August 11, 2020

- **Lesson 2 from the Novartis settlements: Whether here or abroad, using payments for services that were never rendered as a means to reward prescription-writing is prohibited.**
    - There are several lessons to be learned from the recent settlements between the Department of Justice ("DOJ") and Novartis Pharmaceuticals Corporation ("Novartis"). Last week we discussed the first lesson: how not to use charitable foundations to cover patient copayment obligations. This week, we discuss the second: whether here or abroad, using payments for services that were never rendered as a means to reward prescription-writing is prohibited.
    - On July 1, 2020, DOJ announced a settlement with Novartis requiring it to pay $678 million to resolve a False Claims Act ("FCA") suit alleging that its speaker programs and other promotional events were used as vehicles to bribe doctors.
        - From 2002 through 2011, Novartis allegedly hosted tens of thousands of speaker programs and related events under the guise of providing educational content when, in fact, the events served as nothing more than a means to funnel money to doctors for writing prescriptions for Novartis drugs. DOJ alleged that Novartis purportedly paid physicians as compensation for delivering lectures regarding a Novartis drug. But many of the programs were either nonexistent or nothing more than social events held at expensive restaurants, with little or no talk about the Novartis medication.
    - Additionally, on June 25, 2020, DOJ announced that Novartis will pay $234 million to DOJ and $113 million to the U.S. Securities and Exchange Commission to settle Foreign Corrupt Practices Act ("FCPA") probes relating to incredibly similar conduct in Greece and other countries. As part of this settlement, DOJ alleged that between 2012 and 2015, Novartis Greece conspired with others to violate the FCPA. Specifically, Novartis Greece bribed doctors and other employees of state-owned and state-controlled hospitals and clinics by paying for their travel to international medical congresses in exchange for increasing the number of prescriptions they wrote for Lucentis, a prescription drug that Novartis Greece sold.
    - **Key Takeaway:** The conduct alleged in these two cases was particularly brazen. To increase sales of its drugs, Novartis allegedly paid physicians to speak at fictitious educational programs or paid for their travel to international meetings with no legitimate basis for doing so. Such conduct is an obvious violation of U.S. statutes and will garner the attention of whistleblowers, the relators bar and U.S. enforcement officials (the qui tam relator in the FCA case was a former Novartis sales representative). While physicians can be paid (at fair market value) to deliver substantive educational programs, these settlements demonstrate that DOJ will devote significant resources under the Medicare/Medicaid anti-kickback law, the FCA, and the FCPA (among others), to stamp out such conduct.
- **The elimination of the Medicare Inpatient Only List ("IPO List") and expansion of the ASC Covered Procedures List ("ASC CPL") may enhance site of service flexibility and reduce beneficiary out-of-pocket costs, but are likely to create headaches as well.**
    - The Centers for Medicare & Medicaid Services ("CMS") published its Calendar Year 2021 Outpatient Prospective Payment System/Ambulatory Surgery Center Payment System proposed rule (the "2021 Proposed Rule") on August 4, 2020. Among other significant proposals, CMS is proposing to phase out the IPO List by CY 2024, commencing with the removal of some 300 musculoskeletal-related procedures. If the proposal is finalized,

approximately 1,700 additional procedures would become eligible for performance and reimbursement on an outpatient basis.

- CMS simultaneously is proposing to expand the types of procedures eligible for reimbursement when performed in an ambulatory surgery center ("ASC"). For CY 2021, CMS is proposing to add 11 procedures to the ASC covered procedures list ("CPL"), including total hip arthroplasty.

- While the proposed elimination of the IPO List and expansion of the ASC CPL are designed to increase site of service flexibility and reduce out-of-pocket costs, the elimination of the IPO List, in particular, presents challenges. Some stakeholders have expressed concern that elimination of the IPO List could increase risks of surgical complications and reduce quality of care. Elimination of the IPO List also could create headaches under the "two-midnight rule."

  - Originally established by CMS for the 2014 fiscal year, the two-midnight rule generally considers a patient appropriate for inpatient admission and reimbursement under Medicare Part A if the patient is admitted based on an expectation that the patient's hospital stay will cross at least two midnights. Significantly, procedures listed on the IPO List are excepted from the two-midnight rule and associated medical review, and are reimbursed under Medicare Part A regardless of the expected length of stay.

- In recognition that removal of procedures from the IPO List could cause confusion under the two-midnight rule, CMS established a policy to exempt procedures removed from the IPO List from certain referrals to Recovery Audit Contractors ("RACs") and from RAC "patient status" (*i.e.*, site of service) review. The goal of the two-year exemption is to provide for education of practitioners and providers about the two-midnight rule requirement without denying noncompliant claims with respect to site of service.

- As part of the 2021 Proposed Rule, CMS is proposing to retain the two-year exemption. It also is seeking comments on whether the period should be longer or shorter in light of the sheer number of procedures that would ultimately be subject to the two-midnight rule if the IPO List were eliminated. The deadline for submitting comments on the proposed rule is October 5, 2020.

- **Key Takeaway: The** elimination of the IPO List could create challenges under the two-midnight rule and result in site of service claim denials, referrals to RACs and RAC reviews. To the extent the proposal is finalized, practitioners and providers should utilize any associated exemption period to educate themselves on the two-midnight rule compliance and establish systems, policies and procedures to maintain compliance.

- **As states move to establish their own coronavirus-related liability shields for businesses, the future of a federal liability shield remains uncertain; however, proposed legislation provides valuable insight into how businesses may prepare for potential coronavirus-related liability actions down the road.**

  - Senate Republicans recently introduced the "Safeguarding America's Frontline Employees to Offer Work Opportunities Required to Kickstart the Economy Act" or the "SAFE TO WORK Act" (hereinafter, the "Act"). The purpose of the Act is "[t]o lessen the burdens on interstate commerce by discouraging insubstantial lawsuits relating to COVID-19 while preserving the ability of individuals and businesses that have suffered real injury to obtain complete relief."

- The Act seeks to protect individuals and entities "engaged in businesses, services, activities, or accommodations" from coronavirus exposure actions. The Act would require the plaintiff in a coronavirus exposure action to prove, by clear and convincing evidence, the following:
  - (1) the individual or entity, while engaging in businesses, services, activities, or accommodations, was not making reasonable efforts in light of all the circumstances to comply with applicable government standards and guidance in effect at the time of the actual, alleged, feared, or potential for exposure to coronavirus;
  - (2) the individual or entity engaged in gross negligence or willful misconduct that caused an actual exposure to coronavirus; and
  - (3) actual exposure to coronavirus caused the personal injury to the plaintiff.
- The Act describes the circumstances under which an individual or entity is presumed to have taken "reasonable efforts to comply" with applicable government standards and guidance, and explains how the plaintiff can rebut such presumption.
- Although the Act's likelihood of passing the House and Senate in its current form is minimal, its provisions regarding "reasonable efforts to comply" shed some light on how businesses may prepare for potential coronavirus exposure actions in the future.
  - Businesses must have a firm understanding of all applicable federal, state, and local requirements regarding limiting exposure to and transmission of COVID-19.
  - Businesses should confirm that there are written policies and procedures in place regarding exposure to and transmission of COVID-19 that are consistent with applicable government standards and guidance. If businesses amend their written policies and procedures, businesses should document how such changes comply with applicable government standards and guidance.
- **Key Takeaway**: In the face of ever-evolving federal, state, and local requirements regarding limiting exposure to and transmission of COVID-19, maintaining and updating written policies and procedures otherwise documenting compliance efforts and rigorously applying estabished compliance mechanisms, should be helpful to warding off potenital coronavirus-related liability actions in the future.

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