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The Administrative Process

Legislating in the Executive Branch

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The administrative process often appears opaque, cumbersome, and esoteric. This is particularly true of health policy, in which the rulemaking process is often statutorily prescriptive. However, often broad discretion is given to agencies as Congress has granted the executive branch latitude to essentially legislate with its rulemaking powers. Understanding these processes is key for policymakers to effectively shape desired outcomes and advance policy improvements.

This educational brief will outline that process and offer a case study of the promulgation of a new coverage opportunity.

The Basic Principles of Administrative Law

Executive branch agencies derive their authority to take action from either the Constitution or from Congress. In the case of an agency such as the Centers for Medicare & Medicaid Services (CMS) that carries out programs created by Congress, the agency's authority to issue regulations regarding these programs is derived from statutes enacted by Congress. Congress may grant general rulemaking authority to an agency or rulemaking authority regarding a specific provision. An agency may not take action that goes beyond its statutory or Constitutional authority.

Administrative Procedure Act (APA)

Like statutes, agency regulations have the force of law. The promulgation of regulations must be compliant with the Administrative Procedure Act (APA), 5 U.S.C. §§ 551, et seq., as well as any program-specific statutory requirements, e.g., SSA § 1871. They also must comply with several other important requirements that stem from other statutes, such as the Congressional Review Act (CRA), the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act. Non-compliant regulations can be vacated by a court. Presidents often issue executive orders which provide general direction for regulatory action.

Under the APA—absent good cause, an agency must provide notice of a proposed rulemaking, published in the Federal Register. The notice must specify, among other things, the legal authority under which the agency has proposed the rule and the proposed substance of the rule. After notice is given, the agency must solicit and accept public comments on the rule. A comment period is typically required by law to last at least 30 days.

In promulgating a final rule, the agency must explain its basis and purpose. In doing do, the agency must consider and respond to comments received in response to the proposed rule. The rule must contain a regulatory impact analysis (RIA) of the benefits and costs of the regulatory action, although they often fail to consider full economic costs of the regulatory action and instead focus more on paperwork burdens. The regulatory text of final rules is codified in the Code of Federal Regulations.

A final regulation is typically effective at least 30 days after its publication in the Federal Register. If a final regulation is economically significant (i.e., it has an economic effect of $100 million or more), it is usually not effective until at least 60 days after its publication in the Federal Register.

Congressional Review Act (CRA)

Under the Congressional Review Act (CRA), Congress may disapprove a final regulation by passing a disapproval

resolution. This resolution can be signed by the President or enacted after a Congressional override of a veto. Enacted in 1996, the CRA has been used sparingly, except for in 2017. Until 2015, Congress only disapproved one final regulation under the CRA: a 2001 Occupational Safety and Health Administration (OSHA) regulation requiring employers to take measures to curb ergonomic injuries in the workplace. In the 115th Congress alone, Congress repealed 16 rules under the CRA and repealed three more in the 117th Congress.

Subregulatory Guidance

In theory, many administrative actions such as subregulatory guidance do *not* have the force of law, thus making them non-binding and unenforceable. These actions are used by agencies to set forth interpretations of statutes and regulations. Examples include CMS Manuals, the Medicare Advantage (MA) Marketing Guidelines, and Center for Consumer Information and Insurance Oversight (CCIIO) Frequently Asked Questions (FAQs). However, guidance is often treated as a requirement in practice.

An agency is not required to follow the notice-and-comment requirements under the APA when issuing guidance but can choose to request public input. Courts and Congress have cautioned agencies against abusing their authority to issue guidance as a means of circumventing the APA's requirements for regulations.

Many agencies and departments may try to use guidance documents to release significant policy changes to avoid the OIRA review process and public comment. Such guidance can be challenged legally, and OIRA tries to ensure that significant guidance documents go through an extensive vetting process in line with the APA. Following the process better protects the administrative action from litigation risk.

The Role of the White House

While each agency roughly follows the process outlined above, this process is often coordinated through White House leadership. While the role is less pronounced for lower priority or less controversial rules, more sensitive policymaking can often necessitate more significant involvement from the White House.

OMB/OIRA Review

Once a department or agency completes a draft of a proposed or final rule, it sends the text to the Office of Information and Regulatory Affairs (OIRA) within the White House's Office of Management and Budget (OMB) for centralized review and clearance.

OMB is both a statutorily created federal agency and an important component of the Executive Office of the President (EOP). At a high level, OMB has three core functions: 1) preparing and implementing the President's budget policy; 2) reviewing all significant regulatory actions of departments and agencies that report to the President as well as setting and enforcing federal information standards and policy; and 3) setting and enforcing the President's management agenda and a wide range of other management policies and practices.

In its role coordinating regulatory review, OIRA gathers input from all executive branch stakeholders, including departments and agencies, EOP offices, career and political officials, and other key stakeholders. OIRA also attempts to ensure that the rule satisfied the APA and other requirements.

Before and during the reviews driven by the White House, a similar process occurs at the department level, coordinated by the executive secretary of the department. This process involves review and clearance by the components within each department; at HHS, this often includes the Office of the Secretary, CMS, and the general counsel's office. The Department process both precedes and then continues into the White House process, so additional rounds of agency reviews and approvals are nested within each round of White House review.

Once regulatory review reaches the White House, the process is often referred to as "OMB review." Many White House components other than OMB and OIRA are involved in scrutinizing proposed rules. Among them are the National Economic Council (NEC), the Domestic Policy Council (DPC), the Office of Science and Technology Policy (OSTP), the Council of Economic Advisers (CEA), and the White House Counsel. In the Trump administration—either NEC or DPC, depending on the particular topic, oversaw a separate process to reach agreement on health care policy which then was often manifested in particular regulations.

The White House components examine regulations from an agency to ensure that they reflect the policy priorities of the administration, are sensitive to political contexts, and comport with statute and legal requirements. They also analyze financial impacts and potential unintended consequences. OIRA coordinates the regulatory review process, which involves White House components as well as political appointees and career experts at departments and agencies, with a goal of ensuring the Administration moves as one on each rule.

The various components and officials, however, do not always see eye to eye. While they typically engage and cooperate to ensure the White House speaks with one voice, disagreements do happen. When there is such tension, such differences are reconciled and negotiated at the staff level whenever possible. If not possible, the issues go up the chain to higher officials. In very rare cases, the principals—such as the HHS Secretary, OMB Director, and Director of the NEC—directly brief the President, who then makes the final decision.

Case Study: The Individual Coverage Health Reimbursement Arrangement Rule

In the summer of 2017, the NEC convened several meetings of executive branch departments and White House offices to discuss options to help people harmed by the Affordable Care Act (ACA). The Treasury Department proposed an expansion of Health Reimbursement Arrangements (HRAs) because of concern of Obama-era restrictions that prohibited HRAs from reimbursing individual market premiums.

On October 12, 2017, President Trump issued an Executive Order on Promoting Health Care Choice and Competition Across the United States. The Order provided general direction to the executive branch but specifically directed the federal departments to consider rulemaking to expand Association Health Plans, short-term health insurance plans, and HRAs.

For each of these rules, the administration followed the APA process, issuing a proposed rule with a 60-day comment period and finalizing the rule several months later. The HRA rule was issued jointly by the Departments of HHS, Labor, and the Treasury.

The preamble to any rule must contain a legal rationale that provides the basis for rulemaking authority, a policy justification for the rule, and a regulatory impact analysis. This HRA rule was deregulatory since it permitted employers an additional way to offer employee health benefits.

The comment period for this rule closed in late December 2018; comments were received by the IRS. It can take a few months to process and respond to comments, and then the most important decisions about the parameters of the final rule are made. Typically, policy preferences must be balanced with litigation risk; in other words, questions must be asked to consider how selected parameters may increase the risk of a successful legal challenge to the rule.

Almost every decision regarding the HRA rule was made by the NEC-convened working group. As described earlier—typical of the executive branch policymaking process, disagreements in the working group lead to deputies' meetings convened to resolve the issues. If the disagreement remains after the deputies' level, then a principals' meeting is called. If the principals are still not able to reach an agreement, then an Oval Office meeting is scheduled for the President to decide the issue. No such issues rose to the principals' level for the HRA rule.

President Trump announced the HRA rule in a Rose Garden ceremony on June 14, 2019—one day after the rule was finalized. The rule took effect on January 1, 2020. Unlike many Trump administration health policy administrative actions, this one has not been subject to litigation.

Background on individual coverage HRAs

The individual coverage HRA allows employers to reimburse premiums for individual market coverage purchased by workers (and dependents). The employer contribution is not subject to federal income or payroll tax, so this rule effectively equalizes the tax treatment of traditional group plans with individually selected coverage using employer contributions.

A defined contribution structure for health insurance is like 401(k) plans and 403(b) plans for retirement savings where employers provide a set amount of funds with workers having control over the investment. The individual coverage HRA was constructed to maximize employer flexibility if their employees stand to benefit from the arrangement subject to

guardrails to protect the individual market from adverse selection.

The final rule administration projected that by 2025, 800,000 employers—nearly 90 percent of them with fewer than 20 workers—will offer individual coverage HRAs, and more than 11 million people will be enrolled in the individual market using an individual coverage HRA.