Supervision of Radiation Therapy
A White Paper Provided by Coding Strategies Inc.

Radiation therapy uses high-energy radiation to shrink tumors and kill cancer cells. Radiation oncology, often in conjunction with medical and surgical oncology, is one of the primary treatments for cancer. Radiation is currently used to treat approximately 60 percent of all patients diagnosed with a malignancy. This treatment modality is also used for certain non-malignant and non-neoplastic conditions as either a primary or adjunctive therapy. While an effective and widely used therapy, the use of radiation presents obvious patient safety concerns. These concerns have prompted the Centers for Medicare & Medicaid Services (CMS) to periodically revise federal rules governing the supervision of radiation therapy, most significantly in the 2010 and 2011 Hospital Outpatient PPS Final Rules.

Since the revised rules were published, physician supervision of therapeutic services, such as radiation oncology, has been a focus of intense discussion and the subject of several enforcement actions by the federal government. This paper provides an overview of physician supervision requirements for radiation treatment services performed in freestanding (non-hospital-based) centers and hospital outpatient departments (on-campus or off-campus). In particular, this paper describes the proximity requirements for supervising physicians in various clinical settings, the qualifications of supervising practitioner, the best practices for documenting supervision, and the guidance of a leading professional association in radiation oncology.
ASTRO GUIDANCE ON PHYSICIAN SUPERVISION

Appropriate supervision of radiation therapy is a significant issue to both the practitioners who provide therapeutic services, such as radiation oncologists, medical physicists, radiation therapists, radiation oncology nurses, nurse practitioners and other practitioners involved in the delivery of radiation treatment services, and the facility where the services are furnished. According to the American Society for Radiation Oncology (ASTRO):

ASTRO strongly encourages all radiation oncologists to work closely with their compliance officers and/or hospital administrators to ensure compliance with all Medicare supervision requirements.1

While the Medicare rules governing supervision do not specifically require that radiation treatment be supervised by a radiation oncologist, ASTRO and other leading experts suggest that the radiation oncologist is best suited for this role. The ACR-ASTRO Practice Parameter for Radiation Oncology includes the following excerpts: 2

Radiation oncologists are specifically trained to weigh the benefits with the potential risks associated with exposure to ionizing radiation…. A radiation oncologist should be available for direct care and quality review and should be on the premises whenever radiation treatments are being delivered…A radiation oncologist’s availability must be consistent with state and federal requirements.

ASTRO’s Target Safety initiative is focused on providing increased education and awareness of quality assurance and safety issues for the radiation treatment delivery team. Through collaborative discussion and multidisciplinary writing groups, the document, Safety is No Accident, was developed. This book states, in part:3

The safe delivery of radiation therapy was never a simple matter and is now exceedingly complex.

The ASTRO position on supervision requirements adds:

It is ASTRO’s opinion that a Radiation Oncologist is the most clinically appropriate physician to supervise radiation oncology treatments.

ASTRO also authors a document titled “The Role of the Radiation Oncologist in the Process of Care for Patients Undergoing Radiation Therapy” that includes guidelines for the participation of the radiation oncologist during the course of therapy. Excerpts from this document include: 4

Since the emergence of radiation oncology as a distinct specialty and the establishment of ASTRO in 1958, physicians entering the field have been required to undergo a rigorous training program focusing on clinical

4 https://www.astro.org/uploadedFiles/Content/Practice_Management/Role%20of%20the%20Radiation%20Oncologist.pdf

“According to Safety is No Accident, the safe delivery of radiation therapy was never a simple matter and is now exceedingly complex.”

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2 http://www.acr.org/~/media/7B19A9CEF68F4D6DBF0CF25F21155D73.pdf

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radiation oncology as well as the natural history of cancer, radiobiology, medical physics and radiation safety that currently extends over a four-year period following internship. The therapeutic tools employed by the modern radiation oncologist have become significantly more sophisticated with the advent of 3D CRT (three-dimensional conformal radiation therapy), SRS (stereotactic radiation therapy), SBRT (stereotactic body radiation therapy), IORT (intra-operative radiation therapy), HDR (high dose rate) brachytherapy, and proton therapy over the past decade, in addition to the increasing use of chemoradiation therapy regimens and hypofractionation. Such progress, however, comes with an attendant increased risk of significant morbidity for the patient and considerably more physician work. Skillful use of these new tools requires a much deeper understanding of diagnostic imaging and cross-sectional anatomy as well as normal tissue tolerance. This expanding fund of knowledge is necessary for the modern radiation oncologist to safely prescribe a course of radiotherapy and to manage its effects throughout the continuum of treatment and ongoing follow-up.

The scope of knowledge required to provide appropriate medical evaluation, interpretation of complex imaging and laboratory testing, and the decision-making and requisite medical management skills are acquired over years of medical training. A four-year residency period is a minimal requirement to fully understand and appreciate the protean biology of a wide variety of cancers, as well as the radiobiology, radiation physics, and imaging that are necessary to obtain successful therapeutic outcomes while minimizing the associated treatment toxicities. Certification by the American Board of Radiology confirms the acquisition of these skills.

The day-to-day clinical management of the patient is an interactive and cognitive process that requires the expertise of the radiation oncologist.

In a technically complicated specialty such as radiation oncology, it is imperative that the radiation oncologist has the skills necessary to oversee the evaluation, treatment and management of the patient to ensure a safe and error-free environment.
FREESTANDING CENTERS

A freestanding center is a non-hospital-based entity, such as a physician office or other facility that is not classified as a hospital outpatient department. These locations bill professional and technical services on a CMS1500 claim form (globally or separately) and Medicare refers to them as nonprovider-based facilities.

Radiation oncology providers should not be confused by the supervision level indicators included in the Medicare Physician Fee Schedule (MPFS) Relative Value File; these are updated quarterly and apply only to diagnostic tests, not to therapeutic services. CMS provides very specific guidance on radiation therapy supervision performed in a freestanding center in the Medicare Benefit Policy Manual, Chapter 15, Section 90:

90 - X-Ray, Radium, and Radioactive Isotope Therapy (Rev. 1, 10-01-03) B3-2075

These services also include materials and services of technicians. X-ray, radium, and radioactive isotope therapy furnished in a nonprovider facility require direct personal supervision of a physician. The physician need not be in the same room, but must be in the area and immediately available to provide assistance and direction throughout the time the procedure is being performed.

Based on this Manual guidance, it would only be acceptable for radiation therapy services performed for Medicare patients to be supervised by a physician. While the verbiage “direct personal” supervision may sound confusing, CMS is referring to direct supervision since the provider is not required to be in the same room (the definition of personal supervision). The definition of “direct supervision” is located in Section 410.32 of the Code of Federal Regulations:

ii) Direct supervision in the office setting means the physician must be present in the office suite and 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.

CMS further defines “furnish assistance and direction” to mean that the supervisory physician or nonphysician practitioner who is physically present must have the training and knowledge to clinically redirect the service or provide additional orders.

This means that Medicare would not consider a physician who can only observe the services performed in the freestanding center or respond to a patient emergency to be a qualified supervisor; it is essential that the supervising physician be able to redirect care by writing additional orders, changing the course of treatment or otherwise treat the patient. For example, if a physician supervising treatment tells the patient to go home and come back the next day when the radiation oncologist is available, this may not meet the Medicare definition of direct supervision.

The 2016 Medicare Physician Fee Schedule Final Rule reiterated the following information regarding the name of the billing provider:

The proposed policy was not intended to require that the supervising physician or other practitioner must be the same individual as the physician or other practitioner who orders or refers the beneficiary for the services, or who initiates treatment. Rather, we intended to clarify that under circumstances where the supervising practitioner is not the same as the referring, ordering, or treating practitioner, only the supervising practitioner may bill Medicare for the incident to service delivered.

This means that services such as treatment delivery are billed in the name of the physician who supervised the treatment on a daily basis. For example, if Dr. A supervises all treatment delivery in a freestanding center on Monday, all of Monday’s treatments are billed in the name and NPI number of Dr. A, even if he is not the attending physician for all the patients treated. This is not to be confused with services that are personally performed. For example, if Dr. A is in the freestanding center supervising the performance of IGRT, but Dr. B signs, dates and times the images prior to the patient’s next treatment, Dr. B bills for the IGRT service he personally performed.

6 https://www.law.cornell.edu/cfr/text/42/410.32
Hospitals provide two primary types of outpatient services: diagnostic services and therapeutic procedures. Radiation treatment services are therapeutic services that must be furnished under the applicable level of physician or nonphysician practitioner supervision. According to CMS:  

Hospital outpatient therapeutic services and supplies must be furnished under the order of a physician or other practitioner practicing within the extent of the [Social Security] 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.

The 2011 OPPS Final Rule states:  

The definition of direct supervision will be revised simply to require immediate availability, meaning physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure but without reference to any particular physical boundary. Since the new definition will now apply equally in the hospital or in on-campus or off-campus PBDs (Provider-Based Departments), we are removing paragraphs (a)(1)(iv)(A) and (B) of § 410.27 altogether. The new definition of direct supervision under § 410.27(a)(1)(iv) will now state, “For services furnished in the hospital or CAH (Critical Access Hospital) or in an outpatient department of the hospital or CAH, both on- and off-campus, as defined in section 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.

CMS initially proposed that the supervising physician be physically in the department or on the campus. During the rulemaking process, this proposal was scrapped in favor of a simple requirement that the physician be “immediately available.”

In addition, the supervising physician or nonphysician practitioner must also be a person who is clinically appropriate to supervise the services or procedures. Last, the supervisory physician or nonphysician practitioner must have within his or her State scope of practice and hospital-granted privileged the ability to perform the service or procedure. This 2011 OPPS Final Rule includes the following information that relates specifically to radiation oncology:  

Comment: During the past year, we were often questioned about clinical requirements for practitioners supervising extremely specialized services, notably radiation oncology services. One commenter requested that CMS consider the direct supervision requirement to be met for diagnostic or therapeutic radiation oncology services if a non-specialist practitioner who can handle an emergency provides the direct supervision and also has access by phone or other telemedicine link to a specialist who is able to change the plan of care should the need arise. One commenter asserted that one does not have to possess the clinical skills to fully provide a service in order to be an effective supervisor.

Response: As we have stated in the Medicare Benefit Policy Manual (Pub. No. 100-02), Chapter 6, Section 20.5.24, “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 diagnostic or therapeutic equipment, and while in such cases CMS does not expect the supervisory practitioner to operate the equipment instead of a technician, CMS does expect the physician or nonphysician practitioner that supervises the provision of the service must be knowledgeable about the test and clinically appropriate to furnish the test. The supervisory responsibility is more than the capacity to respond to an emergency, and includes furnishing assistance and direction throughout the performance of a procedure and, as appropriate to the supervisory physician or nonphysician practitioner and the patient, to change a procedure or the course of care for a

10 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS1240960.html

OUTPATIENT HOSPITAL SERVICES
particular patient. CMS would not expect that the supervisory practitioner would make all decisions unilaterally without informing or consulting the patient’s treating physician or nonphysician practitioner.” We do not believe it is sufficient or consistent with our rules for direct supervision for the individual on site to be capable of only emergency management. The supervisory physician or nonphysician practitioner who is physically present should have the training and knowledge to clinically redirect the service or provide additional orders.

The Medicare Benefit Policy Manual, Chapter 6 adds:¹¹

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.

In summary, the supervisory physician or nonphysician practitioner must be clinically able to supervise the service or procedure.

Nurses or other nonphysician health care practitioners sometimes participate in the care of patients receiving radiation therapy, typically by providing assistance in the management of some of the minor side effects patients may experience during treatment.

These efforts, however, do not constitute comprehensive weekly management. Examination of the patient by the physician is necessary to assess the patient's response to treatment on an ongoing and regular basis throughout the course of therapy. The patient expects and deserves such face-to-face physician time, not only to manage the medical and technical aspects of their treatment, but also to receive the benefit of personal physician contact and emotional support as the patient and family deal with his or her life-threatening disease. Only a radiation oncologist is qualified to incorporate both the clinical and technical aspects of weekly management and, for that reason, each patient under treatment must have a face-to-face encounter with a radiation oncologist every week, even if there are one or more visits with a nonphysician practitioner.

In ASTRO's "The Role of the Radiation Oncologist in the Process of Care for Patients Undergoing Radiation Therapy" there are standard of practice guidelines for the participation of the radiation oncologist during the course of therapy. Excerpts from this document include:

It must be emphasized that the notion that weekly treatment management requires only evaluation and management of treatment related symptoms falls far short of the radiation oncologist's responsibility...The radiation oncologist must be able to understand and recognize the expected consequences of treatment and to appropriately manage the associated toxicities.

OTHER INSURERS

In general, most non-governmental insurers have a participation agreement or contract that includes a non-discrimination clause stating that the healthcare entity cannot treat their patients in a different manner from the way it treats other plan members. In addition, many insurers simply state that services must be performed “under the appropriate level of physician supervision.” As a result, the same level of supervision should be provided to all patients treated in the radiation oncology center or department.

SUPERVISION DOCUMENTATION

The burden of proof that all required supervision elements were met falls on the freestanding cancer center or hospital. Based on the results of past audits, investigations and settlements, proof will be required (refer to Table 1 for a list of recent settlements). There is no single method of capturing physician presence for the purposes of supervision and some facilities have employed sign in/sign out logs, swipe cards or other methods to support physician presence during all hours of operation.

Computer login information is typically not acceptable because physicians can often sign on remotely from locations other than the cancer center. In addition, a calendar is considered to be a schedule or plan rather a documented record of physician presence. The cancer center should work closely with compliance representatives to ensure that documentation of supervision is clear and defensible.

“ It is ASTRO’s opinion that a Radiation Oncologist is the most clinically appropriate physician to supervise radiation oncology treatments. ”

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In summary:

- CMS requires that a physician must be onsite, immediately available and able to provide assistance and direction in the freestanding center (non-hospital-based setting).
- For hospitals, CMS states that a clinically appropriate physician or non-physician practitioner supervisor must be immediately available, interruptible and able to furnish assistance and direction throughout the procedure.
- Delivery of radiation therapy services is exceedingly complex and requires oversight by a physician who has undergone rigorous training and certification.
- The leading specialty society has determined that a radiation oncologist is the most clinically appropriate physician to supervise radiation oncology treatments.

And, as quoted from Safety is No Accident, "The ultimate goal for radiation treatment is to achieve the best possible outcome for the patient."
### TABLE 1: INVESTIGATIONS AND SETTLEMENTS

<table>
<thead>
<tr>
<th>Settlement</th>
<th>Description</th>
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<tbody>
<tr>
<td><a href="http://www.justice.gov/opa/pr/florida-doctors-hospitals-and-clinics-pay-35-million-settle-allegations-improper-medicare">http://www.justice.gov/opa/pr/florida-doctors-hospitals-and-clinics-pay-35-million-settle-allegations-improper-medicare</a></td>
<td>These settlements included the following key statements:</td>
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<tr>
<td><a href="http://www.justice.gov/opa/pr/vantage-oncology-llc-pay-more-208-million-false-medicare-claims-radiation-oncology-services">http://www.justice.gov/opa/pr/vantage-oncology-llc-pay-more-208-million-false-medicare-claims-radiation-oncology-services</a></td>
<td>• The proper supervision of radiation therapy is a condition of payment for Medicare.</td>
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<tr>
<td><a href="http://www.justice.gov/opa/pr/adventist-health-system-pay-54-million-resolve-false-claims-act-allegations">http://www.justice.gov/opa/pr/adventist-health-system-pay-54-million-resolve-false-claims-act-allegations</a></td>
<td>• The government alleged that between 2007 and 2011, the defendants regularly billed for radiation oncology services that were not supervised by a physician as required by Medicare, Medicaid and TRICARE…</td>
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<td><a href="http://www.justice.gov/opa/pr/baylor-university-medical-center-pay-more-900000-false-medicare-claims-radiation-oncology">http://www.justice.gov/opa/pr/baylor-university-medical-center-pay-more-900000-false-medicare-claims-radiation-oncology</a></td>
<td>• …to settle allegations that they submitted or caused the submission of false claims to the Medicare and TRICARE programs for certain radiation oncology procedures that were allegedly performed without the requisite level of physician supervision.</td>
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<tr>
<td><a href="http://www.justice.gov/usao/sdga/pr/doctors-hospital-augusta-and-radiation-oncology-practice-pay-more-1-million-resolve">http://www.justice.gov/usao/sdga/pr/doctors-hospital-augusta-and-radiation-oncology-practice-pay-more-1-million-resolve</a></td>
<td>• “Medicare and TRICARE patients deserve high quality health care,” said U.S. Attorney A. Lee Bentley III of the Middle District of Florida. “We will not tolerate providers recklessly cutting corners, particularly when furnishing such critical medical services as radiation oncology.”</td>
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<tr>
<td><a href="https://www.fbi.gov/sanfrancisco/press-releases/2015/john-muir-health-agrees-to-pay-550-000-to-resolve-false-claims-allegations">https://www.fbi.gov/sanfrancisco/press-releases/2015/john-muir-health-agrees-to-pay-550-000-to-resolve-false-claims-allegations</a></td>
<td>• “Providing proper supervision of radiation oncology services is an important requirement in federal health care programs such as Medicare,” said Special Agent in Charge Derrick L. Jackson of the U.S. Department of Health and Human Services Office of Inspector General. “Our agency will continue to hold health care providers accountable for meeting the requirements in these taxpayer-funded programs.”</td>
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Thank you /

Coding Strategies thanks Paul Pitts, Esq. for his review and contributions to this White Paper. Paul is a Partner at Reed Smith and is a member of the Firm’s Life Sciences Health Industry Group. Paul can be contacted at PPitts@ReedSmith.com No consulting or legal advice is provided in this document; Coding Strategies recommends that providers review legal issues with their healthcare regulatory counsel.