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May 14, 2012

Commander Krista Pedley
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane,
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857
VIA ELECTRONIC DELIVERY

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

Dear Commander Pedley:

Genentech is writing in response to the request for comments on "Proposed Project: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program (OMB No. 0915–0327)—Revision," published in the *Federal Register* by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA) on March 19, 2012.[1]

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. We are a participating manufacturer in the 340B program. We appreciate the opportunity to comment on this information collection, which is part of HRSA's effort to collect information necessary to help ensure that covered entities enrolled in the 340B drug discount program meet the statutory criteria for 340B eligibility, both at the time of initial enrollment and on an ongoing basis.

Our comments are intended to assist HRSA in its efforts to follow the requirements of the statute and bolster the integrity of the 340B program. Specifically, we believe that the revisions to these forms provide HRSA with an opportunity to strengthen compliance by:

1. ensuring that manufacturers are not inappropriately required to provide 340B discounts to entities (or their child sites) that do not qualify for participation in the 340B program;
2. ensuring that eligible entities provide appropriate data to establish non-profit status, not only for themselves, but also for all of their upstream owner/investor entities and any child sites they may operate; and
3. ensuring that any changes impacting an entity's eligibility for the 340B program are reported to HRSA immediately and reflected, in real time, in HRSA's database of covered entities.

[1] 77 FR 16042.

Comments

Registration of Outpatient Facilities

We are aware that HRSA has been holding webinars for covered entities to assist them with recertification. It is our understanding that during these webinars, HRSA has made statements to the effect that a hospital owned pharmacy can not be registered as a child site (outpatient facility) of a 340B hospital. Such statements are supported by an FAQ posted by OPA.[2] Further, we understand that, in response to these statements, some DSH hospitals with outpatient clinic child sites have been delisting the clinics themselves. As a consequence, drugs purchased for use by both the parent and its (formerly-registered) child sites are all appearing on the chargeback data that manufacturers receive from wholesalers with a single "bill to" address – that of the parent organization.

It is possible that a hospital child site does not qualify for participation in the 340B program. For example, it may not meet CMS' provider-based requirements in relation to the 340B hospital, or it may not have been included in the parent hospital's most recently filed cost report. 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 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.[3] We therefore appreciate that HRSA has reiterated in its FAQs 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."[4]

We strongly recommend that, when registering these child sites, the 340B hospital be required to provide the "bill-to" address for the child sites, rather than a "ship-to" address. The reason for this is that chargeback data currently allows for the inclusion of only a single address, either "ship-to" or "bill-to." 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, we strongly encourage HRSA to require that outpatient facilities list their "bill-to" address. Taking this step will ensure that manufacturers can adequately identify their customers and thus determine whether they are eligible for these discounts.

[2] See http://www.hrsa.gov/opa/faqs/new.htm, last accessed on April 23, 2012.
[3] 59 Fed. Reg. 47884 (Sept. 19, 1994).
[4] Ibid.

Non-Profit Status

Ownership

In 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. As you may know, 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, we recommend that this form require covered entities to include a complete list of all of their parent organizations, including any immediate owners and other owners who may be further removed. 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 as well.

Federal vs. State Requirements

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. We therefore recommend that the certification be modified to indicate that the covered entity qualifies as a non-profit entity under both State and Federal laws.

Timeframe for Notifying HRSA of Changes

In most of the documents associated with this PRA Notice, HRSA instructs entities responsible for filling out the forms to notify OPA of any changes to the information required on the form. In the "Registration Form for Disproportionate Share Outpatient Facilities Using Medicare Cost Report," for example, the covered entity must acknowledge its "responsibility to notify OPA immediately if there is a material change in the 340B eligibility of any facility." Similarly, the "Hospital Certification of Ownership/Operation by a State/Local Government" form requires a covered entity to "inform the Office of Pharmacy Affairs of any changes to our status immediately." Although the remainder of the documents associated with this PRA Notice indicate that covered entities should notify HRSA of any changes in the information required by those forms, they do not specify the time frame in which this notice must be given to HRSA. If covered entities do not promptly notify HRSA of such changes, HRSA will be unable to update its list of participating covered entities promptly and accurately. If this information is incorrect, it may result in sales being made at the 340B price to entities that are not statutorily entitled to 340B pricing and the need for retroactive adjustments of such sales prices. To avoid these problems, we strongly urge HRSA to follow the course it has wisely chosen with the two aforementioned forms and modify all of the other forms associated with this PRA Notice so that they instruct covered entities to notify OPA immediately whenever any changes occur to the information required on these forms.

The statute is very clear about 340B qualifying criteria and does not leave room for entities that no longer are 340B-eligible to continue to participate in the 340B program. OPA should make clear to covered entities that their eligibility for participation in the program ends when they no longer meet the required eligibility criteria. Currently, when a covered entity loses its eligibility, HRSA does not reflect this change in its database until the beginning of the next quarter. We strongly recommend that HRSA update its database in real time, to remove ineligible entities so that manufacturers do not inadvertently extend 340B pricing to entities that no longer qualify for participation in the program. Further, OPA should require that when covered entities fail to notify OPA immediately of a change in their status and continue to obtain

drugs at 340B prices, they are responsible for providing a refund to manufacturers for the discounts that they have thus inappropriately obtained.

Pharmacy Identifier

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. However, this form does not require the listing of the pharmacy NPI, which is the industry standard identifier. To ensure that both HRSA and affected manufacturers may accurately and precisely identify contracted pharmacies, we recommend that this form include a line where covered entities list the NPI of their contracted pharmacies. A corresponding change should also be made in the "340B Participant Change Form."

Conclusion

We thank HRSA for the opportunity to comment on this PRA Notice. If you have any questions regarding our comments, please do not hesitate to contact Stephanie Dyson, Senior Director for Government Affairs, at 202-296-7272 or via email at dyson.stephanie@gene.com.

Sincerely,

/ELM/

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Genentech, Inc.