



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency

April 3, 2020

On January 31, 2020, the Secretary issued a determination, pursuant to section 319 of the Public Health Service Act, that a public health emergency resulting from the outbreak of the novel coronavirus disease 2019 (COVID-19) exists and has existed since January 27, 2020 (COVID-19 Declaration).¹ In response to the unique circumstances resulting from the COVID-19 outbreak and the Secretary's COVID-19 Declaration, the Office of Inspector General (OIG) issues this Policy Statement to notify interested parties that OIG will exercise its enforcement discretion not to impose administrative sanctions under the Federal anti-kickback statute² for certain remuneration related to COVID-19 covered by the Blanket Waivers of Section 1877(g) of the Social Security Act (the Act) issued by the Secretary on March 30, 2020 (the Blanket Waivers),³ subject to the conditions specified herein.

The Secretary issued the Blanket Waivers pursuant to section 1135 of the Act to ensure, to the maximum extent feasible, in any emergency area and during an emergency period that (1) sufficient health care items and services are available to meet the needs of individuals in the emergency area enrolled in Medicare, Medicaid, and the Children's Health Insurance Program programs; and (2) health care providers (as defined in section 1135(g) of the Act) that furnish such items and services in good faith, but are unable to comply with one or more of the specified requirements of section 1877 of the Act and regulations thereunder as a result of the consequences of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent the Government's determination of fraud or abuse. The Blanket Waivers effectuate a waiver of certain sanctions that otherwise apply to violations of the physician self-referral law,⁴ if certain conditions are met.

OIG recognizes that, in the current public health emergency resulting from the COVID-19 outbreak, the health care industry must be focused on delivering needed patient care. As part of

¹ See U.S. Department of Health and Human Services, Determination that a Public Health Emergency Exists (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

² Section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b).

³ See U.S. Department of Health and Human Services, Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency, available at <https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf>.

⁴ Section 1877 of the Act, 42 U.S.C. § 1395nn.

OIG's mission to promote economy, efficiency, and effectiveness in Department of Health and Human Services programs, we are committed to protecting patients by ensuring that health care providers have the regulatory flexibility necessary to respond adequately to COVID-19 concerns. Ordinarily, some financial relationships that implicate the physician self-referral law also may implicate, and potentially violate, the Federal anti-kickback statute. However, recognizing the unique circumstances of the COVID-19 outbreak, OIG will not impose administrative sanctions under sections 1128(b)(7) or 1128A(a)(7) of the Act,⁵ as those sections relate to the commission of acts described in the Federal anti-kickback statute, with respect to remuneration that is covered by section II.B.(1)-(11) of the Blanket Waivers.⁶ All of the conditions and definitions that apply to the Blanket Waivers shall apply to this Policy Statement.

This Policy Statement shall apply to conduct occurring on or after April 3, 2020. This Policy Statement shall terminate on the same date as the date that the Blanket Waivers terminate, as set forth in section 1135(e) of the Act. Parties may not rely on the Policy Statement for conduct that occurs after the expiration of the Blanket Waivers and this Policy Statement.

Through this Policy Statement, OIG seeks to avoid the need for parties to undertake a separate legal review under the Federal anti-kickback statute for arrangements protected by the Blanket Waivers. This Policy Statement has no bearing on arrangements that implicate the Federal anti-kickback statute that are not covered by the Blanket Waivers (*e.g.*, this Policy Statement would not apply to direct financial relationships between pharmaceutical or device manufacturers and physicians or between providers where there is no physician involved). Nonetheless, where an arrangement is covered by a Blanket Waiver, this Policy Statement extends to remuneration that relates to referrals for services furnished to all Federal health care program beneficiaries pursuant to the covered arrangement.

OIG reserves the right to reconsider the issues raised in this Policy Statement and to modify or terminate this Policy Statement.

⁵ 42 U.S.C. §§ 1320a-7(b)(7) and 1320a-7a(a)(7).

⁶ To the extent that interested parties have questions about the application of OIG's administrative sanctions under sections 1128(b)(7) or 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute, to remuneration associated with the referrals described in sections II.(B).(12)–(17) of the Blanket Waivers, we invite parties to submit such questions to OIGComplianceSuggestions@oig.hhs.gov. In your submission, please provide sufficient facts to allow for an understanding of the key parties and terms of the arrangement at issue.