Federal Issues
Legislative

Coronavirus Response Ramps Up
On Friday, President Trump declared a national emergency over the coronavirus (COVID-19) outbreak, paving the way for additional federal dollars for states and localities attempting to contain the spread of the virus. Earlier in the week, the World Health Organization declared the outbreak a global pandemic.

- Trump’s actions came on the heels of an Oval Office address Wednesday night, announcing a 30 day travel suspension for foreign nationals from 26 European countries, excluding those traveling from the U.K. as well as legal permanent U.S. residents and immediate family members of U.S. citizens.
- The President also proposed financial relief from the federal government for those affected by the virus, and urged Congress to support immediate payroll tax relief.

Insurers weigh in: Several health insurance executives, including representatives from AHIP and BCBSA, met last week with President Trump, Vice President Pence, and other Administration officials to discuss the coronavirus response. All attendees agreed
to waive co-pays for COVID-19 testing and to provide coverage of telemedicine in-order to avoid hospital and doctor visits.

- **CMS Proposed Part D Pilot to Reduce Insulin Costs**

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**Congress Acts:** The House late Friday night passed the [Families First Coronavirus Response Act](https://www.congress.gov/bill/116th-congress/house-bill/7) in response to the coronavirus outbreak. The Senate will take up the package this week. It includes:

- **Emergency Leave:** Employers must provide sick leave to full-time employees to quarantine or seek care for coronavirus. Sick leave also can be used to care for a family member or to care for a child whose school has closed or whose child care provider is unavailable due to coronavirus. The bill also provides up to three months of Family Medical Leave for coronavirus. Congress provides tax credits to make up costs to employers.

- **Coverage of Testing:** The bill requires insurers to cover coronavirus tests and related provider visits without cost-sharing or prior authorization requirements. Applies to Medicare, TRICARE, veterans’ health programs, the Indian Health Service and federal employees. Also includes $1 billion to provide testing and related services for uninsured individuals.

- **Medicaid Funding:** Allows for a 6.2 percentage point increase in federal medical assistance percentages (FMAP) if states provide coverage of coronavirus testing without cost-sharing and meet other criteria. States can also get a 100 percent FMAP to cover the cost of tests and related medical visits for uninsured individuals through Medicaid.

- **Food Assistance:** The bill boosts funding for HHS programs that provide meals for the elderly and provides states with the option to adjust their Supplemental Nutrition Assistance Programs (SNAP) for schools closed because of the COVID-19 crisis. Additional funds are provided for food assistance for low-income pregnant women and mothers with young children whose employment is impacted as well as local food banks.

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**Federal Issues**

*Regulatory*
Final Interoperability Rules Released
Last Monday, the Department of Health and Human Services (HHS) finalized rules intended to give patients additional access to their health data. The rules, issued by the Centers for Medicare & Medicaid Services (CMS) (fact sheet) and the Office of the National Coordinator for Health Information Technology (ONC) (fact sheet), implement interoperability and patient access provisions of the 21st Century Cures Act and the Administration’s MyHealthEData initiative.

CMS’ Interoperability and Patient Access Final Rule
Under the Final Rule, Medicare Advantage (MA) organizations, Medicaid state agencies, Medicaid managed care plans, CHIP state agencies and CHIP managed care entities must make available the data they maintain with a date of service on or after January 1, 2016, beginning January 1, 2021. For QHP issuers on federally-facilitated exchanges (FFEs), this applies to data with plan years beginning on or after January 1, 2021.

Key provisions are as follows:
• **Patient Data Access through Application Program Interfaces (APIs):** Implement and maintain a secure, standardized application programming interface (API) that allows patients to access their claims and encounter information along with cost through a third-party application of their choice for plan years on or after January 1, 2021;
• **Privacy and Third-party Applications:** The rule allows third-party applications to retrieve consumer data with the approval and at the discretion of enrollees.
• **Access to Provider Directory Data:** Make publicly available provider directory information via a standards-based API beginning plan years on or after January 1, 2021 (except QHP issuers on the FFEs that already provide machine-readable files); and
• **Payer-to-Payer Data Exchange:** Exchange certain patient clinical data between payers at a patient’s request, allowing the patient to take their information with them as they move from payer to payer beginning January 1, 2022.
• **Future Rule-making on Patient Matching:** CMS did not include patient matching provisions in the Final Rule. CMS indicated that it is in the process of reviewing the RFI comments and may consider them for “potential future rulemaking.”

ONC’s Interoperability, Information Blocking and Health IT Certification Final Rule
The ONC Final Rule implements the information blocking provisions of the 21st Century Cures Act, including identifying reasonable and necessary activities that do not constitute information blocking. The Final Rule also promotes the use of standard based APIs. Importantly, it adopts HL7 FHIR and aligns the definition of electronic health information (EHI) to the definition of electronic protected health information (ePHI) under HIPAA.

The Final Rule provides exceptions to information blocking to prevent unintended consequences, including exceptions for privacy and security. Finally, it provides a six-month compliance delay and would require additional rule-making before penalties could be imposed.

To view the CMS final rule, click here. To view the ONC final rule, click here.

**Insurer perspective:** Matt Eyles, president and CEO of America’s Health Insurance Plans (AHIP), issued this statement: “Health insurance providers share HHS’s vision for expanded consumer data access and are
committed to building a truly interoperable health care system that integrates and shares data seamlessly to enhance care coordination and improve outcomes. However, when it comes to transparency in health care, patients overwhelmingly want two things – for the information to be clear, concise, and customized, and for their privacy to be protected. Any new rules must ensure we protect patient privacy, reduce health care costs, and get personalized information into the hands of patients.

We remain gravely concerned that patient privacy will still be at risk when health care information is transferred outside the protections of federal patient privacy laws. Individually identifiable health care information can readily be bought and sold on the open market and combined with other personal health data by unknown and potentially bad actors. Consumers will ultimately have no control over what data the app developers sell, to whom or for how long."

**Hospital industry position:** Hospitals support giving patients greater access and control over their health data. In fact, nearly all hospitals and health systems have made health information available to patients electronically. However, these final rules fail to protect consumers’ most sensitive information about their personal health. Specifically, the rule lacks the necessary guardrails to protect consumers from actors such as third party apps that are not required to meet the same stringent privacy and security requirements as hospitals. This could lead to third party apps using personal health information in ways in which patients are unaware. Hospitals support protecting patient privacy and strengthening security in these rules.

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**Coronavirus Updates**

- CMS released guidance advising insurers on recommendations related to COVID-19 for Medicare Advantage and Part D beneficiaries. Some recommendations include waiving cost sharing for testing, waiving treatment cost sharing for primary care, emergency room, telehealth services, eliminating prior authorizations, eliminating prescription refill restrictions, decreasing limitations on home or mail order prescription delivery, and increasing access to telehealth services. Individuals over 60 years of age are most at risk of developing a serious illness due to COVID-19.

- The Internal Revenue Service (IRS) and the Department of Treasury (Treasury) released Notice 2020-15 to allow coverage of testing and services related to the coronavirus before the deductible for people with high-deductible health plans and HSAs. The Notices states all medical care services received and items purchased associated with testing for and treatment of COVID-19 provided by a health plan without a deductible, or with a deductible below the minimum annual deductible otherwise required under section 223(C)(2)(A) for an HDHP, will be disregarded for purposes of determining the status of the plan as an HDHP.

- CMS released FAQs that provide information and clarifications regarding COVID-19 testing and other Medicare covered benefits.
  - The COVID-19 FAQs for State Medicaid and CHIP agencies can be found here.
  - The COVID-19 FAQs for EHB can be found here.
  - CMS posted a fact sheet to the CMS.gov website to aid Medicare providers with information relating to the pricing of both the CDC and non CDC tests. You can find the fact sheet here.

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**State Issues**
Delaware
Legislative

Delaware Under State of Emergency To Prepare for Spread of Covid-19
Governor John Carney issued a State of Emergency declaration to prepare for the spread of Coronavirus (COVID-19). The State of Emergency directs the Delaware Emergency Management Agency (DEMA) and the Delaware Department of Health & Social Services’ Division of Public Health to mobilize state agency resources to assist with Delaware’s response to the virus.

The declaration became effective at 8:00 a.m. on Friday, March 13, 2020.

Governor Carney’s emergency declaration also:
- Requires the Delaware National Guard to take precautionary and responsive actions to assist with Delaware’s response to the coronavirus;
- Advises event organizers in Delaware to cancel non-essential public gatherings of 100 people or more, to prevent community spread of coronavirus;
- Allows the State of Delaware to conduct public meetings electronically to prevent unnecessary public gatherings;
- Prohibits price gouging, or an excessive price increase of goods or services, during the coronavirus outbreak.

Delaware General Assembly Postpones Legislative Session
Leaders of the Delaware House and Senate have postponed legislative session. The legislature was scheduled to return from its break for Joint Finance Committee hearings on March 17, but the spread of COVID-19 and recommendations from the Centers for Disease Control, the World Health Organization, and Delaware public health officials prompted this proactive decision. Rep. Schwartzkopf and Sen. McBride issued the following statement:

"At this moment, our postponement will extend until March 24. However, we will carefully monitor the spread of COVID-19 in Delaware and across the country, and we will re-evaluate when to return to session on a weekly basis. As we have said before, this is a rapidly shifting situation and we must remain flexible based on the changing circumstances."

Legislation Introduced:
Behavioral Health Well Visits - HB 307 requires coverage of an annual behavioral health well check. Behavioral health well check means an annual visit with a licensed mental health clinician with at minimum a master’s level degree. The well check must include but not be limited to a review of medical history; evaluation of adverse childhood experiences; use of appropriate battery of validated mental health screening tools; and may include anticipatory behavioral health guidance congruent with stage of life using the diagnosis of “annual behavioral health well check”.

State Issues

Pennsylvania
Legislative
COVID-19 Pandemic Impacts Pennsylvania General Assembly’s Return to Session

The COVID-19 pandemic is affecting the Pennsylvania General Assembly’s scheduled return to Harrisburg to resume their legislative session following budget hearings. The Capitol Building is currently open only to elected officials and staff with access, which means the public in general; including lobbyists, advocacy groups, school groups, etc., is prohibited from visiting the building. As a result, virtually all public meetings, including committee meetings, have been cancelled. The state’s Sunshine Law requires such meetings to be open to the public.

The House of Representatives will conduct an abbreviated legislative session on Monday, March 16. The chamber is slated to vote on a measure that will allow them to conduct legislative business remotely, including voting. The Senate is currently on a 12-hour call – it remains unclear if and when the upper chamber will return to Capitol Hill.

Several health care bills were scheduled for votes this week, however, their consideration is postponed:

- House Bill 546, Dental Direct Payment (Assignment)
- House Bill 1439 and House Bill 1696, Mental Health Parity Reporting Requirements
- Senate Bill 67, Psychology Interjurisdictional Compact Act
- Senate Bill 857, Telehealth / Telemedicine

State Issues

Pennsylvania

Regulatory

Pennsylvania Insurance Department Releases Draft 2021 ACA Rate Filing Guidance

The Pennsylvania Insurance Department on March 9, released its Draft 2021 ACA Rate Filing Guidance. As requested, Highmark submitted its comments on March 13. Final Guidance is to be issued on or about March 19. Also included with the Draft Guidance was a Proposed Timeline which is reproduced below:

<table>
<thead>
<tr>
<th>ACA-Compliant Filing Activities for the 2021 Plan Year</th>
<th>Dates (approximate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(blue shading indicates dates that apply to QHP and non-QHP issuers; green shading indicates dates that apply only to QHP issuers)</td>
<td></td>
</tr>
<tr>
<td>Form, Rate and Binder Submission to PID</td>
<td>All health insurers that wish to issue or renew ACA-compliant individual and small group health insurance coverage on or after January 1, 2021 must file their forms, rates and plan binders containing all the required templates via SERFF beginning May 7, 2020, but no later than May 19, 2020. Late filings will not be accepted.</td>
</tr>
<tr>
<td>Completeness review of Forms and Binders</td>
<td>PID reviews submissions for completeness and provides feedback to issuers</td>
</tr>
</tbody>
</table>
Form, Rate and Binder Review Process

<table>
<thead>
<tr>
<th>Event</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial SERFF Data Transfer</td>
<td>PID uses SERFF to transmit complete and accurate QHP Application Data to CMS</td>
</tr>
<tr>
<td>CMS First Correction Notices</td>
<td>CMS posts results (correction notices) in PM Community</td>
</tr>
<tr>
<td>PID Final Deadline for Corrected Application Data</td>
<td>Issuers submit final forms, rates and binders to PID</td>
</tr>
<tr>
<td>Final SERFF Data Transfer</td>
<td>PID transfers final QHP Application Data to CMS</td>
</tr>
<tr>
<td>Limited Data Correction Window</td>
<td>Issuers with CMS or state identified data errors may submit corrections</td>
</tr>
<tr>
<td>QHP Certification Agreements</td>
<td>CMS sends QHP Certification Agreements to issuers</td>
</tr>
<tr>
<td>Plan Lists</td>
<td>CMS sends final Plan Lists to PID for confirmation</td>
</tr>
<tr>
<td>Final QHP Agreement, Plan Confirmation, and Certification</td>
<td>Issuers send signed Agreements, confirmed Plan Lists, and final Plan Crosswalks to CMS</td>
</tr>
<tr>
<td></td>
<td>PID sends CMS Final Plan Recommendation</td>
</tr>
<tr>
<td></td>
<td>CMS sends Certification Notices with countersigned Agreements and final plan lists to issuers</td>
</tr>
<tr>
<td>Open Enrollment Begins</td>
<td>11/1/2020</td>
</tr>
</tbody>
</table>

**Industry Trends**

**Policy / Market Trends**

**CMS Proposed Part D Pilot to Reduce Insulin Costs**

CMS is proposing the Part D Senior Savings Model for Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug plans (MAPDs) to limit insulin costs to $35 a month for Medicare beneficiaries; however, offering such plans are optional.

**Why this matters:** Over three million Medicare beneficiaries take at least one common form of insulin and the growing price tag has caused some to begin rationing their insulin to reduce their costs. Virginia, New Mexico, Colorado and West Virginia have already taken steps to force insurers to cap out-of-pocket costs for insulin.

Both plans and insulin manufacturers potentially face additional costs from the model; this might lead to increased premiums for participating plans. CMS will expand the existing Part D risk corridor program to help
defray additional costs for PDPs and MAPDs that take on additional insulin-dependent members during the first two years of the demonstration and will give participating plans the opportunity to deploy enhanced medication therapy management and rewards/incentive tools to manage high cost members more successfully. The Model’s initial projections assume it generates over $250 million in savings over five years for the federal government, largely due to pharmaceutical manufacturers paying the additional coverage gap discounts.

**What’s next?** The model is projected to begin January 1, 2021 and the [request for applications is available](#).

The Pennsylvania General Assembly schedule is fluid for this week due to the current public health crisis.

The Delaware Legislature has postponed their legislative session.

The West Virginia Legislature has completed session for 2020.

**Congress**
The U.S. House and the U.S. Senate are closed due to the current public health crisis.

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

- Pennsylvania Legislation: [www.legis.state.pa.us](http://www.legis.state.pa.us)
- West Virginia Legislation: [http://www.legis.state.wv.us/](http://www.legis.state.wv.us/)
- For copies of congressional bills, access the Thomas website – [http://thomas.loc.gov/](http://thomas.loc.gov/).

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