Professional Perspective

Tips for Responding to a DOJ Inquiry Into Pandemic Billing

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Among the many dramatic changes to the face of health-care delivery during the Covid-19 pandemic has been the ability of the Department of Health and Human Services (HHS) to waive not just its own regulations, but even certain statutory requirements. HHS has exercised this authority to an unprecedented degree, issuing dozens of blanket waivers in addition to multiple interim final rules.

As the initial chaos of the early pandemic gives way to a challenging new normal, enforcement scrutiny of new billing practices will begin to rise. But there are steps that in-house legal and compliance functions for health-care providers can take to best position their organizations for successfully engaging with the Department of Justice (DOJ) and state attorneys general on False Claims Act investigations relating to the use of pandemic billing flexibilities.

Background

HHS extended billing flexibilities to providers during the Covid-19 public health emergency (PHE) using several authorities. The most significant shifts arose through HHS's power under Social Security Act Section 1135 to waive or modify certain federal health-care requirements during declared public health emergencies. See 42 U.S.C. § 1320b-5.

The policy purpose animating this unique authority is to ensure that individuals who rely on government health-care programs retain access to medically necessary services in the face of emergencies and that the health-care providers administering such services can continue to receive reimbursement and are temporarily protected against sanctions for failure to comply with certain federal rules. Exemptions from sanctions extend only absent a determination of fraud and abuse.

Generally, HHS has exercised its waiver authority in response to natural disasters, and the waivers have narrowly applied only to providers in discrete areas. That restrained approach changed with the pandemic. On March 16, 2020, following Secretary of HHS Alex Azar's declaration of a PHE and then President Donald Trump's declaration of a national emergency, the Centers for Medicare and Medicaid Services (CMS) announced an initial set of waivers specific to the Covid-19 pandemic.

To address the widespread impact of Covid-19, CMS issued an unprecedented number of Section 1135 "blanket" waivers that are applicable nationwide, without advance approval, to a broad group of providers, for the duration of the PHE. Through waivers, CMS has, among many other flexibilities, significantly altered the scope of Medicare payable telehealth services, exempted certain financial relationships from otherwise-applicable sanctions under the Stark Law, and broadly expanded the circumstances qualifying a patient for Skilled Nursing Facility coverage under Medicare Part A.

To further ensure an agile response to the challenges posed by Covid-19, CMS also used Interim Final Rules with Comment Period (IFCs) to amend, generally on a temporary basis until the close of the PHE, certain regulatory requirements. In 2020, CMS issued four IFCs that expanded patient access to care, such as by allowing existing hospitals to create new treatment sites outside of their traditional brick-and-mortar facilities and still bill as though the services were provided in the hospital (the "Hospitals Without Walls" initiative), and expanding patient access to Covid-19 treatment and testing, such as by broadening the role of pharmacists in ordering and administering tests for Covid-19 and other illnesses with respiratory symptoms.

Regulatory evolution often serves as a catalyst for enforcement scrutiny; for instance, a few years after CMS implemented the Medicare Advantage risk adjustment payment model, DOJ initiated a broad set of enforcement actions across a segment of the health-care industry that had previously received relatively little attention from prosecutors.

DOJ can be expected to closely examine how providers have exercised new flexibilities around claim submission. Once the pandemic has passed, DOJ will assess whether providers overstepped even the broader bounds on what was permissible, such as by providing telehealth services that did not include meaningful, medically necessary care or by engaging in incident-to billing but failing adequately to supervise auxiliary personnel remotely.

Many health care providers will soon be on the receiving end of a DOJ document request relating to their use of pandemic billing flexibilities. Understanding the dynamics of how HHS and DOJ will interact to investigate allegations, and the criteria they will need to satisfy to build a successful case, will serve as an important foundation for reaching a successful resolution.

Open Lines of Communication

Build Strong Internal Lines of Communication

Many employees in legal, compliance, and billing functions within the health-care industry continue to navigate remote work while also tackling an increased workload due to Covid-19. Clearly communicate timelines and expected deliverables with stakeholders assisting with enforcement-related workstreams. Short-term slip-ups, such as missed production deadlines—particularly early on—can undermine your company's credibility with the government.

Begin a Dialogue With the Government

DOJ attorneys, too, are generally working remotely. Building a rapport with prosecutors without any in-person meetings is challenging, so prioritize regular contact with DOJ, including periodic updates. This is particularly important because the pace of some investigations may be slow as government lawyers and agents navigate the challenges of investigating a case during the pandemic. Strong communication can help keep the investigation moving forward toward resolution.

Understanding the Facts

Define the Scope of the Issue

Work to pinpoint the regulatory flexibility under scrutiny and assess the contemporaneous understanding of the scope of the flexibility offered. Once you understand how the company intended to apply the regulatory flexibility, you will need to assess whether the claim submissions in practice deviated from this interpretation. Depending on the type of claim at issue, there may be some benefit to working with an outside expert to conduct a probe sample.

Confirm Your Legal Analysis

If the billing submissions were consistent with internal policy, then you should take a second look at all supplemental CMS guidance relevant to the issue. Engage outside counsel as needed to confirm the reasonableness of the initial interpretation.

Understand the Source of Any Prior Mistakes

If billing submissions were inconsistent with internal policy, you will need to assess why that was the case. For example, did the pandemic create unintentional process breakdowns? Were billing practices nonetheless consistent with a reasonable interpretation of the waiver authority? The answers to these questions will inform the development of your defensive strategy, as they may reflect a scienter inconsistent with liability under the False Claims Act.

Developing a Defense Strategy

Clarify Any Misunderstandings as Soon as Possible

If your fact-finding confirms that the billing submissions were generally consistent with the scope of the regulatory flexibility, it is important to convey this information to DOJ before the government invests significant resources into the case.

This is especially true if the document request was issued by a U.S. Attorney's Office. DOJ attorneys working at Main Justice generally have closer institutional ties to subject matter experts at HHS and likely will have consulted with them, both on the intended scope of the flexibility and on available data analytics, prior to issuing a document request. But particularly given the newness of the HHS False Claims Act Working Group—announced in December 2020—U.S. Attorneys' Offices may not have had a prior opportunity to do so.

Absent a clear conduit for DOJ to HHS's subject matter experts, prosecutors may not fully understand CMS's position on the scope of the regulatory flexibility. Ensuring all stakeholders are on the same page early on can expedite resolution. Depending on the circumstances, additional engagement with HHS may be appropriate, so long as you keep DOJ informed of your outreach.

Assess Falsity

Understand how HHS's regulatory obligations intersect with DOJ's False Claims Act theory of liability. Does the theory of liability rest on a duly-enacted statutory or regulatory obligation? If not, and the theory relies on the violation of a billing rule set forth only in a guidance document, it is not a viable candidate to support False Claims Act liability.

During the Trump administration, both HHS and DOJ expressed interest in tightening up their practices relating to the appropriate use of guidance documents. HHS—through the issuance of its Good Guidance Practices rule—and DOJ, by amending the Justice Manual—committed themselves to complying with the Administrative Procedure Act's (APA) prohibition on using guidance documents to impose binding new obligations on regulated entities. See Department of Health and Human Services Good Guidance Practices Rule, 85 Fed. Reg. 78,770 (Dec. 7, 2020); DOJ, Justice Manual § 1-20.000.

Both departments must additionally grapple with the Medicare Act's unique notice-and-comment obligations, which, as interpreted by the U.S. Supreme Court in Azar v. Allina Health Services, prohibit the use of sub-regulatory issuances in the Medicare context even more broadly than does the APA. See 139 S. Ct. 1804 (2019); HHS Office of the General Counsel, Advisory Opinion No. 20-05 (2020).

While the use of the Section 1135 waiver authority generally involved taking away statutory or regulatory obligations, rather than imposing new ones, the IFCs often amended CMS regulations to impose different, albeit less onerous, regulatory requirements. To the extent CMS issued guidance documents purporting to clarify provisions of an IFC, when in fact those guidance documents expanded upon the rule's requirements, the violation of the terms in the guidance document would not present a strong False Claims Act case.

Assess Materiality

If billing practices differed from expectations, determine whether noncompliance with the agency's originally articulated scope of flexibility should be categorized as material to payment. In many instances, the answer is no. As the U.S. Supreme Court reiterated in *Universal Health Services, Inc. v. United States ex rel. Escobar*, the "materiality standard is demanding," and the False Claims Act is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations." 136 S. Ct. 1989, 2003 (2016).

There are reasons to conclude that in light of the extraordinary demands of the pandemic, CMS would not require perfect compliance with all remaining billing obligations. CMS has repeatedly described its efforts as intended to "equip the American health care system with maximum flexibility" to respond to the public health emergency, and "focus on providing needed care to Medicare and Medicaid beneficiaries." CMS, Hospitals: CMS Flexibilities to Fight Covid-19 (2020). This context will weigh heavily on the materiality analysis.

Assess Scienter

CMS has acknowledged that the public health emergency "produces an immediate change, not only in the circumstances under which services can safely occur, but [it] also results in an immediate change to the business relationships between providers, suppliers, and practitioners." Policy and Regulatory Revisions in Response to the Covid-19 Public Health Emergency, 85 Fed. Reg. 19,230, 19,232 (April 6, 2020). To the extent noncompliance with regulatory flexibilities occurred, it may have been the product of a genuine misunderstanding or an inadvertent failure to adapt to CMS's changed expectations in the middle of the pandemic.

If the provider did not act with at least reckless disregard, any overpayments are more appropriately resolved administratively. Indeed, CMS has recognized this possibility, explaining in its April 21, 2020, Explanatory Guidance on the blanket Stark Law waivers that "[t]he Secretary will work with the Department of Justice to address False Claims Act relator suits where parties using the blanket waivers have a good faith belief that their remuneration or referrals are covered by a blanket waiver." CMS, Explanatory Guidance, March 30, 2020 Waivers of Section 1877(g) of the Social Security Act, at 1 (2020).

