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How President Trump's First Hours Affected the Clinical Research Industry

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Within hours of President Donald Trump's swearing in, he signed his first Executive Order and issued his first Presidential Memorandum. The Executive Order is directed toward the intended repeal of the Patient Protection and Affordable Care Act (PPACA), which includes provisions affecting the clinical trial industry. The first Presidential Memorandum, as is not uncommon for an incoming President, freezes pending regulations and pauses new ones until the new administration has had a chance to evaluate them.

First Executive Order

President Trump's *Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal*[1] orders the Department of Health & Human Services (HHS) and other federal departments to begin the administrative rollback of the PPACA. An Executive Order (EO) affects only the executive branch of government, i.e., anything not tied to an existing law or regulation or the Constitution, where "checks and balances" involve the judicial and legislative branches. The crucial point of this Executive Order is in Section 2:

> To the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products or medications.

Furthermore, for existing regulations that are not under departmental control, Section 5 calls for beginning the rulemaking process to eliminate or, at least, minimize their economic impact:

> To the extent that carrying out the directives in this order would require revision of regulations issued through notice-and-comment rulemaking, the heads of agencies shall comply with the Administrative Procedure Act and other applicable statutes in considering or promulgating such regulatory revisions.

The Sunshine Act

Of keen interest to the clinical research industry is PPACA section 6002 (a.k.a. "The Sunshine Act"). To enact this program, dubbed "Open Payments" by CMS, the PPACA legislation changed the Social Security Act. This means that repealing the Sunshine Act requires an Act of Congress to reset the Social Security Act, not a just an EO, regulatory change, or repeal of the PPACA. Supporters and opponents of this Act should contact their congressional representatives.

PCORI

Section 6301 of the PPACA created and established funding for the Patient Centered Outcomes Research Institute (PCORI). About half of PCORI's funding comes from the Patient Centered Outcome Research Fee imposed on health insurers, which is clearly under the impact of the EO. The other half comes from the general budget, which is only indirectly connected to the EO's mandate. Whether and how the EO will affect PCORI's funding is unclear.

Other Implications

PPACA Section 9008's fees on drug and device manufacturers definitely seem to be on the table. These fees include the mandatory quasi-rebates imposed on pharmaceutical companies based on their percentage of sales to government payors, as well as the 2.3% tax on medical devices. Eliminating mandatory insurance coverage for clinical trials may or may not be under consideration, depending on interpretation. If the PPACA is repealed, this mandate would revert back to the states, along with other potential impacts.[2]

First Presidential Memorandum

President Trump also signed a Presidential Memorandum to the heads of executive departments and agencies, calling for a freeze on any new or pending regulations not related to emergency situations or other urgent circumstances relating to health, safety, financial or national security matters until such time as the new department/agency head has had time to review them (not uncommon upon a change of administration).[3] This freeze affects regulations under development that are required to implement the 21st Century Cures Act.[4]

In addition to freezing new and pending regulations, regulations that were recently published in the Federal Register but had not yet taken effect will have a 60-day delay in implementation to allow time for review by the new department/agency heads for any "questions of fact, law and policy they raise." As the revisions to the Common Rule were published in the Federal Register a day before President Trump signed the Memorandum, and do not take effect until January, 2018, these revisions appear to be subject to the Memorandum.[5] However, the final version is largely uncontroversial and not apparently subject to any questions of fact, law or policy that would delay their implementation.

Conclusion

President Trump's first hours in office raised questions and issues of importance to the clinical research industry. Answers and resolutions will emerge over time, as will, most likely, many other questions and issues.

References

1. Full text of the EO is available at https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and.
2. Vulcano, David M. "What Do the U.S. Election Results Mean to the Clinical Trials Industry?" *Clinical Researcher*. Dec 2016, 30 (6) 30-33; DOI: 10.14524/CR-16-4053.
3. Full text of the Memorandum is available at https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies.
4. The sections of the 21st Century Cures Act most likely to affect clinical research operations can be found at http://firstclinical.com/journal/2017/1701_21st_Century.pdf.

5. The Common Rule amendments are available at https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-protection-of-human-subjects.

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