to penalty for any materially false representation under section 1001 of title 18 of the United States Code. Finally, as recommended in previous sections, we urge HRSA to include a historical accounting of each covered entity's periods of 340B Program eligibility an ineligibility on the public 340B database and ensure that re-registering facilities are not able to overwrite their original registration date.

f. Annual Recertification

BIO supports HRSA's proposed clarification with respect to the annual recertification process for covered entities, including stating that this process will continue to apply to child sites and contract pharmacy arrangements. Requiring covered entities to annually recertify as to their ongoing 340B eligibility, the ongoing eligibility of their child sites and contract pharmacies, as well as their ongoing compliance with 340B Program requirements, is an important reminder for covered entities of the obligations imposed on them by virtue of their participation in the 340B Program. We further support the active role that HRSA proposes to assign to the covered entity's authorizing official in ensuring compliance with the 340B statute and regulations, as well as HRSA's efforts in strengthening the certification language used for purposes of annual recertification, most recently in 2012, as articulated in the comments that we submitted to the Agency at that time.[84] As part of this re-certification, we urge HRSA to require covered entities to certify that, since their entry into the 340B Program, they have always been in compliance with 340B Program requirements and for those covered entities that cannot attest to full historical compliance, to disclose past compliance issues and explain what corrective actions were taken to remedy the non-compliance.

[83] Because of the timeline of Medicare cost report filings, there is generally a significant time lapse between when an outpatient facility is acquired and when it appears on a filed cost report.
[84] See https://www.bio.org/sites/default/files/BIO%20Final%20340B%20Recertification%20Comments%205-18-2012.pdf.

g. GPO Prohibition

i. Application

As HRSA acknowledges in the Proposed Notice, the 340B statute prohibits, as a condition of 340B eligibility, certain covered entities—namely disproportionate share hospitals, children's hospitals, and free-standing hospitals—from "obtain[ing] covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."[85] BIO supports HRSA's efforts to provide additional clarity with respect to this prohibition, in particular HRSA's express recognition that the requirement "takes effect as of the start date of enrollment in the 340B Program."[86] We also support HRSA's proposed clarification that the GPO prohibition applies to "any pharmacy owned or operated by the covered entity," as well as to "off-site outpatient facilities and clinics in the entity's 340B database record."[87] However, we urge HRSA to further clarify, in accordance with statements made its 2013 GPO guidance, that covered entities are "prohibited from having organizations purchase covered outpatient drugs through a GPO on its behalf or otherwise receive covered outpatient drugs purchased through a GPO," and that, because "[a] 340B covered entity purchases and maintains title to the drugs, not a contract pharmacy . . . , a hospital subject to the GPO prohibition cannot use a GPO for covered outpatient drugs, even if the drugs are dispensed at a contract pharmacy."[88]

We also support HRSA's proposed clarification—consistent with other statements in the Proposed Notice—that the GPO prohibition applies to all "covered outpatient drugs" (including those purchased for non-340B patients and at commercial prices),[89] as well as the proposed clarification that hospitals subject to the GPO prohibition must retain auditable records pertaining to compliance with the requirement that all drugs that meet this "covered outpatient drug" definition are purchased using the correct, non-GPO accounts.[90] We note, however, that the Proposed Notice does not explicitly address treatment of products that do not fall within the "covered outpatient drug" definition, specifically vaccines. We therefore urge HRSA, in issuing any final guidance, to specifically state that the GPO prohibition applies only to products that meet the definition of "covered outpatient drug" and that vaccines, even if purchased through a 340B Prime Vendor contract, are not subject to this prohibition.

We also are concerned with HRSA's proposed blanket prohibition on manufacturers conditioning the sale of a covered outpatient drug on covered entity compliance with the

[85] 42 U.S.C. §§ 256b(a)(4)(L)(iii); (M).
[86] 80 Fed. Reg. at 52,304.
[87] Id. at 52,318.
[88] HRSA, 340B Drug Pricing Program Notice, Statutory Prohibition on Group Purchasing Organization Participation, Release No. 2013-1 (Feb. 7, 2013) (hereinafter "2013 HRSA GPO Guidance").
[89] 80 Fed. Reg. at 52,304. As described in greater detail in section (IV), below, we support HRSA's recognition throughout the Proposed Notice that the term "covered outpatient drug" is defined by reference to both the general definition in section 1927(k)(2) of the SSA and the limiting definition in section 1927(k)(3) of the SSA.
[90] Id. at 52,306.

GPO prohibition.[91] As articulated in greater detail in section (VIII)(e), below, HRSA should create exceptions to this general rule when a covered entity has not acted in good faith.

ii. Attestation

BIO also supports HRSA's proposed clarification that, during registration for the 340B Program, the authorizing official for a hospital that is subject to the GPO prohibition must "attest it will comply with the statutory GPO prohibition," and that similar attestations are required as part of the annual recertification process for these hospitals.[92] As noted in section (III)(f), above, attestation obligations for covered entities' authorizing officials provide an important reminder to covered entities with respect to their compliance obligations under the 340B Program. However, we urge HRSA to clarify that any knowing and willful materially false statement made in such attestation is subject to penalty under section 1001 of title 18 of the United States Code.

iii. Proposed Exceptions to the GPO Prohibition

Consistent with the 340B statute and current HRSA policy, HRSA proposes to clarify in the Proposed Notice that the GPO prohibition is inapplicable to: (1) inpatients; and (2) drugs that are not "covered outpatient drugs." HRSA also proposes three new exceptions to the GPO prohibition. While we have some concerns with respect to these new exceptions, we strongly support HRSA's clarification that, "[u]nder no circumstances may the specific conditions noted in these exceptions be used to circumvent the GPO prohibition to supply GPO-purchased covered outpatient drugs to parts of the hospital subject to the GPO prohibition."[93] We discuss each of the proposed exceptions in turn.

1. Off-site facilities that are not participating in the 340B Program or listed on the 340B database.

First, HRSA proposes to exempt from the GPO prohibition "[a]n off-site outpatient clinic of a 340B hospital covered entity if the outpatient clinic is located at a separate physical address from the 340B parent covered entity, is not participating in the 340B Program or listed on the public 340B database, and purchases drugs through a separate account from the 340B parent covered entity."[94] BIO understands that the GPO prohibition does not apply to the extent that an entity is not participating in the 340B Program, and thus understands the need for this particular exception, which we recognize is consistent with HRSA's 2013 GPO guidance. We urge HRSA to also state, however, as a necessary condition for this exception to apply, that the hospital must "maintain[] records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B database,"[95] and, as recommended above, require that the

[91] Id. Instead, HRSA proposes that "[r]emedies for violations would be imposed under the enforcement provisions of the 340B Program, but manufacturers may not unilaterally deny sales based on such violations." Id.
[92] Id. at 52,304.
[93] Id. at 52,305.
[94] Id. at 52,318.
[95] 2013 HRSA GPO Guidance.

hospital maintain records demonstrating that claims originating from these sites are properly identified as non-340B eligible for purposes of an accumulator system.

2. Drugs provided to an inpatient whose status is subsequently changed to outpatient by a third party.

Second, HRSA proposes that "[a] GPO-purchased drug provided to an inpatient who, upon subsequent review (*e.g.*, insurer, Medicare Recovery Audit Contractor, or hospital review), results in a designation of that patient as an outpatient for payment purposes" would not constitute a violation of the GPO prohibition.[96] BIO generally supports this proposal, but believes that it is feasible only if HRSA also adopts a uniform standard for establishing inpatient versus outpatient status across the 340B Program, based on how a particular service was *reimbursed* (rather than billed).

In order to minimize the potential for program abuse, as described in greater detail in section (V)(a) below, BIO strongly recommends that determinations of inpatient versus outpatient status be made based on how a particular claim is *reimbursed*, rather than billed. Basing such determinations on the reimbursement policies of third parties—which are based, in turn, on clinical and other factors unrelated to 340B status—would minimize the likelihood that a covered entity's billing—or, worse, treatment—decisions are affected by a desire to obtain a particular drug at the 340B price. We further believe that this requirement should be established program-wide, so that it applies also in the context of the "covered outpatient drug" definition and the "patient" definition, in addition to the GPO prohibition. At a minimum, we urge HRSA to establish a uniform standard for establishing inpatient versus outpatient status across each of these aspects of the program, to avoid a situation in which a covered entity treats a patient as inpatient for purposes of the GPO prohibition, but outpatient for purposes of 340B eligibility, for instance.

If HRSA adopts our recommendation to use reimbursement status (as opposed to how a given item or service was billed) as the determining factor for inpatient versus outpatient status determinations program-wide, this proposed exception to the GPO prohibition would be necessary to address those limited circumstances in which a claim was initially reimbursed as an inpatient claim, but was later changed to an outpatient claim. That said, HRSA should require that such redeterminations be made by external actors, and not "hospital review," as proposed, to further maintain cross-program consistency and avoid any potential for program abuse. As articulated in section (V), below, a similar exception could be adopted with respect to the "patient" definition as well. In both of these circumstances, we support HRSA's proposed clarification that the exception would apply only "provided there is sufficient documentation of the patient's change of status,"[97] which we believe should be based on documents prepared by insurers in the ordinary course and not with the express purpose of documenting compliance with 340B Program requirements.

[96] 80 Fed. Reg. at 52,318.
[97] Id. at 52,305.

3. Hospitals that cannot access a drug at the 340B price or at Wholesale Acquisition Cost to prevent disruptions in patient care.

Third, HRSA proposes that the GPO prohibition would not be violated when "[a] hospital which can only access a covered outpatient drug through a GPO account"[98] purchases such drugs using the GPO account. The stated purpose for this proposed exception is to "prevent disruptions in patient care." While we support HRSA's intent to impose certain documentation requirements with respect to this proposed exception, we do not believe that the proposed exception itself is consistent with the statutory GPO prohibition, which prohibits certain hospital types from making covered outpatient drug purchases through a GPO, without exception, as a condition of eligibility. Accordingly, we strongly urge HRSA to eliminate this proposal, particularly to the extent that the Agency is unable to articulate a statutory authority therefor. To the extent that HRSA nonetheless finalizes this proposed exception, its application should be limited to the drug and manufacturer in question.

iv. Drug Replenishment Models

BIO supports HRSA's proposed clarification that a hospital that purchases drugs through a replenishment model based on actual prior usage "cannot tally 340B-ineligible outpatient use for drug orders on a GPO account" and that "[a] covered entity may be found in violation of the statutory GPO prohibition if a replenishment model or split billing software is used in a manner contrary to the statute."[99] In our experience, covered entities have relied on the fact that a program violation occurred due to issues with replenishment and other inventory management software in order to categorize such violations as mere "systems" issues.

To illustrate, as we articulated in a recent letter to the Agency,[100] some of our members have received disclosure letters from covered entities indicating that at least one 340B tracking and split billing software vendor experienced what is referred to in the letters as an "accumulator functionality failure," which resulted in covered entities purchasing covered outpatient drugs through a GPO, including 340B-eligible purchases, which affected purchases of covered outpatient drugs by multiple 340B covered entities over the course of nearly a year. Not only did this covered entity violate the GPO prohibition, but it then attempted to reclassify its GPO purchases as 340B transactions. These actions were fundamentally at odds with the fact that the 340B statute imposes the GPO prohibition as a condition of eligibility and that, as HRSA has regularly articulated, violation thereof is grounds for termination from the program. The fact that an inventory system was involved in the violation does not alter the applicability of the GPO prohibition. We believe that these persistent, systematic violations provide an excellent opportunity for HRSA to respond and demonstrate that GPO violations are GPO violations, even if they occur through the use of replenishment models.

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[98] Id. at 52,318.
[99] Id. at 52,305.
[100] See Biotechnology Industry Organization Letter to Commander Pedley, Director, Office of Pharmacy Affairs, HRSA (Sept. 2, 2015) (requesting information from HRSA regarding a troubling situation with respect to the use of GPOs by 340B covered entities).

We further support HRSA's proposed clarification that "[a] covered entity electing to use a replenishment model should be able to clearly demonstrate through auditable records that the replenishment model, along with any associated software, is used in a manner that complies with the statute."[101] We believe, however, that additional clarification is necessary. For instance, we urge HRSA to again acknowledge the Agency's 2013 GPO guidance prohibiting hospitals subject to the GPO prohibition from purchasing covered outpatient drugs through a GPO and subsequently either: (1) "replenishing" through accounting by "replacing" the GPO-purchased drug with a drug purchased under the 340B Program; or (2) otherwise reclassifying the method of purchase after dispensing.[102] As HRSA noted in this guidance at the time, "[t]he GPO prohibition is violated upon use of a GPO to obtain covered outpatient drugs and cannot be fixed or cured by subsequently changing the characterization through accounting or other methods."[103] We also urge HRSA to clarify, analogously to guidance provided to covered entities by Apexus, that "[i]f the entity is subject to the GPO Prohibition . . . its inventory system [may] not allow the entity to obtain covered outpatient drugs from a GPO."[104]

v. Use of Previously-Purchased GPO Drugs

In keeping with the Agency's 2013 GPO guidance, HRSA proposes to clarify that covered entities subject to the GPO prohibition must stop purchasing covered outpatient drugs through a GPO before the first day the covered entity is listed on the public 340B database as eligible to purchase 340B drugs.[105] HRSA similarly proposes to clarify that GPO-purchased drugs remaining in the covered entity's inventory on or after this start date may be used until expended. While we support this proposed clarification, we urge the Agency to further clarify how covered entities should operationalize this requirement in the context of a replenishment model.

vi. GPO Violations

In the Proposed Notice, HRSA expressly reaffirms that, because "[t]he 340B statute makes compliance with the GPO prohibition a condition of eligibility," a covered entity "found in violation of the GPO prohibition will be considered ineligible and removed from the 340B Program."[106] The Agency also attempts to clarify the process for penalizing violations of the GPO prohibition, which would distinguish between purchasing errors that are immediately corrected in the ordinary course and violations of the GPO prohibition, and, within this latter category, those violations that are isolated versus systemic in nature. BIO supports this approach.

Specifically, HRSA notes that the Agency "is aware that manufacturers and covered entities may currently work together to identify and correct errors in GPO purchasing within

[101] 80 Fed. Reg. at 52,318-19.
[102] 2013 HRSA GPO Guidance.
[103] Id.
[104] Apexus, 340B Compliance Self-Assessment: Vendors—A Tool to Help 340B Entity Leaders Assess Contract Pharmacy Vendors (May 6, 2015).
[105] 80 Fed. Reg. at 52,305; 52,319. See also 2013 HRSA GPO Guidance.
[106] 80 Fed. Reg. at 52,319.

30 days of the initial purchase through a credit and rebill process as a standard business practice."[107] BIO supports HRSA's encouragement of the continuation of this practice, as well as the clarification that "[t]his collaboration necessitates a covered entity's frequent monitoring of compliance to identify GPO purchasing errors within 30 days of this erroneous purchase."[108] That said, there may be instances in which errors in GPO purchasing identified during the first 30 days cannot actually be corrected within this timeframe. We therefore urge HRSA to clarify that this proposed exception enables manufacturers and covered entities to work together to *correct* errors in GPO purchasing *identified* (but not necessarily corrected) within 30 days of the initial purchase. We also note that the requirement that covered entities engage in "frequent monitoring" and identify errors within 30 days is addressed only in the "summary" section of the Proposed Notice, not in the "guidance" section. BIO supports this requirement and urges HRSA also to include it in the "guidance" section (rather than merely the preamble discussion) of any final notice.

BIO also supports HRSA's proposal that covered entities found in violation of the GPO prohibition, presumably after this initial 30-day period, would have the opportunity to invoke the Agency's notice and hearing process (discussed in greater detail in section (X), below). If, as part of this process, the covered entity "could demonstrate that the GPO violation was an isolated error as opposed to a systemic violation,"[109] the covered entity would be permitted to remain in the 340B Program upon submission of a corrective action plan. If, on the other hand, the violation were found to be systematic, the covered entity would be deemed ineligible for the program as of the date of the violation and—together with all child sites and contract pharmacy locations—would be immediately removed. Understanding the possibility that covered entities may make isolated, inadvertent mistakes, we support HRSA's efforts to establish a process for covered entities to identify and correct such errors, while removing those entities from the program that have systematically violated the statutory eligibility criteria. That said, we urge HRSA to define the terms "systematic" and "isolated," and seek stakeholder feedback with respect to these definitions, for purposes of this proposal. We also urge HRSA to clarify that covered entities that have committed isolated GPO violations may remain in the 340B Program only if their corrective action plan has been *approved by* (and not merely *submitted to*) HRSA.

BIO further supports HRSA's proposed clarification that covered entities found to be in violation of the GPO prohibition would be required to "offer to repay affected manufacturers for any 340B drug purchase made after the date of the first GPO violation,"[110] although we urge the Agency to clarify that this applies regardless of whether the violation was found to be isolated or systematic. Regardless of whether a violation is isolated or systematic, any GPO violation starts the ineligibility period, which ends only when the violation is resolved. Any GPO purchases made during that period trigger the need for manufacturer repayment.

Finally, BIO also supports HRSA's recognition that, as a general matter, GPO violations that occur at child sites should be attributed to the parent covered entity, and

[107] Id. at 52,305.
[108] Id.
[109] Id.
[110] Id. at 52,305; 52,319.

that such violations can be treated as being limited to child sites only in limited instances supported by appropriate documentation.[111] We agree that "GPO participation cannot be limited to a child site if the parent site also purchases drugs on the same account as the child site."[112]

IV. Part B—Drugs Eligible for Purchase Under 340B

a. Covered Outpatient Drug Definition

The 340B Program relates only to "covered outpatient drugs," and the definition of that term therefore is an important parameter in establishing the scope of the 340B Program. The 340B statute defines the term "covered outpatient drug" by reference to section 1927(k) of the Social Security Act ("SSA"), which establishes the Medicaid Drug Rebate Program.[113] The "covered outpatient drug" definition thus is shared between the 340B Program and the Medicaid Drug Rebate Program and constitutes one of the many linkages between the two. The "covered outpatient drug" definition at section 1927(k)(2) of the SSA incorporates by express cross-reference a "limiting definition" at section 1927(k)(3) of the SSA. This limiting definition establishes that a drug, biological product, or insulin[114] does *not* qualify as a covered outpatient drug if (i) it is provided as part of, or as incident to and in the same setting as, certain enumerated services (e.g., inpatient hospital services, physician's services, outpatient hospital services, renal dialysis), and (ii) payment may be made for the drug "under this subchapter" as part of the payment for the services, and not separately for the drug alone. A drug that satisfies both prongs does not qualify as a "covered outpatient drug" and therefore is not eligible for 340B pricing.

For virtually the entire life of the 340B Program, HRSA has read the second prong of the limiting definition to apply when *any* payor pays for the drug together with one of the enumerated services. However, in the Proposed Notice, HRSA proposes to depart from its decades-old practice and would apply the second prong only when Medicaid, and not any other payor, pays for a covered outpatient drug together with one of the enumerated services. As a result, a greater number of drugs would qualify as "covered outpatient drugs" and would therefore be subject to discounts under the 340B Program.

In 1993, only one year after the inception of the 340B Program, HRSA issued a notice in the *Federal Register* in proposed form adopting verbatim the statutory "covered outpatient drug" definition for purposes of the 340B Program.[115] In May of 1994, HRSA issued the notice in final form.[116] This 1994 notice indicates that HRSA did not receive any comments regarding the adoption of the "covered outpatient drug" definition.[117] In the 1994 notice, HRSA states that, "if a covered drug is included in the per diem rate (i.e.,

[111] See id. at 52,319.
[112] Id. at 52,305.
[113] 42 U.S.C. § 256b(b)(1).
[114] We note that section 1927(k)(2)(C) of the SSA refers to "insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [(FDCA)]," although that prior version of section 506 of the FDCA, relating to certification of drugs containing insulin, has been repealed and replaced by another provision that does not pertain to insulin.
[115] 58 Fed. Reg. 27,289, 27,291 (May 7, 1993).
[116] 59 Fed. Reg. 25,110, 25,113 (May 13, 1994).
[117] Id. at 25,112-13.

bundled with other payments in an all-inclusive, per visit, or an encounter rate), it will not be included in the section 3408 discount program."[118] Only if the drug instead "is billed and paid for instead as a separate line item" does it qualify for the 340B Program.[119] Other HRSA guidance adopts the same approach.[120]

Notably, HRSA's 1994 guidance does not restrict the applicability of the limiting definition to drugs for which payment is received under Medicaid, and that approach accurately reflects the relationship between the Medicaid and 340B statutes. The Medicaid Drug Rebate Program went into effect in the first quarter of 1991, following enactment of the Omnibus Budget Reconciliation Act of 1990. At this time, section 1927(k)(3) was necessarily limited to drugs paid "under this subchapter" (i.e., title XIX of the SSA, or Medicaid), as the covered outpatient drug definition then applied only to the Medicaid program. There were no payors beyond Medicaid to consider at that time. When the 340B Program was subsequently enacted in 1992 and adopted the Medicaid "covered outpatient drug" definition, it was appropriate for HRSA to apply the second prong of the limiting definition to payments by all payors, not just Medicaid, given that other payors also may pay for drugs together with one of the enumerated services. In other words, given the expansion of the application of the term "covered outpatient drug," including its limiting definition, to a context beyond Medicaid, other payors became a relevant consideration where they had not before, and it was appropriate for HRSA to recognize this fact in applying the second prong of the limiting definition.

HRSA's original approach from the 1994 guidance is supported by the language of the statute itself. The limiting definition excludes drugs "[(1)] for which payment may be made under this subchapter as part of payment for the following [services] *and* [(2)] not as direct reimbursement for the drug."[121] Notably, the first phrase refers to "this subchapter" and therefore arguably is tied to Medicaid, but the second phrase is not limited in this way. Congress imported the covered outpatient drug definition into the 340B scheme by expressly cross-referencing it in the 340B statute. The covered outpatient drug definition, and with it, by necessity, the limiting definition, thus must be read as if these provisions were a part of the 340B statute. Read in this manner, the limiting definition excludes, in phrase (1), drugs "for which payment may be made under [Medicaid] as part of payment" for one of the enumerated services, i.e., drugs included in a bundled payment made by Medicaid, and, in phrase (2), drugs "for which payment may be made . . . not as direct reimbursement for the drug," i.e., drugs included in a bundled payment made by *any* payor, including (but not limited to) Medicaid.[122] Although this construction would have served no practical purpose when the covered outpatient drug definition applied only

[118] Id. at 25,113.
[119] Id.
[120] See HRSA Letter from M. Alvarez to J. Bobula, at 4 (Feb. 25, 1993) (specifically noting that the 340B definition of covered outpatient drug incorporates the limiting definition in section 1927); HRSA Letter from M. Alvarez to Covered Entities, at 5 (Mar. 9, 1993) (noting that the "entity cannot use the covered outpatient drug purchased with the statutory discount in excluded services (e.g., inpatient hospitalization, emergency room, other laboratory and x-ray, dental, hospital, and physician)"); HRSA Letter from M. Alvarez to Manufacturers at 4-5 (Apr. 15, 1993) (citing limiting definition).
[121] SSA § 1927(k)(3) (emphasis added).
[122] Under this construction, the drugs described in phrase (1) are a subset of the drugs described by phrase (2). But surplusage is not avoided by the alternative construction, under which the drugs described in phrase (1) are redundant of the drugs described by phrase (2).

to the Medicaid program, it became meaningful when the application of the term was expanded to the 340B context, as evidenced by HRSA's long-standing policy. In addition, phrase (1) refers to products "for which payment *may* be made under this title," indicating that this part of the limiting definition is a sufficient, but not necessary, condition. Phrase (2), on the other hand, includes no such permissive language, and is therefore a necessary condition for the limiting definition to apply.

HRSA's existing 1994 guidance is not only consistent with the statute, but also longstanding, having been in place for virtually the entire life of the 340B Program. And HRSA's proposed about-face on the "covered outpatient drug" definition guidance not only would require a counterintuitive reading of the "covered outpatient drug" definition that ignores the meaning of the statutory text in the 340B context, but also would represent an extraordinarily departure from its 1994 *Federal Register* guidance. Indeed, the Agency has recently reinforced other aspects of its 1994 *Federal Register* guidance—including in its GPO prohibition,[123] and non-discrimination guidance.[124] Troublingly, there is a complete absence of any rationale in the preamble of the Proposed Notice or elsewhere addressing why HRSA believes a change of this aspect of its 1994 guidance would be reasonable and not arbitrary and capricious. Moreover, it is evident that HRSA has not considered the potential impact of this proposed policy on other federal programs and initiatives.[125]

In sum, we believe that the 340B Program's "covered outpatient drug" definition should be clear, as reflected in the Agency's longstanding guidance on this topic. Accordingly, we urge the HRSA to continue to apply the "covered outpatient drug" definition in the manner set forth in the 1994 notice when HRSA issues any final guidance.

HRSA also should take steps to define "covered outpatient drugs" such that drugs approved exclusively for cosmetic use are excluded from the program. Several companies that manufacture both therapeutic and cosmetic-use-only products participate in the Medicaid Drug Rebate Program and the 340B Program and report sales prices for all products to both of these federal programs. Because the current definition of covered outpatient drug under the 340B Program includes any drug or biological approved by the Food and Drug Administration ("FDA"), some cosmetic products are considered covered outpatient drugs under both programs. Some manufacturers have reported instances where 340B covered entities purchase cosmetic products. These same manufacturers also found evidence supporting concerns that some hospitals are purchasing cosmetic products through the 340B Program, and using those products in cosmetic businesses, such as spas, for self-pay patients.

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[123] See 2013 HRSA GPO Guidance.
[124] See HRSA, 340B Drug Pricing Program Notice, Release No. 2011-1.1: Clarification of Non-Discrimination Policy (May 23, 2012) (hereinafter "2012 HRSA Non-Discrimination Guidance").
[125] For example, should HRSA finalize this drastic change in policy, it will put at risk its sister agency, CMS's, moves toward payment system reform. In January 2015, HHS Secretary Burwell stated that 30% of Medicare payments will be made through value-based arrangements. This draft change from HRSA puts that goal at risk. The long-standing policy related to the exclusion from 340B of drugs paid under outpatient bundles allows for hospitals in programs like Medicare ACOs or commercial episodic payments to compete based on an even playing field. Should HRSA finalize a policy to no longer exclude the use of 340B-discounted drugs from these payment arrangements, then non-340B hospitals would be set to a large competitive disadvantage, in any program that compares total cost of care within a regional benchmark.

The 340B Program was designed to give safety-net facilities access to discounted drugs and biologicals for use in treatment of patients. It was never envisioned as a way to enable facilities to purchase cosmetic-use-only products, and to potentially divert those products to self-pay cosmetic businesses. HRSA should be troubled by these revelations and risks, and therefore should take clear, decisive action to strengthen the integrity of the 340B program by expressly exempting from the 340B Program any product approved for cosmetic use only.

b. Covered Entity Compliance Responsibilities with Respect to the Covered Outpatient Drug Definition

BIO supports HRSA's efforts to promote compliance with the covered outpatient drug definition by covered entities. In particular, we support HRSA's recognition that covered entities are obligated to pay manufacturers the difference between the 340B ceiling price and the commercial price when covered entities request the 340B ceiling price for drugs that do not meet the "covered outpatient drug" definition. We are concerned, however, that, while this requirement is currently in place, HRSA has no formal mechanism for ensuring that such payments have been made, or for penalizing those covered entities that fail to make such payments. We urge HRSA to implement such a mechanism, and outline any applicable penalties for noncompliance, when HRSA issues any final guidance. We also urge HRSA to clarify that such a payment is a statutory requirement by including in any final guidance a clear requirement that the covered entity make such payments.

V. Part C—Individuals Eligible to Receive 340B Drugs

a. Criteria

Under the 340B statute's "diversion" prohibition, a covered entity may dispense drugs purchased through the 340B Program only to the entity's own "patients," and the definition of the term "patient" therefore is important to establishing the scope of the 340B Program. However, that critical term is not defined by the 340B statute. Moreover, we are very concerned that the existing definition of "patient," adopted by HRSA in 1996,[126] is not effective in preventing the diversion of 340B drugs to individuals who do not qualify as patients, such as individuals who do not receive medical care directly from the covered entity and individuals who are patients of a contract pharmacy but not of the covered entity. The GAO and OIG share BIO's concern and have repeatedly noted that the lack of clarity regarding key elements of the patient definition has increased the risk that some covered entities will continue to divert 340B covered outpatient drugs to individuals who do not qualify as 340B patients.

For instance, the GAO found in a report issued in 2011 that HRSA's current guidance on the definition of an eligible patient lacks the necessary specificity to clearly define the various situations under which an individual is considered eligible for discounted drugs through the 340B Program.[127] Subsequently, a 2014 OIG report found significant variability in 340B prescription eligibility resulting from the myriad different methods by

[126] See 61 Fed. Reg. 55,156 (Oct. 24, 1996).
[127] 2011 GAO Report.

which contract pharmacies identify 340B-eligible patients, with some of those differences stemming from the varying and inconsistent interpretations of the definition of patient applied by different covered entities.[128] HRSA itself acknowledged this risk of diversion when it sought to revise the "patient" definition in 2007.[129]

BIO recognizes that many covered entities do not engage in questionable practices that can result in diversion because they have interpreted the "patient" definition in good faith and are mindful of both the statute's purpose and HRSA's guidance. However, HRSA must recognize that the financial incentives related to obtaining drugs at a significant discount are significant and must be countered by clearer Agency guidance, as well as enforcement mechanisms.

In light of the many changes both in the health care system and the 340B Program since HRSA issued the current patient definition in 1996—including the increasing use of virtual inventory systems, under which a 340B patient's status is determined retroactively rather than at the point-of-sale, and contract pharmacies, which not only make retroactive patient eligibility determinations but also serve both 340B and non-340B patients—HRSA's existing patient definition is substantially outdated, overly broad, and lacking clarity. As HRSA recognizes in the Proposed Notice, this definition must be revised to address specific risk areas and reflect the realities of the current health care system, administrative processes employed within the 340B Program, and—perhaps most importantly—the financial incentives that the program creates. Accordingly, BIO strongly supports HRSA's efforts to provide clearer, more auditable standards with respect to who qualifies as a "patient" of the covered entity for purposes of the 340B Program.

Specifically, the Proposed Notice would clarify that an individual would be considered a "patient" of a 340B covered entity only if all six of the following criteria are met "on a prescription-by-prescription or order-by-order basis:"

> (1) The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database;
>
> (2) The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider;
>
> (3) An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). An individual will not be considered a patient of the covered entity if the only health care

[128] OIG, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 4, 2014) (hereinafter "2014 OIG Contract Pharmacy Report").
[129] See 72 Fed. Reg. at 1544 ("[I]t is possible that some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program.").

> received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug;
>
> (4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract;
>
> (5) The individual is classified as an outpatient when the drug is ordered or prescribed. The patient's classification status is determined by how the services for the patient are billed to the insurer (e.g., Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently; and
>
> (6) The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each 340B drug.[130]

This proposed patient definition would provide increased clarity and auditability over the existing definition. In particular, BIO supports HRSA's efforts to ensure that a covered entity can document that the covered entity is truly responsible for the care provided to a given patient—and that the care in question exceeds merely the provision of administrative services or the infusing/dispensing of a drug. The following comments describe BIO's support for each of the six criteria of the proposed patient definition articulated in the Proposed Notice, and outline certain aspects of the proposed criteria that could be further clarified in order to ensure that there is an ongoing, tight nexus across three interdependent factors—the *covered entity* serving the individual, the *health care provider* practicing at the covered entity, and the *treatment or health care service* by that health care provider that gives rise to a prescription for a covered outpatient drug—while taking into account the unique care practices across covered entity types, in particular among non-hospital covered entities. Indeed, throughout our comments, we highlight instances where the proposed patient definition could have unintentional consequences on non-hospital covered entities' ability to provide services within the scope of their grant, where additional flexibility may be necessary. That said, to the extent that HRSA adopts any exceptions from the patient definition, as suggested, we urge the Agency to do so only after providing ample public notice and opportunity to comment.

Even with the proposed revisions to the patient definition, BIO believes further clarity may be necessary with respect to how to operationalize the definition, in practice. As HRSA is aware, many 340B prescriptions are managed through virtual inventory systems that rely on certain algorithms that determine whether a given prescription was 340B-eligible after the time the prescription was dispensed. This is particularly true in the contract pharmacy context, because contract pharmacies generally do not have the

[130] 80 Fed. Reg. at 52,319.

capability to distinguish a patient of a covered entity who is eligible for 340B-priced drugs from any other patient filling a prescription. As a result, contract pharmacies generally rely on matching information from the 340B providers (e.g., patient and prescriber lists) with the pharmacy's own prescribing data. Some vendor support programs "link" a prescription to a diagnosis code by matching the therapeutic regimen to a particular International Statistical Classification of Diseases and Related Health Problems ("ICD") code (e.g., ICD-9 or ICD-10). But, in its 2014 contract pharmacy report, OIG found wide variations in the assumptions made by contract pharmacies as part of these eligibility determinations. As just one example, OIG found that three contract pharmacies made three unique determinations with respect to whether a prescription written by a physician who practices at a covered entity, but also has a private practice, should be deemed 340B eligible—always, sometimes, and never. To assist covered entities in applying the proposed patient definition on a prescription-by-prescription (or order-by-order) basis, HRSA should provide further clarification as to how the patient definition should be operationalized in the context of these algorithms, after careful consideration of BIO's recommendations with respect to the proposed patient definition, as well as regarding the use of these algorithms in the contract pharmacy context outlined in section (VII)(d), below. Among other things, HRSA could explore creating a crosswalk of ICD-9/10 codes with therapeutic regimens that could be utilized by all covered entities and their contractors and vendors. As articulated throughout this letter, we also urge HRSA to require covered entities to direct their contract pharmacies to bill for 340B drugs using the covered entity's NPI.

1. <u>The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database.</u>

BIO supports all three aspects of this first criterion, namely that (1) the individual receives a health care service; (2) the service is provided at a facility or clinic site registered with the 340B Program; and (3) the facility or clinic site is listed on the public 340B database. We discuss each of these components in turn.

First, we support HRSA's express statement that the individual must receive at least one health care service from the covered entity supplying the 340B drug. The receipt of a health care service is clearly necessary for an individual to be considered a "patient." Defining "patient" without a requirement that the patient receive health care services from the covered entity would extend 340B pricing to individuals who are more properly considered a "customer" or "client" of the covered entity, rather than a "patient." Indeed, as HRSA has stated in prior *Federal Register* notices, the individual's health care relationship with the covered entity is the *most important factor* in determining whether an individual can or should be considered a "patient of the entity."[131] We further support HRSA's proposed clarification in the preamble of the Proposed Notice that the covered entity must be "medically responsible" for the care of that individual for the person to be considered a "patient."[132] However, consistent with the standards articulated in the sixth

[131] 72 Fed. Reg. at 1544.
[132] 80 Fed. Reg. at 52,306.

criterion of the proposed patient definition,[133] we urge HRSA to further clarify in any final guidance that this responsibility must be directly related to the ordering, prescribing, or dispensing of a drug for that drug to qualify for 340B, and that refills of such orders and prescriptions may only be considered to meet this standard if they are dispensed in accordance with applicable state and federal law. Any prescriptions or refills filled more than 12 months after the initial prescription or order warrant more explicit oversight by HRSA to ensure that the prescription or order in question meets all requirements of the proposed patient definition.

Second, we support HRSA's proposed clarification that the services received by the individual be provided by facilities or clinic sites that are registered with the 340B Program. We believe that this statement is necessary and appropriate in light of the fact that the 340B statute limits program participation to those entities that fall into one of the categories of entities enumerated in the statute.[134] Patients of entities not in one of these categories simply cannot be eligible for drugs purchased at the 340B ceiling price. Accordingly, we further support HRSA's proposed clarification in the preamble text that "[a]n individual who sees a physician in his or her private practice which is not listed on the public 340B database or any other non-340B site of a covered entity, even as follow-up to care at a registered site, would not be eligible to receive 340B drugs for the services provided at these non-340B sites."[135]

Relatedly, we also support the preamble statement proposing to clarify that "[a]n individual will not be considered a patient of the covered entity if the individual's health care is provided by a health care organization that has an affiliation arrangement with the covered entity, even if the covered entity has access to the affiliated organization's records."[136] As HRSA recognizes throughout the Proposed Notice, not all affiliated organizations are sufficiently related to a covered entity such that they may permissibly participate in the 340B Program as "child sites." In cases where the prescription results from health care services provided to the individual by an entity that is not a covered entity or by an affiliated organization that is not sufficiently connected to the covered entity to qualify as a "child site," the individual cannot qualify as a "patient" of the covered entity. The administrative act of obtaining access to the individual's medical records, or incorporating the receipt of such services into the health record maintained by the covered entity, does not constitute a sufficient provider-to-patient relationship for purposes of the 340B Program.[137] Similarly, "[m]ere acceptance *pro forma* or rubberstamping of an outside health care provider's diagnosis or medical opinion [by a covered entity] does not demonstrate . . . responsibility" by the covered entity for the individual's care sufficient to establish a patient relationship with the individual.[138]

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[133] This criterion specifically requires that an individual's medical record document "that the covered entity retains responsibility for the care that results in every 340B drug ordered, dispensed, or prescribed to an individual." Id. at 52,307.
[134] See 42 U.S.C. § 256b(a)(4).
[135] 80 Fed. Reg. at 52,306.
[136] Id.
[137] 72 Fed. Reg. at 1545.
[138] Id.

Third, we support HRSA's proposed clarification that the entity providing the services also be listed in the public 340B database. This proposed clarification is critical for purposes of operationalizing the proposed patient definition because it would permit manufacturers to reliably confirm that the facility providing care to the individual is validly participating in the 340B Program. This proposed requirement would be consistent with HRSA's recently proposed "covered entity" definition,[139] which similarly would require inclusion in the public 340B database in order for the entity itself to be eligible for 340B pricing. As in BIO's comments submitted in that context,[140] we urge HRSA to clarify that the covered entity must appear in the 340B database at the time the 340B drug is both prescribed and provided (e.g., dispensed) to the patient. For instance, assume that a prescription is written in Q1, at which time an entity is 340B-eligible; however, the prescription is later filled in Q2, when the entity is no longer eligible and thus does not appear in the public 340B database at that time. HRSA should clarify that such prescriptions would not be considered 340B-eligible because, while all other criteria of the patient definition are met, the covered entity would not have been listed in the database in the quarter in which the drug is dispensed. This clarification is critical because manufacturers rely on the public 340B database in order to identify those entities that are, in fact, eligible for 340B at the time a drug is provided to the patient (and a chargeback is sent to the manufacturer). An alternative interpretation would thus not only be inconsistent with the proposed patient definition, but would be very difficult, if not impossible, for manufacturers to operationalize.

2. <u>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.</u>

BIO supports HRSA's proposal to clarify that a health care provider must have a documented relationship with the covered entity, under which the covered entity has ultimate responsibility for the care provided, in order for individuals who receive care from that provider to be considered patients of the entity. We also support three clarifying statements that the Agency makes in the preamble text with respect to this proposed criterion.

First, in the Proposed Notice, HRSA notes that "[f]aculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered entity-provider relationships that would meet this standard."[141] BIO agrees that each of these arrangements certainly could qualify as a relationship in which the covered entity is ultimately responsible for the care provided to a degree sufficient to establish a "patient" relationship, particularly if it is the covered entity that ultimately submits a bill for the services on behalf of any such providers. In that regard, we urge HRSA to further clarify that this prong of the patient definition requires

[139] 80 Fed. Reg. at 34,585 (proposed 42 C.F.R. § 10.3).
[140] BIO comments in response to the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation [RIN 0906-AA89] Proposed Rule (Aug. 17, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20CMP%20&%20Ceiling%20Price%20Rule%208_17_15_0.pdf.
[141] 80 Fed. Reg. at 52,306.

that a hospital *does* in fact bill for services on behalf of a provider (not merely that the hospital *may* bill for such services).[142] This billing standard would help ensure that services provided by contractors can form the basis of a patient relationship only while such contractors are actually working on behalf of the covered entity, and would avoid improperly expanding the patient definition to encompass instances in which a hospital outsources care to physician groups (e.g., to run the hospital's emergency department) for which the hospital arguably *may* bill for services, but does not in fact do so given the attenuated relationship between the physician group and the covered entity. To implement this proposed requirement, we further suggest that HRSA require that the health care service that resulted in the prescription be billed under the covered entity's provider number.

Second, we further support the proposed clarification provided in the preamble statement that "simply having privileges or credentials at a covered entity is not sufficient" to establish a "patient" relationship.[143] We suggest that HRSA adopt a clear standard to implement this proposed requirement, such as by requiring that the provider be acting as a "representative" of the covered entity, such that the covered entity is legally liable for the care provided.[144] HRSA should further require that the "contract must be legally binding such that adequate consideration is given by both the covered entity and the professional," and that any remuneration provided by the covered entity for services furnished by any non-employee provider be based on fair market value—both policies recommended by PHPC in 2006.[145]

Along these lines, as HRSA has noted previously, "loose affiliation networks"—under which individuals receive services from affiliated health care providers who may, for instance, have admitting privileges, but do not have contractually enforceable duties or obligations vis-à-vis the covered entity—represent an arrangement in which the ongoing responsibility for an individual's health care resides with the affiliated health care provider and not the covered entity.[146] In any final guidance, we urge to rearticulate this language and to further recognize that professional service arrangements ("PSAs") with physician offices not otherwise affiliated with the covered entity, as well as administrative services alone (e.g., case management services provided by non-health care providers or through third-party providers) are not sufficient to establish a "patient" relationship.

Third, BIO supports HRSA's preamble statement that "[p]rescriptions that result from referrals to non-340B providers are not 340B-eligible," but that, "when the patient returns to the covered entity for ongoing medical care, subsequent prescriptions written by the covered entity's providers may be eligible for 340B discounts,"[147] so long as the

[142] We note that if HRSA in any final guidance retains the permissive "may" formulation here and does not require that the hospital in fact bills for the services on behalf of a provider, the word "may" in the limiting definition of the covered outpatient drug definition ("for which payment *may* be made under this subchapter") must be interpreted similarly broadly, as our comments above suggest.
[143] 80 Fed. Reg. at 52,306.
[144] This "legal liability" standard would essentially assess who would be the "negligent" party in the event of a lawsuit—the covered entity or the practitioner. To operationalize this requirement, HRSA could require the covered entity to attest that the covered entity would be the at-risk party for the care provided.
[145] 2006 PHPC Letter.
[146] 72 Fed. Reg. at 1545.
[147] 80 Fed. Reg. at 52,306-07.

covered entity has assumed responsibility of care back from the referred-to provider and all other aspects of the "patient" definition are met. We agree that care provided through referrals cannot establish a patient relationship with the covered entity. While we appreciate that individuals may receive care from several entities, in order for that individual to be considered a "patient of the entity" with respect to a given prescription or order, ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) that prescription or order must remain with the covered entity. In a referral situation, on the other hand, the referring physician relinquishes responsibility for the care of the individual to the referred physician. Indeed, a referral underscores that the individual *may have been* a patient of the 340B covered entity, but that the individual is no longer a *current* patient of that entity for the relevant condition or disease. We therefore strongly support HRSA's proposed clarification that referral arrangements do not establish a 340B patient relationship. A contrary policy would contradict the "direct clinical care" criterion that Congress specifically envisioned,[148] and would be fundamentally inconsistent with HRSA's 1996 guidance that "responsibility for the care provided *remains* with the covered entity."[149]

That said, we believe that HRSA could conceivably recognize a very limited exception to the general prohibition on referrals for non-hospital covered entities that rely on referrals as part of their model of care in order to furnish holistic, patient-centered services to their patient populations.[150]

3. <u>An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2).</u>

BIO strongly supports the proposed criterion that the individual receive a drug that is ordered or prescribed by the covered entity provider as a result of the service described in the second criterion. This proposed requirement is critical for ensuring the tight nexus between an entity/provider and the 340B-priced drug prescribed to a given individual necessary for that person to be considered a "patient." We believe that HRSA should further clarify, however, that the provider in question must have direct oversight over the individual's care and manages the individual's treatment relative to the covered outpatient drug prescribed.

We further note our strong support for HRSA's proposed clarification that an individual would *not* be considered a 340B "patient" to the extent that the covered entity's sole relationship to the individual is the dispensing or infusion of a drug, "without a covered entity provider-to-patient encounter."[151] In particular, we support HRSA's recognition that infusion services alone are not sufficient to establish a patient relationship. While HRSA has long recognized that the mere dispensing of a drug for home use is not sufficient to establish a patient relationship, this is the first time that HRSA has formally recognized

[148] H.R. Rep. No. 102-384 (II) (1992).
[149] 61 Fed. Reg. at 55,157 (Oct. 24, 1996) (emphasis added).
[150] To the extent that any such exceptions are established, however, we urge the Agency to ensure that the applicable standards are clear and auditable and that the exception does not result in manufacturers being subject to duplicate 340B discounts (i.e., instances in which both the referring and referred-to facilities are covered entities and claim 340B discounts on prescriptions or orders that result from the referral in question).
[151] 80 Fed. Reg. at 52,307.

that infusion services are similarly insufficient. This would be an important clarification that would be consistent with Agency policy and the intent of the 340B Program.

Addressing infusion services is an excellent example of how the 1996 "patient" definition has become outdated in light of the changes that have occurred in the nearly 20 years since its release. Early 340B Program guidance appears to have focused on retail pharmacy products rather than treatments involving physician-administered products. Such products have since become the focus of attempts by some covered entities to maximize 340B Program income resulting from the difference, or "spread," between the 340B ceiling price and insurance reimbursement rates for physician-administered covered outpatient drugs. It therefore is absolutely necessary for HRSA to revise the "patient" definition (and other aspects of the program) to address issues unique to these types of drugs.

As BIO has long articulated in our comments and engagement with the Agency, while infusion services are, in fact, health care services, where a covered entity acts solely as an infusion or administration site for an individual and does not otherwise provide the medical care that results in the prescription or order for the covered outpatient drug, the covered entity's limited role of administering the drug to the individual should not transform that individual into a "patient" of the covered entity. For example, covered entities should not be permitted to implement "kiosk"-like arrangements, under which they carve out space at outlying, privately-owned and operated clinics for the administration of drugs, such as infusions, as such clinics do not provide any health care services to individuals, other than pharmacy services.

We believe that this proposed requirement would align with requirements already in place to determine program eligibility for child sites. Specifically, under HRSA's longstanding guidance, an outpatient facility of a 340B-participating hospital "is considered an integral part of the 'hospital' and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report."[152] HRSA has similarly made clear that "free-standing clinics of the hospital that submit their own cost reports using different Medicare provider numbers (not under the single hospital Medicare provider number) would not be eligible for this benefit."[153] To operationalize this requirement, we urge HRSA to further clarify that drug administration procedure codes (e.g., chemotherapy administration codes) do not, alone, qualify as a provider-to-patient encounter for purposes of establishing a patient relationship under the 340B Program, and may wish to explicitly identify the ineligible services—by billing code—for this purpose. We also believe that this clarification (i.e., that infusion or administration codes would not suffice), also should be made with respect to HRSA's proposal on child site eligibility, which, as proposed, would require these facilities to have associated outpatient charges.

We have strong concerns, however, with respect to HRSA's proposed statement that "[t]he use of telemedicine, telepharmacy, remote, and 'other health care service arrangements' (e.g., medication therapy management) involving the issuance of a prescription by a covered entity is permitted, as long as the practice is authorized under

[152] 59 Fed. Reg. at 47,885.
[153] Id.

State or Federal law and otherwise complies with the 340B Program."[154] Foremost, BIO supports the concept of telemedicine and innovative solutions to deliver care to isolated and medically underserved areas. This support notwithstanding, we are concerned that the recognition of telemedicine services as a basis for forming a "patient" relationship for purposes of the 340B Program could create a massive loophole for expanding the program to cover individuals who have only a brief, virtual, and medically insubstantial relationship with a covered entity. Particularly given that HRSA has not articulated a rationale for the recognition of telemedicine under the "patient" definition, we believe that any benefits of telemedicine are outweighed by the substantial diversion risks presented by this modality of care. Indeed, these risks were even identified to HRSA by the PHPC in 2006, which noted that "[t]elemedicine services, for example, would not create a patient relationship recognizable under 340B if the services simply involve a consultation via telephone or videoconferencing," and thus recommended that services involve "face-to-face visits with a professional."[155] Nothing since 2006 justifies waiving this face-to-face, in-person requirement, especially when HRSA's own audits have revealed significant instances of diversion.

We also are concerned that this proposal, as drafted, is vague and subject to misinterpretation, and potentially abuse. Specifically, HRSA has chosen to use terms that are not defined for purposes of the 340B Program, including "telemedicine" and "telepharmacy"—not to mention that we understand the latter term (telepharmacy) to refer to a care modality that would not result in a prescription, and thus could not result in a "patient" relationship defined on a prescription-by-prescription basis in the first instance. Moreover, the term "other health care services" is not, to our knowledge, defined anywhere. For a program that has already been susceptible to abuse, the adoption of such overly broad and undefined terms would invite more abuses, undermining HRSA's efforts to bring further clarity to the 340B Program by issuing the Proposed Notice. It also is problematic that HRSA's proposed clarification regarding telemedicine and "other health care service arrangements" appears under the third prong of the "patient" definition. Specifically, we believe that this placement could suggest that something less than a formalized relationship between a covered entity and the practitioner furnishing telemedicine or "other health care service[s]" would suffice.

For all of these reasons, we strongly urge the Agency not to include this proposed language in any final guidance. To the extent that HRSA nonetheless includes language of this nature in its final guidance, in spite of the program integrity risks posed, it is absolutely imperative that HRSA articulate certain safeguards, including to restrict the applicability of this language to home-bound and rural patients of non-hospital covered entities. Moreover, HRSA should clearly state that inclusion of telemedicine language is not intended to create a new pathway for 340B discounts, but to clarify parameters for the use of telemedicine by covered entities. Any discussion of telemedicine also should expressly reference the obligation of covered entities to adhere to applicable state and federal law with respect to the use of this care modality and the ownership of care.

[154] 80 Fed. Reg. at 52,307.
[155] 2006 PHPC Letter.

Finally, BIO strongly urges HRSA not to include the vague, overbroad proposed "other health care service arrangements" language in any final guidance. With respect to medication therapy management (MTM) specifically—cited as an example of a "health care service arrangement" in the Proposed Notice—HRSA should clarify that drugs subject to the MTM review cannot be filled with 340B unless, for each prescription, the MTM provider also was the one who wrote the prescription(s) and all other elements of the patient definition also are met.

4. The individual's health care is consistent with the scope of the federal grant, project, designation, or contract.

The fourth prong of HRSA's proposed patient definition would clarify that an individual must have "receive[d] a health care service that is consistent with the covered entity's scope of grant, project, or contract."[156] While we support HRSA's proposed clarification that this prong of the patient definition must be satisfied by each child site of a covered entity,[157] we have two key concerns with respect to this general proposal.

First, HRSA states in the preamble that "[a] covered entity registered as one of the hospital covered entity categories is not subject to this limitation."[158] While we understand that this policy has been in place since HRSA adopted its original patient definition in 1996, we are concerned that HRSA has *never* articulated a rationale for limiting the scope of the patient definition for non-hospital covered entities to those individuals "receiving health care at a covered entity site from a covered entity provider which is consistent with the health care service or range of services designated in the Federal grant, project, designation, or contract"[159] without imposing a similar limitation on hospital covered entities with respect to the governmental powers or public contract that form the basis of their eligibility for the 340B Program. Given that the statutory basis for these hospitals' entry into the 340B Program is similarly tied to formalized relationships with governmental entities of limited scope and duration (e.g., contracts to provide health care services to certain low-income individuals, grants of governmental power), there is no non-arbitrary and non-capricious justification for applying this limitation to these covered entity types, as evidenced by HRSA's failure to explain its basis for this discriminatory policy.

Indeed, as with non-hospital covered entities, these formalized relationships (e.g., contracts and governmental powers) are specific and can be operationalized as part of HRSA's patient definition. Moreover, imposing a similar limitation on hospital covered entities would bring their participation in the 340B Program in line with the mission-oriented participation by non-hospital covered entities, which are required to provide certain services to certain populations as a condition of the federal grants and programs

[156] 80 Fed. Reg. at 52,319.
[157] Id. at 52,307.
[158] Id.
[159] Id. (emphasis added). The only explanatory statements that HRSA has provided with respect to this limitation provide: "We do not consider a limitation on which drug products a covered entity may purchase to be a reasonable component of the definition of covered entity "patient." To the extent that purchasing certain drugs would contravene a Federal or State law or certain PHS grant principles (and this information is brought to the Department's attention), the Department reserves the right to take such action as it deems appropriate." 61 Fed. Reg. at 55,157.

that define the scope of their 340B eligibility. Yet, HRSA has chosen to give effect to similar terms (e.g., "contract(s)" or "grants") in the case of non-hospitals, but has not placed a corollary to that requirement in the case of the private, non-profit hospitals. This approach is inconsistent with the canon of statutory instruction providing that "[a] term appearing in several places in a statutory text is generally read the same way each time it appears,"[160] and completely without basis in the statute. We therefore urge HRSA to impose a similar restriction on hospital covered entities.

Second, we also recommend that HRSA apply this requirement to AIDS Drug Assistance Programs ("ADAPs"). The Proposed Notice, like the 1996 "patient" definition, proposes to exempt ADAPs from the patient definition by stating that an individual enrolled in an ADAP is considered to be a patient, as described in section (V)(d), below. It would appear that ADAPs were carved out of the 1996 patient definition because they generally could not meet all of the definition's requirements, when taken together. That said, there appears to be no reason why an ADAP would be unable to meet this fourth prong of the proposed definition, and we therefore believe that this prong should be applied to ADAPs, notwithstanding the fact that the patient definition otherwise does not apply to this category of covered entity. As a result, the 340B discount would apply only with respect to drugs prescribed, dispensed, or ordered on behalf of individuals served within the scope of the ADAP's federal grants. This approach is consistent with the core purpose of the formation of ADAPs and the expectation of the scope of their operations—that they support the treatment of HIV/AIDS patients.[161]

5. The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.

BIO supports the proposed clarification that the covered entity provide the individual with *outpatient* health care services, given that the 340B Program is limited to covered *outpatient* drugs, as HRSA recognizes in the Proposed Notice.[162]

We are concerned, however, that HRSA has proposed to determine the outpatient status of the health care service based on how the service is *billed* to an insurance company or other third-party payor. In our experience, one area in which the current patient definition is being inappropriately applied occurs when the patient is being improperly characterized as an outpatient instead of an inpatient. Some manufacturers have written inquiry letters to 340B covered entities whose purchasing patterns diverge significantly from national norms (e.g., inpatient-to-outpatient ratios), and a number of the covered entity responses reflect disturbing "justifications" for the unexpectedly high levels of

[160] Ratzlaf v. United States, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it appears.").
[161] 42 U.S.C. § 300ff–26(a) (stating that "[a] State shall use a portion of the amounts provided under a grant awarded under section 300ff–21 of this title to establish a program under section 300ff–22 (b)(3)(B) of this title to provide therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.").
[162] 80 Fed. Reg. at 52,307 ("Section 340B(a)(1) of the PHSA establishes the 340B Program as a drug discount program for covered entities furnishing covered outpatient drugs. Therefore, an individual cannot be considered a patient of the entity furnishing outpatient drugs if his or her care is classified as inpatient.").

"outpatient" (i.e., 340B) use for products, which reveal the inappropriate nature of these entities' claims to 340B pricing.

To illustrate, some covered entities have claimed that 340B pricing was appropriate because the patient received services in an area of their facility that was deemed "outpatient" (e.g., a diagnostic or interventional department, emergency department) at the time of service, even though the patient at issue may have been a registered inpatient at the time. These entities appear to take the position that any services provided in these locations to a registered inpatient are nonetheless "outpatient" services for which the covered entity may utilize 340B-priced drugs, even though, for every other purpose, including billing and reimbursement, the covered entity treats these services as inpatient services. Other covered entities have claimed that using the 340B–priced drugs was appropriate because, at the time the drug was administered to the patient, the patient was considered an "outpatient" in the entity's system. But, based on the high percentage of outpatient use by certain entities and their response to manufacturer questions about such use, BIO is concerned that "outpatient" status has been claimed for patients who received 340B-priced product regardless of whether the patient: (1) was known to require an inpatient admission at the time the "outpatient" service was provided; (2) already had an inpatient admission ordered at the time of administration or dispensing; or (3) was subsequently admitted as an inpatient after the "outpatient" service was provided (with the "outpatient" service being bundled into reimbursement for the "inpatient" admission). In each of these scenarios, the covered entity could conceivably *bill* for the service as outpatient, knowing full well that it would be *reimbursed* on an inpatient basis.

To limit any potential for program abuse, we therefore urge HRSA to clarify that the classification of health care services should be based on how the service is *reimbursed* by payors (or, for those uninsured patients, how the service *would have been reimbursed* by payors). In fact, we believe that this is what the Agency likely intended with respect to this proposal, given the preamble statement proposing to direct covered entities to "maintain auditable records documenting any changes in patient status due to insurer determinations,"[163] which would be unnecessary if the only relevant determination were how the covered entity, in its own discretion, elected to *bill* the insurer for the service in question. As with respect to the exception for changes in inpatient status proposed in the GPO context, we would support HRSA establishing an exception to this criterion of the patient definition where a patient's status is subsequently changed from outpatient to inpatient by an independent third party (e.g., an insurer or Medicare Recovery Audit Contractor (RAC)), so long as HRSA imposes a requirement on covered entities to maintain sufficient documentation of the patient's change of status.[164] To these ends, particularly for those covered entities that rely on a replenishment model of inventory management, HRSA should outline a process to ensure that, once a patient's status has changed, that information is passed from billing back to the pharmacy (in-house or contract) and that the 340B account/accumulation is debited.

While defining outpatient status based on how a service is *reimbursed* would go a long way in preventing diversion, BIO further urges HRSA to outline clear guidance to

[163] Id.
[164] See id. at 52,305.

covered entities with respect to determinations of outpatient status for purposes of the patient definition, to avoid situations in which covered entities are making decisions about patient care based on how the patient definition interfaces with the covered outpatient drug definition. For instance, we strongly urge the Agency to investigate instances in which a covered entity has classified a service as "outpatient," even though the label for the drug in question directs that the product be used in the inpatient setting. For instance, some hospitals have adopted policies that treat individuals as "outpatients" during the period after the determination has been made to admit them, but while they are still "waiting for a bed." HRSA should clearly define that "waiting for a bed" does not somehow convert an inpatient to an outpatient in order to remove these inconsistencies. We also urge HRSA to expressly clarify that it is impermissible to delay or manipulate the timing of inpatient admissions for any purpose related to the 340B Program, including with the intent to increase the utilization of 340B-priced drugs by increasing the volume of "outpatient" use for a product that is used on both an inpatient and outpatient basis. Specifically, once it is established that a patient will need inpatient care, the admissions process should not be manipulated in order to support the use of 340B-priced drugs. To facilitate the Agency's ability to flag improper "outpatient" characterizations, as articulated during BIO's meeting with HRSA on April 1, 2015, BIO continues to urge HRSA to work with CMS, as well as manufacturers, to identify for auditors drugs that are generally administered in the inpatient setting, and direct the Agency's auditors to flag any outliers found for further review.

Relatedly, we strongly urge HRSA to address, in any final guidance, instances in which an individual receives solely inpatient treatment from a covered entity and subsequently fills a "discharge" prescription related to the inpatient treatment. By definition, an inpatient of a covered entity is never eligible for 340B-discounted products, and therefore 340B–priced drugs should not be used to fill discharge prescriptions that are provided to inpatients. Indeed, a prescription should only be considered eligible to be filled with 340B-priced drugs if the prescription is related to the ongoing, *outpatient* treatment of the individual. BIO recommends that HRSA clarify the distinction between drugs prescribed or ordered in connection with ongoing outpatient care and discharge prescriptions for individuals who solely received inpatient treatment from a covered entity, and make clear that, in the latter case, prescriptions do not qualify for fulfillment with 340B-priced drugs. While HRSA could conceivably create a very limited exception to this general requirement for non-hospital covered entities that seek such an exception to manage the care of individuals receiving discharge prescriptions both before and after discharge, any such exception must ensure that all requirements of the proposed patient definition are met on a prescription-by-prescription or order-by-order basis.

Official clarification is needed from the Agency that it will strongly discourage these types of inpatient-outpatient manipulation practices, and will take decisive enforcement action when such manipulations occur. Utilizing 340B-priced drugs for inpatients constitutes diversion, violates the 340B statute, and—most importantly—can have negative consequences for patients in terms of the quality of their care, not to mention by increasing their cost-sharing obligations and qualification for follow-on care under certain federal health care program rules. If it appears that covered entities are improperly characterizing services as outpatient to obtain drugs at 340B discounted prices (e.g.,

treating individuals in the emergency room to qualify for 340B–priced drugs with the knowledge that the individual will be admitted), HRSA should investigate and hold such entities accountable.

6. The individual's patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.

BIO supports this final proposed criterion of HRSA's proposed patient definition which relates to the maintenance of patient records, in particular the requirement that the individual's patient records "demonstrate that the covered entity is responsible for care."[165] We are concerned, however, with the formulation in the proposed criterion suggesting that the medical records need merely be "accessible to the covered entity" or that the covered entity "maintains access" to them.[166] While we agree that a shared electronic record with respect to which several parties have access to and ability to add to/edit the record could be a factor in demonstrating a patient relationship, mere *access* to records, without actual control and maintenance thereof, would not satisfy the requirements of the 340B Program. Indeed, recent incidents of diversion have exposed the fact that covered entities were inappropriately interpreting the term "maintain" in the 1996 guidance—a higher bar than mere access—to require lesser amounts of documentation and control than would be expected of a true provider-to-patient relationship. HRSA therefore should revise its proposed language to require both the ownership and control of medical records as part of any final patient definition.

We note that, in keeping with HRSA's prior clarification that covered entities need not maintain records in a centralized on-site location,[167] this proposed standard need not require that the covered entity possess paper records on-site at all times. Similarly, where a hospital is part of a state system such that the hospital itself cannot maintain legal title (i.e., ownership) of a record, it should be sufficient that the state owns the record. In all cases, however, it is imperative that the covered entity have control and responsibility for maintenance of the record beyond a mere right to access it, and HRSA should create clear, auditable standards for record ownership to facilitate covered entity adherence to this standard. We suggest that such standards include at least the following:

(1) The covered entity is the owner of the records such that the covered entity creates and maintains the records and incurs real and reportable costs in connection with maintaining such records;
(2) The records meet the standards applicable to medical record systems; and
(3) The entity's records are the "system of record" documenting the care event in question, such that the covered entity takes responsibility for the record.[168]

[165] Id. at 52,307.
[166] Id. at 52,319.
[167] 61 Fed. Reg. at 55,157.
[168] We suggest that HRSA examine comparable models of record ownership that were established to protect protected health information ("PHI") under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

As noted above, we strongly support the proposed requirement that the medical record itself "demonstrate that the covered entity is responsible for care."[169] Use of pharmacy records alone or records maintained for administrative purposes only, such as relating to health screenings or drug interaction reports, should be insufficient to qualify an individual as a patient eligible for 340B-priced drugs. Requiring that the medical record is clearly connected to the care in question would greatly enhance the likelihood that a true provider-to-patient relationship exists, as well as the auditability of this standard.

We also support that the language of the proposed criterion itself would clearly specify that the service documented in the medical record actually resulted in the prescription that is filled with 340B-priced drugs, which we believe is important in order to align this criterion with the proposed requirements articulated in the prior five proposed criteria. Specifically, we strongly support the language proposing to clarify that the medical record must document "that the covered entity retains responsibility for the care *that results in every 340B drug ordered, dispensed, or prescribed to an individual*."[170]

We note that, contrary to public statements by covered entities, these are recordkeeping and patient-care standards to which covered entities should be adhering under the existing patient definition, and we therefore do not believe that this would represent a substantive change in covered entities' record-retention obligations. As noted in the following section, we urge HRSA to further clarify that failure to maintain proper records that conform to this standard would result in a finding of diversion, as well as a requirement to refund manufacturers for all applicable discounts.

b. Records

BIO supports HRSA's proposed clarification that, "[p]ursuant to section 340B(a)(5)(C) of the PHSA . . . covered entities must maintain records that demonstrate that all of the criteria [of the proposed patient definition] were met for every prescription or order resulting in a 340B drug being dispensed or accumulated through a replenishment model."[171] As HRSA notes, section 340B(a)(5)(C) permits both HRSA and manufacturers to audit covered entities for their compliance with, among other things, the statutory prohibition on diversion. We agree that auditable records pertaining to compliance with the patient definition are necessary to permit the meaningful performance of such audits. We also urge HRSA to clarify that the failure to retain such records with respect to an individual should automatically result in a determination that the individual was not a patient of the covered entity, including a requirement that the covered entity pay manufacturers the difference between the commercial price and the price at which the covered entity obtained drugs dispensed to that individual. Given that the covered entities in question will not be able to correctly identify such costs—due to the absence or insufficiency of their records—HRSA also should develop a procedure for determining the value of medications purchased through 340B for this purpose.

[169] 80 Fed. Reg. at 52,307.
[170] Id. (emphasis added).
[171] Id.

BIO particularly supports the language recognizing that a covered entity's auditable records must demonstrate compliance with the patient definition on a prescription-by-prescription basis, both when the covered entity determines at the point-of-sale that a prescription may be filled with 340B-priced drugs and fills the prescription with 340B-priced drugs, as well as when the covered entity retroactively determines that the prescription was eligible to be filled with 340B-priced drugs using virtual inventory software and then obtains 340B-priced drugs through a replenishment model. As OIG noted in its recent testimony to the Energy and Commerce Committee of the U.S. House of Representatives, a substantial limitation of HRSA's 1996 patient definition is that it outlines eligibility criteria at the patient level; however, operationally, such determinations generally are made at the prescription level via replenishment models used by covered entities and their contract pharmacies.[172] HRSA's recognition that records must demonstrate compliance with the patient definition on a prescription-specific basis is a positive first step in addressing this concern. However, as articulated above, HRSA should issue further guidance regarding how the patient definition can and should be operationalized by covered entities in the context of replenishment models.

c. Eligibility for Covered Entity Employees

BIO supports HRSA's proposed express clarification that all individuals must meet the 340B Program's patient definition to be eligible to receive 340B-priced drugs, as well as the related proposed clarification that employees of covered entities do not become eligible to receive 340B-priced drugs solely through their employment relationship with the covered entity.[173] In spite of HRSA's FAQ providing that "[c]overed entities may only distribute covered outpatient drugs to their employees if the employees meet the patient definition set forth under the 340B Program,"[174] the lack of specific guidance to date, together with the overly broad definition of "patient" in HRSA's 1996 guidance, have led certain covered entities to potentially treat their own employees as "patients" under the 340B program, without the covered entity performing any substantial role in providing health care services for these individuals.[175]

For example, some covered entities have argued that a self-insured covered entity with access to its employees' insurance claims records "maintains records of the individual's health care," thereby purportedly satisfying the first prong of the 1996 definition of "patient." To forestall such spurious arguments, we strongly support HRSA's proposed clarification in the Proposed Notice that an individual's medical records must demonstrate that the *covered entity* is responsible for the individual's care, as noted above, and that "[c]overed entities that solely have financial responsibility for employees' health care, and contract with prescribing health care professionals loosely affiliated or unaffiliated

[172] Testimony Before the United States House of Representatives Committee on Energy and Commerce: Subcommittee on Health, Ann Maxwell, Assistant Inspector General, Office of Evaluation and Inspections, Office of Inspector General, Dep't of Health & Human Servs. (Mar. 24, 2015).
[173] 80 Fed. Reg. at 52,307.
[174] HRSA, Are employees of a covered entity eligible to receive 340B drugs? http://www.hrsa.gov/opa/faqs/ (last visited Sept. 3, 2015).
[175] Dana Darger, Using Split-Billing Software to Simplify 340B Ordering, 6 Pharmacy Purchasing & Products (Apr. 2009), available at http://www.pppmag.com/article/521/April_2009/Using_SplitBilling_Software_to_Simplify_340B_Ordering/

with the covered entity, would not meet the level of responsibility for health care services as outlined in [HRSA's proposed] guidance" necessary to establish a patient relationship.[176] Indeed, in this scenario, "[a] covered entity would be acting primarily as the insurance provider for these individuals and not as the health care provider for these individuals."[177] As HRSA notes, and BIO strongly supports, "[f]or 340B Program purposes, there is a fundamental difference between the individuals for whom the covered entity provides direct health care services and meets all criteria in [the patient definition] and employees for whom a covered entity only provides insurance coverage."[178]

However, we urge HRSA to further make clear that covered entities cannot transform employees into patients simply by permitting one of their employee or contracted prescribers to re-write prescriptions or orders that employees receive from their own health care providers who are not affiliated with the covered entity. This is yet another practice that would be inconsistent with the proposed requirement that the covered entity be responsible for a patient's outpatient health care services in order for the individual to be eligible to receive 340B-priced drugs. For example, HRSA should specify that employee "Wellness Programs" (e.g., where employees receive an annual physical or health check) are not substantial enough to establish 340B eligibility. Instead, employees, like all other individuals, must meet all criteria of the patient definition in order for the covered entity to be eligible to request covered outpatient drugs at the 340B ceiling price for such individuals.

We also urge HRSA to address a related circumstance involving the use of health coverage to impermissibly expand participation in the 340B Program. Specifically, as we have articulated in prior comments submitted to the Agency, it has come to BIO's attention that at least one Medicare Advantage plan, by virtue of being owned by a 340B covered entity, is steering all of its enrollees to obtain their physician-administered drugs from the covered entity owning the plan, regardless of whether the enrollee's prescribing physician has any relationship with the covered entity.[179] Directed purchases without regard to physician affiliation are completely inconsistent with a program that has as its focus ensuring that covered entities can use discounted covered outpatient drugs only for their own patients, and are the result of the troubling practice of payors using market forces to compel smaller covered entities to share their 340B savings—which is outside of any reasonable interpretation of the intent of the 340B program. Claims that such directed purchases are permissible further illustrate the 1996 "patient" definition's lack of clarity. We therefore urge HRSA to create guidelines for revenue-sharing arrangements (if not expressly prohibit them entirely), and directly clarify that arrangements of the kind described here are impermissible in order to ensure that a for-profit entity (e.g., the Medicare Advantage plan described above) does not seek to benefit by improperly obtaining 340B-priced drugs for its enrollees, which would not only abuse the 340B Program but also potentially harm patients by directing their care for financial, rather than

[176] 80 Fed. Reg. at 52,307.
[177] Id.
[178] Id.
[179] See Winthrop Quigley, Pharmaceutical Savings, Albuquerque J. (Mar. 3, 2012), available at http://www.abqjournal.com/main/2012/03/02/biz/pharmaceutical.html (describing a Medicare Advantage plan owned by a covered entity in New Mexico that will allow members to receive reduced pricing by obtaining drugs through the plan, even if the drug is not prescribed or administered by a physician employed by the plan).

medical, reasons.[180] Moreover, as the trend of hospital systems sponsoring their own health insurance plans continues,[181] HRSA should ensure rigorous compliance with all program requirements such that program integrity is maintained in connection with such arrangements.

d. Exceptions

BIO supports HRSA's decision to propose to reaffirm its longstanding position that "[a]n individual enrolled in a Ryan White HIV/AIDS Program AIDS Drug Assistance Program funded by Title XXVI of the PHSA will be considered a patient of the covered entity for purposes of [the proposed patient] definition."[182] That said, as described in section (V)(a), above, we urge HRSA to nonetheless apply the fourth prong of the proposed "patient" definition to ADAPs, such that their participation in 340B is limited to the scope of their federal grant, as is the case for all other non-hospital covered entities.

BIO also generally supports HRSA's proposed recognition of "the unique circumstances that arise during a public health emergency declared by the Secretary" by proposing to "allow certain flexibilities for demonstrating that an individual is a patient of a covered entity in these situations."[183] For example, we understand that covered entities may not be able to retain robust medical documentation during such periods, necessitating the covered entity to request HRSA's authorization for use of an alternate patient definition (supported by auditable records maintained by the covered entity) that is not contingent on the maintenance of such records, as would otherwise be required by proposed criterion number 6. We are extremely concerned, however, by the suggestion in the preamble text that a covered entity would be permitted during such periods to obtain drugs at the 340B ceiling price when the drug is dispensed through a site that is not listed in the 340B database. While we fully appreciate the exigencies inherent in a public health emergency, and would, as an industry, endeavor to do our part to protect and preserve the public's health in such instances—including under agreements in place between local, state, or federal health agencies to distribute the necessary products during these events—this proposal would expand the 340B Program beyond the scope contemplated or permitted by the 340B statute. Moreover, we note that this proposed provision could create compliance concerns for manufacturers, which rely on the 340B database in order to identify those entities that are properly participating in the 340B Program and therefore entitled to 340B pricing. Accordingly, we urge HRSA to articulate, and seek stakeholder feedback with respect to, the specific, limited exceptions that may apply during a public health emergency, as well as the criteria that HRSA would apply in such instances.

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[180] See Barbara L. McAneny, Presbyterian's Drug Policy Dangerous, Albuquerque J. (Apr. 8, 2012), available at http://www.abqjournal.com/main/2012/04/08/opinion/presbyterians-drug-policy-dangerous.html (describing author's concern that because her patients will have to receive specialty pharmaceuticals through their plan's specialty pharmacy, the cancer center for which she works will no longer have control over the preparation and dispensing of drugs to its patients).

[181] A. Matthews, Hospital Systems Branch Out as Insurers, Wall. St. J. (Dec. 6, 2012), available at http://online.wsj.com/article/SB10001424127887324677204578183041243834084.html; Melanie Evans, Cutting out the Middleman, Modern Healthcare (Mar. 23, 2013), http://www.modernhealthcare.com/article/20130323/MAGAZINE/303239976.

[182] 80 Fed. Reg. at 52,307; 52,319.

[183] Id. at 52,307-08; 52,319.

e. Replenishment

As HRSA recognizes in the Proposed Notice, many covered entities use replenishment models, which involve tallying the drugs dispensed to each type of patient (e.g., inpatients, 340B-eligible outpatients, other outpatients) and then replenishing the drugs used for each patient type by reordering drugs using the appropriate accounts (e.g., GPO, 340B, Wholesale Acquisition Cost ("WAC")). HRSA further notes that some covered entities use accumulator software to track drug use for each of these patient types, which indicates which drugs are available to reorder across the various accounts.

As BIO has noted in numerous communications with HRSA, we are very concerned about the lack of oversight and guidance related to the use of this type of software by covered entities and their agents (e.g., contract pharmacies, third-party administrators). Indeed, as we articulated in a recent letter to the Agency,[184] split-billing software systems and the third-party administrators ("TPAs") that run them are referenced in most of the letters that our members receive from covered entities self-reporting 340B Program violations. For example, a very common 340B compliance issue self-disclosed by covered entities is the "over-purchase" of 340B-priced drugs as a result of errors in the "inventory replenishment system." While described in terms of an error involving the replenishment software system, the actual violation of 340B Program requirements consists of the dispensing of 340B product to an ineligible patient, i.e., diversion. As this example illustrates, the lack of guidance and oversight related to such replenishment software systems results in violations of important 340B Program requirements.

For these reasons, we strongly support HRSA's proposed clarification in the Proposed Notice that, "[t]o avoid a violation of the statutory prohibition on diversion, a covered entity that utilizes a drug replenishment model may only order 340B drugs based on actual prior usage for eligible patients of that covered entity as defined by [HRSA's proposed guidance]."[185] We further support HRSA's recognition in the preamble text that, "[i]f the covered entity improperly accumulates or tallies 340B drug inventory, even if it is prior to placing an order, the covered entity has effectively sold or transferred drugs to a person who is not a patient, in violation of [the prohibition on diversion]."[186] We urge HRSA to assist covered entities and their software vendors with coming into compliance with this standard. We also urge HRSA to articulate how the Agency will monitor and enforce such compliance, as part of the Agency's covered entity audits, or otherwise, and to explicitly re-state that the covered entity is the responsible party if a violation occurs. Regardless of the vendor systems utilized to support a covered entity's ongoing compliance, covered entities must overtly assume responsibility for these vendor systems and the operations thereof.

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[184] See BIO comments in response to 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation [RIN 0906-AA89] Proposed Rule (Aug. 17, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20CMP%20&%20Ceiling%20Price%20Rule%208_17_15_0.pdf.

[185] 80 Fed. Reg. at 52,319.

[186] Id. at 52,308. We also support HRSA's recognition that "[a] similar violation would occur if the recorded number of 340B drugs does not match the actual number of 340B drugs in inventory, if the covered entity maintains a virtual or separate physical inventory." Id.

In the preamble text, HRSA also proposes to provide clarification regarding two distinct categories of reclassifications with respect to 340B drug purchases made through replenishment models. On the one hand, HRSA describes "errors in purchasing data" that are identified within 30 days of the initial purchase. We commend HRSA's support for the current process whereby manufacturers and covered entities work together to both identify and correct such errors through a credit and rebill process. We believe that this is the most efficient and fair mechanism for correcting these errors, which are possible even among those covered entities that maintain robust compliance systems. However, as with similar language elsewhere in the Proposed Notice, we urge HRSA to articulate this 30-day "grace period" in the guidance text (as opposed to merely the preamble) to avoid the potential for confusion.

On the other hand, HRSA describes circumstances in which "covered entities have attempted to retroactively look back over long periods of time at drug purchases not initially identified as 340B eligible"—sometimes over periods of several years—and then "attempt to re-characterize these purchases as 340B eligible and then purchase 340B drugs on the basis of these previous transactions."[187] We very much support HRSA's efforts to distinguish this process—often referred to as "banking"—from the immediate and regular correction of inadvertent purchasing errors, described above. However, particularly given HRSA's recognition that "[c]overed entities are responsible for requesting 340B pricing at the time of the initial purchase," we strongly urge HRSA to expressly prohibit this re-characterization of purchases after the initial 30-day period described above.

BIO further supports HRSA's proposed clarification that covered entities should conduct regular reviews of 340B drug inventory to "ensure that any inventory discrepancy is accounted for and properly documented to demonstrate that 340B drugs are not diverted." We agree that covered entities should follow standard business practices to return unused or expired drugs purchased at the 340B price and appropriately account for waste of such drugs, and that covered entities should maintain policies and procedures, as well as auditable records, regarding 340B drug inventory discrepancies to assist in meeting this standard. However, we urge HRSA to clarify in any final guidance that compliance with these standards is a mandatory requirement for covered entities.

f. Repayment

In the Proposed Notice, HRSA endeavors to interpret section 340B(a)(5)(D), which assigns liability to covered entities that violate the statutory diversion prohibition.[188] Specifically, HRSA notes that "[a] covered entity must notify HHS and each affected manufacturer of diversion"[189] and that the entity "is responsible for offering repayment to all affected manufacturers."[190] Covered entities also are expected to "document [such] notification attempts in auditable records" and "work with manufacturers regarding

[187] Id.
[188] Id. at 52,319. Pursuant to this provision, "[i]f a covered entity is found to have diverted to an individual who is not a patient of the covered entity contrary to the statutory prohibition on diversion, the covered entity is responsible for offering repayment to all affected manufacturers." 42 U.S.C. § 256b(a)(5)(D).
[189] 80 Fed. Reg. at 52,308.
[190] Id. at 52,319.

repayment within 90 days of identifying the violation."[191] BIO generally supports this proposed clarification. However, aside from the general statement that "[t]he covered entity is responsible for reporting a summary of its corrective actions taken to HHS for transparency, compliance, and audit purposes," HRSA fails to describe in any way how HRSA intends to enforce this proposed requirement.

Furthermore, it is not clear when the 90-day clock starts for purposes of working with manufacturers "regarding repayment," and there may be some inconsistency between the preamble and guidance text in this regard. In particular, in spite of the fact that HRSA recently released a proposed rule related to civil monetary penalties on manufacturers that impermissibly charge covered entities more than the 340B ceiling price, the Agency has yet to take steps to implement section 340B(d)(2)(B)(v) of the 340B statute, which relates to the imposition of sanctions "additional to those to which covered entities are subject under subsection (a)(5)(D)" for violations of the diversion prohibition. We not only urge HRSA to address sanctions for both categories of program participants—covered entities and manufacturers—in conjunction with one another, but we believe that the failure to repay manufacturers in accordance with section 340B(a)(5)(D) should be a factor in determining whether a violation of the diversion prohibition was "systematic and egregious" and thus a basis for removal of the covered entity from the 340B Program in accordance with section 340B(d)(2)(B)(v)(II). We suggest that HRSA apply the notice and hearing process described in Part H of the Proposed Notice in this context.

VI. Part D—Covered Entity Requirements

a. Prohibition on Duplicate Discounts

The Medicaid Drug Rebate Program requires participating manufacturers to pay state Medicaid programs a rebate on each unit of their covered outpatient drugs reimbursed by the state Medicaid program. The Affordable Care Act ("ACA") in 2010 expanded this Medicaid rebate liability from fee-for-service ("FFS") Medicaid utilization to include the utilization of Medicaid managed care organizations ("MCOs") as well. As described above, the 340B Program and the Medicaid Drug Rebate Program both relate to "covered outpatient drugs." This overlap means that it is possible that a manufacturer sells a unit of a drug to a covered entity at the discounted 340B ceiling price, only to subsequently receive a rebate invoice from a state Medicaid program for a Medicaid rebate on that same unit, resulting in a duplicate discount. The 340B statute seeks to avoid such duplicate discounts, both for Medicaid FFS and Medicaid MCO utilization, by prohibiting covered entities from billing Medicaid for a unit of a drug purchased at the 340B price.[192]

HRSA's longstanding mechanism for implementing the duplicate discount prohibition with respect to Medicaid FFS utilization has been the "Medicaid Exclusion File." HRSA requires covered entities to elect either to "carve out" (i.e., use only non-340B-priced product for Medicaid patients) or "carve in" (i.e., use 340B-priced product for Medicaid patients). In order to permissibly submit Medicaid claims, covered entities that "carve out" must ensure that none of their Medicaid patients receives 340B-priced

[191] Id.
[192] 42 U.S.C. § 256b(a)(5)(A).

products, while covered entities that "carve in" must ensure that they are listed on the Medicaid Exclusion File, which state Medicaid programs use to exclude the covered entity's Medicaid utilization from rebate invoices submitted to manufacturers. Corresponding obligations are imposed on state Medicaid programs pursuant to the Medicaid statute. Prior to the release of the Proposed Notice, HRSA had not addressed how the duplicate discount prohibition would be implemented with respect to Medicaid MCO utilization.[193]

Since 2010, the potential for duplicate discounts has increased markedly for a number of reasons, including a significant increase in the number of covered entities participating in the 340B Program, partly due to the ACA's addition of new categories of covered entities; HRSA's change in policy with respect to contract pharmacies, leading to a major increase in the use of such arrangements and a corresponding rise in prescriptions filled with 340B-priced drugs; and, perhaps most importantly, the ACA's expansion of participating manufacturers' Medicaid rebate liability to drug utilization by Medicaid MCOs, together with the overall growth in Medicaid MCO enrollment, which now cover over 42.3 million Americans, or roughly 74 percent of the Medicaid population.[194] We are extremely concerned that, particularly over the last five years, manufacturers have been subject to a significant volume of duplicate discounts, in violation of the requirements of the 340B statute. While we are supportive of recent steps taken by both HRSA and CMS to prevent and identify duplicate discounts, we do not believe that these steps are sufficient.

Compliance with the duplicate discount prohibition is a condition of covered entity eligibility for the 340B Program.[195] Moreover, as HRSA itself has said, with the important benefit of 340B participation comes "significant responsibility."[196] Accordingly, those covered entities that ignore the responsibility to comply with this obligation, including those that are waiting to take steps to prevent duplicate discounts until HRSA and CMS establish uniform mechanisms and systems making it easier for them to do so, should not be permitted to participate in the 340B Program. Rather, HRSA not only should act on its statutory mandate to articulate policies for covered entities to prevent, identify, and resolve duplicate discounts (in keeping with the recommendations outlined in the following sections of this letter), but also should require covered entities to demonstrate to the Agency that they have systems in place to ensure compliance with this statutory prohibition. Those entities that fail to do so should be barred from participation in the program.

The following sections outline recommendations for HRSA to improve the Agency's mechanisms—including the Medicaid Exclusion File—for covered entities, states, and manufacturers to prevent, identify, and resolve duplicate discounts, both generally, and in the context of specific types of utilization, such as by Medicaid MCOs, contract pharmacies,

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[193] See Program Release No. 2014-1, in which HRSA stated: "This policy release does not apply to the prevention of duplicate discounts that may occur under MCOs. HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care, and is working with CMS to develop policy in this regard."

[194] Kaiser Family Foundation, kff.org/Medicaid/state-indicator/total-medicaid-mc-enrollment/.

[195] See 42 U.S.C. § 256b(a)(4) ("In this section, the term 'covered entity' means an entity that meets the requirements described in paragraph (5)" of section 340B(a), which includes both the duplicate discount and diversion prohibitions described in subsections (a)(5)(A) and (a)(5)(B), respectively.).

[196] HRSA, Program Requirements, http://www.hrsa.gov/opa/programrequirements/ (last accessed Sept. 22, 2015).

and ADAPs. We note that many of these recommendations mirror those previously made by BIO and other stakeholders, including the National Association of Medicaid Directors (NAMD) in its recent Working Paper entitled "Medicaid and the 340B Program: Alignment and Modernization Opportunities."[197]

i. Duplicate Discounts and Medicaid Managed Care Utilization

BIO appreciates that HRSA has finally taken action to address the duplicate discount prohibition in the context of Medicaid MCO utilization. As noted above, the ACA in 2010 expanded the Medicaid rebate liability from FFS Medicaid utilization to include Medicaid MCO utilization as well. The duplicate discount prohibition in the 340B statute was correspondingly extended at the same time and addresses Medicaid FFS as well as Medicaid MCO utilization. Yet HRSA, until the release of this Proposed Notice, had not taken any steps to implement the duplicate discount prohibition in the Medicaid MCO context.

Instead, the Agency's only pertinent action prior to the issuance of this Proposed Notice was to issue a release in December of 2014 noting that the Medicaid Exclusion File does *not* apply to Medicaid MCO utilization, but relates only to Medicaid FFS utilization. As a result, certain covered entities mistakenly took the position that the *statutory duplicate discount prohibition* also did not apply to Medicaid MCO utilization—an error that we hope that this Proposed Notice will correct. We note, however, that any issuance of final guidance by HRSA, after the passage of many years since the ACA became effective, would in no way undermine the fact that the duplicate discount prohibition has applied to Medicaid MCO utilization since the date on which the ACA's expansion of manufacturers' rebate liability to Medicaid MCO utilization became effective.[198] Accordingly, we urge HRSA to expressly clarify that the duplicate discount prohibition has applied to Medicaid MCO utilization since January 1, 2010.

We also are gravely concerned that the Agency's proposed approach to implementing the duplicate discount prohibition in the Medicaid MCO context would be unworkable and impractical, and would actually *increase* confusion and risk of violations of the duplicate discount prohibition. Substantial evidence supports that even the existing mechanism to implement the duplicate discount prohibition in the Medicaid FFS context—the Medicaid Exclusion File—is not operating adequately. Indeed, in 2010, OIG identified inaccuracies in the Medicaid Exclusion File related to covered entities' enrollment statuses and addresses, as well as billing and shipping information.[199] The GAO's 2011 report similarly found that many state Medicaid programs were not using the Medicaid Exclusion File to identify and eliminate Medicaid FFS utilization by covered entities from manufacturer

[197] NAMD, Working Paper Series, Medicaid and the 340B Program: Alignment and Modernization Opportunities (May 2015).
[198] The Medicaid statute, as amended by the ACA, clearly extends the duplicate discount prohibition to managed care rebates by providing that covered outpatient drugs are not subject to Medicaid drug rebates to the extent that such drugs are dispensed by Medicaid managed care organizations "and subject to discounts under section 340B of the Public Health Service Act." SSA § 1927(j)(1). The ACA also clearly indicates that the same effective date—January 1, 2010—applies to both the extension of Medicaid drug rebates to Medicaid managed care enrollees, as well as the extension of the duplicate discount prohibition to this utilization. ACA §§ 2501(c); (f)(2). Meanwhile the duplicate discount prohibition articulated in the 340B statute is not specific to fee-for-service versus managed care utilization.
[199] OIG, Deficiencies in the 340B Drug Discount Program's Database, OEI-05-02-00071 (May 13, 2010).

rebate invoices, often due to the File's inaccuracy. Although HRSA has since taken steps to improve the quality of the Medicaid Exclusion File, including replacing its PDF/Excel file with an Internet-based, regularly updated Medicaid provider search,[200] HRSA's audit results posted on the Agency's website suggest a covered entity error rate with respect to the duplicate discount prohibition in the range of 24 percent.

Despite these problems that the Medicaid Exclusion File is experiencing in its current form, HRSA in the Proposed Notice appears to propose to expand use of the File to address Medicaid MCO utilization as well. The Proposed Notice essentially re-articulates HRSA's current policy with respect to the Medicaid Exclusion File in the FFS context, where each covered entity must either "carve in" or "carve out" with respect to *all* of its Medicaid FFS utilization. With respect to Medicaid MCO utilization, however, HRSA proposes to permit covered entities to make a different "carve-in"/"carve-out" determination for each of the covered entity's sites, as well as for different Medicaid MCOs. Further, these elections could differ from the covered entity's "carve-in/out" election for Medicaid FFS utilization. The Proposed Notice states that the information regarding a covered entity's Medicaid MCO elections "*may* be made available publicly through an Exclusion File or other mechanism."[201] Although the proposed guidance is not clear, it appears as though HRSA is considering expanding the use of the Medicaid Exclusion File to reflect this information, although the Proposed Guidance may imply that HRSA is contemplating the use of a separate exclusion file. HRSA's proposal seeking to permit covered entities to make many different "carve-in/out" elections in the Medicaid MCO context would add significant complexity and make covered entity compliance more difficult, as evidenced by the fact that even the more simple binary election currently required for FFS utilization is generating the high error rates referenced above.

BIO understands that implementing the duplicate discount prohibition in the Medicaid MCO context is challenging, and that the presence of the Medicaid MCO as an additional link in the chain of data transmission between the covered entity and the state Medicaid programs complicates these efforts substantially. For a covered entity that "carves in" (i.e., uses 340B-priced drugs for Medicaid patients), it would be necessary to ensure that all Medicaid MCOs are either: (1) excluding such covered entity's utilization from the rebate data the MCOs submit to the state Medicaid program (ideally using the Medicaid Exclusion File); or (2) passing along such covered entity's NPI number(s) or another unique identifier(s) together with the rebate data sent to state Medicaid programs so that the state Medicaid programs can exclude the covered entity's Medicaid utilization from the rebate invoices sent to manufacturers. On the other hand, for each covered entity that "carves out" (i.e., does not use 340B-priced drugs for Medicaid patients) it would be necessary that the covered entity can identify who is a Medicaid patient so that the covered entity can ensure that it is not dispensing 340B-priced drugs to that patient, which OIG recently highlighted can be difficult—if not impossible—with respect to Medicaid MCO enrollees due to data and other operational limitations.[202]

[200] http://opanet.hrsa.gov/opa/MedicaidExclusionFiles.aspx.
[201] 80 Fed. Reg. at 52,320.
[202] 2014 OIG Contract Pharmacy Report.

In light of the added level of complexity introduced by Medicaid MCO utilization alone, it is clear that HRSA's proposal to permit covered entities to make various, contradictory "carve-in/out" elections with respect to Medicaid MCO utilization on an MCO-by-MCO and site-by-site basis would not be feasible, could not be monitored, and consequently would make it even more difficult to prevent and identify violations of the duplicate discount prohibition. Although the Proposed Notice is not a proposed regulation, it is instructive to bear in mind that Executive Orders 12,866 and 13,563 include regulatory simplification mandates, of which HRSA's multiple election proposal, if it were a proposed regulation, would clearly run afoul.

Indeed, given that covered entities often lack information regarding which MCOs participate in a given state's Medicaid program, as OIG identified in its recent report, covered entities may not be able to make these elections in the first instance, let alone ensure compliance with the duplicate discount prohibition with respect to Medicaid MCO utilization. The Proposed Notice also proposes to instruct that "a covered entity should have mechanisms in place to identify Medicaid MCO patients."[203] This limited proposed provision, which would provide no meaningful guidance to covered entities, would not only be woefully inadequate to address these concerns, but also would wrongly cast compliance with the duplicate discount prohibition as something that the covered entity "should" undertake, when in fact the 340B statute expressly mandates that covered entities comply with the duplicate discount prohibition. As an alternative to HRSA's flawed approach, we strongly urge HRSA to take the following two steps to address the prohibition against duplicate discounts in the Medicaid MCO context.

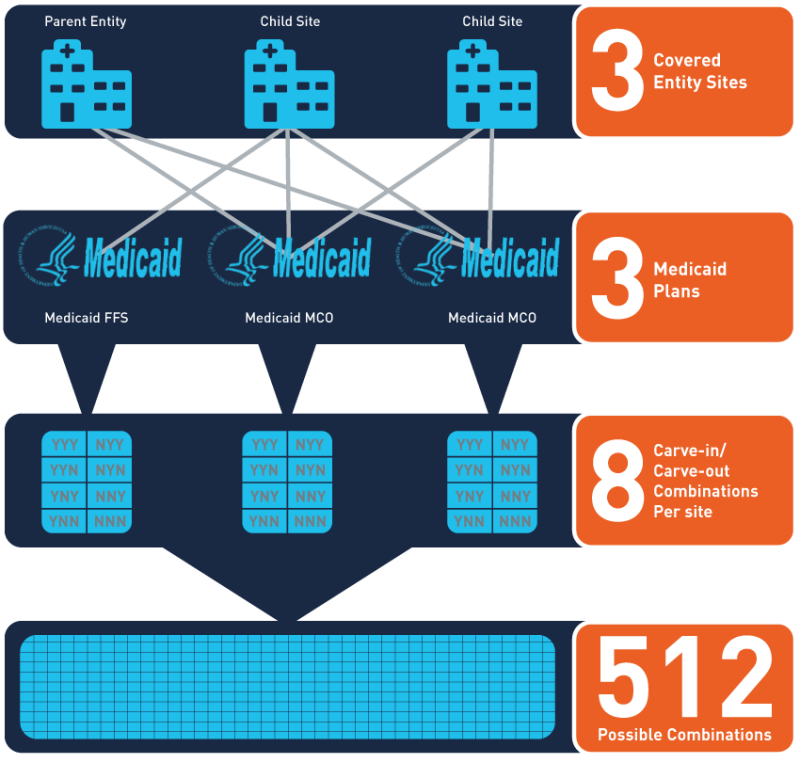
First, we urge HRSA to require covered entities to make one "carve-in"/"carve-out" determination that would apply uniformly across all Medicaid patients, including FFS and MCO patients. As NAMD noted in its Working Paper on duplicate discounts, it is easier for the Medicaid program to identify claims relating to 340B-priced drugs if the covered entity makes the same "carve-in"/"carve-out" decision for FFS utilization as it does for Medicaid MCO utilization. A decision by a covered entity to do otherwise (e.g., "carve out" FFS, but "carve in" MCO) presents challenges for the covered entity, as well as the state Medicaid agency. While we appreciate HRSA's interest in giving covered entities flexibility with respect to their purchasing decisions,[204] HRSA provides no rationale as to why a covered entity would need—or even want—to make unique purchasing decisions for its Medicaid FFS as compared to Medicaid MCO patients. Moreover, allowing covered entities to make elections that are unique to Medicaid FFS or MCO utilization would introduce a level of complexity to the Medicaid Exclusion File (regardless of whether HRSA expands the existing file or creates a new file) that may make it *more* likely that manufacturers will be improperly forced to pay both 340B discounts and Medicaid rebates—exactly the "double dipping" the statutory duplicate discount prohibition was intended to prevent.

This complexity would then only be compounded by the near-limitless permutations of "carve-in"/"carve-out" elections inherent in allowing covered entities to make such

[203] 80 Fed. Reg. at 52,317.
[204] In the Proposed Notice, HRSA seeks comment regarding alternative mechanisms to supplement the 340B Medicaid exclusion file to allow covered entities to take a more nuanced approach to purchasing. 80 Fed. Reg. at 52,309.

decisions on a site- or Medicaid MCO-specific basis. To illustrate, if a covered entity has three total sites (i.e., a parent entity and two child sites) and each entity is able to elect "carve-in/out" status differently for the Medicaid FFS population and the managed Medicaid population for two different managed Medicaid plans (i.e., three different choices), there would be *512 different combinations* for how that covered entity and its two child sites could establish their treatment of Medicaid patients for purposes of the Medicaid Exclusion File (see Figure 1).[205] Moreover, it is not clear that these disparate elections could even be accurately recorded on the File to the extent that HRSA, CMS, and the states do not work together to ensure that each and every covered entity and child site has a unique NPI.

Figure 1. Possible "Carve-in/Out" Combinations under HRSA's Medicaid Exclusion File Proposal: An Illustration



We also note that some states have elected to exclude some or all prescription drugs from the benefits offered by Medicaid MCOs, instead covering such services under Medicaid FFS.[206] In these states, to the extent that covered entities are permitted to "carve

[205] In mathematics, this is called permutations of a multiset. The way to calculate this is as follows: (1) The parent entity has 8 total combinations for how they could choose their Medicaid Exclusion file status for the 3 plan options: YYY, YNY, YNN, YYN, NYY, NNY, NNN, NYN; (2) Each of the child sites has the same number of combinations possible to them; and (3) then they all have to be combined which means you calculate 8*8*8 = 512.

[206] According to the National Conference of State Legislators' website: "At least 21 states 'carve out' a portion of their pharmacy program to retain state control of pharmacy benefits for specific beneficiary groups and classes

in" for FFS and "carve out" for managed care (and vice versa), there also may be the need to identify, on an NDC-by-NDC basis, whether a given product is covered by FFS or managed Medicaid.

All of this complexity may not only significantly complicate use of the Medicaid Exclusion File, but also may disincentivize state Medicaid agency use of the Medicaid Exclusion File in the first instance. A 2011 report issued by the OIG indicates that 30 states had, at that time, developed alternatives to the Medicaid Exclusion File, citing reasons including the inaccuracies of the File.[207] We can imagine that it would require substantial effort on the part of state Medicaid agencies in order to implement HRSA's proposal (e.g., adding additional fields necessary to track the disparate "carve-in/out" determinations across parents, child-sites, FFS, and each MCO), which could drive additional states to discontinue their use of the Medicaid Exclusion File, thereby considerably undermining the utility thereof. Yet, in spite of these issues, HRSA fails to enunciate the basis for this proposed approach and fails to provide a reasonable basis for its proposed policy.

In addition to ensuring that covered entities make only one "carve-in"/"carve out" election, we also ask that HRSA clarify that this determination *will* be clearly identified on the Medicaid Exclusion File—as opposed to the vague statements in the Proposed Notice that such information "may" appear on the Exclusion File *or some other mechanism*.[208] This information is absolutely critical to both state Medicaid programs and manufacturers, which look to the Medicaid Exclusion File as the source of information regarding covered entity "carve-in"/"carve-out" determinations. Providing this information through another format, or potentially not at all, would only further complicate efforts to prevent and identify duplicate discounts by these entities.

Second, HRSA should provide additional detail with respect to its vague proposed directives that covered entities take action to prevent duplicate discounts with respect to Medicaid MCO utilization. For instance, HRSA proposes to direct covered entities to have mechanisms in place to be able to identify Medicaid MCO patients.[209] We agree that this is absolutely critical, particularly for those covered entities that "carve out." Otherwise, these entities will unquestionably be providing 340B-priced products to their Medicaid patients, and, because entities that "carve out" are not listed on the Medicaid Exclusion File, this utilization most likely would not be excluded from Medicaid rebate invoices to manufacturers and thus would result in duplicate discounts. However, there are systemic limitations with respect to covered entities' ability to identify Medicaid MCO patients and Medicaid MCO utilization. For instance, OIG recently found that Bank Identification Number/Processor Control Numbers ("BIN/PCNs")—generally used to identify the payor

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of drugs. Nine states with risk-based Medicaid managed care report carving out all drugs from their managed care contracts; these states are: Delaware, Illinois, Iowa, Massachusetts, Nebraska, New York, North Carolina, Utah and West Virginia. 12 states report carving out pharmacy benefits for specific populations, specific drugs, and/or specific drug classes, including Arizona, California, Colorado, Hawaii, Kansas, Kentucky, Maryland, Michigan, Missouri, New Jersey, Oregon and Washington. Almost one-fifth of respondents indicated they carve out for anti-psychotics or mental health drugs." See http://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx.

[207] OIG, State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs, OEI-05-09-00321 (June 2011) (hereinafter "2011 OIG Report").

[208] See 80 Fed. Reg. at 52,309; 52,320.

[209] Id. at 52,320. See also id. at 52,309.

responsible for a given prescription, a determination often made post-adjudication—may be used across all of a payor's plans, including both Medicaid plans and commercial plans. This makes BINs/PCNs an unreliable basis for distinguishing a Medicaid MCO patient from a commercially insured patient. This limitation is compounded by the fact that state Medicaid programs often fail to provide comprehensive information regarding Medicaid MCO BINs/PCNs, which is particularly problematic given that Medicaid MCOs vary from state to state and are subject to changes over time.

We therefore urge HRSA to work with CMS and states to ensure that Medicaid MCOs have Medicaid-specific BIN/PCN combinations, so that each BIN/PCN combination denotes either Medicaid or commercial utilization, but not both types of utilization. We also urge HRSA to ensure that state Medicaid programs provide access to a list of all Medicaid MCO BINs/PCNs (e.g., on a state website) to the state's Medicaid providers (including all Medicaid-participating 340B covered entities), manufacturers, and any contractors employed by the state in order to process Medicaid rebate invoices. This list should be regularly updated in a specified interval, and any such updates should be provided to covered entities and others in a timely manner. To the extent that a single Medicaid MCO maintains multiple BIN/PCNs that are unique to a particular benefit category (e.g., pharmacy versus medical benefit), all of the MCOs BIN/PCNs should appear on this list, together with information that enables stakeholders to easily identify which BIN/PCNs are specific to pharmacy-dispensed versus physician-administered drugs.

HRSA also notes that covered entities and state Medicaid programs should continue to work together to develop various methods to prevent duplicate discounts (e.g., modifiers and codes to identify claims related to 340B-purchased drugs). We generally agree with this proposed instruction, but continue to be extremely concerned by the lack of specific federal guidance on this topic. Based on our experience engaging with a number of state Medicaid programs, as well as CMS, on the topic of duplicate discounts, we have identified some detailed guidance that HRSA, in coordination with CMS, should issue to both covered entities and state Medicaid programs to implement this proposed requirement. First, we urge HRSA to work with CMS to provide guidance to covered entities and, in particular, state Medicaid programs, with respect to the Medicaid Exclusion File and its operation in both the Medicaid FFS and MCO contexts. The Medicaid Exclusion File should be viewed as the primary mechanism for preventing duplicate discounts, particularly once HRSA implements certain improvements to the file, including those articulated in the following section of this letter. Further, to ensure that state Medicaid programs have the information that they need to exclude 340B utilization from Medicaid drug rebate invoices in reliance on the Medicaid Exclusion File—and manufacturers have the information necessary to verify that this has occurred—we urge HRSA to work with CMS to implement the following recommendations with respect to Medicaid drug rebate program data. We cannot stress enough the need for consistent reporting requirements and formatting across state Medicaid programs, as well as Medicaid MCOs, not only to promote programmatic efficiencies across all participants, but to verify that the necessary information is being reported in a timely and accurate way, such that it can be used to ensure the accuracy of Medicaid rebate invoices provided to manufacturers.

1. HRSA and CMS Should Identify, and Require Reporting of, Standard Summary-Level and Claims-Level Data Points, Including Those Necessary to Prevent Duplicate Discounts.

In order to ensure that state Medicaid programs are accurately and appropriately seeking rebates on both Medicaid FFS and MCO utilization—while excluding products purchased at the 340B price—it is necessary that state Medicaid programs report certain summary-level utilization data points to manufacturers, and that these summary-level data are verifiable by both states and manufacturers on the basis of claims-level detail.

While this is largely the purview of CMS, we urge HRSA to work with CMS to identify the summary-level data points that must be reported for this purpose, ideally those data points identified by CMS in proposed 42 C.F.R. § 447.511,[210] which include: (1) The State code; (2) National Drug Code; (3) Period covered; (4) Product FDA list name; (5) Unit rebate amount; (6) Units reimbursed; (7) Rebate amount claimed; (8) Number of prescriptions; (9) Medicaid amount reimbursed; (10) Non-Medicaid amount reimbursed; and (11) Total amount reimbursed. In addition to these data points, we note that an indicator as to whether Medicare was the primary payor will help manufacturers and others identify and address duplicate discounts with respect to the dual-eligible population (i.e., individuals eligible for both Medicare and Medicaid). To enable states to similarly report accurate summary-level rebate data in the Medicaid managed care context, HRSA also should encourage CMS to similarly apply these reporting requirements to Medicaid managed care plans.

Further, to enable both states and manufacturers to verify these summary-level data, we urge HRSA to work with CMS to identify certain claims-level data that must be reported by Medicaid providers to state Medicaid programs (in the FFS context), and to Medicaid managed care plans (in the MCO context), and the encounter data that must, in turn, be reported by such MCOs to the state Medicaid program. We continue to recommend that both CMS and HRSA adopt the enclosed data points shared with the Agency in June 2014 by the 340B Pharmaceutical Company Operational Work Group, which are based on the National Council for Prescription Drug ("NCPDP") claims elements, for this purpose. Particularly given that covered entities often have difficulty identifying Medicaid patients at the point of sale, as noted previously, BIO believes that HRSA should consider use of these data elements—in particular those related to the 340B status of a given product—by covered entities, regardless of whether the claim has been identified as a Medicaid claim. The universal identification of 340B claims by covered entities also may assist in verifying covered entity compliance with the statutory prohibition on diversion. Perhaps most critically, these claims-level data and encounter data also should be made available to manufacturers to enable their efforts to verify the contents of the summary-level data that they receive from the state Medicaid programs.

[210] See 77 Fed. Reg. 5318, 5345 (Feb. 2, 2012).

2. HRSA and CMS Should Cooperate to Identify, and Require the Use of, Consistent Formatting for the Provision of Summary- and Claims-Level Data.

In order to produce operational efficiencies for states, Medicaid managed care plan sponsors, manufacturers, third-party claims vendors, as well as CMS and HRSA, HRSA also should work with CMS to establish a standardized format for the reporting of rebate utilization data that can be easily and directly utilized by all states and managed care organizations, as well as by manufacturers (e.g., an electronic format rather than a PDF or image file).

With respect to pharmacy-dispensed drugs, we suggest that HRSA consider the NCPDP format as the claims-reporting format to standardize, and therefore streamline, this process.[211] BIO also believes that it is necessary to provide additional guidance to states and managed care plans regarding a standardized format to submit physician-administered drug rebate data. While there is no current industry standard in this area of which BIO is aware, there are coding and claims data best practices that could be applied to achieve this purpose. We therefore recommend further exploring approaches to standardize formatting for physician-administered drug data to set a national standard, and to issue necessary and appropriate guidance to states and managed care plans with respect to all drug types. BIO would welcome the opportunity to provide ongoing feedback on the Agencies' efforts in this area.

ii. Duplicate Discounts Generally

Given the high rates of duplicate discounts identified in HRSA audits and otherwise, in addition to our recommendations specific to Medicaid MCO utilization, we also urge HRSA to take the following six steps to improve the Agency's policies for preventing and identifying duplicate discounts, which largely involve improvements to the Medicaid Exclusion File, and which should apply across both Medicaid FFS and Medicaid MCO utilization.

1. HRSA should address complexities presented by the "replenishment model": Effective use of the Medicaid Exclusion File is complicated by the fact that, under this model, the 340B status of a prescription is determined retroactively, rather than at the point-of-sale. We therefore strongly urge HRSA to work with CMS ensure that there are mechanisms for state Medicaid programs and Medicaid MCOs to identify this utilization as 340B, or to prohibit retroactive identification of 340B claims in this manner.

2. HRSA should implement HRSA-level editing of NPI numbers: As NAMD notes in its Working Paper, there are significant ramifications to Medicaid rebate invoices if a covered entity fails to list all of its provider numbers or makes a typographical error

[211] NCPDP has been widely recognized as the industry standard in this area, and the NCPDP's format is routinely used for processing most pharmacy dispensing and claims adjudication in the United States. Given the increasing adoption of the NCPDP format across payors, including some state Medicaid programs, there seems to be no reason for CMS not to adopt this nationally, and readily available, standardized information format for purposes of the submission of Medicaid managed care plan's pharmacy-dispensed rebate data. For more information about NCPDP, please see: http://www.ncpdp.org/about-us/faq.

when entering its NPI on the Medicaid Exclusion File. There is no HRSA review of the information submitted, and the accuracy of the Medicaid Exclusion File therefore depends solely on accurate and up-to-date reporting by covered entities,[212] and technical errors can persist for multiple quarters. BIO therefore urges HRSA to implement editing against the NPI number for valid formatting to reduce errors, as well as to consider a double exam entry requirement on NPIs to try to reduce keying errors.

3. HRSA and CMS should maintain congruency of NPI and 340B ID: BIO supports NAMD's recommendation that CMS and HRSA maintain congruency between a provider's NPI/340B ID on the Medicaid Exclusion File and the NPIs shown in that provider's Covered Entity File.

4. HRSA should publish a quarterly change file: As NAMD notes in its Working Paper, a full Medicaid Exclusion File is published by HRSA on a quarterly basis, but the Agency does not make a change file available. As a result, state Medicaid programs are required to perform a file comparison to determine additions, deletions, and/or updates to the file. BIO therefore supports NAMD's recommendation that HRSA make a change file available to states to eliminate this work. In addition, because this change file would be insufficient to chronicle a covered entity's "carve-in"/"carve-out" status over time, we further urge HRSA to develop a mechanism to make this full history available to states, MCOs, and manufacturers, which should include, at a minimum, providing this historical information in the public 340B database for each covered entity.

5. HRSA should develop a solution for providers serving Medicaid patients across state lines: As NAMD notes in its Working Paper, out-of-state covered entities present another challenge related to the Medicaid Exclusion File. A covered entity's NPIs are listed on the Exclusion File under the state in which the covered entity is doing business. However, some providers may serve patients from other, nearby states, and thus submit bills to another state's Medicaid program as a border provider or other entity. We agree with NAMD that HRSA should work with both CMS and states to develop a policy for out-of-state providers, including notification of the providers' status on the Medicaid Exclusion File.

6. HRSA should establish mechanisms to improve communications between covered entities and state Medicaid agencies: BIO agrees with NAMD that both CMS and HRSA should collaborate with states on ways to better facilitate covered entity communication with state Medicaid programs with respect to the 340B Program and compliance with applicable program requirements. We also urge HRSA to work with CMS to establish a formal mechanism whereby HRSA and/or manufacturers would work with covered entities and, as appropriate, states, to resolve any potential duplicate discounts and ensure the repayment of the affected manufacturer(s).

[212] See HRSA, Clarification of the Medicaid Exclusion File (Feb. 7, 2013).

iii. 340B Medicaid Exclusion File Changes

BIO strongly supports HRSA's proposed clarification that covered entities may not make retroactive changes in their Medicaid Exclusion File status. Specifically, HRSA proposes to make clear in the preamble to the Proposed Notice that, while covered entities can change their "carve-in"/"carve-out" status at any time, this status only becomes effective on a quarterly basis, and a covered entity can only implement this status once it becomes effective.[213] This would address NAMD's recommendation that HRSA clarify the effective date of a provider's status on the Medicaid Exclusion File, and would avoid the complex issues that could result from allowing covered entities to make retroactive changes to their Medicaid Exclusion File status. However, to avoid any confusion, we urge HRSA to revise the guidance text in any final guidance such that it aligns with the clearer, more detailed language in the preamble.

iv. Duplicate Discounts and Contract Pharmacy Utilization

We urge HRSA to provide additional detail with respect to its proposals to prevent duplicate discounts in the contract pharmacy context, particularly given the unique duplicate discount risks posed by contract pharmacy arrangements.[214] We note that the Medicaid Exclusion File is an inadequate mechanism to identify the "carve-in/out" status of contract pharmacies because contract pharmacies generally bill for both 340B- and non-340B utilization using the same NPI number. As a result, 340B utilization cannot be excluded from Medicaid rebate claims on the basis of this NPI. We therefore support HRSA's restating, in the Proposed Notice, of its current policy under which contract pharmacies generally must "carve-out" (i.e., use non-340B-priced drugs for Medicaid patients) unless the covered entity has an agreement with the state Medicaid agency to prevent duplicate discounts.[215] We also urge HRSA to further expand the required coordination between covered entities, states, and Medicaid MCOs to include any third-party contractors the state retains to administer their drug rebates. We are aware that there are inconsistencies in how duplicate discounts are handled (e.g., the state believes it is excluding 340B utilization using a claims modifier, while the contractor is using the Medicaid Exclusion Files), which could be resolved by such coordination.

We also very strongly support HRSA's proposal that such agreements would require the Agency's approval. However, HRSA should articulate further details with respect to how the Agency would ensure that covered entities that elect the default option (that their contract pharmacies "carve-out") are effectively ensuring that 340B-priced products are not dispensed to Medicaid patients by their contract pharmacies—including for both Medicaid FFS and MCO enrollees. Although the Proposed Notice merely reiterates the current HRSA policy, it is not clear that covered entities are in fact complying with that policy today. To illustrate, 22 of the 30 covered entity administrators recently surveyed by OIG for purposes of OIG's recent contract pharmacy report indicated that, to prevent duplicate discounts, their contract pharmacies do not dispense 340B drugs to Medicaid

[213] 80 Fed. Reg. at 52,309.
[214] 2014 OIG Contract Pharmacy Report ("We also found that contract pharmacy arrangements create complications in preventing duplicate discounts.").
[215] 75 Fed. Reg. 10,272, 10,278 (March 5, 2010).

beneficiaries; however, two of the 22 indicated that they did not actually know whether their contract pharmacies dispense 340B drugs to Medicaid MCO beneficiaries.[216] Accordingly, we strongly urge the Agency to establish a robust review and approval process for this purpose, as well as to issue a model agreement that contains the minimum standards that HRSA expects to see with respect to contract pharmacy arrangements that adopt this default option.

HRSA also proposes, to the extent that a covered entity's contract pharmacy wishes to "carve-in" and HRSA has approved the covered entity's agreement with the state Medicaid agency to prevent duplicate discounts, that the contract pharmacy would be listed in the public 340B database as a contract pharmacy dispensing 340B drugs to Medicaid FFS and/or MCO patients. This proposed clarification also represents HRSA's current policy, but evidence suggests that it also is not being uniformly adhered to by covered entities. For example, of those eight covered entities surveyed by OIG whose contract pharmacies reported dispensing 340B drugs to Medicaid patients, six did not report a method to prevent duplicate discounts, only five had notified their state Medicaid program of this practice, and none had notified HRSA.[217] We therefore strongly urge HRSA to ensure that there are mechanisms in place to verify that covered entities are, indeed, complying with this proposed requirement and to penalize those that are out of compliance.

We also believe that HRSA's proposal under which contract pharmacies could "carve-in" is in need of further clarification in the following four areas. First, we ask HRSA to clarify that information pertaining to a contract pharmacy's "carve-in" status should be reflected on the Medicaid Exclusion File instead of, or in addition to, HRSA's proposal to list it in the "public 340B database."[218] Second, given that contract pharmacies generally serve both Medicaid and non-Medicaid patients, and it is the covered entity (not the contract pharmacy) that actually purchases and retains title to 340B-priced products, we urge HRSA to list in the 340B database the NPI and "bill-to" address of the covered entity, together with the "ship-to" address of the contract pharmacy, for this purpose. As articulated throughout this letter, covered entities should be required to direct their contract pharmacies to bill under the covered entity's NPI. Third, we ask HRSA to require that such "carve-in"/"carve-out" determinations be made uniformly across Medicaid FFS and Medicaid MCO utilization, for the reasons articulated above. Fourth, we urge HRSA to ensure that the applicable agreement with respect to the prevention of duplicate discounts be made publicly available, ideally by providing a link to a copy of the agreement directly on the Medicaid Exclusion File website. At a minimum, this agreement should be made available to manufacturers, upon request, as manufacturers will need access to this information in order to understand and verify the rebate data being provided, as well as the steps that were taken to ensure that 340B utilization was excluded by the relevant parties.

Finally, we note that HRSA's current contract pharmacy guidance makes clear that it is the covered entity that is ultimately responsible for compliance with 340B Program

[216] 2014 OIG Contract Pharmacy Report.
[217] Id.
[218] See 80 Fed. Reg. at 52,320 ("Unless otherwise noted *on the public 340B database*, contract pharmacies will not dispense 340B drugs for Medicaid FFS or MCO patients.") (emphasis added).

requirements, including the duplicate discount prohibition, but the Agency largely relies on covered entity self-policing with respect to the oversight of contract pharmacy arrangements. As described in greater detail in the section of this letter regarding HRSA's contract pharmacy proposals below, HRSA should strengthen accountability mechanisms for ensuring that covered entities monitor their contract pharmacies and 340B third-party administrators to ensure that these entities are properly identifying claims so that duplicate discounts can be avoided.

v. Duplicate Discounts and ADAPs

The prevention of duplicate discounts is particularly challenging with respect to utilization by ADAPs—a type of 340B covered entity—in light of two unique 340B Program policies. First, under HRSA guidance, ADAPs are the only type of 340B covered entity that may access the 340B discount via a post-purchase rebate (as opposed to a point-of-sale discount or the replenishment model).[219] Yet there currently is *no* federal guidance that addresses duplicate discounts where such ADAP 340B post-sale rebates are concerned. Second, ADAPs may use their federal funding to pay cost-sharing and premiums associated with the coverage for certain drugs on behalf of low-income HIV and AIDS patients—including those enrolled in Medicaid.[220] There thus exists a substantial risk that, with respect to a covered outpatient drug for a Medicaid beneficiary for which an ADAP has paid the associated cost-sharing (including even nominal cost-sharing), the state will claim a rebate from the manufacturer and the ADAP will claim a 340B rebate from the manufacturer—precisely the double dipping that the 340B statute expressly prohibits.

To address this risk, we urge HRSA to work with CMS to specify that a Medicaid MCO or FFS Medicaid program is not entitled to a Medicaid rebate if a 340B rebate was claimed by an ADAP. The Agencies also should direct each Medicaid MCO, through their contract with the state, to report to the state each instance in which an ADAP has paid all or part of any cost-sharing associated with a covered outpatient drug for a Medicaid beneficiary, and to further prohibit state Medicaid programs from claiming a Medicaid drug rebate from manufacturers in all such instances. To ensure that all such reporting can more readily be effectuated, HRSA should impose conforming requirements on ADAPs participating as covered entities in the 340B Program.

vi. Repayment

HRSA proposes that, "if the information provided to HHS does not reflect the covered entity's actual billing practices, the covered entity may be found in violation of the duplicate discount prohibition and would be required to repay rebate amounts to manufacturers if duplicate discounts have occurred due to the inaccurate information."[221] BIO supports this proposed clarification, which we believe is consistent with section 340B(a)(5)(D), as HRSA notes. However, we urge HRSA to correct the preamble statement suggesting that covered entities only "may" be required to repay manufacturers in

[219] 63 Fed. Reg. 35,239, 35,242 (June 29, 1998).
[220] See Clarifications Regarding Use of Ryan White HIV/AIDS Program Funds for Premium and Cost-Sharing in Medicaid, Policy Clarification Notice No. 13-06.
[221] 80 Fed. Reg. at 52,309.

instances in which a duplicate discount has occurred; such repayments are a statutory obligation, and HRSA should emphasize, rather than obscure, this fact in its guidance.

HRSA also states that, "[i]n the event that a covered entity is unable to use a 340B drug for a Medicaid FFS or MCO patient in a particular instance, it is expected to document the reason and have a mechanism in place to notify the State Medicaid agency or MCO."[222] We ask HRSA to provide greater guidance with respect to instances in which covered entities dispense/administer drugs to their Medicaid patients that do not conform to the entities' "carve-in"/"carve-out" status. Specifically, HRSA should emphasize that the applicability of this policy is limited to instances in which a covered entity is truly *unable* to use a 340B drug for a Medicaid patient (and vice versa), to prevent covered entities from making determinations whether to use 340B products for Medicaid patients on a case-by-case basis, severely undermining the utility of the Medicaid Exclusion File. In such instances, we further urge HRSA to require such covered entities to: (1) notify and provide appropriate documentation—including the reason the covered entity was required to deviate from its Exclusion File status—to all impacted state Medicaid agencies, manufacturers, as well as HRSA; and (2) ensure that claims have been billed properly according to state Medicaid agency policy. We also urge HRSA to provide the applicable time periods for covered entities to take these steps, as well as the penalties for non-compliance.

BIO firmly believes that HRSA should enforce the compliance with the duplicate discount prohibition and should sanction covered entities for engaging in double dipping as well as for failing to work with the affected manufacturer(s) to resolve the issue in a timely manner (e.g., prospective ineligibility for the 340B Program). Currently, the lack of any such enforcement incentivizes covered entities to delay, or even deny, repayment requested by manufacturers, which, in turn, discourages manufacturers from attempting to address potential duplicate discounts with them. We also urge HRSA to establish a time frame for manufacturers to refund covered entities, particularly given that HRSA is proposing to establish a time frame for manufacturers to refund covered entities, discussed in section (VIII)(h), below. We note that any such mechanisms established by HRSA in accordance with this provision would in no way minimize the authority of manufacturers to audit covered entities for violations of the statutory prohibition against duplicate discounts under section 340B(a)(5)(C).

b. Maintenance of Auditable Records

As HRSA notes in the Proposed Notice, the 340B statute provides both manufacturers and HRSA with the option to audit the records of covered entities—including records retained by their contract pharmacies—for compliance with 340B Program requirements. BIO supports HRSA's proposed clarification that a covered entity's failure to retain auditable records necessary for this purpose constitutes grounds for losing 340B eligibility. We further support that HRSA would provide those covered entities that have failed to retain such records with the opportunity for a notice and hearing prior to removal (a process we discuss further in section (X), below), and that the Agency would use its

[222] 80 Fed. Reg. at 52,320.

discretion not to remove those entities whose failure to retain records is non-systematic. As in other areas in the Proposed Notice in which HRSA has extended the option of a notice and hearing process to covered entities, we support the Agency's efforts to distinguish between truly inadvertent mistakes and systematic violations of program requirements. We recommend that HRSA further clarify that failure to retain auditable records for the requisite timeframe should constitute "reasonable cause" for a manufacturer to conduct an audit of a covered entity.

BIO also supports HRSA's proposed clarification that the program's record retention policies apply to the records not only of covered entities, but also of their child sites and contract pharmacies, as well as to covered entities that no longer participate in the program. BIO also supports HRSA's proposal to extend the record retention period for covered entities to five years. The current three-year record retention policy for covered entities provides HRSA and manufacturers with only a short look-back period for an audit, while it can easily take months of work on retrospective claims data to identify entities with questionable purchases. Significantly longer periods of record retention are required for other health care programs. For example, Medicare Advantage organizations must maintain all documents related to contracts for a period of ten years. Longer record retention timeframes would bring the 340B Program in line with other federal programs. However, we note that requiring covered entities to retain records for longer than three years may require HRSA to amend the Pharmaceutical Pricing Agreement ("PPA"), which currently references a three-year timeframe for this purpose.[223] We further urge HRSA to clarify that a covered entity's failure to maintain proper records would result in a finding of duplicate discounts and would trigger the requirement to refund manufacturers all applicable discounts. Finally, we urge HRSA to clarify what action initiates the five-year clock (e.g., date of transaction, date of refund request, date of restatement), as well as whether, and under what circumstances, the five-year clock may be reset.

VII. Part E—Contract Pharmacy Arrangements

a. Contract Pharmacy Program

Since the inception of the 340B Program in 1992, the 340B statute has never authorized—or even made reference to the concept of—contract pharmacies. Nevertheless, in 1996, HRSA issued guidance allowing covered entities without an on-site pharmacy to contract with a *single* off-site pharmacy.[224] HRSA's subsequent 2010 guidance eliminated the one pharmacy limitation and also permitted all covered entities, regardless whether they maintained an on-site pharmacy, to enter into contract pharmacy arrangements.[225] As a result, the number of contract pharmacies in the 340B Program grew by over 1,200 percent in just three years,[226] and, as of July 1, 2015, there were

[223] PPA § III(c) ("Pursuant to the requirements under section 340B of the Act, the Secretary agrees to the following: . . . to require each covered entity to retain purchasing and dispensing records of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under Title XIX of the Social Security Act for not less than 3 years.").
[224] See 61 Fed. Reg. 43,549 (Aug. 23, 1996).
[225] 75 Fed. Reg. at 10,275.
[226] 2014 OIG Contract Pharmacy Report; Berkeley Research Group Analysis for the Alliance for Integrity and Reform of 340B.

37,719 contract pharmacy arrangements.[227] While BIO appreciates that HRSA is endeavoring to provide additional guidance with respect to contract pharmacy arrangements, we would like to begin by outlining some of our overarching concerns with respect to this feature of how HRSA has implemented the 340B Program.

As an initial matter, we note our fundamental concern with the enforceability of contract pharmacy arrangements as they exist in the 340B Program today. When HRSA initially permitted contract pharmacies in 1996, it did so in a manner that arguably was in keeping with the intent of the 340B statute by permitting covered entities without an on-site pharmacy to actually make use of their 340B eligibility by contracting with a single contract pharmacy. The limitation to a single pharmacy meant that contract pharmacies were analogous to on-site pharmacies and enabled covered entities without an on-site pharmacy to participate in the 340B Program on the same footing as covered entities with an on-site pharmacy. While we recognize that contract pharmacies are an important component of the 340B Program for those covered entity types that typically do not maintain an on-site pharmacy, which frequently are HRSA grantees (i.e., non-hospital covered entities),[228] the proliferation of contract pharmacy arrangements following the release of the 2010 revised guidance is not supported by the 340B statute. BIO therefore urges HRSA to bring the contract pharmacy regime more in line with the 340B statute, or, at a minimum, to establish robust programmatic controls to ensure program integrity in the contract pharmacy context.

HRSA appears to concede the lack of any statutory authority for contract pharmacy arrangements by stating in the preamble that the 340B statute "does not prohibit" the use of contract pharmacies, and that state law can permit covered entities to contract with off-site pharmacies. The absence of a statutory prohibition does not entitle HRSA to create such an option and impose it as a requirement on manufacturers. Nor does the fact that state law, as a general matter, facilitates such arrangements. BIO strongly encourages HRSA to include in any final guidance the legal bases for any requirement that manufacturers honor orders by contract pharmacies on behalf of covered entities, particularly with respect to covered entities that enter into multiple contract pharmacy arrangements. HRSA's policies to date clearly imply such a requirement, but the existence of such a requirement and the basis for it must be articulated if HRSA expects manufacturers to continue to fulfill such requests.

In addition to concerns regarding the enforceability of contract pharmacy arrangements, there also is strong evidence that contract pharmacy arrangements raise program integrity and accountability concerns. HRSA acknowledges this in the Proposed Notice by stating that, "[t]hrough audits of covered entities' arrangements with contract pharmacies, HHS has observed that not all covered entities have sufficient mechanisms in place to ensure their contract pharmacies' compliance with all 340B Program requirements."[229] Further, in its 2014 report, the OIG found that contract pharmacies

[227] Berkeley Research Group Analysis.
[228] For example, in HRSA's 1996 Contract Pharmacy Guidance, the Agency notes that many covered entity types (e.g., community and migrant health centers, hemophilia clinics, and most of the Ryan White HIV service programs) rely on outside pharmacy services. 61 Fed. Reg. at 43,550.
[229] 80 Fed. Reg. at 52,311.

create "complications" in preventing violations of the diversion and duplicate discount prohibitions. The report cites strong indications that covered entities often fail to implement the practices necessary to ensure that these program requirements are met in the contract pharmacy context.[230] HRSA made similar findings in its own audits of covered entities.[231] The 340B statute grants manufacturers the right to audit covered entities' compliance with the prohibitions against diversion and duplicate discounts. However, manufacturers are not party to the agreements underlying contract pharmacy arrangements, and, without an understanding of these arrangements, it is difficult for manufacturers to make meaningful use of their audit right. Indeed, manufacturers that suspect compliance issues with respect to a particular contract pharmacy may only audit the contract pharmacy as part of an audit of the covered entity itself.[232]

Given these concerns and the scope and volume of existing contract pharmacy arrangements, HRSA's oversight resources and ability to monitor and enforce program integrity requirements are clearly insufficient to meaningfully address HRSA's contract pharmacy compliance requirements. BIO therefore is very concerned that the current scale of contract pharmacy arrangements is detrimental to the 340B Program as a whole. For instance, HRSA's 2010 contract pharmacy guidance specifically states that "[c]overed entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts,"[233] and that "HRSA has the ability to exclude covered entities that abuse the program."[234] Unfortunately, in practice, it appears that HRSA is not living up to this stated level of enforcement. The 2014 OIG report found that noncompliance with the diversion and duplicate discount prohibitions does not seem to have resulted in HRSA restricting the ability of noncompliant covered entities to utilize multiple contract pharmacies.[235]

Finally, there is no evidence that contract pharmacy arrangements are benefitting the low-income or otherwise needy patients of covered entities. As we describe in greater

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[230] 2014 OIG Contract Pharmacy Report. Contract pharmacy arrangements make it particularly difficult to detect diversion. In a 2011 report, the GAO found that "increased use of the 340B Program by contract pharmacies and hospitals may result in greater risk of drug diversion, further heightening concerns with HRSA's reliance on participants self-policing to oversee the program. Operating the program through contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." Because participating pharmacies contract with multiple covered entities and sub-entities, it becomes virtually impossible to associate utilization with a specific covered entity. Similarly, contract pharmacy arrangements complicate efforts to prevent duplicate discounts. This is, in part, because the mechanism that HRSA has developed to prevent duplicate discounts—the Medicaid Exclusion File—has extremely limited utility in the contract pharmacy space. On the one hand, the indication that a covered entity "carves in" on the Exclusion File does not necessarily apply to the covered entity's contract pharmacies, as contract pharmacies are generally required to "carve out." On the other hand, if a contract pharmacy does "carve in", the pharmacy's NPI is included on the claim—yet this NPI generally is not included in the Exclusion File.

[231] The 2014 OIG Contract Pharmacy Report noted that "recent HRSA audits of covered entities have found instances of diversion and duplicate discounts related to contract pharmacies. Of the 32 covered entities for which finalized HRSA audits resulted in adverse findings, 10 were cited for diversion and/or duplicate discounts through contract pharmacies." 2014 OIG Contract Pharmacy Report. More recent HRSA audits of covered entities have resulted in similarly substantial rates of violations related to contract pharmacies. See "340B Audit Results" available at http://www.hrsa.gov/opa/index.html (last accessed Oct. 23, 2015).

[232] 75 Fed. Reg. at 10,274 (concluding that, to the extent that a manufacturer believes that there is a reasonable basis to conclude that a covered entity that uses multiple contract pharmacies is in breach of program requirements, it may audit a covered entity consistent with HRSA's audit guidelines).

[233] Id. at 10,273.

[234] Id. at 10,274.

[235] 2014 OIG Contract Pharmacy Report.

detail in the following section, some covered entities have entered into expansive contract pharmacy arrangements, which, in some cases, involve pharmacies in distant locales, raising questions as to whether these pharmacies are truly serving "patient[s] of the entity." Meanwhile, the OIG has found that at least some covered entities using contract pharmacy arrangements "do not offer the discounted 340B price to uninsured patients at their contract pharmacies," which results in "uninsured patients pay[ing] the full non-340B price for their prescription drugs at contract pharmacies,"[236] while for-profit pharmacies derive a profit from their prescriptions. Such an outcome clearly undermines the stated goals of the 340B Program by funneling benefits that otherwise would accrue to needy patients to private, for-profit entities that in many instances are nationally-operating retail pharmacy chains.

It is with these concerns in mind that we provide feedback and recommendations with respect to the contract pharmacy-specific proposals included in the Proposed Notice.

b. Scope of Contract Pharmacy Arrangements

The Proposed Notice states that, "[r]egardless of the availability of an in-house pharmacy, a covered entity may contract with *one or more* licensed pharmacies to dispense 340B drugs to eligible patients of the covered entity."[237] As BIO has articulated in prior comments to the Agency, we strongly urge HRSA to evaluate the size and scope of current contract pharmacy arrangements and whether contract pharmacies actually are promoting patient access to medicines. In the preamble to the 2010 guidance, HRSA considered comments recommending that the Agency limit the scope of contract pharmacy arrangements, but ultimately declined to adopt any such recommendations. BIO believes that the compliance concerns documented in the ensuring periods provide more than enough cause for HRSA to re-consider this decision.

Currently, there are certain covered entities that each have contracted with more than 100 contract pharmacies, some of which are located more than 50 miles from the covered entity itself.[238] It is challenging for us to understand how such arrangements are necessary to serve individuals who legitimately qualify as "patients of the entity." Accordingly, we strongly urge HRSA to issue guidance limiting the number of off-site pharmacies with which each covered entity may contract. Rather than relying on the covered entity to "carefully evaluate its relationships with contract pharmacies . . . to make certain that the relationship benefits the covered entity and is in line with the intent of the Program,"[239] as proposed, HRSA should limit the number of off-site pharmacies with which each covered entity may contract or identify why the Agency is not imposing such a limit, taking into consideration the statutory limitations articulated above. Such a limitation would balance the interest in ensuring patient access to discounted drugs with the need to avoid increased compliance risks. For instance, as BIO recommended in our contract

[236] Id.
[237] 80 Fed. Reg. at 52,320 (emphasis added).
[238] BRG Health Analytics, Contract Pharmacy Mapping Analysis (2014). See also Drug Channels, Walgreens Still Dominates Booming 340B Contract Pharmacy Market, with CMV and Rite Aid Right Behind (Feb. 5, 2014), http://www.drugchannels.net/2014/02/walgreens-still-dominates-booming-340b.html (describing contract pharmacy networks with 50-plus pharmacy locations).
[239] 80 Fed. Reg. at 52,310.

pharmacy letter to the Agency dated April 21, 2015, given that the vast majority (74.7 percent) of covered entities currently contract with five or fewer pharmacies, five contract pharmacy arrangements might be a reasonable limit.[240] HRSA alternatively (or additionally) could consider a requirement that all contract pharmacies be located within a 35-mile radius from the applicable covered entity or child site location. Such a geographic limitation would align with the Medicare provider-based status requirements that we urge HRSA to maintain for purposes of assessing hospital child site eligibility, as described in section (III)(b)(iii), above.[241]

To address the diversity of covered entity types and the geographic areas that they serve, BIO believes that non-hospital covered entities should be exempt from any policy limiting the permissible number and geographic scope of contract pharmacy arrangements. This would be appropriate because non-hospital covered entities generally present fewer program integrity risks. A limitation on the number and/or geographic scope of contract pharmacies also could include an exceptions process under which a hospital covered entity (or non-hospital covered entity, if not uniformly exempt) may seek to enter into contract pharmacy arrangement with additional pharmacies where the covered entity can make a showing that doing so is necessary to ensure access to medications for true "patients of the entity."

We also strongly urge HRSA to take immediate steps to address the unique program integrity risks posed by mail-order pharmacies in the 340B Program. Evidence suggests that mail order pharmacies, including such pharmacies licensed to dispense specialty drugs, are playing an increasing role in the 340B program. However, given that these arrangements lack any face-to-face interaction, they present an increased risk for diversion. Moreover, the use of mail-order pharmacies has been cited as potentially increasing costs to federal healthcare programs, and the health care system as a whole, as the result of waste.[242] We therefore urge HRSA to bar covered entities from registering any type of mail-order contract pharmacies, including pharmacies licensed to dispense specialty drugs, in the 340B Program unless and until the Agency has: (1) conducted a thorough examination of the risks posed by these arrangements, either on its own, or in collaboration with an independent government watchdog, such as the OIG or GAO; and (2) outlined clear, auditable, and specific standards for the prevention of program violations with respect to these arrangements, including a requirement that covered entities attest that the use of mail-order pharmacies is the only available mechanism to secure prescription drug access for their patients and that the covered entity has implemented controls to prevent program violations through such arrangements, including the capability to identify a patient as 340B at the time the drug is dispensed/mailed. Even then, the use of mail-order pharmacies in the 340B Program should be limited to serve the needs of the covered entities' patients who would otherwise lack access to prescription drugs (e.g., home-bound patients, those in rural areas).

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[240] Drug Channels, Analysis of OPA Database (Jan. 3, 2014). Excludes contracts terminated before January 3, 2014.
[241] See 42 C.F.R. § 413.65(e)(3)(i).
[242] NCPA: Mail Order Waste All Too Common; Documented by Federal Officials (Mar. 5, 2013), http://www.pharmacytimes.com/association-news/ncpa-mail-order-waste-all-too-common-documented-by-federal-officials.

c. Contract

HRSA proposes that the Agency will list contract pharmacy locations in a covered entity's 340B database record only when a written contract exists between the covered entity and contract pharmacy. BIO supports this proposed clarification, as well as HRSA's statement that "the written contract should also set forth the requirements contained in [the Proposed Notice]."[243] However, we continue to urge HRSA to develop and publish model contract terms for contract pharmacy arrangements. HRSA expressly declined to articulate "Model Agreement Provisions" in the Agency's 2010 contract pharmacy guidelines,[244] instead opting to outline "Covered Entity Compliance Elements" and "Suggested Contract Provisions," which HRSA noted "are not meant to be comprehensive, exhaustive, or required."[245] We believe that this latter statement, in particular, may have resulted in covered entities and contract pharmacies viewing such terms as optional, which has contributed to program violations described in prior BIO letters, as well as government and other reports.[246] Providing model contract provisions would help standardize practices across the 340B Program, which would in turn simplify the burden on HRSA of monitoring contract pharmacy arrangements.

Specifically, HRSA should provide clear guidance with respect to the terms that must be included in all contract pharmacy agreements. We agree with the Agency that these terms could not be comprehensive or exhaustive given the wide array of both covered entities and contract pharmacies. However, HRSA should nonetheless outline those contractual terms that are necessary to operationalize both HRSA's guidance related to contract pharmacies and the 340B Program requirements implicated by such arrangements. In terms of the specific contractual terms that should be included in all contract pharmacy arrangements, the "Covered Entity Compliance Elements" and "Suggested Contract Provisions" articulated in the 2010 guidance can serve as a basis for developing more comprehensive model contract provisions. Additional detail is necessary, particularly with respect to implementation of the prohibition against diversion (discussed in greater detail below). We also urge the Agency to consider contractual terms that require contract pharmacies to: (1) notify covered entities of any potential program violations stemming from the contract pharmacy's operations; and (2) share with covered entities pharmacy records necessary to ensure patient safety and continuity of care. HRSA also should consider working with the OIG and seeking input from stakeholders to identify additional contractual terms that may be necessary to ensure compliance with 340B Program requirements, as well as with other federal requirements.

In the Proposed Notice, HRSA also suggests that a covered entity may contract with either a pharmacy location or *a pharmacy corporation to include multiple pharmacy locations*.[247] Although HRSA does clarify that "[g]roups or networks of covered entities may not register or contract for pharmacy services on behalf of their individual covered entity members,"[248] and proposes that each contract would have to "include . . . all

[243] 80 Fed. Reg. at 52,310.
[244] 75 Fed. Reg. at 10,276.
[245] Id.
[246] See, e.g., 2014 OIG Contract Pharmacy Report.
[247] 80 Fed. Reg. at 52,310 (emphasis added).
[248] Id.

locations of a single pharmacy company that the covered entity plans to use and all child sites that plan to use the contract pharmacies,"[249] we are concerned that allowing covered entities to establish contract pharmacy arrangements with an unlimited number of off-site pharmacy locations through a single contract with the parent pharmacy corporation does not sufficiently ensure that the covered entity will be capable of adequately overseeing the operation of each particular contract pharmacy location—but that is precisely what the 2010 contract pharmacy guidance and the Proposed Notice require.[250] We therefore ask that HRSA instead require a contract between the covered entity and each specific contract pharmacy location.

HRSA also proposes that, to the extent permitted by law, covered entities may either contract with contract pharmacies on behalf of their child sites, or the child sites may contract with those pharmacies directly themselves.[251] We are concerned that allowing child sites to independently establish arrangements with contract pharmacies could undermine the general principle—consistently articulated in HRSA's 2010 contract pharmacy guidance, as well as in the Proposed Notice—that it is the *covered entity* that is ultimately responsible for compliance with 340B Program requirements. We therefore urge HRSA, at a minimum, to require that covered entities implement mechanisms necessary to oversee contract pharmacy arrangements of their child sites—and ensure they are operated in a compliant manner, including the recommendations regarding standards for 340B prescription verification algorithms described in section (VII)(d), below.

Moreover, it is critical that the relationships among a covered entity, child site, and contract pharmacy are fully and clearly disclosed in the public 340B database. HRSA's proposed clarification that each such relationship must be "recognized and reflected in the covered entity's 340B database record"[252] is useful, but we urge HRSA to further clarify that the information regarding such contract pharmacy arrangements also must appear together with the child site's listing, as applicable. We also urge the Agency to consider creating a unique identification number with respect to each contract pharmacy "ship-to" location for this purpose, as recommended in section (III)(d) above.

d. Compliance with Statutory Requirements

As was the case with the 2010 guidance, the Proposed Notice again does not require that covered entities submit their contracts with contract pharmacies to the Agency,[253] instead noting only that, "[p]ursuant to 340B statutory auditing requirements, the contract should be available to HHS upon request."[254] This suggests that the Agency will review such contracts only in the context of a formal audit and not in the ordinary course. Given that HRSA appears to not intend to review each of these contracts on a regular basis, we are supportive of HRSA's proposal to require covered entities to submit certain documents in order to register contract pharmacy arrangements, including "a covered entity's attestation regarding its arrangement with the covered entity" and "a series of compliance

[249] Id. at 52,320.
[250] Id. at 52,310.
[251] Id. at 52,320; 52,310.
[252] Id. at 52,320.
[253] 75 Fed. Reg. at 10,276.
[254] 80 Fed. Reg. at 52,310.

requirements."[255] We believe, however, that HRSA should provide additional details with respect to the components of each of these requirements, as described below. In addition, HRSA should require covered entities to provide a copy of the contract pharmacy service agreement to manufacturers upon written request.[256] As noted above, manufacturers are severely limited in their ability to evaluate the compliance of such arrangements without knowing their details in the first instance.

1. Covered Entity Attestation Regarding Its Arrangement with the Contract Pharmacy.

We suggest HRSA provide additional detail as to the scope and content of the attestation that covered entities must provide with respect to their contract pharmacy arrangements. Specifically, and at a minimum, covered entities should be required to attest that:

- There is a contract in place between the covered entity (or child site) and the applicable contract pharmacy location;
- The contract includes the model terms described above, or that the covered entity has obtained approval from HRSA to use alternative terms;
- The covered entity has implemented each of the compliance requirements, described below; and
- The covered entity will not require its patients to use the covered entity's contract pharmacy to receive a prescription drug.

Such attestations should be a prerequisite not only to registering each contract pharmacy arrangement for participation in the 340B Program, but also should be a requirement of the annual re-certification process. HRSA should further clarify that any such attestations are subject to penalty for any knowing and willful materially false representation under section 1001 of title 18 of the United States Code.

2. Series of Compliance Requirements.

BIO appreciates HRSA's proposed express clarification that "[a] covered entity must follow all 340B statutory requirements when utilizing a contract pharmacy."[257] We also strongly support HRSA's continued clarification that "[t]he covered entity would retain complete responsibility for contract pharmacy compliance with 340B Program requirements."[258] While we appreciate HRSA's efforts to provide general guidance in the Proposed Notice with respect to the prohibitions against diversion and duplicate discounts, as well as contract pharmacy oversight generally, additional, more detailed guidance is necessary in all three of these areas, which we describe, in turn.

First, we support HRSA's statement that covered entities and contract pharmacies "are expected"[259] to have a system in place to verify patient eligibility and thus promote

[255] Id.
[256] This is notably already identified as a requirement in the 340B University FAQs on Contract Pharmacy Operation.
[257] 80 Fed. Reg. at 52,311.
[258] Id.
[259] Id. at 52,321.

compliance with the statutory prohibition on diversion. However, we suggest HRSA strengthen the language it uses in this regard to make clear that this is not optional. In addition, further detail regarding the compliance system is necessary to assist covered entities with implementing such a system. In particular, contract pharmacies generally do not have the capability at the point of sale to distinguish a patient eligible to receive 340B-priced drugs from any "commercial" patient filling a prescription. Instead, pharmacies generally match information from the 340B covered entity (e.g., patient and prescriber lists) and the pharmacy's own prescribing data after both the dispensing and insurance adjudication have occurred. Contract pharmacies then utilize inventory management software to track prescriptions dispensed to 340B and non-340B patients, as determined after-the-fact, and assign them to different "virtual" inventory categories, and typically use a replenishment model to then replenish the 340B inventory.

HRSA's 2010 contract pharmacy guidance generally stated that "pharmacy and inventory management processes are available that make utilization of more than one pharmacy readily feasible for many covered entities without increasing the risk of diversion,"[260] but HRSA's guidance currently does not address the assumptions or algorithms built into contract pharmacy inventory management software (or the software of TPAs) to ensure that this is the case. The OIG contract pharmacy report found wide variation in the assumptions made by contract pharmacies as part of these eligibility determinations.[261] We believe that this is a blind spot in the Agency's efforts to promote program integrity, as many of the 340B Program requirements—particularly the prohibition on diversion—are operationalized by this software. Indeed, as noted in the March 11, 2015 peer-to-peer webinar: "Operating systems and software *alone do not ensure* compliance. They must be *set up* correctly and *audited* regularly."[262]

Another issue that arises in these arrangements is when a single pharmacy contracts with multiple covered entities—each off which has their own TPA. Under these circumstances, the same exact prescription could be claimed as 340B by two covered entities, and the manufacturer would thus pay the 340B discount twice. This could be further complicated if sub-entities are allowed to contract separately with pharmacies, as discussed in the previous section, as this could involve multiple systems that would not necessarily be required to reconcile against each other.

While HRSA has taken the position that the Agency does not have the authority to directly oversee the actions of any entities operating within the 340B Program aside from covered entities themselves, the Agency does have express authority to ensure program compliance by covered entities.[263] Relying on this authority, we urge HRSA to issue standards for 340B prescription verification algorithms and to require covered entities to include compliance with these standards as a term in their contracts with contract pharmacies and, as applicable, TPAs. For purposes of developing these standards, HRSA

[260] 75 Fed. Reg. at 10,273.
[261] 2014 OIG Contract Pharmacy Report.
[262] Available at http://www.hrsa.gov/opa/peertopeer/webinars.html (emphasis in original).
[263] See Letter from Captain Pedley, Director, Office of Pharmacy Affairs, HRSA to Erin Estey Hertzog, Director of Health Law and Policy, BIO (Sept. 28, 2015) ("HRSA does not have authority over split billing software vendors and third party administrators; the responsibility for compliance in the 340B Program rests with the covered entity, including oversight of these third-party arrangements.").

should consider building upon the "340B Prescription Verification Algorithm" prepared by the Prime Vendor Program, which, while it requires further detail and refinement, nevertheless outlines some of the basic concepts that should be incorporated into any such algorithms. In addition, to help address instances in which multiple covered entities (or covered entity child sites) contract with a single contract pharmacy or TPA, HRSA should require that the site of origin be included as part of the 340B verification process; if the TPA is unable to confirm the site of origin, the script should not be eligible for 340B pricing. Review of these algorithms, as well as their implementation, should be a component of HRSA's audits of covered entities that have contract pharmacy arrangements. Indeed, we urge HRSA to include, as a regular part of the Agency's audits of covered entities, audits of vendors that contract with both covered entities and their contract pharmacies, as discussed in section (X), below. Alternatively, if HRSA finds it impossible to articulate such guidance, the Agency should require that all "patient" determinations be made at the time of service. The bottom line is that covered entities have to comply with the patient definition, and if they cannot ensure compliance via after-the-fact determinations, they must do so at the point-of-sale—and we believe HRSA must take the lead in specifying the mechanics for doing so. Regardless, as articulated throughout these comments, covered entities should be required to direct their contract pharmacies to bill under the NPI of the covered entity for all 340B-priced drugs.

Relatedly, we urge HRSA to require covered entities to disclose to HRSA and manufacturers the identity of the TPA or vendor providing their inventory management software or related services—including where the TPA/vendor is the same entity as the contract pharmacy. This information would help enable both HRSA and manufacturers to monitor compliance with the prohibitions against diversion and duplicate discounts. For example, as many covered entities rely on the same TPA/vendor for this purpose, knowing the TPA/vendor's identity would enable both HRSA and manufacturers to observe trends that may stem from the algorithms and assumptions included in the TPA/vendor's inventory management software. This information should be readily identifiable by the covered entity and easily listed on the database, and will strongly support manufacturer oversight efforts.

Second, we similarly support HRSA's proposed clarification regarding the Agency's policies for the prevention of duplicate discounts in the contract pharmacy context. However, we urge HRSA to take into consideration the recommendations made with respect to those policies in our comments regarding the duplicate discount aspects of the Proposed Notice in section (VI)(a), above.

Third, we strongly support HRSA's proposed clarification with respect to contract pharmacy oversight, in particularly the proposed clarification that covered entities are expected to conduct "quarterly reviews and annual independent audits of each contract pharmacy location" and that the results of such reviews are to be included in the records subject to audits under section 340B(a)(5)(C).[264] However, we urge the Agency to use stronger language and expressly require covered entities to engage in these activities. Specifically, in light of the OIG's recent findings that covered entities do not engage in

[264] 42 U.S.C. § 256b(a)(5)(C).

adequate monitoring activities of their contract pharmacy arrangements—and HRSA's own statements in the Proposed Notice that "covered entities that do not regularly review and audit contract pharmacy operations are at an increased risk for compliance issues"[265]—BIO urges HRSA to reinstate the audit requirement included in the Agency's 1996 guidance.

We also urge HRSA to impose certain additional obligations with respect to contract pharmacy arrangements, including, for example, that covered entities maintain written policies and procedures for preventing diversion and duplicate discounts in their contract pharmacy services. For these purposes, HRSA should consider building upon the "Contract Pharmacy Sample Standard Processes" outlined in Apexus' "Sample 340B Policy & Procedures Manuals," as well as the best practices discussed during recent peer-to-peer webinars about contract pharmacy services. HRSA also should consider working with the OIG to identify those aspects of a compliance program that would help ensure compliance with 340B Program requirements. We also urge HRSA to consider requiring that covered entities implement training programs with respect to these policies and procedures, and to require covered entities to certify that the training programs are in place as part of the contract pharmacy registration process. Copies of these policies and evidence of this training should be provided to HRSA, upon request.

e. Registration

BIO supports HRSA's proposed clarifications with respect to the registration process for contract pharmacies. For instance, we support HRSA's express recognition that a contract pharmacy can dispense 340B-priced drugs to patients of the covered entity only after the contract pharmacy's start date that is listed in the public 340B database, as well as that the contract pharmacy location must cease dispensing such drugs on the date on which the contract pharmacy location is terminated.[266] With respect to the applicable start date, we further support HRSA's proposed clarification that the 340B registration deadlines and effective dates announced elsewhere in the Proposed Notice "apply to all changes in the covered entity's list of contract pharmacies, whether initially registering a contract pharmacy agreement or adding contract pharmacy locations to an existing contract with a pharmacy organization."[267] However, as stated previously, we urge HRSA to both clarify and ensure that contract pharmacies are removed from the database immediately upon their termination from the program, and that—in keeping with HRSA's proposed clarification that "[a]ny changes to existing contract pharmacy arrangements should be reflected on the covered entity record in the public 340B database and requested by submitting an online change form"[268]—changes in the information regarding a contract pharmacy arrangement (e.g., the "ship to" address) are made in the 340B database immediately upon a covered entity's notification to HRSA.

We also support HRSA's proposed clarification that "[m]anufacturers and wholesalers are required to ship only to the authorized shipping addresses listed for the

[265] 80 Fed. Reg. at 52,311.
[266] Id. at 52,320.
[267] Id. at 52,310.
[268] Id.

covered entity in the 340B database,"[269] and that "[a] drug manufacturer would not be required to offer the covered entity a 340B priced-drug when a 340B-eligible patient chooses to have a prescription filled at a non-contract pharmacy or a contract pharmacy not listed on the covered entity's 340B database record."[270] Manufacturers necessarily rely on the public 340B database as the source of information regarding which entities are eligible to purchase and receive 340B products, and BIO thus supports the consistent clarification that those entities not listed in the database are not eligible to receive 340B-priced drugs.[271] As noted previously, we also urge HRSA to consider creating a unique identification number for each contract pharmacy "ship-to" location.

We are concerned, however, with HRSA's proposal that "[a] covered entity can request additional contract pharmacy locations under a public health emergency declared by the Secretary" and that "[s]pecial registration instructions and requirements would be published on the HRSA Office of Pharmacy Affairs Web site."[272] As an initial matter, we are unsure why this proposed exception is necessary where there currently are no limitations on the number or scope of contract pharmacy arrangements into which a covered entity may enter. Moreover, the Agency does not explain what registration practices would be permitted in the context of a public health emergency that are not already generally allowed. While we understand the importance of establishing mechanisms to allow HRSA to respond to public health emergencies, we do not believe that expanded registration of contract pharmacies would be necessary to promote patient access under such circumstances. Indeed, as noted previously, manufacturers may be under existing obligations with state and federal public health bodies to ensure access under such circumstances. In addition, the Proposed Notice does not include a sufficient level of detail with respect to this particular proposal to enable stakeholders to comment on it in a meaningful manner. For example, HRSA does not explain the purpose of this public health emergency exception or provide any information as to how it would be implemented or what, if any, input stakeholders would have into any such implementation. We therefore urge HRSA either to eliminate this proposal, or supply a clear rationale for the proposal, as well as a detailed explanation of how the Agency proposes to apply such an exception, which should, at a minimum, be narrowly tailored to promote patient access during the limited duration of the public health emergency.

f. Termination

BIO supports HRSA's proposal that "HHS may remove a contract pharmacy from the 340B Program if HHS finds the contract pharmacy is not complying with 340B Program requirements."[273] However, because responsibility for program compliance of contract pharmacies is the responsibility of the covered entity, HRSA should further clarify that such program violations may result in the termination not just of the contract pharmacy but also of the sponsoring covered entity. Specifically, contract pharmacies found to be in violation

[269] Id.
[270] Id. at 52,311.
[271] Even when individual contract pharmacy locations are accurately listed in the public 340B database for product shipments on behalf of covered entities, we reiterate our fundamental concern with the enforceability of contract pharmacy arrangements in the 340B Program today.
[272] 80 Fed. Reg. at 52,310-11.
[273] Id. at 52,320.

of program requirements as a result of audits conducted by HRSA, covered entities, or manufacturers (or otherwise) should be required to establish a corrective action plan together with the covered entity. Covered entities should be required to terminate contracts with any pharmacies that are unable to meet the requirements of such plans, and HRSA should similarly terminate such pharmacies from participation in the 340B Program. Covered entities that continue to utilize contract pharmacies that have been excluded from the 340B Program should themselves be removed from the program. If actions of the contract pharmacy and/or the covered entity constitute a violation of state or federal law, HRSA should refer them to the appropriate state or federal authorities (e.g., OIG, Department of Justice, or applicable state law enforcement authorities).

g. HRSA Notification

BIO supports HRSA's proposed clarification that "[a] covered entity should correct any instances of diversion or duplicate discounts found during either the annual audit or quarterly review [of contract pharmacy arrangements] and report corrective action to HHS."[274] We note that this would be consistent with HRSA's 2010 contract pharmacy guidance, which provides that, "[i]n the event a covered entity determines that drug diversion or duplicate discounts have occurred . . . [the covered entity] must take immediate remedial action to assure compliance and notify OPA about such compliance problems and actions taken to remedy those problems."[275] However, we urge HRSA to clarify that covered entities are required to provide such notifications and take such corrective actions, regardless of how the instances of non-compliance were detected (i.e., even if detected outside of an annual audit or quarterly review).

h. Manufacturer Repayment

BIO supports HRSA's proposed clarification that "[t]he covered entity is responsible for offering repayment in the amount of the 340B discount to a manufacturer for 340B drugs dispensed by a contract pharmacy that has not adhered to 340B Program requirements."[276] We note that this language is consistent with HRSA's 2010 contract pharmacy guidance, which makes clear that it is the covered entity—not the contract pharmacy—that purchases and retains title to the drug. Specifically, HRSA notes that a "ship to bill to" procedure is used for purposes of contract pharmacy arrangements, under which "[t]he covered entity will purchase the drug, maintain title to the drug, and assume responsibility for establishing its price."[277] Notably, HRSA's guidance also clearly provides that it is the covered entity that "remains responsible *at all times* for the disposition of covered outpatient drugs it purchases through a contract pharmacy."[278] The contract pharmacy, on the other hand, is not a party to the purchase agreement between the manufacturer and the covered entity, and should serve only as the site to which the drugs are shipped. Accordingly, it is appropriate that it is the covered entity that should remit payment to the affected manufacturers.

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[274] Id. at 52,311.
[275] 75 Fed. Reg. at 10,278.
[276] 80 Fed. Reg. at 52,320.
[277] 75 Fed. Reg. at 10,277.
[278] Id. at 10,278 (emphasis added).

We urge HRSA to provide additional clarification with respect to this proposal, however. Specifically, we urge HRSA to incorporate language form the Agency's "Suggested Contract Provisions," which stipulate that, "[i]f a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer."[279] We also ask HRSA to clarify that, as with all repayments to manufacturers, the covered entity must provide sufficient documentation to the affected manufacturer with respect to the improper purchases in question such that the manufacturer is able to process any such refunds. We suggest that HRSA further strengthen the requirement to repay manufacturers by requiring that the covered entity must have completed any repayments to affected manufacturers, or received written notice from affected manufacturers that such manufacturers decline to accept such repayments, as a condition of continued participation of the covered entity in the 340B Program.

VIII. Part F—Manufacturer Responsibilities

a. Obligation to Offer 340B Prices to Covered Entities

The ACA amended the 340B statute to provide that the PPA "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price," a provision known as the "must offer" provision.[280] The preamble to the Proposed Notice states that, "[b]y signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements, *including any changes that occur after execution of the PPA*."[281] However, the "must offer" provision currently is not binding for manufacturers because the provision has not been implemented through the PPA. By its terms, the modified statute does not direct *manufacturers* to do anything; rather it directs only that *the PPA* must implement the "must offer" provision. The PPA does not currently do so.

Moreover, while HRSA has proposed to amend existing PPAs in order for the "must offer" provision to be binding on manufacturers,[282] we take issue with HRSA's description of this statutory provision in the sections titled "Pharmaceutical Pricing Agreement" and "Obligation to Offer 340B Prices to Covered Entities."[283] Specifically, these sections of the Proposed Notice state that, "[u]nder the PPA, a manufacturer must offer all covered outpatient drugs . . . from each of the manufacturer's labeler codes to covered entities participating in the 340B Program at no more than the statutory ceiling price,"[284] and that "a manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed on the public 340B database,"[285] respectively.

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[279] Id.
[280] 42 U.S.C. § 256b(a)(1).
[281] 80 Fed. Reg. at 52,311 (emphasis added).
[282] 80 Fed. Reg. 63,560 (Oct. 20, 2015).
[283] 80 Fed. Reg. at 52,321.
[284] Id.
[285] Id. See also id. at 52,311.

What the statute in reality requires, however, is that "the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price *if such drug is made available to any other purchaser at any price*."[286] This last phrase, which HRSA omits from the text of the Proposed Notice, is critical because the provision's purpose was to codify in the 340B statute HRSA's longstanding "non-discrimination" policy (i.e., the requirement that manufacturers "not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective").[287] Indeed, HRSA recognized the relationship between its non-discrimination policy and the "must offer" provision in its 2012 "Clarification of Non-Discrimination Policy" Program Notice.[288] The absence of this phrase from the Proposed Notice results in an overbroad application of the "must offer" provision, which has the potential to result not only in confusion, but disputes. We therefore urge HRSA to align its description of the "must offer" provision in the Proposed Notice with the language of the 340B statute itself.

b. Recordkeeping Requirements

BIO also is concerned with the recordkeeping requirement for manufacturers that HRSA proposes in the Proposed Notice, because it would go beyond the requirements of the PPA. In particular, we are concerned with the proposed expectation that manufacturers maintain "auditable records demonstrating 340B Program compliance for no less than five years"[289] and provide such records to HRSA when requested. We note that the PPA, by contrast, requires manufacturers to retain records only for a period of three years, and such records are limited to "a list of such covered outpatient drugs, and the AMP, baseline AMP, and the Best Price of such covered outpatient drugs."[290] The Proposed Notice therefore not only would expand the record retention period from three to five years, but also broaden the types of records that would need to be maintained to include any record demonstrating compliance with program requirements. As with the "must offer" requirement, HRSA must amend the PPA before an expectation to retain these records for a longer period can be considered legally binding on manufacturers. We further urge HRSA to articulate the actions that start this five-year records retention period, and to clarify that the look-back period used for purposes of the 340B program will not exceed this five-year period, even if manufacturers happen to retain their records for a longer period of time.

c. Reliance on Public 340B Database

BIO supports HRSA's proposed clarification that "a manufacturer shall rely on the information in the public 340B database to determine whether the manufacturer must offer the 340B price."[291] As noted above, manufacturers necessarily rely on the public 340B database as the source of information regarding which entities are eligible to purchase and receive 340B products. BIO thus supports the statement that those entities not listed in

[286] 42 U.S.C. § 256b(a)(1) (emphasis added).
[287] See 59 Fed. Reg. 25,110 (May 3, 1994).
[288] 2012 HRSA Non-Discrimination Guidance.
[289] 80 Fed. Reg. at 52,311.
[290] PPA §§ II(c), (d).
[291] 80 Fed. Reg. at 52,312.

the database are not eligible to receive 340B-priced drugs and that the manufacturer is entitled to rely on the public 340B database.

d. Termination

BIO supports HRSA's proposed clarification that participation in the 340B Program is voluntary for manufacturers not subject to a Medicaid Drug Rebate Agreement, and that such manufacturers may voluntarily leave the 340B Program at any time, in accordance with the terms of the PPA. However, while we agree that refunds and credits may still be imposed on a manufacturer for sales that took place while the manufacturer had a PPA in effect, we urge HRSA to consider carefully our recommendations with respect to such processes generally, described in section (VIII)(h), below.

e. Manufacturer Withholding of Discounts in Exceptional Circumstances

In the Proposed Notice, HRSA rearticulates its existing position that "[m]anufacturers may not condition the offer of the 340B ceiling price on a covered entity's assurance of compliance with 340B Program requirements."[292] BIO believes that this approach to 340B compliance is nonsensical, as it requires manufacturers with affirmative knowledge of a covered entity's non-compliance to continue to provide its drugs to that covered entity at the ceiling price. The manufacturer's only possible remedy under this policy is to try to recoup the 340B discount that the covered entity should not have received in the first instance. HRSA should therefore establish a mechanism for manufacturers to obtain approval from HRSA to withhold discounts in such instances and sell to the covered entity at non-340B (i.e., commercial) prices pending an audit or investigation of the covered entity in question. Manufacturers that exercise this option could be required to pay the covered entity the difference between the price paid by the covered entity during this period and the 340B ceiling price, plus interest, if the audit or investigation results in a finding that the covered entity was compliant with program requirements. The current approach is not mandated by the statute, as the preamble text suggests.[293] Nor is it defensible in the context of knowing and intentional covered entity misconduct, particularly where manufacturers are extremely unlikely to be able to recoup improperly obtained discounts. This proposed alternative, which would be subject to HRSA approval before being implemented by any manufacturer as to any particular covered entity, balances manufacturer interests with those of the covered entity and provides a needed alternative to the exclusive "pay and chase" model necessitated by HRSA's current policy.

f. Limited Distribution of Covered Outpatient Drugs

BIO is very concerned with HRSA's proposal to require manufacturers to provide written notification to HRSA prior to implementation of a "limited distribution plan" and the implication that such plans would be subject to approval by HRSA. As a threshold matter, HRSA has failed to articulate the problem that the Agency is aiming to address with this

[292] Id. at 52,321.
[293] See id. at 52,306.

proposal. We have four additional concerns with respect to this proposal and how HRSA proposes to implement it.

First, HRSA cites the "must offer" provision as the basis for this proposal.[294] However, for the reasons described in section (VIII)(a), above, BIO believes that the "must offer" provision currently is not binding. HRSA's proposal that manufacturers ensure that restrictions on the distribution or sale of covered outpatient drugs apply equally across 340B and non-340B sales also is non-binding on manufacturers. Furthermore, a limited distribution plan that applies equally to commercial and 340B customers would not contradict the "must offer" provision, which provides that manufacturers must provide covered entities with access to covered outpatient drugs at the ceiling price to the extent such drugs are available at any price to other customers, nor would it contradict HRSA's non-discrimination guidance, which sets forth the same principle.

Second, HRSA's proposal is both vague and overbroad because HRSA does not clearly define the type of distribution arrangement that would constitute a "limited distribution plan." The types of distribution arrangements cited in the Proposed Notice range from "specialty pharmacy" and "restricted distribution network" approaches to plans to "limit distribution due to potential or actual shortages"[295] or because "a covered outpatient drug must be handled in a special manner (e.g., special refrigeration)."[296] The vagueness of this proposed language further underscores the fact that HRSA has not clearly articulated the problem the Agency is endeavoring to address.

Third, we do not believe there is any statutory basis for requiring manufacturers to provide HRSA with notification of any limited distribution arrangements, or for HRSA to review and/or make changes to such plans before they may be implemented, as HRSA has apparently proposed.[297] We note that such distribution policies may be necessary not only for instances in which the "available supply of a covered outpatient drug is not adequate to meet market demands,"[298] but also to implement Risk Evaluation and Mitigation Strategies (REMS) approved by the FDA, to promote quality patient care and safety, or for other reasons. HRSA's proposal itself acknowledges that certain drugs "may be required to be dispensed by specialty pharmacies,"[299] indicating HRSA's recognition that covered entities' ability to access covered outpatient drugs at the ceiling price through specialty pharmacies is sufficient to meet manufacturers' statutory obligations. We agree and believe that manufacturers should be free to distribute their drugs as they deem most appropriate for patient safety and/or commercial purposes without having to disclose such relationships to HRSA or obtain HRSA's approval therefor.

Indeed, while BIO agrees that the 340B price must be the cap on any sales transactions with covered entities, including those that purchase through a limited distribution arrangement, we are very concerned by the implication that such distribution

[294] See id. at 52,312 ("Pursuant to section 340B(a)(1) of the PHSA . . . the plan will be reviewed by HHS to ensure that the manufacturer is treating 340B covered entities the same as all non-340B providers.").
[295] Id. at 52,321.
[296] Id. at 52,312.
[297] Id.
[298] 2012 HRSA Non-Discrimination Guidance.
[299] 80 Fed. Reg. 52,312 (Aug. 25, 2015)

arrangements somehow must be approved by HRSA in advance. Indeed, notification often would not be possible given the short timeframe between when the need for these plans is identified and their implementation. Moreover, we note that it would not be possible to implement HRSA's proposal to "work with the manufacturer to incorporate mutually agreed upon revisions to the plan" in the REMS context without also obtaining the approval of any such modifications by the FDA.[300] Not to mention that it is not clear that HRSA has the expertise, staff, or resources to do so, even outside of the REMS context. HRSA simply has no authority to require the approval of manufacturers' chosen distribution arrangements, whatever their contours, and that is particularly the case where those arrangements are restricted due to product attributes.

Rather, we urge HRSA to continue to permit covered entities and manufacturers to work together in good faith to resolve any issues or concerns with respect to the distribution of covered outpatient drugs, and to become involved only to the extent that such issues cannot be resolved in this manner. Simply put, HRSA has no authority to interfere with a manufacturer's determination regarding how to commercialize its product(s).

Fourth, we note that there is no statutory basis for publicly disclosing manufacturers' limited distribution plans, as HRSA has proposed.[301] While it is generally good business practice to inform customers regarding changes in product distribution procedures, as well as the start and, if known, end dates for any such policies, we strongly object to HRSA's proposal to make information such as the "specific details of the drug distribution plan" publicly available, in light of the proprietary and commercially sensitive information that necessarily comprise such "details."[302] Further, a publication of these plans would have the very real potential to create a "run on the market," thereby potentially exacerbating the issues that led to the need for the plan in the first instance.

g. Additional Discounts

BIO supports HRSA's proposed clarification in the Proposed Notice that, pursuant to section 340B(a)(10), "a manufacturer may choose to sell a covered outpatient drug below the ceiling price to a covered entity" and that "[s]uch pricing is voluntary and need not be offered to all covered entities."[303]

h. Procedures for Issuance of Refunds and Credits

The 340B statute requires HRSA to establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the

[300] See 21 U.S.C. § 355-1(h).
[301] See 80 Fed. Reg. at 52,312 ("HHS may publish all submitted limited distribution plans on the 340B Web site.").
[302] See id. at 52,321. A limited distribution plan likely would constitute "commercial or financial information" that is "privileged or confidential" within the meaning of Exemption 4 of the Freedom of Information Act (FOIA). 5 U.S.C. § 552(b)(4). We also note that this is one of the several instances in which the preamble and guidance are inconsistent in terms of their language. Specifically, while the guidance refers to "specific details of the drug *distribution* plan," the preamble, HRSA refers to "specific details of the drug *allocation* plan." See 80 Fed. Reg. at 52,312 (emphasis added).
[303] 80 Fed. Reg. at 52,312; 52,321.

manufacturers."[304] The proposed cursory directives articulated in the Proposed Notice fall well short of establishing "procedures" for the issuance of credits and refunds envisioned by the statute, however. As expressed in prior BIO comments, manufacturers should not be required to issue refunds to covered entities unless and until HRSA has established this statutorily required refund *process*. Moreover, in establishing this process, HRSA should propose specific elements for such a system, including specific details around the applicable mechanics and processes, in a manner that imposes the fewest burdens on both manufacturers and covered entities, taking into consideration the following concerns and recommendations.

First, while we agree that manufacturers are required to provide a refund or credit when the manufacturer charges more than the ceiling price, and that the amount of this refund or credit should be equal to the difference between the actual price paid by the covered entity and the 340B ceiling price, we urge HRSA to clarify that this refund should *not* include any upcharges imposed by wholesalers based on the wholesaler's own arrangements with covered entities.

Second, we are extremely concerned that HRSA appears to expect manufacturers to provide refunds to covered entities within 90 days after a determination that a credit or refund is due on the basis of a drug price restatement, and that "[m]ultiple price calculations will be required if the 340B price changed during the affected period of overcharges."[305]

As a threshold matter, we note that there likely will be a high volume of true-ups and refunds based on price changes flowing from routine restatements of AMP and Best Price, which are calculated to seven decimal places and rounded to six, as well as the rising volume of products, covered entities, and manufacturers in the 340B Program; HRSA nevertheless has not yet established a process to restate and reconcile ceiling price numbers, as required under section 340B(d)(1)(B)(iv), as noted above. Particularly given the frequency with which routine restatements of pricing data may occur, standardization of this process is necessary to ensure that manufacturers have an efficient and streamlined mechanism to restate pricing data and provide appropriate refunds. Thus, as noted earlier, no credits and refunds should be due on the basis of retroactive ceiling price adjustments unless and until HRSA has established this process.

In addition, as HRSA notes in the preamble, section 340B(d)(1)(B)(ii)(II) envisions "[o]versight by the Secretary to ensure that the refunds are issued accurately *and within a reasonable period of time*."[306] We do not believe that HRSA's proposal meets this standard. Most critically, we note that recalculations of the pricing metrics that underlie the ceiling price (AMP and URA) are required pursuant to applicable laws and regulations by virtue of manufacturer participation in the MDRP and often arise due to factors outside of a given manufacturer's control. For example, Best Price must be reported 30 days after the end of each quarter but then may be restated within an additional 12 quarters. When submitting "initial" Best Price 30 days after the end of the quarter, manufacturers typically

[304] 42 U.S.C. § 256b(d)(1)(B)(ii).
[305] 80 Fed. Reg. at 52,312.
[306] 42 U.S.C. § 256b(d)(1)(B)(ii)(II) (emphasis added).

use estimated or other proxy values for lagged price concessions (e.g., chargebacks, rebates) because actual data are not yet available. Manufacturers then perform a routine true-up or "actual" Best Price calculation at a later time during the 12-quarter restatement period to incorporate such lagged data. Manufacturers also must restate AMP within 12 quarters to correct any errors. It is therefore possible for a manufacturer to experience multiple AMP and Best Price restatements within the 12 quarters following their initial submissions to CMS, with each restatement potentially resulting in changes of the ceiling price.

Requiring manufacturers to repeatedly provide refunds, which may be nominal in amount, to covered entities during the 12-quarter CMS restatement period is simply not feasible, given that there are over 30,000 entities (covered entities and child sites) that may have purchased a drug at the prior ceiling price.[307] Moreover, multiple restatements could result in ceiling price decreases in the first instance only to be followed by additional restatements that later result in ceiling price increases. HRSA's proposal to require iterative refunds would, in such instances, cause manufacturers to issue refunds that ultimately would not be due without any ability to recoup any amounts for the finalized ceiling prices that result from the last set of restatements. HRSA's proposed approach would create an unsustainable burden not only for manufacturers, but for HRSA, covered entities, and wholesalers as well. Indeed, even were HRSA to adopt BIO's suggestion to require refunds only at the end of the close of the MDRP restatement period, BIO members each expect to expend hundreds of hours, annually, to comply with such a requirement.[308] This burden would be exponentially higher, albeit very difficult to estimate at this time, if HRSA were to require refunds in the case of routine restatements.

We are further concerned that HRSA has proposed that refunds would be due within "90 days of a determination by the manufacturer or HHS that an overcharge occurred."[309] Not only is 90 days an insufficient (i.e., unreasonable) period in which to process such refunds, but it also is not clear what would constitute a "determination" for purposes of starting this 90-day time period. We therefore urge HRSA to instead not require the provision of credits and refunds that result from manufacturer pricing restatements until *after* the 12-quarter restatement period ends, so that manufacturers can confirm that their CMS pricing data are final. To provide a reasonable time period for manufacturers to process and then issue any applicable credits and refunds, we further urge the Agency to identify a 120-day time period for this purpose, which should be specified in the guidance (rather than just the preamble, as is the case with the Proposed Notice) to avoid any confusion. Any lesser standard would impose an undue burden on manufacturers.

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[307] Berkeley Research Group Analysis of public 340B database, July 1, 2015.

[308] This burden estimate is based upon the fact that the issuance of refunds at the end of the restatement period would require a manufacturer to undertake, at a minimum, the following steps: (1) organizing and informing stakeholders across the organization of a restatement event; (2) loading the restated 340B ceiling prices into the appropriate record management system; (3) testing the record management system to ensure it accurately calculates the difference between the original 340B ceiling prices and restated 340B ceiling prices; (4) identifying affected covered entities and calculating the eligible refunds amounts; (5) drafting notification letters to HRSA and covered entities of eligible refunds; (6) allowing covered entities at least 30 days to respond to notification letters; (7) setting up and processing the refunds through a payment system; and (8) resolving refund disputes with covered entities. Each of these steps can further be protracted by necessary review and approval activities to ensure compliance with standard operating procedures.

[309] 80 Fed. Reg. at 52,312.

Third, as noted in prior BIO comments, we are extremely concerned with HRSA's suggestion that "[a] manufacturer may only calculate the refund by NDC, and would not be allowed to calculate refunds in any other manner, including (but not limited to) aggregating purchases, *de minimis* amounts, and netting purchases."[310] We strongly urge HRSA to re-evaluate this approach, and to expressly permit manufacturers to offset or net price changes across NDCs, as well as to establish a materiality threshold. If manufacturers restate their pricing data, a single change can commonly affect multiple different NDCs, which can result in increased ceiling prices for some NDCs and decreased ceiling prices for others. For purposes of efficiency, manufacturers commonly address these changes—which often each represent low-dollar amounts—by offsetting prices across NDCs, such that underpayments (where the manufacturer charged the covered entity more than the ceiling price) are reduced by overpayments (where the manufacturer charged the covered entity a price that is lower than the ceiling price). Given that manufacturers generally employ this "offsetting" approach uniformly across all of their customer types (i.e., 340B and commercial), prohibiting this practice in the context of the 340B Program would be contrary to HRSA's non-discrimination policy, as manufacturers would be directed to treat their 340B customers in a manner distinct from commercial and other customers. HRSA cannot be in the position of requiring non-discrimination only when it benefits covered entities. That is the definition of arbitrary, which is precisely what the Agency's guidance should not and cannot be.

We further note our concern that HRSA's proposal to disallow offsets—together with its proposed requirement that manufacturers issue refunds in the event that restatements in AMP or Best Price result in a recalculated ceiling price—may result in forcing manufacturers to offer sub-ceiling prices. If a 340B ceiling price must be restated due to changes in the data that the manufacturer submitted to the MDRP, it is likely that the price in some periods was too high (overpayment by covered entity) and too low in others (underpayment by covered entity). Under the Proposed Notice, the manufacturer would not be permitted to offset the overcharges and undercharges that would result. The instance in which the ceiling price was too low would thus become a mandatory sub-ceiling price. This would thus transform the voluntary option of providing sub-ceiling prices, as noted above, into a requirement, which would be plainly contrary to the 340B statute.[311] In sum, HRSA should expressly recognize manufacturers' ability to net across NDCs in issuing any final guidance.

We further believe that, in accordance with HRSA's non-discrimination policy, manufacturers should be permitted to adopt materiality standards with respect to refunds and credits, provided that they are implemented uniformly across all customers. Indeed, HRSA has already proposed permitting manufacturers to adopt such a standard with

[310] 80 Fed. Reg. at 52,312.

[311] Although undercharges are not referenced in the 340B statute explicitly, prohibiting them, as HRSA has proposed, is not consistent with the fact that the extension of sub-ceiling prices is expressly considered to be voluntary under the 340B statute. See Utility Air Regulatory Group v. EPA, 573 U.S. ___, 134 S. Ct. 2427 (2014) (relying upon the fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme).

respect to *accepting* repayments from covered entities.[312] Requiring manufacturers to issue refunds to covered entities for *de minimis* amounts would impose a substantial and unwarranted compliance burden on manufacturers. Indeed, in the absence of a *de minimis* threshold, manufacturers could be required to issue credits and refunds, the cost of processing which would exceed the amount in question. Requiring manufacturers to process these credits and refunds also could pose an undue burden on covered entities, which may similarly incur processing costs that outweigh the benefit of the available refund.

Fourth, we are concerned by HRSA's proposal that the covered entity may choose to have the manufacturer apply a credit to its account rather than receive a refund of any incorrect payment. We believe that allowing covered entities to unilaterally decide how they would like to receive credits or refunds would impose undue burdens on manufacturers. For instance, in many cases, the cost of processing a check (e.g., $100) may exceed the value of the overpayment in question. At a minimum, such determinations should be made jointly by both parties.

Fifth, while BIO supports HRSA's proposal that, "[i]f a covered entity fails to act to accept a direct repayment (e.g., cash a check) within 90 days of a manufacturer's refund and the repayment amount is undisputed by the covered entity, the covered entity has waived its right to repayment,"[313] we note that the Proposed Notice fails to recognize the role of the covered entity in obtaining credits and refunds for purposes of the pricing adjustments. This can be contrasted with the Agency's 1995 *Federal Register* guidance, which expressly stated that "there was an attempt [by HRSA] to evenly split the administrative burden of the process between the manufacturer and the entity. If an entity wishes a pricing adjustment, the dollar amount in question, one would expect, must be significant enough to balance the administrative burden involved in documenting and developing the request."[314] As the burden on manufacturers of issuing 340B refunds in connection with new drugs has greatly *increased* since 1995, due largely to the rapid growth in participation of covered entities in the program,[315] HRSA should continue its approach, in place since 1995, of requiring covered entities to request a refund in order to balance this growing administrative burden. HRSA also may wish to establish a reasonable *de minimis* threshold (e.g., $100) for this purpose.

Finally, we are concerned with HRSA's proposal that a manufacturer would be required to provide an explanation, along with the price recalculation information, as to why the overcharge occurred. Specifically, we do not believe that manufacturers should have to disclose to HRSA the methodological basis for a change that is the result of pricing restatements in government programs other than the 340B Program, namely the MDRP.

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[312] In the section of the Proposed Notice related to covered entity repayments to manufacturers for violations of the diversion prohibition, HRSA notes that "[a] manufacturer retains discretion as to whether to request repayment based on its own business considerations," (e.g., to the extent that payments are below a *de minimis* amount). 80 Fed. Reg. at 52,308.
[313] Id. at 52,312.
[314] 60 Fed. Reg. 51,488, 51,488 (Oct. 2, 1995).
[315] For example, the Government Accountability Office (GAO) reports that *forty percent* of U.S. hospitals now participate in the 340B Program. GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015).

The laws and regulations that govern the MDRP are under the sole jurisdiction of CMS and beyond HRSA's authority. Manufacturers simply must be able to confirm that the restatement complies with its CMS obligations, but nothing further should be required.

IX. Part G—Rebate Option for AIDS Drug Assistance Programs

State-run AIDS Drug Assistance Programs ("ADAPs") are a type of covered entity eligible to participate in the 340B Program. This means that they can access the 340B ceiling price when they purchase covered outpatient drugs. In addition, ADAPs are the only type of covered entity that can access this discounted price through a rebate; in these cases, the ADAP pays the full price for the medication and seeks a rebate from the manufacturer so that effectively they have paid only the ceiling price (or lower, in the case of sub-ceiling discounts) for the medication.[316] Congress has also authorized ADAPs to provide HIV/AIDS-related drugs "by paying on behalf of individuals with HIV/AIDS the costs of purchasing or maintaining health insurance or plans whose coverage includes a full range of such therapeutics and appropriate primary care services."[317] Thus, ADAPs can choose to cover some or all of their patients' health insurance costs instead of, or in addition to, providing HIV/AIDS drugs directly. ADAPs that cover health insurance costs do so by helping to pay a patient's premiums and/or cost sharing (i.e., deductibles, copayments, and/or coinsurance).[318]

As a threshold matter, BIO believes the coverage of insurance or cost-sharing obligations for ADAP patients is a reasonable and productive use of an ADAP's federal and state grant funds because it enables ADAPs to "ensure access to HIV medications *and* care."[319] We also applaud HRSA's efforts to address the ADAPs' practice of claiming a "full rebate" from manufacturers, which can exceed thousands of dollars, when they expend only a small amount (e.g., $4) towards the copay or deductible of a patient who already has insurance (known as the "partial pay" rebate policy).

In 2003, the HIV/AIDS Bureau within HRSA ("HAB"), which administers the ADAP program but not the 340B Program, first addressed the question of the applicability of a 340B rebate when an ADAP covers patients' insurance costs rather than purchasing medication directly.[320] HAB explained that ADAPs should claim rebates only on the portion of the retail purchase for which the ADAP paid; in other words, if, for example, an ADAP paid a $10 copayment for each prescription, the ADAP should then divide the total amount of the copayment by the cost of each unit of the drug in order to determine the number of units that receive a 340B discount.[321] In another example, HAB stated that an ADAP that

[316] See 63 Fed. Reg. at 35,242; 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997).
[317] PHS Act § 2616(f)(1).
[318] See HAB, Policy Notice 07-05 (Sept. 19, 2007), available at hab.hrsa.gov/manageyourgrant/files/partbadapfundspn0705.pdf (last visited Oct. 12, 2015).
[319] 80 Fed. Reg. at 52,313 (emphasis added).
[320] See HAB, The ADAP Manual, at 21, available at ftp://ftp.hrsa.gov/hab/ADAP2003.pdf (last visited Oct. 12, 2015) (hereinafter "2003 HAB ADAP Manual") (stating that "HRSA recommends that if an ADAP only pays a co-payment amount or a percentage of the total cost of the prescription at the time of purchase from a retail pharmacy, the ADAP should claim a rebate only on the portion of the retail purchase for which the ADAP provides payment" and providing two examples of the operation of the proportional rebate).
[321] See id.

pays ten percent of the prescription cost can claim a rebate on ten percent of the units purchased.[322]

In 2005, HAB purported to expand the circumstances in which an ADAP may claim a 340B rebate to encompass situations in which an ADAP expends *any* amount to pay the cost-sharing associated with the coverage of a drug, even if its expenditure does not exceed the 340B ceiling price for the drug. Importantly, HAB provided this guidance in a letter addressed to ADAPs that was not distributed to manufacturers.[323] This letter referenced rebates "on partial payments of health insurance policies" or "on partial pay claims."[324] HAB's 2012 ADAP Manual reflects the position expressed in the 2005 letter.[325] Thus, ADAPs began to seek 340B rebates when they cover only a patient's co-pay and not also the patient's insurance premium. This resulted in some ADAPs expending a nominal amount (e.g., $4) for a patient's co-pay and receiving potentially thousands of dollars in 340B rebates from the manufacturer.

In an undated letter signed by then-Administrator Wakefield and posted on the HRSA website in early 2014, HRSA articulated the Agency's intent to "address the extent to which ADAPs can collect rebates from manufacturers when the ADAPs purchase insurance and/or pay premiums, copayments, and deductibles for ADAP patients."[326] The additional thinking set forth in the instant proposal ostensibly reflects the Agency's attempt to do so. Specifically, HRSA is now proposing to limit the availability of such 340B rebates to situations in which the ADAP either: (1) acts as a third-party payor covering eligible patients' drug charges; or (2) pays for an eligible recipient's insurance, covering not only the applicable co-pay and other cost sharing, but also the premium. While questions remain regarding the statutory basis for certain aspects of this proposal, BIO believes that this approach represents a significant improvement in terms of the instances in which HRSA expects manufacturers to remit 340B rebates to ADAPs.[327]

That said, BIO urges HRSA to take into consideration the following recommendations with respect to specific aspects of the Agency's proposed policy. In addition, while BIO appreciates HRSA's efforts to provide program participants, including ADAPs, with additional time to implement the proposed changes to Agency policy,[328] as noted previously, we strongly urge HRSA to issue final guidance within a reasonable timeframe with respect to all aspects of the Agency's 340B Program guidance.

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[322] See id.
[323] See Letter to Title II ADAP Colleagues from Deborah Parham Hopson, Associate HRSA Administrator (Apr. 29, 2005) (available at http://hab.hrsa.gov/manageyourgrant/files/adap340b.pdf).
[324] See id.
[325] See 2012 HAB ADAP Manual at 81 ("[An] ADAP may pursue rebates from manufacturers for drug costs, when they have paid for all *or any part* of the costs of the prescription including cost sharing or co-payments.") (emphasis added). We note that there is no statutory basis for a 340B rebate in this context.
[326] See Letter to Whom It May Concern from Mary K. Wakefield, HRSA Administrator (available at hab.hrsa.gov/manageyourgrant/adap340bletter.pdf) (hereinafter "Wakefield Letter").
[327] See id. ("urg[ing] manufacturers to continue their current ADAP rebate operations [(i.e., pay 340B rebates when ADAPs pay only the applicable cost-sharing)] in order to maintain stability in the ADAP program.").
[328] See 80 Fed. Reg. at 52,314 ("to allow for the development of systems and any other necessary changes in order to make qualified payments on behalf of an ADAP client for those states utilizing the rebate option, HHS is proposing to delay the effective date of section (b) of Part G, defining qualified payment, for 12 months after the publication date of the final guidance.").

First, we support HRSA's proposal that such rebates would be limited to those ADAPs that pursue a direct rebate option or those that employ a combination of direct purchase and rebates (i.e., the "hybrid" option described in the Proposed Notice), and that are listed on the public 340B database.[329] We also support HRSA's proposed clarification in the preamble that ADAPs would be required to inform HRSA of the option that they select (i.e., rebate, direct purchase, or hybrid) during the registration process.[330] We believe, however, that this proposal could be strengthened by adding the notification requirement to the guidance text (as opposed to just the preamble), and further clarifying that the ADAP's selected option will appear on the public 340B database such that manufacturers will have the necessary information regarding each ADAP's selection.

Second, BIO also strongly supports HRSA's proposal to require ADAPs to submit claims-level data to manufacturers "which document a qualified payment was made to support each request for a rebate."[331] To effectuate this requirement, we recommend that ADAPs be required to provide claims-level information regarding not only the drug (e.g., medication name/label name, NDC, package size, date dispensed/administered), but also the provider that dispensed or administered it (e.g., "ship-to" address, "bill-to" address). BIO would be happy to work with ADAPs and HRSA in order to implement this requirement. We also ask HRSA to specify the claims-level detail necessary to support any assurances "that the claim is not for a drug subject to the Medicaid rebate" (e.g., state, payor information (BIN/PCN), billed/paid amounts), and would ask that this language be amended to expressly include a Medicaid managed care rebate. HRSA also should clarify that the proposed delay in the effective date of section (b) of Part G (defining qualified payment) similarly applies with respect to the claims-level data requirement, as there is no reason to require ADAPs to provide the claims-level data to support a requirement that has not yet gone into effect.

On a related note, BIO fully supports HRSA's clarification that no ADAP discount is due on a covered outpatient drug purchased by non-ADAP covered entity at or below the ceiling price.[332] This is consistent with the manufacturer's obligation to charge a covered entity no more than the ceiling price for a covered outpatient drug. Once a manufacturer has discharged that obligation, no further discounting obligation exists. To effectuate this proposal, BIO urges HRSA to outline the claims-level data necessary permit manufacturers to ensure that ADAPs have not obtained 340B pricing (either through a rebate or direct purchase) on a drug purchased by *another* covered entity at or below the 340B ceiling price (e.g., the NCPCP "UD" modifier, which identifies 340B utilization).

Third, as noted earlier, for this proposed policy to apply, HRSA has proposed that the ADAP would be required to pay for an eligible recipient's insurance, covering not only the applicable co-pay and other cost sharing, but also the premium. Accordingly, we also urge HRSA to provide further clarity with respect to the auditable documentation that must be maintained to support that the ADAP has indeed made a "qualified payment" as that term is defined in the guidance (e.g., receipts from insurers and health care providers

[329] Id. at 52,322.
[330] Id. at 52,313.
[331] Id. at 52,322.
[332] Id. at 52,313.

received in the regular course demonstrating that the ADAP paid the applicable copayment/coinsurance/deductible *and* the premium). We further urge HRSA to require that all assurances provided to this effect (i.e., that the ADAP paid the applicable cost-sharing *and* the premium) be subject to penalty for any knowing and willful materially false representation under section 1001 of title 18 of the United States Code.

Fourth, we believe HRSA's proposal that the rebate owed to an ADAP be equal to (or more than, in the case of a voluntary sub-ceiling price) the Medicaid drug rebate amount described in section 1927(c) of the SSA, multiplied by the units of drug included in the rebate claim is an appropriate starting point for calculating the ADAP rebate amount.[333] HRSA asserts that a proportional rebate option would be operationally infeasible. Its assertion is incorrect, and there is precedent for such an option. For example, we are aware that State Pharmacy Assistance Programs claim proportional rebates where they provide wraparound coverage with respect to Medicare Part D. We therefore recommend that HRSA examine this further as an option for manufacturers.

Finally, we urge HRSA to consider carefully BIO's recommendations with respect to the unique issues presented by ADAPs regarding the patient definition and prevention of duplicate discounts, discussed in sections (V) and (VII)(a)(v), respectively. We also ask HRSA to consider adding a claim submission cutoff for ADAP rebates to mitigate the potential for duplicate discounts and diversion.

X. Part H—Program Integrity

a. HHS Audit of a Covered Entity

As HRSA notes in the Proposed Notice, section 340B(a)(5)(C) gives the Agency the authority to audit covered entities to monitor their compliance with the statutory prohibitions on diversion and duplicate discounts. HRSA also may assess a covered entity's compliance with 340B Program requirements more generally, including covered entity eligibility and database information.[334] BIO strongly supports HRSA's efforts to conduct these audits, which we believe are an important means of identifying instances of non-compliance, as well as promoting program integrity more generally.

BIO also supports HRSA's proposed clarification in the Proposed Notice that HRSA's covered entity audits may extend not only to the covered entity, but also to its child sites and contract pharmacies,[335] as well as HRSA's proposed clarification that "HHS may audit other 340B identification numbers associated with the parent or child site."[336] We agree that all entities and organizations affiliated with a covered entity should be subject to HRSA's audits, as appropriate. For example, ensuring compliance with the GPO prohibition and non-profit status requirements—both conditions of 340B eligibility for certain entities—necessarily involves a review of entities with which the covered entity shares ownership, purchasing mechanisms (e.g., GPO contracts), and revenue. As noted previously, we

[333] Id. at 52,323.
[334] 80 Fed. Reg. at 52,314.
[335] Id. at 52,322. See also id. at 52,314.
[336] Id. at 52,314.

therefore urge the Agency to further clarify that any entity that has a formal relationship with the covered entity—in particular, TPAs and software vendors contracted by the covered entity to provide 340B-related services—may similarly be audited by HRSA to verify the covered entity's program compliance. We believe that such audits represent a parallel to HRSA's proposal to audit wholesalers as part of the Agency's audits of manufacturers, described in the following section of this letter.

In addition, BIO supports HRSA's proposed clarification that covered entities must "provide or arrange for" access to all specified records pertaining to 340B Program compliance by a specified deadline and that "[f]ailure to provide records or respond to requests for information within HHS-specified deadlines may result in" the covered entity being "presumed to be out of compliance with that 340B Program requirement [to which the unavailable records pertain,] and subject to the penalty applicable to the requirement," as well as "terminat[ion] from the program."[337] We urge HRSA to further clarify that, to avoid such penalties, the covered entity must be able to produce records that cover the entire applicable records-retention period, as well as the fact that, in accordance with the text of section 340B(a)(5)(D),[338] that such penalties would necessarily involve repayment to *all* affected manufacturers, as necessitated by the violation in question and/or during any periods of ineligibility, not just those manufacturers identified in HRSA's sample of audit results.

We further support HRSA's proposed clarification that covered entities would be provided with a notice and hearing process in order to respond to adverse findings or other notifications of non-compliance, as well as to any proposed loss in 340B Program eligibility. As part of this process, HRSA proposes to provide written notice to a covered entity, which would be sent to the covered entity's authorizing official. We agree with this approach, but urge the Agency to also provide such notice to all impacted manufacturers, which should similarly have the opportunity to receive notice and be heard, given the potential impact any of HRSA's audit findings with respect to 340B covered entities may have on them.

We also support HRSA's proposed clarification that covered entities may respond in writing to each item of non-compliance, including through the provision of appropriate documentation, as well as the identification of a clear timeline for a decision to be rendered by HRSA. We are concerned, however, that the proposal is lacking detail in terms of the official within HHS who will be charged with both "mak[ing] final findings of noncompliance" and "tak[ing] appropriate actions."[339]

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[337] See id. at 52,322 ("Failure to provide records or respond to requests for information within HHS-specified deadlines may result in the penalties specified in this guidance for failure to maintain auditable records and termination from the 340B Program."). See also id. at 52,320 (describing penalties for covered entity failure to maintain auditable records).

[338] 42 U.S.C. § 256b(a)(5)(D) ("If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.").

[339] 80 Fed. Reg. at 52,314-15.

Finally, we support the proposed clarification that a covered entity would be required to submit a corrective action plan if a final determination of noncompliance is made, unless the noncompliance is related to a condition of eligibility, in which case the covered entity would be removed from the program,[340] although we urge HRSA to further specify that this plan must be provided within 30 days, as is specified within the manufacturer context.[341] Indeed, we urge the Agency to provide greater guidance in terms of the timeframe for the entire audit process. We further support the proposed requirements that HRSA outlines with respect to the corrective action plan—including the requirement to work with state Medicaid agencies to correct duplicate discounts, as applicable—as well as HRSA's proposed clarification that failure to submit or adhere to the plan will result in further action from HRSA, including the potential for termination. This corrective action plan should be available to affected manufacturers and, as appropriate, state Medicaid agencies, upon request. We also urge HRSA to develop remuneration guidelines for covered entities with respect to specific liability for repayment to manufacturers, as well as dissemination and coordination with manufacturers.

b. Manufacturer Audit of a Covered Entity

As HRSA notes in the preamble to the Proposed Notice, section 340B(a)(5)(C) also authorizes manufacturers to audit a covered entity's compliance with the statutory prohibitions on diversion and duplicate discounts. While we agree with HRSA that the statute does not authorize manufacturers to audit covered entity compliance with program eligibility requirements (e.g., the GPO prohibition), we note that the auditing for compliance with the diversion and duplicate discount prohibitions necessarily requires an evaluation of covered entity compliance with related requirements (e.g., the "covered outpatient drug" definition).

In keeping with HRSA's longstanding policy, HRSA seeks to clarify in the Proposed Notice that a manufacturer must demonstrate to HRSA that there is "reasonable cause" for an audit before the Agency will authorize the audit. As a threshold matter, BIO is concerned about HRSA's use of a "reasonable cause" standard, which is a very high threshold for a manufacturer to even get into the audit process—which is really the only remedy provided to manufacturers for covered entity non-compliance. The 340B statute also does not provide such a threshold. Moreover, the cost of the audit is borne by the manufacturer per the statute, so that should be adequate deterrence to discourage unfounded audits. Accordingly, we request HRSA to strengthen the ability by manufacturers to perform independent audits of covered entities, such as by allowing manufacturers to conduct a limited number of audits per year without obtaining prior approval from HRSA provided the manufacturers have a reasonable basis for performing such audits.

To the extent that HRSA nonetheless retains "reasonable cause" as the standard for this purpose, BIO supports HRSA's proposal to define the term "reasonable cause" to refer to circumstances in which "a reasonable person could conclude, based on reliable evidence,

[340] Id. at 52,315; 52,322.
[341] See id. at 52,323 ("A corrective action plan is submitted within 30 days of receiving HHS's audit findings of noncompliance.").

that a covered entity, its child sites, or contract pharmacies" have violated either the diversion or the duplicate discount prohibition.[342] We also support the examples of "reasonable cause" outlined in the preamble text. For instance, while we agree that it makes sense for a manufacturer to work in good faith with a covered entity to resolve any concerns before requesting HRSA's approval to audit the covered entity, we also agree that the covered entity's failure to respond to a manufacturer's questions in this context represents an example of reasonable cause sufficient to support HRSA's approval to audit.

BIO also supports HRSA's proposed clarification that, in advance of conducting an audit, manufacturers should submit an audit work plan for HRSA to review, as well as a number of the proposed audit standards (e.g., the protection of confidential patient information).[343] However, we urge the Agency to provide further guidance with respect to the process for manufacturers to request the initiation of covered entity audits, which should be developed taking into account the manufacturer perspective. We also are concerned with HRSA's proposal to continue to require manufacturers to use an independent certified public accountant ("CPA") to conduct the audit, however. This purported requirement is overly burdensome and without justification. Instead, manufacturers should be able to conduct audits of covered entities using an internal CPA to the extent that this individual follows standard audit protocols, including those outlined in the audit work plan submitted to and approved by HRSA.

The Proposed Notice does not propose to impose any requirement on HRSA to act on the audit results generated by a manufacturer's audit (other than the potential for referral to other federal agencies).[344] This is in contrast to HRSA's own audits, which the Proposed Notice specifies could result in a covered entity's termination or a requirement that the covered entity submit a corrective action plan.[345] If HRSA does not commit to acting on manufacturer audit results, the manufacturer audit option is no remedy at all. HRSA cannot encourage manufacturers to conduct such audits and portray them as an avenue for manufacturer oversight if HRSA does nothing to act on those results. This is particularly the case given that HRSA requires manufacturers to retain an independent CPA to conduct the audits in the first instance.

Manufacturer audits performed by CPAs clearly provide a reasonable basis for HRSA to make determinations of covered entity non-compliance. Indeed, we note that HRSA relies on an independent auditor employed by covered entities in a number of circumstances throughout the Proposed Notice to inform official actions and determinations of the Agency (e.g., with respect to eligibility standards for children's hospitals and their child sites).[346] We therefore believe HRSA must similarly respect and take action upon any findings resulting from manufacturer audits conducted by independent CPAs, including relying on such findings to impose corrective actions on covered entities found to be in violation of program requirements. Again, HRSA cannot rely on auditor results only to support covered entity actions but ignore such results when they identify covered entity

[342] Id. at 52,315.
[343] Id. at 52,323.
[344] See id.
[345] See id. at 52,314-15.
[346] See id. at 52,301-03; 52,317.

compliance violations. Such an arbitrary approach is precisely what a government agency cannot condone.

Accordingly, we urge HRSA to review manufacturer audits within 60 days and enforce such findings, including by requiring covered entities to make any applicable repayments to manufacturers, with 120 days. If HRSA is unable to meet these timelines, the Agency should permit affected manufacturers to withhold future discounts until HRSA, the manufacturer, and the covered entity have resolved the findings noted in the manufacturer's audits. Requiring speedy resolution of audit findings is critical for all parties, and most importantly manufacturers to mitigate losses during the pendency of HRSA's review and actions.

c. HHS Audit of a Manufacturer and Its Contractors

As HRSA notes in the preamble to the Proposed Notice, section 340B(d)(1)(B)(v) extends HRSA's audit authority to "[s]elective auditing of manufacturers and wholesalers."[347] As a threshold matter, BIO is concerned that HRSA has not provided information pertaining to the nature and the specific audit requirements imposed on manufacturers, nor has HRSA discussed who would bear the financial costs of conducting such an audit. BIO urges HRSA to establish a standard set of audit principles and objectives prior to any manufacturer audits, and that HRSA bear the cost of performing any and all such audits. We also have three, more specific concerns with respect to this proposal.

First, HRSA proposes to clarify that this audit authority applies to "a manufacturer or wholesaler that manufacturers, processes, or distributes covered outpatient drugs" in the 340B Program, and that the scope of such audits would extend to "all relevant records retained by the manufacturer and its contractors (such as wholesalers) to assess compliance with 340B Program requirements."[348] HRSA must recognize that wholesalers are independent businesses, which have contracts with manufacturers for certain activities in the distribution of products, as well as with covered entities for various services. As such, actions by wholesalers should not be considered to be an action taken by a manufacturer, or otherwise imputed to the manufacturer, unless undertaken as a result of express instructions from the manufacturer. Specifically, neither errors, nor improper actions on the part of wholesalers, can be considered to be the fault of a manufacturer without express instructions from the manufacturer driving the wholesaler's action in question. Thus, in accordance with the 340B statute—which extends HRSA's audit authority separately for "manufacturers" and "wholesalers"—we urge HRSA to recognize, in issuing any final guidance, that wholesaler activities generally are separate from manufacturers and are therefore subject to separate audits by HRSA. Moreover, because Section 340B(d)(1)(B)(v) authorizes HRSA to separately audit independent activities of wholesalers to ensure program integrity, separate and explicit guidance for such audits is required. BIO opposes extending audits to manufacturer contractors beyond wholesalers, as only wholesalers are identified in the 340B statute.

[347] 42 U.S.C. § 256b(d)(1)(B)(v).
[348] 80 Fed. Reg. at 52,315.

Second, we also are very concerned that HRSA has proposed to refer manufacturers for investigation (e.g., to the OIG or the Department of Justice) for "[f]ailure to provide or give access to records or respond to requests for information within HHS-specified timeframes,"[349] without imposing a similar regime in response to an analogous failure by covered entities.[350] This can be contrasted with HRSA's efforts—which we support—to ensure that the Agency's notice and hearing process and corrective action plan policies apply uniformly across program participants, although we also suggest that HRSA provide manufacturers with a similar opportunity to request a time extension in the notice and hearing process that HRSA proposes to afford to covered entities.[351] We also are concerned that HRSA proposes to make audit findings public without assuring that it will safeguard proprietary and sensitive manufacturer information, the disclosure of which could result in irreparable harm.

Finally, we urge HRSA to take into consideration BIO's recommendations regarding these processes, articulated in sections (X)(a) and (X)(b), above, in particular with respect to the need to identify a decision-maker for the proposed notice and hearing process.

XI. Estimated Impact of the Proposed Notice on Manufacturers

Given that the Proposed Notice does not amount to a legislative rulemaking, it is exempt from the requirement to provide an associated regulatory impact analysis (RIA) pursuant to Executive Order 12,866. This is not to say that the guidance, when finalized, would not have an impact on Program participants, including manufacturers. At a minimum, all program participants will need to expend time and resources reviewing the final guidance and assessing its impact on their existing policies, procedures, and operations. This is particularly the case for aspects of the guidance that are either new or represent changes in current HRSA policy. For instance, as noted in BIO's comments in response to HRSA's recent Proposed Rule,[352] before manufacturers can implement any new processes for credits and refunds—a subject briefly addressed by the Proposed Notice—it will be necessary for them to review HRSA's instructions and may necessitate that they update their technology systems, run system and performance testing, adjust their compliance policies and procedures, train personnel, and take other steps to ensure compliance with the new obligations. Furthermore, once these procedures are implemented, it will be extremely time consuming for manufacturers to process all of the attendant credits and refunds, which is a cumulative process that will occur each quarter.

This impact of any new proposals is compounded by the sheer number of covered entities that participate in the 340B program, which means that manufacturers must set up and maintain any applicable processes with respect to 30,000 or more entities (covered

[349] Id. at 52,315. See also 80 Fed. Reg. at 52,323 ("Failure to provide records or respond to requests for information within the HHS-specified time frames may result in further action by HHS or *referral for investigation*.") (emphasis added).
[350] See id. at 52,314.
[351] See id. ("If a covered entity anticipates the inability to respond by a particular deadline, it is expected to request an extension. HHS will consider such requests on a case-by-case basis.").
[352] BIO comments in response to 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation [RIN 0906-AA89] Proposed Rule (Aug. 17, 2015), https://www.bio.org/sites/default/files/FINAL%20BIO%20Comments%20on%20CMP%20&%20Ceiling%20Price%20Rule%208_17_15_0.pdf.

entities and child sites), for whom addresses, parent/child site relationships, bill to/ship to arrangements, and wholesaler arrangements are constantly in flux. Verification of this information, in reliance on HRSA's database, will be necessary on a quarterly basis.

These impacts notwithstanding, BIO strongly urges the Agency to finalize its proposed guidance, taking into account the recommendations and considerations outlined here. The timely issuance of more comprehensive guidance with respect to the 340B Program is absolutely imperative to ensure that the program can truly serve its intended purpose, and to address the widespread concerns regarding the integrity of the program. We believe that the Proposed Notice, with the modifications described here, would be a step in the right direction in this regard.

XII. Conclusion

BIO appreciates the opportunity to comment on the Proposed Notice. We hope that the Agency finds this letter to be constructive in the process of developing comprehensive guidance with respect to the 340B Program for all program participants. Please feel free to contact us at 202-962-9200 if you have any questions regarding any of the issues raised in these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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Reimbursement and Health Policy

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Director
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Enclosure

Header Record				
#	**Invoice Elements**	Definition	Size	Type
1	Record type	Default of US	2	Character
2	State	State	2	Character
3	Invoice Program Name	Program Name of Invoice (e.g. AK-SPAP)	30	Alpha/Numeric
4	Record Id	Indication of what type for rebate eligible utilization (e.g. FFSU vs. MCOU)	4	Character
5	Rebate Quarter	Medicaid Drug Rebate Invoice Number that included the claim in the units billed	5	Numeric QYYYY
6	Date File Generated	Data file was created	8	Numeric CCYYMMDD
Detail Record				
	Provider Elements	Definition	Size	Type
7	Plan Name	Plan name for Managed Medicaid claims (e.g. Blue Cross of State etc)	30	Alpha/Numeric
8	Service Provider ID (NPI)	National ID for the provider who administered the drug	15	Alpha/Numeric
9	Provider 340B ID	340B identifier of the purchasing entity	10	Alpha/Numeric
10	Service Provider ID (Medicaid)	State Medicaid id for the provider who administered the drug	15	Alpha/Numeric
11	Service Provider Name	Name of the provider who administered the claim	30	Alpha/Numeric
12	Provider Street Address	Physical street address of the provider who administered the claim	30	Alpha/Numeric
13	Provider City	Physical city of the provider who administered the claim	30	Alpha/Numeric
14	Provider State	Physical state of the provider who administered the claim	2	Alpha/Numeric
15	Provider Zip Code	Physical zip code of the provider who administered the claim	15	Alpha/Numeric
	Claim Elements	Definition	Size	Type
16	Invoice Cycle Quarter	Medicaid Drug Rebate Invoice Quarter that invoice PPA was sent with original	5	Numeric QYYYY
17	Claim Type	Type of claim for rebate eligible drug product (e.g. pharmacy claim, physician administered claim, crossover etc)	5	Alpha/Numeric
18	Claim Status	Status of claim Paid/Reversed/Voided/Adjusted	2	Alpha/Numeric
19	ICN	Unique identifier of state records for the claim	21	Alpha/Numeric
20	Claim Line #	The claim line number	3	Alpha/Numeric
21	NDC	NDC of the drug administered	11	Alpha/Numeric
22	NDC Description	Description of NDC on claim	30	Alpha/Numeric
23	Package Size	Package size for associated drug product	10	Alpha/Numeric
24	HCPCS	HCPC billed on claim	5	Alpha/Numeric
25	Original Claim Quantity	Number of units submitted on the claim	15	Numeric -
26	Conversion Factor	Conversion Factor applied to original claim quantity.	8	Numeric -99999999.999
27	Invoice Quantity	Invoiced Units	15	Numeric - 99999999999.999
28	State Unit of Measure	State Provider Reimbursement Unit of Measure	15	Alpha/Numeric
29	Days Supply	Indication of how many days a pharmacy claim is meant to last the patient	4	Numeric
30	Prescription Number - RX#	Prescription ID for pharmacy claims	15	Alpha/Numeric
31	Refill Code	Indication of whether the record is a refill for a previously submitted script	2	Numeric
	Invoice Elements	Definition	Size	Type
32	Date of Service	Date that the drug was dispensed	8	Numeric CCYYMMDD
33	Adjudication Date	Date state adjusted the claim in the system	8	Numeric CCYYMMDD
34	Paid Date	Date the state paid the provider for the drug	8	Numeric CCYYMMDD
35	Billed Amount	Amount billed by provider for drug product	12	Numeric - 999999999.99
36	Allowed Amount	Amount Allowed for drug product by the state (EAC, MAC, etc)	12	Numeric - 999999999.99
37	Provider Paid/Reimbursed Amount	Reimbursement to the provider paid by the state, if applicable	12	Numeric - 999999999.99
38	Copay	Patient Co-Pay for the Claim	12	Numeric - 999999999.99
39	Dispensing Fee	Dispensing Fee paid to the provider for the claim	12	Numeric - 999999999.99
40	TPL	The third party amount reimbursed (by non-Medicaid entities) to providers for drug product	12	Numeric - 999999999.99
41	Reimbursement Indicator	Indicator to specify pricing used for claim such as EAC, SMAC, MAC, or 340B acquisition cost	2	Alpha/Numeric
42	BMN/DAW Indicator	Indication of whether the claim required Dispensed as Written authorization	1	Alpha/Numeric
43	Crossover Indicator	Indication of whether the claim was a Crossover Medicare (B or C)	1	Alpha/Numeric
44	Compound Indicator	Indication of whether the record was part of a compounded fill	1	Alpha/Numeric
45	UD modifier	Indication of whether or not the claim reimbursed at PHS acquisition cost or PHS	2	Alpha/Numeric
46	Prescriber ID	Provider id of the physician that prescribed the drug product (prescribing physician	15	Alpha/Numeric
47	Part D Dual Eligible Indicator	Indication of whether recipient is dual eligible (Medicare D)	1	Alpha/Numeric
	Product Elements	Definition	Size	Type
48	PA Indicator	Indicator if product requires PA or Non-PA	1	Alpha/Numeric