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BY ELECTRONIC DELIVERY

CDR Krista Pedley
Director
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Parklawn Building, Room 10C-03
Rockville, MD 20857

Re: Proposed Project: Enrollment and Recertification of Entities in the 340B Drug Pricing Program (OMB No. 0915–0327)—Revision

Dear Commander Pedley:

The Biotechnology Industry Organization ("BIO") is pleased to submit the following comments on the Health Resources and Services Administration ("HRSA") notice on the enrollment and recertification of entities in the 340B pricing program.

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 1,100 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.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO understands the significance of the 340B drug pricing program, which requires manufacturers of covered outpatient drugs to charge no more than a defined ceiling price to certain specified safety net providers, as defined by statute.[1] The 340B drug pricing program significantly lowers prices for drugs to entities that often serve low-income or disadvantaged individuals.

As set forth in Section 7102 of the Patient Protection and Affordable Care Act (PPACA), HRSA is now statutorily required to annually recertify all 340B covered entities. Prior to PPACA, HRSA recertified only certain entities annually (*e.g.*, STD, TB, HIV/AIDS grantees), as expressly required under Section 340B (a)(7) of the Public Health Service Act.[2] As there are currently 20 entity types eligible for the 340B program, each has a unique set of criteria that HRSA uses to determine eligibility. The recertification process, in general, includes verification of grant status, updating contact information, verification of all eligibility requirements as

[1] *See* 42 U.S.C. § 256b (describing the Public Health Service ("PHS") Drug Pricing Program).
[2] *Ibid.*

defined by statute, updating of the entity's intention to bill Medicaid, and when applicable, GPO exclusion attestation.[3]

HRSA began a phased approach to recertification in August 2011, which included a comprehensive communication strategy notifying covered entities' of their recertification requirements. In April 2012, all hospitals entering the program prior to June 1, 2011 were required to recertify entity information with HRSA, marking the first time hospitals were required to recertify eligibility in the 340B program. HRSA has indicated that recertification covers the parent site as well as all registered outpatient child sites in the program database.[4]

To ensure the process is as smooth as possible for hospitals and to answer their outstanding questions, HRSA has hosted a series of webinars and also has posted new FAQs on its website explaining the recertification process. On April 26, HRSA hosted a webinar for manufacturers and wholesalers to update them on the status of hospital recertification. BIO appreciates HRSA's outreach and communication to all stakeholders regarding this very important process, and believes it is reflective of the Agency's commitment to program integrity and compliance.

BIO supports HRSA in its efforts as it administers and oversees the recertification process, and believes that this process will enable the Agency to verify that all covered entities continue to meet the statutory requirements for program participation. We offer the following comments to ensure that the goals of the enrollment and recertification process are met.

Certification Language

BIO believes that when applying for 340B participation and recertifying eligibility for the program, potential covered entities should be required to attest that they meet all of the relevant criteria for the 340B discount and will comply with various aspects of the program. On the April 26 webinar, officials from the Office of Pharmacy Affairs (OPA) presented the updated certification language that covered entities must attest to as part of the recertification process, noting that the statement reflects the strongest certification language HRSA has ever required from an authorizing official.[5] Specifically, the covered entity's authorized public official must certify that:

1. all information listed on the 340B Program Database for that covered entity is complete, accurate, and correct;
2. the hospital has continuously met all 340B Program eligibility requirements since being listed as eligible on the 340B database;
3. the hospital complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not

[3] *See* Letter from Administrator Mary Wakefield to Senator Charles Grassley dated October 21, 2011.
[4] *See*, e.g., HRSA FAQ "My Hospital Covered entity submitted a change request form, does this mean we are recertified?"
[5] Office of Pharmacy Affairs. Webinar presented April 26, entitled, "340B Drug Pricing Program Annual Recertification for Hospitals: An Update for Manufacturers and Wholesalers." Available at: http://www.healthcarecommunities.org/content.aspx?id=4294972723

limited to, the prohibition against duplicate discounts/ rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;

4. the hospital maintains auditable records demonstrating compliance with the requirements described in paragraph (3) above;
5. the hospital has systems/mechanisms in place to reasonably ensure ongoing compliance with the requirements described in paragraph (3) above;
6. if the hospital uses contract pharmacy services, that the contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines including, but not limited to, that the hospital obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (*e.g.*, through an independent audit or other mechanism);
7. the hospital acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material breach by the hospital of any of the foregoing; and
8. if the hospital does not notify OPA in a timely fashion, the hospital acknowledges that it may be required to remit payment back to manufacturers which would represent the difference between the 340B discounted price and the drug's non-340B purchase price.

BIO believes that the certification language above is essential to ensuring that covered entities understand and comply with 340B statute and regulations. We support and appreciate HRSA's efforts in strengthening the certification language and also support the active role of the covered entity's authorizing official in ensuring compliance with the 340B statute and regulations. To ensure that the certification statement encompasses the full array of covered entity compliance-related responsibilities, BIO proposes that HRSA add language to ensure the authorizing official attests that:

- the covered entity, its parent organization, and upstream owner entities (if any) are all non-profit entities, and that all of their child sites are non-profit organizations as well;
- that any electronic systems utilized by the covered entity or related entities (if any) for management of 340B drug and biologic inventory operate in compliance with all program rules and guidance; and
- that any private hospital has the requisite grant of governmental powers or otherwise has a contract in place with a state or local government to provide health care services to low income individuals not entitled to Medicare and Medicaid benefits.

Recertification of Outpatient Facilities

As part of the recertification process, HRSA has clarified that "all clinics located off-site of the parent hospital, regardless of whether those clinics are in the same building, must register with OPA as child sites of the parent 340B-eligible hospital."[6] Registering each outpatient facility as child sites of the parent site will ensure that the entity has been individually reviewed by HRSA as eligible to receive 340B discounted drugs.

[6] *See e.g.*, HRSA FAQ: What outpatient facilities are hospitals required to register on the 340B database? Available at: http://www.hrsa.gov/opa/faqs/new.htm

BIO appreciates OPA's efforts in clarifying how hospitals should identify their associated parent organizations, child sites, and pharmacies in the 340B database, and has additional suggestions as to how OPA can ensure covered entity compliance with this critical part of the recertification process.

Registration of Child Sites

In order for off-site outpatient facilities to purchase 340B drugs and/or provide 340B drugs to its patients, they must be registered with OPA as child sites of the parent organization. In addition, such clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report. While HRSA makes this latter point clear in a new FAQ,[7] it should also make clear in the same FAQ that to be listed on a hospital cost report as reimbursable, and thus to be an "integral part" of a 340B hospital, an outpatient facility also must satisfy the provider-based regulation in 42 CFR 413.65.

If a hospital does not separately register its child sites with HRSA and instead uses a single "bill-to" address for drugs used at multiple sites – including drugs used by the hospital and those used by unregistered child sites – it will be impossible for manufacturers to disaggregate those purchases and distinguish between the legitimate 340B sales (going to the hospital and its registered and otherwise qualified 340B outpatient child sites) and those ultimately going to child sites that do not qualify for and should not receive 340B pricing. Further, this practice would violate long-standing HRSA guidance, which clearly requires that outpatient facilities that qualify as integral parts of a 340B hospital may not obtain 340B drugs until they are registered with HRSA and added to the 340B database.[8]

BIO strongly recommends that, when registering these child sites, the 340B hospital parent site be required to provide both the "bill-to" and "ship-to" addresses for the child sites. The reason for this is that chargeback data currently allows for the inclusion of only a single address, either "ship-to" or "bill-to." Many manufacturers select the "bill-to" address because this address is the one that provides some insight into whether the purchaser is a 340B entity. If the covered entity registers its child sites using the "ship-to" address, manufacturers will not be able to match chargebacks with a registered covered entity site because the chargeback data that manufacturers receive will not list the "ship-to" address.

The form entitled "340B Registration Form for Disproportionate Share Outpatient Facilities Using Medicare Cost Report" has space for listing an address associated with the outpatient facility. However, it is not clear from the heading above this space on the form, whether an outpatient facility would list its street, billing, or ship-to address. As discussed above, BIO strongly encourages HRSA to require that outpatient facilities list both their "bill-to" and "ship-to" addresses. Taking this step will ensure that manufacturers can adequately identify

[7] *See e.g.*, HRSA FAQ: What outpatient facilities are hospitals required to register on the 340B database?
[8] 59 Fed. Reg. 47884 (Sept. 19, 1994).

their customers and thus determine whether they are eligible for these discounts. If only one address must be listed, then we ask that HRSA require the "bill-to" address. Additionally, if only one address must be listed, the form should be updated to distinguish which address, the "bill to," or the "ship-to" is being requested. BIO also asks that new "ship to" locations that appear in the "addresses" tab of the 340B database have both a start date and a termination date. This will help manufacturers to validate the eligibility and the transactions.

Finally, BIO asks that upon recertification, hospitals be required to list the single classification type (*e.g.*, DSH hospital, Sole Community Hospital, etc., if more than one applies) under which it is eligible to participate in the program. This will help manufacturers confirm the criteria under which the eligibility of each covered entity has been certified, including those that may currently be eligible under multiple categories.

Registration of Pharmacies

During its webinar held on April 26, and as reflected in new FAQs, OPA clarified that pharmacies are not eligible 340B covered entities and therefore, should not be listed as a child site with a 340B ID in the database. Pharmacies should be listed only as "ship-to" sites in the 340B database. We support HRSA in its efforts to ensure pharmacies are identified appropriately in the database.

BIO also believes that all covered entities should be required to list the National Provider Identifier (NPI) of their contracted pharmacies as part of the recertification process so that HRSA and manufacturers are able to accurately identify contracted pharmacies when 340B discount claims are made. Currently, the "Contracted Pharmacy Services Self-Certification Form for the 340B Program" requires covered entities to provide information on their contracted pharmacies, including the pharmacy name, address, phone and fax numbers and contact name and email. The NPI should be added to this form as well.

Outpatient Facilities that Provide Referral Services

HRSA recently posted a FAQ on its website which clarifies recertification requirements for outpatient hospitals that provide only referral services. As reflected in its FAQ, HRSA clarifies that outpatient facilities are not required to register with OPA if they merely provide referral services for a 340B entity. HRSA further clarifies that "the outpatient facility that is providing referral services cannot purchase or dispense 340B drugs."[9]

While BIO appreciates this clarification, we believe that this FAQ should be updated to further clarify registration requirements for outpatient facilities that not only "purchase" or "dispense," 340B drugs, but also for those that administer 340B drugs to their patients. BIO believes this will better ensure that referring facilities understand their responsibility to register with OPA if they provide physician-administered 340B drugs and biologicals to patients. Thus,

[9] *See e.g.*, HRSA FAQ: What outpatient facilities are hospitals required to register on the 340B database? Available at: http://www.hrsa.gov/opa/faqs/new.htm

we ask that the FAQ be updated to read, "the outpatient facility that is providing referral services cannot purchase, dispense, or administer 340B drugs."

Recertification of Private Hospitals

In order for private hospitals to be eligible for participation in the 340B program, they must either have a grant of governmental powers or have a contract in place with state or local governments to provide health care services to low income individuals not entitled to Medicare or Medicaid benefits. It is unclear what qualifies as a grant of government powers or what types of contracts HRSA views as sufficient to satisfy this eligibility requirement. BIO asks that HRSA issue additional guidance about these eligibility requirements in order to ensure that all stakeholders understand what qualifies as a grant of governmental powers and can distinguish between the types of contracts that may or may not fulfill the eligibility requirements under the program.

Covered Entity Ownership Status

To be eligible for 340B drug discounts, hospitals must be owned or operated by a state or local government or be a nonprofit hospital that contracts with a state or local government to provide health care services to low income, uninsured individuals.[10] On the "Certification of Contract Between Private, Non-Profit Disproportionate Share Hospital (DSH) and State/Local Government to Provide Health Care Services to Low Income Individuals" form, HRSA requires the covered entity to certify that such a contract is in place, and to list the signatories to such contract.

HRSA verifies the proprietary status of participating hospitals quarterly by matching the list of participating hospitals with CMS's list of hospitals to ensure that ineligible private for-profit hospitals are not participating in the 340B program. However, as HRSA is surely aware, hospitals that enroll in the 340B program when they are non-profits are sometimes acquired by for-profit entities, which, under the terms of the statute, would render them ineligible for continued participation in the 340B program. To guard against violations of this statutory requirement and to protect the integrity of the 340B program, BIO recommends that this form require covered entities to include a complete list of all of parent entities, including any immediate owners, ultimate parents, and those entities in between. We also strongly recommend that HRSA revise the certification language to include a statement that the covered entity, its parent organization, and upstream owner entities (if any) are all non-profit entities. We also recommend that HRSA require covered entities to certify that all of their child sites are non-profit organizations.

[10] Section 340B of the Public Health Service Act defines a covered entity to include "a subsection (d) hospital (as defined in §1886(d)(1)(B) of the Social Security Act that is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a state or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the SSA or eligible for assistance under the State plan under this subchapter." Section 340B(a)(4)(L)(i) (42 U.S.C. 256b(a)(4)(L)(i)).

Federal vs. State Requirements For Non-Profit Status

Federal and state non-profit requirements may differ and it is unclear from the language of the certification form whether Federal or State law is being used to assert non-profit status. Given the requirement to contract with a state or local government entity, as well as the Federal nature of this program, we believe that it is important for covered entities to comply with both Federal and State non-profit requirements. BIO therefore recommends that the certification be modified to indicate that the covered entity qualifies as a non-profit entity under both State and Federal laws.

Recertification Timeframes

During its webinar on April 26, OPA officials explained that while all change requests would be updated in the 340B database in real time, recertification and terminations would occur on a quarterly basis. OPA is interested in feedback regarding allowing terminations to be reflected in real time.

BIO strongly believes that 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.

While BIO strongly supports the need for covered entities to annually recertify their eligibility for the 340B program, we believe that any change that would cause a covered entity to be terminated from the program must be reported to HRSA and reflected in the 340B database immediately and in a readily identifiable and accessible format for manufactures. Moreover, terminations and decertifications that result from change requests should be given effect as soon as possible—without benefit of any grace period. Because the statute does not provide for any "grace period" under which the 340B discount continues, a variety of compliance and reporting requirements flow from the removal of an entity from 340B covered status.

We understand that HRSA may believe it has satisfied this requirement by its listing of the "time stamp" dates in the database, which we understand HRSA uses to identify the date when it changes the status of a covered entity's participation in the program in the database itself. The time stamp date can and by necessity almost always will pre-date the actual termination date listed in the database for a covered entity. While BIO appreciates OPA's efforts in this regard, BIO is concerned that OPA has not issued public and written guidance regarding what the "time stamp" date means and whether manufacturers can deny 340B discounts to participating covered entities as of the time stamp date where the covered entity also is officially listed as not being terminated until the start of the next quarter. Explicit guidance from OPA

regarding what these dates mean and whether and how manufacturers can rely on them is critical to avoid confusion within the program.

Once a covered entity is terminated, any discounts given to that entity may no longer be exempt from "best price" under the Medicaid rebate program.[11] Discounts given to a terminated entity also may have to be included in manufacturer reporting of Average Manufacturer Price (AMP) and Average Sales Price (ASP)—and any sales to the formerly covered entity may be subject to the Medicaid rebate from the time of disqualification. For these reasons, it is critical that OPA issue explicit guidance regarding the effective date of termination decisions. That guidance must be coordinated with CMS to confirm that a manufacturer need not treat as eligible for BP, AMP, or ASP any 340B discounts provided to the covered entity between the time stamp date and the formal termination date listed in the database.

To the extent that OPA confirms that the time stamp date can be used at the manufacturer's option as a real-time termination date, OPA must provide a means for manufacturers to readily identify when such termination-related time stamp dates have been added to the database. Addition of time stamp date to facilitate real-time cessation of 340B discounts can only work where the manufacturers have a reasonable opportunity to learn of such changes in entity eligibility. Most manufacturers check the database on a quarterly basis to identify new and terminated entities. They almost certainly do not have the capability to check on a daily or even weekly basis, hunting through the database to identify these status changes. Given the price reporting implications of covered entity terminations, it is incumbent on OPA to make these changes readily identifiable in the database.

BIO believes that where material delays between documentation of ineligibility for the 340B discount and decertification occur, HRSA should establish a process by which manufacturers can request refunds from previously covered entities of discounts that were improperly claimed. Finally, when these ineligibility determinations are made, HRSA should also establish a process to notify participating manufacturers of the determination with a clearly stated effective date and coordinate with CMS as to the price reporting implications of these status changes.

HRSA Website and Availability of Enrollment and Recertification Information

As HRSA continues administer and oversee the recertification process, BIO would find it helpful for the Agency to devote one area of its website to make all 340B related eligibility, recertification, and registration requirements available as well as all related forms and certification documents necessary for covered entities to provide. We believe that this will ensure that all stakeholders have insight into the enrollment and recertification processes, while easing the administrative burden of navigating the website for this important information.

[11] §1927(c)(1)(C)(i)(I) of the Social Security Act.

Conclusion

BIO appreciates the opportunity to comment on the recertification process. 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 L. Todd
Managing Director,
Reimbursement and Health Policy