



Safety Net Hospitals for Pharmaceutical Access

October 15, 2007

Jimmy Mitchell
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Parklawn Building, Room 10C-03
Rockville, MD 20857

Re: 340B Enrollment of New Disproportionate Share Hospital Sites

Dear Jimmy:

We are writing to express our concern over OPA's position regarding the acceptance of provider-based attestations as a basis for enrollment of new hospital outpatient sites into the 340B program.

To reiterate briefly the relevant history of this issue, HRSA issued final guidelines on September 19, 1994 allowing disproportionate share hospitals (DSH) to enroll into the 340B program any affiliated site that is an "integral part" of the DSH hospital as demonstrated by inclusion of the site's costs on the hospital's Medicare cost report.¹ It was SNHPA's understanding for many years that, pursuant to the 1994 guidelines, when a 340B hospital establishes a new outpatient facility that meets this "integral part" standard, and such facility begins incurring costs that are reimbursable on the hospital's Medicare cost report, the new site could be enrolled in the program effective the first day of the next quarter. In November 2005, OPA informed SNHPA for the first time that new DSH sites could not be enrolled until their costs actually appeared on a cost report already filed with the Medicare program. SNHPA subsequently exchanged several letters with OPA explaining that such a policy could delay enrollment of new sites by as much as twenty months and that, to avoid such excessive delays, OPA should adopt a more reasonable approach.

In July 2006, SNHPA and two member hospitals met with OPA to discuss the issue further. The result of this meeting was what we and our members understood to be an agreement that OPA would accept, as an alternative to an "as filed" cost report, an attestation of a new DSH site's provider-based status as evidence that the site was an

¹ 59 Fed. Reg. 47,884 (Sept. 19, 1994).

“integral part” of the 340B hospital and therefore eligible to participate in the 340B program. Soon afterwards, in August 2006, OPA actually enrolled a member hospital’s outpatient facility in the 340B program on the basis of a provider-based attestation. Based on the July meeting and on this specific application of OPA policy and discretion, SNHPA reported to its members in its October 2006 Bulletin that a provider-based attestation could be used in lieu of an “as filed” cost report to support enrollment of a new DSH site into the 340B program. It bears mention, moreover, that prior to finalizing this Bulletin, SNHPA staff contacted OPA and gained oral approval to communicate to its membership as a whole that a provider-based attestation could be used in support of an application to enroll new DSH sites.

In light of this history, SNHPA was dismayed to learn that OPA recently rejected a member hospital’s new DSH site application on grounds that the provider-based attestation submitted in support of the application could not substitute for an “as filed” cost report as evidence of the relationship between the hospital and its new site. OPA’s apparent reversal of its earlier position has significant financial repercussions for hospitals. The acceptance of provider-based attestations can reduce the wait-time for 340B enrollment of new DSH sites by more than one year. Acquiring or building new sites is often a means through which hospitals seek to achieve the underlying goals of the 340B program – that is, to reach more patients and provide them with more comprehensive services. Establishing an off-site facility or new clinic devoted to the medical needs of the surrounding community can play a vital role in reaching out to patients, especially those who are indigent, uninsured, or underinsured and whose transportation options may be limited. The convenience of a new DSH location is pivotal in whether local indigent patients seek necessary medical care.

However, establishing new facility sites also often requires significant start-up costs, which can be underwritten in part by anticipated savings from the 340B program. Thus, by reducing the delay of a new site’s participation in the program, OPA’s acceptance of provider-based attestations could significantly improve the financial viability of such sites, particularly those that will be treating large numbers of uninsured and underinsured patients who cannot pay for medical services and prescription medications. Some member hospitals now find themselves in the position of lacking significant, anticipated savings for which they have budgeted and planned based upon what seemed to be OPA policy in the latter part of 2006. In some cases, plans to establish new medical facilities that would significantly improve health care delivery to low income communities simply cannot go forward if 340B savings cannot be realized promptly on the medications used and dispensed by those facilities.

This situation seems especially unfair and unnecessary in light of OPA’s apparent agreement with the proposition that a DSH hospital’s off-site facility meeting Medicare criteria for provider-based status is and should be regarded as part of the hospital. Indeed,

there can be no other explanation for the fact that proposed new guidelines on the 340B definition of a “patient,” published in the Federal Register on January 17 of this year, would replace OPA’s current Medicare cost report test with the Medicare provider-based rule for evaluating 340B eligibility of off-site clinics.² OPA has apparently concluded – we think erroneously – that a provider-based test for 340B eligibility of an off-site facility cannot be used at all until the new patient definition guidelines are published in final form, and further, that the provider-based standards cannot be utilized now precisely *because* such a test is set forth in a proposed rather than final guideline. Yet in actuality, the existence of the proposed guidelines poses no legal impediment to present application of the provider-based test in appropriate circumstances.

To begin with, HRSA adopted the Medicare cost report test as a way to measure the level of integration between an off-site DSH facility and the main campus of the 340B-participating DSH hospital with which it is associated. As the existing HRSA guidelines reflect, however, the Medicare cost report test is simply used in the 340B program to address an underlying more fundamental question, namely, whether the new clinic or other off-site facility is an “integral part” of the 340B eligible DSH hospital.³ The cost report test is essentially a procedural means of testing for compliance with the substantive standard of whether a site is an “integral part” of a hospital; the Medicare cost report is not, in and of itself, a 340B relevant standard or criteria. The “integral part” standard, by contrast, flows directly from, and in effect does little more than restate, the statutory limitation of eligibility for 340B participation to specified covered entities. If a facility is not a covered entity, standing alone, it must be part of a covered entity or it will not be 340B eligible at all. The “integral part” standard is thus a logically compelled and undoubtedly valid interpretation of the statutory standard for hospital participation in the 340B program, and as such can be implemented without notice and comment rulemaking.

To the extent HRSA seeks to impose permanent restrictions on the manner in which a covered entity can establish that a site or facility is an integral part of the entity – for example, as HRSA proposes to do through its January 17th guidelines purporting to make provider-based status the *exclusive* test for determining whether a facility is part of an eligible DSH hospital – public notice and comment would be a legal prerequisite to enforcing any such rule.⁴ The non-final status of HRSA’s guidelines therefore *is* a legal impediment to current implementation of a rule defining provider-based criteria as the *only* acceptable means of establishing compliance with the “integral part” standard. This does not prevent OPA, however, from acting in appropriate circumstances to effectuate the “integral part” standard inherent in the governing statute and articulated in current guidelines, through reasoned *ad hoc* decision-making based on relevant facts. It would require no more than a reasoned basis in the facts of a given case for OPA properly to

² 72 Fed. Reg. 1543 (Jan. 17, 2007).

³ 59 Fed. Reg. 47,884 (Sept. 19, 1994).

⁴ 72 Fed. Reg. 1543 (Jan. 17, 2007).

decide to supplement the Medicare cost report test and recognize a showing of compliance with the “integral part” standard in that particular case through application of provider-based criteria. Indeed, in the absence of any legally binding provision of statute or regulation restricting the means to discern whether a facility is part of a larger covered entity, OPA will always have authority, on a reasoned *ad hoc* basis, to supplement whatever test it may articulate in policy guidelines for meeting the “integral part” standard with alternative criteria more appropriate to a particular situation.

Moreover, HRSA’s current guidance on the 340B eligibility of outpatient DSH facilities, which has been in effect since September 1994, can be construed implicitly to incorporate already the Medicare provider-based standards. When the Medicare cost report test was adopted by HRSA in 1994, HRSA described the test by both citing and quoting from Section 2024 of the Medicare State Operations Manual.⁵ Section 2024, among other things, enumerated certain standards that a facility would have to meet in order to be certified as part of a hospital for purposes of the Medicare program. After the provider-based regulation was promulgated by the Centers for Medicare and Medicaid Services (CMS) in April 2000, CMS revised the State Operations Manual to conform to the new regulations. CMS eliminated the language cited in the HRSA guidelines and replaced it with an explicit reference to the Medicare provider-based regulation at 42 C.F.R. § 412.65. So the portion of the State Operations Manual referenced in HRSA’s DSH outpatient facility guidance simply refers to the Medicare provider-based regulation instead of describing the standards that a facility previously had to meet in order to be certified as part of a hospital.⁶ This is important because, when the Medicare cost report test was adopted by HRSA thirteen years ago, its meaning and scope were tied to a set of standards which have since been replaced by CMS with the provider-based standards. Based on this history, there is a strong argument that application of the “integral part” standard under HRSA’s current guidelines should include, as an alternative to the cost report test, application of provider-based standards, including the use of attestations to verify compliance with such standards.

We therefore urge OPA not to adopt artificial restrictions on the scope of its authority to implement the “integral part” standard for 340B eligibility of new sites. A year ago, OPA exercised permissible discretion in admitting a new DSH clinic into the 340B program based on a showing of the site’s provider-based status. This was the right result because the facts of that case made application of the usual cost report test impractical and counterproductive to 340B program goals. The law has not changed. That

⁵ See 59 Fed. Reg. 47,884 at 47,885 (Sept. 19, 1994).


⁶ Section 2024’s reference to the Medicare provider-based rule is indirect. Prior to promulgation of the rule, CMS moved its hospital certification standards from Section 2024 to Section 2004 of the State Operations Manual. After the rule was issued, Section 2004 was modified to explicitly refer to the rule for guidance on provider-based determinations. Section 2024’s reference to the Medicare provider-based rule is thereby by way of Section 2004 of the State Operations Manual.

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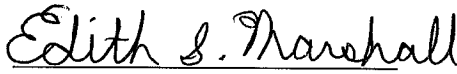
same discretion and authority still exists, notwithstanding the proposal of new and more restrictive policy guidelines. In SNHPA's view, failing to exercise this authority, when circumstances demand it, is both unfair to covered entities and detrimental to the purposes of the 340B program.

We hope that you will carefully consider the points discussed in this letter and will revisit your current stance on how DSH hospitals can enroll new sites into the 340B program. As always, we are available, and would appreciate the opportunity, to discuss these matters with you further should you wish to contact us at the phone numbers listed below or to meet in person.

Sincerely,



William H. von Oehsen
President and General Counsel



Edith S. Marshall
Special Counsel and Director of Legal
Affairs