



**AMERICAN SOCIETY
FOR RADIATION ONCOLOGY**

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February 26, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Administrator Brooks-LaSure,

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with input on the potential ramifications related to the continued use of direct supervision using real-time audio-visual technology or “virtual supervision.” We recognize that the virtual delivery of healthcare has increased exponentially because of the COVID 19 public health emergency (PHE). For many health care services, virtual supervision allows for the safe delivery of care that often increases access. However, for other more intensive procedures and services, in this case, the delivery of ionizing radiation for cancer treatment, use of virtual direct supervision jeopardizes patient safety and quality, with little to no benefit in access. **ASTRO urges CMS to apply direct supervision requirements to all radiation oncology services in all sites of service.**

At the onset of the PHE, some radiation oncology practices utilized virtual direct supervision, via real-time audio-visual technology, to enable cancer patients to complete their treatment, while at the same time reducing COVID-19 transmission rates. Quickly, radiation oncology clinics adapted and implemented protocols to minimize transmission while continuing to provide safe, high-quality care for their population. Radiation oncology practices have returned to pre-pandemic practice patterns, although clinics utilize important telehealth flexibilities for less intensive patient encounters, such as long-term follow-ups.

For radiation therapy services delivered in an episode of care, including consultation, simulation, treatment planning, and treatment delivery, ASTRO disagrees with CMS’s assertion that there is an *“absence of evidence that patient safety is compromised by virtual direct supervision....”*. Despite sophisticated safety and quality in radiation oncology, we do not believe that there are systems in place to accurately measure the safety of virtual supervision with the sensitivity needed to make such a definitive statement.

To the contrary, while uncommon, real-world clinic experiences of radiation oncologists across practice settings demonstrates how an in-person radiation oncology physician can catch and avert near misses. Whether it's the physician in the clinic noticing a treatment set-up error based on a conversation with a therapist; an unexpected complication of treatment when physically examining the patient; or a medical condition unrelated to cancer treatment needing care, experience tells us that care for cancer patients is better when the physician is physically present in the clinic. Here are some specific scenarios:

- A patient with head and neck cancer presents with mucosal toxicity that must be addressed prior to their next treatment.
- A patient with breast cancer presents with a skin reaction that must be addressed prior to their next treatment.
- A patient receiving treatment to multiple tumors has visible treatment fields that do not match according to their radiation treatment plan.

Advances in technology enable the delivery of higher doses of radiation per daily treatment, shortening the overall course of therapy. While shorter courses of treatment are great for patients in that they reduce the length of time a patient is under treatment, they increase the complexity of the treatment due to the higher dose per daily fraction. Lack of proper oversight could lead to errors that harm patients. Radiation treatment is irreversible. Once it's delivered, radiation can't be taken back. Our cancer patients need our full attention, and virtual supervision is a flawed substitute.

There is no argument regarding the application of direct supervision requirements for brachytherapy or stereotactic radiosurgery due to the intensive nature of these treatments, including the physical placement of radioactive materials into the body and extremely high dose of radiation, respectively. However, we strongly recommend applying the same level of direct supervision for more common types of treatments, including three-dimensional (3-D) radiation therapy, intensity modulated radiation therapy (IMRT), electron treatment, proton treatment and image guided radiation therapy (IGRT), as well as "incident to" services related to radiation therapy. All of these treatments benefit from a physician's direct supervision, and furthermore, cancer patients rightfully expect that their radiation oncologist is hands on and present for all aspects of their treatment.

The delivery of radiotherapy is not similar to simply taking a pill or getting an IV. Rather, it is akin to surgery, albeit conducted daily as a series of treatments. Patients expect their surgeons to be physically present or immediately available to the treatment team during surgery. So too, radiotherapy treatments should be provided with a physician present to supervise. Of course, ASTRO believes that there should be practical flexibilities for radiation oncologists to participate in tumor boards and other clinic responsibilities for the good of patient care, as well as given latitude to ensure that patients in rural areas have access to treatments. However, as a general rule, direct supervision is the safest approach to high quality radiation therapy. One incident related to virtual supervision would be too many.

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ASTRO appreciates the opportunity to explain why direct supervision is safest for radiation oncology services, and we would like to meet with you to discuss specific clinical scenarios that further illustrate our concerns about the application of virtual supervision. If you have any questions or require additional information, please contact Adam Greathouse, ASTRO Assistant Director of Health Policy at 703-839-7376 or Adam.Greathouse@astro.org.

Sincerely,



Laura I. Thevenot
Chief Executive Officer



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Chairman of the Board