



Health Policy Briefing

October 7, 2019

President Signs Medicare EO

President Trump signed an [executive order](#) on October 3 titled “Protecting and Improving Medicare for Our Nation’s Seniors,” aimed at strengthening the Medicare program and Medicare Advantage (MA) offerings. During his announcement, the President stated that Medicare-for-All would end Medicare as we know it, promising that, “as long as I’m President, no one will lay a hand on your Medicare benefits.” He further touted his administration’s accomplishments on various health care policies.

Among other things, the EO includes provisions to increase transparency, streamline the process between FDA approval and CMS coverage for new technologies, expand supplemental benefits in MA, increase market-based reimbursement in fee-for-service Medicare, step up efforts on fraud, waste, and abuse, and remove barriers to private contracting. As for timing, the EO does not contain any immediate changes to Medicare policy. Rather, it directs the Department of Health and Human Services (HHS) to issue regulations within specified timeframes to accomplish the policy goals outlined in the EO.

Many expected the EO to contain language related to prescription drug pricing, but it did not. However, in his remarks, the President did state that drug prices must come down and mentioned several prescription drug policies. He predicted that prescription drug importation from Canada and other countries is coming “soon.”

Democrats reacted quickly, with House Majority Leader Steny Hoyer (MD) calling the EO a “thinly veiled effort to disguise his Administration’s dismal record on health care and protecting seniors.” Meanwhile, Senate Minority Leader Schumer (NY) took to Twitter, stating that Republicans “claim to care about pre-existing condition protections but they keep sabotaging our health care law.”

All eyes now turn to HHS, which is tasked with a heavy load of regulatory homework, most of it with a deadline of one year from the EO’s signing.

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Reps. Thornberry and Collins to Leave Congress

Rep. Mac Thornberry (R-Texas) announced last week that he will not seek reelection in 2020. Rep. Thornberry currently serves as the ranking member of the House Armed Services Committee. He is the sixth Texas Republican to announce his retirement this year. He has served in Congress since 1994. His seat representing the state's 13th congressional district is expected to be retained by Republicans.

Rep. Chris Collins (R-N.Y.) submitted his resignation from Congress last week, one day ahead of his guilty plea to federal insider trading charges. Collins won reelection last fall despite being under indictment but was barred by party rules from serving on any committees. Republicans are expected to keep control of his seat representing New York's 27th congressional district.

We&Ms Considers Negotiated Rulemaking Solution to Surprise Billing

Chairman of the House Ways and Means Committee Richard Neal (D-Mass.) has informed the panel's Democratic members of a compromise he has offered to Ranking Member Kevin Brady (R-Texas) in their negotiations to protect patients from unexpected medical bills. According to his letter sent on September 27, Neal is proposing a negotiated rulemaking process to require stakeholders to work out their differences when payment disputes between providers and insurers for out-of-network care arise. He compares the structured process to that used in the Medicare clinical laboratory fee schedule and the durable medical equipment payment system. While the Chairman and Ranking Member agree that any framework from the Ways and Means Committee to address surprise bills will hold the patient harmless, Rep. Neal notes that he and the Ranking Member have "consistently encountered disagreement among stakeholders over reimbursement rates for out-of-network surprise bills and the extent to which a dispute resolution process can determine those rates." The negotiated rulemaking process would require the U.S. departments of Health and Human Services (HHS), Labor, and Treasury and relevant stakeholders to form a committee to identify standards for payment rates for out-of-network care. This group would also determine how and whether to incorporate a dispute resolution process, while also ensuring that health care costs do not increase as a result. The committee's recommendations would be finalized through notice and comment rulemaking. According to Rep. Neal, staff will work during the congressional recess to develop legislative language to be considered by the Committee during the next congressional work period.

In addition to the issue of surprise billing, Chairman Neal states that he expects the panel to address H.R. 3, the ***Lower Drug Costs Now Act***, as well as bills to expand the Medicare benefit and address patient protections for individuals in hospice and nursing homes.

HHS to Fund Development of Two Filovirus Vaccines

The Biomedical Advanced Research and Development Authority (BARDA) announced that it will provide The Albert B. Sabin Vaccine Institute Inc. with technical expertise as well as \$20.5 million in funding to simultaneously develop individual vaccine candidates against the Marburg virus and Sudan ebolavirus infections. Under the contract with the U.S. Department of Health and Human Services (HHS), the Sabin Vaccine Institute will conduct nonclinical studies and complete manufacturing activities to advance the development of each vaccine. BARDA will then have the choice to provide additional funding to move the candidates through Phase 2 clinical development.

FDA Warns of Device Cybersecurity Vulnerabilities

The Food and Drug Administration (FDA), alongside the U.S. Department of Homeland Security (DHS), has issued an urgent advisory warning to stakeholders about cybersecurity vulnerabilities that may be present in the operating systems of certain major medical devices. While the agency said that it is unaware of any adverse events resulting from the vulnerabilities, the risks may allow attackers to gain control of devices or hospital networks, cause denial of services, or leak information. The 11 possible defects originate with a software component used to communicate between computers known as IPNet. IPNet powers a range of medical devices worldwide. The problems may be considered non-critical or may require software patching. The affected manufacturing firms – including GE and Gräger – have issued warnings to their customers, but the FDA states that it expects additional devices with the vulnerabilities to be identified. The agency recommends that networks be monitored for intrusions and that doctors and patients discuss any potential risks. Health care facilities should use technologies such as firewalls and virtual private networks to reduce their risk of exposure, and manufacturers should report any devices identified as vulnerable to the Cybersecurity and Infrastructure Security Agency (CISA).

Celebration of National Penicillin Allergy Day Focused on Common Misperceptions

In recognition of National Penicillin Allergy Day on September 28, several key organizations, including the American Academy of Allergy, Asthma, and Immunology ([AAAAI](#)) and the Infectious Diseases Society of America ([IDSA](#)), took the opportunity to better educate the public about correctly identifying individuals who are truly allergic to penicillin. Given that 9 out of 10 individuals who report a penicillin allergy are not actually allergic, it is important to correctly identify those who are allergic to ensure more appropriate prescribing of antibiotics, which helps combat the growth of antimicrobial resistance and the development of super bugs. The AAAAI [recommends](#) that penicillin allergy testing should be performed routinely in patients with self-reported penicillin allergy. Recently, the Senate Appropriations FY20 Labor-HHS report language encouraged the U.S. Department of Health and Human Services “to educate the public and healthcare providers regarding the importance of penicillin allergy testing.” This education is part of a larger strategy, outlined by the Centers for Disease Control and Prevention (CDC) in its [2018 Update Antibiotic Use in the United States: Progress and Opportunities](#), where they cite that “Correctly identifying if patients are penicillin-allergic can decrease the unnecessary use of broad-spectrum antibiotics.” A congressional briefing on the topic is planned for the morning of November 1 in the Capitol Visitor Center.

POTUS Signs Autism CARES Act into Law

President Trump has signed the Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act of 2019 (H.R. 1058) into law. The legislation would authorize \$370 million annually through fiscal year (FY) 2024 for research, education, and intervention programs for individuals with autism spectrum disorder through the Interagency Autism Coordinating Committee. The bill will allow program participants to receive funding throughout their lifetimes, rather than being limited to their childhood years.

Grassley Continues Inquiry Into Genetic Testing

Senate Finance Committee Chairman Chuck Grassley has [written](#) to leadership at the U.S. Department of Health and Human Services (HHS) requesting information on what the Medicare program is doing to “detect and deter fraudulent genetic screening tests and protect beneficiaries from identity theft.” A recent fraud investigation by the Office of the Inspector General (OIG) uncovered potentially \$2.1 billion in losses due to a scammer using offers of free tests to commit fraud. Sen. Grassley requests a response from Secretary Azar and Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma by October 16.

Senators Request Additional E-Cigarette Restrictions

Sens. Jerry Moran (R-Kansas) and Richard Blumenthal (D-Conn.) are asking that the U.S. Consumer Product Safety Commission use its authority under the 2015 *Child Nicotine Poisoning Prevention Act* to enforce restrictions on the nicotine fluids used in e-cigarettes. While the fluids are supposed to be contained in child-resistant packaging, there have been nearly 3,600 cases reported of poisoning related to e-cigarettes and liquid nicotine among all age groups this year. The lawmakers call for all noncompliant liquid nicotine containers to be removed from the market.

Upcoming Congressional Hearings and Markups

House Energy and Commerce Subcommittee on Health legislative hearing to consider Chairman Frank Pallone, Jr.'s (D-NJ) legislation to respond to the national youth tobacco epidemic; time and place TBD; October 16

Recently Introduced Health Legislation

H.R.4576 — To amend the Internal Revenue Code of 1986 to allow contributions to health savings accounts in the case of individuals with spouses who have health flexible spending accounts. Sponsor: Rep. Wexton, Jennifer [D-VA-10]; Cosponsors: (2); Committees: House - Ways and Means

H.R.4575 — To amend title XXVII of the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to require group health plans and health insurance issuers offering group or individual health insurance coverage to establish a process to address inaccurate information listed in publicly accessible provider directories of such plans and issuers, and for other purposes. Sponsor: Rep. Schrier, Kim [D-WA-8]; Cosponsors: (1); Committees: House - Energy and Commerce, Education and Labor, Ways and Means

H.R.4574 — To amend title 38, United States Code, to provide for a presumption of service connection for certain diseases in veterans who were exposed to burn pits. Sponsor: Rep. Ruiz, Raul [D-CA-36]; Cosponsors: (2); Committees: House - Veterans' Affairs

H.R.4564 — To amend the Public Health Service Act to ensure the provision of high-quality service through the Suicide Prevention Lifeline. Sponsor: Rep. Katko, John [R-NY-24]; Cosponsors: (2); Committees: House - Energy and Commerce

H.R.4563 — To repeal Public Law 114-145 to ensure that the Drug Enforcement Administration has the authority to carry out needed enforcement actions for drug diversion control investigations and operations to combat the opioid epidemic. Sponsor: Rep. Fitzpatrick, Brian K. [R-PA-1]; Cosponsors: (1); Committees: House - Energy and Commerce, Judiciary

H.R.4561 — To promote the provision of exercise or fitness equipment, and exercise or fitness classes and instruction, that are accessible to individuals with disabilities. Sponsor: Rep. DeSaulnier, Mark [D-CA-11]; Cosponsors: (1); Committees: House - Education and Labor

H.R.4560 — To amend the Public Health Service Act to reauthorize Johanna's Law, also known as the Gynecologic Cancer Education and Awareness Act. Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]; Cosponsors: (3); Committees: House - Energy and Commerce

H.R.4550 — To amend the Public Health Service Act to authorize grants to provide treatment for diabetes in minority communities. Sponsor: Rep. Waters, Maxine [D-CA-43]; Cosponsors: (56) Committees: House - Energy and Commerce

H.R.4549 — To amend the Internal Revenue Code of 1986 to restore the deduction for research and experimental expenditures. Sponsor: Rep. Larson, John B. [D-CT-1]; Cosponsors: (1); Committees: House - Ways and Means

H.R.4548 — To authorize the Director of the Centers for Disease Control and Prevention to award grants to eligible counties for the use of mobile clinics and distance learning and telemedicine to diagnose and treat children with asthma in rural areas and medically underserved communities. Sponsor: Rep. Vargas, Juan [D-CA-51]; Cosponsors: (2); Committees: House - Energy and Commerce

H.R.4543 — To amend the Public Health Service Act to provide for a behavioral and mental health outreach and education strategy to reduce stigma associated with mental health among the Hispanic and Latino population. Sponsor: Rep. Napolitano, Grace F. [D-CA-32]; Cosponsors: (16); Committees: House - Energy and Commerce

H.Res.606 — Calling for sickle cell trait research, surveillance, and public education and awareness. Sponsor: Rep. Lee, Barbara [D-CA-13]; Cosponsors: (11); Committees: House - Energy and Commerce

H.Res.605 — Expressing support for the goals and ideals of “National Hydrocephalus Awareness Month”. Sponsor: Rep. Smith, Christopher H. [R-NJ-4]; Cosponsors: (1); Committees: House - Energy and Commerce