

Physician Supervision Requirements For Hospital Outpatient Services

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Presentation Overview



- I. Background and History of Physician Supervision Rules
- II. Current Physician Supervision Requirements
- III. CAHs and Small Rural Hospitals
- IV. Enforcement
- V. Compliance Concerns

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I. Background and History of Physician Supervision Rules

Outpatient Diagnostic vs Therapeutic Services

- 42 CFR 410.27 - Therapeutic services are covered in hospital outpatient departments only when
 - furnished *incident to* the services of physicians in treatment
 - in the hospital or a provider based department (PBD)
 - on physician's order and under supervision
- 42 CFR 410.28 - Diagnostic services (*e.g.*, MRI) are covered directly (*not incident to*)

Supervision Requirement Not In Statute for Medicare Coverage of Hospital Outpatient Services



- 42 USC 1395x(s) – Medicare Part B covers medical and other services, including:
 - Hospital services incident to physicians’ services for outpatients (therapeutic services)
 - Diagnostic services furnished to outpatients and ordinarily furnished for purposes of diagnostic study
 - **SILENT about physician supervision**

Where does it come from?



- Historically, direct physician supervision of outpatient therapeutic services was “*assumed*” in on campus locations

Where does it come from?



- Medicare Intermediary Manual stated:
*“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.” (emphasis added)*

Where does it come from?



- In 2000 when CMS finalized the provider-based rule (42 CFR 413.65), it also changed the physician supervision rules for hospital outpatient services to require physician supervision for both therapeutic and diagnostic services

Provider-Based Department



- CMS published Final Rule in 2000 (*See* 42 CFR 413.65)
- Department that is part of a hospital provider and meets specific requirements
 - Same license as hospital (unless state requires a separate license, such as ASF)
 - Clinical Services and financial operations integrated with main provider (same monitoring and reporting structure)
 - Unified medical record retrieval system
 - Location is held out to public as part of main provider (signage, website, bills, brochures, etc.)
 - Services billed as hospital services and subject to PPS window

Provider Based Department (cont'd)



- Special Rules for Off Campus Locations
 - On campus is 250 yard of main building
 - Off campus is anywhere else
 - Additional ownership and control and administration and supervision requirements
 - Located within 35 mile radius of main provider
 - Special rules for management contracts and joint ventures

2000 OPPS Final Rule Amended Regulations



- 410.27 to require therapeutic services to be provided in the hospital or a department of a provider (designated under 413.65) under direct supervision of a physician
 - **direct supervision = present and on the premises of the location** and immediately available to furnish assistance and direction throughout the performance of the procedure)
 - BUT does not apply to services furnished in a department of a provider located on campus 65 Fed Reg 18,525
- 410.28 to cover diagnostic services at a provider-based location only if furnished under the appropriate level of supervision specified by HCFA. See 410.32 (general, direct, personal)

2000 OPPS Final Rule



- Preamble emphasized that direct supervision requirements for therapeutic services applied only when services are furnished off campus, because:
 - “we **assume** the direct supervision requirement to be met as we explain” in the Intermediary Manual.

2009 OPPS Final Rule “Clarification”



- *“some stakeholders may have misunderstood our use of the term ‘assume’ in the [2000 rulemaking] 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 OPPS 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.”*
- BUT NO CHANGE TO REGULATIONS

2009 Changes



- Transmittal 101 1/16/09
 - Amends Section 20.5.1 Medicare Benefits Policy Manual for therapeutic services furnished 8/1/00-12/31/09 to require direct supervision of therapeutic services regardless of their location
 - Amends Section 20.4.4. for diagnostic services to apply supervision levels in Medicare Physician Fee Schedule (MPFS) Relative Value File

MPFS Supervision Levels



- 42 CFR 410.32
 - Personal means the physician must be in attendance in the room during the procedure
 - Direct means same as 410.27 direct supervision for therapeutic services
 - General means the procedure is furnished under the physician's overall direction and control, but not be present during the performance of the procedure
 - See MPFS Relative Value File

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2010 OPFS Changes Regulations to Clarify/Loosen Location



- 2010 OPFS Final Rule amends 410.27 direct supervision for outpatient therapeutic services furnished in the hospital/CAH or on campus to require the physician or non-physician practitioner to be present **on the same campus** and immediately available to furnish assistance and direction throughout the procedure [NOTE: "**on the same campus**" is more flexible than "**on the premises of the location**"]
- For off campus outpatient PBDs, direct supervision requires the physician or NPP to be **present in the off campus PBD** and immediately available
- Industry, in particular CAHs and small rural hospitals object to staffing supervision on campus or in PBD

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2011 OPPS Final Rule



- Amended 410.27 to remove physical location requirement for therapeutic services

*“Direct supervision means that the physician or NPP must be **immediately available** to furnish assistance and direction throughout the performance of the procedure”*

- No difference between on campus and off campus and no physical presence
- Not on same campus or in off campus PBD

2011 OPPS Final Rule Changes



- Allows supervision from off campus or outside the PBD IF “immediately available”
- Physically available (no telephone)
- Close by but not necessarily in hospital space
- Interruptible (not in surgery or emergency)
- Able to furnish assistance and direction throughout the performance of the procedure

2011 Location and PBDs



- For off campus PBDs (not in hospital or on campus)
 - “any location within a building off campus that houses multiple PBDs” (75 Fed Reg 72008) vs. old rule required supervisor in EACH PBD
 - See Transmittal 137 January 1, 2011 updating Medicare Benefit Policy Manual, Ch 6, 20.4, 20.5 and 20.7 to reflect 2011 OPPS changes effective for CY 2011 therapeutic services

2011 Location is Flexible



- Hospitals can exercise discretion to develop policies based on reasonable judgment of “immediately available”
- Still requires physically present (no telephone or remote technology), interruptible, and able to assist and direct during procedure
- May vary depending on the type of service and the location and design of the hospital
- Must be available “*without interval of time*”
- Documentation is important

2010 OPSS Final Rule Clarified Supervising Physicians



- Supervising physician must have ***within scope of practice and hospital privileges*** the knowledge, ability, and hospital privileges to ***perform*** the services being supervised [can amend hospital bylaws/privileging]
- Supervising physician or NPP must be ***prepared to step in and perform the service***, not just respond to an emergency
- Supervising physician or NPP need not be the same specialty as the procedure, but ... ***must have privileges to perform, and be able to perform, the procedure***

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2010 OPSS Supervising Physician- Therapeutic Services



- Adds NPPs (nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwives, clinical psychologists, licensed clinical social workers)
- Can only supervise services they can personally perform under license and hospital bylaws
- Must meet all Medicare coverage requirements for the service
- CRNAs NOT included and cannot supervise

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2010 OPPS Supervising Physician- Therapeutic Services



- NPPs not permitted to supervise cardiac, intensive cardiac, and pulmonary rehab services
- These services must be supervised by a physician, in some cases having specialized qualifications (See 410.49 cardiac rehab, and 410.47 pulmonary rehab, define supervision by reference to 410.27 which eliminates ***“in the department”*** requirement beginning in 2011)

2010 OPPS Supervising Physician- Diagnostic Services



- Must be supervised by a physician (MD, DO, Dentist, Podiatrist, Optometrist, Chiropractor; no NPPs permitted)
- MPFS supervision levels apply
- See Relative Value File (updated quarterly)
 - Personal = physician in attendance in the room during procedure
 - Direct = consistent with direct supervision for therapeutic services
 - General= overall direction and control, but no physical presence required

Non-Surgical Extended Duration Therapeutic Services (NEDTS)



- 2011 OPPS Final Rule created new subcategory of 16 NEDTS
- Require direct supervision “*at initiation*” and general supervision after the patient is “*stable*”

Non-Surgical Extended Duration Therapeutic Services (NEDTS)



- Can last a long time
- Require substantial monitoring
- Have low risk of requiring a supervisor’s physical presence to assist after the patient is stable
- Excludes surgery and surgical recovery time (because surgeons should do that)

Non-Surgical Extended Duration Therapeutic Services (NEDTS)



- No time lines indicated for transition from “*initiation*” of services to “*stable*” because that is a clinical decision and will vary
- Do not use EMTALA meaning of “*stable*”
- Transition from direct to general supervision must be documented
- Includes observation services and non-chemo injections and infusions; excludes chemo and blood transfusions

II. Current Physician Supervision Requirements



Current Medicare Regulation- Outpatient Therapeutic Services



- 42 CFR 410.27- Medicare Part B pays for hospital/CAH therapeutic services furnished incident to physicians services, if they are furnished:
 - By or under arrangements made by a participating hospital
 - As an integral though incidental part of a physician's services
 - In the hospital/CAH or PBD
 - Under direct supervision of physician/NPP (unless CMS changes level) [*NOT pulmonary, cardiac rehab*]
 - NPPs can supervise services they personally perform
 - NEDTS rule applies

Current Medicare Regulation- Outpatient Diagnostic Services



- 42 CFR 410.28- Medicare Part B pays for hospital/CAH diagnostic services furnished to outpatients if:
 - Furnished by or under arrangements (UA) with participating hospital
 - Ordinarily furnished by hospital to outpatients for purposes of diagnostic study
 - Would be covered if furnished to inpatients
 - Furnished in the hospital or other location operated/supervised by hospital (if UA)
 - Under level of supervision in MPFS
 - For hospital or UA or on campus/off campus PBDs, direct supervision means immediately available

Current OPSS Supervision Rules



- 2011 Hospital Outpatient Prospective Payment System Final Rule
- Direct supervision = immediately available
- Eliminated distinction between on campus and off campus for services requiring direct supervision
- Eliminated physical presence requirement
- Immediately available not clearly defined

Current OPSS Supervision Rules- Therapeutic Services



| <u>Level</u> | <u>Physician or NPP</u> |
|---------------------|--------------------------|
| Direct | Physicians or |
| Except NEDTS | NPPs (if within scope |
| (initiation =direct | practice) |
| after patient | No NPPs for cardiac |
| is stable, can | rehab, intensive cardiac |
| lower to general) | rehab, and pulmonary |
| | rehab |

Current OPPS Supervision Rules- Therapeutic Services



- NEDTS (outpatient therapeutic services that can last a long time, have substantial monitoring component often performed by auxiliary personnel, with low risk of requiring supervising physician/NPP availability)
- “Initiation” means the beginning portion of the NEDTS, ending when patient is “stable” and supervisor determines service can be delivered safely under general supervision

Current OPPS Supervision Rules- Therapeutic Services (cont'd)



On Campus PBD

Immediately

Available

Can be off
campus

Off Campus PBD

Immediately

Available

Can be outside PBD

Old Rule OPSS Supervision Rules- Therapeutic Services



On Campus PBD

Immediately
Available
Must be on
Campus
(250 yards of
Main building)

Off Campus PBD

Immediately
Available
Must be in PBD where
Service furnished

Current OPSS Supervision Rules- Diagnostic Services



Level

See MPFS
(Relative Value
File)
Personal,
Direct, or
General

Physician or NPP

Physician ONLY
NPPs cannot supervise
But NPPs (PA, NP,
CNS, CNMW can
Personally Perform
If within scope practice

Current OPPS Supervision Rules-Diagnostic Services (cont'd)



On Campus PBD

Immediately

Available

Can be off
campus

Off Campus PBD

Immediately

Available

Can be outside PBD

Old Rule OPPS Supervision Rules-Diagnostic Services



On Campus PBD

Immediately

Available

Must be on
Campus
(250 yards of
Main building)

Off Campus PBD

Immediately

Available

Must be in PBD where
service furnished

Current Rule Non-Hospital Locations



Therapeutic

Not applicable
(therapeutic services must be provided in the hospital)

Diagnostic

Supervising Physician must be present in the office suite
(Rule unaffected by recent changes in OPSS supervision rules)

III. Critical Access Hospitals (CAHs) and Small Rural Hospitals



Small Rural Hospitals



- Generally, rural if either geographically located in a rural area or paid through OPSS with wage index for rural area
- For definition, see Medicare Claims Processing Manual (Pub 100-04) Section 70, Chapter 4
- Same definition used under Soc Sec Act 1833(t)(7) used for Transitional OPS

CAH and Small Rural Concerns



- Staffing Challenges following 2009 Clarifications and 2010 Changes
 - Supervisor had to be on campus or in PBD
 - Now following 2011 changes, supervisors can be “immediately available” from a variety of physical locations
 - Still may be risks for 2009, especially for patients admitted by physicians from office

CAH and Small Rural Concerns



- Staffing Challenges
 - ER physicians
 - Does their contract state they will supervise therapeutic services? Are they always interruptible or do you have backup options? Do they have appropriate training and skills to supervise therapeutic or diagnostic services?
 - On-Call physician coverage
 - Are policies clear on meaning of “immediately available”?
 - Physicians supervising from off campus locations
 - Do you need a schedule, especially for after hours?
 - Do you need rules about time or distance from hospital while supervising to ensure “immediately available”?

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CAH Enforcement Suspension



- March, 2010 CMS suspended 2010 enforcement of supervision rules to CAHs
- CMS extended the non-enforcement to CAH and small rural hospitals with 100 or fewer beds twice (through CY 2012)
- Allows CAHs and small rural hospitals more time to make plans to meet new requirements

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IV. Enforcement

2010 OPPS Final Rule

- CMS stated that “clarifications” in 2009 were necessary, but they would not enforce the clarified requirements for services furnished in 2000-2008; however:
 - *“the usual enforcement practices of Medicare contractors are appropriate for services furnished in 2009”*
- In 2010 OPPS Final Rule, CMS stated “we plan to exercise our 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
- Means knowing the requirements in place in 2009 and 2010 (vs. just the current 2011/12 rules) may be important

Enforcement: Which Rules Apply?



- CY 2000-2008: Historical Rule
- CY 2009: 2009 “clarifications” (CMS expects direct physician supervision in hospital and all PBDs, both on and off campus)
- CY 2010: 2010 changes (physician or NPP supervisor must be on campus or in PBD (but N/A for CAH/Small Rural))
- CY 2011: 2011 changes (supervisor must be immediately available; can be off campus and outside PBD (but N/A for CAH/Small Rural))
- CY 2012: Same as CY 2011; APC can change supervision levels (but N/A for CAH/Small Rural)

V. Compliance Concerns



Can ED Physicians Supervise?



- CMS has indicated ED physicians can supervise if can be reasonably interrupted and most ED physicians can appropriately supervise many services within the scope of their knowledge, skills, licensure and hospital granted privileges
- Need not operate equipment in lieu of tech
- Assess level of activity in ED
- Consider qualifications to supervise (radiology with contrast?)

Diagnostic Services in ED



- Is ED physician qualified to supervise when radiologists are absent (overnight)?
- Need not be able to operate equipment, but not merely available to manage emergencies
- Must be knowledgeable about the service to furnish assistance and direction (do they know how to assist/direct in use of contrast? To order correct exam to get diagnostic results?)
- Ability to supervise must be in their hospital privileges

Observation Services



- Patients admitted by physicians not on hospital premises: Is their office nearby enough to be “immediately available” during office hours?
- Admitting physician (or physician/NPP from hospital) must be “immediately available” to initiate observation
- What happens when physician’s office closes at 5 pm? Does hospital have another supervisor for after hours?
- Observation is NEDTS, but supervisor must document in progress notes transition to “stable” and general supervision

Chemo and Blood Transfusions



- Chemo and blood transfusions not included in NEDTS
- Need direct supervision throughout transfusion
- Patients presenting for chemo/blood transfusions that may extend after hours may require additional hospital staffing to maintain physician supervision

Radiation Oncology



- Radiation therapy has its own basis of coverage at Soc Sec Act 1861(s)(4)
 - Not covered under the “incident to” rules applicable to therapeutic services
 - 410.27 is a rule for coverage for services provided “incident to,” including the “direct supervision” requirement
 - Nevertheless, CMS has informally stated direct supervision applies
 - Are supervisors qualified? Can they clinically redirect the service or provide additional orders? (Or do you need a radiation oncologist to supervise?)

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Compliance Checklist



- Identify and document supervising physician/NPP
- CMS has not mandated specific documentation required
- But, must be able to prove have supervisor in place for all OP services by date and time
 - Schedules?
 - Logs?
 - Contracts?
 - Other?

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Compliance Checklist



- Confirm correct supervision level for all diagnostic services (check MPFS Relative Value File for general, direct or personal)
- Check/revise hospital bylaws to indicate which physicians qualified to supervise/perform service
- Prepare policies and procedures for supervision and contacting supervisor
- Educate physicians/NPPs on policies and procedures and their responsibility to supervise and provide necessary training
- Train staff on supervising physician/NPP role and procedure for contacting to assist
- Conduct self-audits on supervisor assistance and response time (“fire drills”)
- Compliance officer/department monitor and report to management on progress

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Compliance Checklist



- Are supervisors meeting “immediately available” standard? Do self-audits on response time “fire drills”
- Not well defined may avoid clear failure to meet a bright line standard (such as within 250 yards of campus), but it can also be vague and subject to varying interpretation
- We don’t really know how CMS will interpret if they audit/enforce

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What will the future bring?



- 2012 OPSS Final Rule APC Committee will review appropriate supervision level and may change them or add/remove NEDTS
- Must monitor APC activities and update for any changes in supervision
- Must also look at MPFS Relative Value File updates for correct supervision level for diagnostic tests

Will Medicare Contractors audit for supervision rule compliance?



- CMS has indicated supervision was not on the Medicare RAC list of issues for CY 2010
- CMS will make sure RACs understand supervision will require knowledge of hospital's staffing and activity levels
- CMS only directed contractors not to enforce requirements for direct supervision of OP therapeutic services for CAHs/Small Rural in 2010 and 2011

Resources



- Bricker Client Bulletins
- CMS FAQs April 23, 2010 (issued before 2011 changes, so not up to date on location issues)
- Medicare Benefit Policy Manual (Pub 100-02, Ch 6)
- MPFS Relative Value File:
<http://www.cms.gov/apps/physician-fee-schedule/overview.asp>

Questions?



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- Provider Based Status Compliance

Provider-Based

- Department of provider
- Provider-based entities
- Remote location of hospital
- Facilities
- Main provider

Provider-Based Compliance



On-campus: 250 yards of the main building
Off-campus: anything else

Provider-Based Compliance



On-Campus Criteria

1. Licensure

Same license except where state requires a separate license for the provider-based department.

On-Campus Criteria, cont'd

2. Clinical Services

Clinical services at the provider-based department are integrated with the main provider as evidenced by:

- Professional staff at facility has clinical privileges of the main provider
- Same monitoring and oversight as any other department
- Medical director maintains a reporting relationship with the chief medical officer of main provider

On-Campus Criteria, cont'd

Clinical Services, cont'd

- Medical staff committees are responsible for the clinical care (quality assurance, utilization review)
- Unified record retrieval system for medical records
- Inpatient and outpatient services of facility and main provider are integrated

On-Campus Criteria, cont'd

3. Financial Integration

The financial operations of the facility and main provider are fully integrated. Patients who are treated at the facility have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department of service of the main provider.

On-Campus Criteria, cont'd

4. Public Awareness

The provider based facility is held out to the public and other payers as part of the main provider. Patients must be aware that when they enter the facility, they are entering the main provider (website, signage, bills, brochures).

On-Campus Criteria, cont'd

5. Obligations of hospital outpatient departments

- Comply with anti-dumping rules
- Physician services must be billed with correct site of service code
- Comply with all the terms of the hospital provider agreement
- Must treat all Medicare patients as hospital outpatient
- Services subject to payment window provisions applicable to PPS hospitals and to hospitals excluded from PPS

Common Non-compliance Problem

- Physician billing wrong site of service code
- Public awareness/name

Additional Off-Campus Criteria

1. Beneficiary Coinsurance Notice

- Prior to recovering services, the hospital must provide a notice stating the amount of the potential financial liability
 - Estimate
 - Notice must be one beneficiary can read and understand

Additional Off-Campus Criteria, cont'd

2. Operation under the ownership and control of the main provider

- Business enterprise is owned 100% by the main provider
- Same governing body
- Common bylaws and operating decisions of the governing body
- Main provider has final responsibility for administrative decisions, contracts with outside third parties, personnel actions, policies, and medical staff appointments

Additional Off-Campus Criteria, cont'd

3. Administration and Supervision

The reporting relationship between the facility and the main provider must have the same frequency, intensity and level of accountability as between main provider and any department

- Direct supervision
- Reporting relationship with manager at main provider
- Accountable to governing body
- Administrative functions are integrated

Additional Off-Campus Criteria, cont'd

4. Location

- Within 35 mile radius of main provider
- Special rules for rural health clinics

Additional Off-Campus Criteria, cont'd

5. Management Contracts

- Main provider must employ staff directly involved in the delivery of patient care
- Administrative functions are integrated with the main provider
- Main provider has significant control over the operations of the facility
- Management contract held by the main provider

Additional Off-Campus Criteria, cont'd

Common Compliance Problems

- Beneficiary Notice
- Management Contract

Attestation Form

- <http://www.bricker.com/legalservices/practice/hcare/payment/asattestation.pdf>