

CAPITOL STREET

July 2, 2024

2025 Hospital Outpatient Rule Preview

NO PAIN & Radiopharm Unbundling with Cyber, More Procedures In ASC

Relevant Companies



»» Our Take & Next Up

CMS is set to release proposed hospital outpatient & physician fee CY25 rules over the next few weeks (due by July 1, but early-to-mid July possible). Our take on the pending rules can be found below and are based on past policy proposals punted on by the agency (CMS) and/or bills pending in Congress, mandates by Congress to CMS. On hospital outpatient departments (HOPD), we could see a near identical MB (~+2.6%) as the proposed inpatient prospective payment system (IPPS), as well as incremental color on radiopharmaceutical (unbundling) along with non-opioid pain coverage policy. More broadly we expect to see additional procedure movement to (lower cost) ambulatory surgery centers (ASC) setting, and potential cybersecurity polices given recent hospital system attacks, as well as possible 340B clean up and site-neutral policy.

»» Key Points

HOSPITAL OUTPATIENT PAY & POLICY

No big surprises are expected with the market basket (MB) update of ~2.6%, the potential for cybersecurity policy measures, site-neutral & continued ASC procedure movement. We expect to see:

- Continued movement of procedures to the ASC setting (per the trend of the last few years).
- Potential cybersecurity quality measures, conditions of participation (COP) is also a possibility.
- 340B payment clean-up is possible, per court case requiring CMS to return pay to 340B hospitals (after Trump era cut of ASP-22.5% (2017) was deemed unlawful).
- Site-neutral expansion unlikely but possibly in the mix, with additional action possible at year-end.

As a reminder CMS proposed a 2025 inpatient MB (+2.6%) (our take [here](#)) which was quickly criticized by hospitals as not considering inflation, operational costs, persistent labor shortages and aging demographics. CMS proposed IPPS pay would provide a + 2.4% pay bump to all hospitals (proprietary & voluntary). New inpatient pay starts Oct 1, 2024, the start of FY25. The final inpatient rule will be sometime in August 2024.

RADIOPHARM

Diagnostic radiopharmaceutical separate pay changes are on the table (ASP+6% or unbundling) in this rule. In the 2024 Outpatient PPS, CMS solicited feedback on patient impact based on radiopharmaceutical use and potential payment approaches for diagnostic radiopharmaceuticals. A majority of comments received urged the agency to provide separate pay for diagnostic radiopharmaceuticals with no agreement on the best way. Potential reimbursement methods suggested by the agency include:

1. Paying separately for radiopharmaceuticals with per-day costs above the OPSS drug packaging threshold of \$140.
2. Establishing a specific per-day cost threshold that may be greater or less than the OPSS drug packaging threshold.
3. Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals.
4. Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials.
5. Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

Meanwhile, an unpackaging radiopharmaceuticals (\$500+) bill is unlikely to pass in 2024 but has made some progress in the House. In mid-May, the House E&C Subcommittee on Health (Chair Guthrie, R-KY) passed the Facilitating Innovative Nuclear Diagnostics Act (*FIND Act*). Link to text here. The *FIND Act* would require CMS to unpackage diagnostic radiopharmaceuticals that have an average daily cost of \$500 or more in 2024 and as adjusted based on a specified fee schedule factor in each following year. Pay would be at the average sales price (ASP) for the drug, to the extent available. In hospital feedback, commenters largely deferred to CMS to pick a threshold with some supporting *FIND Act's* \$500 threshold and others contending that \$500 is too high.

NO PAIN

NO PAIN Act implementation starts in 2025 (for three years). As a reminder, NO PAIN passed in *Consolidated Appropriations Act* in the In the 2024 proposed OPSS last year (here), CMS solicited stakeholder comments on how to implement separate payments for non-opioid treatments for hospital outpatient department services and ASCs. The agency asked for input on what would meet the definition of a non-opioid treatment for pain relief, on appropriate codes and descriptors if no HCPCS codes currently exist, and how to calculate payment limitations.

- **CMS will roll out the reimbursement policy in the upcoming OPSS, particularly around what types of therapies qualify for separate payment.** CMS is likely to be stringent on what qualifies as a non-opioid pain treatment, despite the variety of qualifying treatments suggested (including IV NSAIDS, acupuncture, cold therapy devices, THC oil).
- **Lower reimbursement likely – the payment cannot exceed the estimated average of 18% of the outpatient department (OPD) fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished for.** We do not expect an overly generous payment rate due to this legislated limit. The separate payments also expire at the end of 2027. For payment methodology, CMS proposed using the top five services associated with a potential therapy to determine the volume weighed payment rate and limit. In the example provided, the agency expects a payment limit of \$126 for a volume-weighted payment per claim of \$700.

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