PUBLICATION

OIG Approves Smartphone Loaner Program in Advisory Opinion 19-02

February 2019

The Office of Inspector General (OIG) approved in Advisory Opinion 19-02 a pharmaceutical manufacturer's proposal to implement a loaner program involving limited functionality smartphones containing technology that is integral to optimizing patients' adherence to a medication prescribed for specific disorders. The OIG, relying heavily on the safeguards inherent in the proposal, determined that the program satisfied the Promotes Access to Care Exception to the civil monetary penalty prohibition against beneficiary inducements. The OIG separately considered the application of the Anti-Kickback Statute, but concluded that, based on the safeguards, it would not impose sanctions under the Anti-Kickback Statute.

In the arrangement, a pharmaceutical manufacturer proposed to loan limited-functionality smartphones to patients meeting certain criteria who were also prescribed the digital medicine version of one of the manufacturer's drugs. Medication adherence would be tracked through a sensor in the drug that could be detected by a smartphone application (app). The loaner program would provide phones to patients who did not otherwise have a compatible smartphone, to allow them to use the drug effectively. The loaner smartphones would have all functionality disabled except for the app and telephone call capability. The arrangement would not be advertised to patients, although physicians would be informed about the existence of the program. It would be available only to patients meeting income restrictions who do not have a cell phone capable of running the app. Patients could keep the loaner smartphones for no more than two 12-week periods, which would cover the expected 8 – 12 week duration of their drug therapy.

The OIG made reference to the difference in scope between the beneficiary inducement CMP and the Anti-Kickback Statute in a footnote. While the program was operated by the pharmaceutical manufacturer, the analysis under the beneficiary inducement CMP focused on the possibility that the program might influence the patient's choice of pharmacy. The beneficiary inducement CMP is limited to the selection of a particular provider, practitioner, or supplier. It does not apply to selection of a pharmaceutical manufacturer or the selection of a particular drug. The OIG continues to analyze the arrangement under the Anti-Kickback Statute because its broader scope applies to economic benefits that might influence the selection of a pharmaceutical manufacturer or the selection of a particular drug.

The OIG determined the arrangement would pose a low risk of harm because the arrangement (i) was unlikely to interfere with clinical decision making, (ii) was unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilizations, and (iii) would not raise patient safety or quality of care concerns. The OIG opined that the ability to transmit data might be a factor in a practitioner's decision to prescribe the digital medicine drug at issue, but concluded that a prescriber's decision was not likely to be skewed based on the loaner program. With little effect on prescribing patterns, and with no advertising to patients, the OIG concluded the arrangement was unlikely to increase costs due to inappropriately increased utilization. The OIG concluded that for the same reasons it would not impose sanctions under the Anti-Kickback Statute.

Takeaways of the OIG's Analysis

Most previous analyses of the Promotes Access to Care Exception to the beneficiary inducement CMP have involved meals, lodging or transportation. Thus, Advisory Opinion 19-02 adds a new category of items or services that the OIG may find, under appropriate circumstances, to meet the exception. The analysis seems somewhat results-oriented. For example, the OIG emphasized that the smartphone's limited functionality was critical to its approval of the arrangement. While the OIG noted that the smartphone could be used for regular calls, the OIG cited statistics that 95 percent of Americans have some sort of cell phone. However, the OIG did not mention that those who would be eligible for the program would likely include individuals among the five percent without a cell phone.

The OIG continues to suggest the analysis under the Anti-Kickback Statute could differ from the analysis under the Promotes Access to Care Exception to the beneficiary inducement CMP. However, Advisory Opinion 19-02 is another example of the OIG applying the same basic analysis under both laws.

For assistance with understanding the Anti-Kickback Statute, contact any member of the Baker Ober Health Law Team.