HEALTH CARE

DOJ: PUTTING LIMITS ON GUIDANCE

In early 2018, the Department of Justice released its Brand Memo, which prohibits civil litigators from using agency guidance, instead of laws or regulations, as the basis for enforcement actions, including actions taken under the False Claims Act.

For companies working with federal health care programs, that was welcome news. Each year, they contend with thousands of newly issued or revised guidance documents from a variety of agencies, leaving them struggling with requirements that can be confusing, conflicting, or out of date. At the same time, health care contractors are frequent targets of FCA claims. "The substantial majority of False Claims Act recoveries, which hover between $3 billion and $4 billion a year, comes from the health care and life sciences space," says William Chang, a partner in Crowell & Moring's Health Care Group and a former trial attorney at the DOJ Criminal Division, Fraud Section. The Brand Memo gives those health care contractors a new avenue of defense in FCA litigation.

But in the year since the memo's release, "government contractors and academics alike continue to question how it should be interpreted," says Chang. A key question involves government contracts that typically include "catch-all" language saying that the contractor will follow all relevant government agency guidance. "So even though noncompliance with obligations that appear in only sub-regulatory guidance cannot be a basis for FCA enforcement, contractors wonder if they can still be held accountable under the FCA for noncompliance with a contractual certification to abide by guidance," he says.

Chang says that is unlikely for several reasons.* For example, he explains, the memo is based on the requirements under the Administrative Procedure Act and the constitutional norms of due process, fair notice, and the separation of powers—and these are violated by contract clauses that make contractors accountable for complying with volumes of unspecified guidance that the agencies themselves might not understand. In addition, he says, "FCA claims mostly arise out of government contracts. If government contracts are effectively exempt from the Brand Memo because of the catch-all provisions, why would the memo have been created to deal with FCA claims?" Overall, he says, "the Brand Memo would be pointless if agencies can do an end run around it and effectively create law by putting these broad clauses into contracts."

Recent government actions support that assessment. For example, in a Medicare fraud case filed two years ago, "the initial DOJ complaint said that all Medicare Advantage organizations must comply with laws, regulations, and guidance documents," says Chang. "But after the Brand Memo, the word 'guidance' did not appear in the DOJ's summary judgment motion. Nor did the DOJ continue to allege that Medicare Advantage Organizations 'must comply with requirements set forth in … guidance documents.'" Instead, the amended complaint references only a specific guidance document, which the Medicare Advantage contract had expressly identified and incorporated.

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Looking ahead, Chang says the Brand Memo will probably not result in the DOJ intervening in fewer FCA cases, largely because the DOJ already tends to focus on actions with a strong statutory or regulatory basis. But the memo may result in the DOJ's dismissals of *qui tam* suits. "When the department digs into the *qui tam* and it turns out that the relator is actually relying on guidance documents and talking about requirements that don't exist in a regulation or statute, the DOJ has the authority to dismiss," he says. The department has rarely exercised that authority. Over the past year, however, DOJ leadership has been calling for the dismissal of and actually dismissing more *qui tams*—a view reflected in the department's 2018 Granston Memo, which said that early dismissals were important for controlling the costs and burdens associated with pursuing meritless claims.

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