Supervision Requirements in the 2020 Hospital Outpatient Prospective Payment System
Implications for Cancer Care in the United States

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On November 1, 2019, the Centers for Medicare and Medicaid Services (CMS) released the final 2020 rule for the Hospital Outpatient Prospective Payment System (HOPPS), which updates payment policy for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPD).[1] Although the policy update is often comprised of incremental refinements, this year's HOPPS update contains a notable change with potentially widespread effects on cancer care delivery in the US: the final rule lowers the minimum level of supervision for hospital outpatient therapeutic services from "direct supervision" to "general supervision." Herein we review the impetus behind this change and consider its effect on cancer care in regard to access, safety, and scope of practice.

Medicare Physician Supervision Requirements Under HOPPS

The cost of cancer care in the US is projected to exceed $170 billion annually by 2020.[2] Medicare covers roughly one-third of those expenses.[3] Much of this cost is attributable to physician-administered infused cancer drugs and radiotherapy, largely outpatient services covered under Medicare Part B. Up to 60% of Part B cancer drug and radiotherapy services occur in HOPD, which falls under the purview of HOPPS; the other 40% of services occur in the physician office setting (ie, freestanding centers), which fall under the purview of the Physician Fee Schedule (PFS).[4,5]

Medicare sets physician supervision requirements for covered services as a condition for payment; these requirements differ by type of service and practice setting and can be categorized as personal, direct, or general supervision. Personal supervision mandates the clinician be physically present in the room during the procedure. Direct supervision mandates that the supervising clinician be interruptible and "immediately available to furnish assistance and direction throughout the performance of the procedure."[1] This means that clinicians must be physically present on the premises and able to intervene in a timely fashion. General supervision mandates that the procedure be furnished under the clinician's overall direction and control, but physical presence is not required during the performance of the procedure.

Administration of infused cancer drugs and radiotherapy have traditionally required direct supervision in HOPDs and physician offices. In 2010, CMS began relaxing the enforcement of these HOPDs requirements for critical access and small rural hospitals owing to care access concerns in underserved areas with insufficient staff to furnish direct supervision. The rationale was to mitigate the challenge of recruiting specialists to these areas. Direct supervision in critical specialty cancer services were specifically noted as difficult owing to lack of available expertise.[1]

The subsequent period (2010-2019) of nonenforcement created a 2-tiered system of supervision requirements: critical access and rural hospitals operated under general supervision and other HOPDs under direct supervision. During this period, CMS reports neither supervision-related complaints from beneficiaries or physicians regarding care quality nor any data to suggest a quality detriment.[1] Thus, CMS is now extending general supervision to all HOPDs.

Access to Care

Those who stand to gain the most from relaxed supervision requirements are patients in underserved areas. The physical presence constraint of direct supervision may limit specialty care access at geographically separated facilities. The Centers for Medicare and Medicaid Services directly referred to access as the motivation for the HOPPS rule change. With only 7% of oncologists practicing in rural areas, despite 19% of the US population residing there,[6] both the American Society of Clinical Oncology and the American Society for Radiation Oncology independently convened task forces charged with tackling disparities pervasive in rural cancer care. It is also plausible that changing physician requirements from direct to general supervision can facilitate the adoption of innovative approaches to addressing these rural health disparities, such as telemedicine.

Safety

The foremost concerns in relaxing the physician supervision requirement are the safety and quality of care. General supervision should not be confused with no supervision; rather, it represents a minimum supervision level—physicians now have discretion to apply greater supervision when the level of complexity and risk of services justifies increased scrutiny. In addition, other federal, state, hospital, and specialty societies or accrediting bodies may have their own more stringent supervision and scope of practice laws, regulations, and requirements to ensure safety and quality standards.

Ensuring safety is especially pertinent to modern cancer treatment characterized by increasingly sophisticated care delivery. For example, because more evidence supports the safety and effectiveness of higher doses of radiation delivered over shorter periods of time, the margin for error has substantially decreased—high-dose radiotherapy may now be delivered with submillimeter accuracy. With therapeutic complexity

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increasing in the setting of decreased physician supervision requirements, adjunct quality assurance measures may be necessary. Possible measures include safe practice standards and guidelines by professional societies, implementing prospective risk assessment systems (eg, national error tracking and reporting systems, similar to the Food and Drug Administration's early warning system, the Sentinel Initiative), and harnessing developments in information technology (eg, real-time tumor tracking during radiation, smart pump technology, electronic order-entry systems with decision support).

Scope of Practice

For time-constrained clinicians seeking to optimize care, the direct supervision requirement can be a rate-limiting feature of care delivery. The requirement to be physically present at the infusion or radiotherapy center limits clinician capacity and can introduce workflow inefficiencies. Consider, for example, a specialized physician group practice covering several network hospitals with geographic separation. The physical presence requirement of direct supervision reduces practice flexibility and reach. The HOPPS rule change has the potential to alleviate these constraints.

Although overseeing all aspects of treatment, oncologists are often not on the front lines of patient care. Appropriately trained team members—nurses, advanced practice clinicians, or specially trained and certified radiotherapy technicians—interact daily with patients at the point of care and are always directly available. The HOPPS rule change may facilitate movement toward top of license clinical practice: physicians could devote more effort toward clinical work (evaluating and counseling patients and considering, designing, and managing treatment regimens) and nonphysician team members may be further empowered to provide care at the bedside.

A Way Forward

As we move forward under general supervision in HOPPS, 2 areas deserve continued consideration. First, the safety and quality of care will require continued, close monitoring-both in hospital outpatient (HOPPS) and freestanding centers (PFS). The rule change has effectively enabled another 2-tiered system, where hospital outpatient facilities require general supervision and freestanding centers require direct supervision. It will be important for policy makers to monitor the quality and performance of care between these sites of service. Second, CMS should consider the extent to which this rule change may further expedite consolidation and horizontal integration of health care organizations. Proponents might argue that horizontal consolidation can preserve access with more efficient care. Detractors, however, might argue that further enabling consolidation will hinder competition, choices, and innovation while driving up administrative costs.[7]

Conclusions

The 2020 HOPPS change in physician supervision requirements has the potential to catalyze fundamental changes in cancer care delivery. General supervision requirements may alleviate access concerns for underserved patients and optimize scope of practice by enhancing clinician efficiency. During this transition, CMS should consider investing in prospective assessments of patient safety to confirm that as access is improved, care quality is preserved.

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