CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 267	**Date: February 4, 2020**
	Change Request 11605

Transmittal 266, dated January 15, 2020, is being rescinded and replaced by Transmittal 267, dated, February 4, 2020 to add new section 12.d.Radiopharmaceuticals with Pass-Through Status as a Result of Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020 (Public Law 116-94) and new section 19.Extravascular Implantable Cardioverter Defibrillator (EV ICD). Existing sections 12.d through 12.e. were re-numbered. Old section 12.e. became section 12.f. and existing section 19.Coverage Determinations became section 20. New table 11. Radiopharmaceuticals Receiving Pass-Through Status in Accordance with Public Law 116-94 Effective January 1, 2020, and new table 14. Extravascular Implantable Cardioverter Defibrillator (EV ICD) Effective January 1, 2020, were added and existing tables 11 through 13 were re-numbered. All other information remains the same.

SUBJECT: January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This Change Request implements the change in the manual requirements of chapter 6, the Medicare Benefit Policy Manual 100-02, related to Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2020, finalized in the CY 2020 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Final Rule.

EFFECTIVE DATE: January 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 6, 2020

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	6/Table of Contents
R	6/20.5.2/Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on January 1, 2010 through December 31, 2019
N	6/20.5.3/Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2020 - Changes to Supervision Requirements
R	6/20.7/Non-Surgical Extended Duration Therapeutic Services

III. FUNDING:

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 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.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-02	Transmittal: 267	Date: February 4, 2020	Change Request: 11605

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SUBJECT: January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)

EFFECTIVE DATE: January 1, 2020
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IMPLEMENTATION DATE: January 6, 2020

I. GENERAL INFORMATION

A. Background: This Change Request implements the change in the manual requirements of chapter 6, the Medicare Benefit Policy Manual 100-02, related to Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2020, finalized in the CY 2020 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Final Rule.

B. Policy: 1. Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2020 - Changes to Supervision Requirements

Starting January 1, 2020, CMS requires, as the minimum level of supervision, general supervision by an appropriate physician or non-physician practitioner in the provision of all therapeutic services to hospital outpatients, including Critical Access Hospital (CAH) outpatients. "General supervision" means the definition specified at 42 Code of Federal (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. CMS may assign certain hospital outpatient therapeutic services either direct supervision or personal supervision. When such assignment is made, "direct supervision" means the definition specified at 42 CFR 410.32(b)(3)(ii), that is, the physician must be 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. "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.

Additionally, as we noted in the CY 2020 OPPS final rule, establishing general supervision as the default level of physician supervision for outpatient therapeutic services does not prevent a hospital or CAH from requiring a higher level of supervision for a particular service if they believe such a supervision level is necessary. Providers and physicians have flexibility to require a higher level of physician supervision for any service they furnish if they believe a higher level of supervision is required to ensure the quality and safety of the procedure and to protect a beneficiary from complications that might occur.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11605 - 02.1	Medicare contractors shall refer to publication 100-02, the Medicare Benefit Policy Manual, chapter 6, section 20.5 and 20.7 for the latest revisions.	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11605 - 02.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X		X		

IV. SUPPORTING INFORMATION

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

"Should" denotes 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).

VI. FUNDING

Section A: 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 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.

ATTACHMENTS: 0

Medicare Benefit Policy Manual
Chapter 6 - Hospital Services Covered Under Part B

Table of Contents
(Rev.267, Issued: 02-04-2020)

20.5.2 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on January 1, 2010 *through December 31, 2019*

(Rev.267, Issued: 02-04-2020, Effective: 01-01-2020, Implementation: 01-06-2020)

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 *through December 31, 2019*, 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 *for the period of January 1, 2010 through December 31, 2019* 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.

20.5.3 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2020 – Changes to Supervision Requirements

(Rev.267, Issued: 02-04-2020, Effective: 01-01-2020, Implementation: 01-06-2020)

Starting January 1, 2020, CMS requires, as the minimum level of supervision, general supervision by an appropriate physician or non-physician practitioner in the provision of all therapeutic services to hospital outpatients, including CAH outpatients. "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. CMS may assign certain hospital outpatient therapeutic services either direct supervision or personal supervision. When such assignment is made, "direct supervision" means the definition specified at 42 CFR 410.32(b)(3)(ii), that is, the physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or must be present in the room when the procedure is performed. "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.

The list of services starting January 1, 2020 that must be furnished under direct supervision or that are defined as non-surgical extended duration therapeutic services where the initiation of the service must be performed under direct supervision is available on the OPPS Website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

20.7 - Non-Surgical Extended Duration Therapeutic Services

(Rev.267, Issued: 02-04-2020, Effective: 01-01-2020, Implementation: 01-06-2020)

CMS *can designate certain 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.