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United States Defends Falsity Theory, Use of Debatable Sub-Regulatory Guidance in Medicare Advantage False Claims Act Suit Against Kaiser Permanente

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The False Claims Act actions pending against the Kaiser Permanente Consortium members in the U.S. District Court for the Northern District of California concerning Kaiser's Medicare Advantage risk-adjustment practices are teeing up a possible showdown regarding what constitutes sub-regulatory guidance and when sub-regulatory guidance can support a legal falsity claim.

There are currently four motions to dismiss the False Claims Act allegations pending against Kaiser. Last month, the government filed its opposition to Kaiser's motion to dismiss its complaint—confronting Kaiser's falsity argument head on.

Background on the *Kaiser* Action

At the outset, the government's complaint alleges Kaiser "systematically alter[ed] patient medical records to add diagnoses that either did not exist or were unrelated" to a patient's visit with a Kaiser physician, with the goal of inflating a patient's risk score.[1] The government further alleges Kaiser altered patients' medical records retrospectively by using addenda to add diagnoses months, or even a year after, the patient encounter. Despite Kaiser's alleged knowledge that it could not lawfully submit diagnoses unrelated to the patient encounter, it nonetheless "routinely used these diagnoses to obtain additional payments from Medicare."[2] In total, the government alleges Kaiser added approximately 500,000 diagnoses using addenda between 2009 and 2018.[3]

The False Claims Act imposes liability on any person who submits a claim to the federal government that the person knows (or should know) is false.[4] Kaiser's motion to dismiss the government's complaint focuses primarily on the issue of whether the claims it submitted to the government were indeed false. Claims can be factually false—involving a claim for payment that misrepresents the goods and services provided (e.g., inaccurately coding the level of service provided to receive higher reimbursement). Alternatively, claims can be legally false—involving an express false certification (e.g., falsely certifying compliance with a statute, regulation, or other legal requirement where compliance with that requirement is a condition for payment) or an implied false certification (e.g., requesting payment while making specific representations and failing to disclose noncompliance with material statutory, regulatory, or contractual requirements).

Kaiser's and the Government's Competing Positions on Legal Falsity, Sub-Regulatory Guidance

In its motion to dismiss the government's complaint,[5] filed in June 2022, Kaiser argues the government's "legal falsity" theory improperly relies on non-binding, sub-regulatory and non-governmental coding guidance, including the International Classification of Diseases (ICD) Guidelines (drafted by the Center for Medicare & Medicaid Services (CMS) and the National Center for Health Statistics), the CMS Medicare Managed Care Manual, the CMS Participant Guide, and American Health Information Management Association Practice Briefs.[6] Kaiser claims these guidance documents cannot support an enforcement action as a matter of law.[7]

Under the Medicare Act, and as interpreted in *Azar v. Allina Health Services*, the government must employ formal rulemaking when creating a rule that "establishes or changes a substantive legal standard . . . governing payment for services."[8] According to Kaiser, the government's legal falsity theory "assumes that compliance with certain coding documents is a precondition to payment from CMS," despite the fact that these

coding documents are either sub-regulatory agency guidance that did not result from formal rulemaking, or non-governmental guidance documents altogether.[9] To the extent the government identifies relevant, legally binding regulations that are contained in the Medicare Act itself, Kaiser argues those regulations do not provide a basis for the government's claims because they do not apply to addenda specifically.[10]

Kaiser's argument mirrors the position of the prior administration on the use of sub-regulatory guidance documents in affirmative civil enforcement actions, which was enumerated in the January 2018 "Brand Memo"—issued by former Assistant Attorney General Rachel Brand.[11] The Brand Memo limited the use of agency guidance documents in litigation, stating that the Department of Justice "may not use its enforcement authority to effectively convert agency guidance documents into binding rules" or otherwise "use noncompliance with guidance documents as a basis for proving violations of applicable law" in civil enforcement actions.[12] The principles set forth in the Brand Memo were reinforced by the U.S. Supreme Court in *Azar v. Allina Health Services* in June 2019, when the Court invalidated a Medicare reimbursement policy because it altered a substantive legal standard affecting Medicare payments without proceeding through the required notice-and-comment process.[13] The Court recognized that, unlike the Administrative Procedure Act, the Medicare Act's notice-and-comment requirement does not exempt interpretative rules.[14] The general policies from the Brand Memo were incorporated into two regulations issued at the end of the Trump administration, requiring that the Department of Health and Human Services (HHS) comply with numerous specific procedures prior to both adopting and using sub-regulatory guidance in civil enforcement actions.[15]

Attorney General Merrick Garland rescinded the Brand Memo, however, in a July 1, 2021, memorandum. The "Garland Memo," which came just one month prior to the government's intervention in the Kaiser actions, acknowledges that guidance documents are not binding while also recognizing these same documents may "set forth the Department's interpretation of binding regulations, statutes, and constitutional provisions" and the government "may rely on relevant guidance documents" in pursuing affirmative enforcement actions.[16] The Garland Memo does not articulate a limiting principle. More recently, on July 22, 2022, roughly one year after the Garland Memo was released, HHS issued a Final Rule rescinding the Trump administration's rules regarding the use of agency guidance in civil enforcement actions, stating that the rescinded rules "impose[d] burdensome standards and procedures that interfere with HHS's ability to respond efficiently to public health matters,"[17] and "divert finite Department resources to unnecessary and unhelpful ends."[18]

Of particular importance to Kaiser's argument here is the Ninth Circuit's application of *Allina* in later cases, including *Agendia, Inc. v. Becerra*,[19] which recognizes that informal policy documents may not be subject to the Medicare Act's notice-and-comment requirement where the controlling legal standard is contained in the statute itself.[20] If the guidance merely aids in the application of the standard enumerated in

the statute, then it cannot fairly be said to "establish or change" a substantive legal standard, and the guidance is therefore not subject to the Medicare Act's requirements for notice-and-comment.[21] In *Agendia*, for example, the Ninth Circuit held that non-binding local coverage determinations were not required to go through notice-and-comment rulemaking under the Medicare Act. The Ninth Circuit recognized that "[a]lthough local coverage determinations help [agency] adjudicators apply the reasonable and necessary standard to the facts of a claim, they do not establish or change the standard for reimbursement contained in the statute itself."[22] The debate from *Allina* and *Agendia* regarding what types of guidance are required to undergo notice-and-comment rulemaking under the Medicare Act continues in the motion to dismiss briefing in *Osinek*. Both Kaiser's motion and the government's response focus heavily on what the statute and binding regulations require with regard to the use of the ICD Guidelines.

The government's opposition to Kaiser's motion to dismiss—filed last month—responds directly to Kaiser's challenge to its falsity theory, including the notice-and-comment argument.[23] At the outset, the government argues Kaiser's assertion that the ICD Guidelines have not been adopted through notice and comment, and are thus not enforceable regulations, is inaccurate. In particular, the government argues the CMS regulations require Kaiser to submit risk-adjustment data in a form that conforms to "all relevant national standards."[24] According to the government, HHS has previously adopted, through regulations after notice and comment, the ICD Guidelines as the national standard for diagnosis coding.[25] Thus, the government argues these regulations require compliance with the various guidance on ICD coding, not just the use of the ICD codes. The government does not dispute that the other documents it relies upon, such as the Medicare Managed Care Manual, are sub-regulatory. Although the government does not explicitly rely on the Garland Memo with respect to these documents, its opposition notes that the Justice Manual provides that guidance documents "may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of applicable legal requirements."[26]

Aside from the regulatory enforceability of the various relevant guidance and standards, the government contends that Kaiser's contracts with CMS for the Medicare Advantage program require it to comply with the specified guidance on ICD coding, and the notice-and-comment requirements do not impact the enforceability of those contracts.[27] The government also notes that its complaint alleges Kaiser's own documents acknowledge that all coding documentation must comply with the ICD Guidelines in order to meet the Medicare Advantage requirements. Finally, the government attacks Kaiser's argument that it was not required to use the coding guidelines for addenda specifically, even if it was required to do so for other records. The government frames Kaiser's argument as unreasonable in the face of its contracts, the regulations, or sub-regulatory guidance, because addenda are not substantively different from the records they are modifying.[28]

The relators also respond to Kaiser's arguments opposing their motions to dismiss—focusing on the materiality of compliance with the ICD Guidelines to the payment of claims under Medicare Advantage. The relators assert that the Ninth Circuit has already held that CMS' requirement that Medicare Advantage organizations certify the accuracy, completeness, and truthfulness of the diagnostic data they submit is material as a matter of law under the False Claims Act.

Most recently, Kaiser filed its response to the government and relators' arguments, reiterating their position that "there is no legally binding requirement for [Medicare Advantage Organizations] MAOs to comply with ICD Guidelines when submitting risk-adjustment data to CMS."[29] In particular, Kaiser argues the CMS contracts do not require MAOs to comply with the ICD Guidelines and that the government has failed to point to any statute or regulation requiring MAOs to comply with the ICD Guidelines when they submit diagnosis codes to CMS for risk-adjustment purposes. In other words, Kaiser argues the government's attempt to impose a requirement that MAOs comply with the ICD Guidelines in risk-adjustment data submission is a violation of the principles set forth in *Azar v. Allina*.[30]

Kaiser emphasizes the CMS contracts do not explicitly mention the ICD Guidelines.[31] It asserts the provisions of the contracts that the government relies upon concern *plan design*, not diagnosis coding for payment reimbursement, and do not explicitly condition a MAO's right to payment on strict compliance with the Medicare Managed Care Manual.[32] Kaiser next points to the section of the contract that governs payments, which requires "compliance only with regulations and statutes" and does not mention any nonbinding, sub-regulatory guidance, much less either the Medicare Managed Care Manual or the ICD Guidelines.[33]

Finally, Kaiser challenges the government's identified regulations, asserting that neither defines any right to payment from CMS.[34] In Kaiser's view, the only regulation that explicitly references the ICD Guidelines is limited to nine specified transaction types, which do not include submission of risk-adjustment data to CMS.[35] Similarly, Kaiser challenges the government's reliance on 42 C.F.R. § 422.310 because it addresses "data format" and fails to define the "relevant national standards" it references.[36]

Oral argument on the pending motions to dismiss is set to take place on Oct. 13, 2022.

Looking Ahead

Whether the court chooses to address the parties' arguments concerning the use of sub-regulatory guidance (both debatable and not) in this instance is unclear—it may very well sidestep the issue and decide the case on the heightened pleading standard alone. One thing is clear, however: To the extent any questions remain regarding the government's reaction to the Garland Memo and HHS' accompanying Final Rule, there is no doubt these policy changes almost instantly revived the government's confidence

in using guidance documents to support False Claims Act allegations such as those here. In the end, the parties' briefing in this matter is a stark reminder for health care provider and payers that guidance documents can be used, and will continue to be used, by the government to combat alleged fraud and abuse. Providers and companies alike must therefore ensure awareness of, and compliance with, the ever-changing regulatory landscape in the health care industry, including thoughtfully evaluating the application of sub-regulatory guidance documents to their operations.

**This article should not be construed as legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own lawyer on any specific legal questions you may have concerning your situation.*

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[1] *United States ex rel. Osinek v. Kaiser Permanente*, No. 3:13-cv-03891-EMC, Dkt. No. 110 at 1 (N.D. Cal. Oct. 25, 2021).

[2] *Id.*

[3] *Id.* at 74.

[4] 31 U.S.C. § 3729.

[5] Kaiser also filed motions to dismiss the relators' complaints under the Rule 9(b) heightened pleading standard.

[6] *United States ex rel. Osinek v. Kaiser Permanente*, No. 3:13-cv-03891-EMC, Dkt. No. 178 at 12–14 (N.D. Cal. June 21, 2022).

[7] *Id.*

[8] 42 U.S.C. § 1395hh(a)(2); *see also Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).

[9] *United States ex rel. Osinek v. Kaiser Permanente*, No. 3:13-cv-03891-EMC, Dkt. No. 178 at 13 (N.D. Cal. June 21, 2022).

[10] *United States ex rel. Osinek v. Kaiser Permanente*, No. 3:13-cv-03891-EMC, Dkt. No. 178 at 17 (N.D. Cal. June 21, 2022).

[11] Memorandum from Associate Attorney Gen. Brand to Dep't of Justice, (Jan. 25, 2018), https://www.justice.gov/file/1028756/download.

[12] *Id.* at 2.

[13] *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).

[14] *Id.* at 1814.

[15] *See* Dep't of Health & Human Servs. Transparency and Fairness in Civil Administrative Enforcement Actions, 86 Fed. Reg. 3010 (Jan. 14, 2021) (rescinded); Dep't of Health & Human Servs. Good Guidance Practices, 85 Fed. Reg. 78770 (Dec. 7, 2020) (rescinded).

[16] Memorandum from Attorney Gen. Garland to Dep't of Justice, (July 1, 2021), https://www.justice.gov/opa/page/file/1408606/download.

[17] Dep't of Health and Human Services Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures, 87 Fed. Reg. 44002, 44005 (July 25, 2022) (to be codified 45 C.F.R. Part 1).

[18] *Id.* at 44008.

[19] 4 F.4th 896 (9th Cir. 2021).

[20] *Id.* at 901–02.

[21] *Id.* at 902.

[22] *Id*. at 902.

[23] *United States ex rel. Osinek v. Kaiser Permanente*, No. 3:13-cv-03891-EMC, Dkt. No. 197 (N.D. Cal. Aug. 5, 2022).

[24] *Id.* at 12 (citing 45 C.F.R. § 162.1002(a)(1)).

[25] *Id.* at 3–4, 12–15.

[26] *Id* at 14 n.10.

[27] *Id.* at 9–12.

[28] *Id.* at 15.

[29] *United States ex rel. Osinek v. Kaiser Permanente*, No. 3:13-cv-03891-EMC, Dkt. No. 201 at 9 (N.D. Cal. Sept. 6, 2022).

[30] *Id.* at 10.

[31] *Id.* at 10–12.

[32] *Id.* at 11.

[33] *Id*. at 12

[34] *Id.* at 14.

[35] *Id.* at 12–13 (citing 45 C.F.R. Part 162).

[36] *Id.* at 13–14.