

## ASTRO Guidance on Supervision of Radiation Therapy Services

### Executive Summary of 2020 Changes

On Friday, November 1, 2019 the Centers for Medicare and Medicaid Services (CMS) issued the 2020 Hospital Outpatient Prospective Payment System final rule lowering the supervision level required for hospital-based therapeutic services, including radiation therapy services, from direct to general supervision. After carefully reviewing the rule and clarifying questions with the Agency, the ASTRO Board of Directors approved this updated guidance to help members understand that *the supervision changes are more limited than they appear*.

**Most notably, direct supervision is still required, and the new general supervision policy does NOT apply when:**

- **Radiation therapy is delivered in a freestanding center;**
- **The work of radiation treatment management is performed;**
- **Brachytherapy (CPT codes 77770-77772), stereotactic radiation therapy (CPT codes 77371-77373) and other services described by CPT codes requiring that the radiation oncologist personally provide the services are performed;**
- **Diagnostic services, such as image guidance, are performed; or**
- **A hospital determines that radiation therapy services require direct supervision.**

“Direct supervision” requires that the physician be immediately available to provide assistance throughout the duration of the procedure. “General supervision” means 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.

This ASTRO guidance helps explain that the new supervision policy, which does not apply to freestanding centers delivering radiation therapy, has a limited impact on hospital-based delivery of radiation therapy services, given the patient management requirements associated with a number of radiation oncology services. It will be important for all hospital-based practices to consider existing supervision requirements in the context of this new policy, in combination with requirements associated with the delivery of radiation therapy.

For instance, the work described by CPT codes 77427, 77431, 77432, 77435, and 77469, radiation treatment management, must be provided personally by the radiation oncologist, who is ultimately responsible for the entirety of patient care. Thus, 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. Additionally, direct supervision associated with the delivery of brachytherapy and stereotactic radiation therapy remains.

It should also be noted that the new supervision policy does not apply to diagnostic services such as image guidance. All hospital outpatient diagnostic tests performed in conjunction with

radiation therapy must follow the physician supervision requirements for the individual tests. ASTRO's supervision guidance specifies those requirements.

In the final rule, CMS states that hospital-based practices may adopt more stringent supervision policies. ASTRO urges members to carefully review supervision policies with hospital administrators and compliance officers. [APEX](#) Accreditation standards should be used as a guideline for radiation oncology supervision requirements. ASTRO's opinion is that a board-certified/board-eligible Radiation Oncologist is the clinically appropriate physician to supervise radiation treatments; however, this updated document recognizes that some flexibility is necessary for those practices that deliver care to underserved populations who may experience access to care issues.

### **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 settings. As a condition of Medicare payment, CMS obligates facilities and providers to satisfy supervision requirements. 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. Specific 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.

In the 2020 Hospital Outpatient Prospective Payment System final rule, CMS changed the existing regulatory language regarding the supervision of all hospital outpatient therapeutic services from a combination of “direct” and “general” supervision requirements, depending on the services provided to Medicare beneficiaries, to a blanket “general” supervision policy covering all hospital outpatient therapeutic services.<sup>1</sup> General supervision means 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. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.<sup>2</sup> This change in supervision policy covering hospital outpatient therapeutic services is effective January 1, 2020 and only applies to hospital outpatient therapeutic services.

Supervision requirements associated with diagnostic services, including image guidance, remain unchanged and are covered in section 3 of this document. Additionally, direct supervision associated with the delivery of brachytherapy and stereotactic radiation therapy remain in place and should continue to be followed by practices in hospital outpatient settings. Direct supervision requires that the physician be immediately available to provide assistance throughout the duration of the procedure.

The modification to the supervision policy for hospital outpatient therapeutic services permits the adoption of more stringent supervision policies for particular treatments. Hospitals are subject to specific conditions that complement the general supervision requirement for hospital outpatient therapeutic services to ensure that the medical services Medicare patients receive are properly supervised. These conditions include that the hospital have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to its patients.<sup>3</sup>

Due to the irreversible nature of radiation therapy, to protect patients and to ensure the continued delivery of safe and high-quality radiation therapy services, ASTRO urges practices in hospital outpatient settings to work with hospital administrators and compliance staff to retain appropriate direct supervision requirements for 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.

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<sup>1</sup> 42 CFR §410.27(a)(1)(iv)(A)

<sup>2</sup> 42 CFR §410.32 (b)(3)(i)

<sup>3</sup> 42 CFR §482.22

Existing APEx Accreditation Standards can serve as a guide for hospital supervision requirements.<sup>4</sup> As described below, these standards define staff roles and responsibilities, including supervision requirements associated with the delivery of specific modalities of treatment:

*Standard 6: Safe Staffing Plan*

*The radiation oncology practice (ROP) establishes, measures and maintains staffing requirements for safe operations in clinical radiation therapy.*

*6.1 - Staffing levels and requirements:*

*6.1.1 - The ROP has documentation of staffing requirements for each professional discipline that is derived from measurable criteria.*

*6.1.2 - The documentation specifies the number of each professional discipline required to be on-site, directly involved in patient care or available remotely during operating and non-operating hours.*

*6.1.3 - Coverage requirements include a qualified RO to be on-call 24 hours a day and seven days a week to address patient needs and/or emergency treatments.*

*6.1.4 - There is a documented plan for coverage during planned and unplanned absences of professional staff.*

*Safety is No Accident* provides additional guidance regarding certification requirements that ensure radiation oncologists, physicists and other members of the radiation oncology team are adequately trained and educated on the complexities of radiation treatment delivery.<sup>5</sup> It also provides guidance on continuing education and maintenance of certification requirements that must be adhered to ensure continued delivery of high-quality care.

Finally, it is important for hospital based practices to understand that 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.<sup>6</sup> 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 or she would not be able to serve as a supervisor.

### The Role of Advanced Practice Providers

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.

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<sup>4</sup> "APEx Program Standards" American Society for Radiation Oncology, 2019.

<sup>5</sup> "Safety is No Accident" American Society for Radiation Oncology, 2019

<sup>6</sup> Medicare Benefit Policy Manual, Chapter 6, Section 20.5.2

If State scope of practice requirements do not prevent advance practice providers from supervising the delivery of radiation therapy services, then it is up to the discretion of the hospital to determine appropriate supervisory requirements based on the general supervision requirement. However, the work described by CPT codes 77427, 77431, 77432, 77435 and 77469 must be provided personally by the radiation oncologist, who is ultimately responsible for the entirety of patient care. Thus, 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 supervision of a radiation oncologist, who must continue to independently document her or his involvement in the process.

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. While it is ASTRO's opinion that a board-certified/board-eligible Radiation Oncologist is the clinically appropriate physician to supervise radiation treatments, we recognize that some flexibility is necessary for those practices that deliver care to underserved populations who may experience access to care issues.

### ***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 general supervision must be met to support billing of outpatient therapeutic services. Effective January 1, 2020, under the new general supervision policy, the physician's presence is no longer required to bill for radiation therapy delivery services provided in a hospital outpatient department. **Also, please note that CMS has established separate supervision and billing requirements for image guidance services as discussed in the following section, Diagnostic X-ray Tests (i.e., Image Guidance Services) in a Hospital Outpatient Department and Freestanding Radiation Therapy Center.**

## **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.<sup>7</sup> 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 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.<sup>8</sup> 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; however, we recognize that some flexibility is necessary for those practices that deliver care to underserved populations who may experience access to care issues.*

### ***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 becomes unavailable to directly supervise the services, and no other supervising physician is available, then any radiation therapy delivery services provided during the physician’s absence cannot be covered by Medicare. **Also, please note that CMS has established separate supervision and billing requirements for image guidance services as discussed in the following section, Diagnostic X-ray Tests (i.e., Image Guidance Services) in a Hospital Outpatient Department and Freestanding Radiation Therapy Center.**

### **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

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<sup>7</sup> Medicare Benefit Policy Manual, Chapter 15, Section 90

<sup>8</sup> Social Security Act, Section 1861(r)

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.<sup>9</sup>

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.

- **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 G6001<sup>10</sup> - *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 G6002<sup>11</sup> - *Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy*<sup>12</sup>)
- **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***

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<sup>9</sup> 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.

<sup>10</sup> Medicare deleted CPT 76950 in 2015 and replaced it with G6001

<sup>11</sup> Medicare deleted CPT 77421 in 2015 and replaced it with G6002

<sup>12</sup> 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)

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.<sup>13</sup> 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 immediately available to furnish assistance and direction.<sup>14</sup> 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 a 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 OPFS. 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.

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<sup>13</sup> Medicare Benefit Policy Manual Chapter 6, Section 20.4.4

<sup>14</sup> 42CFR §410.32(b)(3)(ii)

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 separately identifiable part of the facility and cannot be construed to extend throughout the entire facility.<sup>15</sup>

### ***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.

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<sup>15</sup> MLN Matters Number SE0441 (April 2013)

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 to 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](mailto:healthpolicy@astro.org).***