July 28, 2020

- **Budget Neutrality and Payments for Outpatient Services – How Worried Should Hospitals Be About the New Knife in the US Department of Health and Human Service (HHS) Toolbox?**
  - A key element of rate setting authority under the Medicare Outpatient Prospective Payment System (OPPS) mandates offsetting increases in spending with corresponding decreases, or *vice versa* – in short, after fine tuning myriad financial levers and switches that control various individual OPPS payments, the net-net from one year to the next must be budget neutral.
  - At a policy level, by securing the principal of budget neutrality by statute, hospitals were assured that although intramural payment skirmishes might be fought over specific outpatient services, the industry as a whole would not have to contend with payment reductions in the aggregate for outpatient hospital services.
  - Guided by this principal, last September in *American Hospital Association v. Azar*[1], the court ruled the Secretary of HHS could not trim Medicare payments to hospital outpatient departments (OPDs) for Evaluation and Management (E&M) visits provided in off-campus OPDs under the guise of controlling unnecessary increases in the volume of covered OPD services, even though Medicare was spending twice as much on each E&M visit in the OPD setting versus a freestanding physician's office.
  - But in a unanimous decision by a three-judge panel of the D.C. Circuit Court of Appeals[2], the cornerstone principal of budget neutrality took a direct hit, with HHS claiming victory in its power to "develop a method for controlling unnecessary increases in the volume of covered [outpatient] services" by capping the rate paid to off-campus OPDs at the physician fee schedule equivalent rate and without any offsetting increases to other OPPS payments to effect budget neutrality.
  - Beyond "agency wins, industry loses," it is important to consider the manner in which the D.C. Circuit Court of Appeals ruled in favor of HHS – once the court determined that the payment reduction qualified as a "method for controlling unnecessary increases in…volume," the reduction was beyond the scope of judicial review.
  - Perhaps even more importantly, the court recognized that provision of the OPPS law giving HHS the power to develop a "method for controlling" volume increases was untethered from the requirement of budget neutrality, leading the court to conclude that such power authorizes service-specific rate cuts as non-budget-neutral payment adjustments: *"[w]e thus conclude that the OPPS statute does not unambiguously foreclose HHS's adoption of a service-specific, non-budget-neutral rate cut as a 'method for controlling unnecessary increases in' volume."*
  - **Key Takeaway:** Given the appeals court's determination that the rate cut imposed in this case – basically, eliminating a payment differential based on provider status – was a valid method for controlling volume increases, hospitals should recognize the firewall of budget neutrality has been breached, at least in those cases where HHS can seek to control volume by adopting rate cuts through the elimination of payment differentials based on provider status.

[1] 410 F. Supp. 3d 142 (D.D.C. 2019)
[2] No. 19-5352 (D.C. Cir. July 17, 2020)

- **As the number of COVID-19 cases continues to rise, the HHS, Office for Civil Rights (OCR) warns recipients of federal financial assistance, including state and local agencies, hospitals and other health care providers, that they must comply with federal civil rights laws and regulations.**
    - On July 20, 2020, OCR issued a bulletin, "Civil Rights Protections Prohibiting Race, Color and National Origin Discrimination During COVID-19," reminding all health care providers receiving federal financial assistance during the COVID-19 crisis that they must comply with the prohibitions against discrimination based on race, color and national origin under Title VI of the Civil Rights Act of 1964 ("Title VI"). OCR also warns that it has enforcement discretion over potential violations of Title VI.
    - Title VI's protections extend to utilization of "criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin."
    - OCR suggests various ways to further compliance with Title VI during the pandemic, including but not limited to:
        - Providing ambulance service, non-emergency medical transportation and home health services, if such services are part of the program or services offered by the recipient, to all neighborhoods within the recipient's service area, without regard to race, color or national origin;
        - Establishing COVID-19 testing sites that are accessible to racial and ethnic minority populations; and
        - Confirming that individuals from racial and ethnic majority groups are not more likely to be subjected to excessive wait times, rejected for hospital admissions, or denied access to intensive care units as compared to similarly-situated individuals from non-minority groups.
    - This bulletin should be seen as a warning shot putting providers on notice that OCR will not hesitate to bring enforcement actions when it finds federal funds recipients discriminating against racial or ethnic minorities during the pandemic; expect OCR to be hyper-vigilant in the present political climate.
    - Providers must rigorously apply established Title VI compliance mechanisms and document their compliance efforts to avoid (or defend) potential enforcement actions. At the very least, providers should confirm that there are written policies and procedures in place to prevent and address harassment and other unlawful discrimination based on race, color or national origin, and gather data to demonstrate that such policies and procedures are effective.
    - Providers also should document decisions regarding COVID-19 testing sites (and the data supporting them) to demonstrate accessibility by racial and ethnic minority populations.
    - **Key Takeaway**: Recipients of federal funds should not doubt OCR's willingness to exercise its enforcement authority against those who violate Title VI during the COVID-19 crisis. Documentation of compliance efforts and collection of data regarding the effectiveness of those efforts will be key to avoiding or defending potential enforcement actions.

- **Healthcare facilities should expect greater scrutiny from national accreditation organizations (AO) as the Centers for Medicare & Medicaid Services (CMS) continues to ramp up oversight and express increasing concern over AO financial relationships with the facilities they accredit.**

- On July 17, 2020, CMS approved The Joint Commissioner (TJC) for continued recognition as an AO for hospitals seeking to participate in the Medicare and Medicaid programs. Although CMS had authority to grant approval for six years, the approval is set to expire in just two, with CMS explaining "[t]his shorter term of approval is based on our concerns relating to the comparability of TJC's survey process to those of CMS, as well as what CMS has observed on TJC's performance on the survey observation." A decade ago, a two-year expiration for TJC might have seemed unthinkable.
- But CMS's current stance on TJC's hospital accreditation program, which accredits approximately 80% of US hospitals, should not come as a complete surprise. Over the past several years, CMS deliberately increased its oversight of AOs while voicing increasing concern about AO financial relationships with the healthcare facilities they accredit, particularly as to consulting arrangements. As recently as February 2020, CMS Administrator Seema Verma expressed disdain for "the growing trend of accrediting organizations providing fee-based consulting services to the same organizations they accredit," describing the arrangements as a "glaring conflict of interest."
- CMS has been focused on this issue for some time.
  - In December 2018, it issued a request for information seeking input on financial relationships between AOs and healthcare facilities.
  - In April 2019, it announced a proposed rule that would establish a specific process in the event a sale, transfer or purchase of AOs assets.
  - As of February 2020, the Office of Management and Budget (OMB) was reviewing a proposed rule from CMS designed to strengthen AO oversight in part by "addressing conflicts of interest, establishing consistent standards, processes and definitions, and updating the validation and performance standards systems." The proposed rule also would solicit comments on AO oversight standards and processes, and include requests for information on: (i) timeframes and expectations for the submission of AO applications, and (ii) public transparency regarding quality and safety issues.

- **Key Takeaway:** Healthcare facilities should expect CMS's increasing scrutiny of AOs to have a ripple effect, with AOs – and TJC, in particular – ramping up the rigor of their accreditation reviews to avoid termination. Moreover, healthcare facilities should approach AO consulting engagements with caution; if they cannot be avoided, mechanisms to mitigate conflicts of interest should be considered recognizing the stated concerns of CMS and the likelihood of regulation in this area soon.

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