April 29, 2011

BY ELECTRONIC DELIVERY (Notice.Comments@irscounsel.treas.gov) and U.S. MAIL

CC:PA:LPD:PR (Notice 2011-9)
Room 5203
Internal Revenue Service
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Re: Proposed Guidance Regarding Branded Prescription Drug Fee [Notice 2011-9]

Dear Mr. Commissioner:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments to the Internal Revenue Service (IRS) on the preliminary guidance in Notice 2011-9 regarding implementation of Section 9008 of the Patient Protection and Affordable Care Act (PPACA), which imposes an annual fee on manufacturers and importers of certain branded prescription drugs. BIO 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 commends the IRS for its efforts thus far to carry out Section 9008. We urge the IRS to ensure that its implementation of this provision adheres to the statute. We hope that the comments and concerns expressed below and in any subsequent letters will aid those efforts going forward, and BIO welcomes a continued dialogue with the IRS on these important issues.

I. Adjustment Methodology

Section 9008(b)(1) provides that the annual fee paid by manufacturers and importers of branded prescription drugs will be based on sales in the "preceding calendar year." The IRS has determined, however, that the Centers for Medicare and Medicaid Services (CMS) cannot complete its data processing in time to permit the IRS to apportion the fee for a given year based on the preceding year's sales. Therefore, Notice 2011-9 proposes to apportion the annual fee among branded prescription drug manufacturers based on sales in the second year preceding the year in which the fee is apportioned, and then compensate for any over- or understatement of the appropriate apportionment by applying an adjustment to the following year's fee. Notice 2011-9 states that the adjustment will be applied at the NDC level by adding to or subtracting from "the

fee otherwise payable by the covered entity responsible for the NDC in the fee year in which the adjustment is calculated."[1]

BIO understands the difficulty inherent in processing the volume of data that the statute requires the IRS, CMS, and other agencies to address. Nonetheless, we are concerned that the proposed adjustment methodology would not fully compensate for overpayments in some cases because the adjustment is calculated at the NDC level rather than the manufacturer level. For example, if a manufacturer discontinues Drug X at the end of 2011, then it will pay a portion of the fee for Drug X in 2013 based on 2011 sales but will be unable to benefit from any adjustment it would otherwise receive in 2014 because it will pay no fee for Drug X in that year. To ensure that the proposed adjustment is fair and effectively complies with the statute, the IRS should apply the proposed adjustment at the manufacturer level.

We are also concerned about the IRS's indefinite use of this adjustment approach. We understand that the IRS has determined that CMS will be unable to abide by the statutory deadline in the first few years as CMS adjusts its capabilities to meet the new Section 9008 requirements. However, we urge the IRS and CMS to come to agreement on a date by which CMS must provide the data the statute requires and within the time the statute requires. Setting a clear date of compliance will prevent data lags from continuing indefinitely in the future.

BIO may submit additional comments regarding the proposed adjustment as our members evaluate the practical challenges of accurately and effectively implementing the adjustment methodology.

II. Submission of Form 8947

BIO's members are committed to working with the IRS to ensure that it has the data it needs to carry out its responsibilities under Section 9008. We understand that the IRS has decided to carry out those responsibilities in part by requiring manufacturers and importers of branded prescription drugs to submit certain information regarding prescription drug sales and rebate information on Form 8947.

BIO appreciates the difficulty the IRS faces in collecting the necessary information to implement Section 9008. We have concerns, however, regarding the submission of Form 8947 and the information manufacturers are being asked to report.

BIO's members understand that submission of Form 8947 will generally benefit reporting manufacturers, especially because the IRS has indicated that only those price concessions reported on the form will be netted out of the calculation of sales. Our members further

[1] Notice 2011-9, at 4.

understand that submission of the information requested on Form 8947 serves as a valuable cross-check, both for the IRS and for the manufacturer, in a process where large amounts of data are being processed quickly and there is a significant risk of costly errors. Nevertheless, the lack of clarity in the IRS's proposed guidance regarding whether submission of Form 8947 is voluntary also creates serious risks for manufacturers who may choose not to file the form or to file a form with some requested information potentially omitted. The IRS has already suggested in Notice 2011-9 that submission of Form 8947 is voluntary by stating that covered entities "should" submit the form and BIO urges IRS to confirm this understanding.

The IRS should also provide clear guidance to manufacturers on how to amend their submissions on Form 8947. Currently, neither Notice 2011-9 nor Form 8947 provides for an amendment process. Creating a process by which manufacturers may amend their submissions would enhance the benefits of Form 8947 by ensuring that the data on which the allocation of fees is based is as complete and as accurate as possible. Of course, because each manufacturer's share of the annual fee depends on the submissions of the other manufacturers, there is a point beyond which amendments can no longer be accepted. This limited timeline makes it all the more important for the IRS to specify by what means and until what date a manufacturer may submit amended data, so that both the manufacturers and the agencies have enough time to ensure that the data are as accurate as possible.

Finally, the IRS should clarify the legal authority for applying Internal Revenue Code Section 6103 to rebate information submitted on Form 8947. Information regarding Medicare Part D and Medicaid rebates is highly sensitive commercial information. Notice 2011-9 states that the rebate information provided on Form 8947 is confidential "return information" protected by Section 6103. BIO remains concerned, however, that the IRS has not sufficiently laid out its legal authority to protect the confidentiality of rebate information. Section 9008(f) may provide the necessary authority by deeming the annual fee to be a tax for certain purposes under the Internal Revenue Code, which could make Form 8947 a "return" under Section 6103 and the information provided "return information." Even if the fee is deemed a tax for some purposes, however, the information submitted on Form 8947 may still be unprotected by Section 6103 because Section 6103 covers only those taxes that (unlike the annual fee) are imposed under Title 26.[2]

III. Itemized Assessment at the NDC-11 Level

BIO requests that the IRS include the NDC-11-level detail underlying the manufacturer's annual pharmaceutical fee assessment, as opposed to a lump sum amount owed with no product-level detail. Such itemization will increase the transparency of the fee calculation, the accuracy of the fee assessments and reduce the likelihood of challenges to the assessed fee. Additionally,

[2] *See* 26 U.S.C. § 6103(b)(1).

providing NDC-11-level detail of each manufacturer's assessment will facilitate contractual arrangements between companies. In many cases, manufacturers enter into distribution agreements, co-marketing arrangements and other types of shared initiatives. It is typical business practice that when taxes, fees or assessments of any type are levied on a product that is subject to a sharing agreement, that the contract between the partnering companies specify how these costs will be shared. By providing this itemized detail, the IRS will enable the product manufacturer listed by the NDC-11 to have knowledge of fees associated with individual products such that it may share such information with contractual partners when appropriate and when ownership of an NDC-11 may have changed hands. BIO strongly encourages the IRS to itemize the pharmaceutical fee by NDC-11 codes when preparing the assessment to be provided to manufacturers.

IV. Orphan Drug Exemption

BIO appreciates the IRS's continued efforts in Notice 2011-9 to properly implement Section 9008's exemption of orphan drugs from the sum of branded prescription drug sales. Many of BIO's members have worked for years to develop these vital, often life-saving drugs, whose importance Congress has recognized by granting a tax credit to their developers in Section 45C of the Internal Revenue Code.[3] The orphan drug exemption in Section 9008 is also intended to recognize the important role of orphan drugs in improving public health and to incentivize the development of those drugs. It is essential that the IRS implement the exemption in a manner consistent with those goals.

A. The IRS should deny the exemption to qualified drugs that have been approved for an additional indication only if that indication is not itself eligible for orphan status.

Even if the IRS applies the exemption only to orphan drugs for which the credit was actually claimed, BIO urges the IRS to clarify that approval by the Food and Drug Administration (FDA) for another indication does not disqualify a drug from exemption if the other indication is also eligible for orphan status. Because the last sentence of Section 9008(e)(3) is susceptible to more than one interpretation on this point, we recommend that the IRS confirm that gaining approval for additional orphan indications will not result in denial of the orphan drug exemption.

Allowing the exemption for drugs with more than one orphan indication best achieves the purpose of the exemption. Congress cannot have intended to deny a drug the orphan drug exemption simply because that drug happens to fight more than one orphan disease. Such an interpretation would discourage manufacturers of orphan drugs from seeking additional orphan

[3] *See* 26 U.S.C. § 45C.

indications, a result that would be at odds with Congress's longstanding effort to maximize treatments for orphan diseases.

Form 8947 is already consistent with this interpretation. The form asks manufacturers to indicate the name of the section 45C orphan drug, if applicable, then in the next column asks manufacturers to indicate the "date of FDA approval for *non-orphan* drug marketing, if applicable."[4] BIO agrees that it is appropriate to limit reporting of additional indications on Form 8947 to non-orphan indications. We further ask the IRS to confirm in its guidance that FDA approval for an additional indication will result in denial of the orphan drug exemption only if that additional indication is not itself eligible for orphan status.

Our remaining comments below concern the various formulas by which the IRS proposes to calculate each manufacturer's share of the annual fee. BIO recognizes the difficulty of calculating this number quickly, accurately, and in accordance with the statute's requirements. We thank the IRS for its efforts to accommodate these competing concerns. Nevertheless, Congress made a deliberate decision to use the methodologies laid out in the statute with the knowledge that its decision would benefit some manufacturers and harm others. We urge the IRS not to allow the current limitations of the agencies tasked with implementing the legislation to create a different set of benefits and detriments that Congress did not intend.

Following the structure of Notice 2011-9, we have organized our remaining comments according to the federal health care program to which they pertain.

B. <u>The IRS should apply the orphan drug exemption to any drug that could have claimed the Section 45C credit.</u>

We are disappointed that the IRS has proposed in Notice 2011-9 to apply the orphan drug exemption only to drugs for which the manufacturer actually claimed a tax credit under Section 45C.[5] We believe that such an interpretation stands against the intent of the exemption to promote the development of orphan drugs and that the IRS should instead exempt any drug for which a manufacturer could have claimed a 45C credit.

The IRS did not lay out the reasoning for its interpretation in Notice 2011-9 and we are unable to discern any basis for it. The proposed interpretation is not mandated by the language of the statute, which states only that the exemption applies to any drug or biological for which the 45C credit was "allowed."[6] The statute's legislative history is, if anything, more permissive

[4] Form 8947, Part II(g) (emphasis added).
[5] *See* Notice 2011-9, at 6.
[6] *See* PPACA § 9008(e)(3).

than the statute in that it adds that the exemption applies to any drug or biological that "qualified under section 45C."[7]

The proposed interpretation would also be contrary to the purpose of the exemption. Congress recognized that not all manufacturers would want to claim the Section 45C credit each year when it expressly made that credit elective.[8] In fact, there are many reasons that a taxpayer might elect not to claim a tax credit for which it is eligible, such as where there is no tax for the credit to offset in a given year. The IRS has not explained why Congress would have allowed a manufacturer the option of taking the credit in Section 45C only to mandate that it take the credit in order to benefit from a similar exemption in Section 9008. We believe that was not Congress's intent and ask the IRS to carry out the purpose of the exemption by applying it to all drugs for which a 45C credit could have been claimed.

V. Medicare Part D

BIO believes that the IRS must do more to explain how it will take account of all discounts, rebates, and other price concessions that the statute requires to be incorporated into the Medicare Part D net cost figure. Section 9008 instructs the Secretary of Health and Human Services to report to the Secretary of the Treasury, for each branded prescription drug covered by Medicare Part D, the product of per-unit ingredient cost, "minus any per-unit rebate, discount, or other price concession provided by the covered entity," and the number of units paid for under Medicare Part D.[9] The IRS confirmed in Notice 2011-9 that CMS is required to report per-unit ingredient cost "net of any per-unit rebate or other price concessions."[10]

Section 9008 requires the IRS to take account of all price concessions provided by covered manufacturers. BIO's members provide a wide variety of price concessions to their customers, including prompt-pay discounts and on-invoice discounts provided at the time of sale when drugs are sold directly to a possession-taking Part D plan. Form 8947, however, assumes that the only concession that a manufacturer might report is a rebate. Likewise, Notice 2011-9 explains that CMS will report aggregated ingredient cost and units for each NDC, but does not explain how or even whether CMS will subtract from the ingredient cost all the discounts, rebates, and other price concessions offered by manufacturers.

BIO asks the IRS to confirm that there is a mechanism in place to ensure that all discounts, rebates, and any other price concessions offered by the manufacturer are fully accounted for in CMS's report of the per-unit ingredient cost to the IRS, in accordance with the requirements of the statute. We also recommend that Form 8947's Part II column (c) should not

[7] *See* S. Rep. No. 111-89, at 341 n.98 (2009).
[8] *See* 26 U.S.C. § 45C(d)(4).
[9] PPACA § 9008(g)(1).
[10] Notice 2011-9, at 6.

be restricted to rebates but should be revised to allow manufacturers to report any type of price concession under Medicare Part D. It is particularly important that the IRS provide additional guidance on this issue and allow manufacturers maximum flexibility in reporting because Notice 2011-9 states that rebate information will be taken into account in calculating the manufacturer's share of the fee "only if it is reported on a timely filed Form 8947."[11]

We also understand through informal guidance that the IRS considers concessions offered for sales in Puerto Rico and other U.S. territories to be included in the Part D calculation, in accordance with the scope of the Part D benefit.[12] Accurate calculation of each manufacturer's share depends on the reporting of all Part D price concessions, including concessions offered in Puerto Rico and other territories. BIO asks the IRS to confirm in writing that these concessions must be included by CMS in its report or that manufacturers will have the opportunity to report such price concessions themselves on a revised Form 8947.

VI. Medicare Part B

BIO appreciates the IRS's efforts to come to a reasonable estimate of each manufacturer's share of annual Medicare Part B spending on branded prescription drugs. We have several concerns and comments about the proposed calculation.

A. The proposed substitution of Medicare-allowed charges for Average Sales Price (ASP) will result in the overvaluation of the Part B market for drugs with an ASP.

Section 9008 requires the Secretary of Health and Human Services to report annually for each covered entity and each branded prescription drug the product of the per-unit *average sales price* (ASP) (or per-unit Part B payment rate, if no average sales price) and the number of units paid for under Medicare Part B.[13] The IRS proposes instead that the calculation of each branded prescription drug's Part B sales will be based on the total *Medicare-allowed charges* in a given sales year for each HCPCS code associated with a branded prescription drug.[14] Notice 2011-9 does not explain why the IRS is proposing this substitution, particularly when the statute authorizes substitution of the payment rate only where ASP does not exist.

The statute required use of ASP when it explicitly identified ASP as the basis for the Part B market calculation. Had Congress intended to measure the Part B market in the manner that the IRS proposes, it would have cited Section 1847A(b) of the Social Security Act, which includes the 6% physician's office add-on to ASP, and it would have cited the other add-ons that

---

[11] *Id.* at 2.
[12] Because residents of Puerto Rico and other U.S. territories are eligible for coverage under Parts A and B, they are also eligible for coverage under Part D. *See* SSA Publication No. 05-10043, at 8, 10 (January 2011).
[13] PPACA § 9008(g)(2).
[14] Notice 2011-9, at 7.

CMS adopts each year. Instead, the statute cites Section 1847A(c), which speaks only to ASP and does not include any additional reimbursement amounts.

BIO is greatly concerned that the use of Medicare-allowed charges instead of ASP as the valuation of Part B utilization will overvalue the Part B market for drugs that have an ASP. The current Medicare-allowed charge under Part B for drugs with an ASP is ASP +6% for physician's offices[15] and ASP +5% for hospital outpatient drugs.[16] This means that the number that CMS will report for each drug, and the number on which the IRS proposes to base the calculation of each drug's Part B sales, will be 5% to 6% higher than the number that the statute requires the Secretary of Health and Human Services to report.

For certain drugs, the overvaluation of sales due to the use of Medicare-allowed charges would be aggravated by additional add-ons to ASP. For example, blood clotting factors are given an additional reimbursement amount that would presumably also be included in the IRS's proposed sum of Medicare-allowed charges for such drugs.[17]

The use of Medicare-allowed charges will likely result in a calculation of a Part B market valuation that is quite different from the one the statute intended. In addition, because each manufacturer's share of the annual fee is directly related to its share of sales to the specified government programs as calculated by the IRS, use of Medicare-allowed charges rather than ASP likely means that each manufacturer will pay a different share of the annual fee than the statute requires. Because it is impossible to predict which manufacturers will benefit and which will suffer from any substituted calculation, the IRS should implement the fee in strict accordance with the formulas specified by the statute. BIO urges the IRS to follow the statute and reconsider its proposed substitution of Medicare-allowed charges for ASP.

B. <u>For HCPCS codes consisting of multiple prescription drugs, use of ASP sales data to estimate Part B sales would result in the overvaluation of Part B sales for some manufacturers.</u>

BIO recognizes the difficulty of quantifying Part B Sales for a drug that is assigned to a HCPCS code that includes multiple drugs produced by multiple manufacturers. Section 9008 provides only that CMS "shall establish a process for determining the units and the allocated price for purposes of this section for those branded prescription drugs that are not separately payable or for which National Drug Codes are not reported."[18] We appreciate the effort that the IRS has made in Notice 2011-9 to fairly estimate Part B sales in these cases, but we remain

[15] SSA §§ 1842(o)(1)(C); 1847A(b)(1).
[16] 75 Fed. Reg. 71800, 71959-60 (Nov. 24, 2010).
[17] In 2011, the clotting factor add-on is $0.176 per unit. MLN Matters MM7168 (January 1, 2011).
[18] PPACA § 9008(g)(2).

concerned that the proposed method will result in overvaluation of the Part B market for some manufacturers.

The IRS proposes to estimate Part B sales for multiple-drug HCPCS codes by "applying the utilization percentage attributed to each manufacturer as determined under the Medicare Part B program using manufacturer reported Average Sales Price sales data."[19] The data reported by manufacturers for the calculation of ASP, however, is derived from all commercial sales in the United States and not from sales to Part B alone. Thus, in all cases where a manufacturer's share of Part B sales happens to be smaller than its share of the commercial market as a whole, the proposed method would overestimate that manufacturer's share of the utilization for the HCPCS code at issue. Because the statute only takes account of sales to specified government programs and not sales to the commercial market as a whole,[20] the proposed method would force that manufacturer to pay a larger portion of the annual fee than the statute requires.

C. The IRS should address how Part B sales will be calculated for branded prescription drugs reimbursed under a bundled payment rate.

A number of branded prescription drugs are reimbursed under Medicare Part B using a bundled payment rate. For example, certain drugs used in dialysis are reimbursed along with other dialysis services as part of a bundled rate,[21] and many therapies utilized in the outpatient hospital setting are not reimbursed separately.[22] Section 9008 provides that CMS should establish a process for determining the number of units and an allocated price for branded prescription drugs not separately payable or with no NDC. CMS has not described what this process may be, and Notice 2011-9 was silent on this issue. BIO requests that the IRS clarify how it plans to estimate the sales of these drugs with adequate time for stakeholder review of the proposal.

D. The IRS should clarify how it will address branded prescription drugs that are part of a drug/device combination product.

BIO urges the IRS to address the issues raised by drug/device combinations, with particular regard to not subjecting the same product to both the branded prescription drug fee and the medical device tax described in PPACA Sections 9008 and 9009, respectively. Some branded prescription drugs are reimbursed under Medicare Part B or Part D as part of a drug/device combination product, such as pre-filled syringes, auto-injectors and therapies delivered through transdermal patches. It is important that the IRS clarify how it will address these combination products. Congress did not intend to authorize such double-counting, and it is essential that the

[19] Notice 2011-9, at 7.
[20] *See* PPACA § 9008(e)(1).
[21] *See* SSA § 1881(b)(14); 42 C.F.R. § 413.171.
[22] *See* SSA § 1833(t)(16)(B); 75 Fed. Reg. 71800, 71939 (Nov. 24, 2010).

IRS explain how it plans to prevent drug/device combinations from being double-counted. One method for mitigating this situation would be to defer to the assignment made by the FDA's Office of Combination Products. In making these assignments, the OCP determines the "primary mode of action", which is "the single mode of action of a combination product that provides the most important therapeutic action of the combination product."[23] By relying on the FDA's jurisdictional determination of device, drug, or biologic, the IRS will be taking steps to prevent double counting a given therapy.

E. The IRS should confirm that medical devices reimbursed as drugs will not be included in the calculation of Part B prescription drug sales.

Finally, some HCPCS codes are used for medical devices that are reimbursed as drugs under Part B. While such products may be treated as a drug for reimbursement purposes, a medical device does not meet the definition of "branded prescription drug" under the statute. It is neither a "prescription drug" for which an application was submitted under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), nor a "biological product" for which a license was submitted under section 351(a) of the FDCA. In addition, including sales of medical devices reimbursed as drugs in the prescription drug fee calculation again risks double-counting the device's sales under both the drug fee and the device tax. BIO therefore asks the IRS to confirm that sales under HCPCS codes that are used for medical devices reimbursed as drugs will not be included in the calculation of Part B branded prescription drug sales.

VII. Medicaid

A. The proposed substitution of AMP for per-unit ingredient cost paid to pharmacies by States distorts the calculation of Medicaid market share as required by the statute.

Section 9008 requires the Secretary of Health and Human Services to report for each manufacturer and each branded prescription drug the product of the per-unit *ingredient cost* paid to pharmacies by States (minus any per-unit rebate paid by the covered entity under SSA § 1927 and any state supplemental rebate) and the number of units paid for under the Medicaid program.[24] The IRS proposes instead to calculate the Medicaid portion of the fee for each branded prescription drug as "the per-unit *Average Manufacturer Price* less the Unit Rebate Amounts (URA) that CMS calculates based on manufacturer-reported pricing data multiplied by the number of units reported billed by states to manufacturers."[25] Notice 2011-9 does not explain why the IRS is proposing this substitution.

[23] 21 C.F.R. § 3.2 (M)
[24] PPACA § 9008(g)(3) (emphasis added).
[25] Notice 2011-9, at 7 (emphasis added).

BIO is deeply concerned that the use of AMP instead of per-unit ingredient cost actually paid to pharmacies will distort the Medicaid portion of each manufacturer's share of the annual fee. The statute requires that Medicaid sales be calculated using ingredient cost actually paid to pharmacies, and any other valuation will likely result in a different apportionment of the fee than the statute intended.

The distortion would be particularly severe in cases where Medicaid is frequently a secondary payer. State Medicaid programs bill manufacturers for a full unit whenever the state pays any portion of the cost of a drug. When Medicaid is secondary payer, however, it actually pays much less than the full ingredient cost because another payer is required to pay a portion of that cost first. As a result, the IRS's proposed use of units reported billed by states multiplied by AMP instead of ingredient cost actually paid would heavily overvalue the actual amount expended by Medicaid programs in many cases. That overvaluation, in turn, would distort each manufacturer's share of the annual fee.

This problem is particularly acute when Medicaid is a secondary payer to Medicare Part B. In such cases, the IRS proposes to count as part of the manufacturer's government sales both the full Medicare-allowed charges for the Medicare Part B portion of the fee as well as the AMP of each unit billed by Medicaid for the Medicaid portion of the fee, even when Medicare has paid 80% of the cost and Medicaid has paid only 20%. This double-counting heavily distorts the calculation of government sales and the manufacturer's share of the annual fee.

We cannot discern any justification for the proposed substitution of AMP for per-unit ingredient cost actually paid to pharmacies, whether from the statute, from Notice 2011-9 or from any other authority. We urge the IRS to reconsider its proposal to bring it into line with the statute.

B. <u>The IRS should clarify that certain sales of prescription drugs under the Medicaid program will be excluded from the Medicaid market share.</u>

The statute and the proposed calculation in Notice 2011-9 raise several important questions regarding which sales will be included in the calculation of each prescription drug's Medicaid market share. BIO suggests that the IRS clarify the following issues so that manufacturers may accurately calculate and verify their Medicaid market share.

First, BIO asks the IRS to clarify that Medicaid sales in Puerto Rico and other U.S. territories are excluded from the calculation. Section 9008 provides that the Medicaid market share is based in part on "the per-unit ingredient cost paid to pharmacies by States for the branded prescription drug dispensed to Medicaid beneficiaries."[26] Separately, Notice 2011-9

[26] PPACA § 9008(g)(3)(A).

provides that the calculation will be based in part on "the number of units reported billed by states to manufacturers."[27] Neither the statute nor the notice defines "state."

BIO believes that sales in Puerto Rico and other territories should be excluded from the calculation of Medicaid sales. The statute requires the subtraction of per-unit rebates paid under the federal Medicaid drug rebate program from the per-unit ingredient cost. The regulations governing the federal rebate program define "States" to mean "the 50 States and the District of Columbia," hence excluding Puerto Rico and other territories.[28] The statute's exclusion of sales in the territories for purposes of subtracting federal rebates suggests that sales in the territories should be excluded from the rest of the Medicaid sales calculation as well.

BIO also believes and asks the IRS to confirm that branded prescription drugs paid for by Medicaid managed care organizations are excluded from the Medicaid market share. States do not pay pharmacies directly for these units. Rather, states provide a capitated amount to the Medicaid managed care organization, which in turn pays the pharmacy for units of the manufacturers' drugs. For branded prescription drugs paid for by Medicaid managed care organizations, there is thus no "per-unit ingredient cost paid to pharmacies by States" and those sales therefore should be excluded from the calculation of Medicaid market share. This policy, in addition to being consistent with statute, will also mitigate complex data issues to prevent double counting of claims data or inappropriate attribution to the IRS fee.

Finally, BIO asks the IRS to clarify that it will exclude from the calculation of Medicaid sales drugs that are administered rather than dispensed to patients. Within the Medicaid program, "dispensed" is a term of art that refers to drugs delivered to a patient by a pharmacy.[29] The term excludes, for example, injected and infused drugs, which are not "dispensed" by pharmacies but rather "administered" by physicians. Moreover, the presence of "dispensed" and the absence of "administered" in Section 9008 is consistent with the statute's requirement that Medicaid market share be based on the ingredient cost actually "paid to pharmacies by States." Sales of drugs that were not dispensed by a pharmacy should not be included in the Medicaid market share calculation.

VIII. Department of Veterans Affairs/Department of Defense

BIO recommends that the IRS clarify two important issues related to the calculation of each manufacturer's share of sales to federal health care programs under the Department of Veterans Affairs (VA) and the Department of Defense (DOD).

---

[27] Notice 2011-9, at 7.
[28] *See* 42 C.F.R. § 447.502.
[29] *See, e.g.*, CMS Release No. 144, at 2 (December 15, 2006) (discussing "dispensing fee paid as part of the pharmacy claim").

First, we believe that the IRS should urge the DOD and VA to net out the Industrial Funding Fee from their reported calculation of a manufacturer's sales to their respective programs. The Industrial Funding Fee is an administrative fee embedded in prices to VA and DOD purchasers for all Federal Supply Schedule (FSS) purchases. The IFF is not part of the price of a product, but rather an administrative fee paid by government purchasers that is remitted to the VA to cover the costs of managing the FSS program for pharmaceuticals. Manufacturers are required to embed the IFF in the price charged to government purchasers for their FSS purchases, then remit those amounts back to the VA directly on a quarterly basis.

The IFF is essentially a pass-through fee, paid from the VA or DOD purchaser to the VA. It is not part of a manufacturer's sales to VA and DOD purchasers and the manufacturer never retains any portion of the IFF. It is therefore not part of the "total amount paid" for prescription drugs procured by VA or DOD purchasers and should be netted out of the calculation of VA/DOD sales.

Second, we believe the IRS should net out any returns of pharmaceutical products made to manufacturers by VA or DOD purchasers. Unlike other federal health care programs, VA and DOD health care programs permit purchasers to return certain pharmaceutical products to the manufacturer. The value of these returns is not part of the "total amount paid" for prescription drugs and the IRS should net out returns when it calculates each manufacturer's sales to VA and DOD purchasers.

* * *

BIO wishes to thank the IRS for the opportunity to present these comments on Notice 2011-9. We look forward to continuing to work with the IRS and other agencies to ensure that the annual branded prescription drug fee is implemented in a manner that balances fair apportionment of the fee and adherence to the statute with the practical realities of assembling and verifying the data necessary to complete the task.

Please contact Laurel Todd at (202) 962-9220 if you have any questions regarding our comments. Thank you for your attention to this important matter.

Respectfully submitted,

/s/

Laurel Todd
Managing Director,
Reimbursement and Health Policy