

Current Status of Waivers of Federal Fraud & Abuse Laws

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Practice Area: Health Law

NOTE: Another Legal Update was published on March 31, please click [here](#) to read.

Health care providers are rising to meet the challenges posed by the COVID-19 pandemic with evolving strategies on the deployment of human and capital resources and innovative delivery models. Those efforts are hindered by the current health care regulatory climate, however, including the complex and often convoluted requirements of the federal Anti-Kickback Statute (AKS) and Physician Self-Referral Prohibitions (Stark). In connection with his March 13, 2020 declaration¹ of a national emergency, President Trump stated that the Department of Health and Human Services would temporarily waive or modify regulations to give healthcare providers “maximum flexibility” to respond to this emergency, and HHS Secretary Alex Azar issued certain waivers and modifications² under Section 1135 of the Social Security Act that same day. While the Secretary’s Section 1135 waiver pronouncement referenced sanctions under Stark, it is important to note that there are no blanket waivers of Stark or AKS enforcement in place as of the writing of this *Legal Update*. Providers must therefore remain vigilant in ensuring compliance with federal healthcare fraud and abuse laws pending further guidance.

Current Status of Fraud & Abuse Waivers

President Trump’s declaration of an emergency under the Stafford Act, combined with the HHS Secretary’s January 31 declaration³ of a public health emergency under the Public Health Services Act, had the effect of authorizing the Secretary to take action under Section 1135 to temporarily waive or modify certain federal Medicare, Medicaid and CHIP requirements to ensure (a) that sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in any emergency area during an emergency period, and (b) that health care providers who provide such services in good faith may be reimbursed for those items and services and exempted from sanctions for noncompliance absent any determination of fraud and abuse. Section 1135 waivers may be granted on a blanket basis or on a case-by-case basis. Secretary Azar’s March 13 pronouncement includes both approaches.

Blanket waivers were issued with respect to numerous federal health care regulatory requirements and offered relief to a number of industry segments including skilled nursing facilities, critical access hospitals, acute care hospitals, and home health agencies. The Secretary has issued additional waivers since March 13 on telehealth and telepsychiatry, among others.

The Secretary's March 13 Section 1135 waiver did not provide any blanket protection against enforcement and sanctions under Stark, however. Instead, the Secretary waived sanctions under Stark on a case-by-case basis "under such conditions and in such circumstances as the Centers for Medicare and Medicaid Services determines appropriate." To date, CMS has not issued specific guidance on the circumstances under which Stark enforcement and sanctions would be waived, leaving providers in a bit of a quandary as to what flexibility, if any, they may have under Stark. In order to benefit from the Secretary's waiver language under Stark, providers currently need to submit a request for an exemption of a specific arrangement, accompanied by a justification for the waiver and the expected duration of that need. CMS has yet to specify any particular form or format for the request. If CMS grants the waiver, providers will be expected to resume compliance with any waived requirements at the end of the emergency period.

Potential Areas of Concern

The Stark law prohibits hospitals from billing the Medicare program for certain "designated health services" that are delivered pursuant to a referral from a physician with whom the hospital has a financial relationship unless the relationship or arrangement meets one of the detailed statutory or regulatory exceptions. Similarly, the AKS exposes various individuals and entities to sanctions and criminal prosecution arising out of an arrangement where remuneration is intended, in whole or in part, to induce or reward referrals of federal healthcare program business. As with Stark, the AKS statute and regulations offer protection from liability in the form of various exceptions and safe harbors. Strict application of the Stark and AKS requirements will inhibit attempts to address the COVID-19 pandemic through nimble, novel and innovative approaches that do not fit within the narrow and precise confines of those exceptions and safe harbors.

For example, provider flexibility would be enhanced by modifying requirements that professional service agreements be in writing; that compensation be consistent with fair market value at a time where there is no adequate paradigm by which the value of services can be determined; that arrangements meet certain minimum term lengths or that compensation be set in advance; and that otherwise make it difficult to modify existing arrangements to adapt to current economic realities. An example of this latter situation involves compensation arrangements that are based on productivity/wRVUs: proceduralists compensated under these models currently face significant loss of earnings as elective procedures are postponed and ambulatory surgery centers face temporary shutdowns. Innovation might also be fostered by modifying or waiving requirements applicable to academic medical centers and their use of volunteer and primary care physicians; and to so-called gainsharing arrangements subject to the CMP that could help align hospital and physician incentives relative to efficient and effective care delivery in the face of increasing strain on hospital resources.

By letter dated March 19, 2020⁴, the American Hospital Association urged HHS Secretary Azar, Acting Inspector General Joanne Chiedi, and CMS Administrator Seema Verma to take immediate steps to suspend enforcement of Stark and AKS in order to enhance the ability of hospitals and health systems to meet the COVID-19 health care emergency. As to Stark, AHA asked CMS to immediately adopt an exception to the definition of "compensation arrangement" for "any compensation paid to a physician or a physician's immediate family member in return for services necessary to the hospital's response to the COVID-19 public health crisis." For the AKS, AHA asked OIG to "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 and 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 the civil monetary penalties law." AHA sent a follow-up letter⁵ to Attorney General William Barr on March 20, 2020, asking that the Department of Justice "announce that it will exercise prosecutorial discretion and will decline to pursue or prosecute" alleged violations of federal fraud and abuse laws for those same activities mentioned in AHA's March 19 letter.

What's Next?

It is widely expected that CMS will address these concerns in the near future, possibly in conjunction with OIG. This response may be in the form of a blanket waiver, website FAQ or possibly the issuance of an interim final rule. For now, health care providers must continue to navigate the minefield posed by federal fraud and abuse laws. Providers are advised to monitor the CMS website and engage legal counsel as they seek to confront the novel coronavirus pandemic with equally novel solutions.

¹ <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>

² <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>

³ <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html>

⁴ https://www.aha.org/system/files/media/file/2020/03/aha-recommends-enforcement-of-stark-law-and-anti-kickback-statute-be-temporarily-suspended-3-20-2020_0.pdf

⁵ https://www.aha.org/system/files/media/file/2020/03/aha-recommends-enforcement-of-stark-law-and-anti-kickback-statute-be-temporarily-suspended-3-20-2020_0.pdf

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