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Health Care Advisory

Court Invalidates Latest CMS Effort to Reduce Reimbursement at Off-Campus Hospital Outpatient Departments

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KEY POINTS

- On September 17, 2019, the District Court for the District of Columbia rejected the Centers for Medicare and Medicaid Services' (CMS) latest attempt to limit Medicare reimbursement at off-campus outpatient provider-based departments (PBDs)[1] to the lower Physician Fee Schedule-based amounts that would have been paid for those services at physician offices.[2]
- The policy was expected to reduce hospital reimbursement by about $610 million per year.[3]
- This attempted decrease in Outpatient Prospective Payment System (OPPS) reimbursement for services at off-campus outpatient PBDs — also referred to in this context as off-campus hospital outpatient departments or HOPDs — succeeded statutory and regulatory changes effective January 1, 2017 that had excluded *other* off-campus HOPDs from OPPS reimbursement in their entirety.
- Hospitals seeking to maintain or increase outpatient hospital reimbursement by continuing to operate or obtaining outpatient sites with "provider-based" status need to be aware of the circumstances under which that status may no longer generate reimbursement beyond that of a physician's office.
- This advisory presents key changes in HOPD reimbursement in recent years, provides hypothetical examples of their real-life implications, and culminates in a discussion of the most recent limitation imposed by CMS on OPPS reimbursement for HOPDs — and the court decision invalidating it.

[1] PBDs are facilities that meet the applicable criteria in 42 C.F.R. § 413.65 regarding integration with a main provider.

[2] *See American Hospital Association et al. v. Azar II*, No. 1:18–cv–02841 (D.D.C. Sept. 17, 2019).

[3] 83 Fed. Reg. 58818, 59009 (Nov. 21, 2018).

Background:

The Medicare program, in recent years, has been moving toward "site neutrality" — paying comparable reimbursement for comparable services without regard to service site. In particular, "site neutrality" provisions seek to eliminate payment of different reimbursement levels for substantively identical services furnished in HOPDs as compared to physician offices.

The differences in payment between services at HOPDs and services at physician offices flow primarily from the fact that Medicare makes separate payments to the hospital and the physician — typically, an Outpatient Prospective Payment System (OPPS) rate paid to the hospital and a Medicare Physician Fee Schedule (PFS) rate paid to the physician. The PFS rate for physician services in a hospital setting is less than the full PFS rate paid to physicians in a non-facility setting.[4] However, the combined OPPS and PFS payment for services at an HOPD, historically, has well exceeded the "non-facility" PFS rate paid for services in physician offices.

The cost implications are two-fold: Medicare pays more when hospitals receive the full OPPS rate for services at HOPDs than it would pay for comparable services at physician offices; and beneficiaries pay more in the form of 20 percent co-payments applied to the higher amounts. Further, there is an incentive to shift services from physician offices to outpatient hospital settings in circumstances in which higher reimbursement is available but offsetting cost increases are unlikely to be significant.[5]

Reimbursement Changes Limited to "Off-Campus" HOPDs:

CMS's site neutrality regulations, promulgated through its CY2017 OPPS Final Rule,[6] implement Section 603 of the Bipartisan Budget Act of 2015 (BBA 2015), which added subsections (1)(B)(v) and (21) to 42 U.S.C. § 1395l(t). Those statutory provisions address the above-described concerns by excluding from "covered OPD services" (services billable under OPPS) those services furnished on or after January 1, 2017 at off-campus HOPDs (other than dedicated emergency departments) that were not billing under OPPS prior to November 2, 2015.

This exclusion from OPPS applies only to "*off-campus*" HOPDs — those that are neither "on the campus" (within 250 yards) of a hospital (per 42 C.F.R. § 413.65(a)(2)), nor within 250 yards of a remote location of the hospital (i.e. an off-site facility furnishing inpatient services as a remote site of a hospital). The designation of the latter grouping as essentially on-campus for purposes of the site neutrality provisions (despite not falling within the regulatory definition of on-campus) appears to indicate an expectation that services at HOPDs with greater proximity to other hospital facilities are more likely to offer added value as compared to services at physician offices.

Off-campus HOPDs that continue to be able to bill under OPPS (i.e. that are "grandfathered" as to the site neutrality provisions) are referred to as "excepted" sites. Services at *non*-excepted off-campus HOPDs are paid "under the Medicare Physician Fee Schedule" (42 C.F.R. § 419.48(c)), at "site-specific PFS payment rates."[7] These payment rates, when added to the PFS rate for facility-based physician services, are intended to approximate the PFS rate paid to non-facility-based physicians (plus any amounts that are separately payable in the non-facility setting but reimbursed through the OPPS rate in the facility setting).

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[4] Hospital-based physician services are reimbursed at a lower rate because the hospital (not the physician) bears overhead and ancillary costs that would be incurred by, and reimbursed to, the physician in the non-hospital setting.

[5] Hospitals able to participate in the 340B discount drug purchasing program would have an additional financial incentive resulting from any variance between the reimbursement for, less the cost of, pharmaceuticals furnished at the HOPD that are paid separately from OPPS, versus that of the same pharmaceuticals when furnished in a physician office.

[6] 81 Fed. Reg. 79562 (Nov. 14, 2016).

[7] In fact, due to the mechanics of hospital versus physician billing, the hospital technically continues to bill under OPPS, but with a modifier that causes a "[PFS] Relativity Adjustor" to be applied that reduces the rate to the "site-specific PFS payment rate."

Hypothetical Example: Two hospitals with the same owner; Hospital 1 has a non-excepted off-campus HOPD on Hospital 2's campus. If the HOPD is converted to an *on-campus* HOPD of *Hospital* 2, site neutrality provisions will not apply, and services will be billable under OPPS.

"Excepted" Status Preserved Only if No Impermissible Change of Ownership or Location:

Under the regulations, excepted off-campus HOPDs that "impermissibly" relocate or experience a change in ownership lose their excepted status (42 C.F.R. § 419.48) because CMS effectively considers them no longer the same entity that was billing before the cutoff. CMS allows providers, however, to seek CMS determination, on a case by case basis, that certain changes are permissible — *i.e.* that the site remains essentially unaltered for purposes of grandfathering. Still, relocation, in particular, has tended to be viewed by CMS in extremely stark terms — even a change in suite number from that on the provider's pre-November 2, 2015 enrollment application will generally signal a "relocation" that defeats excepted status.

Hypothetical Examples: Address of excepted site changes only due to redrawn town borders or zip code reassignment, or a contiguous non-excepted off-campus site is established adjacent to excepted site, but exact addresses of respective sites are clearly distinct, and physical boundaries of excepted site are unchanged. In either case, provider wishing to retain status of existing excepted site would emphasize: (a) entity is the same in all material respects as the entity billing pre-November 2, 2015 (expressly excepted by statute); and (b) there will be no resulting increase in volume or types of services at excepted site, so the goal of limiting OPPS growth is not implicated.

Changes in Volume and Types of Services Not Directly Limited at Excepted Sites:

In its proposed OPPS rule-making for each of 2017-2019, CMS also considered whether to constrain directly certain increases in volume or changes in the types of services furnished at excepted sites. CMS essentially would deem sites that experienced such changes to be so altered as to effectively no longer constitute entities that met the November 2, 2015 statutory grandfathering cutoff. Such limitations would more directly serve the goal of limiting OPPS growth. CMS, however, determined in each year's final rule that such limitations were not reasonably administrable at the time, while continuing to solicit future comments on the subject.

Hypothetical Example: Existing off-campus HOPD has excess capacity that can be utilized without physically altering the space. That excess capacity can be devoted to increased volume or new types of services without affecting the site's excepted status.

CMS Caps OPPS Rates for Certain Clinic Visits at Excepted HOPDs:

CMS, in its 2019 OPPS Final Rule[8], nevertheless decried the fact that actions to date had done little to stem the growth in, and shift toward, OPPS billing at off-campus HOPDs because the majority of off-campus HOPDs had been grandfathered. CMS concluded that regular clinic visits (for the evalua¬tion and management of hospital outpatients (HCPCS Code G0463) — which CMS suggested were not materially different in the off-campus HOPD versus physician office settings[9] — were substantially responsible for this inflation because they constitute one-third of the visits billed at excepted sites. Yet, CMS could not target visits billed under HCPCS G0463 at excepted sites under the site neutrality provisions of BBA 2015 because an off-campus HOPD is either excepted or not under those provisions. If it is excepted, all services furnished there are grandfathered and remain subject to OPPS.

Instead, CMS announced in the 2019 final rule that it would use its authority under *42 U.S.C. § 1395l(t)(2)(F)* — "the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services" —

[8] *See* n2, *supra.*

[9] These visits likely exhibit less "value added" from the hospital nexus than do more specialized visits – *e.g.*, from higher acuity patients, better technology, or greater continuity of care.

to tamp down the reported OPPS growth. While visits billed under HCPCS Code G0463 at excepted off-campus HOPDs would continue to be covered OPD services under OPPS, CMS created a new OPPS rate "cap" uniquely applicable to those visits — a rate that approximates the same payment to the hospital as hospitals receive for HCPCS G0463 visits furnished at non-excepted off-campus HOPDs, which are effectively paid under the PFS. CMS would achieve this result by capping the OPPS rate at 40 percent of the rate otherwise applicable to such visits, to be phased in over two years by first setting the percentage for 2019 at 70 percent of the otherwise applicable OPPS rate.

Court Invalidates CMS Caps on OPPS Clinic Visit Rates at Excepted HOPDs:

The American Hospital Association, along with the Association of American Medical Colleges and various hospitals and health systems, brought suit against the Secretary of the Department of Health and Human Services,[10] arguing that CMS's establishment of a specific OPPS rate rule applicable only to certain OPPS billable services at only certain types of sites was *ultra vires*. On September 17, 2019, the Court found in favor of Plaintiffs, vacating the rule and remanding to CMS for development of remedies to restore reimbursement that providers would have received had they been paid at the usual OPPS rates for all clinic visits, rather than subjected to the now invalidated cap since January 1, 2019. The Court's determination was that CMS's authority under § 1395l(t)(2)(F) did not extend to targeting certain services and/or classes of providers by directly establishing certain rate rules outside the very detailed rate-setting structure imposed by Congress in 42 U.S.C. § 1395l(t). The Court also determined that CMS's authority did not permit implementing such rules in a non-budget neutral manner such that they failed to maintain the guiding principle that within OPPS, rates must reflect relative resource use.

Given CMS's aggressive stance in other cases recently lost,[11] it seems likely CMS will appeal the decision. Should the rule be reinstated on appeal, however, hospitals seeking to maintain or increase off-campus outpatient reimbursement may still have some useful options — at least so long as CMS declines to establish rules by which changes in volume or types of services at excepted HOPDs could directly precipitate loss of excepted status.

> ***Hypothetical Example:*** Hospital has one excepted and one non-excepted HOPD. Each furnishes outpatient chemotherapy infusion and hyperbaric oxygen therapy, services, as well as services billed under HCPCS Code G0463. Should the cap on HCPCS G0463 OPPS rates be reinstated, Hospital could seek to maximize reimbursement by shifting existing capacity or utilizing excess capacity so that (a) the excepted off-campus site houses exclusively specialty services, and (b) all regular clinic visits are concentrated at the non-excepted site.

[9] *See* n1, *supra.* Similar litigation was also commenced by other providers.

[10] *See, e.g., American Hospital Association et al. v. Azar et al.*, No. 1:18–cv–2084 (D.D.C. Dec. 27, 2018 and May 6, 2019)

CONTACTS

Katten's **Health Care** team continues to monitor these issues. For more information, contact:

Joseph V. Willey
+1.212.940.7087
Joseph.willey@katten.com

Sharon Kantrowitz
+1.212.940.6563
Sharon.kantrowitz@katten.com