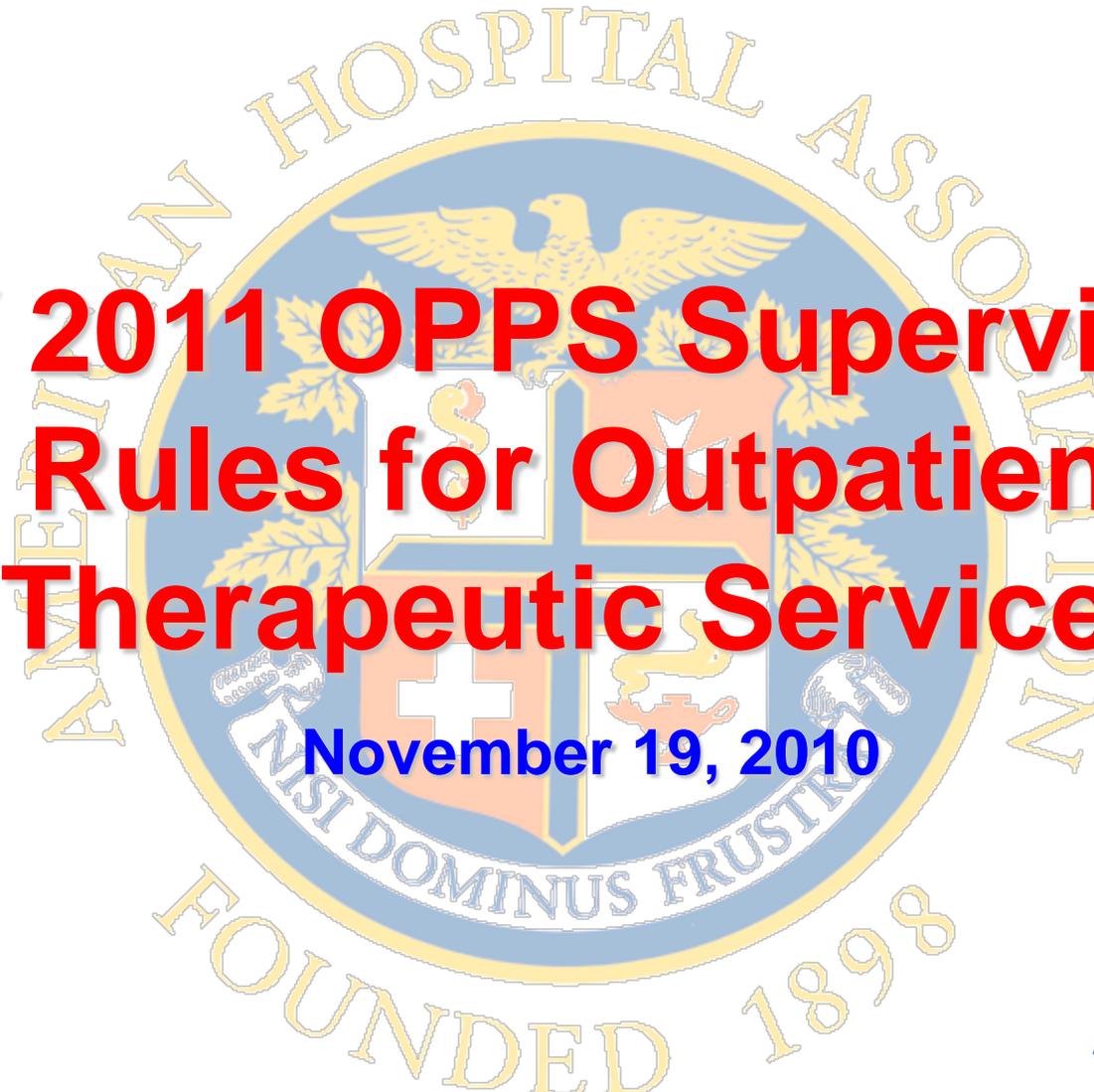


CY 2011 OPPTS Supervision Rules for Outpatient Therapeutic Services

November 19, 2010



**American Hospital
Association**

Agenda

- Background on “Incident to” Services
- 2009/2010 OPPS Rules
- 2011 OPPS Proposed Rule
- AHA Comments and Actions
- 2011 OPPS **FINAL** Rule
- 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.



Which Services are O/P Therapeutic Services?

- **Examples of “incident to” outpatient therapeutic services:**
 - Clinic/emergency department visits
 - Observation services
 - Outpatient psychiatric services
 - Drug infusions and blood transfusions
 - Wound debridement
 - Cardiac rehabilitation, pulmonary rehabilitation (special case but still treated as such)
 - **Outpatient CAH services ARE INCLUDED.**
- **Examples of outpatient services that are NOT outpatient therapeutic services:**
 - Physician services (MPFS)
 - Diagnostic services (x-ray, MRI, CT) (different supervision rules)
 - Physical and occupational therapy (MPFS)
 - Rural Health Clinic and FQHC services (diff payment system)
 - Clinical lab services (CLFS)
 - Dialysis (ESRD PPS)
 - Inpatient services (IPPS)



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.”**



Direct Supervision, Recent Changes to Regs

- 2009: CMS issues a “*restatement and clarification*” of their policy, indicating it had been in place since 2001.
 - Direct physician supervision required for all outpatient therapeutic services, both on-campus and off-campus.
 - A supervising physician-MD/DO-must physically be in the same outpatient department at all times services furnished.
- 2010: CMS revises its policy.
 - In addition to MD/DO, allow certain non-physician practitioners (NPPs) may provide direct supervision, including PAs, NPs, CNSs, CNMs, LCSW, CP.
 - “Clinically appropriate” – state license & hospital privileges
 - For services in the hospital and for services in on-campus provider-based departments (PBDs):
 - Supervising physician or NPP may be anywhere on the hospital’s campus, as long as “immediately available.”
 - Emergency physician can supervise if “immediately available”.
 - For services furnished in off-campus PBDs
 - Supervising physician or NPP must be in the PBD
 - CMS tells contractors not to review/ enforce supervision requirements for CAHs during 2010.



Direction Supervision, 2011 Proposed Policy

- For 2011, CMS proposes to permit a two-tiered level of supervision for a few HOPD therapeutic services.
- Proposed to apply to list of 16 “nonsurgical extended duration therapeutic services”:
 - with a significant monitoring component that can extend for a sizable period of time; not surgical and low risk of complication.
 - These services include:
 - observation services
 - various intravenous and subcutaneous infusions
 - various therapeutic, prophylactic or diagnostic injections
- These services would require **direct supervision for initiation of service, followed by general supervision** for remainder.
- “General supervision” means the service is under a physician’s overall direction and control, but a physician is not required to be present when the service is furnished.
- All other O/P therapeutic services continue to require direct supervision.



AHA Comments

- CMS' proposed change is very small step in right direction
 - Because it acknowledged that not all services covered by Medicare in hospital outpatient departments require direct supervision.
 - Does not go nearly far enough to assure continued access in hospitals, especially small / rural facilities, such as CAHs.
- Two-tiered supervision proposal
 - Policy, as proposed, will NOT provide substantive relief for CAHs or other hospitals.
 - Direct supervision for “initiation” remains problem.
 - Possible “second guessing” by CMS of when “initiation” phase is completed leading to enforcement actions.
 - Too few services on list.



AHA Comments, continued

- **A New Approach is Needed for the Supervision of Outpatient Therapeutic Services**
 - CMS' supervision policy is unwarranted.
 - Due to continuing shortages of physicians and NPPs, many hospitals and CAHs are finding it difficult, if not impossible, to meet CMS' supervision requirements.
 - CMS' requirements are overly restrictive.
 - CAHs are subject to several co-existing and contradictory Medicare regulations – places them in untenable dilemma which threatens their ability to provide care to Medicare beneficiaries in their community.



AHA's Comments, Proposal to CMS

- **Establish a default standard of “*general supervision*” for outpatient therapeutic services**
- **With an *exceptions process* to identify specific high risk/complex procedures that should be subject to direct supervision**
 - Establish a clinical expert panel composed of physicians and NPPs of various specialties who practice in urban and rural communities (CAHs included)
 - Panel’s recommendations should be subjected to notice and comment through a public rulemaking process.
 - Apply a special rule to CAHs due to unique staffing CoPs
- **Revise “direct supervision” definition**
 - Allow “immediate availability” via phone, telemedicine, radio
 - For off-campus services, allow supervisor to be “in close proximity” to the provider-based department
- **Extend enforcement moratorium for CAHs thru 2011**
 - Also apply to small and rural PPS hospitals



AHA Advocacy Activities

- Held multiple calls and meetings with CMS staff, including representatives from CAHs.
- Held member and state association calls to encourage comment letters and letters to Congress.
- Submitted multiple clinical examples and scenarios to CMS.
- Supported Senate letter to CMS expressing concern about proposed rule.
- Helped to draft bill introduced by Rep. Pomeroy (D-ND) and Moran (R-KS), HR 6376.
- AHA comment letter to CMS on proposed rule



CY 2011 Final Rule on Supervision

Extension of Enforcement Moratorium

- CMS extends through CY 2011 its decision not to enforce direct supervision policy for outpatient therapeutic services furnished in CAHs.
- Expands the enforcement delay to include all small rural hospitals with 100 or fewer beds.
 - “Rural” defined to include hospital either geographically located in a rural area or are paid through OPPS with a rural area wage index.
- CMS expectation:
 - “We believe this non-enforcement policy will permit the CAHs and small and rural hospitals that do not consistently meet our direct supervision standard for outpatient therapeutic services *to make appropriate adjustments over the coming year.*”
- Note: does not apply to diagnostic services



CY 2011 Final Rule on Supervision

Revised Definition of “Direct Supervision”

- Removes all references to the physical boundaries within which the supervising physician or NPP must be located.
 - Supervisor no longer required to be “present on the same campus” or “present in the off-campus PBD”
 - Instead, s/he must only be “*immediately available* to furnish assistance and direction throughout the performance of procedure.”
- New definition applies to hospitals and CAHs:
 - Outpatient therapeutic services and those diagnostic services that require direct supervision
 - New definition applies to cardiac and pulmonary rehab.
 - Does not apply to diagnostic services performed “under arrangement” in *non-hospital locations*.



CY 2011 Final Rule on Supervision

More on Revised Definition of “Direct Supervision”

- CMS expectation:
 - “...we are not relaxing the requirement that the supervisory physician or nonphysician practitioner must be *immediately available* meaning that the supervisory practitioner must be *physically present and interruptible*...we continue to expect the supervisory practitioner to be *physically present* for the services he or she is supervising....Removing specific boundaries provides reasonable flexibility but also *holds the practitioner accountable* for determining, in individual circumstances, *how to be physically and immediately available when supervising services..*”
- CMS **does not** recognize “availability” of a supervising physician or NPP by telephone, radio contact, telemedicine or other modes that do not involve physical presence.
 - CMS states their belief that a requirement for physical presence distinguishes direct supervision from general supervision.



CY 2011 Final Rule on Supervision

Two-Tiered Supervision Approach for Certain Services

- CMS finalizes its proposal to permit a two-tiered approach to supervision for a 16 specified “nonsurgical extended duration therapeutic services.”
 - Including observation services, various intravenous and subcutaneous infusions and various therapeutic, prophylactic or diagnostic injections
 - These services will require **direct supervision only for initiation of the service, followed by general supervision** for the remainder of the service.
 - Initiation means: “the beginning portion of the...service which ends when the patient is stable and the supervising physician or appropriate NPP believes the remainder of the service can be delivered safely under general supervision.”
 - CMS adds a requirement that that the transition from direct to general supervision be documented in the progress notes or in the patient’s medical record
 - the manner of documentation is left to the discretion of each supervising practitioner.



CY 2011 Final Rule on Supervision

Two-Tiered Supervision Approach, continued

- For CY 2011, **all other outpatient therapeutic services** not included among the list of 16 “nonsurgical extended duration therapeutic services” **remain subject to direct supervision requirements.**
 - CMS did not accept recommendations from AHA and others to add several other services, such as chemotherapy, blood transfusion, short duration services, and the recovery period for certain surgical services.
 - However, CMS notes that these types of services may be evaluated for reconsideration through a different process....discussed next!



CY 2011 Final Rule on Supervision

Independent Review of Alternate Supervision Levels

- CMS announces its intent to establish, through the CY 2012 OPPTS rulemaking, an independent review process:
 - To allow for an assessment of the appropriate supervision levels for individual hospital outpatient therapeutic services.
 - However...CMS notes “appropriate level of supervision” for a service **could be a higher level of supervision** (e.g. “personal supervision”) as well as a lower level of supervision.
- Process may include:
 - a committee with representation of many types of providers, including rural providers (maybe Federal APC Panel?)
 - a time frame for submitting requests for the assessment of individual services and considering potential changes
 - criteria for evaluating each service
 - a means for documenting recommended supervision levels.
- CMS seeking input on these issues
 - Initial comments to final rule sent by January 3, 2011
 - But CMS is open to additional discussion



CY 2011 Final Rule on Supervision

Other Issues Discussed in Final Rule

- CMS concern about use of protocols, processes, and procedures that may substitute for evaluation by a physician or NPP and orders for treatment.
- Supervising physician does not have to be of the same specialty as the service they are supervising (e.g. internist supervising transfusion)...but not all practitioners are qualified to supervise services of any specialty.
- Regarding “extremely specialized services (e.g. radiation oncology) CMS does not believe that it is sufficient or consistent with direct supervision rules for the supervising professional on-site to be capable of only emergency management– they should have training and knowledge to clinically redirect the service or provide additional orders



DISCUSSION

Questions for Discussion

- General comments/questions on supervision provisions in the OPPS final rule?
 - Does the 1-year delay in enforcement for CAH's and small, rural PPS hospitals help?
 - Does CMS' two-tiered supervision for certain extended duration services help small/rural hospitals and CAHs? Will the documentation requirement pose a problem?
 - Does the new definition of "direct supervision" help?
- Comments on the independent review process:
 - What other potential entities should serve as technical panel?
 - How should this process work?
 - What are potential criteria for evaluating a services for the appropriate level of supervision?
 - What services should the technical panel consider initially?
 - Any other ideas/recommendations?



Contact Information

Roslyne Schulman

**Senior Associate Director
AHA, Policy Development**

rschulman@aha.org



American Hospital
Association



American Hospital Association