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Another Unique Integrity Agreement Signals a Trend towards HHS-OIG's Comfort with a Belt and Suspenders

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In recent years, there have been only a handful of corporate integrity agreements ("CIAs") and integrity agreements ("IAs") that have included a "conditional exclusion release" of the Office of the Inspector General for the United States Department of Health and Human Services' ("HHS-OIG") permissive exclusion authority under 42 U.S.C. § 1320a-7(b)(7) ("Permissive Exclusion Authority").[1] Inclusion of a conditional exclusion release is atypical, as HHS-OIG's historical practice has been to provide an outright release of its Permissive Exclusion Authority in exchange for a CIA or IA. It appears, based on an IA executed last month and the other recent CIAs and IAs, that a trend may be emerging.

Specifically, in December 2022, HHS-OIG entered into an IA with a Georgia-based physician, Aarti D. Pandya, M.D., and his practice, Aarti D. Pandya, M.D. P.C. (collectively, "Dr. Pandya"). In atypical fashion, however, HHS-OIG required the IA to be for five years (as opposed to three years) and held Dr. Pandya to a conditional exclusion release contingent upon Dr. Pandya's satisfactory completion of the IA (as opposed to outright providing a release of its Permissive Exclusion Authority). This IA signals to the industry that HHS-OIG is not bound by precedent and that, perhaps, a belt and suspenders approach to resolving conduct allegedly violating the False Claims Act ("FCA") may be emerging as HHS-OIG's new norm.

Resolution under the FCA

The United States Department of Justice ("DOJ") resolved allegations that, from January 1, 2011 to December 31, 2016, Dr. Pandya violated the FCA when they submitted false claims to Federal health care programs for medically unnecessary cataract extraction surgeries and YAG laser capsulotomies ("Civil Settlement Agreement"). DOJ specifically alleged that Dr. Pandya performed such surgeries and procedures on patients who did not qualify under the accepted standards of medical practice. As a consequence, some of Dr. Pandya's patients were allegedly injured. DOJ also specifically alleged that Dr. Pandya falsely diagnosed patients with glaucoma to justify unnecessary diagnostic testing and treatment that was ultimately billed to the Medicare program. For many of the diagnostic tests that Dr. Pandya ordered, DOJ also alleged that such tests were not properly performed, were performed on a broken machine, or were not interpreted in the medical record, as required by the Medicare program for payment. To resolve these allegations, Dr. Pandya agreed to pay $1.85 million and to forfeit any amounts payable by the Medicare program that had been suspended by HHS in 2019 as a consequence of a qui tam action that had been filed against Dr. Pandya.

IA with HHS-OIG

To protect Federal health care programs and its beneficiaries, prospectively, Dr. Pandya agreed to enter into a five-year IA with HHS-OIG that includes a conditional exclusion release. The IA specifically states, in part, that, in exchange for Dr. Pandya agreeing to enter into the IA, HHS-OIG "has agreed to permit Dr. Pandya to enter into [the] IA with [HHS-OIG] in lieu of" HHS-OIG exercising its Permissive Exclusion Authority upon Dr. Pandya "based on the conduct described in the Civil Settlement Agreement and … Statement of Facts." Such Statement of Facts was attached to and incorporated by reference in the IA, detailing the allegations—down to the CPT Code—resolved by Dr. Pandya in the Civil Settlement Agreement. As stated in the IA, upon Dr. Pandya's satisfaction of the obligations and requirements of the IA "as determined by" HHS-OIG, HHS-OIG agreed to provide a permissive exclusion release to Dr. Pandya for the conduct resolved in the Civil Settlement Agreement.

Consistent with other IAs and CIAs entered into between HHS-OIG and parties resolving allegations of conduct that violate the FCA, and typically dependent on the nature of such conduct resolved, Dr. Pandya agreed to retain an Independent Review Organization to review Dr. Pandya's fee-for-service claims submitted to and reimbursed by the Medicare program and the Medicare managed care program, to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claims were correctly coded, submitted, and reimbursed. Other aspects of typical IAs and CIAs are also evident—including those requirements for Dr. Pandya to implement and maintain sufficient measures to mitigate, address, and resolve risks consistent with HHS-OIG's seven elements of an effective compliance program.[2]

Takeaways

HHS-OIG's IA with Dr. Pandya represents a more robust version of what the industry typically had come to expect and a deviation from historical practice, notwithstanding the few-and-far-between other IAs and CIAs that include a conditional exclusion release. [3]

First, IAs are typically for three-year periods, as compared with CIAs, which are typically for five-year periods. Here, HHS-OIG's IA with Dr. Pandya is for five years—almost twice as long as a typical IA. HHS-OIG's IA with LFAC was also for five years.

Second, when a party resolves allegations of violating the FCA, HHS-OIG typically provides such party with an outright release of its Permissive Exclusion Authority in exchange for entering into an IA or CIA with HHS-OIG, when, e.g., HHS-OIG "concludes that exclusion" under such authority "is not necessary to protect Federal health care programs" and its beneficiaries. Here, HHS-OIG did not provide such release when Dr. Pandya agreed to enter into the IA. Instead, HHS-OIG appears to have determined that a conditional exclusion release was *more* appropriate—ensuring that Dr. Pandya satisfactorily complete their IA obligations before providing any regulatory assurances. The same is evident from HHS-OIG's CIA with Insys and IA with LFAC.

Exclusion for failure to comply with certain requirements of Dr. Pandya's IA is still within HHS-OIG's authority—as it typical for any other IA or CIA and as is codified as a contractual breach remedy. However, HHS-OIG appears, again, to have taken its authority one step further by requiring both a belt (IA) and pair of suspenders (conditional exclusion release).

Lastly, HHS-OIG typically incorporates by reference the conduct resolved in FCA settlement agreements as a basis for providing parties with a release of HHS-OIG's Permissive Exclusion Authority and for requiring an IA or CIA. Here, HHS-OIG, again, took one step further and incorporated by reference, not only such conduct resolved in the Civil Settlement Agreement, but also a Statement of Facts—detailed in an attachment to the IA. Similar attachments are also found in HHS-OIG's CIA with Insys and IA with LFAC. The conduct itself, as set forth in the Statement Facts, is also preserved by incorporating by reference a tolling agreement and eight extensions. And, under the IA, Dr. Pandya agreed to waive any statute of limitations, laches, or other time-related defenses—as is the case also with HHS-OIG's CIA with Insys and IA with LFAC.

The industry should take note of these unique integrity obligations. By entering into this IA with Dr. Pandya, HHS-OIG has indicated, once again, that it is not barred from breaking from the mold of what may be considered "typical" or historically expected in the form and substance of an IA or CIA. Proskauer has broad experience assisting clients with navigating the nuances of negotiating integrity obligations with HHS-OIG. We will remain up-to-date on this and other IAs or CIAs with similar or other unique obligations to see whether the apparent trend becomes a new norm.

[1] See, e.g., Insys Therapeutics, Inc. (executed in 2019) ("Insys") and Lexington Foot and Ankle Center PSC, and Michael C. Allen, DPM (executed in 2020) ("LFAC").

[2] See also HHS-OIG, "Compliance Guidance," *available at* https://oig.hhs.gov/compliance/compliance-guidance/ (last accessed Jan. 12, 2023).

[3] See, supra, note 1 (Insys and LFAC).

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