

President Issues New Executive Order, Requires Agencies to Establish Regulatory Reform Task Forces

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Food, Drug, and Device

On February 24, 2017, President Donald Trump signed an executive order entitled “Enforcing the Regulatory Reform Agenda” (the “Executive Order” or the “Order”).¹ The Order is one of several actions the Trump Administration has taken concerning regulatory reform since inauguration, including:

- On January 20, the Administration issued a memorandum to the heads of executive departments and agencies entitled “Regulatory Freeze Pending Review.”² The memorandum directs all federal agencies to implement a freeze on “new or pending” federal regulations to provide the administration an opportunity for review. Our previous [client alert](#) addresses this memorandum.
- On January 30, the President signed Executive Order 13771 entitled “Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs.”³ The executive order states, in relevant part: “[I]t is important that for every one new regulation issued, at least two prior regulations be identified for elimination...”⁴
- On February 2, the Office of Information and Regulatory Affairs (“OIRA”) issued an interim guidance clarifying Executive Order 13771. Specifically, OIRA states that in Fiscal Year 2017 the order will only apply to new “significant regulatory actions,” as defined in section 3(f) of Executive Order 12866.⁵

¹ The White House (Office of the Press Secretary), “Presidential Executive Order on Enforcing the Regulatory Reform Agenda” (Feb. 24, 2017); *available at* <https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda>.

² The White House (Office of the Press Secretary), “Memorandum for the Heads of Executive Departments and Agencies” (Jan. 20, 2017); *available at* <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies>.

³ Exec. Order No. 13771, 82 Fed. Reg. 9339 (Feb. 3, 2017); *available at* <https://www.gpo.gov/fdsys/pkg/FR-2017-02-03/pdf/2017-02451.pdf>.

⁴ *Id.* at § 1.

⁵ OIRA, “Memorandum: Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, Titled ‘Reducing Regulation and Controlling Regulatory Costs’” (Feb. 2, 2017); *available at* <https://www.whitehouse.gov/the-press-office/2017/02/02/interim-guidance-implementing-section-2-executive-order-january-30-2017>.

- In addition, Congress and the President have utilized the Congressional Review Act (5 U.S.C. Part I, Chapter 8) (“CRA”) to eliminate certain regulations issued in the final months of the Obama administration.

The most recent Executive Order continues these regulatory reform efforts by directing agencies to identify personnel to oversee the implementation of the Administration’s regulatory reform initiatives. In particular, the Executive Order:

- Creates the role of the Regulatory Reform Officer (“RRO”) within each agency;
- Directs each agency to establish a Regulatory Reform Task Force (“RRTF” or “Task Force”); and
- Stipulates that each Task Force must evaluate existing regulations and prepare recommendations to the agency head for possible repeal, replacement, or modification.

In this alert, we further explain these key elements of the Executive Order.

Regulatory Reform Officer

The Order directs the head of each agency to designate an agency official as its RRO within 60 days of the signing of the Executive Order.⁶ The Order does not define the term “agency”; given this, it is possible that FDA could designate its own RRO or that it could implement these initiatives directly under the oversight of the HHS RRO.⁷

Under the Order, the RROs “shall oversee the implementation of regulatory reform initiatives and policies to ensure the agencies effectively carry out regulatory reforms, consistent with applicable law.”⁸ These initiatives and policies include:

- Executive Order 13771;
- Executive Order 12866 (“Regulatory Planning and Review”);
- Section 6 of Executive Order 13563 (“Improving Regulation and Regulatory Review”); and
- The “termination, consistent with applicable law, of programs and activities that derive from or implement Executive Orders, guidance documents, policy memoranda, rule interpretations, and similar documents, or relevant portions thereof, that have been rescinded.”⁹

The RRO must periodically report to the head of the agency and regularly consult agency leadership.¹⁰

⁶ *Supra* note 1 at § 2(a).

⁷ We note that certain provisions of the Order only apply to a specific subset of agencies listed at 31 U.S.C. § 901(b)(1), including the Department of Health and Human Services. The rest of the Executive Order, therefore, appears to apply to a more expansive universe of “agencies”, which could include FDA separate from HHS.

⁸ *Supra* note 1 at § 2(a).

⁹ *Id.*

¹⁰ *Id.* at § 2(b).

Regulatory Reform Task Force

Each agency must also form a RRTF. This Task Force shall consist of: the RRO, the agency Regulatory Policy Officer (designated under Executive Order 12866), and a representative from the agency's central policy office (or equivalent central office).¹¹ For agencies listed in 31 U.S.C. § 901(b)(1), the RRTF shall include "at least three additional senior agency officials as determined by the agency head."

The principal role of the Task Force is to "evaluate existing regulations...and make recommendations to the agency head regarding their repeal, replacement, or modification, consistent with applicable law."¹²

Definition of "Regulation"

The Order incorporates the definition of "regulation" in section 4 of Executive Order 13771: "[A]n agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency, but does not include: (a) regulations issued with respect to a military, national security, or foreign affairs function of the United States; (b) regulations related to agency organization, management, or personnel; or (c) any other category of regulations exempted by the Director."¹³ "Regulation" appears to be broadly defined to potentially include agency guidance.

Evaluation of Existing Regulations

The Task Force must, at a minimum, attempt to identify "regulations" that:

- "eliminate jobs, or inhibit job creation;
- are outdated, unnecessary, or ineffective;
- impose costs that exceed benefits;
- create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;
- are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or
- derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified."¹⁴

When considering the regulatory offsets required by Executive Order 13771, an agency head "should prioritize, to the extent permitted by law, those regulations...identified [by the Task Force] as being outdated, unnecessary, or ineffective...."¹⁵

¹¹ *Id.* at § 3(a).

¹² *Id.* at § 3(d).

¹³ *Supra* note 3 at § 4.

¹⁴ *Supra* note 1 at § 3(d)(i)-(vi).

Public Input and Task Force Reports

The Task Force must seek input and other assistance from “entities significantly affected by Federal regulations,” including consumers, small businesses, and trade associations.¹⁶

The Order directs each agency to measure its progress towards the following goals: (1) improvements in the regulatory reform initiatives, and (2) progress made toward identifying regulations for “repeal, replacement, or modification.”¹⁷ Specifically, each Task Force must, “[w]ithin 90 days of the order and on a schedule determined by the agency head thereafter,” provide a report to the agency head outlining its progress. The agency head must take into account these two goals “in assessing the performance of the [RRTF] and, to the extent permitted by law, those individuals responsible for developing and issuing agency regulations.”¹⁸ Additionally, 31 U.S.C. § 901(b)(1) agencies must incorporate in their annual performance plans “performance indicators that measure progress toward” the two goals.¹⁹ The Director of the Office of Management and Budget (“OMB”) must issue accountability guidance within 60 days of the Order.

Looking Forward

In the coming months, each agency will appoint a RRO and form a RRTF under the requirements of the Executive Order. Although it is unclear how agencies will seek stakeholder input, companies and trade associations will have the opportunity to interact with these agencies and offer input concerning potential “regulations” for repeal, replacement, or modification. Even without knowing how agencies will solicit input, impacted stakeholders could begin compiling data that will assist agencies in identifying “regulations” that meet the criteria set forth in the Executive Order.

Covington & Burling LLP’s Food, Drug, and Device and Public Policy and Government Affairs lawyers are actively monitoring and assisting companies impacted by regulatory reform initiatives under the Trump Administration. If you have any questions concerning the issues discussed in this alert or any other regulatory reform efforts, please contact any of the following attorneys in our Food & Drug Practice group.

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¹⁵ *Id.* at § 3(f).

¹⁶ *Id.* at § 3(e).

¹⁷ *Id.* at § 3(g).

¹⁸ *Id.* at § 4(b).

¹⁹ *Id.* at § 4(a).

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