



Around the world of U.S. healthcare in 360 words or less

Center for Healthcare Regulatory Insight



September 17, 2021 | Issue 298

Editor's note

This note is produced by the KPMG Center for Healthcare Regulatory Insight and is intended to be short and succinct, less than 360 words, to provide a digestible bite of news relevant to our clients and practices. Links are provided to source material (proposed and final regulations, agency guidance and press releases, reports, research, etc.) when available.

Special Supplements: COVID-19 News

In light of the daily volume of COVID-19 activity and news, we are continuing to provide [a supplement](#) to summarize COVID-19 news for the week (attached).

We've also summarized major healthcare provisions advanced by the House Energy & Commerce and Ways & Means Committees, respectively, for the House *Build Back Better* reconciliation package. ***The attached document is for internal use only.***



Healthcare regulatory news

FTC [voted to withdraw 2020 vertical merger guidelines](#)... FTC [warned health app/connected device companies to comply with data breach notifications requirements](#).

HHS [proposed repealing](#) the [Medicare Coverage of Innovative Technology](#) final rule.

An [HHS-Labor-Treasury surprise billing proposed rule](#) would require health plans and air ambulances to [report cost/claims data for air ambulance services](#) and ACA marketplace and short-term, limited duration plans to disclose financial relationships with agents/brokers.

ONC is [considering guidelines to address bias](#) in healthcare-based artificial intelligence... CMS will delay [enforcement of payer-to-payer data exchange requirements](#) pending [future rulemaking](#).

FDA Acting Commissioner Janet Woodcock [urged the patent office to support](#) prescription drug cost containment efforts.



Healthcare law and policy news

White House announced [2.8M people signed up for ACA special enrollment period](#) coverage.

House [Ways & Means](#) and [Energy & Commerce](#) Committees advanced a provision to add Medicare dental, vision, and hearing benefits to the \$3.5T reconciliation bill; Ways & Means also included [provisions on drug pricing](#) and [permanent ACA expanded subsidies](#).

Justice Department [intervened in a False Claims Act suit](#) against Independent Health and its now-defunct risk adjustment subsidiary... A federal whistleblower lawsuit alleges [Aetna secured](#) Pennsylvania Medicaid program contracts by misrepresenting its provider network.

Intermountain and SCL [intend to merge](#)... Northwell Health [signed a five-year strategic partnership](#) with Walgreens to provide telehealth throughout New York... CareFirst [unveiled CloseKnit](#), a virtual primary care practice... Abbvie and Regeneron [entered a partnership \(upwards of \\$1.4B\) to develop/commercialize](#) an eye disease gene therapy... Roche will [partner with Temedica](#) on a multiple sclerosis “digital companion” app... Moderna and AbCellera [will collaborate](#) on [mRNA technology-based antibody therapies](#).

A Community Oncology Alliance-commissioned study found [340B hospitals charged insurers, on average, 3.8 times](#) 340B acquisition costs... *Health Affairs* studies found [private insurers pay upwards of twice as much](#) for infused drugs in hospital outpatient departments compared to physicians’ offices and a majority of high-price hospitals are in [markets with “low”/“moderate” competition](#).

US Census Bureau reported 8.6% of Americans [lacked health insurance in 2020](#)... CDC reported the number of [states where at least 35% of adults are obese](#) has nearly doubled (9 to 16) since 2018 and the [rate of increase in BMI nearly doubled](#) during the pandemic for individuals 2-19.



Questions or comments, please send to us-hclspractice@kpmg.com.

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As of 9/14/2021

Healthcare-related provisions in the Concurrent Resolution on the Budget for Fiscal Year 2022 – Build Back Better Act

Topic	Sec/Version Date	Title	Summary
Mental Health Parity	21005 (9/8/21)	CIVIL MONETARY PENALTIES FOR PARITY VIOLATIONS	Amends ERISA civil enforcement authority to permit imposing civil penalties for failure to meet mental health parity requirements .
Long-Term Care Support Grants	134201 (9/7/21)	REAUTHORIZATION OF FUNDING FOR PROGRAMS TO PREVENT AND INVESTIGATE ELDER ABUSE, NEGLECT AND EXPLOITATION	Appropriation for grants to States, Indian Tribes for training of qualified home health aide, nurse aide, personal care aide, qualified hospice aide, LPN or licensed or certified social worker, or such trainee in the following settings: SNF, NF, HHA, approved HCBS provider, hospice, or tribal ALF. Also grants for States to establish adult protective services, ombudsman programs, linkages to legal services and medical legal partnerships. Also grants to AAAs to address social isolation among vulnerable older adults and people with disabilities.
Long-Term Care Facilities	134301 (9/7/21)	FUNDING TO IMPROVE THE ACCURACY AND RELIABILITY OF CERTAIN SKILLED NURSING FACILITY DATA	Appropriation to collect and authority to reduce payment rates by 2 pp for inaccurate reporting of resident assessment or direct care staffing data.
	134302 (9/7/21)	ENSURING ACCURATE INFORMATION ON COST REPORTS	Appropriations for annual cost report audits for a representative sample of SNFs
	134303 (9/7/21)	SURVEY IMPROVEMENTS	Appropriations for reviews of and technical assistance to improve effectiveness of survey compliance and enforcement effectiveness
	134304 (9/7/21)	NURSING STAFFING REQUIREMENTS	Appropriation for HHS to conduct periodic studies and reports to Congress on the appropriateness of establishing minimum SNF staff-to-resident ratios for nursing staff and NLT 2 years later to issue/update regulations to comply with ability to waive requirements for rural facilities.
Medicare Dental, Hearing and Vision Coverage	134401 (9/7/21)	DENTAL AND ORAL HEALTH CARE	Amends §1861 of SSA (Part B) to cover preventive and certain to-be-specified basic and major dental services in and after 2028. Basic services to be covered at 80% but major services only at 10% in the first year, rising to 50% over the next 4 years. Bundled payment for dentures or other services are permitted. No judicial review of payment rates or covered services. Some dentures subject to competitive acquisition.
	134402 (9/7/21)	PROVIDING COVERAGE FOR HEARING CARE UNDER THE MEDICARE PROGRAM	Amends §1861 to cover aural rehabilitation and treatment services by qualified audiologists and certain hearing aids starting in 10/1/2023. Some hearing aids to be subject to competitive acquisition. Specific appropriations for FY2022 and 2023. No judicial review of covered types of hearing aids or payment rates.
	134403 (9/7/21)	PROVIDING COVERAGE FOR VISION CARE UNDER THE MEDICARE PROGRAM	Amends §1861 to cover routine eye exams, refractive services and contact lens fittings and conventional eyeglasses and contact lenses starting 10/1/2022. Some glasses/contact lenses to be subject to competitive acquisition. Specific appropriations for FY2022 and 2023. No judicial review of covered types of glasses/lenses or payment rates.
Drug Pricing	30501 (9/8/21)	PROVIDING FOR LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS	Amends Title XI of the SSA to add a Fair Price Negotiation Program to negotiate and publish maximum fair prices applicable to plan years starting in 2025 for selected drugs (generally single-source brand products and insulins) covered under Medicare and under commercial plans and the VA if these are voluntarily opted into the resulting manufacturer agreements. An

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			<p>Average International Market (AIM) price will be used to rank and prioritize savings off of list prices to select negotiation eligible drugs and to set the maximum permissible level at 120% of the AIM price. Fair price negotiation program prices to be included in Best Price and AMP. Selected drugs and maximum fair prices not subject to judicial review. Program requires procedures to ensure that NLT 90 days after dispensing, the pharmacy is reimbursed the difference between the lesser of certain measures of acquisition cost and the maximum fair price. Program requires a reasonable dispute resolution mechanism between manufacturers, individuals, and any third party contracted to administer data and funds distribution. Noncompliant manufacturers would be subject to civil monetary penalties and non-deductible excise taxes.</p>
30511 (9/8/21)	MEDICARE PART B REBATE BY MANUFACTURERS		<p>Amends §1834 of SSA starting July 1, 2023 to add a new rebate program beginning July 1, 2023 for manufacturers for single source drug or biological (excluding drugs with annual costs less than \$100 and vaccines) with prices increasing faster than inflation (measured starting July 2015). Coinsurance would be equal to 20% of the inflation-adjusted payment amount. Rebates would be deposited into the Trust Fund and waived for selected drugs with a maximum fair price in effect and may be waived for drugs in shortage. Part B inflation rebates would not be included in ASP or Best Price. Manufacturer noncompliance with providing rebates would be subject to civil money penalty of at least 125% of the rebate amount.</p>
30512 (9/8/21)	MEDICARE PART D REBATE BY MANUFACTURERS		<p>Amends the SSA by adding new section §1860D-14B to add a new rebates program beginning in 2023 to add a new rebate program for manufacturers of single source drug or biological with annual costs less than \$100 and prices increasing faster than inflation (measured starting January 2016). Rebates would be deposited into the Prescription Drug Account in the Trust Fund and waived for selected drugs with a maximum fair price in effect and may be waived for drugs in shortage. No judicial review. Part D inflation rebates would not be included in ASP or Best Price. Manufacturer noncompliance with providing rebates would be subject to civil money penalty of at least 125% of the rebate amount.</p>
30521 (9/8/21)	MEDICARE PART D BENEFIT REDESIGN		<p>Beginning in 2024, the bill reduces the Part D annual out-of-pocket spending threshold to \$2000 in the first applicable year, and eliminates beneficiary cost-sharing above this threshold. The government will provide reinsurance for 20% instead of 80% of costs above this OOP limit.</p> <p>The bill sunsets the current coverage gap discount program, replacing it with a new manufacturer discount program to provide access to discounted prices at the point-of-sale benefit-wide after the deductible – requiring manufacturers to pay for drug coverage in both the initial (10% of costs) and catastrophic (30% of costs) phases of the benefit. Sponsors must apply discounts before any other coverage, make pharmacies whole for any difference between the manufacturer discounted price and the negotiated price with the pharmacy, and reflect manufacturer discount assumptions in their bids. A reasonable dispute resolution mechanism must be established. The Secretary may contract with one or more third parties for administration, but the Secretary shall not receive or distribute funds of a manufacturer. Civil money penalties of 125% for any discounts that were not provided.</p>
30522 (9/8/21)	ALLOWING CERTAIN ENROLLEES OF PRESCRIPTION DRUG PLANS AND MA-PD PLANS UNDER MEDICARE		<p>Amends §1860D-2 of the SSA to require plan sponsors to provide option for non-LIS members with projected costs for a first fill equal to or above the TrOOP threshold to make pre-catastrophic cost sharing in periodic payments over the remainder of the plan year.</p>

		PROGRAM TO SPREAD OUT COST SHARING UNDER CERTAIN CIRCUMSTANCES	
	30531 (9/8/21)	PROHIBITING IMPLEMENTATION OF RULE RELATING TO ELIMINATING THE ANTI-KICKBACK STATUTE SAFE HARBOR PROTECTION FOR PRESCRIPTION DRUG REBATES	Beginning January 1, 2026, the Secretary shall not implement, administer, or enforce the provisions of the final rule published on 11/30/2020 (85 Fed. Reg. 76666).
Affordable Care Act Coverage	30601 (9/9/21)	ENSURING AFFORDABILITY OF COVERAGE FOR CERTAIN LOW-INCOME POPULATIONS	Beginning in 2022 through 2024 temporarily provides the ACA Marketplace cost-sharing reduction assistance to individuals with incomes below 138 percent of the Federal Poverty Level (continuing to exclude those who qualify under Medicaid)
	30602 (9/9/21)	TEMPORARY EXPANSION OF HEALTH INSURANCE PREMIUM TAX CREDITS FOR CERTAIN LOW-INCOME POPULATIONS	Beginning in 2022 through 2024 temporarily provides the ACA Marketplace subsidies to individuals with incomes below 100 percent of the FPL (continuing to exclude those who qualify under Medicaid)
	30603 (9/9/21)	ESTABLISHING A HEALTH INSURANCE AFFORDABILITY FUND.	Makes available \$10 billion annually to states, providing the option for states to establish a state reinsurance program or use the funds to provide financial assistance to reduce out-of-pocket costs. It would also require the Centers for Medicare and Medicaid Services (CMS) during 2023 and 2024 plan years to establish and implement a reinsurance program in states that are not expending amounts under the state plan for all individuals described in section 19902(a)(10)(A)(i)(VIII) <i>[the new section FEDERAL MEDICAID PROGRAM TO CLOSE THE COVERAGE GAP added in the bill]</i> .
Medicaid Program	30701 (9/9/21)	FEDERAL MEDICAID PROGRAM TO CLOSE THE COVERAGE GAP	Establishes a federal Medicaid program for individuals who reside in states that have not expanded Medicaid beginning in 2025. The federal Medicaid program would provide the same benefits and beneficiary protections to individuals as are provided by state Medicaid expansion. It would authorize the Secretary of HHS to contract with third-party entities to operate the federal Medicaid program.
	30711 – 30715 (9/9/21)	EXPANDING ACCESS TO MEDICAID HOME AND COMMUNITY-BASED SERVICES	Provides grants to states to develop plans to expand access to home and community based services (HCBS) and strengthen the HCBS workforce. Provides states with a permanent seven percentage point increase to the federal medical assistance percentage (FMAP) if the state implements an HCBS improvement program to strengthen and expand HCBS. It provides an enhanced FMAP of 80 percent for administrative costs associated with improving HCBS. It also provides a two-year increase to the FMAP of two percentage points if a state adopts an HCBS model that promotes self-direction of care and meets certain other requirements. Requires HHS to track implementation and outcomes of, provide technical assistance to, and develop quality measures for HCBS programs.
	30721 (9/9/21)	PERMANENT EXTENSION OF MEDICAID PROTECTIONS AGAINST SPOUSAL IMPOVERISHMENT FOR RECIPIENTS OF HOME AND COMMUNITY-BASED SERVICES	Permanently extends the protection against spousal impoverishment for individuals whose partners receive Medicaid HCBS.

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	30722 (9/9/21)	PERMANENT EXTENSION OF MONEY FOLLOWS THE PERSON REBALANCING DEMONSTRATION	Provides permanent funding for the Money Follows the Person Rebalancing Demonstration to help states transition folks out of institutions and into HCBS.
	30723 (9/9/21)	EXTENDING CONTINUOUS MEDICAID COVERAGE FOR PREGNANT AND POSTPARTUM WOMEN	Requires that state Medicaid programs provide 12 months of continuous Medicaid eligibility to postpartum women. It also requires that states provide full Medicaid benefits to pregnant and postpartum women.
	30724 (9/9/21)	PROVIDING FOR 1 YEAR OF CONTINUOUS ELIGIBILITY FOR CHILDREN UNDER THE MEDICAID PROGRAM	Requires that state Medicaid programs provide 12 months of continuous eligibility to children enrolled in Medicaid.
	30725 (9/9/21)	ALLOWING FOR MEDICAL ASSISTANCE UNDER MEDICAID FOR INMATES DURING 30-DAY PERIOD PRECEDING RELEASE	Requires that state Medicaid programs cover incarcerated individuals 30 days prior to their release.
Children's Health Insurance Program	30801 (9/9/21)	PERMANENT EXTENSION OF CHILDREN'S HEALTH INSURANCE PROGRAM	Authorizes permanent funding for the Children's Health Insurance Program (CHIP) for low-income children
	30802 (9/9/21)	PERMANENT EXTENSIONS OF OTHER PROGRAMS AND DEMONSTRATION	Provides permanent funding for several programs related to CHIP, including the pediatric quality measures program and the child enrollment contingency fund to provide states with additional funding in the event its CHIP allotment is insufficient.
	30803 (9/9/21)	STATE OPTION TO INCREASE CHILDREN'S ELIGIBILITY FOR MEDICAID AND CHIP	Provides states with the option to increase CHIP income eligibility levels above the existing statutory ceiling.
	30804 (9/9/21)	EXTENDING CONTINUOUS CHIP COVERAGE FOR PREGNANT AND POSTPARTUM WOMEN.	Requires states to provide 12 months of postpartum coverage to women enrolled in CHIP.
	30805 (9/9/21)	PROVIDING FOR 1 YEAR OF CONTINUOUS ELIGIBILITY FOR CHILDREN UNDER THE CHILDREN'S HEALTH INSURANCE PROGRAM	Requires state CHIP programs to provide 12 months of continuous eligibility to children enrolled in CHIP

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COVID-19 News Supplement

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COVID-19 by the Numbers

There have now been [roughly 43.3 million confirmed COVID-19 cases](#) in the US, with a death toll over 670,000... An average of 150,000 Americans contracted COVID-19 each day over the past week, down 8% from the week before, however [deaths are up 33% to an average of 1,888 people per day](#)... Washington Post reported that [1 in 500 Americans have died of COVID-19](#); among people 18 to 39 years old, COVID-19 has killed Black and Hispanic individuals at a rate more than three times that of White people.

383 million COVID-19 [vaccine doses have been administered](#) in the US (roughly 781,000/day over the past week)... Over 210 million Americans ([74.2% of Americans 12 and older](#) and 93% of Americans 65 and older) have received at least one dose of a COVID-19 vaccine; 180 million Americans are fully vaccinated (63.5% of Americans 12 and older).

A [CDC study found](#) that unvaccinated people were 5 times more likely to become infected and more than 10 times more likely to need hospitalization or die from COVID-19 than those who were fully vaccinated.

Executive and Administrative Action

President Biden [will ask global leaders at a virtual summit](#) to commit to a set of “concrete actions” to end the COVID-19 pandemic, including vaccinating 70% of the world’s population by next September.

HHS released [\\$25.5 billion in Provider Relief funding](#), including \$8.5B for those who serve rural patients covered by Medicare and Medicaid.

Federal guidance states that federal employees [must be fully vaccinated by November 22](#) or face progressively harsher discipline, including termination.

Healthcare Law, Business, and Policy News

KFF estimated that [preventable COVID-19 hospitalizations among unvaccinated adults](#) have cost the US \$5.7B since June, including \$3.7B in August alone... Urban Institute estimated that [17 million people will have gained Medicaid coverage during the pandemic](#) by the end of 2021, however, nearly 90% of those enrollees could lose coverage when the public health emergency ends.

A Politico/Morning Consult [poll found that 58%, 57%, and 60% of Americans support](#) a COVID-19 vaccine mandate for large employers, federal workers, and healthcare workers, respectively... An Axios/Ipsos poll found that [60% of Americans support the Biden Administration requirements](#) that federal employees and employees at companies with more than 100 workers be vaccinated.

Surveillance, Testing, and Treatment

FDA's Vaccines and Related Biological Products Advisory Committee will [meet today to discuss COVID-19 booster shots](#) for people 16 and older... Meeting [briefing documents](#) suggest the FDA remains skeptical of endorsing a Pfizer-BioNTech booster shot, including the companies' assertion that a drop in immune protection from the vaccine is due to the passage of time, rather than emergence of new more-contagious variants... The CDC Advisory Committee on Immunization Practices will [meet September 22 and 23](#) and will likely discuss booster shots.

Two senior vaccine officials set to leave FDA argued, along with co-authors, [in The Lancet](#) that current science [does not support giving a booster COVID-19 vaccine](#) dose to most Americans.

Pfizer and BioNTech [expect to seek approval in November](#) for use of their COVID-19 vaccine in kids younger than 5.

Based on clinical trial data [showing waning immunity over time](#), Moderna will [seek FDA emergency use authorization](#) for its COVID-19 vaccine booster shot.

CureVac [cancelled contract manufacturing deals](#) for its experimental COVID-19 vaccine.

A special envoy to the World Health Organization warned that it's [increasingly likely that COVID-19 variants resistant to existing vaccines](#) will begin circulating "in the coming months and years."

HHS [changed the allocation process for COVID-19 monoclonal antibody \(mAb\) therapy](#), establishing a procedure where states are allocated doses based on case-load and utilization metrics and then given the responsibility for allocating doses to provider organizations; providers previously directly requested doses of the therapy from the federal government... The federal government will purchase [1.4 million additional doses of Regeneron's mAb](#) (\$2.94B), to be delivered by Jan. 31, and [388,000 doses of Eli Lilly's mAb](#) (\$330M) to be shipped in Q3 and Q4.

Former FDA Commissioner Scott Gottlieb [expects more approved COVID-19 therapies, including antivirals](#), to come to market.

Roche projected that COVID-19 could [become seasonal with 200 to 500 million new infections](#) each year.

NIH [allocated \\$470 million toward expanding research](#) on long-term effects of COVID-19.