

THE NATIONAL LAW REVIEW

ML Strategies Health Care Preview - Week of October 9, 2018

Wednesday, October 10, 2018

While the House is out on recess, the Senate continues to be in session. This week the Senate has some non-health care related hearings scheduled as well as nomination hearings. We are looking for signals for a deal to finish work and send vulnerable Senators home to campaign.

OFFICE OF INFORMATION AND REGULATORY AFFAIRS

The Office of Information and Regulatory Affairs (OIRA) is a part of the Office of Management and Budget (OMB) that reviews draft and proposed final regulatory actions. OIRA also publishes a list of all pending regulations. On the OIRA dashboard you can find if a pending regulation is economically significant, when it was received, and its title. However, the actual text of the regulation is not available until it clears review.

Currently, there are 16 Health and Human Services (HHS) regulations pending review. There is no timeline for review, so these regulations can clear OIRA review at any time. So although legislative action may begin to cool down, regulatory activity at OIRA could be heating up. Below are the 16 pending regulations and their received date.

HHS Regulations Pending at OIRA

- Nondiscrimination in Health Programs and Activities (04/13/2018)
- Medical Device De Novo Classification Process (05/09/2018)
- Exchange Program Integrity (06/05/2018)
- Removal Of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection (07/18/2018)
- Medicaid and CHIP Managed Care and Medicaid Provider Enrollment and Terminations (08/03/2018)
- Substance Abuse and Mental Health Services Administration Mandatory Guidelines for Federal Workplace Drug Testing Programs (08/06/2018)
- Proficiency Testing Regulations Related to Analytes and Acceptable Performance (08/09/2018)
- Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency (08/21/2018)
- Administrative Simplification: Rescinding the Adoption of the Standard Unique Health Plan Identifier and Other Entity Identifier (08/31/2018)



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- Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2020 (09/11/2018)
- Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph (09/13/2018)
- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (9/17/2018)
- Interoperability and Patient Access (09/21/2018)
- CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B and the Quality Payment Program (09/28/2018)
- CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Value-Based Purchasing Model; Quality Reporting Requirements (10/05/2018)
- Format and Content of Reports Intended to Demonstrate Substantial Equivalence (10/05/2018)

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