
Health Law Daily Wrap Up

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One of President Donald Trump’s first official acts was signing an Executive Order (EO) titled "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal." The EO, signed January 20, 2017, says that it is the Trump Administration’s policy to seek the prompt repeal of the ACA (P.L. 111-148). It further gives executive agencies and departments the authority and discretion to, to the maximum extent permitted by law and in compliance with the Administrative Procedure Act (APA), waive, defer, grant exemptions from, or delay the implementation of many ACA provisions and requirements. That same day, Reince Priebus, the president’s chief of staff, instituted a regulatory freeze pending review to all executive agencies and departments (Executive Order, January 20, 2017).

Executive Order. The EO, which has the full force of law but is subject to judicial review, states that while the Trump Administration is seeking the prompt repeal of the ACA, the Executive Branch must ensure that the law is being implemented efficiently and take steps to minimize the economic and regulatory burdens of the ACA. It also previews the Administration’s view of what an ACA replacement may look like, directing executive agencies and departments to make preparations to give states more flexibility and control of the health care market, including encouraging health insurers to provide policies across state lines.

ACA burdens. Under the EO, the HHS Secretary and the heads of all other executive departments and agencies with authorities and responsibilities under the ACA—that is, the Departments of Labor and the Treasury—are directed to use all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the ACA that would impose (1) a fiscal burden on any state; or (2) a cost, fee, tax, penalty, or regulatory burden on any of the following:

- individuals;
- families;
- health care providers;
- health insurers;
- patients;
- recipients of health care services;
- purchasers of health insurance; or
- makers of medical devices, products, or medications.

Practically speaking, this means that the Secretaries of HHS, Labor, and the Treasury are required, as permitted by law and in accordance with the APA, to do everything in their power to end implementation of the ACA, including provisions covering the individual and employer mandates, Medicaid expansion, contraception coverage, changes to Medicare payments, the medical device tax, and more. However, the EO does not repeal the ACA, which must be done by the legislature, and major changes will require notice-and-comment procedures to revise regulations.

State flexibility, open market. The remainder of the EO deals with making agency preparations for certain changes to health care programs and the health insurance market that the Trump Administration will likely try to include in future laws to replace the ACA or otherwise reform health care and insurance. First, executive departments and agencies are directed to exercise available authority and discretion to provide states with cooperation and greater flexibility in implementing health care programs. This would affect state Medicaid
programs and Children’s Health Insurance Programs (CHIP), including section 1115 waivers. The change aligns with policies announced by Trump during the campaign and presidential transition period, as well as those of Congressional leaders and Trump’s nominee for HHS Secretary, Rep. Tom Price (R-Ga) (see Health and Life Sciences Implications of the Trump Administration, December 28, 2016).

Department and agency heads with responsibilities relating to health care or health insurance are also required to encourage development of “a free and open market in interstate commerce” for both health care services and health insurance. According to the EO, the goal is to achieve and preserve maximum options for patients and consumers. Selling health insurance across state lines has been a talking point for Trump, as well as House Speaker Paul Ryan (R-Wis) and other members of Congress. However, this directive could also impact the Federal Trade Commission (FTC) and Department of Justice (DOJ), for example, as four of the nation’s five largest health insurers are pursuing mergers (see DOJ lawsuit steps in between Aetna-Humana and Anthem-Cigna mergers, July 21, 2016; see also Aetna’s $37 billion purchase of Humana enjoined, in this issue).

**Regulatory freeze.** In a January 20, 2017, memorandum to the heads of executive departments and agencies, Priebus communicated Trump’s plan to manage the federal regulatory process while the Administration is in its early days. With exceptions for regulations subject to statutory or judicial deadlines, and for emergency situations or other urgent circumstances relating to health, safety, financial, or national security matters, there is an immediate regulatory freeze pending review in effect. The freeze affects regulations and guidance documents that (1) have not yet been sent to the Office of the Federal Register (OFR); (2) have been sent to the OFR but not yet published in the Federal Register; and (3) have been published in the Federal Register but have not yet taken effect.

Regulations that have not yet been sent to the OFR should not be sent until Trump’s appointed or designated department or agency head, or his or her designee, reviews and approves the regulation. Regulations that have been sent to the OFR but not yet published should be immediately withdrawn from the OFR consistent with OFR procedures, and then similarly reviewed and approved before being resubmitted for publication.

Regulations that have been published in the Federal Register but have not yet taken effect will have, as permitted by law, a temporary 60-day postponement of the effective date—the earliest effective date for such regulations will now be March 21, 2017. The purpose of the postponement is to review questions of fact, law, and policy raised by each regulation. Agency and department heads are further directed to consider proposing further notice-and-comment rulemaking for regulations that have been delayed to review questions of fact, law, or policy. According to the memorandum, regulations that do raise substantial questions of law or policy after review require notifying the Office of Management and Budget (OMB) and taking further appropriate action in consultation with the OMB Director.

For additional information about affected health care and life sciences regulations, see Sifting through the Obama Administration’s ‘regulatory dump’, January 20, 2017; the HHS Semiannual Regulatory Agenda (81 FR 94741, December 23, 2016); and the weekly Health Law Regulation Tracker published in Health Law Daily.