

October 26, 2018

Washington Update

This Week in Congress

- **House** – The House is in recess until November 13.
- **Senate** – The Senate is in recess until November 13.

Next Week in Congress

- **House** – The House is in recess until November 13.
- **Senate** – The Senate is in recess until November 13.

TAX

President Trump Floats Idea of Additional 10-percent Tax Cut for Middle Class

Key Points:

- *President Trump calls for an additional 10-percent tax cut for the middle-class prior to midterm elections despite Congress not being in session*
- *House Ways and Means Chairman Kevin Brady (R-TX) vows to work with the White House and Treasury on the matter*

Last week, President Trump suggested that a “resolution” on the middle-class tax cuts would be unveiled before the November 6 midterm elections. House Ways and Means Committee Chairman Kevin Brady (R-TX) stated earlier this week that he would “work with the White House and Treasury over the coming weeks to develop an additional 10-percent tax cut focused specifically on middle-class families and workers.” Further details have yet to be released. It should be noted that both the House and Senate are in recess until the week of November 12, eliminating any possibility of

a tax plan being passed before the midterm elections.

The House recently approved three bills in its “tax reform 2.0” package in September, including a bill to make permanent the temporary individual tax cuts in the Tax Cuts and Jobs Act (TCJA). Senate Majority Leader Mitch McConnell (R-KY) has indicated that the tax cut extension will not be considered in the Senate unless it can secure 60 votes. Senate Finance Committee Chairman Orrin Hatch (R-UT) said on Wednesday that it is “highly unlikely” that Republicans will be able to pass the President’s proposal to provide another round of tax cuts for the middle class.

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Tax Extenders Set to be Focal Point After Midterm Elections

Key Points:

- *Congress will have several options to address the expired tax provisions that were passed in early 2018 but will last for only the 2017 year*
- *House Ways and Means Committee has taken the position that it will want to eliminate some extenders and make others permanent*

Congress earlier this year passed a list of twenty-eight temporary tax provisions often referred to as “tax extenders” in the Bipartisan Budget Act of 2018, for the 2017 year only. Following the midterm elections, Congress will have several options for addressing the expired tax provisions. According to a recent Congressional Research Service (CRS) report which outlined possible options: “Provisions that expired at the end of 2017 could be extended. The extension could be retroactive. The extension could be short term, long term, or permanent. Another option would be to allow expired provisions to remain expired.” House Ways and Means members have taken the position that following passage of the Tax Cuts and Jobs Act (TCJA) last year, they would like to eliminate many extenders, while making others permanent. It is possible that tax extenders will be negotiated together with another member and business stakeholder priority of the need for TCJA tax law fixes called technical corrections.

The list of provisions is provided below:

Individual Provisions

- Above-the-Line Deduction for Qualified Tuition and Related Expenses
- Mortgage Insurance Premiums Treated As Qualified Residence Interest

- Exclusion of Discharge of Principal Residence Indebtedness from Gross Income for Individuals

Business Provisions

- Indian Employment Tax Credit
- Accelerated Depreciation for Business Property on Indian Reservation
- American Samoa Economic Development Credit
- Credit for Railroad Track Maintenance
- Seven-Year Recovery for Motorsport Racing Facilities
- Deduction Allowable with Respect to Income Attributable to Domestic Production Activities in Puerto Rico
- Mine Rescue Team Training Credit
- Election to Expense Advanced Mine-Safety Equipment
- Special Expensing Rules for Film, Television, and Live Theatrical Production
- Empowerment Zone Tax Incentives
- Three-Year Depreciation for Race Horses Two Year or Younger
- Special Rate for Qualified Timber Gains

Energy

- Beginning-of-Construction Date for Nonwind Facilities to Claim the Production Tax Credit (PTC) or the Investment Tax Credit (ITC) in Lieu of the PTC
- Special Rule to Implement Electric Transmission Restructuring
- Credit for Construction of Energy Efficient New Homes
- Energy Efficient Commercial Building Deduction
- Credit for Section 25C Nonbusiness Energy Property
- Alternative Fuel Vehicle Refueling Property

- Incentives for Alternative Fuel and Alternative Fuel Mixtures
- Incentives for Biodiesel and Renewable Diesel
- Second Generation (Cellulosic) Biofuel Producer Credit
- Credit for Production of Indian Coal
- Special Depreciation Allowance for Second Generation (Cellulosic) Biofuel Plant Property
- Alternative Motor Vehicle Credit for Qualified Fuel Cell Vehicles
- Credit for Two-Wheeled Plug-In Electric Vehicles

For more information about tax issues you may [email](#) or call Christopher Hatcher at 202-659-8201. Nick Karellas, Henry Homans contributed to this section.

FINANCIAL SERVICES

FSOC Holds Open Meeting, Rescinds Designation of Prudential Financial

Key Points:

- FSOC held an open meeting to discuss alternative reference rates and Brexit.
- The Council also announced that it had rescinded its designation of Prudential Financial for enhanced supervision.

On October 16, the Financial Stability Oversight Council (FSOC or the Council) held an [open meeting](#) and received a presentation on alternative reference rates, voted to approve the collection of data on centrally cleared repurchase agreements by the Office of Financial Research (OFR), and received an update on Brexit. The Council has released a [summary](#) of the meeting.

Federal Reserve Vice Chairman for Supervision Randal Quarles provided the Council with an update on the Federal Reserve's efforts regarding alternative reference rates. He said

FSOC has warned of the risks from the London Interbank Offered Rate (LIBOR) since 2013, noting that the small number of financial transactions underpinning LIBOR raises financial stability concerns. He said the Council previously recommended that regulators work with market participants to identify alternative reference rates which are anchored in observable transactions and to develop plans for an orderly transition. He stated that in 2014 the Federal Reserve Board and the Federal Reserve Bank of New York (FRBNY) convened the Alternative Reference Rates Committee (ARRC). He said the ARRC was asked to identify a robust and transactions-based alternative to U.S. dollar LIBOR, noting that they chose the Secured Overnight Financing Rate (SOFR). He said ARRC focused on selecting the most robust rate possible, noting that SOFR collects data from a variety of platforms. He noted that it will be administered by the FRBNY with the public interest in mind. He said SOFR has an average of \$750 billion in daily transactions underlying it. He said the OFR's proposed data collection rule will help to underpin the data which SOFR is based on. Quarles noted that SOFR began production six months ago. He said market participants have begun work to build liquidity in SOFR futures, offer clearing of SOFR swaps, add SOFR to the list of hedge accounting benchmarks, and add \$10 billion in floating rate debt referencing SOFR. Quarles said FSOC should continue to support the ARRC's work. He said the LIBOR transition raises a number of questions related to banking regulations, including swap margin requirements and market risk rules. He said the Federal Reserve is actively working on this issue with other regulators and with market participants. He noted that the CFTC's Market Risk Advisory Committee (MRAC) has formed a subgroup to consider these issues. He said state and federal regulators are working together through the Federal Financial

Institutions Examination Council (FFIEC) to coordinate efforts on communication and education. He said while the Federal Reserve is not following the FCA's lead on sending letters to the CEOs of its supervised entities, supervisory teams at large firms are including LIBOR in their routine monitoring discussions and supervisory teams at regional and community banks have been advised to engage on LIBOR during routine examinations. He stated that as the transition date approaches the Federal Reserve will expect to see an appropriate level of preparedness at supervised entities. He suggested that the ARRC's plans will materially lessen the risks to the U.S. financial system around LIBOR.

Additionally, on October 17, the Council announced that it had rescinded its determination that material financial distress at Prudential Financial could pose a threat to U.S. financial stability and that Prudential shall be subject to supervision by the Board of Governors of the Federal Reserve System and to enhanced prudential standards. A [press release](#) issued by the Council noted that the vote to rescind the designation was unanimous, with Securities and Exchange Commission (SEC) Chairman Jay Clayton recusing himself and delegating his voting authority to SEC Commissioner Elad Roisman. The Council also released a [document](#) providing notice and explanation for the rescission. Federal Housing Finance Agency (FHFA) Director Mel Watt issued a [statement](#) in which he raised concerns that no independent evaluation has been made by FSOC as to whether Prudential still meets the standard that "the nature, scope, size, scale, concentration, interconnectedness, or mix of activities of the nonbank financial company could pose a threat to the financial stability of the United States."

SEC Takes Action on Market Data Fees; Holds Market Data Roundtable

Key Points:

- *The SEC held that NYSE Arca and Nasdaq did not meet their statutory obligation to show that fees established in 2010 were fair and reasonable under the Exchange Act and remanded over 400 challenges to market data and market access fees that have been filed with the SEC since this action commenced in 2013.*
- *Commissioners Hester Peirce and Elad Roisman issued a statement concurring with the decision but calling on the SEC to review the Order Protection Rule.*

On October 16, the SEC took two actions related to market data fees. First, the Commission held that NYSE Arca and Nasdaq did not meet their statutory obligation to show that fees (filed in 2010 and challenged by SIFMA) were fair and reasonable under the Exchange Act. In a [statement](#), SEC Chairman Jay Clayton explained that the SEC issued a decision to set aside the challenged fees, finding that the exchanges had not met their statutory obligation to demonstrate that the fees were consistent with the Exchange Act. Clayton noted that the ruling by the SEC does not mean that the fees were too high but that "the exchanges have not provided sufficient factual and legal support to continue to charge those fees." Second, the SEC issued an order "remanding" the over 400 challenges to market data and market access fees that have been filed with the SEC since this action was commenced in 2013. These challenges will be returned to the exchanges for further review and if appropriate resubmission to the SEC.

Following the Data Fee Decision, Commissioner Hester Peirce and Commissioner Elad Roisman issued a [joint statement](#) noting their concurrence in the ruling, explaining their rationale and noting the limited precedential effect of this holding,

indicating the type of analysis they would find useful in determining whether a fee field for an exchange's non-core product or service is fair and reasonable. The Commissioners suggested with the Order Protection Rule, the Commission has dulled the market's normal disciplining forces, setting in motion a cascade of unintended consequences. They urged the Commission to do a retrospective review of the Order Protection Rule and other "interrelated aspects of equity market structure."

On October 25, the SEC began a two-day [roundtable](#) on market data and market access. The first day of roundtable focused on "Assessing Current Market Data Products, Market Access Services, and Their Associated Fees." Day One included panels on: (1) Overview of Current Landscape for Market Data Products and Market Access Services; (2) SIP Core Data Products and Exchange Top-Of-Book Data Products; and (3) Exchange Depth-Of-Book Data Products and Market Access Services. Chairman Jay Clayton, said this roundtable is a broad and open minded review of issues that have been on the SEC's docket for "some time." He acknowledged that views on market data are emotionally held and he urged participants to explain what will best serve the interests of Main Street investors over the long term. He stated that he just returned from meetings with the International Organization of Securities Commissions (IOSCO) and Financial Stability Board (FSB), and stressed that SEC actions on market data issues are being closely watched by regulators around the world.

Commissioner Kara Stein noted that the national market system was born 40 years ago when technology and communications were not as fast and data was not as rich. She said Congress sought to protect the priority of public orders with best execution and the transparency of orders. She questioned whether

the initial goals have stood the test of time and fulfilled Congressional intent. She questioned whether market data needs to be instantaneous to be relevant, and what system could be developed to ensure best execution of orders. She added that there are questions about how much that system should cost and who should be required to pay.

Commissioner Robert Jackson emphasized that access to market data affects ordinary investors, adding that fair access to markets is not merely an exchange and broker issue. He criticized the CEO of Nasdaq for saying on a recent earnings call that Main Street investors "pay nothing for data," and he emphasized this is the wrong way to view this issue. He stated that regulating exchange data is among the top priorities at the SEC, and noted that the complexity of exchange rule filings makes this difficult. Jackson argued that a competitive market for data should not create higher costs and expressed concern that there is little information on the costs for exchanges to produce and disseminate their data. He stressed that the time for transparency in these costs is "long overdue."

Commissioner Hester Peirce expressed hope that all roundtable participants will take a broad view of market data issues. She contended that technology and time would have created a national market system without government intervention. She stated that one of the key functions of markets is to produce data. She expressed concern that government interference impedes the market's ability to make data readily available.

Commissioner Elad Roisman, in a [statement](#), expressed interest in a more granular understanding of the Securities Information Processor (SIP) data versus proprietary data feeds. He expressed particular interest in a number of issues. First, noting his previously

voiced concerns about whether the Order Protection Rule might influence demand for market data, he questioned whether other regulatory requirements that are imposed on market participants are affecting demand for market data. He advocated for the SEC to also review other rules such as the Vendor Display Rule and obligations for best execution, and whether these rules encourage market participants toward products they might not otherwise demand. Second, he questioned whether market participants use proprietary data from exchanges to offer similar products and services that compete with the same exchanges. He listed internalizers and crossing platforms, alternative trading systems (ATSS), dark pools, and electronic communication networks (ECNs) as potential examples. He stated that the Commission should consider the extent to which these entities are “bearing their share” of costs. Third, he noted that Regulation NMS contemplated that certain market data fees would be used to bolster self-regulatory organizations’ (SROs) funding. He questioned whether it is time for the SEC to revisit its 2004 Concept Release on SROs, and what is preventing broker dealers from unsubscribing to proprietary feeds if fees get too high. He advocated for examining how SIP products can be improved to meet this demand. Fourth, he questioned how retail investors are affected by market data fees. He questioned what level of price improvement is achieved when broker-dealers trading on behalf of institutional investors rely on proprietary feeds rather than SIP data. He also asked if costs for market data and access were reduced, how much of the savings would be passed on to retail investors.

Roisman noted the importance of determining where market forces versus regulation are driving demand for proprietary products compared to SIP products, and how retail investors are benefiting from regulation in this

area. He also noted the fixed income markets are much larger than the equities markets, yet the Commission has not examined the fixed income market in as fine of detail as the equities markets. He stated that pre-trade transparency in the fixed income markets has not yet been reliably achieved and post-traded transparency is debated in terms of minutes and hours. He praised the creation of the Fixed Income Market Structure Advisory Committee (FIMSAC), but expressed a desire for the Commission to consider how to make the fixed income markets as favorable to investors as the equity markets.

Brett Redfearn, Director, Division of Trading and Markets, in a [statement](#), identified the goal of the roundtables as examining the infrastructure for distributing market data in order to fulfil the SEC’s mission of protecting investors. He noted that under the Securities Exchange Act of 1934 (Exchange Act) the SEC is required to ensure that fees are “fair and reasonable, are not unreasonably discriminatory,” and do not impose an “undue or inappropriate burden on competition.” He said today’s environment requires these criteria to be carefully considered due to the complexity of the market. He emphasized that the goal of these roundtables is to protect individual investors rather than to favor any particular business model. Redfearn noted that there are currently two market data feeds, the SIP and direct, proprietary feeds, and said it is unclear whether this landscape was intended when the national market system was designed in the 1970s. He stated that Congress intended the SIPs to create a level playing field, and contended that consolidated data has been the principal tool for ensuring best execution. Redfearn noted that Regulation NMS did not adopt a competing consolidator model in 2005, but did remove restrictions to allow SROs to offer their own data feed. He explained that the concern was that the competing consolidator

model might undercut the benefits of core data, and that it would require market participants to buy data from each exchange, and therefore diminishing competitive forces to influence the level of fees. He noted that technology has transformed the markets, which raises questions for the two-tiered system or market data and access, including: whether SIP data can meet the basic needs of market participants in today's algorithmic markets; whether proprietary data is necessary to satisfy competitive forces and regulatory duties; and whether SIP data along still qualifies as core data or whether a model has evolved in which the purchase of proprietary data and access products are necessary for core data.

UPCOMING EVENTS

October 29

SEC Fixed Income Market Structure Advisory Committee: The Securities and Exchange Commission Fixed Income Market Structure Advisory Committee (FIMSAC) will meet to discuss updates and presentations from the subcommittees.

October 31

Federal Reserve Board Meeting: The Federal Reserve Board will hold an open meeting to discuss “Prudential Standards for Large Bank Holding Companies, Savings and Loan Holding Companies, and State Member Banks.”

SEC Open Meeting: The SEC will hold an open meeting to consider whether to adopt amendments and related guidance to modernize the property disclosure requirements for mining registrants.

November 5

CFTC Open Meeting: The Commodity Futures Trading Commission will hold an open meeting to consider three items: (1) Final

Rule: Amending the De Minimis Exception to the Swap Dealer Definition; (2) Proposed Rule: Amendments to Regulations on Swap Execution Facilities and the Trade Execution Requirement; and (3) Request for Comment regarding the Practice of “Post-Trade Name Give-Up” on Swap Execution Facilities

November 7

Investor Advisory Committee: The SEC will hold a telephonic meeting of its Investor Advisory Committee. The agenda for the meeting includes a discussion of the Commission's Proposed Regulation Best Interest and Proposed Form CRS Relationship Summary, which may include a recommendation of the Investor as Purchaser Subcommittee.

November 14

Federal Reserve: The House Financial Services Committee will hold a hearing to receive the semi-annual testimony from Federal Reserve Vice Chairman for Supervision Randal Quarles on the efforts, activities, objectives, and plans of the Federal Reserve with respect to the conduct of supervision and regulation of depository institution holding companies and other financial firms supervised by the Federal Reserve.

Fannie Mae and Freddie Mac: The Senate Banking Committee will hold a hearing entitled “Oversight of Pilot Programs at Fannie Mae and Freddie Mac.” The witnesses at the hearing will be Sandra Thompson, Deputy Director, Division of Housing Mission and Goals, Federal Housing Finance Agency; Hugh Frater, Interim Chief Executive Officer, Fannie Mae; and Donald Layton, Chief Executive Officer, Freddie Mac.

November 15

Federal Reserve: The Senate Banking Committee will hold a hearing entitled “The

Semiannual Testimony on the Federal Reserve’s Supervision and Regulation of the Financial System.” The witness at the hearing will be Federal Reserve Vice Chairman for Supervision Randal Quarles.

November 29

Money Laundering: The Senate Banking Committee will hold a hearing entitled “Combating Money Laundering and Other Forms of Illicit Finance: Regulator and Law Enforcement Perspectives on Reform.”

December 12

SEC Government-Business Forum: The SEC will hold its annual Government-Business Forum on Small Business Capital Formation at the Ohio State University Max M. Fisher College of Business.

For more information about financial services issues you may [email](#) or call Joel Oswald at 202-659-8201. Alex Barcham and Rebecca Konst contributed to the articles.

ENERGY AND ENVIRONMENT

McIntyre Steps Down as FERC Chairman

Key Points:

- *President Trump accepted FERC Chairman Kevin McIntyre’s proposal to step down as Chairman but continue as Commissioner.*
- *McIntyre asked for the change to “commit myself fully to my work as Commissioner, while undergoing the treatment necessary to address my health issues.”*
- *The President designated Commissioner Neil Chatterjee as Chairman on Wednesday.*

In a [letter](#) to the President on October 22, Federal Energy Regulatory Commission (FERC) Chairman Kevin McIntyre proposed “to step aside from the position of Chairman and its additional duties so that I can commit myself fully to my work as Commissioner,

while undergoing the treatment necessary to address my health issues.” McIntyre, who underwent surgery and treatment for a brain tumor in 2017, stated that “I very recently experienced a more serious health setback, leaving me currently unable to perform the duties of Chairman with the level of focus that the position demands and that FERC and the American people deserve.” On October 24, President Trump [designated](#) Commissioner Neil Chatterjee as Chairman. The selection of Chairman does not require Senate confirmation and was immediately effective.

In a [statement](#), Chatterjee declared, “It is with a heavy heart that I step into this role while my friend and colleague, Kevin McIntyre, focuses on what’s most important: his recovery and his family.”

The Commission currently has four members following the resignation of Commissioner Robert Powelson in August. This leaves FERC evenly divided on a partisan basis, with two Republican commissioners – McIntyre and Chatterjee, and two Democratic commissioners – Cheryl LaFleur and Richard Glick. The President nominated Bernard McNamee, Director of the Department of Energy’s Office of Policy, to fill Powelson’s slot at the Commission. The Senate Energy and Natural Resources Committee is scheduled to hold a [hearing](#) on Powelson’s nomination on November 15.

Regulatory Developments

Energy and environmental regulatory actions this week included the Federal Energy Regulatory Commission’s (FERC) publication of the [final rule](#) titled “Supply Chain Risk Management Reliability Standards”. The final rule “approves supply chain risk management Reliability Standards CIP-013-1 (Cyber Security—Supply Chain Risk Management),

CIP-005-6 (Cyber Security—Electronic Security Perimeter(s)) and CIP-010-3 (Cyber Security—Configuration Change Management and Vulnerability Assessments) submitted by the North American Electric Reliability Corporation (NERC).” The rule also requires “NERC to develop and submit modifications to the supply chain risk management Reliability Standards so that the scope of the Reliability Standards include Electronic Access Control and Monitoring Systems.”

Upcoming Hearings and Events

November 8

Pipeline Safety Information-Sharing: The Pipeline and Hazardous Material Safety Administration will convene a [meeting](#) of the Voluntary Information-Sharing System Working Group. The meeting will “discuss and identify recommendations to establish a voluntary information-sharing system.” The “Protecting our Infrastructure of Pipelines and Enhancing Safety Act of 2016” (S. 2276, [P.L. 114-183](#)) established the Working Group, and directed it to provide recommendations to submit to the Secretary of Transportation on establishing “a voluntary information-sharing system to encourage collaborative efforts to improve inspection information feedback and information sharing with the purpose of improving gas transmission and hazardous liquid pipeline facility integrity risk analysis.”

November 14

Oil and Gas Sector Emission Standards: The Environmental Protection Agency (EPA) will hold a [public hearing](#) on the Notice of Proposed Rulemaking (NPRM) titled “Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Reconsideration”. The EPA published the [NPRM](#) on October 17, 2018. The NPRM modifies the following provisions of the 2016 Obama Administration [final rule](#) titled “Oil and

Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources”: “(1) fugitive emissions requirements, (2) well site pneumatic pump standards, and (3) the requirements for certification of closed vent systems by a professional engineer...” The hearing will begin at 8:00 a.m. at the EPA’s Region 8 offices in Denver, Colorado.

November 15

Nominations: The Senate Energy and Natural Resources Committee will hold a [hearing](#) on the following nominations: Dr. Rita Baranwal to be an Assistant Secretary of Energy for Nuclear Energy; Bernard McNamee to be a Member of the Federal Energy Regulatory Commission; and Raymond David Vela to be Director of the National Park Service.

FERC Meeting: The Federal Energy Regulatory Commission (FERC) will hold its monthly [open meeting](#).

For more information about energy and environment issues you may [email](#) or call Frank Vlossak at 202-659-8201. Alex Barcham contributed to the articles. Updates on energy and environment issues are also available on [twitter](#).

HEALTH

Trump Administration Releases Proposal for New Medicare Part B Payment Model

Key Points:

- *Trump Administration proposed a new International Pricing Index payment model for Medicare Part B.*
- *The Advance Notice of Proposed Rulemaking follows a report issued by the Department of Health and Human Services detailing the price Medicare pays for drugs under Medicare Part B in comparison to other countries.*

On October 25, the Trump Administration proposed a new payment model for Medicare Part B drugs. The Department of Health and Human Services (HHS) is seeking input on a new International Pricing Index payment model to reduce what seniors in the Medicare program pay for prescription drugs. As described in the Advance Notice of Proposed Rulemaking (ANPRM), Medicare's payments for physician-administered drugs would more closely align with the prices paid for the drug in other countries. Specifically, the new payment model based on international prices would be phased in over a five-year period and would apply to about 50 percent of the country. Additionally, the proposed model would permit physicians and hospitals to receive a set payment for storing and handling drugs that would not be tied to prices. The projected savings of the model is \$17.2 billion over five years with \$3.4 billion in out-of-pocket savings for Medicare beneficiaries. The comment period for the rulemaking closes December 31, 2018.

The proposal follows a detailed report issued by HHS entitled "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" detailing that the prices charged by drug manufacturers to wholesalers and distributors in the U.S. are 1.8 times higher than in other countries. The report examined what Medicare pays for 27 drugs administered under Medicare's Part B program compared to countries including Japan, Germany, and France. According to HHS, Medicare paid the highest price for 19 of the 27 drugs.

Both President Trump and Secretary of HHS Alex Azar commented on the proposed reform agreeing that the payment model will lower prescription costs for seniors and increase access. During an event with Brookings, Secretary Azar emphasized the model is based

on the deals that pharmaceutical companies are already negotiating with other countries. Committee on Energy and Commerce Chairman Greg Walden (R-OR) and Committee on Ways and Means Chairman Kevin Brady (R-TX) also issued a joint statement commending the Trump Administration for their actions to lower drug costs for patients while affirming their commitment to create an affordable marketplace for prescription drugs.

The ANPRM is available [here](#); the fact sheet on the ANPRM is available [here](#); and the report "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" is available [here](#).

President Trump Signs Opioid Legislation

Key Points:

- *President Trump signed the "SUPPORT for Patients and Communities Act" to address the opioid crisis.*
- *The Centers for Medicare and Medicaid Services announced a new demonstration program to assist pregnant women and new mothers struggling with addiction.*

On October 24, President Trump signed the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act" to combat the opioid epidemic. The bill was signed at an event where the President highlighted the work of law enforcement, community members, and companies are doing to combat this crisis.

President Trump said "over the last year, we have mobilized the entire federal government to address this crisis...[and] secured \$6 billion in new funding to combat opioids." He especially highlighted the roll of federal and state and local law enforcement to address the

influx of illegal synthetic opioids and drug traffickers.

Food and Drug Administration (FDA) Commissioner Scott Gottlieb highlighted new authorities for the FDA in the bill. He noted the bill allows the FDA to more efficiently stop illegal, illicit, unapproved, and counterfeit drugs from entering the U.S.; provides the FDA new authority to issue a mandatory recall order for a controlled substance; and advances efforts to reduce exposure to opioids as a way to lower the rate of new addiction.

That same day, the Centers for Medicare and Medicaid Services (CMS) announced a new demonstration program at the Center for Medicare and Medicaid Innovation entitled the Maternal Opioid Misuse (MOM) Model. The model will address fragmentation in the care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder. The goals of the model are to improve the quality of care and reduce expenditures; increase access to treatment, service-delivery capacity, and infrastructure; and create sustainable coverage and payment strategies that support integrated and coordinated care. Read more about the model [here](#).

Administration Releases Proposed Rule on HRAs

Key Point:

- *The Administration announced a proposed rule which would allow health reimbursement arrangements to be used to cover individual market premiums.*

On October 23, the Administration announced a proposed rule which would permit health reimbursement arrangements (HRAs) to be used to cover individual market premiums. According to an estimate from the Department

of Treasury, over 10 million employees would have access to the expanded version of HRAs.

This proposal is the final part of the agency response to President Trump's October 2017 executive order on increasing health care choice and competition. The final rules on short-term limited duration health plans and association health plans were also part of this order. The proposal is expected to give small employers more options for offering health benefits to employees. This reverses previous guidance from the Obama Administration.

Department of Health and Human Services (HHS) Secretary Alex Azar praised the proposal. He contended it "is another example of President Trump's delivering on his promise to provide for more affordable healthcare options for the American people."

The proposed rule was published jointly by the Departments of Treasury, Labor, and HHS. Read the proposed rule [here](#).

CMS Releases New Guidance on Section 1332 Waivers

Key Point:

- *The Centers for Medicare and Medicaid Services announced new guidance to states providing greater flexibility to design alternatives to the Affordable Care Act.*

On October 22, the Centers for Medicare and Medicaid Services (CMS) announced new guidance to states which provide new flexibility to design alternatives to the Affordable Care Act. The Section 1332 waivers are renamed State Relief and Empowerment Waivers to reflect new opportunities to improve insurance markets, increase affordable coverage options, and ensure those with pre-existing conditions are protected.

CMS Administrator Seema Verma said “states know much better than the federal government how their markets work. With today’s announcement, we are making sure that they have the ability to adopt innovative strategies to reduce costs for Americans.”

The new flexibilities include:

- Allowing states to provide consumers with plan options that best meet their needs;
- Expanding the definition of coverage to include more types such as short-term plans;
- Supporting increased variation and flexibility for states that may want to leverage the federal exchange platform for new models; and
- Providing flexibility for states to meet the state legislative authority requirement.

Read the guidance [here](#).

CMS Announces Proposed Rule on Prices in DTC Advertising

Key Points:

- *The Centers for Medicare and Medicaid Services released a proposed rule on placing list prices in direct-to-consumer advertising for pharmaceuticals paid for through Medicare or Medicaid.*
- *Comments on the proposed rule are due December 17, 2018.*

On October 15, the Centers for Medicare and Medicaid Services (CMS) issued a new proposed rule to require the Wholesale Acquisition Cost (WAC), otherwise known as “list price,” to be displayed in direct-to-consumer (DTC) advertising of prescription and biological products paid for through Medicare or Medicaid. Comments on the proposed rule are due December 17, 2018. This

is action is one of many that was outlined in President Trump’s blueprint released in May.

Department of Health and Human Services (HHS) Secretary Alex Azar stated, “this historic proposal is an important way to create new incentives for drug companies to start lowering their list prices.” CMS Administrator Seema Verma stressed CMS is “committed to price transparency across-the-board” and this rulemaking will ensure “patients have the information they need to make informed decisions.

CMS explains the purpose of the proposed rule is to reduce the price of prescription drugs and biologics. It outlines four factors that make list price relevant: (1) in high deductible plans, beneficiaries pay the list price until they meet their deductible; (2) benefit designs are built off list prices; (3) coinsurance paid by patients is a percentage of list price; and (4) few drugs are covered on all formularies, so patients will pay the full list price to access those not on the formulary.

Under the proposed rule, advertisements for certain prescription drugs and biologics on television must contain a statement indicating the list price for a typical 30-day regimen or typical course of treatment as determined on the first day of the quarter during which the advertisement is being broadcast. “Television” includes broadcast, cable, streaming, and satellite. Prescription drugs or biologics with a list price less than \$35 would not need to comply with these transparency requirements. However, the requirement will otherwise apply to any an advertisement for any drug or biologic distributed in the U.S. that is payable under Medicare or Medicaid. The disclosure listed above must be included “in a legible textual statement” at the end of the advertisement. CMS is also proposing the Secretary will maintain a public list that will

include the drugs and biologics identified to be in violation of the rule which will be updated no less than annually.

Earlier this year, Senators Chuck Grassley (R-IA) and Richard Durbin (D-IL) pushed to include an amendment in multiple appropriations bill that would have required disclosure of price in DTC advertising. They first attempted, but failed, to add the amendment to the Department of Agriculture appropriations which includes funding for the Food and Drug Administration. Subsequently, the Senators offered their amendment to the FY 2019 Labor-HHS appropriations bill. The amendment was successfully included in the Senate-passed version of H.R. 6157. However, after the Senate and House negotiated to reconcile their differences, the provision was dropped from the final bill that was passed and signed by the President.

View the proposed rule [here](#).

Upcoming Hearings and Meetings

October 29

Ebola: The Center for Global Development will hold a discussion on “Ebola Then and Now: Lessons to Reshape Our Strategies Amidst New Outlooks.”

October 30

Opioids: The Heritage Foundation will hold a book discussion on “Chemical Slavery: Understanding Addiction and Stopping the Drug Epidemic.”

November 1

Primary Care: The Center for Global Development will hold a forum on “Making

Primary Care Happen: From Aspirations to Reality.”

November 1-2

Medicare: The Medicare Payment Advisory Commission (MedPAC) will hold a public meeting.

For more information about healthcare issues you may [email](#) or call Nicole Ruzinski Bertsch or George Olsen at 202-659-8201. Michaela Boudreaux contributed to this section.

TRADE

Canada Hosts Trade Ministers to Discuss WTO Reforms, U.S. and China Not Invited

Key Points:

- Canada held a meeting of WTO “middle powers” in an attempt to identify reforms that can make the entity more effective.
- Trade ministers believe solving the Appellate Body issue is essential to the WTO’s future.

A group of top trade officials from 12 nations and the European Union held two days of meetings in Ottawa focused on possible reforms to strengthen the World Trade Organization (WTO). A joint statement released by the trade ministers following the meeting said that: “The current situation at the WTO is no longer sustainable. Our resolve for change must be matched with action: we will continue to fight protectionism; and we are committed politically to moving forward urgently on transparency, dispute settlement and developing 21st century trade rules at the WTO.” In a separate statement, the EU called the meeting “an important step toward reform of the WTO.”

Besides the EU and host Canada, other countries in attendance included Australia, Brazil, Chile, Japan, Kenya, South Korea, Mexico, New Zealand, Norway, Singapore and Switzerland. Neither the U.S. nor China, the world's two biggest economies, was invited. Canada said it decided to limit attendance to so-called middle powers, believing this was the best way to find a consensus on the path toward reform. Canadian Trade Minister Jim Carr said the next step in the reform process would be to reach out to the broader WTO membership to inform countries of the discussions ministers had on Thursday. He said he would inform his U.S. and Chinese counterparts in the coming days and weeks about what was discussed in Ottawa.

The joint statement did not single out the U.S. directly in its call for resolving the issue of blocking appointments to the Appellate Body, which is responsible for mediating trade disputes between nations. The trade ministers said the Appellate Body issue is “urgent” and could potentially undermine the entire WTO system. Last month the EU issued a concept paper that included recommendations on transparency and Appellate Body reforms. U.S. Ambassador to the WTO Dennis Shea was critical of the EU's recommendations on the Appellate Body because of their potential to undermine the Body's accountability. The U.S. has been blocking appointments to the Appellate Body since mid-2017, citing issues with the panel's functioning.

House Ways and Means Committee Chairman Kevin Brady (R-TX) released a separate statement calling for “serious reforms” at the WTO. In the statement Brady said, “I strongly support the WTO because strong and enforceable rules are in the U.S. interest. But the WTO urgently needs reform to keep the organization well-functioning and viable, including with respect to negotiations toward

new agreements as well as improving dispute resolution.” Brady's recommended reforms included procedural changes to the Appellate Body and “meaningful consequences” if WTO members continue to ignore their commitments to submit timely notifications as to their compliance with their obligations.”

UPCOMING EVENTS

October 30

USITC - Chinese Aluminum Trade Review: International Trade Commission (USITC) (F.R. Page 33946) holds a hearing on whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of common alloy aluminum sheet from China.

For more information on trade issues you may [email](#) or call Christopher Hatcher at 202-659-8201. Riyad Carey contributed to this section.

This Week in Congress was written by Ryan Schnepf.