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# Hospital Outpatient Services: New CMS Supervision Requirements

## Complying With the New Rules to Protect Medicare Reimbursement

**A Live 90-Minute Teleconference/Webinar with Interactive Q&A**

**Today's panel features:**

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**Thursday, April 22, 2010**

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### Strafford Publications

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## Introduction – Diagnostic and Therapeutic Services covered under OPPS

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- **Hospitals provide two distinct types of services to outpatients covered under Part B:**
  - Diagnostic services (e.g. MRI and clinical laboratory)
  - Therapeutic services (and supplies) that aid the physician in the treatment of the patient.
- **Therapeutic services are covered under OPPS *only when they are incident to the services of physicians in the treatment of patients (410.27)***
  - Includes services furnished in hospital clinics and the emergency room
  - Services must be furnished as an integral, although an incidental, part of the physician's professional service in the course of treatment of an illness or injury
  - Services must be furnished in the hospital or at a provider-based department of the hospital (See 413.65 for provider based rules)
  - Services and supplies must be furnished (1) pursuant to a physician's order (or pursuant to the order of a non-physician practitioner acting within his/her scope of licensure), (2) by hospital personnel ***under supervision.***

### A little history...

**There is no requirement of supervision in the statute—**

- Section 1861(s)(2)(C) of the SS Act authorizes payment for outpatient diagnostic services and section 1861(s)(2)(B) authorizes payment for outpatient therapeutic services, i.e., hospital services incident to physicians' services rendered to outpatients, and neither paragraph mentions the word "supervision."

***So...where does the "supervision" requirement come from ?***

## Supervision Requirement --Diagnostic

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- **Section 2050 of the Medicare Carriers Manual provides that, for purposes of payment under the Physician Fee Schedule (PFS), coverage of services and supplies incident to the professional services of a physician is limited to situations in which there is direct physician supervision of auxiliary personnel.**
- **The CY 1998 PFS final rule (62 FR 59048) codified at 410.32 the direct supervision requirement for *diagnostic tests***
- ***For outpatient diagnostic services*, the 1998 OPSS proposed rule (63 FR 47552) proposed to apply the rules at 410.32 to facilities having provider based status, and this was finalized in the April 7, 2000 OPSS final rule (65 FR 18434) and codified at 410.28**
  - In the CY 2009 OPSS final rule CMS clarified that the rule in 410.28 applies irrespective of whether the provider-based department is on or off-campus (campus = 250 yards from the main hospital location)
  - 410.28 does not address supervision for outpatient diagnostic services rendered in the hospital (main provider location).

## Supervision Requirement -- Therapeutic

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- **Section 3112.4 of the Medicare Intermediary Manual states that outpatient therapy services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. The manual further states:**

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 outside the hospital, they must be rendered under *the direct personal supervision* of a physician who is treating the patient. For example, if a hospital therapist, other than a physical or speech therapist, goes to a patient's home to give treatment and no physician accompanies him, the therapist's services would not be covered” (emphasis added).

## Supervision Requirement -- Therapeutic

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- **In the 1998 proposed OPPTS rule CMS stated:**
  - Provider-based status also raises issues of Medicare coverage. Generally, the services of nonphysician staff furnished in a physician office are covered only as services "incident to" the professional services of a physician under section 1861(s)(2)(A) of the Act. This means that a physician must be available on the premises when the service is furnished, in order to provide *direct supervision* of that service. *In hospital outpatient departments, however, we presume* that the "incident to" requirements are met with respect to hospital services incident to physician services to outpatients (section 1861(s)(2)(B)). *The policy assumed the outpatient department was co-located on the hospital premises and staff physicians would be available nearby to provide necessary oversight.* It is possible that a hospital outpatient clinic may not be in the *immediate vicinity* of the hospital and may furnish nonphysician services without actually providing for direct physician supervision of those services. *We do not believe that such services should be presumed to meet applicable "incident to" requirements* (emphasis added).

## Supervision Requirement -- Therapeutic

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- **In the April 7, 2000 final OPPS final rule CMS stated:**
  - Our intention in the proposed rule was to define "direct supervision" of hospital outpatient services incident to physician services when they are furnished at a department of a hospital to mean that *a physician must be present on the premises of the entity accorded status as a department of the hospital and, therefore, immediately available to furnish assistance and direction . . . .*
  - By "direct supervision" we do not mean that the physician must physically be in the room where a procedure or service is furnished. **Nor does the supervising physician necessarily have to be of the same specialty as the procedure or service that is being performed.** We emphasize that our proposed amendment of §410.27 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 . . . .*
  - Our proposed amendment of t§410.27 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 as we explain in section 3112.4(A) of the Intermediary Manual. . . .*
- **Transmittal 82 (Change Request 5946), Feb, 8, 2008 reiterates the April 7, 2000 final rule ("The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises.")**

## Supervision Requirement ---2009 Proposed OPSS Rule

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- In the 2009 proposed OPSS/ASC Rule (73 FR 41518) CMS issued a “restatement and clarification” of “existing” supervision requirements.
- Specifically, in its response to the industry regarding CMS’ supervision requirements for therapeutic services, CMS stated:
  - ....we are concerned that some stakeholders may have *misunderstood our use of the term ‘assume’* in the [April 2000 final rule], 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 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.
  - 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” (emphasis added).

## Supervision Requirement -- Therapeutic

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- **CY 2009 OPPS final rule repeats the language of the proposed rule**
  - Transmittal 101 (Change Request 6320), 1/16/09, amends section 20.5.1 of Medicare Benefits Policy Manual to ***require direct supervision*** of therapeutic services regardless of site
- **Fallout from the 2009 rule – 12 organizations, including AAMC, FAH and AHA wrote to CMS in April 2009, contending that policy announced in CY 2009 rule, that direct supervision required for services furnished in hospital or on campus was not consistent with prior agency guidelines or commonly understand supervision criteria throughout the industry.**
- **And then we paused....**

## The CY 2010 Final Rule

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- The CY 2010 OPSS final rule made important changes and clarifications to the OPSS supervision requirements with distinctions between *diagnostic* and *therapeutic services*.
- The CY 2010 OPSS rule amends 410.27 to state for the first time in reg text that direct supervision of outpatient therapy services is required for services performed in the hospital or on the hospital's campus.
  - §410.27(a)(1)(iv)(A) states that for services furnished in the hospital or CAH or in an on-campus outpatient department of the hospital or CAH, "direct supervision" means that the **physician or nonphysician practitioner** must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure
- For services furnished in an *off-campus* setting or CAH, "direct supervision" means the physician or nonphysician practitioner must be *present in the off-campus provider-based department* of the hospital or CAH and immediately available to furnish assistance and direction throughout the performance of the procedure.

## Key Points From the 2010 Final OPPS Rule

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- **NPP Supervision for certain *therapeutic services*:**
  - Non-physician practitioners (NPPs) may directly supervise hospital outpatient therapeutic services ***that they may perform themselves in accordance*** with their State law and scope of practice and hospital-granted privileges: physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, and licensed clinical social workers
  - LCSWs were added after comments on proposed rule.
  - However, CMS declined to add pharmacists, RNs, or other medical professionals. CMS said these professionals are not recognized in the statute as providing services that would be physicians' services if performed by a physician and they are not able to enroll in Medicare as independent practitioners and receive payment directly for their professional services.
  - NPPs cannot provide the necessary supervision for cardiac rehab, intensive cardiac rehab, and pulmonary rehab services. See *discussion later*.
  - Whether on or off-campus the physician (or NPP) does not have to be present in the room when the procedure is performed—but, such individual must be ***immediately available to furnish assistance and direction throughout the performance of the procedure***.

## Key Points From the 2010 Final OPSS Rule

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- **On-Campus supervision afforded greater flexibility (the Good News 😊)**
  - For purposes of satisfying the direct supervision requirement for therapeutic services performed *in the hospital or on the hospital's campus*, physician or NPP (acting within scope of their license) need not be in the space (or room) where the therapeutic service is being performed.
  - Physician (or NPP) may be located anywhere on campus.
  - CMS clarifies that physician or NPP may be physically located in a private physician's office in a MOB located on campus provided, of course, such individual is "immediately available..."
- **Off-Campus supervision requires physical presence (the Bad News 😞)**
  - For purposes of satisfying the direct supervision requirement for therapeutic services performed in a provider-based dept *off* campus, physician or NPP must be in the provider-based department (PBD)
  - CMS modifies prior language from "location" to "provider-based department" and clarifies that it is not sufficient if the physician (or NPP) is elsewhere in an MOB that contains the PBD

## Key Points From the 2010 Final OPPS Rule

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- CMS goes to lengths to define “in the hospital” as meaning areas in the main building(s) of a hospital that are under the ownership, financial, and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital’s provider number (§410.27(g))
- However, the key is actually that the **physician/NPP be “present on the same campus,”** and *campus* is not defined in the regulation

## Supervising Physician---What Does it Mean? How Can we meet it?

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- **No regulatory definition of the qualifications of the “supervising physician”**
- **Comments in Final Rule State that Supervising physician or NPP:**
  - Must have knowledge, ability (within his or her State scope of practice) and hospital privileges to perform services being supervised.
  - Must be prepared to step in and perform the service, not just to respond to an emergency.
  - Need not be of the same specialty as the procedure or service being performed.

## Immediately Available-- How Quickly must I get there?

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- **Run, don't walk (and always carry your cell phone)?**
- **The regulation does not define “immediately available.”**
- **CMS comments in the Final Rule:**
  - Physician/NPP would not be considered immediately available if performing another procedure that he or she could not interrupt.
  - Would not be “immediately available” if “so physically far away on the main campus from the location where hospital outpatient services are being furnished that he or she could not intervene right away.”
  - Must be available “without interval of time.” What constitutes an “interval?”

## Miscellaneous Points flowing out of the CY 2010 Final Rule

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- **Not applicable to PT/OT/SLP/ESRD**
  - Supervision requirements do not apply to physical therapy, speech-language pathology, occupational therapy, and ESRD services to hospital outpatients, because not paid under OPPS
  - Presumably, not applicable to other diagnostic services paid outside OPPS such as clinical diagnostic laboratory
- **Only general supervision is required for CMHC partial hospitalization services but direct supervision for PHP services provided by a hospital outpatient department**
  - CMS solicits comments on having the same supervision requirement for both CMHCs and hospitals providing PHP
- **Not applicable to inpatient services (yet...)**
  - CMS has not established standards for inpatient services because it believes “hospitals would have physicians or other qualified practitioners available at all times...” But, if this proves not to be the case, future regulations may be considered...

## Special Provisions and Cautionary Notes in Final OPPS Rules

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- **Supervision for Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR) and Pulmonary Rehabilitation (PR) Services must be performed by physician (not an NPP)**
  - CMS said it has no discretion to allow NPPs to supervise these services because Congress (Section 144 of MIPPA) described each service as a “physician-supervised program.”

- **Diagnostic test supervision must be furnished under applicable level of physician supervision for each particular test (See 410.32)**
  - General Supervision (furnished under physician's overall direction and control, but the physician's presence is not required)
  - Direct Supervision (physician must be present in the office suite and immediately available throughout performance of the procedure)
  - Personal Supervision (physician must be in attendance in the room throughout performance of the procedure.)

Special Provisions and Cautionary Notes in Final OPPS Rules:  
*Diagnostic Tests*

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- **Remember--diagnostic test level supervision is set by the local MAC by CPT.**
- **Remember—MRI and CT contrast procedures currently require “direct supervision.” Accordingly, hospital-based imaging centers require that the physician be located in the imaging center.**
- **Diagnostic tests can only be supervised by a “physician” and not an NPP.**

Special Provisions and Cautionary Notes in Final OPSS Rules: *The Effective Date & Enforcement*

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- The Final OPSS rules are effective January 1, 2010.
- CMS continues to assert that the “restatement and clarification” issued in the CY 2009 Proposed and Final OPSS Rule made “no change to longstanding hospital outpatient physician direct supervision policies.”

***So what does this mean for enforcement?***

Special Provisions and Cautionary Notes in Final OPSS Rules: *The Effective Date & Enforcement*

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- CMS states the “usual enforcement practices of Medicare contractors are appropriate for services furnished in CY 2009.”
- CMS states that supervision rules for off-campus PBDs were “clearly and consistently stated in the April 2000 OPSS final rule.”
- CMS does indicate that for outpatient therapeutic services furnished *on-campus* in 2000 thru 2008, it plans to “exercise discretion and decline to enforce in situations involving claims where the hospital’s noncompliance with the direct physician supervision policy resulted from error or mistake.”

***So..stay tuned***

## Legal Issues

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- Prior to effective date of CY 2010 OPPS Final Rule, is direct supervision enforceable as a requirement for outpatient therapy services performed in the hospital or on campus?
- Is it enforceable *prior* to effective date of CY 2009 OPPS Final Rule?
- Is it enforceable after effective date of CY 2009 OPPS Final Rule (and prior to effective date of CY 2010 OPPS Final rule)?

## Legal Issues Cont'd

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- **Is requirement that, for services provided *off campus*, supervising physician be located in provider-based department, a new requirement or a clarification?**
  - Previously, 410.27 said direct supervision means the physician must be “present and on the premises of the **location**”

## Legal Issues Cont'd

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4. **Is there Potential False Claims Act Liability if violated policy is based on unclear instructions or an invalid substantive rule?**
- Is retention of the money for services billed w/o direct supervision a “reverse false claim?”
  - Under PPACA, providers must now refund any overpayment within 60 days after the overpayment is "identified." Failure to do so could result in a False Claims Act violation, a civil monetary penalty, or other penalties
  - Does absence of language in CMS preambles that it would deny services and take back money, mean that failure to provide direct supervision is not material for purposes of FCA?
  - FCA now defines "material," as having "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." CMS may see appropriate supervision as material to whether a claim should be paid

**. . . Is there Potential False Claims Act Liability if violated policy is based on unclear instructions or an invalid substantive rule?**

- **Concerns for small, rural hospitals**
  - CMS announced in March that it will not enforce the therapeutic supervision rules against CAHs for the balance of 2010.
  - Still, small rural non-CAHs may still have practical difficulty in arranging for 24/7 outpatient coverage by a sufficiently qualified physician or NPP
  - Can such a hospital provide essential outpatient services to Medicare beneficiaries if it cannot assure adequate supervision?

## Questions and Discussion

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