

## HALL RENDER'S THIS WEEK IN WASHINGTON - JUNE 22, 2018

### CMS ISSUES RFI FOR STARK LAW

On June 20, CMS released a request for information ("RFI") seeking feedback on ways to improve the Stark Law, which limits how doctors can refer patients to businesses in which they have a financial interest. Largely seen as a barrier to value-based care arrangements, the agency is asking for information on how Stark regulations hinder care coordination and how to overcome those barriers. Health and Human Services Secretary Alex Azar said that laws like Stark drive unwanted consolidation in the health care industry.

Specifically, the agency seeks feedback on the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements, the need for revisions or additions to exceptions to the physician self-referral law and terminology related to alternative payment models and the physician self-referral law. CMS Administrator Seema Verma said in a statement that she's looking for "bold ideas."

The RFI comes as interest in Stark Law reform has increased on Capitol Hill and within the Trump administration. For several years, the Hall Render Stark Law Correction Coalition has pushed for Congress to pass the Stark Administrative Simplification Act, which creates a limit on the penalties providers can incur for technical violations of the law and an expedited review process for their resolution by CMS. The coalition has also called on CMS to make certain regulatory changes to the Stark Law, which include creating an objective standard for "takes into account," a rebuttable presumption for fair market value and a definition of commercially reasonable. The agency asks stakeholders to respond to these recommendations in questions 9, 10 and 11 of the RFI.

Those who wish to provide answers to the 20 questions found in the RFI must do so by August 24. Answers may be submitted electronically to [www.regulations.gov](http://www.regulations.gov) by regular mail or by express or overnight mail.

### HOUSE PASSES OPIOID LEGISLATION PACKAGE

The House of Representatives today passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (**H.R. 6**), which was introduced by the chairmen and ranking members of the House Energy and Commerce and Ways and Means committees. Passing by a bipartisan vote of 396-14, the bill assembles many opioid-focused measures that have passed the House over the past two weeks.

This comes after the House spent the last week voting on about 60 bills that address various aspects of the opioid crisis. On June 19, the House passed several noncontroversial bills that would make various changes to Medicare, simplify the process to return or destroy opioids and enhance the Department of Homeland Security's operations to stop illegal drugs at the border.

On June 20, the House deliberated and ultimately passed two opioid bills related to patient privacy and Medicaid coverage for inpatient treatment. **H.R. 5797** allows states to receive federal matching funds for up to 30 days per year for services provided to adult Medicaid beneficiaries with an opioid use disorder in an Institution for Mental Disease and expands treatment coverage. A patient privacy bill, **H.R. 6082**, would align 42 CFR Part 2 regulations with the Health Insurance Portability and Accountability Act to allow health care providers to responsibly share substance use disorder treatment information

### SENATE HELP HEARING EXAMINES HRSA PERSPECTIVE ON 340B

On June 19, the Senate Health, Education, Labor, and Pensions ("HELP") Committee held the third in a series of hearings examining the 340B drug savings program. The hearing featured testimony from Capt. Krista Pedley, the Director of the Office of Pharmacy Affairs at the Health Resources and Services Administration, which oversees the program.

HELP Chairman Lamar Alexander (R-TN) conveyed a desire to see how 340B savings are being used by hospitals and other covered entities, but he said "it would be unnecessary for us to write a narrow definition of how hospitals and clinics should spend the money." While Sen. Bill Cassidy (R-LA) talked about problems with the program, all the others stressed how the 340B Program enables hospitals to provide care for at-risk patients and provided anecdotes about how the program is helping in their states.

## HEALTH-RELATED BILLS INTRODUCED THIS WEEK

Sen. Jack Reed (D-RI) introduced **S.3095** to amend the Public Health Service Act to help build a stronger health care workforce.

Rep. Devin Nunes (R-CA) introduced H.R. 6138 to amend Title XVIII of the Social Security Act to provide for ambulatory surgical center representation during the review of hospital outpatient payment rates under Part B of the Medicare program.

Rep. Norma Torres (D-CA) introduced **H.R.6154** to establish a pilot program for emergency medical systems.

Rep. Lloyd Doggett (D-TX) introduced **H.R. 6114** to amend Title XVIII of the Social Security Act to prohibit health plans and pharmacy benefit managers from restricting pharmacies from informing individuals regarding the prices for certain drugs and biologicals.

## NEXT WEEK IN WASHINGTON

The House and Senate are back next week for a full legislative work week. House and Senate Appropriations committees will focus on the fiscal 2019 Labor-HHS spending bills. The House committee this week deferred action on its bill and plans to meet on June 26 to finalize its \$177.1 billion measure. Hearings slated for next week include the start of a series of sessions by the Senate HELP Committee exploring ways to reduce health care costs. On June 26, the Senate Finance Committee will hear testimony from HHS Secretary Azar on how the administration's plan to reduce drug prices.

The Senate HELP Committee will **mark up** several bills on June 26, including **S. 3029**, the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Reauthorization Act of 2018; **S. 1112**, the Maternal Health Accountability Act of 2017; **S. 808**, the Sports Licensure Medical Clarity Act of 2017; and **S. 3039**, the Using Data to Help Protect Children and Families Act.

## This Week in Washington in History

**1966, 52 years ago this week** - The Senate passes a landmark auto safety bill, which later became known as the National Traffic and Motor Vehicle Safety Act. Signed into law the following September by President Lyndon B. Johnson, the act created the nation's first mandatory federal safety standards for motor vehicles.

**1944, 74 years ago this week** - Franklin D. Roosevelt signs the G.I. Bill designed to compensate returning members of the armed services for their efforts in World War II.

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