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Client Alert: Good News for Hospitals and Providers Seeking to Assist Patients

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Hospital systems and other health care providers often desire to assist their patients who are burdened with bills that the patients cannot pay or to alleviate other access challenges. In the past few months, the Department of Health and Human Services Office of Inspector General (OIG) has published advisory opinions that give hope to those providers who wish to lend a greater helping hand to patients in need.

It should be noted that there are limits on the applicability of advisory opinions, and one should discuss these opinions with experienced health care counsel before proceeding on any creative mission.

We are providing the following synopsis of several potentially relevant advisory opinions. In some cases, we have quoted from the OIG advisory opinion.

OIG Advisory Opinion 22-08

In Advisory opinion 22-08 (dated April 22, 2022), the OIG was requested to provide an opinion regarding the provision of limited use smartphones to patients. The Requestor stated that the arrangement would be as follows:

Requestor is a federally qualified health center that serves predominantly low-income individuals, including Federal health care program beneficiaries. Requestor offers telehealth services to its patients through a telehealth application that can be downloaded on a smartphone. The patients currently in possession of a loaned smartphone are the only patients who are or will participate in the Arrangement, and the smartphones currently being used by those patients are the only smartphones involved in the Arrangement (i.e., the Arrangement is not available to new patients, and Requestor will not loan any additional smartphones). The smartphones Requestor 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 Requestor, and viewing the respective patient’s medical records. Requestor certified that the purposes of the Arrangement are to enable patients to access health care services via telehealth and to combat social isolation by allowing patients to talk and text with others, including during the coronavirus disease 2019 (“COVID-19”) public health emergency (the “PHE”). Requestor certified that the telehealth services it offers to patients via the limited-use smartphones are medically necessary services that

are currently covered by Medicare and the State Medicaid Program.

A patient can keep the smartphone under the Arrangement as long as Requestor has furnished at least one service to the patient in the prior 24-month period (regardless of whether it was a telehealth service). As a condition of lending the smartphone, Requestor asked patients to return the smartphones if they are no longer receiving services (e.g., they have relocated from the Requestor's service area).

Requestor does not prohibit patients from using the smartphones for telemedicine visits with other health care providers; however, given the smartphones' use limitations, the only telemedicine application patients can use is the one used by Requestor.

The Requestor disclosed that it received funding from the federal government and a local charity to purchase the smartphones. The mission of the local charity was not limited to health care. The funding covered the voice and data use plans for 12 months, and the Requestor covered two additional months. Thereafter, the patient would be responsible for acquiring a data plan.

The OIG noted that such an arrangement could implicate both the Federal anti-kickback statute and the Beneficiary Inducements Civil Monetary Penalty (CMP); OIG stated that it would not impose administrative sanctions on the Requestor.

OIG Advisory Opinion 22-05

A Manufacturer of an investigational therapy device requested an opinion regarding whether Requestor could "pay cost-sharing obligations that Medicare beneficiaries participating in the Study otherwise would owe for Medicare-reimbursable items and services provided during the Study." Requestor would pay these funds to the institution. The availability of cost sharing would not be advertised, but information regarding such would be included in the informed consent documents.

The OIG determined that cost sharing could implicate both the Federal anti-kickback statute and the Beneficiary Inducements CMP, and the OIG would not impose administrative sanctions under those laws.

AG 22-10 (modifying AG 15-14)

The Requestor is a nonprofit that provides resources and support to individuals with a specific disease state. The Requestor asked whether it could cover the costs of current and certain historical MRIs to individuals who meet the current eligibility standards. The Requestor also provides certain clinical cooling and mobility devices to low-income individuals diagnosed with this disease state. The Requestor certified that no donor could influence the selection of individuals, and it does not bill any payor for the items. The distribution of the items is funded by donors who contribute to the Requestor. Some of the donors may include participating provider or suppliers in federal health care programs.

The OIG determined that covering the costs of the MRIs could implicate both the Federal anti-kickback statute and the Beneficiary Inducements CMP, but the OIG would not impose administrative sanctions under those laws.

AG 22-02

Requestor is a nonprofit children's hospital. Two individuals entered into an agreement with the hospital under which the donors would donate to a fund. The individuals are not providers or suppliers of health care items or services. The donation would establish a restricted fund that would subsidize patient bills for families with children who have an established relationship with physicians employed at the hospital. The

fund would pay out-of-pocket costs owed to Requestor by the qualified families. The fund would initially be used for patients of the cancer, cardiac, and neurosurgical programs. The hospital would submit a bill to the relevant payor. For families who qualify under the hospital financial assistance policy, the hospital would apply a financial need reduction, and the fund would pay the remaining amount. The fund would not be advertised. The hospital would not report any unbilled cost sharing as bad debt on cost reports.

The OIG determined that the fund could implicate both the Federal ant-kickback statute and the Beneficiary Inducements CMP, and the OIG would not impose administrative sanctions under those laws.

Therefore, for providers who may wish to assist patients with overcoming financial or other access barriers, these advisory opinions may provide additional avenues for supporting patients. As always, these opinions have limitations, and any provider seeking to implement a creative plan should consult an experienced healthcare lawyer before proceeding.