September 29, 2020

- **Moving the Goalposts: The New Notice of Reporting Requirements for Provider Relief Fund ("PRF") General and Targeted Distributions**
  - On September 19, the Centers for Medicare and Medicaid Services ("CMS") published its *General and Targeted Distribution Post-Payment Notice of Reporting Requirements* ("Reporting Requirements"). The Reporting Requirements make material changes to prior reporting guidance from CMS, switching from lost revenues to lost profits and requiring qualifying expenses to be reimbursed first, before lost revenues (profits) can be considered.
  - Prior to publication of the Reporting Requirements, the CARES Act and relevant guidance reflected that PRF payments could be used "to reimburse … eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus." This was presented as an "either-or" proposition: providers could use PRF payments to reimburse qualifying expenses *or* lost revenues; there was no indication that providers had to count both, or that one would have priority over the other.
  - Moreover, in a June 19, 2020 frequently asked question ("FAQ") addressing which "expenses or lost revenues are considered eligible for reimbursement" from PRF payments, CMS indicated providers would have great flexibility when it came to quantifying lost revenues.
    - "The term 'lost revenues that are attributable to coronavirus' means any revenue that you as a health care provider lost due to coronavirus. This may include revenue losses associated with fewer outpatient visits, canceled elective procedures or services, or increased uncompensated care."
    - "You may use any reasonable method of estimating … revenue" including the "difference between your budgeted revenue and actual revenue" or a comparison to revenues in the same period in the prior year.
  - The Reporting Requirements establish a completely different approach.
    - First, in a significant deviation from the statutory language, "lost revenues" now means lost profits: "lost revenues [are] represented as a negative change in year-over-year net patient care operating income (i.e., patient care revenue less patient care related expenses for the Reporting Entity … that received funding.)"
    - Second, expenses attributable to coronavirus must now be tracked and reimbursed from PRF payments first. "PRF payment amounts not fully expended on healthcare related expenses attributable to coronavirus are then applied to lost revenues."
  - Health care providers that have accounted for the "earned" portion of PRF based on the prior guidance from CMS and reported such amounts in public filings should reconsider their historical accounting methodology based on the new Reporting Requirements.
  - **Key Takeaway:** The Reporting Requirements establish a new, unexpected paradigm for reporting and accounting for use of PRF payments. Providers must pay careful attention to new definitions in the Reporting Requirements and ensure they have systems in place to track all required reporting elements, including any they may not have been tracking prior to September 19.

- **HCA Nurses Vote to Unionize in North Carolina: A Harbinger of More to Come?**
  - Earlier this month, a group of registered nurses at HCA Mission Hospital in Ashville, North Carolina voted overwhelmingly to unionize with the National Nurses Organizing Committee/National Nurses United (the "Union"). The vote tally – 965 in favor of the Union to only 411 against – marks a stunning end to the largest hospital unionization effort at any Southern-based nonunion hospital since the 1970s.
  - The Union's campaign garnered significant media attention and the support of local politicians and community leaders alike. The Union alleged the hospital had cut both staff and resources, which led to lower nurse-to-patient ratios and reduced employee morale.
  - While it is far from clear whether the Union's claims about Mission Hospital are valid, the result of the union vote should serve as a wake-up call for healthcare employers across the country, and especially in the South. The large margin of victory suggests a high level of support for the Union existed within the facility.
  - As we noted in this space earlier this summer, the industry's struggle to deal with the unprecedented challenge of COVID-19 may be leaving hospitals vulnerable to similar unionization efforts. Longer working hours and shifts, coupled with the perception of increased personal risk, could increase employee disaffection and expose employers to a higher risk of unionization.
  - **Key Takeaway:** Hospitals and health systems should review their employee engagement strategies and plans for mitigating potential union organizing vulnerabilities without delay. It will be too late to do so effectively if employers wait until the Union has gained a foothold.
- **OIG Advisory Opinion ("AdvOp") 20-05: A Lesson From The Administration's War on Drug Pricing**
  - On September 23, the Department of Health and Human Services Office of Inspector General ("OIG") fired a missile into a drug manufacturer's proposed financial assistance program ("Subsidy Program") for what some called "the most expensive [cardiovascular] drug ever launched in the United States" – warning the proposed Subsidy Program "would generate remuneration under the anti-kickback statute [AKS] if the requisite intent to induce or reward referrals … were present and that [OIG] could potentially impose administrative sanctions" on the manufacturer. Translation: If implemented, ***OIG could impose fines, and DOJ could charge felonies.***
    - While aimed directly at one drug, AdvOp 20-05 is clearly a warning shot at the pharmaceutical industry underscoring the perils of trying to blunt the impact of excessively high drug prices by thwarting Medicare's beneficiary cost-sharing requirements.
    - Previously, OIG has blessed a variety of financial assistance arrangements to help low income Medicare beneficiaries obtain costly treatments or drugs without the full impact of Medicare's cost-sharing requirements. For example, AdvOp 20-02 approved manufacturer-provided financial assistance for travel, lodging, and other expenses to certain patients prescribed the manufacturer's drug. But in AdvOp 20-05, the OIG found no redeeming attributes.
  - Most noteworthy in OIG's analysis was the level of independent inquiry and review of "Additional Publicly Available Background Information" that OIG undertook in condemning the proposal. Key OIG observations included:
    - By setting the eligibility hurdle at 800 percent of the federal poverty level, over 90 percent of Medicare beneficiaries affected by the disease could receive financial assistance from the manufacturer's free drug program, its Subsidy Program, or the Medicare Low-Income Subsidy.

- The Subsidy Program would virtually eliminate beneficiary cost-sharing under Part D, reducing monthly patient copays from over $1,000 to $35. Compared with the portion of the price Medicare Part D would pay, the Subsidy Program would shift close to 100 percent of the drug expense to the Medicare program.
- OIG also emphasized the dim view it seems to be taking of pharmaceutical manufacturer assistance programs generally, pointing to enforcement actions totaling more than $900 million against ten manufacturers and four foundations "for conduct solely involving the allegedly illegal use of foundations that operate patient assistance programs as conduits for improper payments to patients."[1]

- Although AdvOp 20-05 redacts the names of the drug and the manufacturer, publicly available information strongly suggests the drug is tafamidis and tamafidis meglumine, used to treat cardiomyopathy caused by transthyretin amyloidosis (ATTR-CM) and launched by Pfizer in 2019 for an annual list price of $225,000, a price described by physicians as "not justified and … a particularly egregious example of price gouging."
- **Key Takeaway:** OIG's complete rejection of Pfizer's patient assistance program is understandable, as the program appears designed not to provide assistance to those unable to pay, but primarily to induce purchases of high priced drugs by eliminating the price sensitivity that cost-sharing requirements under Part D are intended to impose. While this outcome may mark a departure from prior OIG Advisory Opinions protecting patient assistance programs, it is entirely consistent with the current Administration's efforts to combat drug prices that appear to bear no rational relationship to production costs.

Contacts

Mark S. Hedberg
mhedberg@HuntonAK.com

James M. Pinna
jpinna@HuntonAK.com

Holly E. Cerasano
hcerasano@HuntonAK.com

Matthew D. Jenkins
mjenkins@HuntonAK.com

Elizabeth A. Breen
ebreen@HuntonAK.com

Kurt G. Larkin
klarkin@HuntonAK.com

[1] AdvOp 05-20 at 13. "Central to these allegations is a concern that pharmaceutical manufacturers blunt the impact of patient cost sharing to induce patients to fill prescriptions for costly medications."