THREE KEY THINGS IN HEALTH CARE

HUNTON ANDREWS KURTH

August 4, 2020

- **Lesson 1 from the Novartis settlement: how not to use charitable foundations to cover patient copayment obligations.**
    - There are several lessons to be learned from the recent settlements between the Department of Justice ("DOJ") and Novartis Pharmaceuticals Corporation ("Novartis"); the first is that the line between charitable acts and a False Claims Act violation is being actively policed.
    - Can nonprofits be used to pay copayments appropriately? Yes. When structured properly, a charitable organization can remove insurance barriers by helping qualified patients afford co-payments, coinsurance, and deductibles in order to access medical treatments. Several 501(c)(3) co-payment assistance foundations exist to provide just this service.
    - Over the past two years, however, DOJ has been looking closely at the relationships between pharmaceutical companies and co-payment assistance foundations.[1] A July 1, 2020 Novartis settlement agreement lays out a scheme in which Novartis allegedly coordinated with three foundations to funnel money through the foundations to patients to cover their co-pays on Novartis's drugs Gilenya–used to treat multiple sclerosis–and Afinitor–used to treat advanced renal cell carcinoma and progressive neuroendocrine tumors of pancreatic origin.
        - In each case, Novartis allegedly structured support for the foundations involved in a manner designed to ensure that Novartis's funding would disproportionately go to Medicare patients taking Gilenya or Afinitor.
        - According to DOJ, Novartis's conduct no longer qualified as charitable based on the arrangement. Instead, DOJ alleged that Novartis and the foundations carried out a scheme to pay kickbacks to Medicare patients (in the form of targeted copayment assistance), illegally subsidizing the high costs of Novartis's drugs, undermining the structure of the Medicare program and eliminating the high cost of Novartis drugs as a consideration of the affected patients.
        - Although the settlement agreement contained no admission of liability, Novartis agreed to pay $51.25 million to settle the allegations.
    - **Key Takeaway:** Foundations providing assistance with copayments and other financial obligations of needy Medicare patients must operate in an independent and neutral fashion. Coordination with pharmaceutical manufacturers regarding timing, eligibility or other factors designed to steer support payments disproportionately to patients taking the manufacturers' drug(s) implicates the Medicare anti-kickback law and the False Claims Act, and risks direct enforcement action by DOJ or a complaint filed by a *qui tam* relator.

[1] https://www.justice.gov/usao-ma/pr/third-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay-kickbacks; https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid; https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks

- **Covered entities and their business associates need to remain vigilant about HIPAA compliance, even in the midst of the COVID-19 pandemic.**
  - Two recent settlements announced by the U.S. Department of Health and Human Services Office for Civil Rights ("OCR") reflect that OCR remains willing to extract monetary settlements from covered entities to settle allegations of HIPAA violations.
    - On July 23, 2020, OCR announced that a federally qualified health center ("FQHC") in rural North Carolina had agreed to pay $25,000 and enter into a corrective action plan to settle potential violations of the HIPAA Security Rule. The settlement stemmed from a breach involving the disclosure of protected health information ("PHI") to an unknown email account affecting 1,263 patients. OCR's investigation revealed longstanding, systematic noncompliance at the center, including a failure to conduct any risk analyses, failure to implement required policies and procedures, and the failure, prior to 2016, to provide security awareness training to its workforce. Although the settlement's dollar value may be relatively small, OCR specifically observed that the entity's status as a FQHC factored into the settlement.
    - On July 27, 2020, OCR announced that Lifespan Health System Affiliated Covered Entity ("Lifespan ACE"), a Rhode Island-based nonprofit health system, had agreed to pay $1.04 million and enter into a corrective action plan to settle potential violations of the HIPAA Privacy and Security Rules stemming from a breach involving a stolen laptop. The laptop contained unencrypted electronic PHI ("ePHI") on some 20,431 individuals. OCR's investigation revealed systematic noncompliance, including failure to encrypt ePHI on laptop computers, lack of device and media controls, and a failure of the Lifespan ACE to have in place business associate agreement ("BAA") with its parent company.
  - Although these settlements predate the COVID-19 pandemic, they serve as a reminder that in the midst of the current public health emergency, with substantially more workforce members potentially working remotely, covered entities and their business associates ("BAs") must remain vigilant about HIPAA compliance.
  - While the COVID-19 pandemic has prompted OCR to exercise its enforcement discretion to not impose penalties for noncompliance with certain HIPAA regulatory requirements, the scope of this relief is relatively narrow:
    - good faith provision of telehealth services using any non-public facing remote communication product, whether or not the telehealth service was provided to diagnose or treat COVID-19;
    - failure to enter into BAAs with video communication vendors in connection with the good faith provision of telehealth services during the COVID-19 nationwide public health emergency;
    - good faith uses and disclosures of PHI by BAs for public health and health oversight activities during the COVID-19 nationwide public health emergency; and
    - good faith participation in the operation of Community Based-Testing Sites ("CBTS"), including mobile, drive-through, or walk-up sites that only provide COVID-19 specimen collection or testing services to the public.

© 2020 Hunton Andrews Kurth LLP

- **Key Takeaway:** OCR's exercise of its enforcement discretion is designed to facilitate certain uses and disclosures of PHI in very narrow circumstances in response to the COVID-19 pandemic. Covered entities and their BAs must continue to remain vigilant about HIPAA compliance, even as resources are redirected in response to the public health emergency.

- **Additional signs are pointing towards affiliations between payors and providers.**
  - COVID-19 continues to have disparate impacts on providers and payors, with most providers continuing to experience some level of financial distress while payors are reporting robust profits. UnitedHealth Group recently reported second quarter net income of nearly double the amount for the same period last year.
  - UnitedHealth Group's Optum division also announced that it had finalized a partnership with Boulder Community Health in Colorado to take over back-end administrative functions. Optum announced a similar partnership with John Muir Health in California last year and has multiple health system partnerships through its Surgical Care Affiliates subsidiary.
  - The benefits of these provider-payor affiliations have become more manifest with COVID-19. Health plans can help diversify financial risk for health systems and provide greater resources in responding to pandemics and population health issues more broadly. Payors have also recognized the benefits of a provider platform in managing costs for insured populations, as evidenced by UnitedHealth Group's significant investment in its provider-focused Optum division.
  - The spike in payor profits, driven by reduced utilization of non-urgent health care services, is also temporary and likely to be equipoised with a future spike in health care costs that inevitably comes as a result of patients deferring or delaying care. Payors that have partnered with health systems will be better positioned to manage this future risk and might also be better equipped to prevent the most harmful deferrals of patient care.
  - **Key takeaway:** COVID-19 has further underscored the ways in which both providers and payors can benefit from affiliations and we should expect more provider-payor affiliations going forward in an effort to manage both financial and population health risks.

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

Sean B. O'Connell
soconnell@HuntonAK.com

© 2020 Hunton Andrews Kurth LLP. Attorney advertising materials. These materials have been prepared for informational purposes only and are not legal advice. This information is not intended to create an attorney-client or similar relationship. Please do not send us confidential information. Past successes cannot be an assurance of future success. Whether you need legal services and which lawyer you select are important decisions that should not be based solely upon these materials.