

Issues for the week ending July 29, 2022

Federal Issues

Legislative

Senators Reach Budget Reconciliation Deal

Sen. Joe Manchin (D-WV) and Senate Majority Leader Chuck Schumer (D-NY) <u>announced</u> on Wednesday that they reached a deal on a broad budget reconciliation package addressing energy, climate, and taxes. The new deal – the <u>Inflation Reduction Act of</u> <u>2022</u> -- will be coupled with the health care reconciliation provisions that had been being readied for floor activity.

Why this matters: In addition to climate and energy, the package will invest approximately \$300 billion in deficit reduction, including \$288 billion in savings from prescription drug pricing reform. The deal also makes a \$64 billion investment in the Affordable Care Act (ACA).

Schumer and Manchin issued a one-page <u>summary</u> of the reconciliation package, which includes:

- Extending the ACA tax credits expanded by the American Rescue Plan Act (ARPA) for 3 years, through 2025;
- Allowing Medicare to negotiate drug prices and applying inflationary rebates;

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• Restructuring the Part D benefit, including an annual maximum out-of-pocket cap at \$2,000

Insulin in? The bill does not currently address insulin prices but discussions are underway about possibly adding an insulin copay cap after separate bipartisan negotiations on the issue have broken down.

The Senate plans to vote on the bill this week, once it is fully reviewed by the parliamentarian. House Speaker Nancy Pelosi (D-CA) has indicated she will call the House back to vote on the deal so it can quickly be signed into law. The White House also issued a <u>press release</u> announcing the President's support for the Inflation Reduction Act of 2022.



House Panel Advances Medicare Advantage Prior Authorization Bill

On Wednesday, the House Ways and Means Committee unanimously <u>passed</u> the "<u>Improving Seniors</u>' <u>Timely Access to Care Act</u>," legislation that mandates electronic prior authorization (ePA) in Medicare Advantage (MA).

Why this matters: The MA program has come under scrutiny on Capitol Hill recently, bolstered by an <u>HHS</u> <u>OIG report</u> that raised questions about the use of prior authorization in MA plans.

The bipartisan bill includes:

- Requirements for submission and timing of ePA requests
- An exceptions process for extenuating circumstances
- A requirement that HHS finalize electronic transaction standards by July 1, 2023
- Mandated timely reviews for prior authorization requests
- Increased transparency including HHS publication of publish plans' approval and denial rates

Next Steps: The Energy and Commerce Committee is likely to also markup the bill in September and the bill could then move quickly toward House passage. While a vote on a stand alone bill in the Senate is unlikely, the measure could be included in a year-end appropriations package or other "must-pass" vehicle.

Federal Issues Regulatory

HHS OCR Releases Proposed Rule on ACA Section 1557 Nondiscrimination

HHS' Office of Civil Rights (OCR) released a proposed rule on the ACA's Section 1557 regarding nondiscrimination along with a <u>press release</u> and <u>fact sheet</u>. Comments on the proposed rule are due 60 days after publication in the *Federal Register*.

Background: Section 1557 has been widely tested in the courts not only because Section 1557 confers a private right of action, but also because religiously affiliated institutions and patient rights groups have challenged different iterations of the implementing regulations under the Obama and Trump administrations. This proposed rule seeks to restore and refine many of the aspects of the Obama-era rule.

Specifically, Section 1557, prohibiting discrimination on the basis of race, color, national origin, sex, age, or disability in covered health programs and activities, would be expanded to:

- All recipients of federal financial assistance for all HHS health programs and activities. This would newly include Part B providers and virtually all health insurance issuers and health insurance or health coverage including short-term plans and excepted benefits.
- The rule would reinstate the interpretation in the 2016 rule to include discrimination based on gender identity, sex characteristics, and sexual orientation as a type of prohibited sex-based discrimination.

HHS does not seek to make specific proposals related to abortion access. HHS does seek comment on whether and how the Department should do so. It also seeks comment on what impact, if any, the Supreme Court decision in Dobbs has on the implementation of Section 1557 and these regulations. In light of the Dobbs decision and E.O. 14076, the Department also seeks comments on other approaches to ensure nondiscriminatory access to care under this provision.

Unlike in previous 1557 rules, HHS proposes to establish a process for any recipient of federal funding for HHS programs to notify HHS of their views regarding the application of federal conscience or religious freedom laws. OCR will review the notification and consider the objection when responding to a complaint or otherwise determining, on a case-by-case basis, whether to proceed with an investigation or enforcement action regarding compliance with any relevant provision of these regulations.

Major provisions of the proposed rule include:

- Reinstating the previous scope of Section 1557 covered entities to include all health programs or activities that receive federal financial assistance, administered by HHS, or administered by an entity under Title I of the ACA.
- Codifying provisions that discrimination on the basis of sex would include sexual orientation, gender identity, and basis of pregnancy or related conditions, including pregnancy termination.
- Providing notice of nondiscrimination along with information about language assistance services in at least the 15 most common languages spoken by limited English proficiency (LEP) individuals on an annual basis, upon request, in prominent physical locations, and in conspicuous locations on websites, and allows for individuals to opt-out of receiving notices on an annual basis.

- Providing notice of availability of language assistance services (formerly known as "taglines") with the notice of nondiscrimination as well as *Health Insurance Portability and Accountability Act of 1996* (HIPAA) privacy notices, application and intake forms, notices of denial or termination of eligibility, benefits, or services, including Explanations of Benefits (EOB) and notices of appeal and grievance rights; and several other scenarios. Additional alternative, optional methods may also be used to comply with this requirement.
- Ensuring requirements to prevent and combat discrimination are operationalized by entities receiving federal funding by requiring civil rights policies and procedures.
- Requiring entities to give staff training on the provision of language assistance services for individuals with limited English proficiency (LEP), and effective communication and reasonable modifications to policies and procedures for people with disabilities.
- Explicitly prohibiting discrimination in the use of clinical algorithms to support decision-making in covered health programs and activities.
- Clarifying that nondiscrimination requirements applicable to health programs and activities include those services offered via telehealth, which must be accessible to LEP individuals and individuals with disabilities.
- Interpreting Medicare Part B as federal financial assistance.
- Refining and strengthening the process for raising conscience and religious freedom objections.

HHS Repeals Good Guidance Practices Final Rule

The Department of Health and Human Services (HHS) issued <u>a final rule</u> that includes the repeal of the <u>Good Guidance Practices (GGP) final rule</u>.

Why this matters: The GGP rule governs the protocols HHS is required to use to release and maintain sub-regulatory guidance documents for HHS agencies, including the maintenance of a guidance repository. (HHS' <u>final rule</u> also repeals a previously issued final rule on civil administrative enforcement actions.)

In the final rule, HHS states that "the Final Rules establish procedures well beyond anything required by applicable law. Moreover, in significantly burdening the Department, these procedures are inconsistent with the policies and goals of the current Administration to ensure that HHS can appropriately leverage administrative tools to protect and advance the public health and welfare." Furthermore, HHS indicates the "Department plans to maintain a central guidance repository even after the Guidance rule is repealed, without the problematic rescission requirement for documents not in the repository."

The insurance industry is generally supportive of this repeal.

CMS Releases RFI on Improving Medicare Advantage

The Centers for Medicare & Medicaid Services (CMS) <u>released</u> a <u>request for information (RFI)</u> on the Medicare Advantage program. The RFI specifically seeks information on the following topics:

- Advance Health Equity
- Expand Access: Coverage and Care
- Drive Innovation to Promote Person-Centered Care
- Support Affordability and Sustainability
- Engage Partners

Comments are due to CMS by Wednesday, August 31.

Tri-Agencies Issue Guidance on Contraception Coverage

The Health and Human Services (HHS), Labor (DOL), and the Treasury Departments (the Tri-Agencies) published new <u>guidance</u> regarding contraception coverage requirements under the Affordable Care Act (ACA), including 14 frequently asked questions (FAQs).

Why this matters: The guidance reiterates health plans and issuers must cover, without cost-sharing, any FDA-approved, granted, or cleared contraceptive service and product that an individual and their attending provider have determined to be medically appropriate. The FAQs include:

- Plans and issuers may use reasonable medical management for contraceptive products only if multiple, substantially similar services or products that are not included in a category described in the HRSA Guidelines are available and are medically appropriate for the individual.
- Plans are required to cover FDA-approved emergency contraception, without cost sharing, including over-the-counter products, when the product is prescribed for an individual by their attending provider. This includes when they are prescribed for advanced provision.
- In response to some states considering limiting access to certain forms of contraception, the FAQ states federal law preempts state laws.

HHS Posts 2023 Proposed Rate Increases

On July 28, HHS posted proposed rate changes for plan year 2023 for both the individual and small group markets. The proposed rates are posted for each issuer offering coverage in a state.

CMS Releases Maternity Care Action Plan

The Centers for Medicare & Medicaid Services (CMS) released a <u>Maternity Care Action Plan</u> as part of the effort to improve health outcomes and reduce inequities for people during pregnancy, childbirth, and the postpartum period.

Why this matters:

The Maternity Care Action Plan focuses on five key areas to address the maternal care crisis:

- 1. **Coverage and Access to Care**, including 12-month postpartum Medicaid coverage, contraceptive coverage, and protecting patients from surprise bills through the *No Surprises Act*.
- 2. **Data**, including expanding CMS' data collection efforts, stratifying data to identify disparities in care, and coordination across programs to identify gaps.
- Quality of Care, including working with key stakeholders to improve the quality of care that Medicaid, CHIP, Medicare, and the Marketplace enrollees receive before, during, and after pregnancy.
- 4. **Workforce**, including identifying opportunities to expand and improve access to a diverse maternity care workforce.
- 5. **Social Supports**, including identifying Medicaid linkages to social supports, such as tenancy-related services, housing vouchers, nutrition services, and others.

The CMS Administrator also encouraged industry leaders, including health insurance providers, to <u>share</u> <u>proposed commitments</u> with the agency to improving maternal health outcomes. CMS stated they will convene industry stakeholders and use the proposed commitments to guide that conversation on strengthening maternal health.

CMS also <u>approved</u> waivers in Connecticut, Massachusetts, and Kansas to extend post-partum Medicaid and Children's Health Insurance Program (CHIP) coverage to 12 months after pregnancy. CMS estimates 4,000 in Connecticut; 8,000 in Massachusetts; and 7,000 in Kansas will now have access to Medicaid or CHIP coverage for a full year after pregnancy. With the approval of the new waivers, 18 states and D.C. are eligible for 12 months of postpartum coverage through the state option established through the American Rescue Plan Act.

Court Vacates Air Ambulance Provisions of Surprise Billing IFR

Judge Daniel Kernoodle of the U.S. District Court for the Eastern District of Texas vacated and remanded sections of the October 2021 <u>interim final rule</u> (IFR) which instructs Certified IDR Entities how to evaluate considerations relating to out-of-network air ambulance payments. These provisions are similar to, but distinct from, those vacated by the same court in Texas Medical Association (TMA) litigation before Judge Kernoodle, which vacated parallel regulatory provisions relating to other health care facilities and providers.

Why this matters: In sum, the decision held that the provision of the IFR conflicted with the unambiguous terms of the *No Surprises Act* and that the government improperly bypassed notice and comment rulemaking in implementing the challenged portion of the rule. Judge Kernoodle also denied HHS' request to transfer the case to the U.S. District Court for the District of Columbia.

Like its prior ruling in TMA, the decision surgically strikes the weighting portion of the regulation at 45 C.F.R. 149.520(b)(2) (and parallel provisions in the tax and labor regulations): "This information must also clearly

demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate." The remainder of the regulations relating to air ambulances were not impacted.

AHIP <u>filed</u> an amicus brief supporting this provision of the IFR *in Association of Air Medical Services v. HHS* in the U.S. District Court for the District of Columbia.

HHS has stated that a final *No Surprises Act* rule addressing the issues raised in litigation will be issued this summer and is currently under OMB review.

Industry Trends

Policy / Market Trends

AHIP Responds to NYT Article on Rising Health Care Costs

President and CEO of AHIP, Matt Eyles, <u>responded</u> to an <u>opinion piece</u> in *The New York Times* about outof-pocket medical spending and medical debt. The article focused on a symptom of rising health care costs, rather than a cause.

Eyles explains that, "by law, health insurance <u>must spend at least 80 cents</u> of every premium dollar on medical care. Therefore, health insurance costs are driven by the underlying prices of care, including hospitals, prescriptions and services that plans are mandated to cover. Some plans offer higher deductibles as a way to lower premiums — a choice that allows more consumers to obtain coverage."

Healthy <u>market competition</u> among drug makers, health systems, and other care providers gives health insurance providers the leverage to negotiate lower costs for patients. AHIP continues to advocate for healthy markets to ensure that when it comes to health care, Americans have more choices, better quality, and lower costs.

CMS Holds Third PHE Unwinding Stakeholder Call

Last Wednesday, CMS hosted the third webinar in the series "Medicaid and CHIP Continuous Enrollment Unwinding: What to Know and How to Prepare." During the webinar, CMS staff shared resources available through the Connecting Kids to Coverage program that states and their partners can use for outreach to families about Medicaid and CHIP coverage. CMS noted that as many as 7 million children could be disenrolled from Medicaid at the end of the PHE, and encouraged states and other stakeholders to identify opportunities to share information on Medicaid enrollment and renewals with families as children head back to school. CMS also highlighted the Affordable Connectivity Program (ACP), which provides eligible households \$30/month (or \$75/month on Tribal lands) toward an internet service plan, as well as a one-time discount to purchase a computer or other connecting device. Additionally, CMS noted the availability of an outreach toolkit, which partners can use to share information about the ACP with the populations they serve. Webinar slides and a recording of the session will be available on the <u>National Stakeholders Calls</u> page in the coming days.

Read More

- <u>Connecting Kids to Coverage Outreach Tool Library</u>
- Affordable Connectivity Program Outreach Toolkit

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

Delaware State Legislation: http://legis.delaware.gov/. New York Legislation: https://nyassembly.gov/leg/ 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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