



Insight

Explaining the Executive Orders on Guidance

DAN BOSCH | OCTOBER 10, 2019

EXECUTIVE SUMMARY

- President Trump signed two executive orders (EOs) aimed at curtailing agency abuses of guidance documents, which have been used to justify enforcement action against regulated entities despite not being produced through the same rulemaking process as proper regulations.
- The EOs will make guidance more transparent, easier to find, and give regulated entities more opportunities to challenge potential violations.
- The ultimate success of the EOs will depend on a forthcoming memorandum detailing the new requirements for agency guidance.

INTRODUCTION

President Trump signed two executive orders (EOs) aimed at addressing long-held concerns about how federal agencies create and enforce “guidance.” Guidance documents are communications from regulatory agencies that help to clarify the obligations of regulated entities. They are useful in that they can provide some level of certainty. They are supposed to be non-binding, meaning that if something is written or shown in guidance that is not in the regulatory code, the regulated entity should not be punished for deviating from the guidance if they are following the underlying regulation. In practice, however, agencies have used guidance as the basis for legal enforcement.

ISSUES WITH GUIDANCE DOCUMENTS

Some agencies have used guidance, in the form of memos, letters, and even blog posts, to assert more authority than is written in their regulations. Agencies often use these supplementary guidance communications because an agency can simply draft and issue guidance, rather than go through the deliberative rulemaking process.

The problem is that agencies have enforced this expanded authority, and courts have upheld those enforcements in some cases. In addition, the mere fact that an agency has issued the guidance – which is effectively the agency’s interpretation of its own regulations – gives the guidance an air of enforceability.

As an example, in 2017 the Food and Drug Administration (FDA) issued a [guidance document](#), rather than further regulatory code changes, regarding its menu labeling rule. This document showed images of compliant and non-compliant establishments. Though no enforcement actions have been taken, one could envision how a court could rule in favor of the FDA if it penalized an establishment that labeled their menu in some fashion not exactly mirroring the guidance document. The result of these precedent-setting decisions is that it is virtually impossible for a regulated entity to fully achieve compliance, as their actions will almost certainly deviate in at least some small way from the guidance examples.

Several other problems exist with guidance documents. For one, no one knows how many of them there are. In January 2018, the House of Representatives Committee on Oversight and Government Reform embarked on an effort to get agencies to report back how many new guidance documents had been issued in the previous 10 years. The committee got back an initial inventory of more than [13,000](#), although it added in its report that substantially more likely exist in unknown regions of agency websites.

Another problem is transparency. Unlike regulations, which are all published in the Federal Register and thus satisfy requirements to make the public aware of their availability, few guidance documents are published so publicly. As a result, the public likely has no idea that most of them exist and does not have an obvious way to find them.

Last, guidance documents are not held to the same procedural requirements as rules. The public can weigh in on regulations, but it rarely gets that opportunity for guidance, even though its implications can be just as significant.

EXECUTIVE ORDERS

The two EOs signed on October 9 aim to help alleviate these problems. The first EO, [Promoting the Rule of Law Through Improved Agency Guidance Documents](#), increases transparency around guidance documents. It requires federal agencies to establish a repository page on their website where all of that agency's guidance documents can be found. This repository will make it easier for someone to find guidance on a subject affecting their business. The EO also states that any guidance document not found on the issuing agency's website is considered no longer in effect. Further, the EO requires agencies to make draft versions of new, major guidance available for public input at least 30 days before they are finalized.

A second EO, [Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication](#), deals with penalties stemming from guidance documents and other unannounced policy interpretations. It prevents agencies from "unfair surprise" enforcement actions — primarily through citing violations of guidance documents — and provides anyone receiving a notice of violation more opportunities to contest potential violations.

OUTLOOK

The fact that agencies sometimes use guidance documents to justify penalizing regulated entities has been an open secret in Washington. While guidance documents can be helpful, they are decidedly less rigorous than formal regulations, and they should not be the basis for enforcement action as a result. While these EOs are a good start toward rectifying this problem, the details in an Office of Management and Budget (OMB) memorandum will ultimately determine their success. This memo is due in 120 days and will spell out specifically what types of guidance are covered. It will be important for OMB to strike the appropriate balance between making guidance documents truly a compliance-assistance tool and not disincentivizing agencies from producing assistance materials that help provide certainty to regulated entities.

One area in the EOs that could be improved is the requirement for agencies to post their guidance documents in one place on their website. While this reform certainly is an improvement over the status quo, a better solution would be for the federal government to have one searchable webpage with all agency guidance, similar to [Regulations.gov](#). Less legally sophisticated regulated entities, such as small businesses and individual members of the public, often are not even aware of all the agencies that might have jurisdiction over them. If these users do not know who regulates them, they are unlikely to find important information on the websites of those

regulators.