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In Proposed OPPS Rule, IPO List Is Back, Fines Are Higher for Transparency Noncompliance

By Nina Youngstrom

In a stunning reversal, CMS won't eliminate the inpatient-only list (IPO) and will return 298 procedures it moved off the list in 2021 because of concerns about the safety of Medicare beneficiaries when procedures like limb amputations are performed on outpatients, according to the proposed 2022 outpatient prospective payment system (OPPS) rule announced July 19.[1] If the provision is finalized, CMS would revert to moving procedures off the IPO list one at a time and sparing them from medical review for two years. At the same time, CMS proposed to erase its 2021 policy of covering 258 procedures when they're performed at ambulatory surgery centers (ASCs) in 2021. With the two moves, CMS is assuming more responsibility for patient safety at a population level, experts say.

"CMS has taken a very different approach and determined relying on individual decisions by physicians and other safeguards are not sufficient to ensure the safety of beneficiaries," said Edward Hu, M.D., system executive director of physician advisor services at UNC Health in Chapel Hill, North Carolina.

The proposal brings financial relief to hospitals because Medicare only pays for procedures on the IPO list when they're performed on inpatients. Other procedures and medical admissions fall under the two-midnight rule. "When you talk to a surgeon, their mouth hangs open," said Al Gore, M.D., physician advisor and director of utilization management at St. Joseph Health System in Santa Rosa, California. "How can you do this procedure as outpatient?" He says device implants are a theme with many orthopedic procedures off the IPO list and cardiac procedures that were headed in that direction. If the device costs $30,000 and an ambulatory payment classification (APC) for the procedure pays $15,000, Gore wondered how hospitals would absorb the cost of all procedures without an IPO list.

'The Compliance Nightmare of the Century'

But the proposal may put hospitals between a rock and a hard place during the five months before the OPPS rule takes effect. "This is the compliance nightmare of the century," said Ronald Hirsch, M.D., vice president of R1 RCM. It seems strange to push the two-midnight rule on physicians for the 298 procedures when CMS told them to forget what it said about the IPO list. "One possible solution that would check all boxes is to stop all physician education and allow them to continue what they're doing," Hirsch said. To prevent improper claims, hospitals would then review every inpatient admission for the 298 surgeries before claims are submitted to determine if they comply with admission requirements, Hirsch said. He noted that total hip and knee replacements and some spine procedures will stay off the IPO list because they were individually removed before CMS's wholesale policy change.

CMS: Few Procedures Shifted to Outpatient

The upheaval began when CMS announced the three-year phaseout of the IPO list. Most, but not all, of the 298 procedures are musculoskeletal. Unless CMS finalizes the proposal, by 2024, all 1,740 procedures will be off the

IPO list. Because this was such a monumental change, CMS indefinitely paused medical reviews.

When it implemented the change, CMS said it was relying on physician judgment, conditions of participation and other safeguards to protect patient safety, and with the increasing capacity for monitoring quality of care, "we believed that quality of care was unlikely to be affected by the elimination of the IPO list," the rule explained.

But CMS has had a change of heart. The proposed rule says procedures will be removed from the list after they are individually considered, and CMS will resume using five criteria to decide whether to move a procedure off the IPO list. The criteria includes whether "the procedure is related to codes that we have already removed from the IPO list" and "a determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis."

CMS acknowledged the value of the IPO list and said some procedures "cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting, and therefore, it would be inappropriate for us to assign them separately payable status indicators and establish payment rates in the OPPS (78 FR 75055)."

Part of the reason for nixing the elimination of the IPO list is it didn't have much of an effect. In the proposed rule, CMS said 2021 billing data through May showed that 131 of the 298 codes showed up on zero or one OPPS claim and 269 appeared on fewer than 100.

'Focus Is Back on Safety'

CMS is also putting itself in the driver's seat when it comes to patient safety, Hu said. "We recognize that while physicians are able to make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries, that is, the typical Medicare beneficiary." This comes across in both the OPPS and ASC proposed rules. In addition to restoring the IPO list, CMS is proposing to reinstate the patient-safety criteria for adding procedures to the ASC covered procedures list that was in place pre-2021 and remove 258 of 267 procedures approved in the 2021 rule. Hu said that's a big deal, because when procedures are moved off the IPO list, they eventually can migrate to ASCs, although there must be at least one year between leaving the IPO list and joining the ASC list.

"The main thing is the focus is back on safety," Hu said. "CMS acknowledged there is a difference in patient safety between an inpatient and outpatient department." For example, there were more outpatient claims for some services, including lumbar spine fusion and shoulder replacement, but they have long lengths of stay and extensive post-operative care needs that indicate they may not be a good fit for the outpatient setting, the rule noted. It means "CMS is clearly taking greater ownership of patient safety decisions from a population-based level rather than leaving it to a beneficiary-level decision," Hu said.

But Hirsch thinks the "safety issue is a false issue." Patient status is purely a reimbursement construct. "The patient is still having surgery in a hospital setting with the same equipment and personnel whether they're inpatient or outpatient," he said. "I suspect the problem was when CMS had so many surgeries to assign to APCs, they didn't have enough time to adequately assign the true costs of the surgeries and assign them to an appropriate APC. Either they were drastically overpaying hospitals or no APCs were high enough to pay enough." Gore noted that most shoulder replacements are performed on outpatients at his hospital. "It used to be an inpatient-only procedure, but the length of stay was less than one day," he said. "You get two doses of antibiotics. That was the limiting factor, and you can't support an inpatient admission." The majority of admissions wouldn't survive an audit, "but now that will be a moot point" if the proposal is finalized.

Hirsch was disappointed CMS didn't shed any light on the case-by-case exception to the two-midnight rule. It will be a refuge over the five months for the 298 procedures moved off the IPO list in 2021. As far as he's

concerned, last week, the bar for admission of one-day stays was pretty high for procedures moved off the IPO list when the documentation wasn't great. But he feels it's lower now that "CMS has admitted it made a mistake."

Andy Ruskin, an attorney with K&L Gates in Washington, D.C., suggested hospitals document very carefully over the next five months. "It's a catch-22," he said. Hospitals don't enjoy the presumption that admissions of procedures formerly on the IPO list are compliant, and now the rule indicates CMS is skeptical the outpatient setting is safe and appropriate. Whichever route hospitals take, they "better be able to explain," Ruskin said.

CMS Hikes Penalties for Transparency Noncompliance

In another OPPS surprise, CMS has increased the penalties for noncompliance with price transparency requirements, with some hospitals facing a maximum of $2 million if the provision is finalized.

Since Jan. 1, 2021, hospitals have been required to reveal to the world five sets of charges for all items and services: gross charges, payer-specific negotiated charges, the discounted cash price, and the minimum and maximum payment amount they accept from payers for every item and service without identifying the payers, according to the 2020 price transparency rule.[2] They also have to post a "shoppable" list of 300 payer-specific negotiated charges for common services in a consumer-friendly way, or they can develop an internet-based price estimator tool for patients to ballpark their cost.

Penalties for noncompliance also were established in the final transparency rule. CMS starts with a written warning, moves to a corrective action plan and then imposes a civil monetary penalty up to $300 a day.

Because CMS has found "a trend toward a high rate of hospital noncompliance identified by CMS through sampling and reviews to date," it's proposing to increase penalties using a "scaling factor":

- Noncompliant hospitals with 30 or fewer beds would face a maximum daily penalty of $300.
- Noncompliant hospitals with 31 to 550 beds would be fined a maximum daily penalty of the number of beds times $10.
- Noncompliant hospitals with more than 550 beds would face a maximum daily penalty of $5,500.

Nothing would change for a noncompliant hospital with fewer than 30 beds. But a noncompliant 200-bed hospital would be fined $2,000 a day or $730,000 a year and a noncompliant 550-bed hospital would be fined $5,500 a day or $2 million a year, CMS said.

All this infuriates Ruskin, who hopes the American Hospital Association (AHA) challenges the fines in court "and wins this time," because "CMS should not be able to create programs with the smallest of words in a statute and attach significant penalties to it." AHA lost an earlier challenge to the price transparency requirement, but Ruskin said the creation of a new price matrix creates new grounds for a lawsuit. CMS has "almost no statutory authority for the program," he said. An overbearing regulatory edifice was built on one sentence in the Affordable Care Act.

That was also the case with the site neutrality payment policy and 340B drug payment cuts, Ruskin said. He was concerned "the Trump administration was not being faithful to the language" of the statutes, and "here we have a new administration that generally carries itself with more aplomb, but they are ratifying policies that don't have a firm foundation in law." The proposed 2022 OPPS rule reiterates the 340B drug payment cut (average sales price minus 22.5% instead of ASP plus 6%) implemented in the 2018 OPPS rule.

AHA lost its battles over site neutrality and 340B in court, but recently the U.S. Supreme Court agreed to hear AHA's appeal of the 340B payment cut. AHA sued and won both cases in federal district court, but those decisions were reversed at the U.S. Court of Appeals for the D.C. Circuit. AHA and other hospital associations then asked the Supreme Court for relief in both cases. The high court, however, declined to hear an appeal of the site neutrality policy.

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1 CMS, "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals," proposed rule, July 19, 2021, https://bit.ly/2UYb7j0.
2 Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals To Make Standard Charges Public, 84 Fed. Reg. 65,524 (November 27, 2019), https://bit.ly/3rsTZhw.