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Integrating experiential learning in compliance education

an interview with Professor Paul Fiorelli

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COLUMNS

DEPARTMENTS

by Steve Lokensgard, Frank Swain, and Mike Adelberg

The Trump 2-for-1 Executive Order and its impact on healthcare

» Agencies must repeal two existing regulations when promulgating new regulations.
» CMS reimbursement rules are not impacted by the 2-for-1 rule.
» The HIPAA Privacy Rule would be impacted by the 2-for-1 rule.
» Each agency will appoint regulatory reform task forces.
» This regulatory reform has enforcement provisions.

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The Centers for Medicare & Medicaid Services (CMS) has been a little quiet lately. Are President Trump's de-regulation efforts having an impact? That answer is, maybe—but the recent lull won't last long. The majority of significant regulations regularly issued by CMS will not be impacted by the controversial "2-for-1" Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs),[1] but it may present an opportunity to reduce the regulatory burden on healthcare providers.

In an effort to promote de-regulation and lower the cost of federal regulations on businesses, President Trump signed EO 13771, which requires agencies to identify two existing regulations to be repealed whenever a new regulation is proposed. He reinforced that initiative by issuing Executive Order 13777 (Enforcing the Regulatory Reform Agenda),[2] which requires each federal agency to appoint a Regulatory Reform Officer and Regulatory Reform Task Forces to ensure that agencies effectively carry out these regulatory reform initiatives.

In addition to the relatively simplistic 2-for-1 rule, EO 13771 requires an evaluation of the total incremental cost of a regulation. This will require healthcare regulatory readers to venture into sections of every rule that are usually ignored—sections dealing with Collection of Information requirements and the Regulatory Impact Analysis. Each agency will be given a regulatory budget each fiscal year, and agencies cannot issue regulations over the course of the year in excess of the amount budgeted.

Hospitals and health systems can probably think of a few regulations that they could do without. In December of 2016, the American Hospital Association sent President-elect Trump a letter identifying 33 specific actions that could be taken to immediately reduce the regulatory


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burden on hospitals.[3] But the fact is that the most significant reimbursement rules issued by CMS are exempt from EO 13771. Still, CMS will be required to revisit old regulations with significant burden on providers in order to pass new initiatives.

Transfer rules are exempt

Guidance, issued shortly after EO 13771 was signed, clarified that transfer rules are not subject to the 2-for-1 rule.[4] Federal regulations are viewed as either prescriptive rules or transfer rules. Prescriptive rules are rules that restrict behavior, such as the handling of protected health information (PHI), or regulations prohibiting unlawful patient inducement. Transfer rules deal with the transfer of money or goods from one group to another, such as reimbursement of Medicare providers, or changes to coinsurance to be paid by Medicare beneficiaries. On April 5, the Office of Information and Regulatory Affairs (OIRA) issued further guidance.

Some of the most significant regulations issued each year by CMS are considered transfer rules. The regulatory impact analysis section in the proposed 2018 Inpatient Prospective Payment System (IPPS) rule mentions EO 13771, notes the exemption related to transfer rules, and that the "implications of the rule's costs and cost savings will be further considered" in the final rule.[5] Previously, other rules such as the OPPS final rule and the Physician Fee Schedule final rule note that all "expenditures are classified as transfers to Medicare providers." The significant rule issued by CMS last November implementing the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was a transfer rule.[6] Regulations relating to accountable care organizations (ACOs) and Medicare Advantage and Part D plans would also be considered transfer rules, because they deal in general with payments from the government to Medicare providers.

The best example of a prescriptive rule is the HIPAA Privacy Rule. It does not involve the transfer of money from the federal government to Medicare providers, but establishes strict rules for safeguarding PHI. Politics is nothing new to the Privacy Rule. The cost of implementing the rule was likely significantly reduced when the new Bush Administration arrived in 2001 and amended the Clinton Administration's proposed rule by making consent optional for the use and disclosure of PHI for treatment, payment, and healthcare operations.

It may not be that easy to simply say that transfer rules are exempt and prescriptive rules are subject to EO 13771. For example, the 2016 Physician Fee Schedule final rule, issued Nov. 16, 2015, was largely a transfer rule, but it included requirements to collect and report information to CMS to implement the Physician Quality Reporting System (PQRS). In the section of the rule dealing with information collection requirements, CMS estimated that the total cost of annual recordkeeping and reporting requirements was $488 million.[7] The guidance from the White House indicated that transfer rules are not covered by EO 13771. "However, in cases where these rules impose requirements on non-Federal entities, such as reporting or recordkeeping, agencies would need to account for these costs." In other words, unless additional guidance is provided, it appears that CMS would have to offset $488 million in incremental costs before issuing such a requirement.

Minor rules exempt

The White House also clarified that EO 13771 applies only to "significant regulatory actions." To determine whether a regulation is "significant," an agency must analyze the rule in accordance with criteria contained in Executive Order 12866 (Regulatory Planning and Review).[8] In general, a regulation is considered "significant" if it involves a cost to

individuals or entities of more than $100 million per year, but an agency can designate other regulations as "significant."

For example, in 2014 CMS promulgated a final rule that did not meet the $100 million cost threshold, but was designated by the agency as a "significant" regulation. CMS amended the HIPAA Privacy Rule to allow patients to get their lab results directly from a lab instead of their doctor.[9] The regulation would increase costs to labs by requiring them to add staff to respond to record requests and to revise their Notice of Privacy Practices. The cost of these measures was estimated to be between $3 million and $63 million in the first year, lower in later years.[10] A Regulatory Impact Analysis was conducted because the rule was designated as a "significant regulatory action."[11]

Assuming a similar regulation was finalized in fiscal year 2017 (prior to September 30, 2017), CMS would have to identify two additional regulations that would provide, collectively, a regulatory cost savings in excess of $63 million. All of this suggests that agencies that oversee multiple and complex programs—such as CMS—might be tempted to exercise creativity in deploying methodologies that keep certain proposed regulations under the "significant" threshold. Public commenters on draft regulations will want to pay greater attention to government cost estimates—a part of the draft regulation that frequently draws scant attention—to assure credible and replicable financial projections. Correspondingly, CMS and other agencies might face greater pressure to expound upon public comments on costs estimates in the preamble of final regulations.

The threshold may cause agencies to issue smaller changes to regulations more frequently. But there will likely be additional guidance coming out of the White House or the Regulatory Reform Task Forces to ensure that agencies don't find ways to game the system. Alternatively, OIRA, a part of the Office of Management and Budget (OMB)—which will be responsible for policing the executive agencies subject to this order—could, without additional resources, become overwhelmed by the added responsibility of enforcing the new Administration's many executive orders.

In the early months of the Trump Administration, we have already seen some selectivity from the new Administration in enforcing these new orders. For example, we have seen regulations on the 340B Drug Discount program and Medicare Bundled Payment program delayed, while other regulations issued in the final months of the Obama Administration have gone forward. And we have seen the Trump Administration issue a new and significant regulation—impacting the insurance markets remade by the Affordable Care Act—without withdrawing two others. CMS noted that the regulation does not impose significant regulatory costs and is therefore exempt from EO 13771.[12] OMB has the power to approve exceptions to these executive orders, and appears poised to do so when necessary.

Litigation over the Executive Order

Federal agencies don't have the power to issue new rules simply because the agency considers the new rule to be in the country's best interest. Agency power derives from statutes passed by Congress. The statute is interpreted and implemented by the Executive branch through a federal agency.

The Administrative Procedure Act (APA)[13] limits an agency's ability to publish regulations. A regulation cannot be "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law." And a rigorous rulemaking process must be followed with any new rule. The agency must publish a proposed rule, solicit and consider comments, and issue a final rule.

The same standards and procedures apply to repealing regulations. The agency must articulate its rationale for repealing the regulation, issue a proposed rule, consider comments, and then issue a final rule. It is not as easy to repeal a rule as it is to sign an executive order. Congress also has limited power to repeal regulations issued in the final months of an administration through the Congressional Review Act. The new Republican Congress used this tool to strike down 14 Obama Administration regulations, but none of these regulations are from the Department of Health & Human Services, and the window is now closed for using this tool until the next change in Administrations.

A week after EO 13771 was issued, a lawsuit was filed claiming that the requirement to repeal two regulations for every new one would violate the APA. Public Citizen, the Natural Resources Defense Council, and the Communications Workers of America claimed that President Trump exceeded his constitutional authority in issuing the order, because it would require arbitrarily repealing administrative regulations in violation of the APA. Of course, EO 13771 is a general performance standard, and Courts will presumably require that any repeal of an existing rule will have to comply with APA requirements. The Administration could win the battle of EO 13771, but lose battles over specific regulatory repeals.

Conclusion

Quantifying the financial impact of regulations and record keeping requirements is nothing new to federal agencies. This kind of analysis has been required for years. President Jimmy Carter issued executive orders relating to centralizing regulatory management at OMB.[14] The Paperwork Reduction Act and OIRA were approved in 1980, and President Bill Clinton issued the executive order that required OIRA to review the cost and benefits of "economically significant rules"—those with an economic impact more than $100 million annually.[15] Part of the rulemaking process has been, for more than 20 years, to require an agency to specifically calculate and publicize if the overall benefits of a proposed regulation are outweighed by its regulatory costs, and empowering OIRA to refuse to allow publication of regulations from Executive Branch agencies, which it does not approve.

In 1993, EO 12866 required each agency to periodically review its existing regulations, so as to ensure that the screen of cost benefit analysis did not exempt rules already on the books, but that provision has proven, despite some efforts by various administrations, to be unenforceable. OIRA doesn't "hold the stick" over an existing rule that it does over a new rule, and there is no APA right of action for failure to review.

The new Trump Executive Order 13771 attaches further consequences to the regulatory analysis of new proposed rules by insisting upon a balancing of new and old regulatory costs. This may allow, 22 years after EO 12866, at last some meaningful review of existing rules. It is hard to know how all of this will play out in the coming months but, at least for now, events seem to lean toward fewer requirements being placed on healthcare providers in the future.

1. Office of the Federal Register: Reducing Regulation and Controlling Regulatory Costs. February 3, 2017. Available at http://bit.ly/2tNAFQz
2. Federal Register: Enforcing the Regulatory Reform Agenda. March 1, 2017. Available at http://bit.ly/2tr7Cji
3. See American Hospital Association: Letter to Mr. Donald Trump. December 2, 2016. Available at http://bit.ly/2tSq6MF
4. Press Office of the White House, press release: Memorandum on Reducing Regulation and Controlling Regulatory Costs. February 2, 2017. Available at http://bit.ly/2sNPBtB
5. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates, 82 Fed. Reg. 19796, 20228 (April 28, 2017). Available at 82 Fed. Reg. 19796
6. See 81 FR 77008, 77536, Table 64 (November 4, 2016).
7. See 80 FR 70886, 71354, Table 59 (November 16, 2015).
8. Executive Order 12866: Regulatory Planning and Review (September 30, 1993).
9. See 79 FR 7290 (February 6, 2014).
10. Id. at 7312.
11. Id. at 7310.
12. See 82 FR 10980, 10997 (February 17, 2017)
13. 5 USC 501 et seq
14. Executive Order 12044: Improving Government Regulations (March 23, 1978)
15. Ibid., Ref #8.