

Presidential and Congressional Transitions Mean Uncertainty for Some Obama Administration Rules

January 17, 2017

Health Care

With Republicans controlling the Congress and set to control the White House, the new Congress or President-Elect Trump could seek to delay, amend, or reverse regulations that the Obama Administration has promulgated, particularly so-called “midnight” rules issued toward the end of President Obama’s term.

There are a number of ways by which the new President or Congress could alter or reverse rules issued by the Obama Administration. Any administration can change a rule issued by a prior administration by means of a new notice-and-comment rulemaking, under standard APA practice. Similarly, any Congress can undo an administrative rule by means of a statutory change.

In addition, two specific procedures for altering previously finalized rules come into play in a change of administration: Congressional use of a fast-track process to overturn regulations finalized at the end of the prior administration; and Presidential directions to delay rules not in effect or not published as of Inauguration Day. The confluence of a Republican Congress and White House following a Democratic Presidency make the use of these two procedures more likely than they would be during other Presidential transitions. As explained below, while HHS has issued a number of rulemakings in the last several months, few are likely subject to delay or change through these procedures.

Congress May Utilize the Congressional Review Act to Disapprove Certain Final Rules

With Republicans controlling the White House and Congress in 2017, Congress will have the rare opportunity to use fast-track Congressional Review Act (CRA) procedures to disapprove rules with which Congress disagrees.

The CRA, 5 U.S.C. § 801 *et seq.*, requires that agencies submit to Congress a report on every final rule before the rule takes effect. *Id.* § 801(a)(1). For “major rules,” the CRA prevents the rule from taking effect before a specified time period (generally 60 days after Congress receives the rule) and requires the Comptroller General to report on whether the agency complied with certain legal requirements (e.g., performing required regulatory analyses). *Id.* § 801(a)(2). The CRA also provides Congress with an expedited process to “disapprove” rules with which Congress disagrees. *Id.* § 802. The Act gives Congress 60 “session” or “legislative” days from the date each house receives a rule to introduce a joint resolution disapproving the rule. *Id.* § 802(a). The primary advantages of this process are the expedited timelines for consideration

and general insulation from filibuster in the Senate. Additionally, for rules sent to Congress within 60 session or legislative days before final *sine die* adjournment (sometimes called “midnight rules”), the 60-day disapproval period is “reset” in the new Congress.

The above CRA procedures apply to all agency rules but are most useful for rules submitted during the final months of a Presidential Administration when the incoming President is of a different party than the current President. This is because Presidents are likely to veto any CRA resolution that disapproves a rule finalized during that President’s term. In fact, five of the six disapproval resolutions that Congress has passed under the CRA have been vetoed. See Congressional Research Service, R43992, The Congressional Review Act: Frequently Asked Questions (Nov. 17, 2016). Congress has successfully disapproved only one rule: an ergonomics standards rule that the Department of Labor issued in November 2000 near the end of President Clinton’s second term. Because the Department submitted the rule to Congress within the final 60 days of the legislative session, the CRA disapproval period reset in the following year and the new Congress disapproved the rule after reconvening in 2001. Incoming President George W. Bush then signed the disapproval into law.

Based on the date of the House’s adjournment *sine die*, the Congressional Research Service calculates that rules submitted to Congress after June 13, 2016, will be subject to the renewed CRA review period.¹ The Obama Administration finalized a number of health-related rules after this date that could be subject to disapproval in the new Congress, including, but not limited to, final rules to:

- Revise conditions of participation for home health agencies under Medicare and Medicaid. 82 Fed. Reg. 4504 (Jan. 13, 2017) (effective July 13, 2017);
- Amend regulations related to the Office of Inspector General’s (OIG’s) exclusion authorities. 82 Fed. Reg. 4100 (Jan. 12, 2017) (effective Feb. 13, 2017);
- Establish the calculation of the 340B ceiling price and application of civil monetary penalties. 82 Fed. Reg. 1210 (Jan. 5, 2017) (effective Mar. 6, 2017);
- Set forth the Affordable Care Act 2018 benefit and payment parameters, finalize additional qualified health plans requirements. 81 Fed. Reg. 94058 (Dec. 22, 2016) (effective Jan. 17, 2017);
- Implement new requirements related to dialysis facility payments of premiums for patients. 81 Fed. Reg. 90211 (Dec. 14, 2016) (Interim Final Rule with comment period effective Jan. 13, 2017);
- Add new safe harbors to the anti-kickback statute and amend CMP rules. 81 Fed. Reg. 88368 (Dec. 7, 2016) (effective Jan. 6, 2017);
- Amend OIG civil monetary penalty rules to incorporate new authorities. Effective January 6, 2017. 81 Fed. Reg. 88334 (Dec. 7, 2016) (effective Jan. 6, 2017);

¹ See CRS Insight, Agency Final Rules Submitted on or After June 13, 2016, May Be Subject to Disapproval by the 115th Congress (Dec. 15, 2016) (calculating date based on anticipated sine die adjournment in House of January 3, 2017); 162 Cong. Rec. 186 (Jan. 3, 2017) (recording sine die adjournment). CRS calculations are not binding.

- Amend Medicaid and CHIP eligibility and appeals regulations. 81 Fed. Reg. 86382 (Nov. 30, 2016) (effective Jan. 20, 2017);
- Delay the extension of Medicaid Drug Rebate program provisions to the U.S. territories. 81 Fed. Reg. 80003 (Nov. 15, 2016) (Interim Final Rule with comment period, effective Nov. 15, 2016);
- Modify and establish new requirements under the ONC Health IT Certification Program. 81 Fed. Reg. 72404 (Oct. 19, 2016) (effective Dec. 19, 2016);
- Revise requirements for long-term care facilities participating in Medicaid or Medicare. 81 Fed. Reg. 68688 (Oct. 4, 2016) (effective Nov. 28, 2016);
- Establish national emergency preparedness requirements for providers and suppliers participating in Medicare or Medicaid. 81 Fed. Reg. 63860 (Sept. 16, 2016); and
- Implement numerous annual Medicare reimbursement changes.

HHS issued several other final rules just before the estimated June 13, 2016, trigger date and these are unlikely to be subject to renewed CRA procedures. For example, HHS finalized the Medicaid managed care rule in late April and sent it to Congress shortly thereafter. And in May 2016, HHS sent Congress a final rule implementing the Affordable Care Act prohibition on nondiscrimination in health programs.

In any case, Congress is unlikely to disapprove many of the regulations clearly subject to a reset CRA disapproval period. CRA disapproval resolutions are “all or nothing” and cannot be used to disapprove only a portion of a rule. Thus, although the CRA has the advantage of avoiding a potential Senate filibuster, Republicans may seek to accomplish any desired changes through the normal legislative process which can be tailored to particular provisions of concern. Moreover, with the incoming Republican President, HHS might reinstate the notice-and-comment rulemaking process to alter portions of rules that the Obama Administration issued.

Incoming Presidents Often Request that Agencies Delay Rulemaking

Over the last 35 years, four incoming Presidents have sought to delay certain regulations issued by the previous administration.

President Reagan took the most prescriptive approach by directing Cabinet Secretaries and the EPA Administrator, “[t]o the extent permitted by law,” to postpone the effective dates of regulations slated to take effect during approximately the first 60 days of his Presidency, and to refrain from promulgating any final rules during that period. Memorandum Postponing Pending Federal Regulations (Jan. 29, 1981), *available at* <http://www.presidency.ucsb.edu/ws/index.php?pid=44134>.

Presidents Clinton, George W. Bush, and Obama each requested, but did not explicitly mandate, that agencies delay certain regulations. For example, upon President Clinton’s inauguration, his Office of Management and Budget Director “request[ed]” that agency heads delay sending any proposed or final rule for Federal Register publication until a Clinton-appointed agency head had approved it, and that agencies withdraw from the Federal Register any regulations submitted but not yet published. See Memorandum For the Heads and Acting Heads of Agencies Described in Section 1(d) of Executive Order 12291 (Jan. 22, 1983), 58 Fed. Reg. 6074 (Jan. 25, 1993). Similarly, upon President George W. Bush’s inauguration, his Chief

of Staff issued a memorandum “ask[ing] on behalf of the President” that agencies: postpone for 60 days any regulations that had been published but were not yet effective; not propose or finalize new rules until an agency head appointed by President Bush had approved the action; and withdraw any regulations that had been sent to the Office of the Federal Register, but not yet published. See Memorandum for the Heads and Acting Heads of Executive Departments and Agencies (Jan. 20, 2001), 66 Fed. Reg. 7702 (Jan. 24, 2001). Finally, President Obama’s then-Chief of Staff likewise requested that agencies delay sending proposed or final rules for Federal Register publication; withdraw any rules submitted but not yet been published; and “consider” extending for 60 days the effective date of any regulation that had been published but had not yet taken effect. See Memorandum for the Heads of Executive Departments and Agencies (Jan. 20, 2009), 74 Fed. Reg. 4435–36 (Jan. 26, 2009).

It is quite possible that President-Elect Trump will take similar measures and will request that agencies delay rulemaking activity until Trump-nominated officials can approve the actions.

If you have any questions concerning the material discussed in this client advisory, please contact the following members of our Health Care Industry practice group:

Caroline Brown

+1 202 662 5219

cbrown@cov.com

Anna Kraus

+1 202 662 5320

akraus@cov.com

Paige Jennings

+1 202 662 5855

pjennings@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.