Federal Issues
Legislative

Senate Passes USMCA Trade Agreement
On Thursday, full Senate passed H.R. 5430, the United States-Mexico-Canada Trade Agreement (USMCA) in a 89-10 vote.

Why this matters: The trade deal is being touted as a victory by President Trump, who has been critical of its predecessor, the North American Free Trade Agreement (NAFTA).

- Improved health care provisions: The final version of the legislation removed provisions that would have extended biologic exclusivity and patents for known products; revised data protection limitations and regulatory review processes; and expanded provisions related to regulatory approval and patent terms to foster generic competition and increase access to affordable drugs.

The bill is expected to be signed into law by the President this week, but the deal will not go into effect until Canada’s House of Commons votes to approve the agreement, likely in the coming weeks.

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“CSRxP applauds lawmakers in the U.S. Senate for standing up to Big Pharma to pass this historic trade deal that puts American patients first by supporting generic and biosimilar competition,” said Lauren Aronson of The Campaign for Sustainable Rx Pricing (CSRxP), a coalition of health groups that includes hospitals, doctors and insurance plans.

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Federal Issues
Regulatory

Hospital Trade Groups Sue HHS Over CY 2020 Outpatient Payment Policy
The American Hospital Association (AHA), joined by Association of American Medical Colleges (AAMC) and several hospitals, filed a lawsuit against the Department of Health and Human Services for continuing to reduce in calendar year 2020 payments for hospital outpatient services provided in off-campus provider-based departments grandfathered under the Bipartisan Budget Act of 2015.

A federal judge recently ruled in favor of the AHA and the hospital groups and said the Centers for Medicare & Medicaid Services exceeded its statutory authority when it reduced CY 2019 payments for hospital outpatient services provided in off-campus provider-based departments grandfathered under the Bipartisan Budget Act of 2015.

Why this matters: These cuts directly undercut the clear intent of Congress to protect hospital outpatient departments because of the real and crucial differences between them and other sites of care,” said AHA President and CEO Rick Pollack. “For example, patients who receive care in a hospital outpatient department are more likely to be poorer and have more severe chronic conditions than patients treated in an independent physician office. In addition, only hospitals provide 24/7 access to care for patients, regardless of their ability to pay, hospitals are held to far higher regulatory requirements, and hospital outpatient departments in inner cities and rural areas are often the only sites of care that provide the services they do.”

DOL Issues Final Rule on Joint Employer Status
On January 16, the Department of Labor published a final rule in the Federal Register updating and clarifying how it interprets joint employer status under the Fair Labor Standards Act, which aims to promote certainty for employers and employees, reduce litigation and encourage innovation in the economy. The effective date of the final rule is March 16, 2020.

Under the FLSA, an employee may have—in addition to his or her employer—one or more joint employers, additional individuals or entities who are jointly and severally liable with the employer for the employee’s required minimum wage and overtime pay.
Key provisions of the rule: The final rule provides a four-factor test for determining FLSA joint employer status in situations where an employee performs work for one employer that simultaneously benefits another entity or individual. The test examines whether the potential joint employer:

- hires or fires the employee;
- supervises and controls the employee’s work schedule or conditions of employment to a substantial degree;
- determines the employee’s rate and method of payment; and
- maintains the employee’s employment records.

The potential joint employer’s maintenance of the employee’s employment records alone will not lead to a finding of joint employer status. The final rule also clarifies factors that are not relevant to determining joint employer status.

Why this matters: This is the first major update to DOL’s joint employer guidelines since 1958.

Federal Health IT Strategic Plan Draft Released for Public Comment

Last week, the draft 2020-2025 Federal Health IT Strategic Plan was released by the U.S. Department of Health and Human Services’ Office of the National Coordinator for Health Information Technology (ONC). This plan serves as a roadmap for initiatives to advance interoperability and further promote the use of electronic health information to improve health, advance research, and inform outcomes.

ONC highlighted the four primary goals on which the strategic plan is based:

1. Promote Health and Wellness
2. Enhance the Delivery and Experience of Care
3. Build a Secure, Data-Driven Culture to Accelerate Research and Innovation
4. Connect Health Care and Health Data through an Interoperable Health IT Infrastructure

The draft is available for public comment until March 18, 2020, after which an updated, final version will be released.

The final strategic plan will:

- Provide guidance about how best to prioritize federal resources
- Ensure alignment and coordination of efforts
- Serve as a catalyst and priority indicator for the private sector
- Serve as a benchmark from which progress can be measured

Why this matters: The Federal Health IT Strategic Plan represents the work being done to help ensure that patients and their providers can electronically access the health information they need to help them manage their care. All stakeholders in the healthcare sector will benefit from a fully connected health system that empowers patients, caregivers, and their healthcare providers to securely access, exchange, and use electronic health information.

The American Hospital Association will provide feedback to help guide the federal government’s strategy to have a more connected health system that better serves patients.
MedPAC Approves 2021 Payment Recommendations
The Medicare Payment Advisory Commission recommended that Congress provide a 2% market-basket update for the hospital inpatient and outpatient prospective payment systems in 2021. The commission also recommended using the difference between the update and amount specified in current law to increase hospital payments through its proposed Hospital Value Incentive Program (HVIP), which would replace the four current hospital quality payment programs with a single alternative program.

The American Hospital Association said it supports the concept of appropriately linking quality performance to payment, but has significant concerns with the design of the HVIP.

In other action, MedPAC recommended that:
- the Health and Human Services Secretary increase the fiscal year 2020 Medicare base payment rates for long-term care hospitals by 2% in 2021;
- Congress reduce the FY 2020 Medicare base payment rate for inpatient rehabilitation facilities by 5% in 2021;
- Congress eliminate the FY 2021 update to the Medicare payment rates for skilled nursing facilities;
- Congress increase the calendar year 2021 Medicare payment rates for physician and other health professional services by the amount specified in current law;
- Congress reduce the CY 2020 Medicare base payment rate for home health agencies by 7% in 2021;
- Congress eliminate the CY 2021 update to the Medicare conversion factor for ambulatory surgical centers, and HHS require ASCs to report cost data;
- Congress eliminate the FY 2021 update to Medicare base payment rates for hospice providers; and
- Congress increase the calendar year 2021 Medicare end-stage renal disease prospective payment system base rate by the amount specified in current law.

Additionally, commissioners discussed a staff analysis of the relationship between the 340B drug savings program and oncology drug costs, requested by the House Energy and Commerce Committee in 2018. The findings were inconclusive overall, showing higher spending for some cancer drugs but not others, and not generalizable to other conditions. The study will be included along with MedPAC’s previous work on hospital consolidation in a chapter of the commission’s March report to Congress.

Commissioners also discussed potential changes to how beneficiaries are assigned to Medicare Accountable Care Organizations, including the identifier used to assign beneficiaries and retrospective versus prospective assignment, but concluded they need more detail on the different approaches before making a recommendation.

In addition, the panel discussed potential approaches to restructuring the Part D program and redesigning the Medicare Advantage quality bonus program.

Why this matters: The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency established by the Balanced Budget Act of 1997 to advise the U.S. Congress on issues affecting the Medicare program. The Commission’s statutory mandate is quite broad: In addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare’s traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.
Two reports—issued in March and June each year—are the primary outlet for Commission recommendations. In addition to these reports and others on subjects requested by the Congress, MedPAC advises the Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary of the Department of Health and Human Services, testimony, and briefings for congressional staff.

Insurers Recommend CMS Expand Copay Accumulators to All Drugs
In the 2020 Notice of Benefits and Payment Parameters (NBPP) - a rule released each year to set policies for private health insurance plans in the individual, small group, and large group markets - health plans could cease counting drug makers' copay coupons toward enrollees' out-of-pocket (OOP) maximums, but only for drugs with an available generic equivalent, and only when an appeals or exceptions process has found that the brand name drug is not medically necessary.

Industry position
- The Blue Cross Blue Shield Association (BCBSA) and America’s Health Insurance Plans (AHIP) argue health plans should be able to exclude drug manufacturer coupons from OOP maximums for all drugs and not just for drugs with a generic equivalent.
- BCBSA and AHIP want CMS to remove the phrase “available and medically appropriate generic equivalent.”
- BCBSA and AHIP also want CMS to make it easier to track financial assistance offered by drug manufacturers and pharmacies, which would include co-pay coupons along with any other financial assistance programs. One proposal would require pharmacies submit coupon information or any financial assistance on the National Council for Prescription Drug Programs’ claim transaction, which would provide insurers with more information on available coupons to design tools and benefits to promote cheaper drugs. Medicare Part D plans would also be able to track coupon usage, which has the potential to enhance CMS oversight.

Why this matters
- Last August, CMS released a report stating the provision could be read to imply group health plans and issuers were required to count the copay coupon amounts toward the annual limit on cost-sharing. However, such a requirement would create a conflict with rules for high-deductible health plans, which permit individuals to create health savings accounts.
- CMS indicated it would work to clarify this in the 2021 NBPP and would not take any action against an insurer that excluded drug manufacturer coupons from annual cost-sharing limits.

Supreme Court will Decide if States Can Regulate PBMs
The Supreme Court agreed to hear Rutledge v. Pharmaceutical Care Management Association, No. 18-540, which could revive an Arkansas law regulating pharmacy benefit managers (PBMs) that required PBMs to reimburse pharmacies for generic drugs at a price at least equal to the pharmacies’ cost for the drug, based on the invoice from the wholesaler. The 2015 law also created an appeal procedures for pharmacies wanting to a PBM’s reimbursement rate as well as a “decline-to-dispense” option for pharmacies that would lose money on a transaction. The intent behind the law was to prevent closures of independent and rural pharmacies in Arkansas.
In 2018, the U.S. Court of Appeals for the 8th Circuit struck down the law, which prompted Arkansas to petition the Supreme Court to review the decision. Thirty other states, as well as the Trump Administration, supported Arkansas’s request.

However, the Pharmaceutical Care Management Association (PCMA), the trade group for PBMs, opposed Arkansas’s request to the Supreme Court.

**Why this matters:** This case may have widespread implications for the 38 states that have laws restricting the conduct of PBMs.

**What’s next?** The Supreme Court will now set the case for briefing and oral arguments, the latter of which would likely occur in March or April 2020.
State Issues

Pennsylvania
Legislative

Vote Postponed on Provider Direct Payment Bill
House leadership postponed consideration of House Bill 564, legislation that would require insurers to pay all clean claims directly to a participating or non-participating healthcare provider. This practice exposes patients to “surprise balance bills” – the difference between the provider's charge and the insurer’s payment.

Medicaid Fraud Package to Include State False Claims Measure
This week Attorney General Josh Shapiro and a bipartisan group of elected officials including Rep. Seth Grove (R-York), Senator Lindsey Williams (D-Allegheny), Rep. Clint Owlett (R-Tioga) and Rep. Tommy Sankey (R-Clearfield), held a press conference to highlight the findings from a report issued by the House Government Oversight Committee that addressed Medicaid provider fraud and improper payments made under the program.

Why this matters:
- Medicaid fraud is a huge expense for the Commonwealth, totaling over $640 million annually in improper payments.
- At the federal level, 10% of Medicaid expenses are credited to fraud or improper payments, which means that of the $31 billion spent on Medicaid in Pennsylvania, there is an estimated $3 billion being wasted.

To alleviate the financial burden on state taxpayers, Shapiro and members of the Senate and House believe offenders must be held accountable civilly and recommend legislation that would:
- Require a state provider number;
- Have a date and time for all payments and claims;
- Provide standardized training; and
- Institute a State False Claims Act to encourage whistleblowers to come forward.

David Arnold Prevails in 48th District Senate Special Election
On Tuesday, January 14, voters in the 48th senatorial district – covering Lebanon and parts of Dauphin and York Counties – elected Lebanon County District Attorney David Arnold to replace former GOP state Senator Mike Folmer. Arnold defeated Democrat Michael Schroeder. Arnold will be sworn in when the Senate returns next week.

State Issues
West Virginia
Legislative

**Action Nears on West Virginia Health Care Legislation**
In the near future, the West Virginia Legislature is scheduled to take up several health insurance / health care proposals. In brief, they include:

**House Bill 4003—Telemedicine / Virtual Health Payment Parity**
House Bill 4003 would establish payment parity (at 90% of the in-person rate) and coverage parity for telemedicine.

**Senate Bill 291—Mental Health Parity for Government and Private Plans**
This bill would require all insurance carriers, including the West Virginia Public Employees Insurance Agency (PEIA) and managed care organizations, provide mental health parity between behavioral health (including autism), mental health, substance use disorders and medical/surgical procedures.

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The Pennsylvania House of Representatives is in session January 21-22.

The Delaware Legislature is in session January 21-23.

The West Virginia Legislature is in session January 8 - March 7.

**Congress**
The U.S. House is in recess the week of January 20. The U.S. Senate is in session.

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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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