Physician Supervision Requirements in the Hospital Outpatient Setting 2009 Hospital Outpatient Prospective Payment System Regulation

The ACR has received many questions related to physician supervision in hospitals and provider-based departments of hospitals. These questions have arisen because of a recent clarification of Medicare policy by the Centers of Medicare and Medicaid Services (CMS) in the Hospital Outpatient Prospective Payment System (HOPPS) proposed and final rules for calendar year (CY) 2009.[1,2] CMS included a discussion of physician supervision requirements in these rules to provide an "up-to-date clarification of the existing policy." The ACR and other stakeholders are concerned that CMS has not provided an up-to-date clarification of the existing policy but rather an expansion of policy without the opportunity to provide public comment. Nonetheless, we believe it is important for radiologists to be aware of the latest CMS interpretations of the physician supervision rules and we provide them in this article. In addition, we include a brief summary of previous CMS guidance that supports our position that CMS has issued new policy.

Consistent with the CY 2009 HOPPS rules and the CMS manuals, this article focuses on two key hospital outpatient policies: 1) physician supervision of diagnostic tests and 2) physician supervision of therapeutic services.

Physician Supervision of Diagnostic Tests for Hospital Outpatients

The requirements for physician supervision of diagnostic tests in physicians' offices and free-standing centers were first implemented by CMS in the CY 1998 Medicare Physician Fee Schedule (MPFS) final rule.[3] For each diagnostic test subject to the physician supervision requirements, CMS identified the level of supervision as general, direct or personal. In this CY 1998 final rule, CMS stated that the supervision requirements for diagnostic tests only applied in settings in which the Part B carrier pays for the technical components under the physician fee schedule (e.g., physicians' offices and free-standing centers) and that the requirements did not apply in hospital settings.

In April 2000, CMS published the Hospital Outpatient Prospective Payment Systems (HOPPS) final rule. Here, CMS indicated that the requirements for physician supervision (i.e., general, direct or personal) applied to hospital outpatient diagnostic services when those services are furnished at an entity with provider-based status.[4] Fiscal intermediaries and hospitals were advised to follow the MPFS supervision levels from the 1998 MPFS final rule. Notably, CMS did not clearly indicate whether these requirements applied to services furnished in a department of a hospital that is located on the campus of that hospital. Consequently, many stakeholders interpreted the HOPPS final rule to mean that the physician supervision requirements for diagnostic tests applied only to entities with provider-based status located off the campus of the main provider.

CMS defines a provider-based entity as "a provider of health care services that is either created by, or acquired by, a main provider for the purpose of furnishing a health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider. A provider-based entity as an entity that comprises both the specific physician facility that serves as the site of services of a type for which payment could

[1] CY 2009 HOPPS Proposed Rule. Federal Register. Vol. 73, No. 139. July 18, 2008. p41518.
[2] CY 2009 HOPPS Final Rule. Federal Register. Vol. 73, No. 223. November 18, 2008. p68702.
[3] CY 1998 Physician Fee Schedule Final Rule. Federal Register. Vol. 62, No. 211. October 31, 1997. p59058.
[4] CY 2000 HOPPS Final Rule. Federal Register. Vol. 65, No. 68. April 7, 2000. p18524.

be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the serves at that facility."

In addition to the lack of clarity regarding the specific outpatient hospital locations to which the physician supervision requirements were meant to be applied, the physician community was not generally aware of these new requirements. In fact, subsequent to the publication of the HOPPS final rule, CMS revised Section 2070 of the Medicare Carriers Manual through Transmittal 1725 on September 27, 2001 to clarify, in part, the scope of the physician supervision requirements. As stated in the revised manual: "This section sets forth the levels of physician supervision required for furnishing the technical component of diagnostic tests for a Medicare beneficiary who is ***not a hospital inpatient or outpatient*** [emphasis added].

Since 2001 when these instructions were issued, CMS has revised its overall system of manuals. The policy statement above currently appears in the Medicare Benefit Manual with only minor changes. The policy statement currently reads: "This section describes the levels of physician supervision required for furnishing the technical component of diagnostic tests for a Medicare beneficiary who is ***not a hospital inpatient or outpatient*** [emphasis added].[5]

CMS has now clarified in the HOPPS final rule for CY 2009 that the physician supervision requirements for diagnostic tests apply to "all provider-based departments providing diagnostic services, whether on or off the hospital's main campus."[6] The ACR recommends that radiologists who interpret exams in the outpatient hospital setting continue to work with their hospital administrators to insure their staffs are in compliance with all Medicare supervision requirements. Radiologists also should confer with qualified outside health care lawyers if they have questions about their department's compliance responsibilities.

The code-specific levels of supervision for 2009 are available in the file RVU09A which is available for download from the CMS website at http://www.cms.hhs.gov/PhysicianFeeSched/PFSRVF/. Diagnostic tests done in all provider-based departments, whether on or off the hospital's main campus, should follow the same supervision rules as those for the TC in the office settings, pursuant to the familiar levels of general, direct, or personal supervision. For ease of reference, relevant sections from the Code of Federal Regulations that define the levels of supervision[7] are copied below for ease of reference:

- General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure.
- Direct supervision in the office setting means the physician must be present in the office suite 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.
- Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

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[5] Medicare Benefit Policy (PUB. 100-02). - Basic Coverage Rules. Chapter 15 - Covered Medical and Other Health Services. Section 80 - Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests (Updated through Rev. 94; Effective: 01/01/03; Issued: 08/29/08).
[6] CY 2009 HOPPS Final Rule. Op Cit. p68704.
[7] Code of Federal Regulations. Title 42. Section 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

Physician Supervision of Therapeutic Services for Hospital Outpatients

The physician supervision requirements for therapeutic services provided to hospital outpatients differ from those for diagnostic tests, primarily because the statutory basis for Medicare coverage is different. Medicare coverage of diagnostic tests is based on section 1861(s)(3) of the Social Security Act while Medicare coverage of therapeutic services for hospital outpatients is based on Section 1861(s)(2)(B) of the Act which authorizes payment for hospital services ''incident to physicians' services rendered to outpatients.'' CMS has further defined the requirements for outpatient hospital therapeutic services and supplies ''incident to'' a physician's service in section 410.27 of Title 42 of the Code of Federal Regulations. Section 410.27(f) states:

> "Services furnished at a department of a provider, as defined in § 413.65(a)(2) of this subchapter, that has provider based status in relation to a hospital under § 413.65 of this subchapter, 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.''

In the CY 2009 HOPPS final rule, CMS notes this language makes no distinction between on-campus and off-campus provider-based departments. While this is true, it is inconsistent with the discussion of the physician supervision requirements that were included in the preamble of the CY 2000 HOPPS final rule. In that discussion, CMS stated that the language of section 410.27(f) ''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 § 413.65.'' CMS also stated that, for services furnished in a department of a hospital that is located on the campus of a hospital, ''we assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital.''[8]

In the CY 2009 HOPPS proposed rule, CMS restated the "existing" policy because the agency was concerned that some stakeholders may have misunderstood the use of the term ''assume'' in the CY 2000 HOPPS final rule, believing that the statement meant that CMS does not require any supervision in the hospital or in an on-campus provider-based department for therapeutic OPPS services, or that CMS only requires general supervision for those services. In the CY 2009 HOPPS final rule, CMS clearly indicates that this is not the case and states:

> "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."[9]

As with the physician supervision requirements for diagnostic tests discussed in the previous section of this article, ACR does not view this as a clarification of existing policy but as new policy. Nonetheless, the ACR wants radiologists to be aware of the current physician supervision rules for therapeutic services for hospital outpatient services and has summarized below the key points from Chapter 6 of the Medicare Benefit Policy Manual:[10]

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[8] CY 2000 HOPPS Final Rule. Op Cit. p18525.
[9] CY 2009 HOPPS final Rule. Op Cit. p68703.
[10] Medicare Benefit Policy (PUB. 100-02). Chapter 6. Section 20.5.1 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After August 1, 2000. (Rev. 90, Issued: 06-19-08; Effective: 07-01-08; Implementation: 07-07-08).

- Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services.
- To be covered as incident to physicians' services, the services and supplies must be furnished by the hospital or under arrangement made by the hospital. The services and supplies must be furnished as an integral, although incidental, part of the physician's professional service in the course of treatment of an illness or injury.
- The services and supplies must be furnished in the hospital or at a department of the hospital which has provider-based status.
- The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. This does not mean that each occasion of service by a non-physician need also be the occasion of the actual rendition of a personal professional service by the physician responsible for care of the patient. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment.
- The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises. The hospital medical staff that supervises the services need not be in the same department as the ordering physician. However, if the services are furnished at a department of the hospital which has provider-based status, the services must be rendered 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.

The ACR recommends radiologists who provide therapeutic services in the outpatient hospital setting to continue to work with their hospital administrators to insure their staffs are in compliance with all Medicare supervision requirements. Radiologists also should confer with qualified outside health care lawyers if they have questions about their department's compliance responsibilities.

If you have any question regarding physician supervision regulation, you may contact Helen Olkaba in the ACR Economics and Health Policy Department at holkaba@acr.org."