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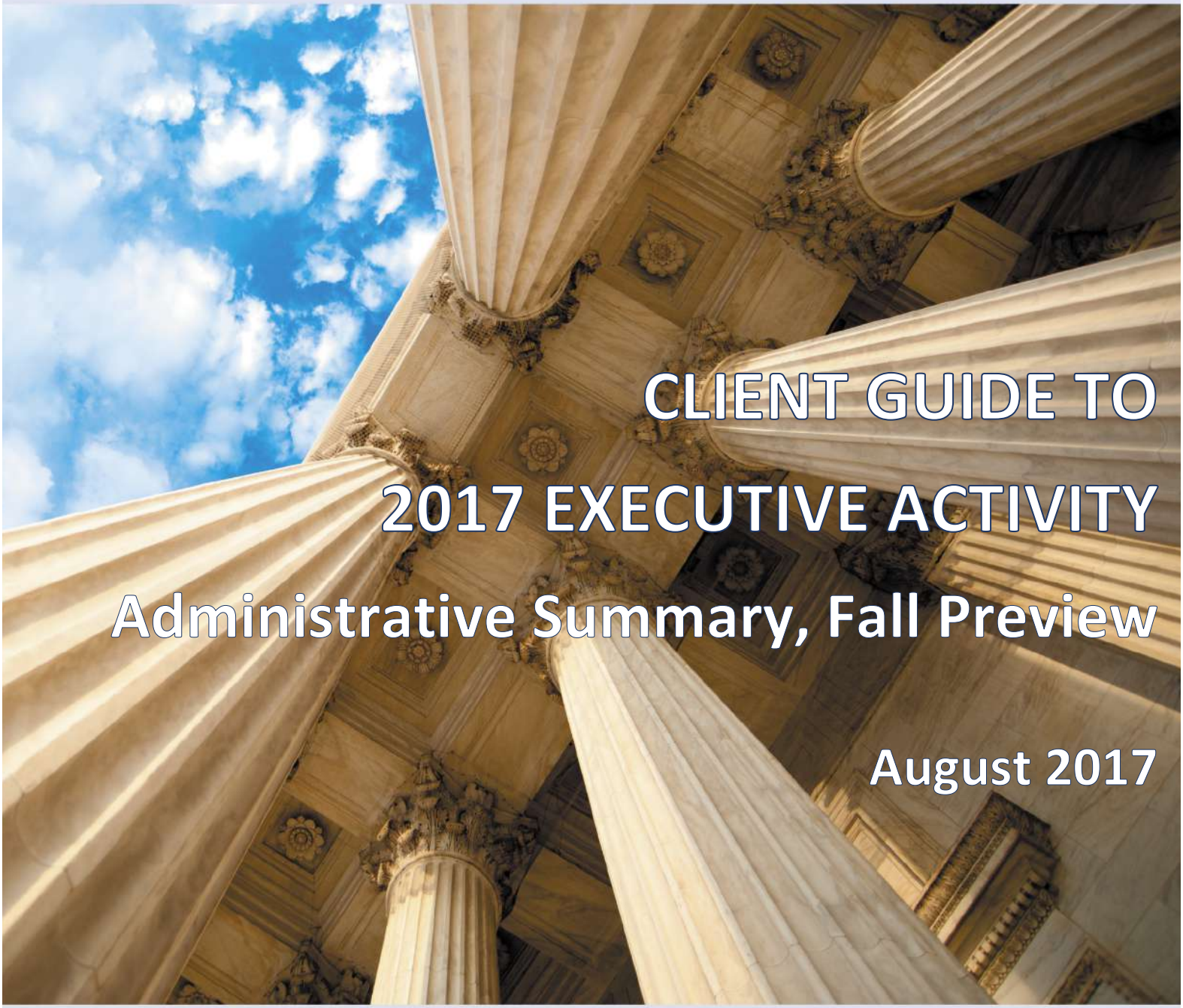

CLIENT GUIDE TO 2017 EXECUTIVE ACTIVITY

Administrative Summary, Fall Preview

August 2017

Overview

This report provides an overview of administrative action, including federal regulations and executive orders, since the beginning of President Trump's term through the start of the Congressional summer recess period. The report also discusses congressional hearings on the 340B Drug Discount Program, delays to the mandatory Medicare bundled payment models, and the ongoing court case regarding payment of the Marketplace Cost Sharing Reduction (CSR) subsidies.

Introduction

Throughout his campaign and during his first months in office, President Donald J. Trump remained a vocal critic of federal government regulations. The president has long stated that overregulation is hampering America's economic growth, and plans for decreasing regulation got top billing in his 100-day action plan. In a January meeting with business leaders, the newly-inaugurated president pledged to cut regulations by as much as 75 percent.

On January 20, the Trump administration issued a government-wide memo advising agency heads to temporarily postpone (for 60 days from January 20) the effective dates of all regulations that had been published in the *Federal Register* but had not taken effect, for review of "questions of fact, law, and policy." Ten days later, President Trump signed an executive order requiring every federal agency to establish a Regulatory Reform Task Force to evaluate existing regulations and identify candidates for repeal or modification. The executive order also required that, for each new federal regulation, two existing regulations must be eliminating.

At the same time, in his first 200 days in office, President Trump signed 42 executive orders, most of which reversed Obama-era regulations, efforts to protect the environment, and policies he says stymie business. Health care was an early focus; the president's first executive order directed executive departments and agencies to exercise all authority and discretion to waive, defer, grant exemptions from, or delay the implementation of any Affordable Care Act (ACA) requirement or provision that levies a fiscal burden on states, businesses, providers, or individuals. Notably, this executive order did not allow departments or agencies to violate the ACA's statutory directives, absent an amendment to or repeal of the ACA.

Regulations

While Congress debated repealing and replacing the Affordable Care Act during the first half of 2017, it was "business as usual" for the Centers for Medicare and Medicaid Services (CMS). With the exception of the 60-day regulatory delay, the agency has continued issuing notices, proposed rules, and final rules at the same rate and time frame as it has in previous years. Since the beginning of President Trump's term, CMS has issued rules that update Medicare and Medicaid payment policies, implement ACA requirements and programs, and expand upon the value- and quality-based programs enacted by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

Finalized Regulations

ACA Insurer Market Stabilization

Patient Protection and Affordable Care Act; Market Stabilization
Publication Date: April 18, 2017
Effective Date: June 19, 2017
Comments due: March 7, 2017

- *Network adequacy:* Under the ACA, qualified health plans (QHPs) participating in the exchange are required to "ensure a sufficient choice of providers" and to provide information on the availability of in-network and out-of-network providers. Until now, CMS has been responsible for determining compliance with this standard. Under the final rule, CMS will, beginning with the 2018 plan year, rely instead on state regulators to ensure network adequacy.

- *Essential community providers (ECPs):* Under prior rulemaking, QHPs had to include within their network at least 30 percent of essential community providers (e.g., community health centers, safety-net hospitals, and children's hospitals) in their area. Under the final rule, this requirement is reduced to 20 percent.

- *Open enrollment:* The final rule reduces the open enrollment period for 2018 to 45 days, down from roughly 90 days in previous years. The next open enrollment period will start on November 1, 2017, and run through December 15, 2017.

- *Special enrollment periods:* The final rule requires individuals to submit supporting documentation for special enrollment periods as of June 2017. Consumers will be given 30 days to either upload or mail documentary verification. Once approved, coverage will be retroactive to the date of plan selection. CMS will not require state-based exchanges that do not use HealthCare.gov to conduct pre-enrollment verification.

- *Metal-level coverage upgrades:* The final rule limits, with some exceptions, the ability of existing exchange enrollees to upgrade from one metal level (e.g., bronze, silver, gold) to another during the coverage year by using a special enrollment period.

- *Actuarial value:* The ACA allows limited variation in the actuarial value (AV) of exchange plans; this limit was previously defined as +/- 2 percent. The final rule changes this requirement by allowing a variation from -4 to +2 percentage points beginning with the 2018 plan year. This will allow insurers to market plans with higher cost sharing but lower premiums.

Inpatient Rehabilitation

FY 2018 Inpatient Rehabilitation Facility (IRF) Prospective Payment System
Publication date: August 3, 2017
Effective date: October 1, 2017

- *Payment update:* This final rule provides for a 1 percent increase in IRF payment rates for FY 2018 (approximately $75 million in additional payments).

- *60 Percent Rule:* The final rule revises the lists of ICD-10-CM diagnosis codes that are used to determine compliance with the requirement that at least 60 percent of a facility's patient population have one of 13 qualifying conditions. Specifically, the final rule revises the code lists for traumatic brain injury, hip fracture, and major multiple trauma codes to ensure that these code lists more accurately reflect the relevant conditions CMS believes should count presumptively toward the 60 percent rule.

- *25 percent payment penalty:* The final rule eliminates the 25 percent payment penalty that applies to late IRF patient assessment instrument submissions.

Skilled Nursing Facilities

FY 2018 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs)
Publication date: August 4, 2017
Effective date: October 1, 2017

- This final rule increases payment rates used under the PPS for SNFs for FY 2018 by 1 percent (approximately $370 million).

- The rule also finalizes revisions to the SNF Quality Reporting Program (QRP), including updating the pressure ulcer measure and adopting four new measures that address functional status beginning with FY 2020 program year.

- In addition, the final rule finalizes policies for the SNF Value-Based Purchasing (VBP) Program, including an exchange function approach to implement value-based incentive payment adjustments beginning October 1, 2018.

Hospice

FY 2018 Hospice Wage Index and Payment Rate Update
Publication date: August 4, 2017
Effective date: October 1, 2017

- This final rule updates the hospice wage index, payment rates, and cap amount for FY 2018. The market basket adjustment will increase FY 2018 hospice payment rates by 1 percent (approximately $180 million). The rule also includes new quality measures and provides an update on the hospice quality reporting program.

Inpatient Hospitals

FY 2018 Inpatient Prospective Payment System Rates for Acute Care Hospitals
Publication date: August 14, 2017
Effective date: October 1, 2017

- *Payment update:* The final rule increases inpatient operating rates by 1.2 percent for general acute care hospitals under the IPPS that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users.

- *Medicare DSH:* The total estimated Medicare DSH payments will be increased from $9.6 billion in FY 2017 to $10.65 billion in FY 2018. For FY 2018, CMS will use Worksheet S-10 data to determine the distribution of uncompensated care payments.

- *Hospital Readmissions Reduction Program (HRRP):* CMS is implementing provisions of the 21st Century Cures Act that require the agency to adjust HRRP penalties based on socioeconomic status. Beginning in FY 2018, CMS will assess penalties based on a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and full-benefit Medicaid.

- *HCAHPS Survey:* Beginning with surveys administered in January 2018, the final rule replaces the pain management questions in the HCAHPS Survey to focus on the hospital's communications with patients about the patients' pain during the hospital stay.

- *LTCH 25-percent threshold:* Under the "25-percent threshold," a long-term acute care hospital (LTCH) is allowed to admit up to 25 percent of its patients from a single general acute care hospital; for patients admitted past the 25 percent threshold, an LTCH faces a significant Medicare reimbursement reduction. The final rule delays for one year the implementation of the 25-percent threshold policy while CMS conducts an evaluation of whether the policy is still needed.

- *Accrediting organization transparency:* The final rule reverses a provision of the proposed rule that would have required agency-approved accrediting organizations to post hospital survey reports and plans of correction on their websites.

- *Clinical Quality Measure (CQM) reporting:* The final rule eases CQM reporting requirements for the Hospital Inpatient Quality Reporting (IQR) Program and the Electronic Health Record (EHR) Incentive

- Program, and shortens the reporting period for the latter from one year to 90 days in order match the performance period established under MIPS.

Proposed Regulations

Long-Term Care Facilities

Revision of Requirements for Long-Term Care Facilities' Arbitration Agreements
Publication date: June 8, 2017
Comments due: August 7, 2017

- In an October 2016 final rule, CMS prohibited the use of pre-dispute binding arbitration agreements with residents of long-term care (LTC) facilities. Under this new proposed rule, arbitration agreements are permissible, but they must be written in plain language. If the arbitration provision is a condition of admission to the LTC facility, the agreement also must be included in the admission contract.

Physician Quality Payment Program

CY 2018 Updates to the Quality Payment Program
Publication date: June 30, 2017
Comments due: August 21, 2017

- This proposed rule includes updates for the second and future years of the Quality Payment Program (QPP) established by MACRA. Under the QPP, eligible clinicians can participate via one of two tracks: the Merit-based Incentive Payment System (MIPS) or Advanced Alternative Payment Models (APMs).

Advanced Alternative Payment Models

- *Downside risk for Advanced APMs:* Under current regulations, in order to qualify for payment incentives under the Advanced Alternative Payment Model (APM) framework, an APM must expose participating providers to a specified level of downside financial risk. For performance years 2019 and 2020, CMS proposes in this final rule to maintain the minimum level of downside risk at the current rate of 8 percent of the participant's total Medicare Parts A and B revenues.

- *Downside risk for Medical Home Models:* As an alternative to the above standard, existing regulations allow an APM to qualify as an Advanced APM by meeting the definition of a Medical Home Model, which allows for lower downside risk. The proposed rule relaxes the current risk threshold for this model, reducing the minimum downside risk from 3 percent to 2 percent in performance year 2018, from 4 percent to 3 percent in 2019, and 5 percent to 4 percent in 2020. The minimum risk would remain at its current level of 5 percent for performance year 2021 and beyond.

Merit-based Incentive Payment System

- *Exemption threshold for MIPS:* Under current regulations, clinicians not participating in Advanced APMs are required to participate in MIPS if they bill Medicare more than $30,000 a year or provide care for more than 100 Medicare patients. The proposed rule raises this threshold to only cover providers who bill Medicare more than $90,000 a year or provide care for more than 200 Medicare patients. CMS projects 585,560 clinicians will fall under this exclusion.

- *MIPS weighting:* CMS proposes the following weighting for 2018 performance year/2020 payment year: Quality – 60 percent; Improvement – 15 percent; Advancing Care Information – 25 percent; Cost – 0 percent.

- *MIPS virtual groups:* The proposed rule would allow solo practitioners and practices with ten or fewer MIPS-eligible providers to form larger groups for MIPS participation. Providers would then be able to submit their MIPS reporting based on that "virtual group" rather than as individuals.

- *MIPS reporting flexibility:* The proposed rule would give clinicians the option to choose how they will participate in MIPS, ranging from a full year performance period for the quality and cost performance categories to a 90-day minimum for the advancing care information and improvement activities.

- *Facility-based practitioners:* Under the proposed rule, practitioners whose primary professional responsibilities are in a healthcare facility would be allowed to submit that facility's Hospital Value Based Purchasing Program scores as a proxy for the individual practitioner's performance in the quality and cost categories.

Hospital Outpatient / Ambulatory Surgery Centers

CY 2018 Hospital OPPS and ASC Payment Rule
Publication date: July 20, 2017
Comments due: September 11, 2017

- This proposed rule would update hospital rates by 1.75 percent in CY 2018 compared to CY 2017.

- The proposed rule would also make deep cuts to how much CMS reimburses hospitals for 340B drugs. Currently, hospitals are reimbursed for the 340B drugs at their average sales price plus 6 percent. Under the proposed rule, CMS would pay average sale price minus 22.5 percent.

Physician Reimbursement

CY 2018 Medicare Physician Fee Schedule
Publication date: July 21, 2017
Comments due: September 11, 2017

This proposed rule addresses changes to the Medicare physician fee schedule (MPFS) and other Medicare Part B payment policies for CY 2018.

- *Overall payment update and misvalued code target:* CMS estimates a 0.31 percent overall increase in physician payment rates for 2018. This update reflects the 0.50 percent increase established under MACRA, reduced by 0.19 percent due to a recapture of overpayments due to misvalued codes. To determine the payment rate for a particular service, the sum of three geographically adjusted RVUs is multiplied by a conversion factor (CF) in dollars. Under the proposed rule, the conversion factor for CY 2018 is $35.99, which is slightly more than the 2017 CF of $35.89.

- *Site-neutral payment policies for off-campus HOPDs:* The proposed rule proposes changes to site-neutral policies under Section 603 of the Bipartisan Budget Act of 2015, paying hospitals 25 percent rather than 50 percent of the OPPS rate for non-excepted services. CMS indicated that it may be willing to finalize a less severe cut (e.g., 40 percent) depending upon feedback received on the PFS proposed rule.

- *Medicare telehealth services:* CMS proposes to pay for new telehealth services, including psychotherapy for crisis, health risk assessments, and care planning for chronic care management.

Medicaid DSH

Medicaid Disproportionate Share Hospital Allotment Reductions
Publication date: July 28, 2017
Comments due: August 28, 2017

- This proposed rule outlines a methodology to implement the ACA's annual Medicaid DSH allotment reductions. The methodology separates states into two groups (low DSH and non-low DSH) for reductions starting in FY 2018. Over the next eight years, from FY 2018 to FY 2025, federal DSH funding is slated to be reduced by $43 billion.

- The proposed rule does not include the FY 2018 DSH funding for each state, but does include a chart that hypothetically applies the proposed methodology to current FY 2017 DSH allotments. Under the proposed methodology, FY 2017 funding would have been reduced by $2 billion nationwide ($153.7 million in New Jersey; $121 million in Pennsylvania).

Home Health

CY 2018 Home Health Prospective Payment System Rate Update; Value-Based Purchasing Model; and Quality Reporting Requirements
Publication date: July 28, 2017
Comments due: September 25, 2017

- This proposed rule would result in a 0.4 percent decrease (-$80 million) in payments to Home Health Agencies (HHAs) in CY 2018.

- For CY 2019 payments, CMS proposes to implement an alternative case-mix adjustment methodology, the Home Health Groupings Model (HHGM). The HHGM would use 30-day periods, rather than 60-day episodes, and rely more heavily on clinical characteristics and other patient information (e.g., principal diagnosis, functional level, comorbid conditions, referral source, and timing) to place patients into more meaningful payment categories.

Medical Technology

Expedited Coverage of Innovative Technology
Publication date: N/A
Comments due: N/A

- This proposed rule would provisionally cover certain medical devices and diagnostics following FDA approval while the manufacturer continues to collect additional data on the technology.

Inpatient Psychiatric Facilities

FY 2018 Inpatient Psychiatric Facilities Prospective Payment System - Rate Update
Publication date: August 7, 2017
Effective date: October 1, 2017
Comments due: October 6, 2017

- This notice with comment period updates the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs). CMS estimates IPF payments to increase by 0.99 percent or $45 million in FY 2018.

- CMS is also soliciting comments on improvements that can be made to the healthcare delivery system that would reduce unnecessary burden for clinicians, providers such as IPFs, and patients and their families.

Cardiac / Joint Replacement Payment Models

Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model
Publication date: August 17, 2017
Comments due: October 16, 2017

- This proposed rule would cancel the Episode Payment Models (EPMs) and Cardiac Rehabilitation (CR) incentive payment model. It would also reduce by half the number of metropolitan statistical areas (MSAs) that are required to participate in the Comprehensive Care for Joint Replacement (CJR) model, and gives newly-excluded hospitals a one-time option to opt back in. the CJR model would continue

on a mandatory basis in approximately half of the selected geographic areas (34 of the 67 MSAs), with an exception for low-volume and rural hospitals, and continue on a voluntary basis in the other areas (33 of the 67 MSAs).

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties
Publication date: August 21, 2017
Comments due: September 20, 2017

- HHS is soliciting comments on delaying until July 2018 the effective date of the January 2017 final rule that sets forth the calculation of the ceiling price and application of civil monetary penalties in the 340B Drug Pricing Program. The rule, which was supposed to take effect in April, would also authorize HHS to levy fines against drug manufacturers that intentionally charge a hospital more than the ceiling price. HHS says that there are " substantial questions of fact, law and policy raised by the rule" and that it needs more time to fully consider previous objections to it, including compliance challenges.

Executive Orders

During his first 200 days in office, President Trump signed 42 executive orders, more than any president in the last 70 years. Executive orders are assigned numbers and published in the *Federal Register*, similar to laws passed by Congress, and they typically direct members of the executive branch to follow a new policy or directive. While President Trump's orders have run the gamut from immigration to voter fraud, the president placed an early priority on rolling back Obama-era health care regulations, as well as efforts to address the nationwide opioid epidemic.

Minimizing the Economic Burden of PPACA Pending Repeal

On January 20, President Trump issued the first executive order of his presidency, aiming to "minimize the unwarranted economic and regulatory burdens" of the Affordable Care Act. The order gives the HHS Secretary and the heads of all other relevant executive departments and agencies the authority to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the ACA that "would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications."

Reducing Regulation and Controlling Regulatory Costs

On January 30, President Trump issued an executive order requiring executive departments and agencies to slash two regulations for every one new regulation proposed. Regulation spending cannot exceed $0, and any costs associated with regulations must be offset with eliminations. The order also directs the head of each agency to keep records of the cost savings, to be sent to the president.

President's Commission on Combating Drug Addiction and the Opioid Crisis

On March 29, President Trump issued an executive order establishing a commission charged with studying the scope and effectiveness of the federal response to drug addiction and the opioid crisis and making recommendations to the president for improving that response. The Commission, chaired by New Jersey governor Chris Christie, released its interim report on July 31. According to the interim report, the first and most urgent recommendation of the Commission is for President Trump to declare a national public health emergency to combat the ongoing crisis.

A report containing the Commission's final findings and recommendations are due to the president by October 1, 2017.

Notable Events

340b Drug Discount Program

The 340B Drug Discount Program is a federal program created in 1992 that requires drug manufacturers, as a condition for having their drugs covered by Medicaid, to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. These savings could then be used to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The program is administered by the Office of Pharmacy Affairs (OPA), located within the Health Resources and Services Administration (HRSA). OPA estimates that the savings to 340B providers attributable to the program in 2015 was $6 billion.

The program has grown significantly in recent years. According to the Government Accountability Office, the number of covered entity sites that take advantage of the 340B program – currently about 38,000 – has nearly doubled in the past five years. In response to the rapid growth of the program, drug makers and some lawmakers have called for greater oversight of the program in light of complaints that some hospitals are receiving discounted drug benefits despite serving a small number of low-income patients.

On June 1, 2017, the House Energy and Commerce (E&C) Committee sent a letter to HRSA requesting 340B program audit documents from the last two fiscal years. In the letter, the leaders cited multiple

concerns with the program, including entities billing for duplicate discounts on the same medication, and that uninsured or underinsured patients may be paying the full price of a drug even though they are getting it through an entity within the 340B program.

On July 18, 2017, the E&C Subcommittee on Oversight and Investigations held a hearing entitled "Examining HRSA's Oversight of the 340B Drug Pricing Program." Witnesses included representatives from HRSA, the Government Accountability Office, and the HHS Office of Inspector General. Committee members from both parties expressed support for the goals of the 340B program, while also acknowledging the need to ensure program integrity through increased transparency and clarity in the definition of "eligible patients." Committee members also suggested that future hearings on the 340B program be held to consider possible legislation addressing oversight of the program.

Bundled Payment Demonstrations

On August 15, CMS issued a proposed rule that would cancel the Episode Payment Models (EPMs) and Cardiac Rehabilitation (CR) incentive payment model. It also reduces by half the number of metropolitan statistical areas (MSAs) that are required to participate in the Comprehensive Care for Joint Replacement (CJR) model, and gives newly-excluded hospitals a one-time option to opt back in.

Cancellation of the EPMs and CR Incentive Payment Model

Based on additional review and consideration of stakeholder feedback – particularly concerns regarding participation requirements, data, pricing, and quality measures, among others – CMS proposes to cancel the EPMs and CR incentive payment model before they begin.

CMS notes that, if the proposal to cancel the EPMs and CR incentive payment model is finalized, providers interested in participating in bundled payment models may still have an opportunity to do so in CY 2018 via new voluntary bundled payment models that would meet the criteria to be an Advanced Alternative Payment Model (APM).

Changes to the CJR Model Participation Requirement

Participation requirements: The CJR model would continue on a mandatory basis in approximately half of the selected geographic areas (34 of the 67 MSAs), with an exception for low-volume and rural hospitals, and continue on a voluntary basis in the other areas (33 of the 67 MSAs).

Low-volume and rural exclusion: CMS proposes to exclude and automatically withdraw low-volume and rural hospitals in the proposed 34 mandatory participation MSAs. For the purposes of this model, CMS defines a low-volume hospital as a hospital with fewer than 20 LEJR episodes in total across the 3 historical years of data used to calculate the performance year 1 target prices.

Op-in option: Hospitals in the proposed 33 voluntary participation MSAs and hospitals that are low-volume or rural would have a one-time opportunity to notify CMS of their election to continue their participation in the CJR model on a voluntary basis **(opt-in)** for performance years 3, 4, and 5. These hospitals would be subject to all model requirements.

Comment solicitation: In order to keep hospitals in all MSAs selected for participation in the CJR model actively participating in the model, CMS is soliciting comment on ways to further incentivize eligible hospitals to elect to continue participating in the CJR model for the remaining years of the model

Relevant Mandatory Participation MSAs

MSA Name	Wage-adjusted Episode Payments (in $)
Harrisburg-Carlisle, PA	28,360
New York-Newark-Jersey City, NY-NJ-PA	31,076
Pittsburgh, PA	30,886
Reading, PA	28,679

ACA Market Reforms

CSR Subsidies

In November 2014, the House of Representatives filed a lawsuit against the Obama administration claiming that the administration was illegally reimbursing marketplace insurers for cost-sharing reduction (CSR) subsidies. The House argued that Congress had never appropriated the money to pay the insurers.

On May 12, 2016, the U.S. District Court for the District of Columbia ruled in favor of the House and enjoined future payments until an appropriation was forthcoming. On July 16, 2016, the Obama administration filed an appeal.

On December 5, 2016, after the election of Donald Trump, the Court of Appeals for the D.C. Circuit stayed further proceedings in the case at the request of the House of Representatives. On February 21, 2017, the House of Representatives and the Trump administration Justice Department filed a joint motion in *House v. Price* (formerly *House v. Burwell*) asking the court to continue to hold the case in abeyance while the two parties negotiated a settlement.

After the failure of the Senate healthcare bill in late July, President Trump threatened to drop the *House v. Price* appeal - effectively ending CSR payments to insurers - a move that would potentially leave tens of thousands more without coverage options in 2018. Also in late July, a bipartisan group of legislators

known as the "Problem Solvers Caucus" reached an agreement to stabilize the individual market. The proposal includes bringing CSR payments under congressional oversight, and thereby protecting them from President Trump's threat to drop the appeal.

On August 1, a federal court ruled that more than a dozen Democratic state attorneys general could intervene in the lawsuit. The ruling ensures that the states can still continue to fight for the payments in court, even if the Trump administration ultimately refuses to defend them.

The uncertainty surrounding the CSR subsidies has led to insurance markets destabilizing across the country. CMS released a press statement on July 10 stating that only 141 insurers had applied for participation in the federal exchange for 2018 in the 39 states it serves. This is down from the 227 initial applicants for 2017 and the 167 insurers that actually offered coverage that year.