

Federal Issues

Legislative

117th Congress Convenes

The 117th Congress convened on Sunday with U.S. House Speaker Nancy Pelosi (D-CA) being reelected by Democrats to her fourth term as speaker, which is likely her last as she has indicated she intends to retire after this term.

In the Senate, all eyes will be on Georgia Tuesday as two runoff elections will determine control of the chamber. Sens. Mitch McConnell (R-KY) and Chuck Schumer (D-NY) were both re-elected to their leadership positions in November.

In addition, on Wednesday, Congress is set to certify the Electoral College vote and President-elect Joe Biden's victory, with several Republicans planning to raise objections.

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Federal Issues

Regulatory

CMS Issues Final Rule on Medicaid Drug Utilization and VBP

The Centers for Medicare & Medicaid Services (CMS) [issued](#) the Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) [final rule](#) to incentivize value-based purchasing arrangements between manufacturers and state and commercial health insurance providers in Medicaid ([fact sheet](#)).

Why this matters: The final rule codifies a broad definition of VBP to align pricing and payment to observed or expected evidence and/or outcome-based measures in a targeted population. The final rule also allows manufacturers to report multiple best prices instead of a single best price when offering their VBP arrangements to all states.

The regulation also finalizes a regulatory definition of a line extension, which will become effective on January 1, 2022 for the purposes of the alternative rebate calculation under the Medicaid Drug Rebate Program.

Finally, the rule clarifies the requirements for cost-sharing assistance, applying discounts from copayment assistance directly to patients' deductible or cost sharing obligation as opposed to offsetting what the health insurance company would have to normally reimburse the pharmacy. CMS is delaying the effective date of this policy until January 1, 2023 in order to give manufacturers and payers time to make any necessary changes.

CMS Issues Final Rule on Part D E-Prescribing Transaction Standard

The Centers for Medicare & Medicaid Services (CMS) issued a pre-publication version of a final rule, [Secure Electronic Prior Authorization For Medicare Part D](#), which establishes a new transaction standard for the Part D e-prescribing program, as required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.

Why this matters: The final rule amends the Part D e-prescribing regulations “to require Part D plan sponsors’ support of version 2017071 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for use in certain electronic Prior Authorization (ePA) transactions with prescribers regarding Part D-covered drugs to Part D-eligible individuals.” Part D sponsors may begin using the new

standard for prior authorizations beginning January 1, 2021, but will not be required to use the standard until January 1, 2022.

Coronavirus Updates

- The Food and Drug Administration (FDA) issued an [emergency use authorization](#) for the Moderna COVID-19 vaccine. The Advisory Committee on Immunization Practices (ACIP) voted 11-0 to [recommend](#) the vaccine for use in Americans 18 and older, and recommended that people 75 and older and essential frontline workers should be the next in line for limited supplies of COVID-19 vaccines.
 - HHS and DoD [announced](#) the purchase of an additional 100 million doses of COVID-19 vaccine from Pfizer. Under the terms of the agreement, Pfizer will deliver at least 70 million doses by June 30, 2021, with the balance of the 100 million doses to be delivered no later than July 31, 2021. This adds to the first 100 million doses contracted with Pfizer earlier this year.
 - On December 20, the CDC's ACIP [updated](#) interim vaccine allocation recommendations. In Phase 1b, the COVID-19 vaccine should be offered to persons aged ≥ 75 years and non-health care frontline essential workers, and in Phase 1c, to persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and essential workers not included in Phase 1b.
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Senators Urge CMS to Make MA Telehealth Flexibilities Permanent

Sens. Tim Scott (R-SC) and Mike Crapo (R-ID) sent a [letter](#) to the Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma thanking CMS for their speed and innovation in facilitating emergency flexibilities in the Medicare Advantage (MA) program during the COVID-19 crisis, and urging CMS to make certain temporary telehealth policy changes permanent.

Specifically, the letter requests CMS to use its authority under the CHRONIC CARE Act provisions of the Bipartisan Budget Act of 2018 to allow diagnoses obtained through video telehealth services to be used for MA risk adjustment purposes on a permanent basis. It also asks CMS to account for the costs associated with care management for ESRD patients and the continued response to the COVID-19 virus when finalizing rates and policies for plan year 2022, and to provide more clarity around cost projections related to the COVID-19 pandemic, including estimated vaccine costs and utilization changes to help plan sponsors in 2022 bid development.

Appeals Court Rules Against Hospitals' Challenge to CMS' Price Transparency Regulation

A federal appeals court on December 29 ruled against the American Hospital Association's (AHA) legal challenge to the Centers for Medicare & Medicaid Services' (CMS) final rule mandating that hospitals disclose their privately negotiated charges with commercial health insurers. The rule went into effect January 1, 2021.

Joining the AHA in the [lawsuit](#) are the Association of American Medical Colleges, the Children's Hospital Association, and the Federation of American Hospitals, as well as member hospitals Memorial Community

Hospital and Health System in Blair, NE; Bothwell Regional Health Center in Sedalia, MO; and Providence Holy Cross Medical Center in Mission Hills, CA.

Hospital industry position: In a [statement](#), AHA General Counsel Melinda Hatton said, America's hospitals and health systems support the goal of increasing price transparency by making patient out-of-pocket cost estimates easier to access and understand. Our focus remains on providing patients with the knowledge they actually need to make informed decisions about their health care. That is why we are disappointed in the decision to uphold the District Court rejection of hospitals' challenge to the rule. Further, the decision to decline a stay in enforcement ignores the overwhelming burden of the pandemic on hospitals.

The AHA and many individual hospitals, including AHN, submitted comments strongly opposing the proposed and final price transparency regulations. Earlier in 2020, the AHA and other national associations asked the Department of Health and Human Services (HHS) to delay the implementation date of the rule due to the burden it would represent for hospitals and health systems in the midst of responding to the COVID-19 public health emergency. AHA reiterated its request in a December letter to HHS.

For these reasons, the AHA has urged the incoming Biden administration to evaluate whether the rule should be revised and to exercise enforcement discretion for the duration of the public health emergency.

Why this matters: Hospitals continue to believe that the disclosure of privately negotiated rates does nothing to help patients understand what they will actually pay for treatment and will create widespread confusion for them. Additionally, the requirement imposes significant costs on care providers at a time when scarce resources are needed to fight COVID-19.

State Issues

Delaware

Regulatory

COVID-19 Immunization Availability and Coverage

The Delaware Department of Insurance released [Bulletin 123](#), to remind health insurance carriers and producers of the availability and coverage requirements concerning vaccines for COVID-19. As of December 21, 2020, Delaware has received 8,776 doses of the Pfizer vaccine and additional shipments are expected weekly. Vaccine doses are to be provided at no cost; however, vaccine providers will be able to charge an administration fee for administering the vaccine.

This administration fee can be reimbursed through patients' private or public insurance and uninsured patients will be able to be reimbursed through the Health Resources and Services Administration's Provider Relief Fund. As a reminder, carriers are required under 18 Del. C. §§ 3363 and 3558 to cover certain immunizations for children and adults. Such provisions also prohibit carriers from imposing cost-sharing requirements with respect to office visits if the immunization is not billed separately or tracked as an individual encounter when the primary purpose of the visit is the delivery of the immunization.

State Issues

Pennsylvania

Regulatory

Changes to the Mandated Newborn Screening and Genetics Screening Panels

Senate Bill 983 was passed on November 25, 2020. It amends the act of September 9, 1965 known as the Newborn Child Testing Act. This legislation was introduced to provide for mandated screening and follow up. This law requires submitters (hospitals, midwives, and birth centers) to screen for the following disorders:

- I. Phenylketonuria (PKU)
- II. Maple syrup urine disease (MSUD)
- III. Sickle-cell disease (hemoglobinopathies)
- IV. Galactosemia (GALT)
- V. Congenital adrenal hyperplasia (CAH)
- VI. Primary congenital hypothyroidism (CH)
- VII. Glycogen storage disease type II (Pompe)
- VIII. Hurler syndrome (MPS I)
- IX. Adrenoleukodystrophy (ALD)
- X. Spinal muscular atrophy (SMA)
- XI. Isovaleric acidemia/Isovaleryl-CoA dehydrogenase deficiency (IVA)
- XII. Glutaric acidemia Type I/Glutaryl-CoA dehydrogenase deficiency Type I (GA I)
- XIII. 3-Hydroxy 3-Methylglutaryl-CoA lyase deficiency (HMG)
- XIV. Multiple carboxylase deficiency (MCD)
- XV. Methylmalonic acidemia (mutase deficiency) (MUT)
- XVI. Methylmalonic acidemia (Cbl A, B)
- XVII. 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC)
- XVIII. Propionic acidemia/propionyl-CoA carboxylase deficiency (PROP)
- XIX. Beta-Ketothiolase deficiency (BKT)
- XX. Medium chain acyl-CoA dehydrogenase deficiency (MCAD)
- XXI. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)
- XXII. Long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHAD)
- XXIII. Trifunctional protein deficiency (TFP)
- XXIV. Carnitine uptake defect (CUD)
- XXV. Homocystinuria (HCY)
- XXVI. Tyrosinemia type I (TYR I)
- XXVII. Argininosuccinic acidemia (ASA)
- XXVIII. Citrullinemia (CIT)
- XXIX. HB S/Beta-thalassemia (Hb S/Th)
- XXX. HB S/C disease (Hb S/C)
- XXXI. Biotinidase deficiency (BIOT)
- XXXII. Cystic fibrosis (CF)
- XXXIII. Severe combined immunodeficiency disease (SCID)
- XXXIV. Globoid cell leukodystrophy (Krabbe)

The Department of Health will be responsible for the screening costs of disorders I through X as previously listed. The submitter will be responsible for the screening costs of disorders XI through XXXIV as previously listed. For screening of the disorders previously listed and any disorders added to the newborn screening panel, the submitter is required to utilize and enter into an agreement with the newborn screening laboratory contracted with the Department.

Industry Trends

Policy / Market Trends

CMS Publishes Final Snapshot of 2021 Open Enrollment

The Centers for Medicare & Medicaid Services (CMS) [released](#) the weekly enrollment [snapshot](#) that shows 4,416,057 people selected plans using HealthCare.gov, or were automatically re-enrolled in a plan in Week Six (December 6-15) of the 2021 Open Enrollment period. CMS reports that new consumers accounted for 911,390 plan selections during this period.

Over 8.2 million people selected plans by end of the final day of the 2021 Open Enrollment Period, December 15, 2020. This total preliminary enrollment figure is nearly as high as 2020's 8.3 million enrollments, despite the fact that New Jersey and Pennsylvania transitioned to State-based Exchange platforms for the 2021 Open Enrollment Period. Comparing year-over-year trends shows plan selections this year increased by 6.6% from 2020, 6.3% from 2019, and 2.2% from 2018.

These numbers are preliminary and do not represent final 2021 Exchange Open Enrollment Period figures, though the data indicates enrollment continues to remain stable. CMS plans to release an updated snapshot in January with the final enrollment data.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: <http://legis.delaware.gov/>.

Pennsylvania Legislation: www.legis.state.pa.us.

West Virginia Legislation: <http://www.legis.state.wv.us/>

For copies of congressional bills, access the Thomas website – <http://thomas.loc.gov/>.

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