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***BY ELECTRONIC AND POST DELIVERY***

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Contracts and Purchasing Section  
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**Re: Notice of Request for Proposal: Specialty Pharmacy Drugs and Services Program (Solicitation Number YH10-0004)**

Dear Mr. Schultz:

On behalf of the Biotechnology Industry Organization (BIO), we are writing to share our concerns about the Arizona Health Care Cost Containment System (AHCCCS) Administration's Notice of Request for Proposal (RFP) on the Specialty Pharmacy Drugs and Services Program (Solicitation Number YH10-0004).<sup>1</sup> 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 in the United States. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO is a strong supporter of access among indigent and vulnerable populations to important drugs and biologicals made possible by the 340B program. The 340B program allows certain health care providers to obtain access to Medicaid-level drug discounts on drugs and biological therapies for their patients. We understand and support the AHCCCS Administration's desire to "achieve greater cost efficiencies in the purchase of medically necessary specialty drugs, services and related products and supplies"<sup>2</sup> for patients in need.

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<sup>1</sup> Notice of Request for Proposal: Specialty Pharmacy Drugs and Services Program, Solicitation Number YH10-0004, available at <http://www.azahcccs.gov/commercial/Downloads/Solicitations/Open/RFPs/YH10-0004/YH10-0004.pdf> (hereinafter "RFP").

<sup>2</sup> Id. at 5.

We are concerned, however, that the contract described in the RFP appears to be incompatible with the 340B program's requirement that discounted drugs be dispensed only to patients of the entity receiving the discount, a requirement intended to prevent diversion of discounted drugs to unintended and often fully insured patients. As described in the RFP, the contractor would be required to provide drugs at 340B prices to any individual covered by certain AHCCCS programs, without adequate safeguards to ensure that the individual meets the 340B program's specific definition of a "patient." BIO asks you to ensure that any contract awarded in response to this RFP fully complies with the 340B program's requirements. In addition, we are concerned that the RFP does not address all of the services necessary to ensure continued access to effective therapy. We ask you to ensure that any contractor selected for this program is able to provide the full range of specialty pharmacy services essential to appropriate use of these drugs and biologicals. We also want to bring to your attention provisions in the pending federal health reform legislation to expand Medicaid rebates to drugs provided through Medicaid managed care plans that, if enacted, could affect implementation of the proposed contract.

#### The RFP Does Not Comply with the 340B Program's Requirement to Dispense Drugs Only to Patients of Covered Entities

Through this RFP, AHCCCS seeks to contract with a single 340B-designated pharmacy to provide specialty pharmacy drugs and services to patients in AHCCCS-contracted health plans, the AHCCCS FFS enrolled members and other publicly funded programs with a pharmacy benefit for the State of Arizona.<sup>3</sup> The contractor would provide these drugs and services for 11 categories of chronic medical conditions.<sup>4</sup> The drugs obtained under this contract would be priced at the "340B designated entity pharmacy's acquisition cost" plus a fee that includes a dispensing fee, the cost of supplies to administer the medication, and costs associated with delivery of the medication to the patient or prescribing clinician's office.<sup>5</sup> The RFP would require the contractor to "[c]oordinate and ensure that the definition of the 340B one-to-one relationship between the 340B designated entity pharmacy, the prescribing clinician and the patient has been achieved between all parties and is compliant."<sup>6</sup>

The relationship of the 340B covered entity to the patient is critical to compliance with the program's guidelines. A covered entity under the 340B

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<sup>3</sup> Id. at 4-5.

<sup>4</sup> Id. at 6.

<sup>5</sup> Id. at 8.

<sup>6</sup> Id. at 8.

program may dispense drugs at the program's discounted prices only to that entity's patients.<sup>7</sup> Under the 340B program's guidelines, an individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.<sup>8</sup>

Moreover, "[a]n individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting."<sup>9</sup>

We are concerned that it will not be possible for an entity awarded a contract based on this RFP to comply with the 340B program's requirements. Although the RFP states that the contractor would be required to "ensure that the definition of the 340B one-to-one relationship between the 340B designated entity pharmacy, the prescribing clinician and the patient has been achieved between all parties and is compliant,"<sup>10</sup> nothing in the RFP explains how a single pharmacy would be able to comply with the 340B program's guidance for all AHCCCS patients and also with the conditions addressed in the RFP.

To comply with the 340B guidelines, the contractor would need to have an established relationship with each patient served under the contract and an employment or other contractual arrangement with each patient's physician. We believe it would be extremely difficult for a single contractor to establish these

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<sup>7</sup> Public Health Service Act § 340B(a)(5)(B), 42 U.S.C. § 256b(a)(5)(B).

<sup>8</sup> 61 Fed. Reg. 55156, 55157-58 (Oct. 24, 1996).

<sup>9</sup> Id. at 55158.

<sup>10</sup> RFP at 8.

relationships for all patients the AHCCCS Administration seeks to serve under this contract. In addition, the entity must provide a health care service or range of services to each patient, in addition to dispensing drugs, for a patient relationship to exist. The RFP does not even address the need for any contractor to be able to supply such services, which is a clear prerequisite for the existence of the compliant patient relationship that the RFP states is its goal.

Because the RFP appears to require the contractor to provide 340B drugs to all AHCCCS beneficiaries needing the categories of drugs identified in the RFP, regardless of whether those beneficiaries comply with the 340B program's definition of a "patient" and regardless of whether the contractor even has the capability to provide the health services needed for a patient relationship to exist, any contract awarded under this RFP could present a significant risk of diversion. Such diversion, if it were to occur, would constitute a violation of the 340B statute and any contracting covered entity's legal obligations. BIO asks the AHCCCS Administration to exercise caution as it proceeds with this RFP and ensure that any contract awarded specifically addresses how compliance with the 340B program's definition of "patient" would be ensured.

#### The RFP Does Not Address the Full Range of Specialty Pharmacy Services Required to Protect Access to These Drugs and Biologicals

Although the RFP would require the contractor to provide some "clinical supportive services,"<sup>11</sup> the RFP does not address the full range of services required for safe and effective use of many specialty pharmaceuticals. Specialty drugs and biologicals, such as therapies for the chronic conditions addressed by this RFP, often require extensive pharmacy services to ensure that the patient receives the therapy in the most effective manner. For example, the Food and Drug Administration requires Risk Evaluation and Management Strategies (REMS) for some drugs that involve distribution of medication guides and educational materials for patients and practitioners, restrictions on the practitioners who may provide the drug, and monitoring of patients who receive the drug for potential adverse events. The specialty pharmacy plays an important role in making sure these requirements are met. Drugs without REMS also can require extensive patient support services, including careful monitoring of patient adherence, coordination of care with the prescribing physician, and compliance with special handling requirements to preserve the drug's integrity. When a patient changes providers, specialty pharmacies take additional steps to coordinate care and ensure continued compliance with the therapy's requirements.

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<sup>11</sup> RFP at 8 (referring to "clinical supportive services that are designed to optimize therapy management and improve and monitor treatment adherence and persistency").

It is critical that any contractor selected for this program have experience in providing all of these services. Specialty pharmacies have experience providing these services for a variety of drugs, but many 340B pharmacies that might respond to this RFP do not. If the AHCCCS Administration selects an inexperienced pharmacy for this program, it could result in disruptions in care and increased risk of complications in addition to continuity of care problems that often occur when a patient changes health care providers. We urge the AHCCCS Administration to require any specialty pharmacy chosen under this RFP to demonstrate its experience in performing the full range of services needed to protect access to effective therapy with specialty pharmaceuticals.

#### Potential Effect of Federal Health Reform Legislation on the Proposed Contract

In addition, we are concerned that the contract to be awarded under this RFP could conflict with provisions of the federal health reform legislation that, if enacted, would require pharmaceutical manufacturers to pay Medicaid rebates on drugs reimbursed by Medicaid managed care plans. The 340B statute prohibits duplicate discounts or rebates, including Medicaid rebates, on drugs purchased through the 340B program.<sup>12</sup> The RFP notes that the Secretary of Health and Human Services has exempted AHCCCS from participation in the Medicaid rebate program,<sup>13</sup> therefore the prohibition against duplicate rebates would not apply to drugs obtained under the contract issued pursuant to this RFP. If the health reform legislation currently before both houses of Congress is enacted, however, manufacturers would be required to pay rebates on drugs purchased by Medicaid managed care programs, including AHCCCS.<sup>14</sup> We thought you should be aware that this potential change in the law would require revisions to the program described in the RFP to ensure that duplicate rebates are not collected on any drugs purchased at 340B prices.

BIO appreciates your attention to our concerns about this RFP. If you have any questions about these matters, please contact India Valentine or Laurel Todd at (202) 962-9200.

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<sup>12</sup> Public Health Service Act § 340B(a)(5)(A), 42 U.S.C. § 256b(a)(5)(A).

<sup>13</sup> RFP at 5.

<sup>14</sup> See, e.g., America's Healthy Future Act of 2009, as approved by the Senate Finance Committee on Oct. 13, 2009, at 67-68

[http://www.finance.senate.gov/sitepages/leg/LEG%202009/100209\\_Americas\\_Healthy\\_Future\\_Act\\_AMENDED.pdf](http://www.finance.senate.gov/sitepages/leg/LEG%202009/100209_Americas_Healthy_Future_Act_AMENDED.pdf) (the Chairman's Mark, as amended and approved by the Senate Finance Committee, states, "Drugs purchased through the 340B Drug Discount Program would not be subject to the rebates collected on behalf of Medicaid MCOs [Managed Care Organizations]."); America's Affordable Health Choices Act of 2009, § 1743, [http://energycommerce.house.gov/Press\\_111/20090714/aahca.pdf](http://energycommerce.house.gov/Press_111/20090714/aahca.pdf).

BIO comments Re: Notice of Request for Proposal: Specialty Pharmacy Drugs and

Sincerely,

/s/

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/s/

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