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Report on Medicare Compliance Volume 28, Number 11. March 25, 2019
Guidance on Co-Location in Provider-Based Space Is Coming; Yes to Elevators, No to Staff

By Nina Youngstrom

Any moment now, CMS will release guidance on the co-location of space and services at provider-based departments, a persistent compliance challenge for some hospitals, and it will focus on health and safety, a CMS official said. The guidance will probably say that provider-based departments are permitted to share some space with freestanding clinics, such as waiting rooms, elevators and bathrooms, without jeopardizing their provider-based status.

"It's hard to justify that's a risk to health and safety," said David Wright, acting deputy director of the CMS Center for Clinical Standards and Quality, March 21 at the Institute on Medicare and Medicaid Payment Issues sponsored by the American Health Lawyers Association in Baltimore. Other aspects of co-location worry CMS. For example, "we can't allow shared staffing" because provider-based entities are required to be distinct operating units and independently meet the Medicare conditions of participation. He also said "we have concerns about the commingling of patients" for health and safety reasons, which will be addressed in the guidance. "We talk about shared hallways if patients have to go to inpatient space to get from one service to another. It's important to have restrictions" for privacy, confidentiality and infection control. The forthcoming guidance will discuss lease arrangements "in terms of being able to allow physicians to use space in hospitals and see patients, especially in rural hospitals. But we don't want to get in the way of doing that," Wright said. And some things clearly shouldn't be shared, such as crash carts, "so there's no confusion about who is responsible for providing what."

The guidance will be fewer than 10 pages and may come in the form of a survey and certification letter for surveyors who evaluate compliance with Medicare conditions of participation. Hospitals should expect it "very soon—in days or weeks tops," Wright said. The guidance is designed "to provide clarity to surveyors and hospitals about our expectations. Co-location has been a hodgepodge of regional office guidance, and it has created a lot of confusion."

Wright said CMS will set forth expectations "and let hospitals decide how to meet them." When it's issued, people will be invited to comment on the co-location guidance.

Co-location has bedeviled hospitals for the past seven or eight years, whether provider-based space is on or off campus, says Boston attorney Larry Vernaglia, with Foley & Lardner, who also spoke at the conference. Hospitals wonder to what extent they can share space with a freestanding clinic and still qualify as provider-based. For example, it's very common for hospitals to invite specialists to perform clinics one day every week or month and lease that space to the physician in compliance with the Stark Law exceptions and Anti-Kickback Statute's safe harbors, Vernaglia explained. But the relationships have been called into question since 2011 by CMS's developing statements on co-location.

'Regulations Are Silent on Co-Location'

Consensus doesn't come easy because "the regulations are totally silent on co-location," and CMS regional

offices are inconsistent in their enforcement of CMS's informal disapproval of it, he said. But provider-based entities may lose their designation or payment if CMS regional offices conclude space is shared with freestanding clinics (i.e., non-provider-based space) inappropriately. "Over the past eight years, CMS has taken a relatively bright-line position on the prohibition of co-location of space to the point where many organizations were in fear their operations were out of compliance with this ill-defined, non-regulatory restriction," Vernaglia said. "Many organizations have changed their behavior to accommodate the agency's statements. Others have been waiting for more definitive guidance." Now it's coming, and in light of Wright's comments, "I think the provider community will be extremely satisfied," he said.

Co-location has cost some hospitals. One CMS regional office recovered the hospital's Medicare payments for provider-based services back to the date it had attested to its compliance with provider-based status. In a letter to the hospital, the regional office explained its reasoning: "When a would-be hospital department shares space with freestanding offices, CMS must consider the entire space that contains the purported hospital department and the space's relationship to the hospital's conditions of participation…and provider-based status requirements and obligations. Since hospital components must be considered in their entirety, it is not possible to consider only parts of a singularly contained, clearly defined space. CMS may consider a suite in a medical office building to be a singular component for compliance with the hospital CoPs and Medicare provider-based status requirements and obligations for the component to be considered a part of a hospital. However, CMS cannot consider only portions of a singular component when determining if these criteria are met."

Hospitals May Reconfigure On-Campus Buildings

Co-location is far from the only challenge hospitals face with provider-based departments. Between Sec. 603 of the Bipartisan Budget Act of 2015 and CMS's new site neutrality payment policy, the advantages of provider-based space have faded. Under Sec. 603, Congress ended outpatient prospective payment system (OPPS) billing by off-campus provider-based departments established after Nov. 2, 2015, which are now paid 40% of the OPPS payment rate under the Medicare Physician Fee Schedule. Life was good for a while for provider-based departments that billed OPPS before Nov. 2, 2015, which CMS calls "excepted," but then came CMS's site neutrality policy on Jan. 1, 2019. Now all off-campus provider-based departments are treated like freestanding physician practices for payment purposes, although this only applies to evaluation and management services (HCPCS code G0463) and is being phased in over two years.

"You have to ask yourself, where is the better place to furnish services from a reimbursement and compliance perspective?" said attorney Andy Ruskin, with Morgan Lewis in Washington, D.C., who spoke at the conference. Unless a legal challenge to site neutrality is successful, the only reason he sees for provider-based departments to keep their designation vs. becoming a freestanding entity (e.g., physician office, infusion clinic) is if they continue to have a significant number of outpatient prescriptions "that qualify for being filled by 340B drugs in contract pharmacies," he said. "A lot of hospitals generate incredible savings in contract pharmacies," although he notes they are under scrutiny. "If you were to make your sites freestanding, unless you could make them a reimbursable cost center, you can't generate those cost savings," Ruskin said. But they have fewer regulatory burdens.

Even the 340B drug discount program has been slashed, although a federal court nixed the cuts for now. In the 2018 OPPS regulation, CMS decreased reimbursement for 340B drugs and biologicals from average sales price (ASP) plus 6% to ASP minus 22.5%. That was devastating for hospitals, but on Dec. 28, the U.S. District Court for the District of Columbia granted a motion for a permanent injunction to end the cuts and repay hospitals what they've lost since CMS implemented them ("Court Voids 340B Payment Cut; With More to Come, Hospitals Are Advised to Use Modifiers," *RMC* 28, no. 1). The motion was sought by the American Hospital Association and others in a lawsuit against HHS, and the details are still being sorted out. "The AHA's lawsuit regarding cuts to

the 340B Drug Pricing Program is ongoing," says Colin Milligan, AHA's senior associate director of media relations. "The district court has issued a ruling agreeing with the AHA and other plaintiffs that the cuts are unlawful, but it has not yet decided on a remedy. The government has indicated it plans to move forward with an appeal following a decision on the remedy in the case."

Meanwhile, because of Sec. 603 and site neutrality, the on-campus definition of provider-based space "has new importance," Vernaglia said. On-campus provider-based departments are not subject to site neutrality, and therefore they're allowed to continue billing OPPS, which means hospitals are reimbursed for the full facility fee separately from the physician's professional fee. "If you can declare a provider-based department on campus, you don't have to worry about Sec. 603," he explained. "The question is, what's on campus?" The provider-based regulations (42 CFR 413.65) state that buildings must be within 250 yards of the main hospital. "Providers that have sprawling campuses are doing careful measuring. We are looking carefully at site maps," he said.

Some hospitals are reportedly considering tearing down parking garages and other on-campus structures and "reconstituting" them as provider-based space, Vernaglia said. It's on-campus, so hospitals don't have to worry about the Sec. 603 demarcation line. "It's a good approach, but it's a dumb thing to have to do," he remarked.

"Hospitals cannot make a rational decision about siting needed clinical services in the community without risking significant losses on Medicare funding," Vernaglia said. "Building on campus is not only inconvenient for many patients, it is likely much more expensive to the overall health system."

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