HINSHAW

Alerts

OIG Advisory Opinion 22-08 Permits a Federally Qualified Health Center to Provide Smartphones to Patients to Promote Access to Telehealth and Social Isolation/Loneliness Benefits

May 20, 2022
Health Care Alert

Attorneys

Michael A. Dowell

Telehealth—the provision and coordination of healthcare remotely by means of telecommunications technology—is now an essential tool in the delivery of health care services. The COVID-19 pandemic created an incentive for federally qualified health centers (FQHCs) to quickly adopt telemedicine, eVisits, Virtual Check-Ins, remote patient monitoring, and other forms of virtual care. Medicare Advantage Plans and State Medicaid Managed Care Plans have recently added benefits that address social isolation//loneliness to combat feelings of isolation that can create emotional distress that exacerbates health conditions and may result in early mortality.

The Proposed Arrangement

The U.S. Department of Health and Human Services' Office of Inspector General (OIG) recently issued Advisory Opinion 22-08 which allowed a FQHC to provide free smartphones to its existing patients to expand access to telehealth services and address social isolation/loneliness issues by enabling patients to talk and text with others. The FQHC serves a low-income population where 94 percent of its patients have incomes below 200 percent of the federal poverty level—including Federal health care program Medicare and Medicaid beneficiaries—and offers telehealth services to its patients through a telehealth application that can be downloaded on a smartphone.

The FQHC loaned approximately 3,000 limited-use smartphones and chargers on a first-come, first-served basis to existing FQHC patients who did not have a device capable of running the application required to access telehealth services from the FQHC (hereinafter referred to as the "Arrangement"). The Arrangement was not advertised or made available to new patients, and the smartphones loaned under the Arrangement are "locked," meaning they restrict use to making and receiving telephone calls, sending and receiving text messages, using the telehealth application used by the FQHC, and viewing the respective patient's medical records. All other functionality commonly associated with smartphones would be disabled, including video streaming apps, music streaming apps, the camera, games, internet browsers, and the ability to download additional apps. The FQHC certified that the purposes of the Arrangement are to enable patients to access medically necessary health care

©2024 Hinshaw & Culbertson LLP

services that Medicare and the State Medicaid Program currently cover.

The smartphones and related voice and data services for 12-months were funded by a Federal Communications Commission (FCC) COVID-19 Telehealth grant program and a grant from a local charity. The FQHC used its own funds to provide voice and data service for two months after the initial voice and data services funding expired. Thereafter, it required FQHC patients participating in the Arrangement to secure their own voice and data services via direct payment or submission of applications for voice and data services funding under the FCC's Affordable Connectivity Program. The patients were required to return the smartphones if they were no longer receiving services (e.g., they relocated from the FQHC's service area or did not obtain services from the FQHC in the prior 24 months).

The OIG stated that the Arrangement would implicate both the Civil Monetary Penalties Law (CMPL) on Beneficiary Inducements and the federal Anti-Kickback Statute (AKS) because the free smartphones and chargers could motivate patients to obtain items and services from the FQHC that are reimbursable by Medicare and/or Medicaid and could motivate patients to select the FQHC as their primary care provider.

Beneficiary Inducements Civil Monetary Penalty Legal Analysis

The CMPL on Beneficiary Inducements provides for the imposition of civil monetary penalties and/or exclusion from Federal health care programs against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program.

Section 1128A(i)(6) of the Social Security Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value." Section 1128A(i)(6) of the Social Security Act contains an exception to the definition of "remuneration" that may apply in the context of the Arrangement. Section 1128A(i)(6)(F) of the Social Security Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not include remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs" (the "Promotes Access to Care Exception").

The Promotes Access to Care Exception to the Beneficiary Inducements CMPL is applicable to items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs because it is: (i) unlikely to interfere with, or skew, clinical decision making; (ii) unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns.

The OIG analyzed the Arrangement and concluded that it satisfied the Promotes Access to Care Exception for the following reasons:

- Promotes Access to Care. The OIG noted that because the Arrangement is only applicable to low-income persons, the Arrangement may remove socioeconomic barriers to accessing telehealth services. Additionally, the FQHC would utilize smartphones only for patients who do not already have a device capable of running the telehealth application required to access telehealth services from the FQHC. Those safeguards—in combination with the fact that the telehealth services the FQHC offers to patients via the smartphones are currently covered by Medicare and the State Medicaid Program—were the basis of the OIG's conclusion that the smartphones and chargers improve the ability of patients who are Medicare or Medicaid beneficiaries to access telehealth services during the Public Health Emergency ("PHE");
- No Interference with Clinical Decision Making. The OIG concluded that the FQHC's provision of the limited-use smartphones and chargers to eligible patients did not appear likely to interfere with clinical decision-making due to the limited value of the smartphone and the restrictive eligibility requirements;
- Does Not Promote Overutilization or Inappropriate Utilization. While the Arrangement may result in increased utilization of telehealth services, there is nothing in the Arrangement to suggest that any such increase in utilization would be inappropriate. The Arrangement is limited tto existing patients, and each patient is required to receive only one service from the FQHC over a 24-month period to retain the smartphone, which mitigates the risk of overutilization

©2024 Hinshaw & Culbertson LLP

- or inappropriate utilization. Those safeguards—in combination with the limited functionality of the smartphones and the requirement for patients to secure funding for voice and data services through a source other than FQHC—reduce the risk that patients will seek out services from the FQHC solely to maintain use of a loaned smartphone under the Arrangement; and
- No Patient Safety or Quality of Care Concerns. The OIG concluded that the Arrangement does not create patient safety or quality-of-care concerns because the use of telehealth services during the public health emergency may promote patient safety and quality of care by allowing patients to seek health care services without coming into physical contact with providers, staff, and other Additionally, nothing in the Arrangement suggests that Requestor would provide telehealth services when doing so could pose patient safety or quality-of-care concerns.

Federal Anti-Kickback Statute Legal Analysis

The Federal Anti-Kickback Statute (AKS) makes it a criminal offense to knowingly and willfully offer or receive remuneration in an effort to induce or reward referrals of items or services reimbursable by federal health care programs. The Arrangement does not satisfy a safe harbor to the AKS. However, based on the combination of the following safeguards present in the Arrangement, the OIG concluded that the Arrangement presents no more than a minimal risk of fraud and abuse under the AKS:

- The Smartphones Were Provided by An Entity with No Financial Interest. The FQHC Requestor received funding from the FCC and the Local Charity—both entities with no financial interest in patients receiving services from Requestor—to purchase smartphones needed to provide telehealth services in response to the PHE;
- Compliance with Grant Requirements. The FQHC certified that it used the funding in compliance with all requirements imposed by the FCC and the Local Charity in connection with receiving the funding; and
- Does Not Promote Overutilization or Inappropriate Utilization. There is nothing in the facts to suggest that—after the PHE has ended—the FQHC will use the smartphones to inappropriately increase the utilization of federally reimbursable services from

Key Takeaways and Issues to Consider

The OIG concluded that the Arrangement did not constitute grounds for Civil Monetary Penalties. And that although the Arrangement could cause remuneration under the AKS, the OIG would not impose sanctions on the FQHC regarding the Arrangement based on its low-risk nature. OIG Advisory Opinions are limited in scope and duration to their facts and circumstances and can only be relied upon by the specific company that requested the advisory opinion. Thus, companies that wish to provide health care technology to patients utilizing the "Promotes Access to Care Exception" should consult with competent counsel.

Key Takeaways

Notwithstanding the above, the OIG's analysis (i) demonstrates the OIG's willingness to remove barriers to the adoption of health care technology that improves access to care for low-income patients; (ii) provides guidance to FQHC's considering arrangements to increase access to telehealth services; and (iii) provides insight into the OIG's view on how and when health care technology can promote access to care as well as the safeguards required to qualify for the "Promotes Access to Care Exception."

Other key takeaways from Advisory Opinion 22-08 include:

- Not Limited to the PHE. The OIG stated that it would not impose sanctions on the arrangement even if the PHE ended, and the telehealth services would no longer be covered by Medicare and Medicaid because the factors listed above sufficiently reduced the risks of improper beneficiary inducement.
- Smartphone Functionality. In OIG Advisory Opinion 19-02, the OIG approved an arrangement by a pharmaceutical manufacturer to loan smartphones to low income patients to track medication adherence. However, the smartphones were locked in a manner to prohibit texting. Advisory Opinion 22-08 allowed the loaned smartphones to be utilized for

©2024 Hinshaw & Culbertson LLP

texting.

- Use of the Promotes Access to Care Exception Criteria for AKS Analysis. The OIG relied on the Promotes Access to Care exception analysis under the CMPL's beneficiary inducement prohibition in its analysis of the AKS. This suggests that the factors set forth in the Promotes Access to Care exception should be considered when analyzing the risk of an arrangement that implicates the AKS but does not meet an AKS safe harbor.

Issues to Consider

Medicaid social isolation/loneliness benefits often use smartphones and other health care technology to provide services to patients. A key issue to consider is the fact that the OIG Analysis did not include any discussion of smartphone use to combat social isolation/loneliness. Thus, we do not know if the OIG would have permitted the FQHC to provide the smartphone for that purpose alone.

Likewise, one must consider whether the OIG would have approved the Arrangement if the FQHC paid for the smartphones directly (or for the patient's voice and data plans) rather than having them paid for by a third party with no financial interest.

Hinshaw health care law attorneys have significant experience in advising FQHCs and other health care organizations on licensure and federal qualification, nonprofit governance, Section 330 Public Health Service Act compliance, the Section 340B pharmacy discount program, mergers, acquisitions, joint ventures, affiliations, tax-exempt bond financing, tax-exempt organization regulation and policy, political activity and federal election campaign law, business transactions, general contracts and agreements, healthcare regulatory, fraud and abuse, data privacy and cyber security, reimbursement and operational issues.

©2024 Hinshaw & Culbertson LLP