Highmark's Weekly Capitol Hill Report

Issues for the week ending January 8, 2021

Federal Issues

Legislative

Congress Certifies Electoral College Results; Democrats Take Control of Senate

On Thursday, the House and Senate confirmed President-elect Joe Biden as the winner of the 2020 presidential election. Lawmakers certified the electoral vote totals, a constitutionally required process that marks the final step in certifying the transition of power before Biden's inauguration on January 20. The certification was disrupted but ultimately completed following the violent disruption of the proceedings at the Capitol Building.

Also last week, Democrats gained two additional seats in the U.S. Senate after Jon Ossoff (D-GA) and Raphael Warnock (D-GA) won runoff elections against Sens. David Perdue (R-GA) and Kelly Loeffler (R-GA), respectively. The Senate chamber will now be split 50-50, with Vice President-elect Kamala Harris empowered to cast tie-breaking floor votes.

Why this matters: Full control by Democrats increases the likelihood of additional COVID-19 relief as well as policy changes such as Medicare expansion, ACA reforms, including a public option, and government drug price negotiation. However, the

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Democrats' razor-thin majority in both chambers could limit what is ultimately achievable.

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Cybersecurity Bill Signed into Law

On January 5, President Trump signed into law a bill (H.R. 7898) that provides even more incentive for Health Insurance Portability and Accountability Act (HIPAA)-covered entities and business associates to develop robust security compliance programs. Specifically, the proposal would amend the HITECH Act to require the Department of Health and Human Services to take into consideration whether a covered entity or business associate has met recognized security practices when making certain determinations, such as enforcement actions or for other regulatory purposes.

The legislation would also require HHS to take cybersecurity into consideration when determining fines related to security incidents, as well as decreasing the length and extent of an audit when it's determined the provider has met best practice cybersecurity requirements.

Recognized security practices refer to standards, guidelines, best practices, methodologies, procedures, and processes developed by the National Institute of Standards and Technology (NIST) and other programs that adequately address cybersecurity and recognized by other statutory authorities.

The bill recognizes cybersecurity practices established under the National Institute of Standards and Technology Act and approaches established under Section 405(d) of the Cybersecurity Act of 2015 by the Healthcare and Public Health Sector Coordinating Council (HSCC) Working Group, whose members include the American Hospital Association, Americas Health Insurance Plans, and the Blue Cross Blue Shield Association.

The HSCC is a coalition of industry stakeholders interested in healthcare-related security issues and has been a platform for collaboration among healthcare industry leaders and the government for more than a decade to address the most pressing security and resiliency challenges to the healthcare sector as a whole.

The HSCC expressed strong support for the provisions in H.R. 7898.

In terms of its effective date, the law states that it "shall take effect as if included in the enactment of the 21st Century Cures Act." This likely means that this new law will go into effect on January 1, 2021 (since many of the provisions of the 21st Century Cures Act go into effect on that date) and will not apply retroactively.

Additionally, HHS will need to go through the notice and rulemaking process in order for the new law to be implemented, which may be delayed by the fact that HHS recently proposed changes to the HIPAA Privacy Rule and will likely be working towards implementing those revisions.

Why this matters: The new law is a welcome sign for HIPAA-covered businesses that have taken steps to document their security compliance.

Healthcare organizations are facing increasingly sophisticated operational and cybersecurity threats and vulnerabilities that can cascade across the value chain of the healthcare sector, ultimately affecting patient safety, security, and privacy.

Hospital industry perspective: "This law will have long lasting positive impact for the entire health care sector in securing patient data and protecting patients from cyber risks," said John Riggi, AHA senior advisor for cybersecurity and risk. "The law provides the right balance of incentivizing voluntary, enhanced cybersecurity protocols in exchange for regulatory relief and recognition that breached organizations are victims, not the perpetrators."

Federal Issues

Regulatory

CMS Issues Guidance on MA & Part D Plan Access to COVID-19 Vaccination Data

CMS issued a memorandum to provide guidance to Medicare Advantage (MA) plans, Medicare-Medicaid Plans (MMPs), and Part D Prescription Drug Plans (PDPs) on obtaining COVID-19 vaccination data regarding plan enrollees.

According to the memorandum, "CMS will allow plans to request certain COVAX data from CMS regarding their enrollees, subject to CMS approval, if that data is the minimum necessary and is requested for the plans' health care operations such as case management, care coordination, or population-based activities to improve the health of their enrollees." The memorandum provides additional details, including specific information on the paths to access data.

EEOC Proposes New Workplace Wellness Rules

The Equal Employment Opportunity Commission (EEOC) issued pre-publication versions of two proposed rules affecting workplace wellness programs, one amending regulations under the Americans with Disabilities Act (ADA) and another amending regulations under the Genetic Information Nondiscrimination Act (GINA). These Notices of Proposed Rulemaking (NPRMs) follow the EEOC's vote on June 11, 2020 to advance new regulations after sections of regulations proposed in 2015 and finalized in 2016 were vacated after years of litigation in federal courts. Comments are due **60 days** following publication in the Federal Register.

Highlights of the Proposed Rules include:

- **"De Minimis" Incentives for Participation-Only Wellness Program:** Employers offering workplace wellness programs and subject to certain titles of the ADA and GINA may offer employees "de minimis" incentives to voluntarily participate in participation-only wellness programs.
- **Insurance Safe Harbor Exception and 30-Percent Maximum Incentive for Health Contingent Wellness Programs:** The ADA proposed rule interprets the ADA's insurance "safe harbor" as an exception to the "de minimis" rule for health-contingent wellness programs that meet ACA/HIPAA requirements. This would allow health-contingent wellness programs included as part of a group

health plan to use data obtained from the wellness program to impose a maximum penalty of 30 of the total premium for participants who do not satisfy certain metrics.

Coronavirus Updates

Department of Health and Human Services (HHS) Secretary Alex Azar renewed the COVID-19 national public health emergency (PHE) declaration for an additional 90 days, effective January 21, 2020.

The Centers for Disease Control and Prevention (CDC) updated its clinical guidance related to mRNA vaccines. The updated guidance includes additional information on antibody therapies and COVID-19 vaccination, COVID-19 vaccination and outbreak management, vaccination of immunocompromised persons, COVID-19 vaccination and tuberculin skin testing, and updates to contraindications and precautions to vaccination. It is unknown whether vaccine reimbursement rates will have to be modified to accommodate for the larger group requiring a longer period of observation.

The CDC also updated information on the emerging SARS-CoV-2 variants.

The Food and Drug Administration (FDA) released a statement on the importance of receiving COVID-19 vaccines according to their authorized use in order to safely receive the benefit observed in the large randomized trials supporting their effectiveness. This statement came in response to Operation Warp Speed chief adviser Moncef Slaoui indicating evidence that two half doses in people between the ages of 18 and 55 provides “identical immune response” to the recommended dose.

The Centers for Disease Control and Prevention (CDC) announced 21 of the first 1.9 million of Americans receiving the COVID-19 vaccine in mid-December experienced the severe allergic reaction known as anaphylaxis. The CDC recommends people with a history of drug allergies receiving either of the two available COVID-19 vaccines be observed for 30 minutes, while people without a known history should be observed for 15 minutes.

The Department of Health and Human Services (HHS) announced two upcoming actions by the CDC to provide more than $22 billion in funding to states, localities, and territories in support of the nation's response to the COVID-19 pandemic from the Coronavirus Response and Relief Supplemental Appropriations Act. Funding will provide support for testing and vaccination-related activities to jurisdictions before January 19, 2021:

- More than $19 billion will be allocated to jurisdictions through the existing CDC Epidemiology and Laboratory Capacity (ELC) cooperative agreement. These awards will support testing, contract tracing, surveillance, containment, and mitigation to monitor and suppress the spread of COVID-19. Award recipients will include 64 jurisdictions including all 50 states, the District of Columbia, five major cities, and U.S. territories/islands. Consistent with Congressional direction, funds will be allocated by a population-based formula.
- Over $3 billion will be made available in an initial award to jurisdictions through the existing CDC Immunization and Vaccines for Children cooperative agreement. These awards will support a range of COVID-19 vaccination activities across jurisdictions. Award recipients will include 64 jurisdictions including all 50 states, the District of Columbia, five major cities, and U.S. territories/islands. Consistent with Congressional direction, funds will be allocated by a population-based formula.

The Trump administration announced the launch of a federal program to begin vaccination of high-risk groups through pharmacies. The program is a partnership with 19 pharmacy chains and associations,

including Walmart, CVS, Walgreens, and Costco. State will elect whether or not to participate in the program and will allocate doses of vaccines to the pharmacies.

The Centers for Medicare & Medicaid Services (CMS) posted additional Frequently Asked Questions (FAQs) to aid state Medicaid and Children's Health Insurance Program (CHIP) agencies in their response to the COVID-19 pandemic.

The incoming Biden Administration has requested that Operation Warp Speed (OWS) executive Moncef Slaoui remain as a temporary consultant through the transition to ensure continuity in the COVID-19 vaccine work that has been accomplished. OWS chief operating officer Gen. Gustave Penra will also continue to control the logistics of vaccine distribution.

The Centers for Medicare & Medicaid Services (CMS) updated the Toolkit on COVID-19 Vaccine—Health Insurance Issuers and Medicare Advantage Plans. CMS issued this toolkit to help health insurance issuers and Medicare Advantage plans identify issues to consider and address when providing coverage and reimbursement for COVID-19 vaccine administration. Specifically, this toolkit updates information for issuers and health plans on the Moderna COVID-19 vaccine and provides additional information on coverage requirements, claims and coding and vaccine outreach.

- Of note, the federal government will not provide reimbursement for outreach activities by issuers. For purposes of MLR reporting, some issuers may be able to include vaccination outreach costs as community benefit expenditures.

Agencies Start Work Implementing Surprise Billing Legislation

Congress passed the bipartisan No Surprises Act included within the Consolidated Appropriations Act of 2021. The surprise billing law, applicable to most types of private insurance including grandfathered plans and self-funded group health plans, contains several statutory deadlines, prompting the tri-agencies responsible for implementing the law to begin their work immediately.

Last week, the Department of Labor issued a notice to solicit nominations for a 15-member advisory committee to advise on the standardized format for the voluntary reporting, by group health plans to State All Payer Claims Databases (APCDs), of medical claims, pharmacy claims, dental claims, and eligibility and provider files collected from private and public payers. About 21 states have implemented APCDs to date, with the goal to inform more data-driven health policies both at the state and federal levels including provider reimbursement or insurance rate regulation and health plan network adequacy. Due to the Supreme Court precedent, states cannot require ERISA plans to participate in APCDs, but some do so voluntarily, and the work of the Committee may lead to more participation. The Act provides $125 million total in new grant funding to states to establish APCDs.

CMS Releases Final Guidance on MLR Treatment of Damages in Risk Corridors Litigation

Last Thursday, the Centers for Medicare & Medicaid Services (CMS) released final guidance on the treatment of damages resulting from the government's failure to meet risk corridors (RC) obligations. Consistent with the draft guidance, the final guidance specifies that for medical loss ratio (MLR) purposes the damage amounts will be considered to be inputs for the MLR filing years the money was originally owed, 2015-2018.

Issuers that have already been paid damages and owe new rebates must submit reports and provide new rebates within 150 days of the publication of this guidance, by approximately May 30, 2021. Issuers that have not yet been paid, but that ultimately owe new rebates, must report and dispense rebates within 150 days of being paid damages**.**

The proposals in draft guidance are finalized largely as proposed. Notable changes include:

- Reporting and Rebate Deadlines**:** The date to report and dispense rebates has been updated to 150 days after the publication of the final guidance or the receipt of damage payments, whichever is later. CMS may direct an issuer with an open MLR examination or audit to adhere to an alternate timeline.
- Notices: Issuers may use either the standard notices with a cover letter or a modified version of the standard notice, such as the examples attached to the guidance.
- Taxes: The following language was added: *"For purposes of revising the prior year MLR reporting form(s), issuers should treat the taxes attributable to the recovered RC payment amounts in accordance with established accounting principles and tax guidelines, and using allocation methods consistent with 45 C.F.R. § 158.170, including ensuring that any such tax amounts are not double-counted in multiple reporting years."*

Highlights in the guidance that are unchanged since the draft include:

- Issuers must submit a revised MLR reporting form(s) for the 2015 through 2018 reporting years for each state, market, and year in which the issuer has a greater rebate liability based on inclusion of the recovered RC payment amount.
- Issuers must pay the outstanding rebate amounts to the enrollees who were enrolled in the respective MLR reporting year.

Issuers that do not have a higher rebate obligation based on the inclusion of the recovered RC payment amounts for any of the applicable reporting years do not need to submit a revised MLR reporting form.

CMS Withdraws Medicaid Fiscal Accountability Rule, Citing Recent Legislation

On Thursday, Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma announced her intent to formally post a notice in the Federal Register that the Medicaid Fiscal Accountability Regulation (or MFAR) would be withdrawn.

Why this matters: The rule, proposed in November 2019, would have thrown many states' Medicaid financing mechanisms into serious trouble, creating billions of dollars in shortfalls that would have been easily remedied given the pandemic's effect on state revenue streams.

Verma left an opening to finalize the MFAR, which had yet to be withdrawn, in November 2020 when she implied the goals of MFAR continue to be pursued. However, the Consolidated Appropriations Act of 2021, enacted into law December 27, 2020, included some reforms that advance MFAR's goals. Specifically, CMS is authorized to collect information from states regarding their Medicaid supplemental payments and make a report of such information publicly available. This information could inform longer term policies.

Insurer Perspective: AHIP released a statement in response to the rule's withdrawal applauding CMS' action. Insurers have advocated before Congress and the Administration in favor of rescission of the rule, including a July letter to Congress submitted with other stakeholders.

State Issues

Delaware

Legislative

The 151st General Assembly Set to Begin Virtually

The Delaware General Assembly will start its 2021 legislative session on Tuesday, January 12. Due to COVID-19 restrictions, the session will be virtual. Tuesday's actions in the House of Representatives will include the administration of the Oaths of Office, the adoption of House Rules, and the examination of the Certificates of Election. While the General Assembly is meeting virtually, the public will have an opportunity to watch a live stream and will also be able to playback the recorded proceedings.

Committee meetings will be streamed online and citizens will be able to offer testimony during the virtual events. Committee meetings and floor debates will be livestreamed and archived on the General Assembly's website at legis.delaware.gov.

Members of the public can offer comment on bills by registering for each meeting that will be posted on the website's committee meetings page found here. That page also has information about when lawmakers will hold committee meetings and what bills each meeting will cover. Committee meeting notices will be posted on the Thursday preceding the week they are scheduled.

The Following bills have been pre-filed for consideration:

House Bill 62: This Act is based on a Model Act to Prevent Excessive and Unconscionable Prices for Prescription Drugs developed by the National Academy for State Health Policy. It prohibits manufacturers from raising the price of prescription drugs outside of certain market conditions that might justify a price hike. It is specifically limited to the prices charged to consumers in the State of Delaware for generic and off-patent drugs. It authorizes the Attorney General to investigate price increases identified by State agencies above a certain threshold. Manufacturers or distributors may be fined up to $10,000 per day for sales which violate the Act.

House Bill 48: This Act establishes a Health Care Provider Loan Repayment Program for new primary care providers to be administered by the Delaware Health Care Commission. Under the loan repayment program, the Health Care Commission may award education loan repayment grants to new primary care providers of up to $50,000 per year for a maximum of four years.

Why this matters: This act is intended to help expand the number of primary care providers in Delaware, especially in underserved areas.

House Bill 39: Prohibiting Surprise Billing. This bill requires that inadvertent out-of-network services (surprise billing) be included in individual and group health insurance policies as well as group and blank health insurance policies. This bill defines inadvertent out-of-network services are those services that are covered under a policy or contract of health insurances, but are provided by an out-of-network provider in an in-network facility, or when in-network health care services are unavailable or not made available to the

insured in the facility. Inadvertent out-of-network services also includes laboratory testing ordered by an in-network provider but performed by an out-of-network laboratory.

Why this matters: This legislation helps protect individuals from surprise out of network bills by prohibiting providers from balance billing the patient. It establishes an arbitration system for billing disputes between the insurer and the provider. Similar legislation was recently passed at the federal level but does not take effect until January 1, 2022.

House Bill 33: This bill changes the relationship between physicians and physician assistants from supervisory to collaborative, in recognition of the evolving role of physician assistants and reflecting the education, training, and experience required for licensing, which emphasizes the team-based practice model. The bill retains a 1:4 ratio of physician assistants to physicians, unless a regulation of the Board increases or decreases the number. This bill was introduced last year but due to COVID-19 was not acted upon.

Why this matters: If enacted, this legislation could expand access to primary care services in Delaware.

House Bill 21: Relating to Advanced Practice Registered Nurse (APRN) Compact. Under the Compact, APRNs licensed in a Compact member state may practice in another Compact member state. In adopting the Compact, the state-based licensure system is preserved but communication between states is enhanced.

Why this matters: The Compact benefits the public by improving continuity of care, increasing license portability for advanced practice registered nurses, and increasing access to APRN care.

State Issues

Pennsylvania

Regulatory

Pennsylvania Updates its COVID-19 Vaccine Distribution Plan

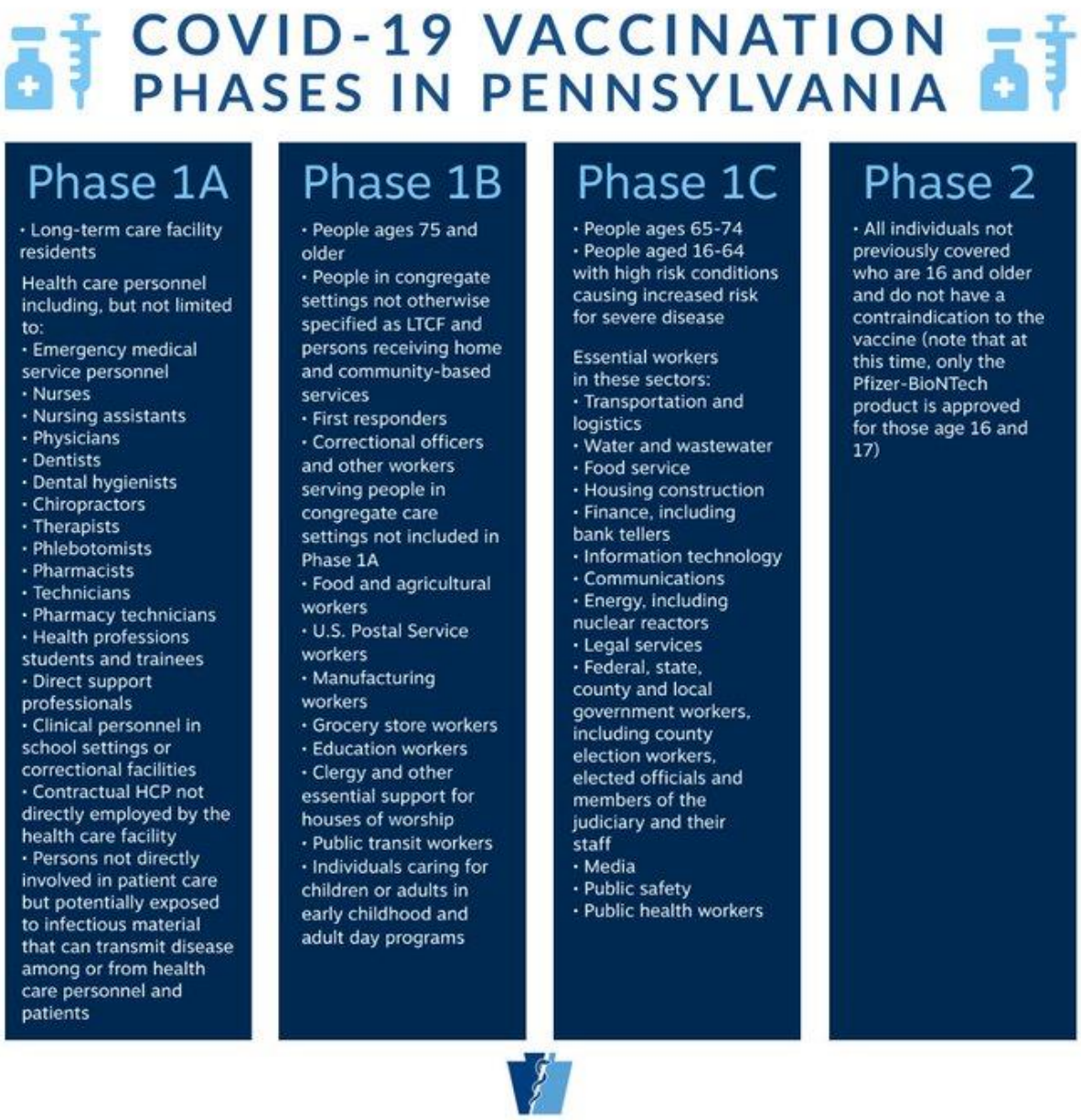
Pennsylvania has issued its fourth iteration of its vaccine distribution plan. With COVID-19 continuing to spread throughout Pennsylvania, health officials have cautioned that the state is still months away from having enough doses of the two approved vaccines for the general public. Secretary of Health, Dr. Rachel Levine believes that it will take several months before the vaccine is available for everyone.

To date, the federal government has allocated more than 827,000 doses of the Pfizer and Moderna vaccines to Pennsylvania. It is estimated that more than 235,000 shots have been given, although the actual number may certainly be higher because there is a lag time of about three days in reporting by hospitals and pharmacies.

The initial phase or Phase 1A includes doctors, nurses, pharmacists, and other health workers, as well as residents and staff at nursing homes and long-term care facilities. No timeline has been offered for when

the initial phase will be completed. Phase1B under the state's revised vaccine plan includes people 75 and older, frontline essential workers, first responders, prison guards, school staff, food, manufacturing, postal, public transportation, and grocery store workers. Phase 1C will extend to people ages 65 to 74, those with serious health conditions, and workers in industries ranging from banking to energy. Phase 2 of the plan opens up vaccine distribution to the general public.

Secretary Levine said the state's vaccine plan tracks with recommendations from the U.S. Centers for Disease Control and Prevention.



For the most up to date information on the COVID-19 Vaccine plan in Pennsylvania please visit the Department of Health's website.

The Pennsylvania House of Representatives are in session January 11-13.

The Delaware Legislature is in session January 12-14.

The West Virginia Legislature begins January 13 then recesses for 30 days. Session runs from February 10 through April 10, 2021.

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/.**