



Issues for the week ending April 14, 2023

### **Federal Issues**

Legislative

## President Biden Signs Bill Ending the COVID-19 National Emergency

President Biden <u>signed</u> a bill into law on April 10, 2023 officially ending the COVID-19 National Emergency, effective immediately. A National Emergency was declared by the President on March 13, 2020, due to the coronavirus disease 2019 (COVID-19) pandemic. Separately, a Public Health Emergency (PHE) under section 319 of the Public Health Service Act, was declared by the Secretary of Health and Human Services. The PHE remains in effect and is set to expire on May 11, 2023.

The end of the National Emergency affects certain deadlines under the Employee Retirement Income Security Act of 1974 (ERISA), which were suspended until the earlier of one year from the date of the event or until 60 days after the end of the National Emergency. We expect the Department of Labor (DOL) to issue guidance about how the end of the National Emergency on April 10, rather than the planned termination date of May 11, affects relief provided to ERISA group health plans.

The plan sponsor relief under the National Emergency includes the following:

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- Extension of timeframes for disclosure of documents required under Title I of ERISA
- Suspended timeframes for a plan sponsor to provide a Consolidated Omnibus Budget Reconciliation Act (COBRA) election notice to qualified beneficiaries

## The participant relief under the National Emergency includes the following:

- The 30-day period (or 60-day period, if applicable) to request a special enrollment
- The 60-day election period for COBRA continuation coverage
- The date for making COBRA premium payments
- The date for individuals to notify the plan of a qualifying event or determination of disability under COBRA
- The date within which individuals may file a benefit claim under the group health plan's claims procedures
- The date within which claimants may file an appeal of an adverse benefit determination under the group health plan's claims procedures
- The date within which claimants may file a request for an external review after receipt of a final internal adverse benefit determination
- The date within which a claimant may file information to perfect a request for external review upon finding that the request was not complete pursuant to applicable appeal rules

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#### Federal Issues

Regulatory

### ONC Releases Proposed Rule on Health, Data, Technology, and Interoperability

On April 11, 2023 the Office of the National Coordinator for Health Information Technology (ONC) <u>issued</u> a Proposed Rule to implement provisions of the 21st Century Cures Act and make updates to the ONC Health IT Certification Program (Certification Program) with new and updated standards, implementation specifications, and certification criteria.

Why this matters: ONC proposes several updates to the Certification Program including the adoption of Version 3 of the United States Core Data for Interoperability (USCDI) categories of information that electronic health record vendors are required to support and share. ONC also proposes new requirements for developers of certified health IT that enables or interfaces with predictive decision support interventions to provide greater transparency about the use of algorithms, and new requirements around privacy and security.

However, the rule does not propose new requirements for developers of certified IT to build connections to the Prior Authorization Requirements, Documentation and Decision (PARDD) API that CMS proposed impacted payers maintain in the Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule. To ensure adoption and maximize the value of electronic prior authorization, AHIP has advocated for commensurate requirements on developers of certified health IT to build and health care providers to use the APIs.

## Matt Eyles, President and CEO of AHIP, issued a <u>statement</u> following the release by ONC. Highlights include:

"Evidence-based medical management programs and services, including tools such as prior authorization, are key to delivering on that commitment, promoting the delivery of clinically appropriate high-quality care, reducing waste, and improving affordability for all Americans. That is why we are disappointed that the HTI-1 proposed rule would not require certified electronic health record technologies (CEHRT) to include electronic prior authorization (ePA). Studies and pilots have shown that moving to ePA can dramatically speed care for patients, reduce the burden of a paper-based system for patients and providers alike, and reduce costs."

The proposed rule is scheduled to be published in the Federal Register on April 18, 2023. Comments are due to ONC by June 20, 2023. Please see ONC's <u>website</u> and <u>press release</u> for more information.

## **HHS Proposes Measures to Bolster Patient-Provider Confidentiality Around Reproductive Health Care**

On April 12, the U.S. Department of Health and Human Services (HHS) issued a Notice of Proposed Rulemaking (NPRM) and Notice of Tribal consultation to modify the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the Health Information Technology for Economic and Clinical Health Act (HITECH) Act regulations in an effort to protect those seeking, obtaining, providing, or facilitating reproductive health care. HHS also issued a press release and fact sheet on the NPRM.

Why this matters: The rule would prohibit uses and disclosures of protected health information (PHI) for criminal, civil, or administrative investigations or proceedings against individuals, covered entities, their business associates, or other persons related to reproductive health care. Specifically, HHS proposes regulatory changes to prevent the use or disclosure of an individual's PHI as a "pretext" for obtaining PHI related to reproductive health care for a non-health care purpose where such use or disclosure would be detrimental to an individual.

Reproductive health care would be defined to include, but not be limited to, prenatal care, abortion, miscarriage management, infertility treatment, contraception use, and treatment for reproductive-related conditions such as ovarian cancer.

The NPRM is expected to be published in the Federal Register on April 17, and public comments are due June 16, 2023.

## Biden Administration Clarifies Immediate Effects of ACA Preventive Services Coverage After Court Decision

The Departments of HHS, Labor and Treasury issued Frequently Asked Questions (FAQs) Part 59 to address how the recent *Braidwood Management Inc. v. Becerra* decision impacts coverage requirements for preventive services under the ACA.

Why it matters: If the ruling is ultimately upheld, insurers and employers can choose whether to cover certain preventive care services, and, if so, whether to do so without cost-sharing.

**The details:** The FAQs clarify that for items and services recommended with an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF) by or before March 23, 2010, plans and issuers must continue to cover without cost-sharing.

For items and services recommended with an "A" or "B" rating by USPSTF on or after March 23, 2010:

- The Departments will no longer enforce coverage requirements.
- States are not prevented from enacting or enforcing state laws requiring coverage.
- **High Deductible Health Plans** may continue to provide benefits before the minimum annual deductible has been met.
- Carriers offering plans in the Federal Employees Health Benefits Program are required to continue to cover.

**Yes, and:** Health plans are required to continue covering, without cost-sharing, items and services recommended by the Advisory Committee on Immunization Practices or the Health Resources and Services Administration, even if they also are recommended by the USPSTF, *on or after* March 23, 2010.

#### BCBSA released a statement on the ruling:

"...It is vitally important for patients to know that their care and coverage will not change because of today's court decision. Blue Cross and Blue Shield companies strongly encourage their members to continue to access these services to promote their continued well-being."

What's next: HHS has appealed the decision.

## Fifth Circuit Grants Stay in Mifepristone Case

In a ruling late Friday, the Fifth Circuit granted a <u>stay</u> on a lower court ruling, maintaining access for pregnant women who have been prescribed the drug mifepristone—a drug often used in combination with misoprostol for the medical termination of a pregnancy through 70 days gestation or for treating miscarriage.

- The stay, which is limited, was requested by the DOJ and the drug's manufacturer, Danco Laboratories. The stay does not include expansions to access since 2016, which can still be challenged.
- **The details:** Citing "legitimate safety concerns," the U.S. Northern District Court of Texas ruled Friday, April 7, that the FDA acted improperly in approving mifepristone in 2000. Plaintiffs argued that the FDA improperly stonewalled adequate judicial review of and granted priority review to mifepristone.
- **Plaintiffs also cited concerns** about changes in the way the drug is administered, such as allowing non-physician providers to prescribe it.
- Yes, and: In tandem, the U.S. Eastern District Court of Washington issued a preliminary injunction preventing the FDA from removing mifepristone from the market or impeding patient access to the drug in 17 states and D.C.
- The decision was in response to a case filed by over a dozen Democratic attorneys general
  compelling the FDA to drop restrictions on mifepristone, citing the established safety and clinical
  efficacy of the drug.
- **The government** has asked the judge to "clarify" the effect of his decision, given the conflicting decision from Texas.

The Supreme Court then issued <u>an order</u> on Friday temporarily ensuring that mifepristone would remain widely available while the Supreme Court considered whether to grant the Biden administration's emergency request to preserve the Food and Drug Administration's approval of the drug.

The order was meant to maintain the status quo while the justices studied the briefs and lower court rulings, and it did not forecast how the court would ultimately rule. The stay itself is set to expire on Wednesday at midnight, meaning the court is very likely to act before then.

**CMS Updates to Risk Adjustment Telehealth and Telephone Services** 

CMS has updated the Risk Adjustment Telehealth and Telephone Services During COVID-10 FAQs to extend the guidance through the entire year of 2023. Due to operational complexities associated with including CPT/HCPCS codes in HHS-operated risk adjustment for only part of the benefit year, and with the COVID-19 PHE ending in May 2023, CMS is continuing to recognize the expanded set of telehealth-related codes in the HHS-operated risk adjustment program, subject to applicable state law requirements, for the entire 2023 benefit year. CMS intends to reconsider these codes' inclusion for future benefit years, as appropriate.

## White House Announces Plan to Expand Medicaid and Marketplace Coverage to DACA Recipients

President Biden <u>announced</u> a plan to expand health coverage for recipients of the Deferred Action for Childhood Arrivals (DACA) program.

**Why this matters**: HHS "will shortly propose a rule amending the definition of 'lawful presence,' for purposes of Medicaid and Affordable Care Act coverage, to include DACA recipients," the White House noted in a <u>fact sheet</u>.

In a <u>statement</u> issued last Thursday, HHS Secretary Xavier Becerra said 34% of the nearly 580,000 DACA recipients do not have health insurance coverage. If finalized, the rule would allow them to apply for coverage through the Affordable Care Act's Health Insurance Marketplaces, where they may qualify for financial assistance based on income, and through their state Medicaid agency.

The proposed rule, "Clarifying Eligibility for a Qualified Health Plan through an Exchange, Advance Payments of the Premium Tax Credit, Cost-Sharing Reductions, a Basic Health Program and for Medicaid and CHIP" was submitted to the Office of Management and Budget for review.

# CMS Outlines Implementation for Repayment of Nursing and Allied Health Education Program Recouped Payments

Legislation enacted by Congress at the end of 2022 provides relief for hospital-based nurse education programs from the recoupment of nursing and allied health education (NAHE) payments. The recently issued proposed inpatient payment rule outlines the Centers for Medicare & Medicaid Services' (CMS) intent in implementing the legislation.

**Background:** During 2020, CMS discovered it had made an error in the administration of Direct Graduate Medical Education (DGME) payments by failing to apply a statutorily required cap on total payments for NAHE programs. CMS initiated the recoupment of payments, requiring hospital-based schools to pay back millions of dollars received up to a decade ago.

Section 4143 of the Consolidated Appropriations Act (CAA), 2023 holds hospital-based programs harmless from the consequences of CMS' more-than-a-decade-old mistake by making a technical fix to adjust for the overpayments made to hospitals participating in the Medicare Advantage Nursing and Allied Health Professional Education program between 2010 and 2018. This relief only applies to hospitals that, as of the date of enactment of the CAA, were continuing to operate a school of nursing or allied health entitled to

receive reasonable cost education payments. Section 4143 of the CAA also provided that CMS shall not reduce a hospital's DGME Medicare Advantage (MA) payments to offset the increase in nursing and allied health MA education payments.

**Legislative fix:** On April 10, 2023, CMS released the fiscal year (FY) 2024 Inpatient Prospective Payment System (IPPS) proposed rule. The proposed rule details the process CMS is instructing the MAC to use to implement section 4143. In summary, CMS instructs the MACs to recalculate a hospital's total nursing and allied health education MA payments for 2010 through 2019 using information in the proposed rule. Each hospital would receive a revised share of the aggregate pool of funds provided in the proposed rule based on the ratio of its own MA days compared national aggregate MA days.

The MAC will then compare the hospital's share of nursing and allied health MA payments from these calculations and reconcile them with any prior amounts already recouped or received from the hospital. Amounts previously recouped will be returned to hospitals, and recoupments that would have occurred if not for the enactment of Section 4143 of the CAA 2023 will not occur.

The IPPS proposed rule does not provide a timetable for hospitals being refunded amounts previously recouped.

CMS will be accepting public comments on the proposed rule until June 9, 2023. Publication of the IPPS final rule will occur no later than August 2, 2023. After that time, CMS would be expected to issue instructions to the MACs to implement the refund process.

Why this matters: The federal government made an error and miscalculated funding for hospital-based nursing schools for nearly two decades, and then planned to force these schools to refund the money during the worst health care workforce crisis in decades. About 120 nursing schools across the country, many in Pennsylvania, are impacted and the schools have reported the recoupment could force cutbacks and even closures. Analysts estimate that these nursing schools could be responsible for around \$1 billion in repayments.

CMS Releases Annual Proposed Inpatient, Long-Term Care Hospital Payment Rules
Last week, CMS issued the proposed Inpatient Prospective Payment System (IPPS) and the Long-Term
Care Hospital (LTCH) Prospective Payment System (PPS) proposed rules for fiscal year (FY) 2024. The
proposed regulations set Medicare payment policies and rates for inpatient services and long-term care
hospitals.

Most notably, the IPPS proposed rule will result in a 2.8 percent increase for hospitals that successfully participate in the Hospital Inpatient Quality Reporting program and are meaningful electronic health record users. This reflects a projected FY 2024 hospital market basket percentage increase of 3 percent, reduced by a 0.2 percentage point productivity adjustment.

The rule also includes several proposals to improve patient safety and promote health equity.

#### Additionally, the FY 2024 IPPS proposed rule recommends policies to:

- Allow for graduate medical education payments to be made to Rural Emergency Hospitals
- Reinstate program restrictions for physician-owned hospitals approved as "high Medicaid facilities"

- Permit the use of web-based surveys for Hospital Consumer Assessment of Healthcare Providers and Systems
- Implement several changes to the quality reporting and value programs

#### The FY 2023 LTCH proposed rule would:

- Decrease LTCH aggregate payments by 0.9 percent, or \$24 million in FY 2024 primarily due to a projected decrease in high-cost outlier payments in FY 2024 compared to FY 2023
- Implement several changes to the quality reporting program

The final rules for IPPS and LTCH will be published around August 1, and the policies and payment rates will take effect October 1. A <u>fact sheet</u> has been published on the CMS website. CMS will accept comments related to the proposed rules through June 9.

Prior to the release of the proposed rule, members of Pennsylvania's congressional delegation urged CMS to support hospitals and ensure Medicare payments accurately reflected the cost of inpatient care.

**Industry position:** The American Hospital Association said they are deeply concerned with CMS' woefully inadequate proposed inpatient hospital payment update of 2.8 percent given the near decades-high inflation and increased costs for labor, equipment, drugs, and supplies. Moreover, long-term care hospitals would see a staggering negative 2.5 percent payment update under this proposal.

#### State Issues

#### **New York**

Legislative

#### **Bills in Committee**

- NYSHIP claims data (S.4097-A)/A.5817) directs the New York Health Insurance Program (NYSHIP the state employee health program) to collect health care claims data to issue a report on variation in hospital prices.
- Provider financial assistance policy (S.1366/A.6027)— seeks to protect New Yorkers from unfair medical bills and aggressive debt collection practices by providers by requiring providers to implement a uniform financial assistance policy and utilize a simplified standard form.
- Codifying Medicaid quality incentive (S.3146/A.6021)—The proposal would establish the Medicaid managed care quality incentive (QI) program in statute, with funding subject to appropriation.
- CHIP network requirement prohibition (S.4922)— prohibit health plans that administer the Child Health Plus program from requiring that participating health care providers also sign up for the plan's commercial health care network.

- Home care claim forms (5750/S.6123) requires claims for services provided by home care agencies be done on forms approved by the Centers for Medicare and Medicaid services.
- MLTC supplemental quality payments (A.5795/S.6072 creates a process for supplemental quality improvement payments for managed long term care plans that meet certain criteria.

Although there are reports that the Governor and legislative leaders are getting closer to a budget agreement, legislators are expected to pass another extender this week to allow the state to make payroll.

### Regulatory

### 2024 Rate Setting Update

The Department of Financial Services last week hosted a final meeting with plan actuaries to provide updates on the 2024 rate setting process for the individual and small group markets. Staff opened the meeting noting that the lateness of the state budget impacts some of the exhibits because of certain elements that are tied to provisions in the proposed budget. With that caveat, DFS reported that the 2024 exhibits, as well as the standard plan screenshots and rate notice templates are now available on the Department's website. DFS and NY State of Health staff each reviewed their respective timelines. Key dates include:

- May 10 Plan applications and proposed rates due.
- May 26 Tentative date for DFS to post applications to its website, which triggers the 30-day
  public comment period and also the requirement for plans to send initial rate notices to
  policyholders.
- **July 31** DFS rate decisions due but will not be announced until the Department has discussed decisions with plans, with the announcement tentatively expected the second week in August.

Further complicating this year's rate setting process is the delay in the state's filing its application for a Section 1332 State Innovation Waiver to expand Essential Plan eligibility from 200% to 250% FPL, which, if approved, would start in January of 2024. Because this will impact the Qualified Health Plan market, and with a decision on the waiver not expected until early September, plans are being directed to prepare two sets of finalized materials, including two rate tables, (with and without the EP waiver) for review in the rate filing. DFS indicated it is hoping to let plans know by September 12 which set of final rates should be used.

#### State Issues

## **Pennsylvania**

Regulatory

## Pennsylvania Insurance Department Proposes to Amend 31 Pa. Code CH. 89 Related to the Preparation of Forms and the Collection of Demographic Data

The Pennsylvania Insurance Department proposes to amend Chapter 89 (relating to approval of life, accident and health insurance), allowing for the voluntary collection of demographic data, including questions related to race and ethnicity when certain criteria are met. The proposed rulemaking can be found here.

Why this matters: Specifically, the proposed amendment to § 89.12 (relating to application forms) will allow insurers to collect data that will help them develop better tools to address inequities in life, accident and health insurance coverage.

- Moreover, this proposed amendment will be consistent with Federal and State efforts to address equity issues across society generally.
- Amending § 89.12(e) will allow Pennsylvania health insurers to comply with Federal requirement set forth is the 2023 Notice of Benefit and Payment Parameters (NBPP) and remove an inconsistency between Federal and State provisions.

Questions as to race or color are not permitted on the application. However, an insurer may include questions as to demographic factors, including race and ethnicity on an application, subject to certain exceptions, including but not limited to use for underwriting, rating and eligibility.

**Background:** On October 11, 2022, the Department circulated an exposure draft similar to this proposed rulemaking to several industry participants including the Insurance Federation of Pennsylvania, Inc., the Pennsylvania Association of Mutual Insurance Companies and several health insurers. The Department also discussed this topic informally with industry members over the past year. The Department considered all comments, responded to several questions and incorporated revisions to this proposed rulemaking based upon stakeholder feedback.

This proposed rulemaking will affect foreign and domestic insurers that issue individual and group life, accident and health insurance contracts in Pennsylvania and will become effective immediately upon final-form publication in the *Pennsylvania Bulletin*.

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

Delaware State Legislation: <a href="http://legis.delaware.gov/">http://legis.delaware.gov/</a>.

New York Legislation: <a href="https://nyassembly.gov/leg/">https://nyassembly.gov/leg/</a>

Pennsylvania Legislation: <a href="http://www.legis.state.pa.us">www.legis.state.pa.us</a>.

West Virginia Legislation: <a href="http://www.legis.state.wv.us/">http://www.legis.state.wv.us/</a>

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

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