BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC DELIVERY

Dorcas Ann Taylor
Public Health Analyst
Office of Pharmacy Affairs (OPA)
Heath Systems Bureau (HSB)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Room 10C-03
Rockville, MD 20857

Re: Comments on Dispute Resolution

Dear Ms. Taylor:

The Biotechnology Industry Organization ("BIO") appreciates this opportunity to respond to HRSA's September 20, 2010 advance notice of proposed rulemaking and request for comments ("ANPRM") seeking to obtain information and public comment on how to efficiently and effectively implement the administrative process for dispute resolution authorized in Section 7102 of the Patient Protection and Affordable Care Act ("Affordable Care Act"), Pub. L. 111-148. *See* 75 Fed. Reg. 57,233 (Sept. 20, 2010). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. It represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO supported passage of the Affordable Care Act.

BIO appreciates that HRSA is proceeding with care to develop standards for implementing the newly authorized administrative process for dispute resolution. We believe that the administrative process will include significant changes to the 340B Program that require stakeholders to have an opportunity to fully review, analyze, and comment on any proposal to ensure that all perspectives are accounted for before any proposal is finalized. We proceed to address each of the topics on which HRSA is expressly seeking comment. Additionally, we have included in the appendix a letter that BIO previously sent to HRSA outlining a number of issues in which we seek further guidance.

Although HRSA does not specifically solicit comments on the definition of a "patient," of a covered entity, we note that this definition may well arise as an issue of disagreement that would be subject to the dispute resolution process contemplated by this notice. On January 12, 2007, HRSA proposed clarifications to the definition of a "patient" for whom a covered entity can purchase discounted pharmaceuticals under the 340B Program (see 72 FR 1543). To date,

this guidance has not been finalized. As HRSA moves forward with the implementation of the dispute resolution process, BIO urges the agency to also finalize the guidance issued on January 12, 2007.

I. Administrative Procedures

BIO suggests that the administrative process for dispute resolution should be initiated by a manufacturer or covered entity filing a notice of intent to seek dispute resolution with HRSA. Ideally, HRSA would publish on its website the official contact person at each manufacturer and covered entity so that the notice is sent to the proper individual.

During the administrative process, the Federal Rules of Evidence should not apply and all evidence that is not irrelevant, immaterial, or privileged should be admissible. A notice of intent to seek dispute resolution should spell out, similar to a complaint in a civil litigation matter, a covered entity's allegations that it was overcharged (including the specific product(s), time frame(s), price(s) charged and the factual basis for alleging the purchase involved an overcharge) or a manufacturer's allegations that a covered entity improperly received double discounts or rebates or engaged in diversion or prohibited re-selling (including the specific product(s), time frame(e), the factual basis for alleging a double discount or other improper rebate, diversion, or re-selling occurred, and the audit findings supporting that assertion). The parties to the administrative process will include the manufacturer(s) and covered entity/entities.

We suggest that the parties to the administrative process be given the option of voluntarily entering mediation instead of arbitration, but that if all parties do not agree to mediation or if the mediation is ultimately unsuccessful, the process move to binding arbitration. For mediated disputes, the agency would provide a trained, neutral third party to help negotiate a resolution to the dispute through joint and private sessions with the parties. If mediation is unsuccessful or the parties do not agree to mediate the dispute, the next step of the administrative process would be arbitration—where we suggest a panel of wholly independent trained arbitrators would determine, after a hearing, if wrongdoing occurred and what the appropriate compensation is for that misconduct. BIO proposes that the panel issue a proposed determination, provide the parties an option to file objections, and then issue a final, binding determination (subject to internal and judicial review for error).

Both processes should be confidential, and there should be no notice to third parties or the public before there is a negotiated resolution or a determination by the arbitration panel. We suggest that one term of any negotiated resolution could be whether the resolution is made public. In some situations, it may be easier to reach a resolution in a closed proceeding.

II. Existing Models

One of the more successful dispute resolution models seems to be that used by the Department of Justice. Over the last three years, between 69-79% of proceedings using voluntary alternative dispute resolution through the Department of Justice ("DOJ") have resulted in resolution of the issue. *See* DOJ Statistics, http://www.justice.gov/odr/doj-statistics.htm; see 61 Fed. Reg. 36,895 (July 15, 1996) (setting out policy); *see also* Jeffrey M. Senger, *Federal*

Dispute Resolution: Using ADR With the United States Government (Jossey-Bass/John Wiley & Sons, 2004) (Foreword, Preface, and Chapter One *available at* http://www.justice.gov/odr/articles.htm). The DOJ proceedings have involved a wide-ranging variety of matters, including disputes arising in the antitrust, environmental, tax, civil rights, and civil contexts. The structure of DOJ's dispute resolution includes numerous techniques that employ a neutral third-party to assist in resolution of a dispute, and could provide a model for HRSA. Alternatively, HRSA could consider using a private organization, such as the American Arbitration Association, which has a National Healthcare Roster of individuals with health industry experience. *See* American Arbitration Association, Healthcare ADR Services, http://www.adr.org/sp.asp?id=28810.

In the ANPRM, HRSA commented that one of the "most useful" models for dispute resolution is the current voluntary dispute resolution guidelines for the 340B Program, 61 Fed. Reg. 65,406 (Dec. 12, 1996). BIO does not agree that this model is useful or with the statement that this model has been underutilized only because it is a voluntary process. As an initial matter, the model has not just been "underutilized"—which would suggest it has been utilized at all, but not to its full potential—but rather, as HRSA staff, pharmaceutical manufacturers, entities, and other industry experts have admitted, "no one has engaged in the dispute resolution process." Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG"), *Deficiencies in Oversight of the 340B Drug Pricing Program* at 16 (Oct. 2005) (OEI-05-02-0072); *id.* at 17 (referring to HRSA's current authority through the voluntary dispute resolution process as "ineffective[ ]"). While in the time since that report, we understand that one dispute resolution matter was initiated, and that one of the parties to that dispute refused to participate. As such, it is our understanding that no disputes have ever been resolved through the existing model.

The current dispute resolution process clearly has to be substantially recalibrated to be useful. It has not been used because it is overly burdensome and overly costly to manufacturers. In particular, the way the audit process has been implemented requires considerable retooling. Manufacturers are unlikely to be able to document an allegation of diversion or duplicate discounts absent an audit of the covered entity. Under the 1996 guidance, a manufacturer must submit an audit work plan for the Department's review and to establish reasonable cause, 61 Fed. Reg. at 65,406, and then hire an independent public accountant to perform the audit, *id.* at 65,408. Simply put, these steps are too costly and burdensome for manufacturers. Manufacturers need access to the necessary data without having to incur the considerable expense of hiring an independent audit firm. There is no reason to require manufacturers to use auditors other than their internal auditors, who could audit a covered entity at significantly less expense and with more efficiency for all parties.

BIO instead suggests that, using the existing reasonable cause standard, the manufacturer need only submit an audit plan to HRSA, giving HRSA 30 days to raise an objection to the plan. If no objection is raised, BIO believes the manufacturer should be able to conduct the audit spelled out in the audit plan either itself or through a third-party firm identified in the audit plan, and submit the resulting audit report to HRSA. If HRSA objects to any part of the plan, the manufacturer can submit a revised plan, triggering a new 30-day response period for the agency. BIO also suggests that HRSA establish a process through which a redacted version of the audit report findings can be made available to other manufacturers that want to audit the same covered

entity for a similar reason in a similar timeframe—thereby further decreasing the cost and burden associated with the audit process.

As for covered entity audits of manufacturers, BIO requests that HRSA clarify that any audit of ceiling price accuracy cannot extend to the accuracy of the underlying pricing figures, *i.e.*, average manufacturer price ("AMP") and/or best price ("BP"). Such audits must be limited to whether the manufacturer has correctly calculated the ceiling price based on its reported AMP and the unit rebate amount ("URA"). In so doing, the covered entity cannot seek to use an audit to analyze whether the manufacturer correctly calculated AMP and URA. Those calculations are governed by distinct standards, regulations, and guidance from the Centers for Medicare and Medicaid Services and are an inappropriate subject for covered entity review.

III. Threshold Requirements

BIO proposes that a party seeking alternative dispute resolution be required to set for facts showing that: (1) it engaged in good faith efforts to resolve its difference with the other side; (2) its claim can meet a materiality standard; and (3) it has good cause for bringing the case to dispute resolution. In addition, should develop a mechanism for a defendant in a dispute resolution proceeding to seek dismissal on grounds akin to Federal Rule of Civil Procedure 12(b).

BIO strenuously objects to HRSA's suggestion that an overcharge subject to dispute resolution could include an allegation of a manufacturer's refusal to sell a covered outpatient drug at the 340B ceiling price. First, CMPs are restricted to situations involving an overcharge, and a refusal to sell is not an overcharge. Second, even if it were an overcharge, a manufacturer will not have obligation to offer until HRSA issues a new Provider Participation Agreement ("PPA") and manufacturers contractually obligate themselves to offer the ceiling price to covered entities by signing it. Until the Affordable Care Act was enacted, manufacturers had no obligation to offer their products to 340B covered entities. Nowhere in the 340B Program is there a mandate to offer products or a specific requirement that all, or any particular portion of a 340B entity's request to purchase product be fulfilled. Consistent with the Program requirements, the PPA currently in effect only governs the price that manufacturers can charge covered entities for covered outpatient drugs.

IV. Hearings

BIO agrees that the dispute resolution mechanisms adopted by HRSA should include the opportunity for a hearing. The type of hearing and rules regarding the hearing practice will necessarily turn to some degree on the particular dispute resolution mechanism(s) at play. For instance, *ex parte* communications may be part of a mediation session as a mediator speaks in private with each side of a dispute in a way, but *ex parte* communication should not be part of an arbitration process. The regulations should provide for hearing conferences, subpoenas to ensure the availability of discovery—including third-party discovery, and detail the form and service requirements for a motions practice, evidentiary rules, and post-hearing briefs.

Alternative dispute resolution should not be bound by the Federal Rules of Evidence, although the dispute resolution body (whether mediator or arbitrators) should exclude evidence

that is irrelevant, immaterial, privileged, that was part of a settlement offer, or where the probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues or considerations of undue delay or needless presentation of cumulative evidence. That is typically the way dispute resolution works. *See, e.g.*, Rule 31, Commercial Arbitration Rules and Mediation, *available at* http://www.adr.org/sp.asp?id=22440#R31 ("Conformity to legal rules of evidence shall not be necessary. . . . The arbitrator shall determine the admissibility, relevance, and materiality of the evidence offered and may exclude evidence deemed by the arbitrator to be cumulative or irrelevant. . . . The arbitrator shall take into account applicable principles of legal privilege, such as those involving the confidentiality of communications between a lawyer and client."). Rebuttal witness and evidence should be permitted, and the burden of proof should be a preponderance of the evidence, as is generally applicable in civil proceedings.

In connection with or in preparation for the hearing, a manufacturer may need to obtain materials to defend itself, including from non-parties to the dispute resolution proceeding, such as wholesalers or distributors. Program guidance makes clear that manufacturers must make the ceiling price available through wholesalers when the manufacturer sells through wholesalers, and that the use of wholesalers is for the convenience of both the manufacturers and the covered entities. *See* 59 Fed. Reg. 25110 (May 13, 1994). The dispute resolution process should ensure that a manufacturer has access to third-party discovery and testimony needed to present its affirmative case or defense.

V. Decision-making Official or Body

We suggest that the decision making official or body should vary with whether the parties are pursuing mediation or arbitration as the dispute resolution mechanism. In mediation, there is generally a single mediator who works to negotiate a resolution of the issues. In arbitration, in contrast, there is often a decision-making panel that has expertise in the area of law. BIO proposes that the panel be drawn from a list of wholly independent qualified arbitrators maintained by the agency. Each side would then have input into setting up the arbitration panel that will have the authority to offer a binding resolution of the dispute (subject to appeal), such as a set number of strikes to exercise.

VI. Appropriate Appeals Procedure

Parties submitting a dispute to binding arbitration as a means of alternative dispute resolution should have access to judicial review for errors of fact or law. Parties who reach a mediated settlement should have access to the judicial process only to enforce an agreed-upon settlement, which would be enforceable just as any other contract would be.

VII. Deadlines

Given the record keeping costs and burdens of maintaining sufficient records to bring or defend a claim through dispute resolution, BIO suggests that the same four year statute of limitations apply to dispute resolution as BIO has suggested should apply to HRSA's civil monetary penalty authority. Parties should typically be granted 30 days to respond to any filing,

to balance the need for a timely response with the time necessary to investigate, research, and adequately respond to assertions and evidence submitted by the other side; and notice of a hearing date should give all parties at least 60 days to prepare.

VIII. Discovery Procedures

The mediator or arbitrators should use a preliminary hearing to establish the extent to which discovery is necessary and shall be conducted and the procedure for issuance of subpoenas. In general, information, reports, answers, records, accounts, papers, and other documentary evidence should be discoverable so long as it may lead to relevant, material evidence. Discovery should be limited, and protective orders should be available, only where a party can demonstrate that the information sought is irrelevant, immaterial, privileged, or would be unduly burdensome to produce. A protective order should also be available to protect all parties' confidential business information. To the extent documentary evidence is needed from a non-manufacturer, non-covered entity third party, HRSA should utilize its maximum regulatory authority—direct or indirect—over those entities to ensure that material is produced. For example, if a wholesaler refuses to provide such documentary materials in a third-party discovery context, HRSA should exclude any claims based on transactions with that wholesaler. If manufacturers cannot get the wholesaler data necessary to defend themselves, then those claims should be dropped from dispute resolution procedures.

IX. Manufacturer Audits

As discussed above, the current process for manufacturer audits has to be substantially recalibrated to be useful. It has not been used to date because it is overly burdensome and overly costly to manufacturers.

X-XI. Consolidation of Manufacturer and Covered Entity Claims

BIO agrees that there should be a process for consolidating manufacturer and covered entity claims. The standard should be the same for both categories of entities. If HRSA adopts a presumption in favor of allowing consolidation of covered entity claims, as a matter of balance and fairness, it should apply the same presumption in favor of allowing consolidation of manufacturer claims. A consolidation determination should rest primarily on consideration of whether the claims present common questions of law or fact such that it is more cost- and time-efficient to consolidate them and whether consolidation presents any fairness concerns. Consolidation requests should occur at the initial stages of dispute resolution so that all of the parties are established before the process gets underway. Furthermore, before becoming part of a consolidated request, each entity should demonstrate that it individually meets the criteria for seeking alternative dispute resolution, as outlined above in our comment on "Threshold Requirements."

XII. Claims by Organizations Representing Covered Entities.

BIO supports HRSA's effort to ensure that organizations claiming to represent covered entities have a signed agreement with the covered entities indicating that the organization is

authorized to bring a claim on behalf of the covered entities; the precise nature of the claim; the covered entities' agreement to participate in good faith and abide by discovery procedures; and the covered entities' agreement to be bound by any decision of the decision-making official or body. BIO requests that HRSA provide a parallel mechanism for an organization representing manufacturer claims, with parallel requirements for such claims to proceed.

XIII. Integration of Dispute Resolution with Other Provisions in the Affordable Care Act

BIO agrees that it is appropriate for HRSA to carefully implement the administrative process for dispute resolution with the other oversight mechanisms. Given the significant changes to the 340B Program enacted in the Affordable Care Act, we suggest that it makes sense to ensure that certain changes to the program—(1) developing and publishing HRSA's standards and methodology for calculating ceiling prices through a notice and comment rulemaking process; (2) establishing a single, universal, and standardized identification system to readily identify covered entities; and (3) establishing credit and refund mechanisms—are in place before activating use of the dispute resolution mechanism for claims involving these issues. Only then could the dispute resolution process be used in a fair and efficient manner as an oversight mechanism. BIO again reiterates the importance of granting stakeholders an opportunity to fully review, analyze, and comment on any dispute resolution proposal to ensure that all perspectives are accounted for before any proposal is finalized.

Conclusion

BIO looks forward to working with HRSA over the coming months and years to implement the dispute resolution process contemplated in the Affordable Care Act. We hope that the agency finds this letter to be helpful as it begins this process. Please feel free to contact Laurel Todd at 202-962-9220 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/

Laurel Todd
Managing Director, Reimbursement and Health Policy

Sandra Dennis
Deputy General Counsel, Health

APPENDIX

September 3, 2010

BY ELECTRONIC DELIVERY

Commander Krista Pedley
Director
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Rockville, MD 20857

Re: Implementation of the Patient Protection and Affordable Care Act, as Amended by the Health Care and Education Reconciliation Act of 2010

Dear Commander Pedley:

The Biotechnology Industry Organization (BIO) is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. Accordingly, we were pleased to support passage of the Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act of 2010 (HCERA) (collectively, the Act).

Now that PPACA and HCERA have been enacted, we recognize HRSA has responsibility for implementing many of the Act's provisions relating to the 340B drug pricing program. We understand that HRSA is considering issuing a rulemaking to implement these requirements. BIO applauds HRSA for pursuing this approach, as we believe that changes of this significance should be implemented only through a notice-and-comment rulemaking process, allowing stakeholders to fully review, analyze, and comment on those proposals ensuring all perspectives are accounted for before any proposal is finalized.

In this regard, and to assist the agency in its implementation work, BIO would like to take this opportunity to bring to your attention a number of issues that we believe need to be addressed in any guidance or proposed rules HRSA issues related to sections 7101 and 7102 of PPACA, and section 2302 of HCERA, which make changes to section 340B of the Public Health Services Act. We also highlight ongoing issues relating to enforcement of the existing statutory prohibitions on duplicate discounts and diversion under the 340B statute.

I. Expansion of 340B Program and Retroactive Rebates

Section 7101(a) of PPACA amended the definition of a covered entity under section 340B to include new categories of hospitals. HRSA has implemented a rolling admission

process for these new entity types, beginning August 2, 2010 through September 30, 2010. Neither HRSA's July 28 webinar regarding this enrollment process nor the enrollment guidance provided on HRSA's website state that the new covered entity types are eligible for retroactive rebates back to January 1, 2010, the effective date of section 7101. By comparison, when HRSA issued its guidance regarding registration of children's hospitals pursuant to the Deficit Reduction Act of 2005 (DRA), its Final Notice expressly authorized those entities to request retroactive rebates and defined the process for doing so.[1] BIO interprets the absence of guidance to date regarding retroactive rebates for the section 7101 new entity types to mean that HRSA is not permitting those entities to seek such rebates and requests that HRSA confirm that is the case.

To the extent that HRSA will permit these newly eligible entities to seek retroactive rebates on covered outpatient drugs back to January 1, 2010, it is crucial that HRSA require the entity to demonstrate its eligibility for the entire period for which rebates are sought and also to certify its satisfaction of program requirements during that same period, consistent with OPA's previously defined approach for children's hospitals that seek retroactive rebates. BIO believes that HRSA should implement this same procedure with regard to retroactive rebates requested by the new covered entity hospital types, if such rebates are permitted, because manufacturers have experience in coordinating with covered entities regarding such requests. Consistent with this approach, HRSA also should limit the time period for covered entity requests for rebates to a period of 30 days post enrollment. Finally, BIO asks that HRSA include in its system for verifying the accuracy of information provided by covered entities, as discussed further below, a distinct identifier for those entities eligible for retroactive pricing and discounts.

II. Amendment to Pharmaceutical Pricing Agreement (PPA)

Section 7102(b) of PPACA amends section 340B to add two new requirements for the Secretary's PPA with the manufacturer. The first requirement is for manufacturer submission of ceiling price data to the Secretary and the second requirement is that "the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." BIO asks that HRSA confirm that these new requirements will be implemented either through a new PPA or an amendment to manufacturers' existing PPA and that HRSA notify manufacturers regarding when HRSA expects to issue this new agreement or amendment.

As to the second, "must offer," requirement, we also request that HRSA confirm that manufacturers may use a reasonable allocation methodology, so long as that methodology does not discriminate based on a customer's 340B status. Where the FDA imposes requirements on the manufacturer regarding the distribution of a drug, such as Risk Evaluation and Mitigation Strategies, or REMS, and those FDA mandates limit a manufacturer's distribution avenues for particular products and/or impose compliance requirements on those entities that wish to dispense or administer a particular drug to a patient, HRSA should make clear that the manufacturer need not offer a product for sale to a covered entity unless and until the covered

[1] 74 Fed. Reg. 45206 (Sep. 1, 2009).

entity can qualify under those FDA-required standards. Finally, we request that should a manufacturer choose to seek guidance from the agency regarding implementation of such an allocation procedure, HRSA identify a point of contact to address such questions.

III. Program Integrity Changes to 340B Program

A. Ceiling Price Website

We understand that section 7102 requires the Secretary to develop a system to verify the accuracy of ceiling prices calculated by manufacturers and also to make 340B prices accessible to covered entities through an Internet website. BIO recommends that this website allow manufacturers to load their pricing data directly, similar to the Drug Data Reporting (DDR) system manufacturers currently use to report pricing and product data under the Medicaid drug rebate program, and that manufacturers be required to enter such data by the first day of the start of each quarter. The website also should include a flag to indicate to covered entities when the ceiling price for a particular drug has been updated, as discussed further below.

In implementing this provision, the Secretary is required to provide covered entities with access to these pricing data "in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized redisclosure." BIO is concerned that password protection alone is not sufficient to protect manufacturer data from unauthorized redisclosure, as required by the statute. We urge HRSA to implement additional safeguards to adequately protect against such redisclosure, including the establishment of penalties for covered entities that disclose ceiling price data. In developing these safeguards, we also ask that HRSA create procedures that address specific scenarios that are likely to arise, such as where a covered entity loses eligibility, or where an employee leaves one covered entity and becomes employed by another. HRSA's security procedures should address how it will manage passwords and control access to manufacturer data in such circumstances to ensure unauthorized disclosure does not occur.

B. True-Up of Ceiling Prices

Section 7102 requires the Secretary to establish procedures for manufacturers to issue appropriate refunds to covered entities in the event of an "overcharge," including where the overcharge results from a routine restatement of average manufacturer price (AMP) or Best Price (BP) data. BIO requests that HRSA confirm that any such procedures will apply prospectively only. BIO also strongly recommends that in establishing procedures for such refunds, HRSA include a materiality standard, a right to offset against undercharges, and a standardized process for issuing refunds, as discussed below. Finally, while BIO includes proposals below regarding how to operationalize the true-up and refund process, BIO strongly encourages HRSA to create a working group of stakeholders to further review and advise HRSA regarding the creation and implementation of such operational concerns.

1. The True-Up Requirement Should Apply Prospectively Only

Section 7102 requires HRSA to provide for the "establishment of procedures" and the "development of a mechanism" for the issuance of refunds to covered entities in the event of a change in a prior ceiling price. Although PPACA section 7101(e)(2) states that the amendments made by section 7102 shall be effective on January 1, 2010 and shall apply to drugs purchased after that date, it more specifically directs that a process must be established from appropriated funds so that manufacturers may make the refund payments. BIO believes, therefore, that the proper reading of the statute is that these processes, once created, will apply on a prospective basis only. We also recommend that these processes be reflected in the new PPA or PPA amendment, as discussed in Section II above. BIO also believes that this is the only workable approach from an operational perspective. The application of these processes, which are still undefined and will be complex to implement even on a prospective basis, will almost certainly present even greater if not insurmountable barriers if any attempt is made to apply them to prior periods. As should be apparent from the proposals discussed below, the implementation of the true-up and refund requirements will involve tremendous operational complexity for manufacturers of all sizes, as well as the entities who will benefit. Such complexities can be addressed and overcome when the parties have notice and time to develop and implement appropriate systems on a prospective basis. Application of such systems to prior periods, where the data and processes in place before were not designed to account for such requirements, will almost certainly result in errors and enormous administrative burdens on all parties involved.

2. HRSA Should Establish a Materiality Standard

Routine restatements of AMP and/or BP data have the potential to cause changes to prior ceiling prices that are material and where a refund to the covered entity would be appropriate under PPACA. However, BIO understands that such AMP and BP revisions (these figures are calculated to seven decimal places and rounded to six) are equally likely to result in ceiling price changes that are *de minimis*, such that only nominal refunds, whether issued by credit memo or check, would be due. Requiring manufacturers to issue such nominal refunds to each of the over 14,800 covered entities that may have purchased a drug at the prior ceiling price anytime there is a change to that price would be tremendously burdensome on manufacturers, OPA, covered entities, and wholesalers. BIO therefore urges HRSA establish a *de minimis* or materiality threshold for ceiling price changes that require refunds, such that the manufacturer would not be obligated to issue a refund where the restatement of AMP or BP for the quarter results in a decrease that is less than 2.0 percent of the original ceiling price paid by the covered entity. Where the change in the ceiling price exceeds this threshold, we further recommend that HRSA require refunds only where the total amount due the covered entity for all material ceiling price changes for that quarter across all products is at least $200.00. We note that the administrative cost to the manufacturer of issuing a check of any sort typically is approximately $100.00 and so is the appropriate materiality threshold for refunds.

Numerous federal standards, including those adopted by the Department of Health and Human Services, support the application of a materiality standard in different contexts where government funds are at issue. While the above proposed materiality standards would apply to

the payment of refunds to covered entities, and so would not involve refunds to the federal government itself, the government's own willingness to apply such standards to its own fiscal matters clearly supports the reasonableness of doing so as to covered entities as well. The standards we discuss below are the government's Cost Accounting Standards (CAS) as well as three materiality standards from the Department of Health and Human Services (HHS), all of which rely on a 5% materiality threshold – significantly higher than what BIO is requesting here.

The CAS are a set of accounting principles intended to improve uniformity and consistency in the measurement, assignment, and allocation of costs to government contracts. They apply to negotiated contracts and subcontracts in excess of $650,000, subject to certain exceptions.[2] Under CAS, the contractor's Administrative Contracting Officer (ACO) must determine whether CAS noncompliance or changes to the contractor's cost accounting practices results in increased costs to the Government. As part of that review, the ACO makes a determination of materiality of the cost impact. If the change or noncompliance is deemed to have an immaterial cost impact, then no contract adjustments are made.[3] The materiality standard is set forth at 48 C.F.R. § 9903.305:

> In determining whether amounts of cost are material or immaterial, the following criteria shall be considered where appropriate; no one criterion is necessarily determinative:
>
> > (a) The absolute dollar amount involved. The larger the dollar amount, the more likely that it will be material.
> >
> > (b) The amount of contract cost compared with the amount under consideration. The larger the proportion of the amount under consideration to contract cost, the more likely it is to be material.
> >
> > (c) The relationship between a cost item and a cost objective. Direct cost items, especially if the amounts are themselves part of a base for allocation of indirect costs, will normally have more impact than the same amount of indirect costs.
> >
> > (d) The impact on Government funding. Changes in accounting treatment will have more impact if they influence the distribution of costs between Government and non-Government cost objectives than if all cost objectives have Government financial support.

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[2] There are exceptions to application of CAS for, among other things, contracts and subcontracts with small businesses, fixed-price contracts, and subcontracts for commercial items, etc. 48 CFR 9903.201-1,2.

[3] 48 C.F.R. § 30.602.

> (e) The cumulative impact of individually immaterial items. It is appropriate to consider whether such impacts:
>
> > (1) Tend to offset one another, or
> > (2) Tend to be in the same direction and hence to accumulate into a material amount.
>
> (f) The cost of administrative processing of the price adjustment modification shall be considered. If the cost to process exceeds the amount to be recovered, it is less likely the amount will be material.

We believe these factors, which weigh both the absolute and proportionate dollar amount involved as well as the costs of administrative processing, are equally applicable to and supportive of the creation of a materiality threshold for ceiling price revisions and covered entity refunds.

Within HHS, the Office of Inspector General (OIG) has adopted a five percent materiality threshold with regard to the Independent Review Organization (IRO) review of a manufacturer's reported average manufacturer prices (AMPs) and average sales prices (ASPs) pursuant to a Corporate Integrity Agreement (CIA) with the OIG. In at least three separate CIAs, the OIG has applied a threshold of "a net dollar error rate of 5% or greater" for purposes of the IRO's review.[4] Under this standard, if the Error Rate is lower than five percent, the data is not reviewed by the OIG at all.

Again with HHS, the National Institutes of Health has adopted a materiality standard in relation to cost accounting under federal grants, where charges to a grant for salaries and wages of persons working on the grant are based on the percentage of time the employee spends on the grant versus other institutional work the employee performs. For example, if the employee spends 50 percent of his/her time on the grant, then 50 percent of his/her salary can appropriately be charged to the grant. The rate at which a salary is charged to a grant typically is set at the

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[4] Merck CIA, available at http://oig.hhs.gov/fraud/cia/cia_list.asp#b (Feb. 5, 2008) ("If any discovery sample defined in Section II.C.1 reveals a net dollar Error Rate of 5% or greater, Merck and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings."); Bristol-Myers Squibb Company CIA, available at http://oig.hhs.gov/fraud/cia/cia_list.asp#b (Sep. 26, 2007) ("The IRO shall test a probe sample of 30 Transactions from each universe of Transactions Types for the selected quarter. If the IRO finds a net dollar error rate of 5% or more of the total sample size in any probe sample, BMS and the IRO shall hold an interim conference with the OIG to discuss the IRO's preliminary findings."); Aventis Inc. et al. CIA, available at http://oig.hhs.gov/fraud/cia/cia_list.asp#b (Aug. 29, 2007) ("The IRO shall test a probe sample of 30 Transactions from each universe of Transactions Types for the selected quarter. If the IRO finds a net dollar error rate of 5% or more of the total sample size in any probe sample, API and the IRO shall hold an interim conference with the OIG to discuss the IRO's preliminary findings.").

outset of the grant based on anticipated effort, before the work is performed, and then reviewed after a set period to verify the accuracy of the effort. If there is a "significant" change between the actual effort versus budgeted effort, an adjustment needs to be made.[5] There is no specific definition of "significant", but the NIH has adopted a general rule that a change of five percent or more of an employee's total effort would require an adjustment to the effort report (and accordingly, the amount chargeable to the grant).[6]

The Medicare program also applies a materiality standard with respect to the substitution of the average sales price (ASP) for purposes of setting Medicare reimbursement. Section 1847A(d)(3) of the Social Security Act permits the Secretary of HHS in setting reimbursement rates under Medicare Part B to disregard the ASP of a drug and substitute an alternative price as the basis for Part B reimbursement rates where an ASP exceeds the widely available market price (WAMP) or the AMP for the drug by an applicable threshold. Congress established an initial threshold of five percent through 2006, likely based on its own balancing of the savings generated by such price substitutions versus the burden imposed on both CMS and Medicare contractors by such substitutions. Although the Secretary has discretion under the statute to adjust the threshold for years after 2006, the Secretary has yet to do so.

These materiality criteria and standards make clear that the government itself, and HHS specifically, has recognized that the balancing of the dollars involved versus the burden of all parties is an appropriate consideration when determining refund obligations to the government. There is no reason why the same should not be true with respect to refund obligations to a covered entity. Based on the government's prior adoption of these factors, we believe the only question left for HRSA to consider is what the materiality standard should be. We believe our suggested thresholds are appropriate and reasonable, particularly given that HHS itself has adopted a higher 5% threshold in similar contexts.

3. HRSA Should Permit a Right of Offset

Where AMP and/or BP changes require changes to prior ceiling prices, we also urge HRSA to permit manufacturers to offset any overcharges due to retroactive decreases to ceiling prices by the amount of any undercharges made to the same covered entity that result from AMP and/or BP changes that cause ceiling prices to increase. The new statutory true-up requirement is intended to correct prior ceiling prices so that they accurately reflect any changes in the underlying pricing data. Those AMP and BP changes are as likely to move the ceiling price up as they are to move the price down. The new statutory language does not prohibit such upward adjustment to ceiling prices but rather specifies the need for "appropriate" credits and refunds. To ensure that ceiling price corrections fully reflect the actual underlying pricing data, we believe a fair approach would be to require manufacturers to true-up ceiling prices in both directions but allow manufacturers to offset upward adjustments in ceiling prices only up to the

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[5] OMB Circular A-21, Cost Principles for Educational Institutions.

[6] Joe Ellis, Acting Director of NIH's Office of Extramural Research Administration, Effort Reporting: Total Professional Activity vs. Institutional Activity (Enclosure A) (undated).

amount of any credit that otherwise is due to an entity for downward adjustments to ceiling prices. Specifically, these offsets would be on an entity-wide and quarterly basis, so that any refunds owed to an entity for any (material) ceiling price decreases in a past quarter would be offset by undercharges to that same covered entity for (material) ceiling price increases in that same quarter. *In this way, covered entities would never be obligated to make affirmative supplemental payments in relation to prior purchases; only the amount of any credit otherwise due would be decreased.*[7]

While we believe this offset approach is fair in its own right, we also believe that any OPA policy that prohibits manufacturers from offsetting refunds to covered entities in this manner would violate the provisions of the 340B statute and PPA, which both specifically permit but do not require manufacturers to offer sub-ceiling prices. We understand HRSA may view AMP/BP revisions that would cause a ceiling price to increase as converting a previous price set at the ceiling price level into a voluntary sub-ceiling price that therefore cannot be adjusted. This position ignores actual manufacturer intent and practice in setting the original price. A good faith ceiling price offered by a manufacturer is not transformed into a voluntary sub-ceiling price merely based on later, unintended, and legally mandated changes to AMP and/or BP. The 340B statute[8] and PPA[9] both make clear that manufacturers are permitted, but not required, to offer sub-ceiling prices. A policy that does not permit manufacturers to upwardly reconcile ceiling prices due to AMP/BP changes would, we believe, act as a de facto sub-ceiling mandate and a violation of the statute and agreement terms. We also believe manufacturers are entitled to such offsets based on principles of common law restitution.

We understand that HRSA may believe that refund offsets due to upward adjustments to ceiling prices may be unfair because the covered entity relied on the original, lower, ceiling price when making a purchase decision. The argument, as we understand it, is that if the covered entity had been aware that the ceiling price at which it originally purchased a particular drug would be upwardly adjusted, the covered entity instead would have purchased any equivalent product that was available at a price lower than the restated ceiling price. To the extent this argument may have merit, it would be valid only in following limited circumstances

1. The drug at issue would have to be a multiple source covered outpatient drug, because only multiple source drugs can be interchangeable such that price alone could be (although is not necessarily) the determining purchase criterion, *and*
2. The alternative multiple source drug would have to have been available at a price that is both higher than the original ceiling price of the product the covered entity did purchase, but still lower than the restated price, because only a product with a price between the

[7] Upward adjustments to ceiling prices should be subject to the same *de minimis* threshold applicable to downward adjustments to ceiling prices.
[8] 42 U.S.C. § 256b.
[9] 58 Fed. Reg. 27293 (May 7, 1993) (requiring manufacturers to enter into a pricing agreement); Department of Health and Human Services, Pharmaceutical Pricing Agreement (PPA) at 8 (Feb. 8, 2006).

original and restated ceiling prices price could be viewed as more attractive based on price alone.

Given the limited circumstances in which this concern could have any merit, it cannot provide a basis for barring offsets for all covered outpatient drugs in all circumstances. In the case of BIO member products specifically, which generally are biologics and therefore not multiple source drugs, this argument is simply not applicable at all.

To address those limited situations in which these concerns may be applicable, BIO believes it would be appropriate for HRSA to permit the covered entity to demonstrate to the manufacturer that there was another, alternative multiple source product available at the time of the original purchase that was priced less than the restated price but more than the initial price. It is appropriate to require the covered entity to raise this issue because only the covered entity will have access to the ceiling prices of the alternative multiple source drugs – manufacturers will not have access to ceiling price data from other manufacturers. For the same reason, we ask that HRSA review and validate such claims to confirm that an alternative drug was in fact available at the lower price. Where the covered entity is able to make such a showing, as verified by HRSA, the manufacturer would be required to modify its offset of any refund to the entity by recalculating the undercharge based on the difference between the new, higher ceiling price and the price of the alternative multiple source product (rather than the original ceiling price). For example, assume that a covered entity purchased a unit of a multiple source covered outpatient drug at a ceiling price of $1.00, and that this price subsequently was revised to $1.10 as a result of an AMP/BP restatement. If the covered entity is able to demonstrate that an alternative product was available at the time of the purchase at a price of $1.05, the manufacturer would be permitted to offset any refunds to the covered entity only by the amount of $0.05 per unit, rather than $0.10 per unit.

4. HRSA Should Establish a Standardized Process for Issuing Refunds

Finally, BIO strongly recommends that HRSA establish a standardized process for manufacturer issuance of refunds to covered entities that minimizes the administrative burden for manufacturers, covered entities, wholesalers, and HRSA itself. The standardization of this process is important because of the high volume of true-ups and refunds that are likely to occur due to the volume of products, covered entities, and manufacturers participating in the program. For example, manufacturers could be required to update the manufacturer's prices on the OPA website (as discussed above) to reflect revisions to ceiling prices. In this way, the OPA website could provide a centralized notification system through which covered entities could learn of price changes and the potential availability of refunds, particularly if the OPA ceiling price website includes a "flag" that indicates prices that have been updated. Such an indicator may be particularly useful in light of the fact that manufacturers are obligated to correct their AMP and BP figures within three years of when those figures originally were due, and some manufacturers may make corrections multiple times during that period.[10]

[10] See 42 C.F.R. §447.510(b).

We further recommend that HRSA define the refund process to be one in which the manufacturers are responsible for calculating refund amounts due and issuing those refunds to covered entities via designated contact, such as through the issuance of credits to a specified wholesaler. Where the credit is not taken by the covered entity within one year of being issued and after reasonable follow-up by the manufacturer, including seeking HRSA's assistance as needed, we recommend that the manufacturer be permitted to cancel the credit. The manufacturer would be required to maintain documentation regarding the calculation of the refund due, which would have to be made available to the covered entity upon request, but would not otherwise be required to be affirmatively issued to the covered entity. The covered entity identification system that the Secretary is required to develop, as discussed further below, should include the identification of either the entity's designated wholesaler to which refund credits should be issued on the entity's behalf (preferably the wholesaler through which the entity purchased the product), or other contact for receipt of refunds. The covered entity would be responsible for keeping this information current as well as following up with the manufacturer, as needed, with questions regarding such credits. Finally, manufacturers should be given at least 90 days after the revision of any AMP/BP figures to calculate the resulting price changes and credits due before being obligated to update the prior pricing data, to provide sufficient time to ensure that the revised pricing and credits are accurate. Manufacturers should be permitted to seek an extension to this 90-day time period in extraordinary circumstances, such as where a particularly high volume of price changes, drugs, or covered entities are involved. We also recommend that HRSA's dispute resolution procedures, as discussed further in Section IV, specifically address disputes regarding these issues.

Historically, the 340B program has sought to share the administrative burdens of the program between the manufacturer and the covered entity and so the recommended process above does so as well. For example, for new covered outpatient drugs for which AMP and BP data are not yet available, the manufacturer must estimate the ceiling price in accordance with OPA guidance because there are no historic AMP or URA data with which to calculate the ceiling price.[11] The manufacturer must provide a refund *as requested by a covered entity* where the estimated ceiling price exceeds the actual ceiling price for that same quarter. As OPA explained in its Final Notice, the mechanism for retroactive pricing adjustment reflects "an attempt 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."[12] Consistent with this historic approach, BIO believes setting forth the streamlined, cooperative process for issuing credits described above will ensure that covered entities receive accurate refunds in the most rapid and efficient manner while also limiting the administrative burden on all parties involved.

[11] 60 Fed. Reg. 51488 (Oct. 2, 1995).
[12] Id.

We understand that the 340B Program's prime vendor may be particularly and uniquely suited to play a role in the development and administration of this process. While BIO welcomes the prime vendor's valuable input on these issues, and certainly believes the prime vendor should be a member of any workgroup, as proposed below, created to discuss implementation processes, BIO also believes it will continue to be important to give all parties – manufacturers and covered entities – the choice as to whether to partner with the prime vendor on these operational matters. As is currently the case in the 340B program, we believe HRSA should continue to encourage but not require program participants to work with the prime vendor as to any aspect of the 340B Program.

Finally, given the highly operational nature of the issues related to establishing a single standardized process for issuing refunds to covered entities in the event of a ceiling price change, BIO recommends that HRSA create a working group of stakeholders that includes covered entities, manufacturers, and wholesalers to collaborate on the implementation of this process and any related operational concerns that may arise. Only through such a group is HRSA sure to fully identify and consider the multitude of operational issues that will play a role in implementing this new statutory requirement.

C. Verification of Covered Entity Eligibility and Implementation of a Standard Identifier

Section 7102 obligates the Secretary to develop a procedure to enable and require covered entities to regularly update their eligibility information and for HRSA to verify the accuracy of that information. In validating covered entity eligibility, HRSA should not permit those entities that no longer meet the statutory definition of a covered entity to continue receiving discounts under the 340B program while they work towards eligibility during that period. The 340B statute expressly limits the manufacturer's obligation to provide the ceiling price to covered entities as defined by the statute and does not permit a "grace period" for those non-eligible entities seeking to re-qualify. BIO also requests that HRSA address whether its system for verifying covered entity eligibility will include auditing or spot-checks of the registration information provided by the covered entity to ensure that such information is accurate.

PPACA also requires the Secretary to establish "a single, universal, and standardized identification system by which each covered entity site can be identified" for purposes of facilitating ordering, purchasing and delivery of covered outpatient drugs as well as the processing of chargebacks. BIO recommends that HRSA use Health Industry Numbers (HINs) for this purpose, because these universal identification numbers are already used by many end-customers, wholesalers and manufacturers alike, including for identifying end-customers in chargeback-based sales. HRSA should continue to assign and use the 340B ID number as well for back-up identification, because not all entities have a HIN. If both identification numbers are listed for each covered entity on the OPA database, manufacturers will be better able to identify and validate covered entity eligibility for ceiling prices and ensure those discounts are provided

as appropriate. We ask that HRSA require that covered entities submit both identifiers to the wholesaler at all times.

IV. Administrative Dispute Resolution Regulations and Process for Imposition of Sanctions

PPACA requires the Secretary to promulgate regulations to establish and implement an administrative process for resolution of claims by covered entities and manufacturers, within 180 days of enactment. The Secretary also must establish a process for determining non-compliance by manufacturers and covered entities and for imposition of sanctions. In implementing these requirements, BIO urges HRSA to include in its proposed rule and process the following elements, to best protect the interests of all parties:

- The evidentiary standard (e.g., a preponderance of the evidence);
- Right to discovery and discovery procedures;
- Available remedies, if any, beyond those specified by the statute; and
- Confidentiality of the proceedings and the resolution.

V. Audits of Manufacturers and Wholesalers

Section 7102 of PPACA requires the Secretary to provide for "[s]elective auditing of manufactures and wholesalers." BIO requests that to the extent HRSA permits covered entities to conduct such audits, it apply the same standards that currently apply to audits by manufacturers under HRSA's existing audit guidelines.[13] These safeguards, including submission of an audit work plan documenting reasonable cause for the audit and retention of an independent auditor, will help to minimize the risk of disclosure of the manufacturer's confidential information as well as reduce the administrative burden on manufacturers.

VI. Audits of Covered Entities

The 340B statute permits the Secretary or a manufacturer to audit the records of the covered entity directly pertaining to the entity's compliance with the statute with respect to the manufacturer's covered outpatient drugs.[14] BIO requests that HRSA address whether the HHS Office of the Inspector General (OIG) will regularly audit participating covered entities for compliance with the requirements for eligibility and participation under the 340B program, as well as whether the OIG will audit a particular covered entity within a reasonable timeframe of a manufacturer's request. BIO believes that the OIG is best suited for such reviews because of its audit expertise and believes any such reviews should focus on covered entity eligibility, diversion, and duplicate discount compliance.

VII. Exemption for Drugs Designated as Orphan Drugs

[13] 61 Fed. Reg. 65406 (Dec. 12, 1996).
[14] 42 U.S.C. § 256b(a)(5)(C).

BIO understands that certain covered entities that previously were enrolled in the 340B program as disproportionate share hospitals may seek to re-enroll in the program as one of the new covered entity hospital types added by PPACA. We request that HRSA confirm our understanding that the exception to the ceiling price obligation for drugs that are designated as orphan drugs applies effective with the covered entity's change in designation, such that the manufacturer is no longer obligated to offer that drug at the 340B ceiling price to the covered entity.

Similarly, we ask that HRSA confirm that where a covered entity meets the requirements for more than one type of covered entity under 42 USC 256b(a)(4), the applicability of the exception for orphan drugs is determined based on the "Entity Type" of the covered entity that is making the purchase, as set forth in HRSA's covered entity database. For example, a manufacturer would not be obligated to offer the ceiling price on an orphan drug to a covered entity that is identified in HRSA's database as a children's hospital, regardless of whether that hospital may also qualify as an eligible hemophilia treatment center under the 340B statute.

Finally, we also ask HRSA to confirm that the orphan drug exception does not apply to purchases made by children's hospitals during the period prior to enactment of HCERA. Section 2302 of HCERA, which created the orphan drug exception, amended the 340B statute itself (as amended by PPACA). While certain of PPACA's amendments to the 340B statute have a stated effective date of January 1, 2010, this provision in HCERA has no stated effective date and so we believe the orphan drug exception is effective only as of HCERA's enactment. We ask HRSA to confirm that interpretation.

VIII. Enforcement of Prohibitions on Duplicate Discounts and Diversion

PPACA and HCERA expanded the Medicaid rebate program to Medicaid managed care organization (MCO) utilization, but simultaneously exempted from Medicaid rebates those covered outpatient drugs subject to discount under the 340B program. This exclusion is consistent with the existing prohibition on duplicate discounts on Medicaid fee-for-service utilization. BIO urges HRSA to implement standards that will provide Medicaid MCOs and state Medicaid programs with the information necessary to exclude such utilization from their rebate claims to manufacturers. Although HRSA has defined such standards with respect to Medicaid fee-for-service utilization, state Medicaid agencies have not always been diligent in ensuring that such 340B utilization is excluded from their rebate claims. Adopting an effective policy for enforcing the duplicate discount prohibition will only become more important as the number of Medicaid enrollees increases under the various other provisions of PPACA and HCERA. BIO urges HRSA to implement a policy to more stringently enforce this provision, including a mechanism for manufacturers to seek enforcement where needed, either on their own or through the Secretary.

BIO also asks that HRSA address the issue of diversion of drugs purchased at the 340B discount to individuals who are not patients of the covered entity, including any controls that

HRSA is developing to ensure compliance with the existing prohibition on such diversion. In connection with this effort, we urge HRSA to finalize its January 2007 Notice regarding the definition of a "patient" for purposes of the 340B program.[15] As HRSA stated in that Notice, it is possible that some covered entities may have interpreted the current definition of a "patient" too broadly, resulting in the potential for diversion of 340B-priced drugs.[16] BIO believes providing covered entities with the explicit guidance set forth in the January 2007 notice regarding the necessary relationship between the covered entity and the individual patient is critical to reducing the risk of diversion of drugs purchased under the 340B program.

In particular, the January 2007 notice reiterates guidance issued by HRSA more than ten years ago making clear that employees of a covered entity must meet the definition of patient in order to be considered "patients" of the covered entity:

> *Comment*: Employees of covered entities should be either specifically precluded or included as eligible patients to receive discounted drug products.
>
> *Response*: Any employee of a covered entity who meets the criteria of the definition of covered entity "patient" would be eligible to access 340B pricing.[17]

To the extent that covered entities have been extending 340B pricing to their non-patient employees, they have been doing so contrary to this long-standing, public declaration by HRSA that employees are not patients of the covered entity unless they meet the three prongs of the patient definition test. The January 2007 Notice explicitly incorporates this pre-existing standard and puts to rest the apparent misconception by covered entities that their employees can qualify as patients either by virtue of being employed by the covered entity or under some lesser standard than that required for non-employees.[18] BIO strongly supports finalizing this clarification in order to protect the integrity of the 340B program.

Finally, BIO believes that it is particularly important that HRSA address the procedures and controls it will use to limit diversion and duplicate discounts now as covered entities implement multiple contract pharmacy arrangements pursuant to HRSA's March 2010 Final Notice.[19] The participation of additional contract pharmacies may increase the risk that 340B-priced drugs are diverted to individuals who are not patients of the covered entity and that Medicaid rebates are sought on 340B discounted drugs. BIO urges HRSA to address these considerations as it continues to implement measures to enforce the statutory prohibitions on duplicate discounts and diversion.

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[15] 72 Fed. Reg. 1543 (Jan. 12, 2007).
[16] Id. at 1544.
[17] See 61 Fed. Reg. 55156, 55157 (Oct. 24, 1996).
[18] See 72 Fed. Reg. at 1546.
[19] 75 Fed. Reg. 10272 (March 5, 2010).

IX. Applicability of Changes to Medicaid Rebate Formula

PPACA implemented a number of changes to the Medicaid rebate formula, effective for rebate periods beginning January 1, 2010, including an increase in the Medicaid base rebate, a change in the rebate calculation for a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, and a cap on the total unit rebate amount for all single source and innovator multiple source drugs equal to 100% of the AMP. BIO requests that HRSA confirm that these changes to the Medicaid rebate formula do not impact the calculation of the 340B ceiling price until the third quarter 2010. This is consistent with long-standing HRSA guidance directing that manufacturers may calculate the ceiling price using Medicaid data for a period that is two quarters prior to the effective quarter of the ceiling price.[20] As HRSA has not issued any change to this guidance, we ask that HRSA confirm our understanding that the Medicaid rebate amounts calculated under the revised rebate formula must be reflected in the ceiling price calculation beginning with the third quarter 2010.

X. Conclusion

BIO looks forward to working with HRSA over the coming months and years to implement PPACA and HCERA. We hope that the agency finds this letter to be a helpful tool as it begins the process. Please feel free to contact Laurel Todd at (202) 962-9220 if you have any questions regarding any of the issues raised herein. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel Todd
Managing Director, Reimbursement and Health Policy

[20] See HRSA, Dear Manufacturer and Wholesaler Letter (Aug. 17, 1993); see also HRSA, Letter to Joel Bobula from Marsha Alvarez (Feb. 25, 1993); HRSA, Dear Manufacturer Letter (Apr. 15, 1993); HRSA, Dear Manufacturer and Wholesaler Letter (Feb. 1, 1995).