Bloomberg Law

Drug Diagnosis Code Data Sought by HHS OIG May Cue Enforcement

July 12, 2021
By Jaime L.M. Jones, Brenna Jenny, and Matt Bergs

The HHS Office of the Inspector General recently advocated for a new mandate that physicians include a diagnosis code with prescriptions and may indicate the OIG intends to use it as an investigative tool, Sidley Austin attorneys write. The government may use data analysis to probe pharmaceutical companies for off-label promotion of prescription drugs, so drug companies should proactively use data to mitigate risk, they say.

Leadership from the Department of Health and Human Services Office of Inspector General recently advocated for new mandates that physicians include a diagnosis code with each prescription and that claims data capture this information. This followed on the heels of a Congressional Research Service report suggesting that Congress should pass legislation requiring prescribers to include diagnostic information in prescriptions.

There appears to be a mismatch between the OIG's law enforcement function and the public health concerns it articulated as a basis for this policy proposal, raising questions about the OIG's primary interest in having access to diagnosis code data.

The OIG points to the "dramatic increase in the number of prescriptions written for hydroxychloroquine" in the spring and summer of 2020 and expresses frustration at how "difficult [it was] to determine the reason for the spike in prescribing because the data shed no light on why the drug was prescribed." But far from being in the dark, off-label use of hydroxychloroquine for Covid-19 enjoyed such a spotlight that it even received mention in a Saturday Night Live skit. Although an extreme example of off-label use entering the common lexicon, it previews a tension pervasive in the remainder of the op-ed.

The OIG asserts that including diagnosis codes on prescriptions and in claims data would advance public health and safety objectives, including by "motivat[ing patients] to fill their prescriptions and take them as prescribed" and "prevent[ing] dispensing errors where illegibility causes a pharmacist to confuse one drug with another."

These are laudable policy goals but ones that appear more in the province of the HHS itself, rather than the focus of an inspector general whose self-described primary focus for its 1,600 employees is to be "at the forefront of the Nation's efforts to fight waste, fraud and abuse in Medicare, Medicaid and more than 100 other" HHS programs.

Nonetheless, the OIG's interest in obtaining diagnosis codes in claims data may in fact reflect its law enforcement function, because the OIG may see diagnosis code data as a tool to engage in nuanced investigations into pharmaceutical companies for off-label promotion of prescription drugs.

Data Analytics to Identify Off-Label Promotion for Enforcement

The OIG's interest in additional data sources that could facilitate oversight of off-label promotion is consistent with a broader trend among law enforcement toward leveraging data analytics. The OIG's most recent strategic plan includes repeated references to how it uses "advanced data analytics to more effectively assess risk across HHS programs." This mirrors recent remarks by the Department of Justice leadership about the growing use of data analytics to identify targets for investigation.

Although the role of the whistleblower will likely remain relevant, the DOJ and OIG have expressed a newfound appreciation for the power of data analytics to reveal patterns or outliers potentially indicative of fraud, without having to wait for a whistleblower to file a qui tam suit. The government may be searching for a way to apply data analytics to prescription data in a way that could provide signals of potential off-label usage as a first step in connecting these patterns to drug manufacturer conduct.

In the 2000s and early 2010s, off-label promotion enforcement actions frequently produced staggering, billion-dollar settlements under the False Claims Act. But, in the face of growing judicial recognition of First Amendment protection for truthful, non-misleading statements about off-label uses, the DOJ more recently has narrowed its focus to off-label promotion involving false or misleading statements. Press releases for recent off-label settlements exemplify the DOJ's current posture by emphasizing details of how company representatives allegedly made false or misleading statements.

Diagnosis Codes Afford Improved Off-Label Promotion Data Analytics

As the OIG intimated, although settlements involving alleged off-label promotion no longer drive FCA recoveries from drug manufacturers, law enforcement remains interested in exploring liability on this issue. Yet while the DOJ and OIG currently have access to a rich array of claims data, they have only limited visibility through existing data sets into off-label uses of prescription drugs. As a result, they must rely on proxies, such as a physician whose primary specialty is pediatrics, writing a high volume of prescriptions for a drug that is not FDA-approved for use in children.

Requiring diagnosis codes to be included in the claims data that law enforcement already can access—and increasingly is analyzing—would allow the DOJ and OIG to turn their new analytical capabilities toward identifying signals of potential off-label promotion. The assumption that areas of high off-label use may correspond to promotional practices the government deems improper may lead to follow-up inquiries.

Drug manufacturers should remain vigilant in ensuring that information conveyed about their products is truthful and non-misleading. But law enforcement's new focus on data calls for new compliance tools as well. Drug manufacturers should consider engaging in their own data analytics so they understand the trends and outliers in off-label use that could lead to government scrutiny.

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Author Information

Jaime L.M. Jones is global co-leader of the Healthcare practice at Sidley Austin LLP and serves on the firm's Covid-19 task force. She represents leading institutional health-care providers and life sciences companies in civil and criminal government enforcement matters and FCA litigation.

Brenna E. Jenny is a partner in Sidley's Healthcare practice and Life Sciences group. She previously served as the principal deputy general counsel at the HHS and the chief legal officer for the Centers for Medicare & Medicaid Services.

Matt Bergs is an associate in Sidley's Healthcare practice. He focuses his practice on healthcare enforcement and litigation matters.