

April 14, 2009

VIA ELECTRONIC AND U.S. MAIL

Jonathan Blum
Director
Center for Medicare Management
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW Room 314G
Washington, DC 20201

Re: Physician Supervision for Hospital Outpatient Therapeutic Services

The undersigned organizations write to request that the Centers for Medicare & Medicaid Services (CMS) withdraw or delay the recent policy change regarding physician supervision of hospital outpatient therapeutic services as described below, and that it immediately instruct contractors that no enforcement actions should be initiated or pursued until the issues raised in this letter are addressed. The policy announced in the 2009 outpatient prospective payment system (OPPS) final rule, published on November 18, 2008, requires a physician privileged by the hospital to provide supervision to be physically present in the outpatient department at all times that outpatient therapeutic services are furnished, regardless of whether the services are furnished in the hospital, on the hospital campus or off-campus. This represents a significant change in Medicare payment policy. (*See 73 Fed. Reg. 68,702.*)

CMS' intent to revisit and alter this policy – identified by CMS as a “clarification” – was not clear in the 2009 OPPS proposed rule. There was a clear lack of effective and adequate notice about the CMS policy change, which as a result, affected the opportunity to comment on the proposal. Therefore, many in the field missed the opportunity to address the substantial impact this policy change would have on providers and physicians. The significance of this policy change became clear in January 2009 only as a result of an Open Door Forum call and the issuance of a revised Medicare manual provision well after the 2009 OPPS final rule was issued. Since that time, the specifics of the new policy have caused great concern due to the negative effects it would have on both hospitals and physicians, which are summarized in this letter.

We urge CMS to schedule a Special Open Door Forum or Town Hall meeting where affected providers can provide feedback to CMS about the impact of this new policy. Then, CMS should publish another discussion of the issue, including any proposed changes, in the 2010 OPPS proposed rule and offer alternate solutions.

If CMS decides not to revisit this onerous new interpretation, the agency still should provide for a delayed effective date. There are two reasons such a delay is necessary: (1) the agency did not provide adequate time for hospitals to modify their operations to be compliant with this new

policy by the January 1, 2009 effective date, and (2) this change was characterized in the *Federal Register* as a “restatement and clarification,” thereby causing many affected parties to fail to understand its significance or to provide adequate comments. The Agency also should impose an enforcement moratorium because of the steps hospitals and physicians need to take to achieve compliance for on-campus provider-based departments. If CMS objects to revisiting the policy in the 2010 OPPTS rulemaking, the agency nevertheless should provide a more robust explanation of why the new policy is necessary.

The new policy places a considerable burden on hospitals, requiring them to engage more physicians for direct supervisory coverage without a clear clinical need. This change comes at a time when relationships between physicians and hospitals are changing substantially and physician shortages in various specialties continue. It presents an issue of special concern for critical access hospitals (CAH) and for communities in which the shortage of physicians is especially severe. It may lead to patient access problems if hospitals are forced to discontinue certain outpatient services or shy away from opening new ones. The *Federal Register* discussion provides scant rationale for the new policy or any indication of whether other alternatives were considered. Therefore, it remains unclear as to why this change in policy is necessary from a clinical perspective.

I. Background

Currently, Medicare pays for outpatient therapeutic hospital services furnished “incident to” a physician’s service. (Social Security Act § 1861(s)(2)(B).) Medicare regulations set three basic conditions of payment for hospital incident to services: (1) services furnished by or under arrangement made by a hospital; (2) as an integral though incidental part of a physician’s service; and (3) furnished in the hospital or at a department of a provider, as defined in §413.65(a)(2), that has provided-based status. (42 C.F.R. §410.27(a)(1)(i)-(iii).)

CMS has addressed Medicare payment policy for incident to services in hospital outpatient departments at various times over the years. In 1998, CMS (then the Health Care Financing Administration) explained that “as a matter of policy, we require that the services and supplies be furnished on a physician’s order by hospital personnel and under a physician’s supervision.” (63 *Fed. Reg.* 47,593.) At the time, the Medicare Intermediary Manual (“MIM”) served as the source of this policy and did not require a specified level of physician supervision for payment of incident-to hospital services. (*See* MIM § 3112.4(A).) Specifically, the MIM provided only that “[t]he services and supplies must be furnished on a physician’s order by hospital personnel and under a physician’s supervision.”

The 1998 proposed rule stated that “[w]hen ‘incident to’ services are furnished on hospital premises, we assume the physician supervision requirement to be met because staff physicians would be present nearby within the hospital.” Further, the rule states that CMS equates “the location of the hospital outpatient department or hospital clinic within the hospital’s walls, or their co-location on the same campus, with being ‘on the premises,’ and we assume physician supervision is always at hand.” (63 *Fed. Reg.* at 47,593.)

Medicare policy did not specify a level of required physician supervision for incident to hospital outpatient services until this 1998 proposed rule, when CMS proposed a regulatory change to

require direct physician supervision for services furnished in a department or clinic “offsite and that is not on the hospital premises.” The scope of the proposed policy was decidedly narrow due to CMS’ clear statement that “on the premises of the hospital” included services furnished within the hospital’s main buildings and in any department or clinic co-located on the same campus as the hospital. Thus, the generally held view of this proposal by the hospital and physician communities was that it only imposed a direct supervision requirement for off-campus provider-based entities only. CMS did not express the same concerns about services rendered in hospitals and in on-campus provider-based departments, and therefore those sites of service remained subject only to the policy requirement of “under a physician’s supervision.”

The 2001 OPPTS final rule fully supported the field’s view. In adding subsection (f) to 42 C.F.R. § 410.27, CMS sought to require direct physician supervision as a condition of payment for hospital outpatient incident to services rendered in provider-based departments. In the preamble, CMS drew a narrow application when it stated unequivocally that “[o]ur proposed amendment of §410.27 to require direct supervision . . . does not apply to services furnished in a department of a provider that is located on the campus of the hospital.” (65 *Fed. Reg.* 18,525.) Notably, the 2001 OPPTS final rule did not impose any specific supervision requirements for hospital outpatient incident to services furnished in the hospital. Therefore, the regulation did not then – and does not now – require any specific level of supervision for outpatient therapeutic services furnished in the main buildings of a hospital or on a hospital campus.

Based on these pronouncements by CMS, hospitals have long believed that direct physician supervision is required only for hospital outpatient incident to services furnished in off-campus provider-based departments. Incident to services rendered in hospitals and at on-campus provider-based departments are required to be furnished under a physician’s supervision, although that supervision did not rise to the level of direct supervision as the term is defined in the incident-to regulations governing the physician office setting (42 C.F.R. §410.32(b)(3)(ii)) and the outpatient hospital setting (42 C.F.R. §410.27(f)).

In 2008, CMS revisited the scope of its direct physician supervision policy in the 2009 OPPTS rulemaking. The 2009 OPPTS final rule states that there may have been a “misunderstanding” about what, if any, level of physician supervision is required for incident to services furnished in a hospital or an on-campus provider-based department, and that a “restatement and clarification of the policy” was necessary. (73 *Fed. Reg.* 68,702.) In addressing the apparent misunderstanding, CMS stated “[i]t is our expectation that hospital outpatient therapeutic services are provided under the direct supervision of physicians in the hospital and in all provider-based departments of the hospital, specifically both on-campus and off-campus departments of the hospital.”

CMS has since memorialized this “expectation” in section 20.5.1 of the Medicare Benefit Policy Manual. (*See* Transmittal 101, Change Request 6320, Pub. 100-02 [Jan. 16, 2009].) Furthermore, the policy has gone beyond previous discussions regarding direct physician supervision in setting a strict physician proximity standard that would require the physician supervising the outpatient therapeutic service to be physically present in the provider-based department, regardless of whether the services are provided on campus or off campus, at all times that services are furnished. This new policy represents a major change for outpatient

hospital therapeutic services furnished in the hospital and on-campus provider-based departments.

II. CMS Should Withdraw the New Payment Policy or, at a Minimum, Delay the Effective Date

The 2009 OPPTS final rule discussion characterizes CMS' new policy on physician supervision for hospitals and on-campus provider-based departments as a "restatement and clarification" of existing policy. In reality, as demonstrated above, the final rule represents a significant change in policy for certain sites of service, such as outpatient infusion clinics and outpatient psychiatric facilities.

The undersigned organizations recommend that CMS immediately withdraw this onerous and unnecessary new policy. If CMS is unwilling to do so, then at a minimum, we urge CMS to delay the effective date for at least a year to allow hospitals to bring their on-campus arrangements into compliance. At the same time, CMS should direct all Medicare contractors to refrain from initiating or pursuing any enforcement actions based on this new policy until CMS provides additional direction. Given the significance of the changes, hospitals and physicians should be afforded ample time to make operational modifications when necessary, given that compliance with the new policy cannot be achieved immediately. The sixty-day notice before the policy's effective date was insufficient for hospitals to find and enter into arrangements with physicians to provide direct supervision in the additional sites of service required by the new policy. As a result, many hospitals now face a period of potential non-compliance while they seek to find physicians to provide direct supervision in on-campus provider-based departments.

Likewise, if CMS is unable to immediately withdraw this problematic policy, a delay also will allow the agency time to consider the suggestions made in this letter, such as holding a public meeting and engaging in further discussion in the 2010 OPPTS rulemaking process. Even if CMS ultimately decides not to revisit the policy, a delayed implementation date and parallel enforcement moratorium is nevertheless appropriate to allow hospitals and physicians to make necessary modifications to existing on-campus provider-based department arrangements.

III. CMS Should Seek Additional Public Input Before a New Policy is Implemented

It is unclear why CMS changed this policy. As stated above, the 2009 OPPTS final rule explains that CMS is concerned that there may have been a misunderstanding about what, if any, level of physician supervision is required for incident-to services furnished in a hospital or an on-campus provider-based department. (73 *Fed. Reg.* 68,702.) Because of this purported misunderstanding, CMS announced its "expectation" that direct physician supervision is a payment condition for incident to hospital outpatient therapeutic services furnished in the hospital and in all provider-based departments of the hospital, including on-campus and off-campus departments of the hospital. CMS argues that this "expectation" is rooted in longstanding Medicare policy, which it outlines in the CY 2009 OPPTS final rule's preamble.

This "expectation" is not supported by any regulation or previous policy statements related to services furnished in a hospital or on-campus provider-based departments. For incident to services furnished in the hospital, neither the governing regulation nor any other CMS policy has

previously imposed a direct physician supervision requirement. Although the “expectation” included in the 2009 OPSS rulemaking for services furnished in the hospital is not authorized by the governing regulation, CMS did not seek to change that regulation to properly implement this significant policy change. In our view, a regulatory change would be necessary to effectuate the new policy applicable to services furnished “in the hospital.”

For provider-based departments located on a hospital’s campus, the 2001 OPSS final rule unequivocally states that the direct supervision requirement does not apply. (65 *Fed. Reg.* 18,525.) This statement leads to the conclusion that the “expectation” is really new policy for sites of service other than off-campus provider-based departments.

In the 2009 OPSS final rule, CMS suggests that lack of direct physician supervision would be considered a “quality concern.” (73 *Fed. Reg.* 68,703.) Beyond this statement, CMS offers no evidence to support the assertion that quality is affected at these sites of service when there is no direct supervision. If quality is one of the reasons for imposing this new requirement, then CMS must make available the data that supports this contention.

Additionally, none of the sources CMS identifies as longstanding policy support for this expectation specifically mention, let alone require, direct supervision. Instead, “under a physician’s supervision” has been the operative standard. Clearly, this does not rise to the level of direct supervision. Furthermore, because direct supervision is one of three specified levels of physician supervision in 42 C.F.R. § 410.32, it is difficult to understand how long standing Medicare policy supports the expectation of direct supervision (over general or personal supervision) when the 2009 OPSS rulemaking was the first time that such terminology was used for sites other than off-campus provider-based entities. More telling, CMS refers to the changing landscape for hospital services caused by new technology and practice patterns, which seems to be an impetus for CMS’ new policy now seeking a more specific level of physician supervision.

It is unclear whether CMS considered alternative approaches for changing its physician supervision policy. One possibility could be a policy that is similar to the outpatient diagnostic services policy, which acknowledges that different outpatient therapeutic services warrant different levels of supervision by requiring one of three levels of supervision (*i.e.*, general, direct, or personal). CMS should re-visit the policy in the 2010 OPSS rulemaking and seek comment on this approach and other possible alternatives. If concerns lie with the framework of certain on-campus arrangements and the ready access of a physician supervisor, modifications to CMS’ provider-based policies may address them.

In sum, there are other alternatives to CMS’ across-the-board direct physician supervision policy for hospital outpatient therapeutic services, and those alternatives should be more fully vetted before CMS decides upon a final policy. The new policy will affect many existing hospital services and challenge hospitals to produce sufficient physician supervisors to keep all existing outpatient service lines open in order to avoid access problems for patients. It will limit physicians in their ability to provide patient care if they must spend time providing direct supervision of services that to date have been provided effectively without such supervision. The impact will be particularly severe for small or rural hospitals, such as CAHs, which are often the only source of outpatient hospital services within many miles and which are in locations

Jonathan Blum

April 14, 2009

Page 6 of 6

which may have only one or two physicians in the entire community. CMS should take into account all of these factors in its quality of care cost/benefit analysis.

We respectfully urge CMS to withdraw the new policy and return to the former policy long understood by the hospital and physician communities. If CMS is unwilling to do so, then we urge the agency, at a minimum, to immediately impose a delay in the effective date of this new policy, to suspend enforcement, and to reopen the new policy for additional public input and consideration of alternatives. A Special Open Door Forum or Town Hall meeting would be an important first step for the agency to ensure it provides the hospital and physician community with the opportunity to provide full feedback on the new policy's impact. Following this public discussion, CMS should reopen the discussion of the merits of this policy change for further public comment during the 2010 OPSS rulemaking process, including a discussion about whether such a change in policy is clinically warranted. In doing so, CMS should consider alternate approaches to addressing the agency's concerns. Under any scenario, CMS should explain in more detail the reasons for making this policy change.

* * * * *

Thank you for your consideration of our letter. We would appreciate the opportunity to meet with you soon to discuss our requests and related issues in more detail.

Sincerely,

Association of American Medical Colleges
American Association of Cardiovascular and Pulmonary Rehabilitation
American Hospital Association
American Psychiatric Association
American Society for Radiology Oncology
Catholic Health Association
Federation of American Hospitals
National Association for Medical Direction of Respiratory Care
National Association of Psychiatric Health Systems
National Rural Health Association
Premier
VHA Inc.