

Forty-Five Days and Counting for Current HHS Leadership: Implications for Rulemaking

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Before we all turn our full attention to the nominations of Representative Tom Price as Secretary of Health and Human Services, and policy consultant Seema Verma to lead CMS, we need to remember that there are still approximately 45 days remaining in the current administration. A perusal of the Federal Register reveals that in the wake of the election, federal agencies are issuing proposed and final rules at a swift pace.

So it may be wise to consider what HHS rules have been published, and what rules could still be acted on by the **Office of Management and Budget** (OMB) and published before the inauguration of the new administration. And we also need to consider what action Congress may take on those rules.

Recently Published Rules

In recent days, HHS agencies have published several new proposed rules.

- On November 22, 2016, CMS published a **Proposed Rule** to amend the procedures governing pass-through payments in Medicaid Managed Care. The rule was published with a 30-day comment period, meaning it is unlikely that the present CMS leadership will be in a position to finalize this rule
- On November 30, 2016, CMS published Proposed Rules to revise existing rules governing Medicaid and CHIP eligibility and enrollment, and the appeals process related to that eligibility and reenrollment. Many of the changes would align appeals processes across Medicaid and exchange plan eligibility. The 60-day comment period for these rule changes assures that decisions on any finalization will fall to new CMS leadership.
- On December 7, 2016, OIG published the long awaited **Final Rules** on HHS-OIG Safe Harbors Regarding Beneficiary Inducement and Gainsharing. The Proposed Rules were first issued in October 2014, and among other things addressed the breadth of the statutory beneficiary inducement safe harbor, excluding beneficiary incentives that “promote access to care and pose a low risk of harm to patients and federally funded health care programs,” from the definition of prohibited remuneration. After more than 18 months of comment review, the final rules were submitted to OMB in mid-August 2016, OMB review was completed on November 16, 2016, and OIG went ahead with publication. One change in the final rules was the distinction that OIG draws between beneficiary inducement that “removes obstacles to compliance with treatment,” which qualifies for the safe harbor, as opposed to beneficiary inducement that “rewards treatment adherence” which does not qualify for the safe harbor.
- On December 7, 2018 OIG also published a **Final Rule** revising HHS-OIG’s Civil Monetary Penalty Rules impacting Medicare and State Health Care Programs. This Final Rule was submitted to OMB mid-August 2016, and review was completed by OMB on November 16, 2016. Changes of note in this rule include methodologies for calculating penalties, including penalties for overpayments.

Rules That May Still Be Published

Proposed and final rules, and certain types of agency guidance, must be reviewed by the OMB before the agency can publish the rules in the Federal Register. The OMB Office of Information and Regulatory Affairs is **reporting** daily on the status of OMB review of rules.

There are several key HHS provisions that OMB is still reviewing. There is still time for OMB to complete review, and for the Agency to elect to go forward with publication before the new administration takes office. These provisions include:

- The 340B Program Omnibus Guidelines, which HHS-HRSA forwarded to OMB for review on September 1, 2016. We **blogged** on these Guidelines when first proposed in the fall of 2015. Given the controversial nature of the Guidelines, and the uncertainty as to their enforceability, conventional wisdom is that even if OMB completes review, HRSA may elect **not** to issue the Guidelines. Stay tuned on this one.

- Also from HHS-HRSA, Final Rules on 340B Civil Monetary Penalties for Manufacturers and Ceiling Price Regulations. Unlike the Omnibus Guidelines, HRSA actually does have statutory rule-making authority for these rules, and it is more likely that if OMB review is completed, the rules will actually be issued. OMB received these rules from HRSA on October 21, 2016.
- A Proposed Rule from HHS that, per its title, would revise the procedures for appeals of payment and coverage determinations to Administrative Law Judges involving items and services furnished to Medicare beneficiaries, enrollees in MA and PDP plans, as well as appeals of Medicare beneficiary and entitlement determinations. Given the significant backlog of appeals that exists, one might think these rule revisions would be of the highest priority, but OMB did not receive the proposed rule for review from HHS until November 18, 2016. Review is pending.
- From HHS-CMS, a Proposed Rule on Medicaid Supplemental Payments and Accountability. This Proposed Rule has been at OMB since July 19, 2016 and is still pending OMB review. Even if it passes out and is published, there is no likelihood the rule would be finalized before the new administration takes office.
- A Final Rule from HHS-OIG, revising OIG's Exclusion Authorities. The rule was not forwarded to OMB for review until October 27, 2016.
- And as evidence that CMS is not standing pat, in the last week it forwarded two new rules for OMB review: an Interim Final Rule impacting the Conditions of Coverage for ESRD facilities was submitted to OMB on December 2, 2016, and a Final Rule on CY 2018 Notice of Benefit and Payment Parameters was submitted on December 5, 2016.

Congress and the Congressional Review Act

Congress is already telegraphing its intent to closely scrutinize any rules adopted in the waning days of the present administration. On November 17, 2016, the Congressional Research Service published a [Memorandum](#) with the title: *Major Obama Administration Rules Potentially Eligible to be Overturned under the Congressional Review Act in the 115th Congress*. As noted in the Memorandum, the Congressional Review Act gives Congress the authority to adopt "disapproval resolutions" the effect of which would be to overturn any rules or regulations adopted within 60 days prior to the present Congress' adjournment. The Act only applies to final rules/regulations; proposed rules or guidance can be withdrawn at the new Administration's discretion.

The Memorandum lists a number of rules which could be overturned through such a resolution. One would assume the list could be supplemented with any rules adopted after November 17th, including those listed above.

What Comes Next?

An ancient Chinese saying which roughly translates to: *May you live in interesting times* can be viewed alternatively as a blessing or a curse. Whether a blessing or curse, this much is true: the next few months are going to be quite interesting for those of us who closely follow health care law and policy.

The knee-jerk expectation of some is that the incoming Administration will simply withdraw all of the proposed regulations discussed above, and consider action under the CRA to rescind all the final rules. That is far from certain. The next administration will have to carefully decide which regulations they want to significantly alter and which they may want to let move forward through the process. Having no regulations on each of these subjects is may not be realistic.

While we cannot give you much in the way of certainty, we can say we will be following developments and blogging as appropriate. We hope you will follow us on this journey.

Authors