

Federal Issues

Regulatory

CMS Finalizes Guidance for First Round of Medicare Drug Price Negotiations for 2026

CMS [released final revised guidance](#) implementing the initial round of drug price negotiations for 10 CMS-selected Part D covered drugs. The first set of negotiations will take place in 2023 and 2024 for prices effective in 2026. The agency indicates they are releasing the revised guidance with changes from the initial guidance to improve transparency and foster an effective negotiation process.

Why this matters: The 198-page guidance is the last substantive [round of guidance](#) expected before CMS releases the initial list of drugs that will be subject to negotiations for 2026, the initial price applicability year, which is expected by September 1, 2023.

- In the [revised guidance](#), CMS clarifies how it will identify selected drugs, revises the process for participating drug companies, provides clarifications regarding Part D formulary inclusion for selected drugs, addresses more opportunities for stakeholder engagement, among other changes. CMS also provides a section-by-section summary of changes from

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the initial guidance as well as a summary of public comments on the initial guidance.

Background: The guidance comes after four lawsuits have been filed by a group of manufacturers, PhRMA, and organizations representing health care providers and patients. The guidance appears to have been revised in response to at least some of these legal challenges, including a clarification that manufacturers under a negotiation process will not be under a gag clause to not discuss publicly the negotiation. In addition, CMS will release information about the negotiation when it releases the explanation of how it arrived at the maximum fair price, which is expected by March 1, 2025, for the first round of negotiations. CMS also clarifies that manufacturers are not required to honor maximum fair prices to beneficiaries who are not using Part D benefits to pay for the drug, such as individuals who are using benefits provided through a Retiree Drug Subsidy, prescription drug discount card, or cash.

In a clarification that is important to rare disease drug manufacturers and stakeholders, CMS clarifies that it “does not have the statutory authority to exclude a drug under the Orphan Drug Exclusion that has designations for multiple rare diseases or conditions, even if the drug has been approved only for indication(s) within a single rare disease or condition. However, the law gives CMS the ability to consider the impact of a selected drug on specific populations and the extent to which a selected drug meets an unmet medical need when setting CMS’ initial price offer.

- **Acting Insurance Commissioner Confirmed by Senate; Acting Department of Human Services Secretary Confirmed without Senate Approval**
- **Governor Shapiro Withdraws Department Health’s of Secretary’s Nomination**
- **State House Passes Nurse Staffing Ratios Mandate**

CMS Approves 12-Month Extension of Postpartum Medicaid & CHIP Coverage in New York
CMS [announced](#) New York will extend Medicaid and Children’s Health Insurance Program (CHIP) coverage for 12 months after enrollees give birth. The American Rescue Plan Act provided states with the flexibility to temporarily extend Medicaid postpartum coverage from 60 days to 12 months, and the Consolidated Appropriations Act (2023) made this option permanent.

Why this matters: CMS [estimates](#) an additional 26,000 people will benefit from the extension of coverage. With the approval of New York’s extension, 35 states and the District of Columbia now offer extended coverage for 1 year. CMS is also working actively with other states to extend postpartum coverage.

CMS Releases Guidance for Medicaid and CHIP Coverage of Adult Vaccines

The Centers for Medicare & Medicaid Services (CMS) released [guidance](#) to states concerning mandatory coverage of approved adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and their administration, without cost sharing.

Why this matters: Beginning October 1, 2023, provisions of the Inflation Reduction Act (IRA) require Medicaid and Children’s Health Insurance Programs (CHIP) to cover and pay for adult vaccine services. The guidance also reviews requirements states must meet to claim enhanced federal medical assistance percentage (FMAP) for these services. For more information on Medicaid and CHIP coverage of adult vaccinations, please refer to the state health official [letter](#) and [fact sheet](#).

CMS Issues Guidance on Medicaid Unwinding for D-SNPs and PACE Organizations

The Centers for Medicare & Medicaid Services (CMS) recently issued a memorandum to provide guidance to Medicare Advantage (MA) dual eligible special needs plans (D-SNPs) and Programs of All-Inclusive Care for the Elderly (PACE) organizations on enrollee communications during state Medicaid agencies’ unwinding periods.

- CMS encourages D-SNPs and PACE Organizations to communicate to dual eligible enrollees to update their contact information, check their postal mail and email, and to complete their Medicaid renewal form; as well as provide direct outreach and support to enrollees renewing their Medicare coverage.
- The agency also reminds D-SNPs that if the plan “determines that an individual who no longer meets [Medicaid] eligibility criteria can reasonably be expected to again meet all eligibility criteria within a 6-month period, the enrollee may be deemed to continue to be eligible for the MA special needs plan for a period of not less than 30 days but not to exceed six months.” D-SNPs must provide enrollees with written notice regarding the loss of special needs status within 10 calendar days of learning of the loss of special needs status.

CMS provides more information in the memorandum, including guidance on deemed continued eligibility for PACE plan participants and beneficiary contact and the Medicare Communications and Marketing Rules.

IRA Extends Insulin Caps to Medicare Part B and MA starting July 1

Starting July 1, people with Medicare Part B and Medicare Advantage coverage who get their insulin through a traditional pump will see insulin costs capped at \$35 per month per each covered insulin. CMS created a [series of resources](#), including an FAQ, social media toolkit, and more.

HHS Office of Inspector General Final Rule on Information Blocking

The U.S. Department of Health and Human Services' Office of the Inspector General [posted its long-awaited final rule](#) implementing information blocking penalties.

Why this matters: This final rule — which applies to health IT developers of certified health IT, entities offering certified health IT, health information exchanges (HIEs) and health information networks (HINs) — adds teeth to the longstanding ONC Information Blocking Rule (IBR). Specifically, HHS OIG has confirmed possible penalties of up to \$1 million per violation, consistent with the 2020 proposed rule.

The final rule clarifies the “look back” period once IBR enforcement begins: OIG “will not impose a penalty on information blocking conduct occurring before 60 days after publication of the final rule in the *Federal Register*.” That said, HHS OIG does reserve discretion to consider an actor’s prior history when determining how to evaluate information blocking practices that are subject to an investigation. Still, any enforcement action against a health IT developer, entity offering certified health IT, HIE, or HIN could precede that against a health care provider, as HHS has yet to even propose a rule addressing IBR enforcement against health care providers. A proposed rule from the National Coordinator at HHS is expected by the fall of 2023, according to the Spring 2023 unified agenda.

State Issues

Delaware

Legislative

Legislative Session Wraps Up for 2023

The 2023 Legislative Session came to a close with Speaker of the House Pete Schwartzkopf stepping down from his post, citing family health issues. Rep. Valerie Longhurst, who had been the House Majority Leader, was selected by the full House of Representatives as the new speaker, the first time in Delaware's history that a woman will occupy the seat. The House Democratic Caucus chose Rep. Melissa Minor-Brown to move from House Majority Whip to House Majority Leader -- the first woman of color to serve in the position.

Key Bills Enacted or Awaiting Governor’s Signature

- [House Substitute 1 for House Bill 60 w/ HA 1](#): This Act requires that all insurance policies issued or renewed in this State include coverage of supplemental and diagnostic breast examinations on terms that are at least as favorable as the coverage of annual screening mammograms. The Act covers all group, blanket, and individual health insurance policies as well as the State employee

healthcare plan and Medicaid. This substitute bill differs from the original bill in that it makes technical corrections, excludes certain health, and adds to the definition of breast MRI.

- [House Bill 54](#) – Expanded requirement to include at least 1 formulation of epinephrine autoinjectors in lowest tier of carrier’s drug formulary regardless of age.
- [Senate Bill 31](#) This Act corrects a technical error in SB 227 (149th General Assembly) by establishing requirements for group and blanket health insurance plans that align with existing requirements for individual and State employee health insurance plans. As introduced, SB 227 specified that coverage for chronic care management under all 3 of these health insurance plan types cannot be subject to patient deductibles, copayments, or fees. Senate Amendment 1 to SB 227 made various intentional changes to SB 227 but also accidentally deleted the line that applied this chronic care management requirement to group and blanket plans. This bill corrects that error.
- [House Bill 80](#) :This Act requires that doula services be covered by Medicaid in Delaware by January 1, 2024.
- [House Bill 146](#): This bill increases the assessments charged to insurance companies to fund the increased costs of the operation of the Fraud Prevention Bureau.

Bills Held Over For Consideration Next Year

- [Senate Bill 10](#)- Known as the Pre-authorization Reform Act, this legislation makes a number of changes to the laws governing prior authorization. Stakeholders will meet over the next several months to discuss concerns and craft compromise language.
 - [House Substitute 1 for HB 110](#) – This Act requires all health benefit plans delivered or issued for commercial, Medicaid, and State Of Delaware plan to cover services related to the termination of pregnancy. Coverage provided under this section would not be subject to any deductible, coinsurance, copayment, or any other cost-sharing requirement and must cover the full scope of services permissible under the law.
 - [House Bill 230](#) This Act updates House Bill 455 from the 151st General Assembly by providing the same legal protections afforded providers of contraceptive and abortion services to providers of gender-affirming health care.
 - [Senate Bill 143](#) Known as the Clean Claim bill, this Act makes several changes intended to improve the claims payment process by health insurers.
 - [House Bill 253](#) This Act requires health insurance companies, including State employee/retiree health plans and Medicaid, to cover annual mammograms for the purpose of early detection for a woman 40 years of age or older, with or without referral from the woman’s health care provider. Highmark is already in compliance with this act.
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Pennsylvania

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House Advances Preventive Services Legislation

On Monday, June 26, the House advanced [House Bill 1050](#) (Boyle, D – Philadelphia). House Bill 1050 seeks to preserve the ACA preventive service requirements in response to a recent federal district court decision in *Braidwood Management, Inc. v. Becerra*, which would prevent enforcement of certain preventive services required by the ACA.

House Bill 1050 now awaits consideration from the Senate Banking and Insurance Committee.

Why this matters: Highmark expressed support for advancing House Bill 1050 and preserving the ACA preventive services requirements in Pennsylvania as preventive services provide a vital benefit our members and patients.

Senate Committee Advances Telemedicine Legislation

On Tuesday, June 27, the Senate Banking and Insurance Committee unanimously advanced [Senate Bill 739](#) (Vogel, R-Beaver). Senate Bill 739 would define telemedicine services, offer guidelines outlining who can provide telemedicine services, and establish requirements on health insurance company reimbursement for telemedicine services.

Senate Bill 739 now awaits consideration from the full Senate.

Why this matters: Highmark supports virtual care and continues working to expand its use and availability to customers and patients. The COVID-19 pandemic accelerated the adoption of virtual care among many of Highmark's provider partners and members.

Acting Insurance Commissioner Confirmed by Senate; Acting Department of Human Services Secretary Confirmed without Senate Approval

- On Monday, June 26, the Senate unanimously confirmed Michael Humphreys to serve as Insurance Commissioner of the Pennsylvania Insurance Department. Commissioner Humphreys served as Acting Insurance Commissioner since February 2022. Prior to being appointed, Commissioner Humphreys served as the Chief of Staff for the Insurance Department beginning in September 2019.
- On Thursday, June 29, Acting Secretary Dr. Val Arkoosh became the Department of Human Services official Secretary without Senate approval due to the Senate failing to act on the nominee within the 25th legislative day of consideration. Prior to being appointed, Secretary Arkoosh served on the Montgomery County Board of Commissioners since first being appointed to fill a vacancy on the Commission in January 2015. Secretary Arkoosh won election to a full four-year term in November 2015 and served as Commission Vice Chair until her election as Commission Chair in November 2016, the first woman to assume this role. She was re-elected in November 2019 and unanimously chosen to serve as Chair in January 2020. Prior to stepping into public service,

Secretary Arkoosh was Professor of Clinical Anesthesiology and Clinical Obstetrics and Gynecology at the Perelman School of Medicine of the University of Pennsylvania.

Governor Shapiro Withdraws Department of Health Secretary's Nomination

On Tuesday, June 27, Governor Shapiro withdrew Dr. Debra Bogen's nomination for Secretary of the Department of Health. Prior to the governor's nomination withdrawal, Dr. Bogen appeared before the Senate Health and Human Services Committee to consider her nomination. Dr. Bogen's nomination was re-referred to the Senate Committee on Rules and Executive Nominations with no recommendation. The governor's office did not provide a reason for the withdrawal and will announce more regarding next steps in the coming days. Prior to being appointed, Dr. Bogen served as the Director of the Allegheny County Health Department since March 2020. Prior serving as the Director of the Allegheny County Health Department, Dr. Bogen served as member of the Pittsburgh region medical and research community for more than two decades.

State House Passes Nurse Staffing Ratios Mandate

The state House of Representatives on June 28 approved legislation that would impose government-mandated nurse staffing ratios in Pennsylvania hospitals, sending the measure to the Senate where lawmakers have already expressed reservations.

- Representatives approved [House Bill 106](#) with a 119-84 vote after adopting changes related to fines, implementation dates, and emergency exceptions. Hospitals continue to raise concerns and oppose the bill as the legislative process advances.
- Despite aggressively working to recruit and retain nurses—offering extraordinary pay raises, bonuses, loan repayment, schedule flexibility, and other incentives—hospitals report being unable to fill, on average, more than 30 percent of open bedside registered nurse positions and cite finding qualified candidates as their top barrier.

Earlier this year, the Hospital & Healthsystem Association of Pennsylvania (HAP) shared comprehensive policy recommendations for growing and supporting the health care workforce. **Among other initiatives, HAP is calling for:**

- Making health care education more affordable and accessible by funding nursing scholarships and tuition assistance, expanding student loan forgiveness for nurses, investing in health care education programs, and offering incentives for clinicians to work as health care faculty and preceptors.
- Helping nurses quickly get to work by addressing licensing delays and administrative barriers.
- Empowering registered nurses to practice at the top of their abilities by supporting innovative care models like virtual nursing and team-based care.
- Prioritizing efforts to grow the health care workforce by establishing a health care workforce council that coordinates across state agencies.

What's next in the legislative process? The House vote was a step in the legislative process. The hospital community's advocacy effort now turns to the Senate. Senators have already raised concerns

about the bill in its current form. The House [fiscal note](#) issued last week also added new considerations for lawmakers, estimating that state's seven behavioral health hospitals alone would need to hire an additional 500 nurses at an estimated cost of \$62.5 million before federal matching funds.

Why this matters: Hospitals are encouraging policymakers focus on solutions that support health care teams and bring more nurses to the bedside.

Hospitals stand ready to partner with the General Assembly and Shapiro administration on strategies that build the health care workforce and bring more nurses to the bedside. This approach will support safe and high-quality care for Pennsylvanians and reduce stress on health care teams.

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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