Robinson+Cole

Health Law Diagnosis

Monitoring the Pulse of Health Care and Life Sciences

October 24, 2023

The Robinson+Cole Health Law Group is committed to examining and reporting on issues important to the health care and life sciences industries. For more updates on news and developments for the health care and life sciences industries, we invite you to subscribe to our Health Law Diagnosis *blog.*

DEA Further Extends COVID-19 Telemedicine Prescribing Flexibilities through December 31, 2024

Authored by: Conor O. Duffy

On October 10, 2023, the federal Drug Enforcement Administration (DEA) issued another extension (Second Temporary Rule) of its pandemic-era telehealth flexibilities "in light of the need to further evaluate the best course of action" with respect to the prescribing of controlled substances via telemedicine. DEA is issuing a limited extension in order to give itself more time to finalize new standards governing tele-prescribing of controlled substances.

The Second Temporary Rule makes key updates to provisions of the First Temporary Rule (which we analyzed here) as follows:

- Under the First Temporary Rule, DEA extended all pandemic-era flexibilities for the prescription of controlled substances based on a practitioner-patient relationship established via telemedicine through November 11, 2023, thus allowing practitioners and patients to form new relationships involving the prescription of controlled substances via telemedicine (i.e., without an in-person medical evaluation) through that date.
    - This Second Temporary Rule extends the period during which new practitioner-patient relationships involving the prescription of controlled substances may be formed via telemedicine through December 31, 2024.
- Under the First Temporary Rule, DEA established a one-year grace period – until November 11, 2024 – for those established (as of November 11, 2023) practitioner-patient relationships to continue via telemedicine before an in-person visit was required to permit continued prescribing of controlled substances via telemedicine.
    - Because the Second Temporary Rule extends the effective date of the regulatory flexibilities through December 31, 2024, DEA notes that this effectively "subsume[s]" the previous grace period and it is no longer necessary.

During the period of the Secondary Temporary Rule's extension, controlled substance prescribing via a telemedicine relationship will continue to be required to meet the standards set forth in the First Temporary Rule, including that each prescription be issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice, and must be issued pursuant to an interactive audio-video telecommunications system (or audio-only for certain mental health and buprenorphine prescribing if the patient does not consent to video).

DEA explains that this Second Temporary Rule is necessary "to ensure a smooth transition for patients and practitioners" who are reliant on telemedicine for access to care, and to allow providers "adequate time… to come into compliance" with new regulatory requirements. DEA is seeking to balance the public health benefits associated with continued access to care and controlled substance treatment via telemedicine, including the urgent public health need for continued buprenorphine access amidst an ongoing opioid epidemic, against the

risk of diversion and entrenchment of practices by telemedicine companies that "might encourage or enable problematic prescribing practices."

DEA projects that it will promulgate new standards and safeguards "by the fall of 2024."

OIG Issues Favorable Opinion Regarding Physician Group's Proposal to Pay Bonuses to its Employed Physicians Based on Net Profits

Authored by: Michael G. Lisitano and Nathaniel T. Arden

On October 13, 2023, the Office of Inspector General (OIG) published Advisory Opinion 23-07 (Advisory Opinion), in which the OIG issued a favorable opinion regarding a physician group employer's proposal to pay bonuses to its employed physicians based on net profits derived from certain procedures performed by the physicians at ambulatory surgery centers.

Proposed Bonus Arrangement

In the Advisory Opinion, the requestor was a multi-specialty physician practice group (the "Group") that provided services through its physician employees, and which services included those for which payment was made by federal health care programs. Under the proposed arrangement, the Group would pay its physician employees a bonus, in addition to the physicians' base compensation. The bonus would be equal to 30 percent of the Group's net profits derived from two ambulatory surgical centers' facility fee collections attributable to that physician's procedures. Those procedures could include procedures referred to the ambulatory surgery center by the performing physician. The two ambulatory surgical centers in question would be operated as "divisions" of the Group and not as separate legal entities. The bonus due to the physician employees would be calculated on a quarterly basis.

OIG Analysis

According to the OIG, because the physician employees would receive a bonus payment for each surgical procedure performed at a Group ambulatory surgical center, and procedures may be referred to such facility by the employee physician and reimbursable by a federal health care program, the Anti-Kickback Statute is implicated.

However, the OIG determined that the proposed bonus arrangement is protected by the bona fide employee statutory exception and regulatory safe harbor of the Anti-Kickback Statute and would therefore not generate prohibited remuneration. The OIG concluded that because (1) each of the physicians eligible for a bonus is a bona-fide employee of the Group, and (2) the bonus compensation is an amount paid by an employer to a bona fide employee for furnishing a reimbursable item or service, the employee exception and safe harbor to the Anti-Kickback Statute would be satisfied.

Notably, the OIG differentiated the Group's proposed arrangement from similar arrangements where the physicians had an ownership interest in the ambulatory surgical centers and received the bonus described in this Advisory Opinion. The OIG reasoned that such bonuses "may raise fraud and abuse concerns under the Federal anti-kickback statute," and in the case of physician ownership of the ambulatory surgical center, the bona fide employee exception and safe harbor would likely not apply. Additionally, OIG made a general statement that "[p]ayment structures that tie compensation to profits generated from services furnished to patients referred by the compensated party are suspect under the Federal anti-kickback statute" making clear that the proposed bonus arrangement was only acceptable because of its ability to satisfy a statutory exception and regulatory safe harbor.

Finally, the Group certified that it would not provide any designated health services, and that the proposed arrangement would not implicate the Physician Self-Referral Law (known as the Stark Law).

Key Takeaways

Physician bonus compensation arrangements are often the subject of fraud and abuse law scrutiny, particularly when tied to physician referrals. Notwithstanding, OIG's analysis in the Advisory Opinion demonstrates that when properly structured to comply with statutory exceptions and regulatory safe harbors, certain bonus compensation arrangements of this sort may be permissible. As bonus compensation remains a prevalent and important method of physician employee incentivization and retention, this Advisory Opinion is an important reminder for health care provider entities to ensure compensation arrangements are properly structured to comply with fraud

and abuse laws.

As the OIG has emphasized, its Advisory Opinions are issued only to the requestors of the opinion, and have no application to, and cannot be relied upon by, any individual or entity, nor may they be introduced into evidence by anyone other than the requestors to prove the individual or entity did not violate the anti-kickback statute or any other law.

If you have any questions, please contact any member of Robinson+Cole's Health Law Group.

Lisa M. Boyle **(Chair)** | Nathaniel T. Arden | Conor O. Duffy | Kathleen G. Healy | Leslie J. Levinson

Danielle H. Tangorre | Melissa (Lisa) Thompson | Theodore J. Tucci | Patricia D. Weitzman

Yelena Greenberg | Michael G. Lisitano | Peter H. Struzzi | Erin C. Turkis

Above is a post from our *Health Law Diagnosis* blog, where we post on fraud and abuse, government enforcement, Medicare and Medicaid, reimbursement, hospitals and health systems, pharmaceuticals, medical devices, and other areas of interest.

For more updates on news and developments for the health care and life sciences industries, we invite you to subscribe.

Boston | Hartford | New York | Washington, DC | Providence | Miami
Stamford | Wilmington | Philadelphia | Los Angeles | Albany | **rc.com**