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CMS Rules: Direct Supervision Is Gone, Prior Auth Is Here; Documentation Fix Has Limits

By Nina Youngstrom

CMS has given the green light to prior authorization for five types of procedures in an attempt to control "unnecessary increases" in these procedures as part of its Medicare program integrity strategy, according to the final 2020 Outpatient Prospective Payment System (OPPS) regulation[1] announced Nov. 1. There will be more prior authorization in the future, which will challenge hospitals to improve their pre-service coverage analysis. But they got relief from the direct physician supervision requirement for outpatient hospital therapeutic services. CMS shifted it to the more relaxed general supervision standard in the OPPS regulation and did the same thing for certain services, including remote patient monitoring and physician assistants' services, in the final Medicare Physician Fee Schedule (MPFS) regulation,[2] also announced Nov. 1.

Absent from the OPPS final regulation is a controversial provision on price transparency.[3] The proposed regulation would have required hospitals to post the charges they've negotiated with all payers, as well as prices for a subset of "shoppable" services, which many attorneys consider impractical for hospitals. "What was really gratifying was when you look at the comments, providers and payers were in lockstep that payers have the best information for patients on this," says Valerie Rinkle, president of Valorize Consulting. Before hospitals get too sanguine, another version of a price transparency regulation is now at the Office of Management and Budget for review, but its content, timing and fate are unknown. Rinkle is hoping it will capitalize on the portals and other tools that payers already have to share the price of services.

There's a lot of activity on the documentation and evaluation and management (E/M) front in the MPFS regulation. Medicare will continue to pay separately for all office/outpatient visit levels of service, which will have different values to better capture their work relative value units (RVUs). CMS is adopting work RVUs for office/outpatient E/M codes and the new prolonged services add-on code recommended by the RVS Update Committee of the American Medical Association (AMA), and ditching the lowest level CPT code, 99201, for new patients in 2021. At the same time, CMS erased its two-year-old policy for paying non-face-to-face prolonged service codes 99358 and 99359. But a heralded change in the documentation required to support E/M services—allowing physicians the option of using medical decision-making (without exam and history) or time spent with the patient to select the E/M code level—applies only to office/outpatient visits, which limits its usefulness, experts say.

"Whether the changes will achieve CMS's goals may be debated, but CMS certainly appears to be attempting to reduce burden and align Medicare with requirements of other regulations and other state laws," says attorney Richelle Marting, with the Forbes Law Group in Overland Park, Kansas.

Will Prior Auth Shift Procedures to ASCs?

CMS stuck to its plan to implement prior authorization for blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation. "We believe that the use of prior authorization in the [outpatient department] context will be an effective tool in controlling unnecessary increases in the volume of covered OPD

services by ensuring that the correct payments are made for medically necessary OPD services, while also being consistent with our overall strategy of protecting the Medicare Trust Fund from improper payments, reducing the number of Medicare appeals, and improving provider compliance with Medicare program requirements."

A prior-authorization denial would extend to all "associated services," including physician services, anesthesiology and/or facility services. However, hospitals can get free from prior authorization if their services are approved 90% of the time over 180 days. CMS will exempt hospitals "once you have proven you can self-govern," Rinkle says.

But pre-service coverage analysis is a blind spot at hospitals. "Many hospitals don't understand you can't code and bill for something if you don't have coverage," she explains. Their order of operations should be: confirm patient eligibility; confirm coverage of the services and that they are medically necessary; and "then and only then do you render them, code them and bill them," because all the recovery audit contractor, targeted probe and educate, and comprehensive error rate testing contractor activities have shown that hospitals lack processes to validate coverage for services and procedures, Rinkle says. She suggests hospital leaders meet with the medical staff and explain how coverage and prior authorization affect all of them. Physicians may have supporting documentation in their clinic records, out of the immediate reach of the hospital. With blepharoplasty, for example, physicians perform the eye tests that show the medical necessity for the procedure because the patients' eyelids block their sight. Hospitals don't do the sight tests again before the procedure, assuming the physicians have done them in their office visit, yet hospitals need the proof of these tests to support medical necessity and also will need them for prior authorization, Rinkle says.

CMS has made it clear it will expand prior authorization "pretty aggressively," Rinkle said. "The only logical response hospitals should have is to get in place a pre-service coverage analysis process tout suite." With an effective process, hospitals shouldn't ask for prior authorization unless they're 100% confident it will be granted, which will accelerate their chance to cross the 90% threshold.

There's also fear of "the unintended consequences or possibly intended consequences" of prior authorization, which could be to shift the site where the five procedures are performed away from hospitals, Rinkle says. After Medicare denies prior authorization for procedures a few times, the ordering physician may start performing them in an ambulatory surgery center, which is not part of the prior authorization process.

In another audit realm, CMS said quality improvement organizations (QIOs) will continue to audit claims for inpatient-only procedures (IPOs) for site of service, but QIOs won't deny claims that aren't compliant with the two-midnight rule for two years after they're removed from the list of IPOs, and hospitals won't be referred to recovery audit contractors for "persistent noncompliance," according to the regulation.

"CMS has realized that doctors are used to ordering inpatient status on all patients undergoing an inpatient-only surgery, and when that procedure is removed from the inpatient-only list, status determination is tricky to figure out," says Ronald Hirsch, M.D., vice president of R1 RCM. "Now they have to decide if inpatient or outpatient is appropriate even though both will be done in the hospital in the same operating room with the same equipment and method. So CMS is giving a two-year grace period for doctors, hospitals, and the auditors to figure out which patients warrant inpatient admission. CMS expects that within two years that ambiguity should be sorted out, but the last two years have really done nothing to help clarify which patients warrant inpatient admission for total knee arthroplasty. But it should be noted that these admissions are not immune from audit and denial for medical necessity of the surgery itself."

Some Documentation Changes Help More Than Others

On E/M coding for 2021, CMS reduced the levels of CPT codes for office/outpatient E/M visits for new patients to

four but keeps five levels of CPT codes for established patients, which aligns with changes adopted by the AMA CPT Editorial Panel. CMS added medical decision-making and time as options for supporting the E/M levels of service, but this only applies to office/outpatient visits. Physicians are limited to the 1995/1997 Medicare documentation guidelines for every other type of visit, including inpatient, observation and emergency room services. That's a little disappointing, because physicians probably are not going to document differently on the front end based on the type of visit, Marting says. Hospital and physician group executives have told her they will continue to educate physicians on the current documentation requirements.

The upside of the flexibility is that providers won't self-deny their claims if the documentation doesn't meet the former history and examination requirements for office visits. Providers may also benefit through fewer audits on office visit levels of service. Marting hopes CMS and AMA are "beta testing" to see if the documentation options are effective with office/outpatient visits, and will roll them out to additional services in the future, which would make more of a dent in reducing provider burden.

There are, however, other changes to documentation requirements with more potential to lighten the providers' load, she says. CMS finalized a proposal, with a clarification, to free physicians from documenting services that are already documented by other members of the medical team. Physicians, physician assistants (PAs) and advanced practice registered nurses may review and verify (by signing/dating) the information documented by physicians, residents, nurses, students, or other "appropriate members of the medical team." CMS clarified who qualifies as students, listing medical students and PAs, nurse practitioners, clinical nurse specialists, certified nurse midwives and certified registered nurse anesthetist students.

Site Neutrality, 340B Cuts Are 'Mindboggling'

In the OPPS regulation, CMS "performs CPR on its site neutrality payment policy," which the U.S. District Court for the District of Columbia voided in a Sept. 17 court decision, one attorney says.[4] Judge Rosemary Collyer ruled in favor of the American Hospital Association and dozens of hospitals, which argued that CMS overstepped its bounds when it cut payments to all off-campus outpatient provider-based departments (PBDs), partly because the cuts aren't budget neutral. The move to site neutrality was motivated by concern over increased spending on hospital outpatient services. Medicare pays more for the same services when they're performed in provider-based space versus freestanding physician practices, and there's a push to end the disparity.

Congress set site neutrality in motion when it ended OPPS billing by off-campus, outpatient PBDs established after Nov. 2, 2015, under Sec. 603 of the 2015 Bipartisan Budget Act. They are now paid 40% of the OPPS payment rate under the MPFS. Then CMS announced its site neutrality payment policy in the 2019 OPPS regulation, which treats all off-campus PBDs like freestanding physician practices for payment purposes, at least for E/M services (HCPCS code G0463). The cuts are being phased in—30% this year, and double in 2020.

The court decision should have put a stop to the payment cuts, but CMS is rolling on like nothing happened, says the attorney, who prefers not to be identified. In the 2020 final OPPS regulation, CMS stands by its reasoning for site neutrality and the way it got there, and believes the "growth in clinic visits paid under the OPPS is unnecessary." While CMS said it's working to ensure that 2019 clinic visits are paid consistent with the court order, "we do not believe it is appropriate at this time to make a change to the second year of the two-year phase-in of the clinic visit policy. The government has appeal rights, and is still evaluating the rulings and considering, at the time of this writing, whether to appeal from the final judgment."

Where does this leave hospitals? They could appeal claims for PBD clinic visits that are paid at the reduced rates. They can do the same thing for 340B claims, because CMS also said in the OPPS 2020 final rule it would move ahead with plans to reduce reimbursement for drugs and biologicals from average sales price (ASP) plus 6% to

ASP minus 22.5%, even though the U.S. District Court for the District of Columbia voided them in December 2018[5] and again on May 6. Judge Rudolph Contreras said the cuts in the 2018 and 2019 rules were unlawful but gave CMS first crack at finding a remedy to avoid wreaking "havoc" on Medicare. But now the OPPS regulation is hedging its bets. "Because we hope to prevail on appeal and have our 340B policy upheld, we believe it is appropriate to finalize our proposal of ASP minus 22.5 percent rather than an alternative payment amount of either ASP+3 percent or ASP+6 percent... In the event of an adverse decision on appeal, we solicited public comments on the appropriate remedy for use in the CY 2021 rulemaking."

Rinkle finds this "mindboggling. It feels like the administration is thumbing its nose at the courts, and you wonder how this will help them with appeals."

CMS Creates Bundle for Opioid Treatment

In terms of new physician services, CMS finalized a bundled payment for the management and treatment of opioid use disorders (HCPCS codes G2086, G2087, G2088). The monthly payment covers medical management, care coordination and psychotherapy for opioids. "Outside of the global surgery package, it's a new concept to bundle episodes of care in a physician's office, and in the proposed rule, CMS asked if there are other services it could bundle payments for," Marting says. "We are going to see more examples of that in the next couple of years." The MPFS also establishes bundled payments when the management and treatment of opioid use disorders are provided by telehealth. The patient's home can be the originating site, and the services aren't limited to rural areas, two of the usual Medicare requirements for telehealth services.

CMS finalized its proposal to change supervision from direct to general for remote patient monitoring (RPM). The 2019 MPFS added three codes for RPM, which allows providers to receive patient data, such as blood pressure, glucose levels and heart rate, using software applications on the patient's smartphone, tablet or other device. Originally, CMS didn't allow incident-to billing with RPM, but fixed that in a March 15 correction to the MPFS, because clinical staff is in the best position to manage the data and alert the physician when patients need to come in, Marting says. But incident-to billing only got providers halfway there, because it required direct physician supervision, and they were less likely to use RPM because of the expense that entailed. That problem is gone now because the RPM can be provided under general supervision. Questions were raised in the MPFS final regulation, however, about definitions related to remote patient monitoring, such as whether a patient can call to report data, and CMS said it would issue guidance.

CMS also will now allow PAs to perform services incident to the physician's services with general supervision instead of direct supervision, as long as it's within their scope of practice under state law. "They are deferring to whatever the state law's supervision requirements are," Marting says. "If you can practice with general supervision in your state, you can do it under Medicare now. Some states may require closer supervision, and Medicare will defer to the state's more stringent law."

Although it was flirting with significant changes to the lab exceptions policy for advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests,[6] CMS decided to make only one revision. In the OPPS regulation, CMS excluded blood banks or centers from the laboratory date-of-service exceptions policy, which requires labs to bill Medicare directly for ADLTs and molecular pathology tests. Labs have to report the date of service as the day the test was performed (not the day the specimen was collected), when a test meets all other conditions in the current lab date-of-service exceptions policy. But blood banks or centers have now been given a pass. "We believe that the burden on hospitals will be mitigated with the policy we are finalizing," CMS said.

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1 CMS, "CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1717-P)," RIN 0938-AT74, to be published November 12, 2019, http://bit.ly/2CmMMan.
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3 Nina Youngstrom, "CMS Rule Would Expand Price Transparency, Includes M.D.s, Fines; Viability Is Doubted," *Report on Medicare Compliance* 28, no. 28 (August 5, 2019), http://bit.ly/36MSlgi.
4 Nina Youngstrom, "Court Voids Payment Cuts to Provider-Based Departments, Ends Site Neutrality for Now,"*Report on Medicare Compliance* 28, no. 33 (September 23, 2019), http://bit.ly/2PXfTJm.
5 Nina Youngstrom, "Court Voids 340B Payment Cut; With More to Come, Hospitals Are Advised to Use Modifiers," *Report on Medicare Compliance* 28, no. 1 (January 14, 2019), http://bit.ly/2Q7kuJ5.
6 Nina Youngstrom, "Lab Exceptions Policy Takes Effect Jan. 2; OPPS Rule May Revise It," *Report on Medicare Compliance* 28, no. 39 (November 4, 2019), http://bit.ly/34CO50O.