

Requirements for Physician Supervision of Therapeutic Hospital Outpatient Services: Clarification or Confusion?

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In the preamble discussions to the 2009 Outpatient Prospective Payment System update (2009 OPSS Rule), the Centers for Medicare & Medicaid Services (CMS) set forth a discussion of what it characterized as a “restatement and clarification” of the physician supervision requirements for therapeutic hospital outpatient services.¹ More specifically, CMS clarified that “direct supervision” is required of all “incident to” services provided in a hospital outpatient department, regardless of whether the services are provided on or off the hospital’s main campus. While CMS describes its position as a clarification of existing rules, many characterize the change as dramatic and one that requires hospitals to re-examine physician supervision not only in off-campus locations, but also on-campus. Indeed, for certain aspects of the discussion set forth in the 2009 OPSS Rule, the asserted “restatement and clarification” by CMS is perhaps more aptly described as a “change in interpretation.”

Hospital Outpatient Therapeutic Services

The Social Security Act provides Medicare coverage for services “incident to physicians’ services rendered to outpatients.”² Prior to the implementation of the 2000 Outpatient Prospective Payment System rule (2000 OPSS Rule), Medicare regulations generally provided coverage if the therapeutic services were furnished (1) by or under arrangements made by a participating hospital; and (2) as an integral though incidental part of a physician’s services.³

With the implementation of more formal provider-based rules in the 2000 OPSS Rule, an extra provision was added to the regulations.⁴ The new provision provided that therapeutic services also must be furnished: (3) In the hospital or at a location (other than an RHC or an FQHC) that [CMS] designates as a department of a provider under § 413.65 of this chapter [the provider-based regulations].⁵

In other words, CMS would cover outpatient hospital therapeutic services furnished at the hospital and at provider-based facilities. At the same time, CMS also added the following provision to the regulations:

(f) Services furnished at a location (other than an RHC or an FQHC) that [CMS] designates as a department of a provider under § 413.65 of this chapter must be



under the direct supervision of a physician. “Direct supervision” means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.⁶

These requirements have remained virtually unchanged since implemented in 2000.

Providers’ Understanding of Supervision on the Hospital Campus

As noted above, the regulations make a distinction between provider-based locations and the hospital. It is important to understand some of the reasoning that may exist behind the distinction between a hospital and a provider-based location in analyzing the Medicare supervision requirements. The requirement for adequate supervision arguably stems from a concern related to quality of care and patient care needs. In a hospital setting, physicians are nearby and available to respond to patient care issues. Consequently, the Medicare program has historically assumed that therapeutic services furnished at a hospital campus have adequate physician supervision. With respect to a provider-based setting, one may raise patient care concerns where the provider-based facility is located away from the hospital campus and may not have adequate physician supervision to address any patient care concerns that arise in the furnishing of services. Consequently, CMS implemented a specific requirement for direct supervision in provider-based facilities in the 2000 OPSS Rule.

As a result of the above interpretation, hospitals generally believed that physician supervision requirements for on-campus outpatient therapeutic services were automatically met. This

belief was not only based on the regulations, but also on CMS' articulated position regarding the applicability of the direct physician supervision requirement to outpatient services, as set forth in the 2000 OPSS Rule:

We emphasize that our proposed amendment of [the Outpatient Therapeutic Services Regulation] to require direct supervision of hospital services furnished incident to a physician service to outpatients *applies to services furnished at an entity that is located off the campus of a hospital* that we designate as having provider-based status as a department of a hospital in accordance with [the provider-based status rules]. Our proposed amendment of [the Outpatient Therapeutic Services Regulation] to require direct supervision of hospital services furnished incident to a physician service to outpatients **does not apply** to services furnished in a department of a hospital that is located on the campus of that hospital. For hospital services furnished incident to a physician service to outpatients in a department of a hospital that is located on the campus of the hospital, we assume the direct supervision requirement to be met. We assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital.⁷

The discussion regarding supervision requirements being met on the campus of the hospital was also consistent with historical Medicare guidance in the Intermediary Manual.⁸ Based on this guidance, hospitals routinely interpreted Medicare requirements to mean that if outpatient therapeutic services are provided on a hospital's campus, the supervision requirements implemented in the 2000 OPSS Rule did not apply.

CMS' Recent Clarification

The 2009 OPSS Rule blurred the assumption regarding deemed physician supervision when outpatient therapeutic services are provided on a hospital's campus. In the 2009 OPSS Rule, CMS states, "we require direct supervision for therapeutic services provided in the hospital or in provider-based department of the hospital."⁹ Accordingly, CMS now seems to require the "direct supervision" of "incident to" services provided in a hospital outpatient department to be the same, regardless of whether the outpatient department is on the hospital's main campus or at provider-based locations.

The apparent lack of distinction is important because as noted above, CMS defines "direct supervision" as requiring a physician to be: (1) "present on the premises of the location;" and (2) "immediately available to furnish assistance and direction throughout the performance of the procedure."¹⁰ Moreover, CMS interprets "present on the premises" to require a physician to be "present on the premises of the entity accorded status as a department of the hospital."¹¹ CMS further states that the "present on the premises" requirement parallels the Medicare Physician Fee Schedule's "direct supervision" requirement for "incident to" services provided in physician offices, which specifically requires that the supervising physician be present in the same office suite where the services are being provided.¹²

Accordingly, if the provider-based regulatory requirements are applied to the on-campus hospital setting, CMS may try to require that a physician be housed in every on-campus department of the hospital for services in such areas to be covered. This interpretation is arguably more restrictive and contrary to historical application of the Medicare supervision rules for therapeutic services. This interpretation also arguably ignores the quality of care and safety distinctions that can be made between a hospital and a provider-based location.

In attempting to explain the "clarification," CMS stated its concern that the term "assume" was misunderstood in the 2000 OPSS Rule.

[W]e restated the existing policy because we were concerned that some stakeholders may have misunderstood our use of the term "assume" in the April 7, 2000 OPSS final rule with comment period, believing that our statement meant that we do not require any supervision in the hospital or in an on-campus provider-based department for therapeutic OPSS services, or that we only require general supervision for those services. This is not the case. It has been 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. The expectation that a physician would always be nearby predates the OPSS and is related to the statutory authority for payment of hospital outpatient services--that Medicare makes payment for hospital outpatient services 'incident to' the services of physicians in the treatment of patients as described in Section 1861(s)(2)(B) of the Act.¹³

While these statements by CMS may be true as read, it is important to note that they would not necessarily require a change in Medicare's historical treatment of the supervision requirement, nor in how such requirement may be met on the hospital campus. In other words, the fact that a hospital has physicians on staff and in the hospital would still arguably meet the supervision requirement and relieve any patient care concerns set forth above for services furnished on-campus at the hospital. CMS acknowledged in the 2009 OPSS Rule that "safe and high quality" services are the focus of the supervision requirement.¹⁴ This focus has been and arguably continues to be met on the hospital campus.

Practical Implications

While CMS indicated that its position in the 2009 OPSS Rule was a "clarification" of policy rather than a "change" in policy, the clarification from CMS does more to blur the issue than to clarify it with respect to services furnished at a hospital. As a result, the CMS clarification has created both significant confusion and potential liability for hospitals.

In its discussion, CMS is trying to create bright-line tests for physician supervision for hospital outpatient services, while at the same time acknowledging that hospital campuses—both

on- and off-campus—come in all different shapes and sizes, making such bright-line tests impractical in many situations. It is clear that hospitals need to review their physician supervision of hospital outpatient services both on and off the hospital's campus to ensure that the physician supervision requirement is met, but the question now stands—what exactly do hospitals have to do to ensure compliance?

For provider-based departments, the direct supervision requirement mandates that the supervising physician be present “on the premises of the location” of the outpatient department. For large, multi-city-block hospital campuses, what does “premises of the location” actually require? Is the supervising physician required to be in the same facility where the service is being provided? The same building? The portion of the building that comprises the department in question (if that can be determined)? The same office suite? A good starting point for these hospitals would be to review their previously submitted provider-based attestations to ensure that they accurately describe the space in which hospital outpatient services are provided. While on-campus provider-based attestations do not require great detail in their description of the department premises, hospitals should keep in mind that it is foreseeable for CMS to use provider-based attestations to define what constitutes the “premises of the location” for the purposes of direct supervision.

Additionally, for services furnished at the hospital, it is unclear whether CMS will require that a physician be housed in every department in order for outpatient therapeutic services furnished in such areas to be covered. There is arguably no basis for CMS to take such a new interpretation that is contrary to past Medicare policy. Nonetheless, absent any further clarifications, hospitals are now faced with monitoring their operations to ensure physician presence in all areas of the hospital or risk a potential recoupment of alleged Medicare overpayments, even where physician supervision may have been only steps away or across the hall.

- 1 See 73 Fed. Reg. 68502, 68702 (Nov. 18, 2008).
- 2 See Soc. Sec. Act § 1861(s)(2)(B); see also 42 C.F.R. § 410.27.
- 3 See 42 C.F.R. § 410.27(a) (1999).
- 4 See 65 Fed. Reg. 18434 (April 7, 2000).
- 5 See 42 C.F.R. § 410.27(a) (2000).
- 6 See 42 C.F.R. § 410.27(f) (2000).
- 7 65 Fed. Reg. 18434, 18525 (April 7, 2000) (emphasis added).
- 8 See Medicare Intermediary Manual § 3112.4.
- 9 73 Fed. Reg. at 68704.
- 10 42 C.F.R. § 410.27(f).
- 11 73 Fed. Reg. at 68704.
- 12 *Id.*
- 13 73 Fed. Reg. at 68702-68703.
- 14 See 73 Fed. Reg. at 68704.

Chair's Column

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This marks my last column as Chair of the Hospitals and Health Systems Practice Group (HHS PG). Over the past three years, I have been blessed with the opportunity to work with some of the finest health lawyers in the country—as authors of our publications, presenters at our teleconferences and meetings, and of course as the Vice Chairs and Affinity Group leaders of the outstanding HHS PG. Likewise, it has been a pleasure to work with AHLA Executive Vice President/CEO Peter Leibold and the wonderful team that he has created at AHLA—who never fail to deliver top-notch service, advice, and support!

We have always strived to bring you—our colleagues and friends—the finest in professional and educational materials. Likewise, we have made it our goal to create professional opportunities for all members of AHLA: be they long-standing members who regularly write and speak, new members engaged in their first foray into a professional association, or perhaps most importantly, those long term members who are seeking a chance to become more actively involved in AHLA for the first time. I am hopeful that if you are not among those that have participated with us in the past, you will consider doing so in the near future!



Today we in the healthcare bar face both unprecedented opportunities and challenges—we will be called upon in an unprecedented way by our fellow citizens to confront and resolve challenges that have previously been deferred or ignored. No longer will “kicking the can down the road” be a responsible or defensible position. And, I believe that it is organizations such as AHLA and groups such as the HHS PG that will become critically important resources to the industry and its stakeholders in these efforts. To those that follow in the leadership of this wonderful Practice Group, I wish you nothing but success and fulfillment.

Best of health to each of you,

Brian