

March 19, 2020

Alex M. Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Joanne M. Chiedi
Acting Inspector General
Office of Inspector General
U.S. Department of Health & Human Services
330 Independence Avenue, S.W., 5521
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W., 445-G
Washington, DC 20201

Dear Secretary Azar, Ms. Verma and Ms. Chiedi:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) requests that enforcement of the Stark Law and Anti-Kickback Statute be suspended to enable hospitals and health systems to meet the unique and exigent circumstances created by the COVID-19 public health emergency.

The COVID-19 public health crisis is posing unprecedented demands on hospitals and health systems to redeploy existing resources, including physician, paraprofessional and nursing resources from existing service lines to infectious disease, respiratory and pulmonology. As the crisis continues, hospitals are working to *reduce* referrals for other services so they can preserve and expand their capacity to treat COVID-19 patients. As evidenced by recent action authorized by the Health and Human Services (HHS) Secretary and adopted by HHS Office of Inspector General (OIG) with respect to telehealth, current statutory and regulatory restrictions on financial relationships between hospitals and referral sources pose significant legal barriers to rapid adoption of new models of care rendered necessary by the demands of the COVID-19 pandemic on U.S. hospitals.

The AHA urges the HHS Secretary, the Centers for Medicare & Medicaid Services (CMS) Administrator, the Acting IG and the Attorney General to temporarily



suspend enforcement of both the Stark Law, 42 USC 1395nn, and the Anti-Kickback Statute, 42 USC 1320a-7b(b) to enable hospitals to efficiently meet the demands of the public health crisis and compensate referring physicians and their family members.

Stark Law Relief. 42 USC 1395nn prohibits hospitals from billing Medicare for inpatient and outpatient services, as well as other designated health services, delivered on referral from a physician who has a financial relationship with a hospital or an entity affiliated with a hospital and a physician or whose immediate family member has such a relationship. The statute and its implementing regulations exclude from the definition of prohibited financial relationship certain compensation relationships that meet the precise terms of specific prescriptive exceptions. None of those exceptions clearly applies to the exigencies of a public health crisis of uncertain duration when the “fair market value” of a physician’s services may be immeasurable. **By interim final rule with comment period or exercise of its waiver authority, CMS should immediately adopt an exception to the definition of “compensation arrangement” under 42 USC 1395nn for any compensation paid to a physician or a physician’s immediate family member in return for a service necessary to the hospitals response to the COVID-19 public health crisis.**

Anti-Kickback Statute Relief. Of similar effect, the Anti-Kickback Statute can subject a hospital, a physician, or other vendors on whom the hospital relies for supplies and services to criminal prosecution or administrative sanctions if any remuneration is paid or accepted where any one purpose for the remuneration is deemed to be rewarding or inducing referrals. The statute and implementing regulations promulgated by the HHS OIG exempt certain forms of remuneration, including certain compensation arrangements, from triggering liability if the arrangement meets the precise terms of specific prescriptive exceptions of “safe harbors.” As with the Stark Law, none of those exceptions clearly applies to the exigencies of a public health crisis of uncertain duration when the “fair market value” of a physician’s services may be immeasurable.

OIG, in coordination with the Department of Justice (DOJ), should make clear by whatever means are appropriate that any transaction between hospitals, physicians and other potential referral sources, or any vendor who delivers services and supplies to hospitals, that has as its primary purpose the delivery of supplies or services necessary to the hospital’s response to the COVID-19 public health crisis will not be subject to prosecution or sanctions under the Anti-Kickback Statute or civil monetary penalties law. In addition, similar action should be taken to make clear that hospital support for patients that is necessary in responding to the COVID-19 public health crisis will not be subject to prosecution or sanctions under the Anti-Kickback Statute or civil monetary penalties law. Patients may need assistance with living arrangements and other support in the community in addition to COVID-19 testing and treatment. None of the current safe harbors apply to the exigencies of the current public health crisis.

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During the crisis, hospitals and their various partners on the frontline need to be able to engage in a wide array of transactions – from barter to short-term contracts and leases – without worrying about the niceties of complying with the technical requirements of a particular Stark Law exception or an Anti-Kickback Statute safe harbor. CMS, OIG and DOJ should take immediate steps to eliminate that worry.

We greatly appreciate the leadership you have provided on ensuring our nation's ability to respond to COVID-19, and we look forward to continuing to work with you during this critical time to protect the health of our nation.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President