

ASTRO Guidance on Supervision of Radiation Therapy Services

The Centers for Medicare and Medicaid Services (CMS) sets Medicare physician supervision requirements that apply to services, including radiation therapy, furnished in hospital outpatient and physician office (freestanding) settings. As a condition of Medicare payment, CMS has established physician supervision requirements that apply to specified services furnished in the hospital outpatient department and physician office settings. These requirements differ according to the type of service and the practice setting where the service is rendered, as defined by the various benefit categories under Title XVIII of the Social Security Act. In addition to statutory requirements, additional guidance regarding physician supervision is published in the Code of Federal Regulations and the Medicare Benefit Policy Manual. These requirements and their application in the hospital outpatient department and the physician office (e.g., freestanding radiation therapy center) are detailed in the following four sections:

- 1. Radiation Therapy Services in a Hospital Outpatient Department**
- 2. Radiation Therapy Services in a Freestanding Radiation Therapy Center**
- 3. Diagnostic X-ray Tests (i.e., Image Guidance Services) in a Hospital Outpatient Department and Freestanding Radiation Therapy Center**
- 4. "Incident To" Services in a Hospital Outpatient Department and Freestanding Radiation Therapy Center**

In the following sections, the supervision requirements for these categories are summarized, and their implications for radiation oncologists are discussed. Citations and pertinent summaries of applicable Federal regulations are also provided.

1. Physician Supervision of Radiation Therapy Services in a Hospital Outpatient Department

Therapeutic services provided by hospitals on an outpatient basis and furnished as an integral part of a physician's professional service in the treatment of an illness are a covered Medicare benefit under Section 1861(s)(2)(B) of the Social Security Act. Regulatory guidance pertinent to physician supervision of these services is provided under Section 410.27 of the Code of Federal Regulations, Title 42.

Direct supervision is required for radiation therapy services provided in the hospital outpatient department. In general and per Medicare regulations, either a physician or a non-physician practitioner may directly supervise hospital outpatient therapeutic services.¹ However, the supervising physician or non-physician practitioner must have within his or her State scope of practice and hospital-granted privileges the ability to perform the service or procedure that he or she supervises.² As it specifically pertains to radiation therapy services, many states (as well as hospital privilege guidelines) are likely to limit a non-physician practitioner's scope of practice such that he

¹ 42 CFR §410.27(a)(1)(iv)(A)

² Medicare Benefit Policy Manual, Chapter 6, Section 20.5.2

or she would not be able to serve as a supervisor. Therefore, the remainder of this section references only the physician as the supervisor of outpatient radiation therapy services.

Direct supervision means that the physician must be immediately available, meaning physically present, interruptible and able to furnish assistance and direction throughout the performance of the procedure. The physician is not required to be present in the room during the procedure or within any other physical boundary as long as he or she is immediately available.

CMS has not defined "immediate" in terms of time or distance; however, examples of a lack of immediate availability include when a physician is performing another procedure or service that cannot be interrupted, or when a physician is so physically distant on-campus from where the services are being furnished that he or she could not intervene in a timely manner. The hospital or supervising physician must judge the physician's relative location to ensure that he or she is immediately available.

The supervising physician must also have the clinical expertise to supervise the service or procedure. More specifically, CMS guidance states that the physician must be available to furnish assistance and direction throughout the performance of the procedure. This means that the supervisor must be prepared to take over the performance of the procedure or provide additional orders, not just respond to an emergency. While CMS acknowledges that specially trained technicians are the primary operators of some specialized therapeutic equipment and does not expect the supervising provider to operate such equipment, CMS does expect the supervising provider to be knowledgeable about the therapeutic service and clinically appropriate to furnish the service. The supervisor does not necessarily need to be of the same specialty as the professional who is performing the service or from the same department as the ordering physician. However, the supervisory physician must have within his or her State scope of practice and hospital-granted privileges, the ability to perform the service or procedure.

Advanced practice providers (nurse practitioners and physicians assistants) and other non-physician members of the radiation oncology treatment team can play an important role in the ongoing management of patients receiving radiation therapy. These individuals can assist the radiation oncologist in the recognition and documentation of treatment-related symptoms and advise or prescribe interventions to mitigate acute or chronic treatment-related toxicity. However, the weekly management of patients receiving radiation therapy, which involves all technical and medical aspects of managing the patient through a treatment course, is always conducted under the direct supervision of a radiation oncologist, who must continue to independently document her or his involvement in the process. The work described by CPT codes 77427, 77431, 77432, 77435 and 77469 is provided personally by the radiation oncologist, who is ultimately responsible for the entirety of patient care.

In summary, the supervising physician 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 or provide additional orders. The supervisory responsibility is more than the capacity to respond to an emergency. It is ASTRO's opinion that a board-certified/board-eligible Radiation Oncologist is the clinically appropriate physician to supervise radiation treatments.

Billing of Appropriately Supervised Radiation Therapy Services in the Hospital Outpatient Department

Although this document primarily addresses CMS’s physician supervision requirements of radiation oncology services and procedures, this section additionally addresses common billing matters as they relate to the supervision of radiation therapy delivery in the hospital outpatient setting. Requirements of immediate availability and of a clinically appropriate supervising provider must be met to support billing of outpatient therapeutic services. For example, if radiation therapy services are provided in a hospital outpatient department and the supervising radiation oncologist leaves the hospital campus, a clinically appropriate physician needs to be immediately available to supervise subsequent radiation therapy delivery services performed in the department. If there is no clinically appropriate supervising provider immediately available, then radiation therapy delivery services cannot be covered by Medicare.

Critical Access Hospital and Small Rural Hospital Exception

CMS has not enforced its supervision requirements for outpatient therapeutic services among critical access hospitals (CAH) and small rural hospitals (with 100 or fewer beds) since 2010³. CMS considers hospitals to be rural if they are either geographically located in a rural area or are paid through the OPPS with a wage index for rural areas.⁴ In 2014, 2015, 2016, and 2017, Congress passed legislation preventing CMS from enforcing direct physician supervision requirements for CAH and small rural hospitals.⁵ Per the 2018 Hospital Outpatient Prospective Payment Program final rule, CMS has again extended the nonenforcement policy effective January 1, 2018 through December 31, 2019. According to CMS, this non-enforcement period is designed to allow CAHs and small rural hospitals more time to comply with the supervision requirements for outpatient therapeutic services.

2. Physician Supervision of Radiation Therapy Services in a Freestanding Radiation Therapy Center

Radiation therapy services furnished in a freestanding radiation therapy center are covered under a separate benefit category from therapeutic services provided in a hospital outpatient department. Freestanding center radiation therapy services are specifically covered under Section 1861(s)(4) of the Social Security Act. Further guidance pertinent to physician supervision of these services is provided in Chapter 15, Section 90 of the Medicare Benefit Policy Manual.

Direct personal supervision by a physician is required for radiation therapy services provided in the freestanding setting.⁶ Although the Code of Federal Regulations does not define “direct personal supervision”, the Medicare Benefit Policy Manual does provide a description that is similar to the definition of “direct supervision” under the CFR. Per the Manual, the physician does not need to be in the same room where the therapeutic service is performed, but must be in the area and

³ Medicare Physician Fee Schedule, 2010-2013

⁴ Medicare Claims Processing Manual, Chapter 4, Section 70

⁵ 21st Century Cures Act, Section 51007

⁶ Medicare Benefit Policy Manual, Chapter 15, Section 90

immediately available to provide assistance and direction throughout the performance of the procedure.

Regarding clinical qualifications for the supervising provider of freestanding radiation therapy services, CMS only indicates that direct personal supervision by a physician is required. A "physician" is defined by the Social Security Act as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function.⁷ Therefore, non-physician practitioners are not eligible to supervise radiation therapy services in the office setting. While CMS does not explicitly state that a radiation oncologist must supervise radiation therapy, it is ASTRO's opinion that a board-certified/board-eligible Radiation Oncologist is the clinically appropriate physician to supervise radiation treatments.

Billing of Appropriately Supervised Radiation Therapy Services in the Freestanding Radiation Therapy Center

Although this document primarily addresses CMS's physician supervision requirements of radiation oncology services and procedures, this section additionally addresses common billing matters as they relate to the supervision of radiation therapy delivery in the freestanding setting.

The immediate availability by the supervising physician is one of the requirements that must be met to support billing for therapeutic services in the freestanding setting. For example, if the supervising physician leaves the office and no other supervising physician is available, then any radiation therapy delivery services provided during the physician's absence cannot be covered by Medicare.

3. Diagnostic X-ray Tests (i.e., Image Guidance Services) in a Hospital Outpatient Department and Freestanding Radiation Therapy Center

Diagnostic x-ray tests provided by hospital outpatient departments and freestanding radiation therapy centers to assist in the accurate placement of radiation fields (i.e., image guidance services) are a covered Medicare benefit under Section 1861(s)(3) of the Social Security Act. Regulatory guidance pertinent to physician supervision of these services is provided under Sections 410.28(e)(1), 410.32(b)(1) and 410.32(b)(3) of the Code of Federal Regulations, Title 42.

Section 410.32(b)(1) of the Code of Federal Regulations, Title 42 establishes that diagnostic x-ray tests may only be furnished under the supervision of a physician. Services furnished without the required level of physician supervision are not covered under Medicare.⁸

Section 410.32(b)(3) of the Code of Federal Regulations, Title 42 defines three different levels of physician supervision required for the various diagnostic imaging tests used in image-guided radiation therapy (IGRT). The IGRT codes assigned to a given level are provided in parentheses.

⁷ Social Security Act, Section 1861(r)

⁸ Medicare Benefit Policy Manual Chapter 15, Section 80 states that diagnostic tests covered under §1861(s)(3) of the Social Security Act and payable under the physician fee schedule have to be performed under the supervision of an individual meeting the definition of a physician (§1861(r) of the Act) to be considered reasonable and necessary and, therefore, covered under Medicare.

Medicare's Physician Supervision Requirements
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- **General Supervision:** The procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. (76950 or G6001⁹ - *Ultrasonic guidance for placement of radiation therapy fields* and 77417 - *Therapeutic radiology port film(s)*)
- **Direct Supervision:** The physician must be present and immediately available to furnish assistance and direction throughout the performance of the procedure. The physician does not need to be present in the room when the procedure is performed. (77014 - *Computed tomography guidance for placement of radiation therapy fields* and 77421 or G6002¹⁰ - *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy*¹¹)
- **Personal Supervision:** The physician must be in attendance in the room during the performance of the procedure. (76965 - *Ultrasonic guidance for interstitial radioelement application*).

Nearly 1000 diagnostic tests as defined by CPT® or HCPCS codes are subject to these supervision requirements. The Medicare Physician Fee Schedule Relative Value Unit (MPFS RVU) File provides physician supervision level indicators for each such code. The MPFS RVU File is updated quarterly and is available on the CMS Web site at: <http://www.cms.gov/PhysicianFeeSched/>.

Application in a Hospital Outpatient Department

All hospital outpatient diagnostic tests performed in conjunction with radiation therapy must follow the physician supervision requirements for the individual tests as indicated above. Additionally, diagnostic tests must be supervised by a physician and may not be supervised by non-physician practitioners.¹² The supervisory physician must have within his or her State scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service.

The vast majority of image guidance services in radiation therapy involve stereoscopic x-ray or computed tomography guidance and are therefore subject to the direct supervision requirement as described previously. Direct supervision of outpatient diagnostic tests requires that the supervising physician must be physically present on campus and immediately available, interruptible and able to furnish assistance and direction throughout the performance of the procedure.

Application in a Freestanding Radiation Therapy Center

All diagnostic tests furnished in the freestanding setting must follow the physician supervision requirements for the individual tests as indicated above. Direct supervision of diagnostic x-ray tests in the freestanding center requires a physician be physically present in the office suite and

⁹ Medicare deleted CPT 76950 in 2015 and replaced it with G6001

¹⁰ Medicare deleted CPT 77421 in 2015 and replaced it with G6002

¹¹ The level of supervision for 77421 was changed from personal to direct, effective for services on or after January 1, 2009 in the July Update to the 2009 Medicare Physician Fee Schedule Database (Transmittal 1748, Change Request 6484, May 29, 2009)

¹² Medicare Benefit Policy Manual Chapter 6, Section 20.4.4

immediately available to furnish assistance and direction.¹³ Non-physician practitioners cannot function as supervisors of diagnostic x-ray tests performed in conjunction with radiation therapy.

4. Physician Supervision of “Incident To” Services in an Hospital Outpatient Department and Freestanding Radiation Therapy Center

Services and supplies furnished by auxiliary personnel in the care of a patient and “Incident To” a physician’s professional services are a covered Medicare benefit under Section 1861(s)(2)(A) of the Social Security Act. Regulatory guidance pertinent to physician supervision of “Incident To” services is provided under Section 410.26 of the Code of Federal Regulations, Title 42.

As a point of clarification, Medicare also applies the term “Incident To” as it relates to therapeutic services rendered to hospital outpatients, which are covered under a separate benefit category – Section 1861(s)(2)(B) of the Social Security Act – and are therefore subject to separately defined regulations and described previously in Section 1 of this document. Furthermore, hospital “Incident To” benefits are paid under the OPPS. In this section, “Incident To” refers to those benefits covered under Section 1861(s)(2)(A) of the Act and paid under the PFS. Examples of this type of “Incident To” benefit include providing non-self-administrable drugs, taking vital signs, changing dressings and follow-up visits of established patients.

To qualify as an “Incident To” service, a service must be part of the patient’s normal course of treatment, during which a physician personally performed an initial service (e.g., a consultation) and remains actively involved in the treatment course. Although the physician does not have to personally examine the patient every time other staff members provide services, the physician must perform services subsequent to the initial service of a frequency reflective of ongoing and active management. “Incident To” services must also meet all of the following requirements for coverage:

- Furnished in a non-institutional setting to non-institutional patients (i.e., services for either inpatients or outpatients in a Part A covered skilled nursing facility do not qualify as “Incident To”);
- Be an integral, though incidental, part of the service of a physician in the course of diagnosis or treatment of an injury or illness;
- Of a type commonly furnished in a physician’s office or department;
- Commonly rendered without charge or included in the physician’s bills; and
- Represent an expense to the physician and practice.

“Incident To” services by auxiliary personnel must be performed under the direct supervision of a physician – that is, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time other staff are providing services. Examples of auxiliary personnel in radiation oncology include nurses, technicians, nurse practitioners, clinical nurse specialists and physician assistants.

Within hospitals or provider-based facilities (i.e., off-campus practice sites owned by hospitals), qualified “Incident To” services must be furnished in a department or office that is confined to a

¹³ 42CFR §410.32(b)(3)(ii)

separately identifiable part of the facility and cannot be construed to extend throughout the entire facility.¹⁴

Billing of Appropriately Supervised “Incident To” Services

Although this document primarily addresses CMS’s physician supervision requirements of radiation oncology services and procedures, this section additionally addresses common billing matters as they relate to the supervision of “Incident To” services covered under Section 1861(s)(2)(A) of the Social Security Act.

In addition to physicians, other practitioners including nurse practitioners and physician assistants are allowed to bill “Incident To” under their NPI for specified services (under separate benefit categories) within their State scopes of practice and hospital-granted privileges. Those practitioners are then paid at their applicable Medicare payment rate if the “Incident To” service provided by auxiliary personnel were appropriately supervised. For example, physician claims for “Incident To” services are paid at 100 percent of the fee schedule amount, whereas similar claims submitted under a nurse practitioner’s NPI are paid at 85 percent of the fee schedule amount.

In the 2016 PFS Final Rule, CMS finalized its proposal to amend the “Incident To” regulations to state that only the physician or other practitioner who directly supervises auxiliary personnel who provide an “Incident To” services may bill Medicare for the service. CMS is not requiring the supervising practitioner be the same individual who orders the service or initiates treatment. Rather, CMS is requiring that under circumstances where the supervising practitioner is not the same as the ordering practitioner, only the supervising practitioner may bill Medicare for the “Incident To” service.

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If you have questions regarding this summary or any of the references to the Medicare laws and regulations, please contact the ASTRO Health Policy Department at 1-800-962-7876 or at healthpolicy@astro.org.

¹⁴ MLN Matters Number SE0441 (April 2013)