

One In - Two Out and Healthcare Regulation

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President Trump signed an executive order (the “Order”) on January 30th, 2017 aiming to reduce bureaucracy by requiring agencies to remove two regulations for every one new regulation they implement. The cost of any new regulation should be offset by the elimination of these other two previously issued regulations. The Order could have major consequences in the healthcare industry but the changes it may bring are at this point unpredictable.

Some in the healthcare field welcomed the “one in, two out” idea. Rules and regulations in the healthcare world come from several agencies and cover a broad array of practices. 2016 brought several including the Nondiscrimination in Health Programs and Activities Rule, which expands on nondiscrimination requirements found in Section 1557 of the Affordable Care Act, and regulations to implement the Medicare Access and CHIP Reauthorization Act (MACRA) physician payment system, among others.

The Order has also brought about confusion. First, the Order left the future uncertain as to what may happen with these most recent regulations and the many other regulations that have helped shape the healthcare industry. While regulations have costs associated with them, regulated entities have already invested in compliance, and will now have to pay close attention as requirements may shift in this upcoming year. Second, it is unclear how the Order may affect any Medicare and other health care payment system regulations, including MACRA, which may involve costs to implement, but are ultimately designed to streamline CMS payment systems. Finally, the Order is vague and may turn out to have no effect on the healthcare industry at all. The executive Order allows the Office of Management and Budget (“OMB”) director the flexibility to interpret and carry out the Order, which could mean the Order will change nothing at all with regard to healthcare regulation.

A few days following the Executive Order, a Memorandum offering interim guidance on the Order was released. This clarifies that the Order applies only to “significant regulatory actions” as defined in Section 3(f) of a separate Executive Order. In addition, it only

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applies to those regulations released between January 20th and September 30th of 2017. Federal spending rules that cause income transfers from taxpayers to program beneficiaries, for example Medicare spending, are not covered by this Order. It appears, then, that the Centers for Medicare and Medicaid Services (“CMS”) may not need to adhere to the “one in, two out” framework when promulgated annual rulemakings for Medicare payment for hospital inpatient, hospital outpatient, and physician and other Medicare Part B services.

In addition, the Memorandum stated that agency guidance or interpretive documents that are not formal rulemakings may or may not be covered by the Order; OMB will address these guidance documents on a case by case basis. Purely deregulatory actions that confer only savings will not trigger the Order, but if there are costs associated with the rulemaking the agency will need to offset those costs.

The “one in, two out” idea is simple and attractive, from a regulatory burden perspective. However, the healthcare industry and its regulation involve complex systems with numerous stakeholders, and a variety of perspectives from which one could view the cost burden of regulations. How the Order will be implemented and the magnitude of its impact on health care regulation is at this point unpredictable, and ultimately will be in the discretion of the Executive Office of the President.