June 1, 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

Dear Mr. Blum:

Thank you for arranging our recent meeting with your staff on the issue of physician supervision for incident-to outpatient hospital therapeutic services. The meeting was a productive conversation about whether from a clinical perspective direct supervision by a physician is necessary for these services. In our view, a different policy that reflects the true clinical needs of patients and the practical availability of physicians to supervise the services would better serve the Medicare program and its beneficiaries.

Separately, our members remain very concerned about certain CMS statements from the 2009 OPPS rulemaking that have the potential to subject hospitals to substantially heightened and unwarranted enforcement scrutiny. As the agency considers next steps related to its policy, we strongly urge CMS to take immediate steps to mitigate the new and inappropriate enforcement risks that the troubling CMS statements have created.

I. Background

At issue is the 2009 OPPS rulemaking's characterization that a "restatement and clarification" of the physician supervision policy was necessary because there may have been a "misunderstanding" about what, if any, level of physician supervision was required for incident-to outpatient therapeutic services. (73 *Fed.Reg.* 68,702.) The rulemaking further states that "[i]t is our expectation that hospital outpatient therapeutic services are provided under 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."

Our hospitals believe strongly that the 2009 OPPS rulemaking was a significant policy change for certain settings, not a restatement or clarification of existing policy. The record is clear that "direct supervision" by a physician has been a requirement since 2001 only for incident-to outpatient therapeutic services furnished in a department that is located off the hospital's

campus. We believe the record is equally clear that, prior to January 1, 2009, direct supervision by a physician was not required for incident-to outpatient therapeutic services furnished in a hospital or in a department located on a hospital's campus. The 2001 OPPS final rule supports our view and could not be more specific: "[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.) This same policy position was adopted for services furnished "in the hospital." For CMS now to say otherwise about past time periods opens up the entire hospital community to misplaced enforcement scrutiny, including by potential *qui tam* relators, for services furnished in a hospital or on a hospital's campus before January 1, 2009.

II. The 2009 OPPS Preamble Exposes Hospitals To Significant Enforcement Scrutiny

Through our ongoing dialogue with CMS, we learned that an assumption made by CMS in 2001 may be the root cause for the concerns related to the policy. During the 2001 rulemaking, CMS assumed that when services are furnished "on the premises" (a location description that CMS determined included both in a hospital and on a hospital's campus), "physician supervision is always at hand." (63 *Fed.Reg.* 47,593.) The stated assumption, however, does not specify any particular level of physician supervision that CMS expected to be available. As a result, most hospitals interpreted the policy to require only "general supervision" by a physician for services furnished in a hospital or on a hospital's campus.

It now seems that CMS had an expectation that "direct supervision" was the applicable standard adopted at that time. However, the extensive regulatory analysis contained in our previous letter shows that while physician supervision was required, the 2001 rulemaking does not support a policy of direct supervision by a physician for services furnished in a hospital or on a hospital's campus, which is what CMS now desires. The 2009 rulemaking, in fact, is the first time the direct supervision by a physician requirement was applied to all settings for incident-to outpatient therapeutic services.

Because of CMS's statements about the 2009 rulemaking being a "restatement and clarification" of policy, the enforcement risk for periods prior to the 2009 rulemaking statements has now increased exponentially. By asserting that since 2001 the agency's policy has required direct supervision by a physician, CMS now exposes hospitals to potential recoupments and whistleblowers who can claim that a hospital did not have appropriate direct physician supervision arrangements in place in some or all of its affected departments dating back to 2001.

Such claims are often attractive to whistleblowers because of the lucrative amounts of Medicare reimbursement at issue, which is determined based upon the nature of the direct physician supervision requirement, its impact on the payment status of all services furnished to Medicare

beneficiaries in that department, and the construct of the penalty and damages provisions of the federal False Claims Act.

III. CMS Should Withdraw Immediately Its 2009 Preamble Statement Regarding Restatement and Clarification of 2001 Policy

Hospitals' concerns related to the enforcement scrutiny are real and CMS's statements currently leave hospitals exposed. We urge CMS to take quick action to communicate to the field on the status of the policy and its history. It seems clear that the CMS's expectations related to this policy were not fully appreciated and understood by hospitals, and one of the key reasons for that appears to be the unclear and imprecise drafting of prior policy discussions.

We believe it is in the best of interests of CMS, hospitals, and patients to revisit the policy, hopefully in the context of the 2010 OPPS rulemaking. In doing so, we hope to find an acceptable approach which best serves patients from a quality perspective while also properly balancing other realities, such as the clinical need for, and availability of, physicians to provide supervisory services. However, the potential for an explosion of enforcement scrutiny emanating from CMS's characterization of the new policy as a "restatement and clarification" could easily affect the ability to achieve that goal in a meaningful and non-adversarial way.

Therefore, we urge CMS to immediately acknowledge the field's concerns about the ambiguity and uncertainty around this policy, and to recognize that the agency's expectations for the policy were not communicated clearly in the 2001 rulemaking. We believe this could best be accomplished by rescinding Transmittal 101, Change Request 6320, Pub. 100-02 [Jan. 16, 2009].) Also, this can be communicated as part of the 2010 OPPS rulemaking preamble discussion. We suggest CMS use the following language in all related communications:

> Following publication of the 2009 final rule, we learned of significant disagreement over whether Medicare payment policy has required since 2001 that incident-to outpatient therapeutic services furnished in a hospital or on a hospital's campus be provided under the direct supervision of a physician. As we stated in the 2009 preamble, Medicare policy is clear that physician supervision is required. However, upon closer review of earlier rulemaking discussions about specific levels of physician supervision and the settings to which they would apply, we now believe statements in the 2001 preamble appear to be inconsistent with our 2009 preamble characterization that we were merely restating and clarifying the 2001 policy. Many hospital and physician groups have written us expressly stating this view and we recognize the merits of these concerns, as well as the need to work with providers, patient groups and others to establish appropriate policy regarding physician supervision for outpatient therapeutic

> services. Therefore, we invite public comment on this policy going forward, and withdraw our characterization, expressed in the 2009 preamble, that policy requiring direct physician supervision for therapeutic services other than those furnished in off campus departments was a restatement and clarification of existing policy.

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Thank you for your willingness to work with us on this important issue. We would appreciate the opportunity to meet with you directly to further discuss our concerns about the possible enforcement impact of the 2009 preamble discussion.

Sincerely,

Association of American Medical Colleges
American Hospital Association
Federation of American Hospitals
National Association of Psychiatric Health Systems