



Minnesota Hospital Association

Direct Supervision of Outpatient Therapeutic Services



Adaptation Toolkit

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Direct Supervision of Outpatient Therapeutic Services

Adaptation Toolkit

For many years, hospitals had flexibility to provide outpatient therapeutic care in a manner that protected patient safety, delivered high quality care and offered access to needed services even in rural communities. In 2009, however, the Centers for Medicare and Medicaid Services (CMS) made an abrupt policy shift by stating that outpatient therapeutic services delivered in a hospital must be directly supervised by a physician or one of an enumerated list of nonphysician practitioners (NPPs). Other than claiming that this was nothing more than articulating the agency's long-standing policy, CMS did not offer any explanation or evidence demonstrating why the new regulatory restriction was needed.

The Minnesota Hospital Association (MHA) and the American Hospital Association (AHA) repeatedly urged CMS to repeal or revise its policy. In particular, the associations argued that the new physician supervision policy would decrease access to care in rural areas and increase the cost of care as hospitals scramble to meet artificial and unnecessary direct supervision requirements in times of workforce shortages. The associations also pointed to the absence of any clinical evidence showing that existing therapeutic service delivery models jeopardized patient safety, hindered high quality care or otherwise hampered overall Medicare policy goals.

Despite the associations' efforts, CMS refused to repeal or back away from its new interpretation. Instead, the agency agreed to refrain from enforcing the policy in critical access hospitals (CAHs) and small rural prospective payment system (PPS) hospitals with fewer than 100 beds.¹ The agency also established a Hospital Outpatient Panel (HOP) to make recommendations for exceptions to or modifications to the direct supervision requirements for certain individual services.² The HOP met several times and identified dozens of services that it believed should be subject to different supervision standards. Unfortunately, CMS refused to adopt all of those recommendations.

In 2012, CMS announced that its period of non-enforcement of the physician supervision policy in CAHs and rural PPS hospitals would end in 2013 and the new standards would be in force beginning in 2014.

In 2012, CMS announced that its period of non-enforcement of the physician supervision policy in CAHs and rural PPS hospitals would end in 2013 and the new standards would be in force beginning in 2014.³ While MHA and AHA continue to urge CMS to change its position and encourage Congress to take legislative action to clarify physician supervision requirements so they are more reasonable and practical,⁴ MHA also wants to provide help and support for hospitals that must prepare to operate

1 See, e.g., 76 Federal Register 74371 (2012 OPPTS Final Rule) (extending nonenforcement of policy through 2012 and indicating intention to retain nonenforcement through 2013); 77 Federal Register 68426 (2013 OPPTS Final Rule) (extending enforcement moratorium through 2013 and stating that CMS does not intend to extend the moratorium beyond 2013).

2 See 77 Federal Register 68219.

3 76 Federal Register 74371 (2012 OPPTS Final Rule); see also 77 Federal Register 68426.

4 Minnesota's Representative Collin Peterson (D), together with Representative Kristi Noem (R-SD), introduced the House version of "Protecting Access to Rural Therapy Services Act" (H.R. 2801). Representative Tim Walz (D-MN) joined as a co-sponsor of the House legislation. Both Minnesota Senators Amy Klobuchar (D) and Al Franken (D) are co-sponsors of the Senate version of the bill (S.1143).

H.R. 2801/S.1143 would allow general supervision by a physician or NPP for many outpatient therapy services. The bill would require CMS to allow a default setting of general supervision, rather than direct supervision, for outpatient therapy services and create an advisory panel to establish an

under the new standards in challenging environments, such as rural communities experiencing health care workforce shortages, if CMS does not revise its policy or extend the enforcement moratorium.⁵

At the outset it is important to note that the direct supervision policy is a condition of payment, not a Condition of Participation (CoP). In other words, the policy is established and enforceable only with respect to whether the particular service is considered “covered,” and therefore reimbursable, by Medicare. It does not determine whether a particular hospital violated its CoPs.

The CMS Policy

At the outset it is important to note that the direct supervision policy is a condition of payment, not a Condition of Participation (CoP). In other words, the policy is established and enforceable only with respect to whether the particular service is considered “covered,” and therefore reimbursable, by Medicare. It does not determine whether a particular hospital violated its CoPs.

The definitions of the supervision levels and other supervision requirements are laid out in 42 CFR 410.27⁶ and the Medicare Benefit Policy Manual.⁷ According to the federal rule, Medicare pays hospitals for outpatient therapeutic “services and supplies furnished incident to a physician or nonphysician practitioner service to outpatients”⁸ if they meet certain conditions.

For purposes of this analysis, the most relevant condition is that the services must be provided “[u]nder the direct supervision of a physician or a nonphysician practitioner.”⁹ CMS defines “direct supervision” to mean that “the physician or nonphysician practitioner must be immediately available to furnish assistance and

direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.”¹⁰

This direct supervision requirement applies to services delivered “in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus.”¹¹ CMS considers a service to be delivered in a hospital if it occurs “in the main building(s) of the hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital or CAH; and for which the hospital or CAH bills the services furnished under the hospital’s or CAH’s CMS Certification Number.”¹²

exceptions process for risky and complex outpatient services. The legislation would create a special rule for CAHs that recognizes their unique size and Medicare conditions of participation. Importantly, the legislation would hold hospitals harmless from civil or criminal action for failing to meet the direct supervision requirements applied to outpatient therapeutic services furnished since 2001. The legislation is supported by MHA and AHA, as well as numerous hospital and health care organizations across the country.

5 At the time this document was written, CMS had not issued the 2014 OPPS Final Rule definitively stating whether any additional changes to the direct supervision policy or extension of the nonenforcement policy will apply in 2014.

6 Attached as Appendix C.

7 Medicare Benefit Policy Manual, (Pub. 100-02) Ch. 6, sec. 20.5 – 20.7 (effective date April 1, 2013) available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c06.pdf> and attached as Appendix D.

8 42 CFR 410.27 (a) attached as Appendix C.

9 *Id.* at (a)(1)(iv).

10 *Id.*

11 *Id.*

12 Medicare Benefit Policy Manual, Ch. 6, sec. 20.5.2.

Because CMS takes the position that its direct supervision policy is not new, but rather a restatement of long-standing requirements, the agency expects that hospitals have policies or bylaws pertaining to the need for direct supervision by a physician or NPP if another caregiver is going to furnish an outpatient therapeutic service.¹³

Adaptation Note: *Ensure that a hospital's bylaws and procedures address the need for outpatient therapeutic services delivered to Medicare patients be provided by caregivers within their scope of practice, in accordance with any applicable federal or state law and, if the service is not delivered by a physician or nonphysician practitioner, under the direct supervision of a physician or nonphysician practitioner.*

Appendix A contains a flow chart analysis that attempts to summarize the decisions and compliance steps necessary for hospitals to adapt their care practices to the direct supervision policy. Narrative examples of the application of the policy to drug infusion and emergency department services are included below.

Outpatient Therapeutic Services

The direct supervision policy at issue here applies solely to outpatient therapeutic services and supplies. CMS defines and describes these as follows:

Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities and drugs and biologicals that cannot be self-administered) which are not diagnostic services, are furnished to outpatients incident to the services of physicians and practitioners and which aid them in the treatment of patients.¹⁴

Outpatient therapeutic services include emergency department, clinic and observation services that are not diagnostic services.

CMS explicitly includes emergency department, clinic and observation services within its definition of outpatient therapeutic services subject to the direct supervision requirement.¹⁵

On the other hand, CMS explicitly excludes certain services from the direct supervision standard. First, CMS does not allow nonphysician practitioners to supervise pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, which are not covered under different rules.

Another exclusion from the direct supervision standard is any service that is not paid for through the Outpatient Prospective Payment System (OPPS)¹⁶ or the CAH program.¹⁷ Accordingly, physician, inpatient, ambulance,

¹³ See *id.*, stating as follows:

CMS would expect that hospitals already have the credentialing procedures, bylaws, and other policies in place to ensure that hospital outpatient services furnished to Medicare beneficiaries are being provided only by qualified practitioners in accordance with all applicable laws and regulations. For services not furnished directly by a physician or nonphysician practitioner, CMS would expect that . . . hospital bylaws and policies would ensure that therapeutic services are being supervised in a manner commensurate with their complexity, including personal supervision where appropriate.

¹⁴ *Id.*

¹⁵ See *id.*

¹⁶ See 77 Federal Register 68218 (Nov. 15, 2012) available at <http://www.gpo.gov/fdsys/pkg/FR-2012-11-15/pdf/2012-26902.pdf> (containing guidance and commentary regarding the 2013 Outpatient Prospective Payment System Final Rule).

¹⁷ See *id.* at p. 68424.

occupational therapy, physical therapy and speech therapy are not subject to the direct supervision standard because they are paid through mechanisms other than the OPPS.¹⁸ Likewise, lab services paid through the Clinical Laboratory Fee Schedule (CLFS) and end-stage renal disease services paid through the ESRD are excluded from the direct supervision policy.¹⁹

Supervising Physicians and Non-Physician Practitioners (NPPs)

Often, those who follow health care policy refer to the direct supervision standard “direct physician supervision.” However, with the exception of a few enumerated services, the direct supervision standard can be satisfied by either a physician or one of a number of nonphysician practitioners (NPPs).²⁰ The types of caregivers that qualify to supervise outpatient therapeutic services are as follows:

- physicians;
- clinical psychologists;
- licensed clinical social workers;
- physician assistants;
- nurse practitioners;
- clinical nurse specialists and
- certified nurse-midwives.²¹

For any caregiver to be considered a supervising physician or NPP, however, the particular therapeutic service must be one that he/she can personally deliver within the profession’s scope of practice, the hospital’s granted privileges, and all applicable state laws and rules governing the particular service.²² In addition, the supervised service must be one that the physician or NPP has the “knowledge, skills, ability, and privileges to perform,” to be able take over care delivery in the case of an emergency, to provide additional orders, or to change the course of treatment.²³

Adaptation Note: *Nothing in the federal rule or CMS guidelines require that the physician or NPP who ordered the particular outpatient service be the one to serve as the supervising physician or NPP when the service is delivered.*

CMS recognizes that some outpatient services depend upon specially trained ancillary staff and technicians who are often the primary operators of some of the equipment used to provide the service. In these cases, CMS states that it does not expect the supervisory physician or NPP to have the particular knowledge and expertise to operate such equipment instead of the specially trained personnel. Nevertheless, CMS expects the physician or NPP to “be knowledgeable about the therapeutic service and clinically able to furnish the service.”²⁴

¹⁸ *Id.* at p. 68218; *see also* 42 CFR 419.22 (setting forth services excluded from OPPS).

¹⁹ *Id.*

²⁰ *Cf.* 42 CFR 410.27(a)(1)(iv).

²¹ *See* 42 CFR 410.27(g)

²² *See* Medicare Benefit Policy Manual, Ch. 6, sec. 20.5.2.

²³ *Id.*

²⁴ *Id.*

Accordingly, although a clinical psychologist is listed as a NPP, he/she will be unqualified to serve as a supervising NPP of trauma care in the emergency department because such care is beyond his/her scope of practice under state law. Likewise, a physician who does not have hospital privileges or the skills and knowledge to conduct surgery cannot be relied upon to satisfy the direct supervision standard with respect to outpatient surgical services.

Immediately Available

In a nutshell, the physician or NPP who supervises a service must be “immediately available to furnish assistance and direction throughout the performance of the procedure.”²⁵ For CMS, being “immediately available” by telephone is not sufficient; nor is it enough for the physician or NPP to be on the hospital’s campus. Instead, according to CMS, “Immediate availability requires the immediate physical presence of the supervisory physician or nonphysician practitioner.”²⁶ On the other hand, the supervising physician or NPP does not necessarily need to be in the room during the service.²⁷

Other than requiring the immediate physical presence of the supervisor, CMS does not establish a definitive time or distance threshold. It has stated that a physician or NPP is not immediately available if he/she is “performing another procedure or service that he or she could not interrupt.”²⁸ This expectation often precludes emergency department physicians and NPPs from constituting the supervisor for outpatient services delivered outside the emergency room because if an emergency patient arrives the physician or NPP cannot interrupt that emergency care to attend to another outpatient service.

Thus, some commentators have inferred that the “immediately available” threshold will be met if the supervising professional (1) knows that he/she is responsible for supervising the service; (2) is physically close enough to the patient that he/she can arrive in person quickly if called upon, and (3) is capable of being interrupted and leaving whatever else he/she might be doing to attend to the outpatient if requested.

Services with Modified Supervision Standards

While the federal rule establishes the direct supervision standard, CMS reserves the authority to modify the standard for particular services.²⁹ One of the modified standards used by CMS is “general supervision,” which means “the procedure or service is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure.”³⁰

Another modified supervision standard used by CMS is a two-tiered standard for “Non-surgical Extended Duration

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.* The list of services for which CMS has modified the supervision standards, as of November 2013, can be found at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf> and attached as Appendix E. This list was last modified on November 27, 2012.

³⁰ *Id.*; see also 42 CFR 410.32(b)(3)(i).

Therapeutic Services” (NSEDTS). Under this standard, a service must begin under direct supervision of a physician or NPP, but then the standard can shift to general supervision once the patient is stabilized.³¹

Adaptation Note: *CMS requires that the patient’s medical record include documentation of this transition.*³²

Hospital Outpatient Payment Panel

When stakeholders expressed significant concerns about the direct supervision policy, CMS responded in part by expanding the scope of the previously named Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to include making recommendations on the appropriate level of supervision for individual hospital outpatient therapeutic services.³³ The APC Panel was renamed the Hospital Outpatient Payment Panel (HOP or the Panel). The Panel meets up to three times per year³⁴ and addresses supervision standards on an individual service-by-service basis.

The HOP can have up to 19 members and is not limited to using data provided by CMS.³⁵ However, the criteria and process for bringing services to the HOP for consideration is highly technical.³⁶

31 Medicare Benefit Policy Manual, Ch. 6, sec. 20.7.

32 *Id.* CMS does not prescribe a particular format of medical record documentation, but rather leaves the manner in which the transition from direct to general supervision to the discretion of the physician or nonphysician practitioner.

33 See 77 Federal Register 68219.

34 “Advisory Panel on Hospital Outpatient Payment,” CMS website (Nov. 6, 2013) available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

35 See 77 Federal Register 68219.

36 See http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage for information regarding HOP’s membership, charter, meeting dates, agendas and process.

Example: Direct Supervision, EMTALA and CoPs for Critical Access Hospitals

One question many CAHs ask is what steps are necessary to simultaneously comply with the Emergency Medical Treatment and Active Labor Act (EMTALA), CoPs and the direct supervision policy with respect to therapeutic services provided in the emergency department (ED).

As indicated by the question posed, there are multiple requirements related to health professional services and coverage in a hospital's emergency department.

First, with respect to the direct supervision policy, it does apply to therapeutic services provided in the ED. Therefore, in order for a hospital to bill and get paid from Medicare for ED services provided to a beneficiary, the outpatient therapeutic service must have been directly supervised by a physician or a NPP. This standard, however, does not change the requirements of Medicare's CoPs or EMTALA regarding what kind of staffing and response a hospital must provide in its ED.

The CoPs require a CAH to demonstrate that it has adequate ED coverage in order to be qualified to participate in the Medicare program. The CoPs for CAHs state that the hospital must have "a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within . . . 30 minutes, on a 24-hour a day basis."³⁷ This requirement means that a CAH must be able to have an emergency-trained or experienced physician, PA, APRN or clinical nurse specialist on site within 30 minutes 24 hours a day, seven days a week.

The CoPs and EMTALA requirements are similar, but not identical. To summarize, there are four general requirements:

1. Under the CoPs, a qualified medical professional must be immediately available by phone and able to come to the emergency department within 30 minutes when patient care requires a qualified medical professional;
2. CoPs also require that a physician be available on a 24-hour basis to accept phone calls about patients, provide advice about care, and make referrals;
3. EMTALA requires that a qualified medical professional be available in the emergency department to perform (a) a screening examination and (b) stabilizing treatment for a patient; and
4. EMTALA requires the hospital to maintain a list of on-call physicians who can be called for advice and consultation and who will come to the emergency department "within a reasonable amount of time" when requested.

Requirements 1 and 3 can be satisfied by a physician, physician assistant or nurse practitioner, each of whom also satisfies the direct supervision requirements assuming the services provided are within the scope of practice, hospital privileges and caregiver's knowledge and skills.

The second CoP requirement may only be met by a physician, but the physician does not have to be physically present

³⁷ 42 CFR 485.618 (d)(1) (including certain exceptions for CAHs in areas with fewer than six residents per square mile).

in the emergency department so the obligation could be met by a telehealth physician.

The fourth requirement essentially requires a physician to be available within the area, although CMS has provided some leeway for remote hospitals with particularly small medical staffs. PAs, NPs, or telemedicine physicians cannot meet the EMTALA requirement that the hospital maintain a list of on-call physicians and that a physician be available to come to the emergency department “within a reasonable amount of time” when requested.

Accordingly, it is entirely possible for a hospital to meet the requirements set forth in the CoPs and EMTALA but be unable to get reimbursed for services provided because they were delivered without direct supervision. For example, services provided to a patient by non-physician caregivers who do not meet the NPP definition while a physician is en route to the CAH within the CoP and EMTALA standards, but those services could not be billed to or reimbursed by Medicare because they were not directly supervised by a physician or NPP.

Example: Drug Infusion Therapy

Drug infusion therapy, such as in chemotherapy services, is an outpatient therapeutic service, and therefore subject to the direct supervision policy when used to treat Medicare beneficiaries in a hospital.

As discussed earlier, CMS modified the direct supervision policy for certain defined services, including some infusion services, (specifically CPT codes C8957, and 96360 through 96368 related to infusion therapies). CMS categorized these infusion services as NSEDTS and applied the two-tiered standard, which requires direct supervision of a physician or non-physician practitioner who is immediately available to respond to the Medicare patient's needs at the beginning of the service, but then is followed by a standard of general supervision after the service has been initiated and the patient is stabilized. This two-tiered standard applies to the initial infusion for a patient, each sequential infusion when a new drug or substance is introduced, and concurrent infusions.

Consequently, each time a treatment regimen changes to a different drug or substance or to add another drug or substance, such as anti-nausea medication, then the direct supervision requirement must be met at the initiation of the newly changed treatment regimen followed by general supervision when the patient is stabilized.

On the other hand, if the Medicare beneficiary previously received an initial infusion treatment that began with direct supervision followed by general supervision and is returning to receive a subsequent infusion of the same drug or substance, then only general supervision is required for the second and subsequent infusions.

Minnesota Hospital Association



Appendix B

Glossary of Acronyms

AHA	American Hospital Association
APC Panel	Ambulatory Payment Classification Groups Panel
APRN	Advanced Practice Registered Nurse
CAH	Critical Access Hospital
CFR	Code of Federal Regulations
CLFS	Clinical Laboratory Fee Schedule
CMS	Centers for Medicare and Medicaid Services
CoP	Condition of Participation
ED	Emergency Department
EMTALA	Emergency Medical Treatment and Active Labor Act
ESRD	End-Stage Renal Disease
HOP	Hospital Outpatient Payment Panel
MHA	Minnesota Hospital Association
NPP	Nonphysician Practitioner
NSEDTS	Non-Surgical Extended Duration Therapeutic Services
OPPS	Outpatient Prospective Payment System
PPS	Prospective Payment System

Appendix C

42 CFR 410.27. **Outpatient hospital or CAH services and supplies incident to a physician or nonphysician practitioner service: Conditions.**

(a) Medicare Part B pays for hospital or CAH services and supplies furnished incident to a physician or nonphysician practitioner service to outpatients, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by the participating hospital or CAH, except in the case of a SNF resident as provided in § [411.15\(p\)](#) of this chapter;

(ii) As an integral though incidental part of a physician's or nonphysician practitioner's services;

(iii) In the hospital or CAH or in a department of the hospital or CAH, as defined in § 413.65 of this subchapter;

(iv) Under the direct supervision of a physician or a nonphysician practitioner as specified in paragraph (f) of this section. Nonphysician practitioners may directly supervise services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ [410.71](#), [410.73](#), [410.74](#), [410.75](#), [410.76](#), and [410.77](#). For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this subchapter, “direct supervision” means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or osteopathy, as specified in §§ [410.47](#) and [410.49](#), respectively; and

(v) As nonsurgical extended duration therapeutic services.

(A) *Nonsurgical extended duration therapeutic services (extended duration services)* are hospital outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature. For these services, Medicare requires a minimum of direct supervision during the initiation of the service which may be followed by

general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. For these services, “direct supervision” means the definition specified in paragraph (a)(1)(iv) of this section. “General supervision” means the definition specified at § [410.32\(b\)\(3\)\(i\)](#).

(B) “Initiation” means the beginning portion of the non-surgical extended duration therapeutic service which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner believes the remainder of the service can be delivered safely under general supervision.

(2) In the case of partial hospitalization services, also meet the conditions of paragraph (d) of this section.

(b) Drugs and biologicals are also subject to the limitations specified in § [410.168](#).

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in § [410.168](#).

(d) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part [424 of this chapter](#); and

(2) Furnished under a plan of treatment as required under subpart B of part [424 of this chapter](#).

(e) Services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § [410.42\(a\)](#).

(f) For purposes of this section, “nonphysician practitioner” means a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

Appendix D

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 169	Date: March 1, 2013
	Change Request 8228

SUBJECT: April 2013 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: CMS is revising the reference link in the Medicare Benefit Policy Manual for the list of hospital outpatient therapeutic services that may be furnished under general supervision or are defined as non-surgical extended duration therapeutic services (NSEDTS).

EFFECTIVE DATE: April 1, 2013

IMPLEMENTATION DATE: April 1, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	6/20.5.2/Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2010
R	6/20.7/Non-Surgical Extended Duration Therapeutic Services

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

For Medicare Administrative Contractors (MACs):

The Medicare Administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment – Recurring Update Notification

Pub. 100-02	Transmittal: 169	Date: March 1, 2013	Change Request: 8228
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SUBJECT: April 2013 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: April 1, 2013

IMPLEMENTATION DATE: April 1, 2013

I. GENERAL INFORMATION

A. Background: CMS is revising the reference link in the Medicare Benefit Policy Manual for the list of hospital outpatient therapeutic services that may be furnished under general supervision or are defined as non-surgical extended duration therapeutic services (NSEDTS).

B. Policy:

Hospital Outpatient Therapeutic Services

CMS is updating the reference link in the Medicare Benefit Policy Manual, Chapter 6, Sections 20.5.2 and 20.7, to the list of hospital outpatient therapeutic services that may be furnished under general supervision or are defined as non-surgical extended duration therapeutic services (NSEDTS). The revised list of services reflects changes in the required supervision level for certain services in 2012 and 2013, based upon the recommendations of the Hospital Outpatient Payment Panel.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement.

Number	Requirement	Responsibility										
		A/B MAC		D M E	F I	C A R R I E R	R H I	Shared- System Maintainers				Other
		P a r t	P a r t					M A C	F I S S	M C S	V M S	
		A	B									
8228-02.1	Medicare contractors shall refer to Pub.100-02, Medicare Benefit Policy Manual, Chapter 6, Sections 20.5.2 and 20.7, for the updated link to the list of current services furnished under general supervision and extended duration services for the payment year.	X			X		X					COBC

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC	D M E	F I	C A R R I E R	R H H I	Other
		P a r t A	P a r t B	M A C			
8228-02.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X	X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Marina Kushnirova, marina.kushnirova@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

Section B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

20.5.2 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2010

(Rev. 169, Issued: 03- 01- 13, Effective: 04-01-13, Implementation: 04- 01-13)

Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities and drugs and biologicals that cannot be self-administered) which are not diagnostic services, are furnished to outpatients incident to the services of physicians and practitioners and which aid them in the treatment of patients. These services include clinic services, emergency room services, and observation services. Policies for hospital outpatient therapeutic services furnished incident to physicians' services differ in some respects from policies that pertain to "incident to" services furnished in office and physician-directed clinic settings. See Chapter 15, "Covered Medical and Other Health Services," Section 60.

To be covered as hospital outpatient therapeutic services, the services and supplies must be furnished by the hospital or CAH or under arrangement made by the hospital or CAH (see section 20.1.1 of this chapter). The services and supplies must be furnished as an integral, although incidental, part of the physician or nonphysician practitioner'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 that has provider-based status in relation to the hospital under 42 CFR 413.65. For therapeutic services furnished during CY 2010, as specified at 42 CFR 410.27(g), "in the hospital or CAH" means areas in the main building(s) of the hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital or CAH; and for which the hospital or CAH bills the services furnished under the hospital's or CAH's CMS Certification Number.

Hospital outpatient therapeutic services and supplies must be furnished under the order of a physician or other practitioner practicing within the extent of the Act, the Code of Federal Regulations, and State law. They must be furnished by hospital personnel under the appropriate supervision of a physician or nonphysician practitioner as required in this manual and by 42 CFR 410.27 and 482.12. This does not mean that each occasion of service by a nonphysician 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, when 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.

CMS requires direct supervision (defined below) by an appropriate physician or non-physician practitioner in the provision of all therapeutic services to hospital outpatients, including CAH outpatients. CMS may assign certain hospital outpatient therapeutic

services either general supervision or personal supervision. When such assignment is made, “general supervision” means the definition specified at 42 CFR 410.32(b)(3)(i), that is, the procedure or service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. “Personal supervision” means the definition specified at 42 CFR 410.32(b)(3)(iii), that is, the physician must be in attendance in the room during the performance of the service or procedure.

Effective January 1, 2011, hospitals may change to general supervision for a portion of services defined as non-surgical extended duration therapeutic services (“extended duration services”) but only as specified in this manual for those services (see section 20.7). Pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services require direct supervision which must be furnished by a doctor of medicine or osteopathy, as specified at 42 CFR 410.47 and 410.49, respectively.

The list of services that may be furnished under general supervision or that are defined as non-surgical extended duration therapeutic services is available on the OPPS Website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

Beginning January 1, 2010, according to 42 CFR 410.27, in addition to physicians and clinical psychologists, licensed clinical social workers, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives may furnish the required supervision of hospital outpatient therapeutic services that they may personally furnish in accordance with State law and all additional rules governing the provision of their services, including those specified at 42 CFR Part 410. These nonphysician practitioners are specified at 42 CFR 410.27(g).

Considering that hospitals furnish a wide array of very complex outpatient services and procedures, including surgical procedures, CMS would expect that hospitals already have the credentialing procedures, bylaws, and other policies in place to ensure that hospital outpatient services furnished to Medicare beneficiaries are being provided only by qualified practitioners in accordance with all applicable laws and regulations. For services not furnished directly by a physician or nonphysician practitioner, CMS would expect that these hospital bylaws and policies would ensure that the therapeutic services are being supervised in a manner commensurate with their complexity, including personal supervision where appropriate.

For therapeutic services furnished during CY 2010 in the hospital or CAH or in an on-campus outpatient department of the hospital or CAH, as defined at 42 CFR 413.65, “direct supervision” means that the physician or nonphysician practitioner must be present on the same campus where the services are being furnished. For services furnished in an off-campus provider based department as defined in 42 CFR 413.65, he or she must be present within the off-campus provider based department. The physician or nonphysician practitioner must be immediately available to furnish assistance and

direction throughout the performance of the procedure. The physician or nonphysician practitioner does not have to be present in the room when the procedure is performed.

For therapeutic services furnished during CY 2011 and following, whether in the hospital or CAH or in an on-campus or off-campus outpatient department of the hospital or CAH as defined at 42 CFR 413.65, “direct supervision” means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. As discussed below, the physician is not required to be present in the room where the procedure is performed or within any other physical boundary as long as he or she is immediately available.

Immediate availability requires the immediate physical presence of the supervisory physician or nonphysician practitioner. CMS has not specifically defined the word “immediate” in terms of time or distance; however, an example of a lack of immediate availability would be situations where the supervisory physician or nonphysician practitioner is performing another procedure or service that he or she could not interrupt. Also, for services furnished on-campus, the supervisory physician or nonphysician practitioner may not be so physically distant on-campus from the location where hospital/CAH outpatient services are being furnished that he or she could not intervene right away. The hospital or supervisory practitioner must judge the supervisory practitioner’s relative location to ensure that he or she is immediately available.

For services furnished in CY 2011 and following, a supervisory practitioner may furnish direct supervision from a physician office or other nonhospital space that is not officially part of the hospital or CAH campus where the services are being furnished as long as he or she remains immediately available. Similarly, as of CY 2011, an allowed practitioner can furnish direct supervision from any location in or near an off-campus hospital or CAH building that houses multiple hospital provider-based departments where the services are being furnished as long as the supervisory practitioner is immediately available.

The supervisory physician or nonphysician practitioner must have, within his or her State scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service or procedure. Specially trained ancillary staff and technicians are the primary operators of some specialized therapeutic equipment, and while in such cases CMS does not expect the supervisory physician or nonphysician practitioner to operate this equipment instead of technician, CMS does expect the physician or nonphysician practitioner to be knowledgeable about the therapeutic service and clinically able to furnish the service.

The supervisory responsibility is more than the capacity to respond to an emergency, and includes the ability to take over performance of a procedure or provide additional orders. CMS would not expect that the supervisory physician or nonphysician practitioner would make all decisions unilaterally without informing or consulting the patient’s treating physician or nonphysician practitioner. In summary, the supervisory physician or nonphysician practitioner must be clinically able to supervise the service or procedure.

20.7 - Non-Surgical Extended Duration Therapeutic Services

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CMS designates a limited set of therapeutic services meeting specific criteria as nonsurgical extended duration therapeutic services (“extended duration services”), defined in 42 CFR 410.27(a)(1)(v). These are outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the supervisory practitioner’s immediate availability to furnish assistance and direction after the initiation of the service, and that are not primarily surgical in nature. In the provision of these services, CMS requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision for the remainder of the service at the discretion of the supervisory practitioner. The CMS OPPS Website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html> includes a table listing the current extended duration services for the payment year.

For these services, direct supervision means the definition specified for all outpatient therapeutic services in 410.27(a)(1)(iv), that is, immediate availability to furnish assistance and direction throughout the performance of the procedure. General supervision means the definition specified in the physician fee schedule at 410.32(b)(3)(i), that the service is performed under the supervisory practitioner’s overall direction and control but his or her presence is not required during the performance of the procedure.

“Initiation” means the beginning portion of the extended duration service, ending when the supervisory practitioner believes the patient is stable enough for the remainder of the service to be safely administered under general supervision. The point of transition to general supervision must be documented in the patient’s progress notes or medical record. The manner of documentation is otherwise at the discretion of each supervisory practitioner.

Appendix E

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Supervision File - Hospital Outpatient Therapeutic Services

The following table lists the hospital outpatient therapeutic services that, as of the listed effective dates, are either designated as non-surgical extended duration therapeutic services (NSEDTS or “extended duration services”) or may be furnished under general supervision in accordance with applicable Medicare regulations and policies. All other hospital outpatient therapeutic services require a minimum of direct supervision. The definitions of the supervision levels and other supervision requirements are delineated in 42 CFR 410.27 and the Medicare Benefit Policy Manual (Pub. 100-02) Chapter 6, Sections 20.5 - 20.7. For new code(s), we list the effective date for the predecessor code(s).

HCPCS Code	Descriptor	Minimum Required Supervision Level	Effective Date
C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump	NSEDTS	1/1/2011
G0008	Administration of influenza virus vaccine	General	1/1/2013
G0009	Administration of pneumococcal virus vaccine	General	1/1/2013
G0010	Administration of hepatitis B vaccine	General	1/1/2013
G0127	Trimming of dystrophic nails, any number	General	1/1/2013
G0177	Training and educational services related to the care and treatment of patient’s disabling mental health problems per session (45 minutes or more)	General	7/1/2012
G0378	Hospital observation service, per hour	NSEDTS	1/1/2011
G0379	Direct referral for hospital observation care	NSEDTS	1/1/2011
G0410	Group psychotherapy other than of a multiple-family group, in a partial hospitalization setting, approximately 45 to 50 minutes	General	7/1/2012
G0411	Interactive group psychotherapy, in a partial hospitalization setting, approximately 45 to 50 minutes	General	7/1/2012
11719	Trimming of nondystrophic nails, any number	General	1/1/2013
29580	Strapping; Unna boot	General	1/1/2013
29581	Application of multi-layer compression system; leg (below knee), including ankle and foot	General	1/1/2013
36000	Introduction of needle or intracatheter, vein	General	1/1/2013
36591	Collection of blood specimen from a completely implantable venous access device	General	1/1/2013
36592	Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified	General	1/1/2013
51700	Bladder irrigation, simple, lavage and/or instillation	General	1/1/2013
51701	Insertion of non-indwelling bladder catheter (eg, straight catheterization for residual urine)	General	7/1/2012
51702	Insertion of temporary indwelling bladder catheter; simple (e.g., Foley)	General	1/1/2013
51705	Change of cystostomy tube; simple	General	1/1/2013
51798	Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging	General	1/1/2013
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	General	7/1/2012

90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (list separately in addition to code for primary procedure)	General	7/1/2012
90473	Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)	General	7/1/2012
90474	Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid) (list separately in addition to code for primary procedure)	General	7/1/2012
90785	Interactive Complexity (List separately in addition to the code for primary procedure)	General	7/1/2012
90832	Psychotherapy, 30 minutes with patient and/or family member	General	7/1/2012
90834	Psychotherapy, 45 minutes with patient and/or family member	General	7/1/2012
90837	Psychotherapy, 60 minutes with patient and/or family member	General	7/1/2012
90846	Family psychotherapy (without the patient present)	General	7/1/2012
90847	Family psychotherapy (conjoint psychotherapy) (with patient present)	General	7/1/2012
90849	Multiple-family group psychotherapy	General	7/1/2012
90853	Group psychotherapy (other than of a multiple-family group)	General	7/1/2012
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour	NSEDTS (1/1/2011 – 12/31/2012) General (1/1/2013)	
96361	Intravenous infusion, hydration; each additional hour (list separately in addition to code for primary procedure)	NSEDTS (1/1/2011 – 12/31/2012) General (1/1/2013)	
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	NSEDTS	1/1/2011
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	NSEDTS (1/1/2011 – 12/31/2012) General (1/1/2013)	
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure)	NSEDTS	1/1/2011
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)	NSEDTS	1/1/2011
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)	NSEDTS	1/1/2011
96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)	NSEDTS	1/1/2011
96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)	NSEDTS	1/1/2011
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	NSEDTS (1/1/2011 – 12/31/2012) General (1/1/2013)	

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96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug	NSEDTS	1/1/2011
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/ drug (list separately in addition to code for primary procedure)	NSEDTS	1/1/2011
96376	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/ drug provided in a facility (list separately in addition to code for primary procedure)	NSEDTS (1/1/2011 – 12/31/2012) General (1/1/2013)	
96521	Refilling and maintenance of portable pump	General	1/1/2013
96523	Irrigation of implanted venous access device for drug delivery systems	General	1/1/2013
99406	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes	General	7/1/2012
99407	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes	General	7/1/2012