ASTRO Supervision FAQ

Who sets supervision requirements?

The Centers for Medicare and Medicaid Services (CMS) sets Medicare physician supervision requirements that apply to all covered services, including radiation therapy, furnished in hospital outpatient and physician office settings. As a condition of Medicare participation, CMS obligates facilities and providers to satisfy certain 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. Additionally, several Medicare Administrative Contractor Local Coverage Determinations include supervision requirements specific to radiation oncology services.

What are the different types of supervision?

- 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.
- 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.
- Personal Supervision: The physician must be in attendance in the room during the performance of the procedure.
- Virtual Direct Supervision: CMS temporarily modified the definition of direct supervision to include "virtual presence" of the supervising clinician through the use of real-time audio and video technology.

What was the supervision policy prior to the COVID 19 Public Health Emergency (PHE)?

<u>Freestanding Supervision Policy</u>
Medicare policy required adherence to "direct supervision" for radiation oncology services paid under the Physician Fee Schedule. "Direct supervision" requires that the physician be "immediately available" to provide assistance throughout the duration of the procedure.

<u>Hospital Supervision Policy</u>
In 2020 CMS established a "general supervision" policy applicable to all hospital therapeutic services. 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.

Prior to 2020, CMS required direct supervision of radiation oncology services in the hospital setting. CMS said the decision to change the policy was made to establish a uniform system among hospitals. While direct supervision was required for most hospital therapeutic services, a "non-enforcement" policy, established in 2010, allowed for general supervision of services at critical access hospitals (CAHs) and at hospitals with 100 or fewer beds. When CMS modified the hospital supervision policy in 2020, the Agency stated that "providers have the flexibility to establish what they believe is the appropriate level

of physician supervision for these procedures, which may be higher than the requirements for general supervision."

More information about pre-COVID 19 PHE supervision requirements can be found in ASTRO's supervision guidance document.

How did supervision policy change due to COVID?

During the COVID 19 Public Health Emergency (PHE), CMS modified Medicare's direct supervision policy in the freestanding setting to allow for the use of real-time audio-visual virtual technology (virtual supervision) to support a physician's ability to continue treating patients, while at the same time mitigating COVID transmission risk.

This policy also applied to the OTV portion of CPT code 77427 *Radiation Treatment Management* through inclusion of the code on the temporary tele-health list. In the 2021 Medicare Physician Fee Schedule (MPFS)the Agency noted its intent to remove 77427 from the telehealth list. ASTRO supports the removal of 77427 from the telehealth list, and the Agency is expected to make a final determination in rulemaking this summer.

Why did ASTRO submit this letter to CMS in February?

In the 2024 MPFS, CMS extended the use of virtual direct supervision through the end of 2024. The Agency expressed concern about the work involved and potential confusion associated with reinstituting previous direct supervision policies. Additionally, CMS stated that it would consider permanent use of virtual supervision in future rulemaking given that, to-date, there has been no evidence of patient harm associated with the use of the technology and sought feedback on that proposal.

ASTRO agreed with extending the use of virtual direct supervision through the end of 2024 but asked for more consideration before permanently extending virtual direct supervision. Given the role that direct supervision plays in the delivery and valuation of radiation therapy services, particularly in the freestanding setting, ASTRO submitted the letter in February to provide the Agency with guidance to inform the 2025 proposed rule.

What are the Implications of tele-radiation oncology?

The net result of such a shift in supervision requirements would allow for the proliferation of tele-radiation oncology, in which no on-site radiation oncologist is required for the entire process of care, from consultation to simulation to treatment planning to treatment delivery to weekly management. A patient could receive their entire treatment course in Florida while their treating radiation oncologist was in another part of the state, or anywhere else in the United States.

ASTRO appreciates the role of tele-health and supports its use for routine evaluation and management codes, particularly follow up visits. ASTRO believes that the optimal RT course is delivered with an on-site radiation oncologist and that the radiation oncologist should be available in person, except in situations where this is not possible, due to other clinical demands or in remote areas, where ASTRO supports flexibility on direct supervision requirements. ASTRO believes that patients deserve to see a radiation oncologist, face-to-face, and at a minimum of one time per week for weekly management.

How does supervision impact payment?

CMS values services based on the time and intensity associated with the cognitive clinical work required for the service involved, as well as the complexity of the care delivered. Many radiation therapy services specifically include physician presence in the CPT code descriptor and are valued accordingly. Changes in physician presence can impact valuation, therefore a shift to virtual supervision is likely to result in reduced reimbursement to radiation oncologists for services.

What about rural areas?

There are a variety of different ways to define rural areas, and ASTRO believes the use of Rural Urban Continuum Codes (RUUC) is the best approach to defining and identifying radiation therapy centers in rural areas. Based on an ASTRO 2019 analysis, depending on which specific RUCC codes are used to define rural, as many as 13% of radiation therapy facilities may be located in rural (non-metro) counties, which cover about 15% of the US population.

ASTRO believes that when possible, direct supervision is the best approach regardless of setting. However, we recognize that providing access to radiation therapy services in rural areas requires greater flexibility, and therefore believe that if regular on-site presence by a trained radiation oncologist is not possible, non-enforcement of direct supervision by CMS should be allowed in these areas for treatment delivery. Certain professional codes, including 77427, should be furnished by an on-site radiation oncologist, face to face with the patient.

What about patient care responsibilities?

The definition of "immediately available and interruptible" has never been clearly defined. A radiation oncologist should be available to patients and RT staff in a timely manner. However, a specific distance and/or time measure has not been uniformly applied.

ASTRO believes there are critical aspects of cancer care for which non-enforcement of direct supervision is appropriate. Examples include, but are not limited to, radiation oncologist's engagement in tumor boards, operative procedures or in-patient consultations. With proper planning, we believe that these activities can occur with minimal to no disruption of patient treatments.

What about personal situations?

CMS realizes that emergencies happen warranting flexibility in how supervision policies are applied. This is one of the reasons the definition of direct supervision does not specifically define or provide parameters around the meaning of "immediately available and interruptible." This allows practices to formulate their own polices for meeting supervision requirements, including policies that recognize that supervision requirements may occasionally not be met due to unforeseen circumstances. The Agency's enforcement of supervision has been focused on cases where there was failure to meet supervision requirements, which resulted in routine/flagrant abuse and in some instances patient harm, rather than enforcement of strict policies that dictate when and where the physician should be at all times.

Is there data showing that the virtual supervision during the pandemic resulted in greater incidents as compared to pre-pandemic?

We do not have specific data since 2020 on changes in RT events due to virtual supervision. Despite the allowance for virtual supervison during the PHE to mitigate the spread of COVID-19, most clinics in the

country were well-equipped to provide direct on-site supervision. ASTRO believes that this is a critical part of ensuring patient safety and one of the main rationales for our position.

What programs does ASTRO offer to promote high-quality, safe care?

Significant RT events are often anecdotal but are well documented. For historical context, significant RT events led to a series of New York Times articles in 2010, which in turn led to a Congressional hearing on RT safety. A result of this was an increased commitment to safety across the field of radiation oncology. ASTRO created an accreditation program (APEX) and an incident reporting system (RO-ILS). Supervision requirements were also addressed through best practice white papers. The net result of all of this has been a prolonged period of safety in the field of radiation therapy.

Note: This summary is intended to assist physicians in understanding the ASTRO policy position and is not intended to advise regarding legal requirements.