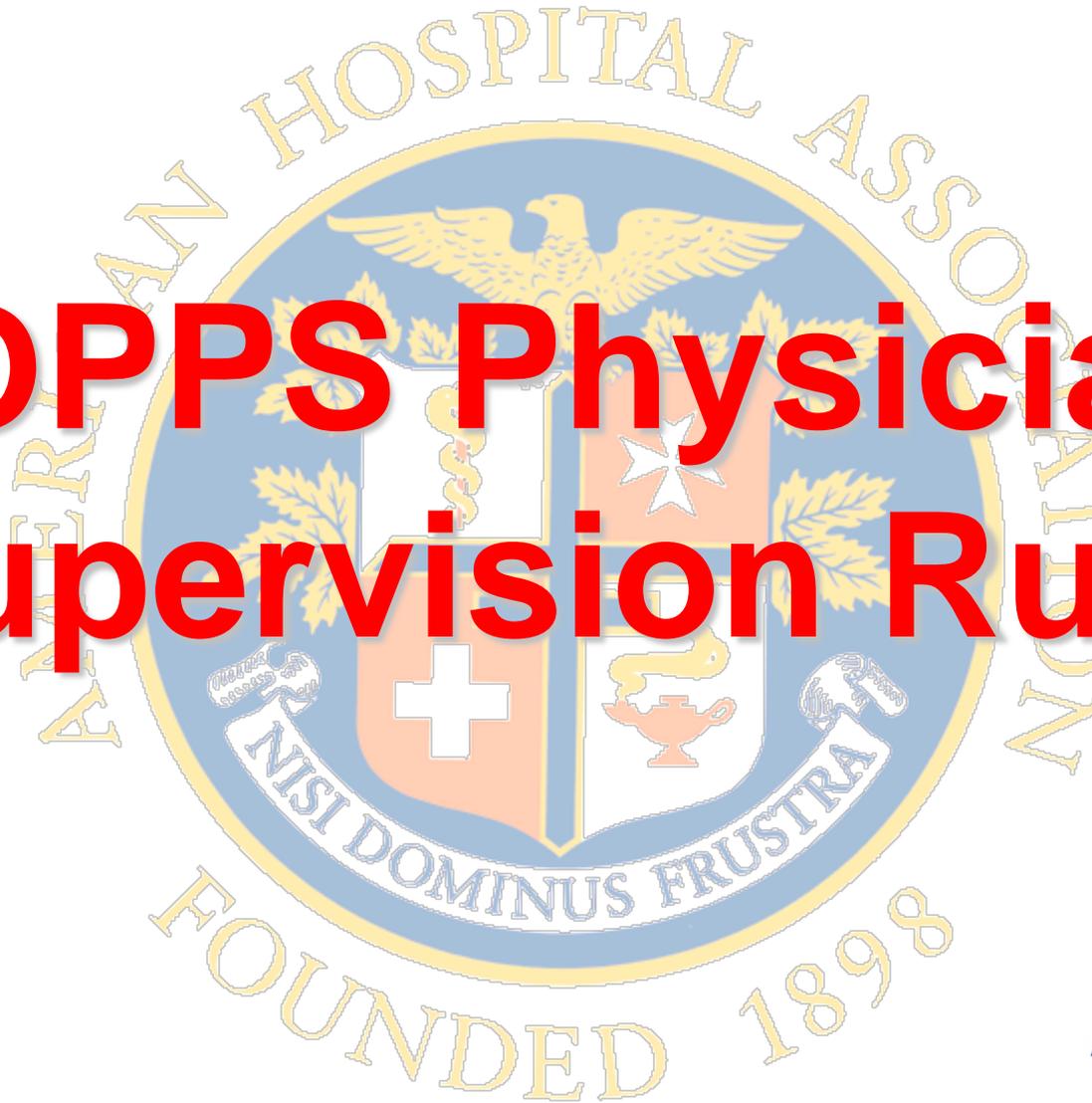


# OPPS Physician Supervision Rules



American Hospital  
Association

# Agenda

- **Background and History of Regulations on “Incident to” Services**
- **2009 OPPS Rules**
- **AHA Comments and Actions**
- **2010 OPPS Rules**
- **Next Steps and a Workable Solution**
- **AHA Questions for Discussion**



# Outpatient Therapeutic Services are “Incident to”

- **THE LAW: Social Security Act § 1861(s)(2)(B)**
  - Medicare pays for hospital outpatient therapeutic services furnished “incident to” a physician’s service.
- **THE REGS (BEFORE 2010): 42 CFR §410.27(a)(1)(i)-(iii):**
  - Hospital “incident to” services conditions:
    - (i) services furnished by or under arrangement made by a hospital;
    - (ii) as an **integral though incidental part of a physician’s services**; and
    - (iii) furnished in the hospital or at a department of a hospital, as defined in §413.65(a)(2), that has provider-based status.



# Which Services are O/P Therapeutic Services?

- **Examples of outpatient therapeutic services:**
  - Clinic/emergency department visits
  - Observation services
  - Outpatient psychiatric services
  - Drug infusions and blood transfusions
  - Wound debridement
  - Cardiac rehabilitation, pulmonary rehabilitation
  - **Outpatient CAH services ARE INCLUDED.**
- **Examples of outpatient services that are NOT outpatient therapeutic services:**
  - Diagnostic services (x-ray, MRI, CT)
  - Physical and occupational therapy, speech language therapy
  - Clinical lab services
  - Dialysis
  - Rural Health Clinic and Federally Qualified Health Center services
  - Inpatient services



# Until 1998, Medicare Intermediary Manual

## Medicare Intermediary Manual (§ 3112.4(A))

- Did not require a specified level of physician supervision for payment of incident-to hospital outpatient department services
  - “the services and supplies must be furnished on a physician’s order by hospital personnel and **under a physician’s supervision.**”



# 1998 OPPTS Proposed Rule & 2001 Final Rule

- First time that a **specific level** of physician supervision required for “incident to” hospital outpatient services.
  - Off-campus PBDs: Require **“direct physician supervision”** for services furnished in a department or clinic **“offsite and that is not on the hospital premises.”**
    - § 410.27(f): “Direct supervision means that 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.”
  - BUT.....



# 1998 OPPS proposed rule & 2001 final rule, cont.

## On-campus PBDs:

- “[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.)

## In the hospital:

- No specific supervision requirements



# Medicare Benefit Policy Manual, Sec. 20.5.1

**Between 2001 and 2009, this “expectation” lived in section 20.5.1 of the Medicare Benefit Policy Manual.**

- **“The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises.”**



# 2009 OPPTS Proposed & Final Rules

- In 2009 rule, CMS rewrote history: (73 Fed. Reg. 68,702.)
  - “Misunderstanding” about what, if any, level of physician supervision is required for incident to services furnished in a hospital or an on-campus PBD
  - “Restatement and clarification of the policy”
    - “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.”
- Subsequently, in Open Door Forum calls, CMS states:
  - Physician providing “direct supervision” must be *physically present in the department* during all times services are provided
  - Supervising physician must have *hospital privileges* to perform the services they are supervising
  - Clarifies that *applies to both hospitals and CAHs.*



# Major Concerns About 2009 “Clarification”

- **Looking back: Jan. 1, 2001 to Dec. 31, 2009**
  - CMS characterization as “restatement and clarification” of existing policy **exposes hospitals to significant enforcement scrutiny**
    - CMS, OIG, DOJ, RAC, etc.
    - Whistle-blower lawsuits
- **Looking forward: 2010 and beyond**
  - Burden on hospitals, requiring more physicians to be engaged for direct supervisory coverage without a clear clinical need.
  - Special concern for CAHs and for communities with severe physician shortages.
  - Will impact patient access to O/P therapeutic services, especially in rural areas.



# Apr. 14, 2009 Letter to CMS

The undersigned organizations write to request that the 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.

**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.**



**American Hospital  
Association**

# June 1 Letter to Director Blum

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.

**Association of American Medical Colleges**

**American Hospital Association**

**Federation of American Hospitals**

**National Association of Psychiatric Health Systems**



**American Hospital  
Association**

# Director Blum's June 11 Reply



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid

7500 Security Boulevard  
Baltimore, MD 21244-1850

JUN 11 2009

Roslyne D.W. Schulman  
Senior Associate Director  
American Hospital Association  
Liberty Place, Suite 700  
325 Seventh Street, NW  
Washington, DC 20004-2802

Dear Ms. Schulman:

As we stated in last year's final rule, this policy was a clarification of long-standing policy. While we understand that you disagree that we were only describing a clarification, any change to this policy would have to be adopted through notice and comment rulemaking. We will consider the points made in your letter as we develop the CY 2010 OPPS proposed rule.

While we understand that you disagree that we were only describing a clarification, any change to this policy would have to be adopted through notice and comment rulemaking. We will consider the points made in your letter as we develop the CY 2010 OPPS proposed rule.

I hope this information is helpful.

Sincerely,

A handwritten signature in black ink, appearing to read "Jonathan Blum".

Jonathan D. Blum  
Director, Center for Medicare Management  
Acting Director, Center for Drug and Health Plan Choice



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# 2010 OPPS Final Rule, Mixed News

## Bad news first....

- Does not resolve vulnerability for CYs 2001 thru 2008
  - CMS continues to explicitly assert that:
    - The 2009 “restatement and clarification” made no change to long-standing supervision policies.
  - Outpatient therapeutic services furnished in “off-campus PBDs”:
    - Continued enforcement emphasis for direct physician supervision in *off-campus provider-based departments*
  - Outpatient therapeutic services furnished “on-campus”:
    - “[W]e plan to exercise our discretion and *decline to enforce* in situations involving claims *where the hospital noncompliance with the direct physician supervision policy resulted from error or mistake.*”



# 2010 OPPS Final Rule, Mixed News

- Outpatient therapeutic services in **CY 2009**
- **Serious enforcement vulnerability** regardless of whether services furnished on or off-campus.
  - “...restatement and clarification made no change to longstanding hospital outpatient physician direct supervision policies...”
  - “...we provided for public notice and comment regarding these...policies”
  - **“Therefore, we believe that the usual enforcement practices of Medicare contractors are appropriate for services furnished in CY 2009”**



# 2010 Final Rule, Mixed News

Good (?) news for CY 2010 and beyond.. CMS decides:

- Non-physician practitioners (NPPs) may directly supervise outpatient therapeutic services:
  - PAs, NPs, CNSs, CNM, LCSWs and clinical psychologists may directly supervise if services are:
    - within State license scope of practice and *hospital-granted privileges*
  - Applies to **ON-CAMPUS** and **OFF-CAMPUS** services
- Caveat: This proposed policy **WOULD NOT** apply to cardiac or pulmonary rehab due to statutory issues.
- Caveat: This proposed policy **WOULD NOT** apply to outpatient diagnostic services.
- Big caveat: Will hospitals give NPPs privileges to perform the services that they supervise?



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# 2010 OPPTS Final Rule, Mixed News

Loosening of physical presence standard for “direct supervision” when outpatient services provided **on-campus**

- For outpatient services furnished *in a hospital (or CAH), or in an on-campus department*, CMS revises definition of “direct supervision”:
  - Supervisory physician or NPP *may be present anywhere on the same campus,*
  - *as long as they are “immediately available to furnish assistance and direction throughout the performance of procedure.”*
- BUT, CMS says, “immediately available” means “without passage of time”.
  - So supervising physician or NPP cannot be engaged in any activity that prevents them from leaving immediately.
- “Throughout the performance of the procedure”
  - 24/7 presence: Consider implications for observation, blood transfusions and other services that take place at all hours.



# 2010 OPPTS Final Rule, Mixed News

## For outpatient therapeutic services furnished in an *off-campus PBP*

- Supervision may be provided by NPPs
- However no change in definition of “direct supervision” for off-campus PBDs
  - The physician or NPP **must be present in the off-campus PBD** and immediately available to furnish assistance and direction throughout the performance of the procedure



# Dilemma for Critical Access Hospitals

## CAH Conditions of Participation versus Payment Coverage rules

- **CoP: 42 CFR § 485.618: Emergency services.**
  - The CAH provides emergency care necessary to meet the needs of its inpatients and *outpatients*.
    - “there must be a doctor of medicine or osteopathy, a PA, a NP, or a CNS...on call and immediately available by telephone or radio contact, and *available on site...[w]ithin 30 minutes, on a 24-hour a day basis...*”
- **Coverage and Payment: 42 CFR § 420.27(a)**
  - “Medicare pays for...CAH services and supplies...if they are furnished...[u]nder the direct supervision of a physician or a NPP..”
  - “‘direct supervision’ means that the physician or NPP must be *present on the same campus and immediately available... throughout the performance of the procedure....*”



# 2010 OPPTS Final Rule: Diagnostic Services

## Outpatient Diagnostic Services

Medicare mandates (at 42 CFR 410.28) that *outpatient diagnostic services paid under the OPPTS*, must have appropriate level of physician supervision:

- Level of supervision varies by individual tests, as listed in the Medicare Physician Fee Schedule Relative Value File.
- **There are currently no specific physician supervision requirements that apply to outpatient diagnostic services in CAHs**
- But for non-CAH outpatient diagnostic services that require “**direct physician supervision**”
  - ONLY a physician (MD or DO) may supervise – not NPPs
  - If furnished ***in the hospital or in an on-campus PBD***,
    - Supervising physician must be present on same campus...
  - If furnished in an ***off-campus PBD***,
    - Physician must be present in off-campus PBD...



# Next Steps...

- **AHA continues to place a high priority on addressing these concerns and we continue to push for further changes**
  - **We are continuing to pursue multiple approaches at this time, including recommending further changes to the regulations, changes to law and even, potentially, legal action.**



# Next Steps...

- **Changes to the regulations**
  - Increase Congressional political pressure on CMS to consider the impact on CAHs.
  - Continue to raise concerns at every opportunity, including in the upcoming 2011 OPSS proposed rule
- **Changes to the law**
  - Working on a bill that would address both enforcement vulnerability for years between 2001-2010 and would provide a more reasonable approach for future years.
- **Potentially, even legal action**
  - We will need your help!



# A Workable Solution?

- A fundamental change in supervision policy is needed
- A workable solution would include:
  - Default standard of “**general supervision**” for outpatient therapeutic services
    - “General Supervision defined at 42 CFR410.32 (b)(3)(i): “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.”
  - **Exceptions process** to be established to identify high-risk or clinically complex services that merit direct supervision
    - Determining the exceptions to involve clinical expert opinion and subject to public notice and comment.
    - For CAHs, “direct supervision” would be defined to be consistent with the CAH CoPs.
  - NPPs can provide direct supervision for cardiac and pulmonary rehab and outpatient diagnostic services



# A Workable Solution?

- **Communicating Congressional “Findings”**
  - Direct supervision requirement was never intended for coverage of outpatient hospital therapeutic services “incident to” the services of a physician.
- **Prohibiting enforcement of CMS’ retroactive re-interpretation regarding “direct supervision”**
  - For services furnished from January 1, 2001 through the date of enactment of the bill.



# DISCUSSION

## Questions for Discussion

- **How are you putting the rules into place in your facility?**
- **How would you make changes to the rules so that patient care is protected but so is access to care? Will AHA's approach work?**
- **Would you be willing to step forward in a more public way in order to make the case for the harm that the rule causes your facility?**



# Contact Information

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# American Hospital Association