Recent Changes to DOJ's "Justice Manual" Addressing De-Facto Regulations and Agency Guidance Documents

(December 27, 2018): On November 16, 2017, Attorney General Jeff Sessions issued a memorandum[1] (Sessions Memo) implementing the principles set out in President Trump's Executive Order 13777.[2] The Sessions Memo was addressed to all components of the U.S. Department of Justice (DOJ) and noted the fact that in the past, some DOJ guidance documents had not gone through the rulemaking process but had still been issued and used to bind private parties. As the memorandum further noted:

"Effective immediately, Department components may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local, and tribal governments)."

The purpose of this memorandum was fairly straight-forward. Regulated parties should be able to rely on statutory and regulatory requirements that have been implemented in accordance with the legislative and rulemaking process. Guidance documents that have not gone through this formal process shouldn't be used to establish obligations or rights with respect to regulated private parties. The Sessions Memo was intended to prevent DOJ components from ***"evading required rulemaking processes by using guidance memos to create de facto regulations."***[3] **(emphasis added).**

Several months after the issuance of Attorney General's memorandum, Associate Attorney General Rachel Brand issued a related memorandum (Brand Memo) addressing this issue.[4] The Brand Memo made it clear that the principles set out in the Attorney General's memorandum should also be used by DOJ prosecutors when determining whether guidance documents issued by ***other*** federal agencies should be considered "binding" when the requirements set out in the guidance documents are not supported by existing statutes and / or regulations. As the Brand Memo states:

> ***". . . the Department should not treat a party's noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation. That a party fails to comply with agency guidance expanding upon statutory or regulatory requirements does not mean that the party violated those underlying legal requirements; agency guidance documents cannot create any additional legal obligations."*** **(emphasis added).**

Although the Brand Memo was directed at the use of guidance documents in False Claims Act and other affirmative civil enforcement cases,[5] as we will discuss in the sections below, the principles set out in the memorandum should also applicable to criminal enforcement actions.

Not surprisingly, the role of agency guidance when assessing a health care provider's obligations under the law have been debated ever since the Sessions and Brand memoranda were first issued. Almost a year after the Brand Memo was released, the DOJ has recently expanded upon these principles in its revised issuance of the "***Justice Manual***."[6] This article reviews these new provisions and discusses how DOJ's guidance may impact fraud cases brought against health care providers and suppliers.

I. Impact of the DOJ's Position in Civil and Criminal Health Care Fraud Cases:

At this point, you may be thinking ***"Why should I care about these directives?*** As discussed below, the possible impact of the Sessions and Brand memos on health care providers and suppliers can be substantial. Moreover, depending on the facts in your particular case, DOJ's consideration of agency guidance (that is not based on an existing regulation or statute) may make, or break the government's fraud case against a health care provider or supplier. On or about December 18, 2018, the DOJ published its latest guidance in the Justice Manual (§§ 1-19.000[7] and 1-20.000[8]) on the limitations of issuance and use of agency guidance documents. These Justice Manual provisions are discussed in more detail below.

II. Justice Manual, § 1-19.000 – Limitation on Issuance of Guidance Documents:

As § 1-19.000 of the Justice Manual provides, when issuing non-binding guidance documents, DOJ components should expressly identify the documents as guidance that does not carry the force or effect of law. Moreover, DOJ components should clearly state that noncompliance with these **"*voluntary standards will not, in itself, result in any enforcement action*."** It is important to note that DOJ components may still issue guidance documents that are intended as voluntary guidelines or standards for private entities to consider and follow. However, such guidance documents must make it clear that the instructions set out in the guidance is not legally binding and may be beyond an entity's legal obligations under existing statutes and regulations.

What constitutes an agency guidance document? Great question. As § 1-19.000 reflects, the term "guidance document" does ***not*** include:

- ***Decisions, orders, or other documents issued in adjudicatory actions that do not purport to or have the effect of binding anyone beyond the parties to the adjudication.***
- ***Documents informing the public of the agency's enforcement priorities or factors the agency considers in exercising its prosecutorial discretion.***
- ***Internal directives, memoranda, legal and strategy monographs, or training materials for agency personnel directing them on how to carry out their duties, positions taken by an agency in litigation, or legal advice provided by the Department.***

III. Justice Manual § 1-20.000 – Limitation on Use of Guidance Documents in Litigation:

In contrast to § 1-19.000 (which covers the **ISSUANCE** of guidance documents by DOJ components), § 1-20.000 of the Justice Manual focuses on the **USE** of guidance documents issued by other federal agencies in litigation. As § 1-20.100 of the manual provides:

"Criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation." **(emphasis added).**

Justice Manual § 1-20.201 notes that if an agency guidance document describes a statutory or regulatory provision, federal prosecutors are still permitted to use and rely on agency guidance documents to argue that a party's awareness of the guidance document shows that the party had the requisite notice or knowledge of the law. Justice Manual § 1-20.202 further provides that an agency guidance document can be used as probative evidence that:

> ***". . . a party has satisfied, or failed to satisfy, professional or industry standards or practices relating to applicable statutory or regulatory requirements."***[9]

This section of the Justice Manual further notes that this rationale applies ***"broadly"*** in the healthcare arena and expressly cites guidance documents issued by the Centers for Medicare and Medicaid Services (CMS) such as the agency's Medicare Benefit Policy Manual and Local

Coverage Determinations (LCDs) as relevant evidence that procedures may (or may not) be medically reasonable and necessary.[10] For example:

". . . if a primary care physician writes prescriptions in excess of the CDC Guideline for Prescribing Opioids for Chronic Pain, which contain medical recommendations for primary care physicians, that fact may be offered as evidence that the prescriptions were made and opioids dispensed without any "legitimate medical purpose" and outside "the usual course of professional practice," 21 C.F.R. § 1306.04(a), in violation of the Controlled Substances Act."

Justice Manual § 1-20.204 further notes that DOJ may cite an agency guidance document ***"where a party's compliance, or failure to comply, with the agency guidance is itself relevant to the claims at issue."*** For example, if a health care provider falsely certifies compliance with a guidance document **AND** the certification is material to a decision by CMS (including its contractors) to pay a claim, the false certification may be offered by DOJ prosecutors to establish the elements of falsity, materiality and knowledge. As the section further provides:

> ***". . . when a government contract or provider agreement requires compliance with some agency guidance document, it is the contract—not the agency guidance itself—that makes the agency guidance pertinent and, in these cases, violations of that guidance undertaken with the requisite mental state may expose individuals to liability."***

IV. Conclusion:

From a practical standpoint, the Sessions and Brand memoranda and the recent updates to the Justice Manual will likely only come into play if the DOJ is directly involved in a case, either before or after a civil or criminal case has been filed. Having said that, the DOJ is not the only government entity tasked with complying with Executive Order 13777. All federal agencies, including those of the Department of Health and Human Services (such as the Centers for Medicare and Medicaid Services(CMS)) are required to identify and repeal existing guidance documents that are outdated, unnecessary, inconsistent with existing law, or otherwise improper.

In light of this mandate, CMS published its Proposed Rule entitled *"Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,"* **[11]** on September 20, 2018. To its credit, CMS has issued a number of proposals that are intended to alleviate the regulatory burden on Ambulatory Surgical Centers, Hospices, Home Health Agencies, Hospitals, Transplant Centers, Community Mental Health Centers, Rural Health Clinics and various other types of health care provider and suppliers.

Unfortunately, almost all of the proposed changes have been aimed at specific types of health care

providers and suppliers. For the most part, CMS's Proposed Rule does not touch upon the quasi-legal obligations that have been imposed on health care providers and suppliers in the form of National Coverage Determination rules (NCDs), Local Coverage Determination rules (LCDs), manual provisions (such as the Medicare Program Integrity Manual (PIM), Medicare Claims Processing Manual (MCPM), and Medicare Benefit Policy Manual (MBPM)), along with practically countless issuances of policy guidance memoranda and other documents. Although some of this guidance is, in fact, based on already existing statutory and regulatory requirements that have been properly vetted through the rule-making process, much of this information would undoubtedly qualify as ***"de facto regulations"*** that are not statutorily based.

Unless CMS takes further action in this regard, all health care providers and suppliers participating in Medicare, Medicaid and / or other federal health benefits providers should continue to comply with all applicable guidance that has been issued by federal or state sponsored health plans (or their contractors, such as Medicare Administrative Contractors) which set out the specific requirements that must be met in order for a health care service or item to qualify for coverage and payment. These requirements include, but are not limited to specific guidance regarding the medical necessity of certain services, frequency and dosage restrictions, documentation mandates and billing / coding requirements.

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[1] Memorandum dated November 16, 2017, titled ***"Prohibition on Improper Guidance Documents."***

[2] On March 21, 2017, President Trump signed **Executive Order 13777.** Simply put, pursuant to Executive Order 13777, federal agencies are required to identify and repeal existing guidance documents that are outdated, unnecessary, inconsistent with existing law, or other improper. Citing Executive Order 13777 and the Sessions Memo, on December 21, 2018, Acting Attorney General Matthew Whitaker announced in a **Press Release** that the DOJ was rescinding an additional 69

guidance documents that were either ***"unnecessary, outdated, inconsistent with existing law, or otherwise improper."*** The Regulatory Task Force established by the DOJ pursuant to Executive Order 13777 has been active in its efforts to rescind guidance documents that have been determined to be unnecessary, inconsistent with existing law, or improper. In December 2017, DOJ's Regulatory Task Force identified 25 guidance documents to be repealed. The Task Force subsequently identified 24 additional guidance documents to be repealed in July 2018.

[3] See Press Release titled ***"Attorney General Sessions Ends the Department's Practice of Regulation by Guidance"*** issued November 17, 2017.

[4] Memorandum dated January 25, 2018, titled ***"Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases."***

[5] The term "Affirmative Civil Enforcement" refers to the filing of *"civil lawsuits on behalf of the United States. The purpose of these civil actions is to recover government money lost to fraud or other misconduct or to impose penalties for violations of Federal health, safety, civil rights or environmental laws."*

[6] The Justice Manual was previously known as the United States Attorneys' Manual. It was revised and renamed the **Justice Manual** in 2018.

[7] Justice Manual § 1-19.000 can be found at this **link**.

[8] Justice Manual § 1-20.000 can be found at this **link.**

[9] See Justice Manual *§ 1-20.202.*

[10] As set out in *United States ex rel Polukoff v. St. Mark's Hospital*, No. 17-4014, at 14-15 (10th Cir. July 7, 2017), the use of agency guidance documents ***"does not give these documents the force of law, but rather aids in demonstrating that the standards in the relevant statutory and regulatory requirements have been or have not been satisfied."***

[11] *"Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction*," September 20, 2018. 83 FR 47686.