
Tuesday, October 6, 2020

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## CMS Finalizes Radiation Oncology Model

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## President Trump Makes Series of Health Care Announcements Ahead of Election

On September 24, President Trump made a series of announcements regarding prescription drug prices, surprise billing, and pre-existing conditions. While the moves align with the President's stated health policy ambitions, many outside observers have noted that the announcements themselves are limited in scope and are likely an attempt to draw attention to health care in the upcoming election.
At a campaign rally in Charlotte, N.C., President Trump announced a plan to distribute $200 discount cards to Medicare beneficiaries to help cover prescription drug costs. While concrete details of the proposal have yet to be finalized, HHS officials have suggested that the program will be administrated as a CMMI demonstration program with the approximately $6 billion need to fund the program to come from the savings realized through the recently proposed Most-Favored Nation drug pricing proposal, which itself has not yet been finalized.

On the same day, the Food and Drug Administration (FDA) released a final rule to allow states and pharmacies to import prescription drugs from Canada. The rule formalizes the process by which states can apply and have their programs approved by the FDA. The policy excludes certain drugs from importation, including biologics, intravenous drugs, and controlled substances.

The President also signed an executive order to address surprise billing and protect healthcare coverage for those with pre-existing conditions. The surprising billing proposal directs HHS to update the Hospital Compare website to inform Medicare beneficiaries about hospital billing practices within six months. Further, the order directs HHS to work with Congress to reach a legislative solution on surprise billing by December 31, 2020, and if that effort fails, the order directs HHS to take administrative action. The order concerning pre-existing conditions simply clarifies that it is the policy of the United States to "ensure that Americans with pre-existing conditions can obtain the insurance of their choice at affordable rates."

To view the Health Care Executive Order, CLICK HERE.

To view the Drug Importation Final Rule, CLICK HERE.

## Amy Coney Barrett Nominated to Replace Justice Ginsberg on the Supreme Court

On September 26, President Trump officially nominated Seventh-Circuit Judge Amy Coney Barrett to replace the late-Justice Ruth Bader Ginsburg on the Supreme Court. Judge Barrett is widely viewed as a strict constitutionalist who would cement the conservative balance of the Court.
Senate Republicans, led by Majority Leader Mitch McConnell (R-KY), have sought to hold hearings starting the week of October 12 and vote on Barrett's nomination prior to the November 3 election. Democrats have argued that a vote shouldn't take place until after the election or even until the next president's inauguration in January.

Judge Barrett has spoken out against the Affordable Care Act in the past. In 2017, she wrote a law review article criticizing the Supreme Court's 5-4 decision in NFIB v. Sebelius to uphold the law's individual mandate because she believed that the Court inappropriately stretched the ACA's plausible meaning and failed to apply the clear text of the statute and the Constitution in making the decision. When it comes to King v. Burwell, which found that the ACA's tax credits were constitutional, Judge Barrett commended Justice Scalia's dissent because, in her view, the majority imposed their personal preferences instead of following their constitutional duties.

Democrats and liberal-leaning interest groups have been quick to criticize Judge Barrett's positions and have publicly warned that the future of the ACA would be in jeopardy if she were confirmed to the high court.

To read more about Judge Barrett's nomination, CLICK HERE.

To read more about the upcoming Senate hearings on Judge Barrett's nomination, CLICK HERE.

## President Trump Signs Bill to Fund Government Through Early December, House Passes Updated COVID-19 Relief Package

On October 1, President Trump signed legislation to fund the government through December 11. The stopgap spending measure averts the threat of a shutdown but sets up another funding fight after the election.

The House passed an updated COVID-19 relief package on October 1, after negotiations with Treasury Secretary Steve Mnuchin – who has served as the Administration's chief liaison with Congress throughout the COVID-19 relief talks – failed to progress. The $2.2 trillion bill is significantly less than the $3.4 trillion COVID-19 relief bill passed by the House in May, mainly because it covers a shorter time period. It includes another round of $1,200 stimulus checks, extended unemployment benefits, more funding for the Provider Relief Fund, additional small business relief, funding for state and local governments, and it also provides a $120 billion fund for the restaurant industry and $28 billion for the airline industry. The Trump Administration had offered $1.5 trillion, leaving a $1 trillion gap between the two sides.

House Appropriations Ranking Member Kay Granger (R-TX) said the bill was too costly and contained too many provisions that had little to do with the pandemic. The bill passed the House along party lines by a vote of 214-207. House members have since returned home to hit the campaign trail and the bill is not expected to be considered by the Senate.

To view the Updated Heroes Act, CLICK HERE.

## CMS Finalizes Radiation Oncology Model

On Friday, September 18, the Centers for Medicare and Medicaid Services (CMS) issued the long-awaited Radiation Oncology (RO) Model final rule. The five-year RO Model will begin on January 1, 2021 and run through December 31, 2025. Radiation therapy providers and suppliers were randomly selected for participation based on Core-Based Statistical Areas (CBSAs), and 33 sites from 14 practices in The Network are included in the zip codes selected for participation.

Per the accompanying CMS fact sheet, the Model aims to test "whether bundled, prospective, site neutral, modality agnostic, episode-based payments to physician group practices, hospital outpatient departments, and freestanding radiation therapy centers for radiation therapy episodes of care reduces Medicare expenditures, while preserving or enhancing quality of care for Medicare beneficiaries." The Model's episode payment is designed "to give radiotherapy providers and suppliers greater predictability in payment and greater opportunity to clinically manage the episode, rather than being driven by fee-for-service (FFS) payment incentives." In response to the final rule, The Network released a statement warning the RO Model failed to accommodate stakeholder input and includes an unreasonable and unrealistic implementation date. While CMS made some minor

improvements to the Model, The Network expressed disappointment that the final rule largely dismissed provider concerns.

“This tremendously short runway from CMS to launch an untested Model, expecting 30% of the radiation oncology community to come into full compliance within a matter of 3 months, is simply unrealistic— especially as our practices continue to be battered by the evolving COVID-19 pandemic,” said Vivek Kavadi, MD, FASTRO, The Network’s chief radiation oncologist.

The Network is actively communicating these concerns to CMS and Congress and working with allied stakeholders to request a delay in the RO Model’s start date.

To contact your Member of Congress to urge a delay in the Model’s implementation, CLICK HERE.

To visit the CMMI Radiation Oncology Model Website, CLICK HERE.

To read the Radiation Oncology Model FAQs, CLICK HERE.

## Dispute Over 340B Discounts Continues as HRSA, Lawmakers Weigh In

The ongoing dispute between drug manufacturers and 340B providers took a turn after the Health Resources and Services Administration (HRSA), which administers the 340B drug discount program, sent a letter to Eli Lilly clarifying that it has yet to make a final decision as to whether it will take action in response to the drug manufacturer’s new policy of limiting discounts through contract pharmacies.

Earlier in the summer, several drug manufacturers including Eli Lilly and AstraZeneca announced they would no longer provide discounted 340B drugs to the contract pharmacies that provide drugs to hospitals if the hospitals have their own on-site pharmacy. The companies allege that hospitals are using their relationship with contract pharmacies to secure duplicate discounts through the 340B program and are pocketing the savings rather than putting it towards charity care as the program was originally intended.

The move has prompted pushback from lawmakers from both parties. On September 14, 243 House lawmakers sent a letter to HHS Secretary Alex Azar urging him to take immediate action to ensure covered entities continue to receive drug discounts through the 340B program. The National Association of Community Health Centers, which believes its members were caught in the crossfire in a dispute between large hospital systems and drug manufacturers, threatened to sue the HHS if it doesn’t penalize Eli Lilly and other companies by October 1.

To view the letter from HRSA to Eli Lilly, CLICK HERE.

To view the bipartisan lawmaker letter to Secretary Azar, CLICK HERE.

## New Research Highlights Impact of COVID-19 Pandemic on Cancer Cases, Health Disparities

On September 16, the American Association for Cancer Research (AACR) released its first-ever annual report on cancer disparities in the United States. The report, “Cancer Disparities Progress Report 2020: Achieving The Bold Vision Of Health Equity For Racial And Ethnic Minorities And Other Underserved Populations,” found that while cancer death disparities have become less pronounced

than they were in the early 2000s, there is still a troubling difference in outcomes across racial and ethnic groups.

Specifically, AACR found that progress in reducing cancer health disparities is being made, as illustrated by the narrowing of the disparity in the overall cancer death rate for African Americans compared with whites from 33 percent higher in 1990 to 14 percent higher in 2016. While overall cancer deaths dropped for all groups between 2000 and 2017, including a 30% decrease amongst African Americans, men and women of color are more likely to develop certain types of cancers and die from them than their white counterparts.

The report also featured a section on the parallels of cancer disparities with COVID-19. For example, racial and ethnic minorities are more likely to be impacted by COVID-19, with Hispanics who make up about 18% of the U.S. population, accounting for more than one-third of all coronavirus cases. The disparities in COVID-19, like cancer, are driven primarily by social determinants of health and underlying health conditions.

To read the American Association for Cancer Research, CLICK HERE.

To watch the briefing on cancer disparities, CLICK HERE.

To read Axios' reporting on the analysis CLICK HERE and HERE.

## Pharmaceutical Executives Testify at House Oversight Committee Hearing

On September 30, pharmaceutical company executives began testifying during a two-day hearing on drug pricing practices held by the House Oversight Committee. The hearing, titled "Unsustainable Drug Prices: Testimony from the CEOs," comes amid an 18-month investigation by the committee into rising drug prices, executive compensation, and potentially anticompetitive patent strategies. The Committee also released five staff reports and accompanying document packets regarding the investigation's findings, including reports on cancer drugs Revlimid and Gleevec.

Among the executives who testified were Celgene Corporation CEO Mark Alles, Bristol Myers Squibb CEO Giovanni Caforio, Teva Pharmaceuticals CEO Kåre Schultz, Amgen CEO Robert Bradway, Mallinckrodt Pharmaceuticals CEO Mark Trudeau, and Novartis AG President Thomas Kendris.

"These companies sell medications that are critical to our health and well-being, but their skyrocketing prices are simply unsustainable," Chairwoman Maloney said in her opening statement. "For nearly two years, our Committee has aggressively investigated why drug companies continuously increase prices, how they use their massive profits, and what steps can be taken to make prescriptions more affordable for the American people."

To watch the hearing and see the testimony, CLICK HERE and HERE.

To view the staff reports on the investigation's findings, CLICK HERE.