SNHPA
Safety Net Hospitals for Pharmaceutical Access

May 18, 2012

Reva Harris
Acting Director, Division of Policy and
Information Coordination
c/o HRSA Reports Clearance Officer
Room 10-29, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

RE: Comments On Proposed Project: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program (OMB No. 0915-0327) 53 Fed Reg 16042 (March 19, 2012)

Dear Ms. Harris:

We are submitting comments on behalf of Safety Net Hospitals for Pharmaceutical Access (SNHPA) in response to the notice published in the Federal Register on March 19, 2012 requesting comments on a proposed collection of information by the Health Resources and Services Administration (HRSA).[1] SNHPA represents over 800 safety net hospitals that qualify for and participate in the 340B Drug Pricing Program by virtue of serving a disproportionate share of low income Americans. The notice states that comments are being sought on a proposed project by the Health Resources and Services Administration (HRSA) to revise materials relating to enrollment and recertification of entities in the 340B drug pricing program (OMB No. 0915-0327).

SNHPA strongly supports HRSA's recertification of covered entities and, in fact, played an instrumental role in ensuring that federal authority to perform recertification was included in the Patient Protection and Affordable Care Act. It is critical that 340B enrollment information on HRSA's website be accurate in order for the 340B program to function effectively. Notwithstanding, SNHPA believes that collection of enrollment-related information by HRSA could be improved by modifying aspects of the certification statement that is part of the collection process. In addition, because collection of information through the recertification process is already underway, SNHPA is concerned that such collection activities may be invalid because (1) they have not yet been approved by OMB, (2) the collection of information does not carry a valid OMB control number, and (3) there was no reasonable notice given to covered entities of HRSA's collection efforts and the information being collected.

[1] 53 Fed. Reg. 16042 (March 19, 2012)

Background

The Federal Register notice requesting comments on the 340B collection of enrollment information states that, to determine eligibility for the 340B Drug Pricing Program, HRSA's Office of Pharmacy Affairs (OPA) requires health care providers to submit: (1) administrative information (e.g., shipping and billing arrangements, Medicaid participation), (2) "certifying information", and (3) signatures from appropriate entity level authorizing officials and state/local government representatives. The notice further explains that, to maintain accurate records, OPA requires that entities recertify eligibility annually and that they notify OPA of updates to the administrative information submitted when initially enrolled into the program. According to the notice, the anticipated burden on hospitals subject to annual recertification is a half hour. Comments are sought in four areas:

a. The proposed collection of information for the proper performance of the functions of the agency
b. the accuracy of the agency's estimate of the burden of the proposed collection of information;
c. ways to enhance the quality, utility, and clarity of the information to be collected: and
d. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology

SNHPA's comments focus on the collection of information that is being used to recertify hospitals annually. We understand that OPA began the recertification process for hospitals on April 20, and that hospitals were given three weeks to complete the process. It was conducted in three stages, each stage covering a specific category of hospitals, with the final stage ending on May 17. The recertification process consists essentially of two parts, with the first part requiring hospitals to update the data that appears on the OPA website regarding their 340B eligible facilities, and the second part requiring the hospital's "authorizing official" to certify to the following eight statements:

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 being eligible on the 340B database.
3. The hospital complies with all 340B requirements and restrictions and any accompanying regulations or guidelines including, but not 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 their compliance with the requirements described in (3) above.
5. The hospital has systems/mechanisms in place to reasonably ensure ongoing compliance with the requirements described in (3) above.

6. If the hospital uses contract pharmacy services, this contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines including, but not limited to, the hospital obtains sufficient information from the contractor to ensure compliance with the applicable policy and legal requirements and the hospital has utilized an appropriate methodology to ensure compliance (e.g. through an independent auditor or other mechanism).
7. The hospital acknowledges the responsibility to contact OPA as soon as reasonably possible if there is any material breach by the hospital of any of the foregoing.
8. If the hospital does not notify OPA in a timely fashion, it acknowledges 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.

Our comments regarding this collection of information are set forth below.

A. Comments Relating to the Evaluation of Whether the Proposed Collection of Information Is Necessary for the Proper Performance of the Functions of the Agency

SNHPA believes that some of the certification statements are not necessary for the proper performance of the functions of HRSA because they will generate information that cannot be legally relied upon. Of particular concern to SNHPA is statement #2, relating to continuous compliance with eligibility requirements since enrollment. This statement will not have practical utility as it is very difficult, if not impossible, for many hospitals to legally certify to this statement. As a result, HRSA should not rely on such statements, meaning that the statement will have no practical utility.

Statement #2 seems to require certification that, since the date of the hospital's enrollment in the 340B program, the hospital has continued (1) to be either a public institution or a private non-profit hospital under contract with a state or local government to provide indigent care; (2) to receive a disproportionate share (DSH) adjustment percentage above the statutory minimum; and (3) to comply with the prohibition against purchasing covered outpatient drugs through a group purchasing organization (GPO). Because the 340B program was established in 1992, certification to statement #2 could require an authorizing official to attest to his or her hospital's 340B compliance status for a period covering almost twenty years. It seems legally impossible for someone to certify to actions that took place that long ago, especially since the individuals in charge of a hospital's 340B program today are probably not the same individuals who were in charge of it when the hospital first enrolled.

Further, the 340B eligibility requirements applicable to hospitals are not always clear-cut. For example, OPA had a frequently asked question (FAQ) on its website stating that hospitals may use a GPO during a "reasonable phase-in" period when they first enroll in the program. That FAQ no longer appears on the website. There is no notice on OPA's website as to when this FAQ was taken down, and we are not aware of OPA publishing such information or otherwise informing hospitals of its policy on this issue. Without such knowledge, hospitals are

unable to determine exactly when this OPA policy applied. Such uncertainty means that 340B hospitals are unable to determine their continuous compliance with eligibility requirements which, in turn, renders the requisite certification less reliable.

B. Comments Regarding the Accuracy of the Agency's Estimate of the Burden of the Proposed Collection of Information

The notice includes an estimate that it will take hospitals approximately a half hour to complete annual recertifications. This is a significant underestimate of the time involved. In the case of statement #2 alone, hospitals could be in the position of having to review records and/or try to interview former employees going back almost twenty years. In addition, due to the fact that the eligibility requirements are not always clear cut, hospitals must also take the time to identify what guidance was available during various time periods in the almost twenty years since the program began. These efforts are guaranteed to take longer than a half hour for statement #2 alone. Many 340B hospitals have turned to SNHPA for assistance in understanding and implementing HRSA's recertification process. SNHPA has spent far more than half an hour on the phone with many member hospitals discussing these matters.

C. Comments on Ways To Enhance the Quality, Utility, and Clarity of the Information To Be Collected

To the extent that HRSA would like reliable evidence of compliance by covered entities, SNHPA recommends revising statement #2 so that it reflects a covered entity's compliance status at the time of the certification. Making this change would increase the quality, and therefore, the utility of the information collected.

D. Comments on Ways to Minimize the Burden of the Collection of Information on Respondents, Including Through the Use of Automated Collection Techniques or Other Forms of Information Technology

As discussed above, requiring that hospitals certify to actions that occurred almost twenty years ago is very burdensome. One way to minimize the burden would be to adopt the recommendation above that statement #2 be revised to reflect a covered entity's compliance status at the time of the certification. Another way to minimize the burden would be to notify covered entities in advance of the language contained in the certification statements. As discussed above, in the current hospital recertification process, hospitals do not see the certification statement until after they have completed all the screens necessary to confirm the accuracy of their administrative information. As a result, many hospitals did not know that they would be required to certify to the eight statements listed above until they were very close to the deadline for completing the certification. Having only a few days, or in some cases a few hours, to research the accuracy of the certification statements, hospitals found themselves scrambling to find the necessary staff and resources to do the research and complete the process. Hospitals complained to SNHPA that they found the process to be confusing and disruptive of normal operations.

E. Concerns Regarding Compliance with Federal Administrative Procedures

We are concerned that OPA's use of the attestation statements in the recertification process runs the risk of violating the rule-making provisions of the federal Administrative Procedure Act[2] and OMB's Final Bulletin for Agency Good Guidance Practices.[3] The APA generally requires notice and an opportunity to offer public comment when a whole or part of an agency statement is "legislative," i.e., of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy describing the organization, procedures, or practice requirements of the agency.[4] In an effort to improve compliance with the APA, OMB issued in 2007 its Bulletin on Agency Good Guidance Practices in order to ensure that guidance documents of federal departments and agencies are: (1) developed with appropriate review and public participation, (2) accessible and transparent to the public, (3) of high quality, and (4) not improperly treated as legally binding requirements. OMB said that all federal offices are expected to follow the policies and procedures outlined in the Bulletin.[5] Those policies and procedures very closely parallel the policies and procedures outlined in the regulations implementing the APA.

We appreciate that OPA, like any other federal agency, has discretion to interpret its own rules and guidelines on a case-by-case basis and that it may communicate interpretive guidelines without publishing them or providing the public the opportunity to comment. However, guidelines that cross into the "legislative area" – that is, those that create new duties, rights, or obligations by substantively modifying existing policy – must be promulgated through formal administrative procedures that include publication and an opportunity for affected stakeholders to provide public comment.

In this case, HRSA's certification statements clearly create new duties and rights because, among other things, statements #2, #7 and #8 are inconsistent with final 340B guidelines published by HRSA. For example, according to HRSA guidance published in the Federal Register in 2010, covered entities engaged in contract pharmacy arrangements are expected to perform audits of their contract pharmacies to ensure compliance. If evidence of drug diversion or duplicate discounts is uncovered by the covered entity, it is required under the guidance to "notify OPA about such compliance problems and the actions taken to remedy those problems."[6] There is no mention of this disclosure requirement applying to entities outside the context of contract pharmacy arrangements, as would be required under certification statement #7. In fact, guidance published in the Federal Register in December 1996 regarding HRSA's informal dispute resolution process encourages covered entities to attempt to resolve disputes themselves,

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[2] 5 U.S.C. §§551 and 553.
[3] Office of Management and Budget Bulletin No. 07-02, Final Bulletin for Agency Good Guidance Practices (Jan. 18, 2007).
[4] 5 U.S.C. §§ 551(4), 553.
[5] Office of Management and Budget Bulletin No. 07-02, Final Bulletin for Agency Good Guidance Practices (Jan. 18, 2007), at 4.
[6] 75 Fed. Reg. 10272, 10278 (March 5, 2010).

before approaching HRSA.[7] Only if the covered entity and the manufacturer cannot resolve a dispute may one of the parties approach HRSA.[8] Under this guidance, if a covered entity discovers a violation of 340B requirements after having been contacted by a manufacturer, and the violation is due to an error by the covered entity, the covered entity and the manufacturer are encouraged to resolve the issue without having to go to OPA. There is no self-disclosure requirement mentioned in that guidance.

Similarly, requirements relating to recertification have been included in past published guidance by HRSA, but differ significantly with what is included in the compliance statements that hospitals are being asked to certify. The final contract pharmacy guidance referenced above includes a section on recertification, stating that OPA may administer a recertification process periodically (most likely annually) where covered entities affirmatively certify as to their ongoing compliance with 340B requirements.[9] The final guidance further states that it is expected for the annual process to include a certification that the covered entity "met the 340B eligibility requirements throughout the prior year and continues to do so."[10] This language stands in stark contrast to statement #2 requiring certification dating back to a hospital's initial enrollment in the program, and thereby creating new duties and obligations that require notice and an opportunity to comment.

F. Concerns Regarding Compliance with OMB Approval Requirements

Federal law requires that, before a federal agency undertakes collection of information, several requirements have to be met, including (1) the collection of information must be approved by OMB,[11] (2) the collection process must carry a valid OMB control number,[12] and (3) the collecting agency must provide reasonable notice of the collection to the person to whom the collection is addressed.[13] The certification component of HRSA's 340B collection activities constitutes a "collection of information" because it is being used by OPA as a way to collect evidence of a 340B covered entity's compliance with applicable regulatory standards.[14] As such, it creates a burden that goes beyond the burden associated with identifying the respondent, the date, the respondent's address and the nature of the instrument.[15]

We understand that the certification statement has not been approved by OMB, nor has it ever been previously included in any OPA document that has been approved by OMB. It also does not appear to carry a valid OMB control number. Further, there has been no reasonable notice of the collection. There is no provision in the 340B statute requiring that covered entities

[7] 61 Fed. Reg. 65406, 65412 (December 12, 1996).
[8] Id.
[9] 75 Fed. Reg. 10272, 10279 (March 5, 2010).
[10] Id.
[11] 5 C.F.R. §1320.5(2).
[12] 5 C.F.R. §1320.5(3).
[13] 5 C.F.R. §1320.5(1)(i); 5 C.F.R. §1320.8(a)(3).
[14] *Dole v. United Steelworkers of America*, 494 U.S. 26 (1990); *Action Alliance of Senior Citizens of Greater Philadelphia v. Sullivan*, 930 F.2d 77 (D.C. Cir. 1991).
[15] 5 C.F.R. §1320.3(h)(1).

attest to continuous compliance since their enrollment in the program. Nor is there any provision imposing a mandatory disclosure requirement. The Patient Protection and Affordable Care Act added language to the 340B statute requiring the Secretary to develop a system for covered entities to regularly update the information on OPA's internet website and a system to verify the accuracy of information regarding covered entities listed on the website, but it does not say anything about requiring verification of past actions, especially going back potentially twenty years.[16]

Not only is there no notice in the statute or published guidance, but even the Federal Register notice discussing this collection of information references only the collection of administrative information. Specifically, relating to recertification, the notice states that OPA "requires that entities recertify eligibility annually and that they notify the program of updates to any administrative information that they submitted when initially enrolling into the program."[17] There is no mention of the fact that the recertification will also collect information relating to a hospital's past and ongoing compliance.

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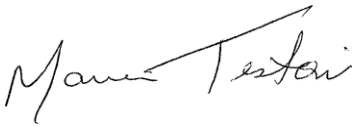
As discussed above, SNHPA believes that HRSA's collection of information as part of the 340B recertification process could be improved by modifying aspects of the certification statement that is part of the collection. In addition, to the extent that the collection is being used now, SNHPA believes it is invalid because it has not yet been approved by OMB, does not carry a valid OMB control number, and there was no reasonable notice given to covered entities of the collection of information.

Thank you for considering our comments. Should you have any questions, please feel free to contact us at 202-552-5851.

Sincerely,



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[16] 340B(d)(2)(B)(i) and (ii).
[17] 77 Fed. Reg. 16042, 16043 (March 19, 2012).