



## Federal Issues

### Regulatory

#### **Medicare Releases Pricing Information, Billing Guidance for Updated COVID-19 Vaccines**

The Centers for Medicare & Medicaid Services (CMS) [released](#) new information regarding pricing, billing, and coding for updated COVID-19 vaccines.

This follows the Food and Drug Administration's (FDA) September 11 [announcement](#) that it approved and authorized for emergency use updated Moderna and Pfizer-BioNTech COVID-19 monovalent vaccines formulated to more closely target currently circulating variants, and the Centers for Disease Control and Prevention (CDC) September 12 [recommendation](#) that everyone 6 months and older get the updated COVID-19 vaccine. A memo describing these actions can be found [here](#).

**CMS Announcement** : On September 14, CMS [announced](#) new guidance regarding billing and coding in relation to last week's FDA and CDC activity. **It also released the [pricing](#) for the vaccine product. CMS confirmed the federal government is not purchasing these products**

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and Medicare Part B pays for the drug and its administration under the applicable Medicare Part B payment policy.

Effective September 11, 2023, Medicare will use six new CPT codes, developed and approved by the AMA CPT Panel describing updated COVID-19 vaccine products and administration.

**The six product codes, Medicare payment allowances, and effective dates are:**

<b>Code/Description</b>	<b>Medicare Payment Allowance</b>	<b>Effective Dates for Medicare Payment</b>
90480 - COVID-19 Vaccine Administration	\$40.00	09/11/2023 - TBD
91318 - COVID-19 Vaccine, 3 mcg/0.2 mL	\$65.36	09/11/2023 - TBD
91319 - COVID-19 Vaccine, 10 mcg	\$87.78	09/11/2023 - TBD
91320 - COVID-19 Vaccine, 30 mcg	\$131.10	09/11/2023 - TBD
91321 - COVID-19 Vaccine, 25 mcg	\$145.92	09/11/2023 - TBD
91322 - COVID-19 Vaccine, 50 mcg	\$145.92	09/11/2023 - TBD

- **Legislation Would Mandate Disclosure of AI in Utilization Review**

### Industry Trends

#### Policy / Market Trends

- **BCBSA/BHI Analysis Found Costs for Common Procedures Significantly Higher in HOPDs**

With this update, CMS also announced that Medicare **will no longer pay for the following CPT codes** that described older COVID-19 vaccine formulations and their administration, **effective September 12:**

- 91312, 91313, 91314, 91315, 91316, 91317, 0121A, 0124A, 0134A, 0141A, 0142A, 0144A, 0151A, 0154A, 0164A, 0171A, 0172A, 0173A, and 0174A

### **CPT Panel Guidance**

To prepare for the updated vaccine formulations, the AMA CPT Panel had already put in place new CPT codes describing updated products and administration services, also announcing a streamlined approach to COVID-19 vaccine administration and product reporting. These codes are generally effective September 11, 2023, per updated AMA guidance, which aligns with CMS' guidance.

On August 14, the CPT Panel [announced](#) it would streamline the reporting of COVID-19 immunizations by consolidating over 50 codes (describing specific products and their administration) down to one vaccine administration code (CPT code 90480) and a limited set of vaccine product codes (91318-91322). It retained the Novavax product code (91304).

### **Vaccine administration services (effective September 11, 2023):**

- Addition of a single administration code (90480) for administration of new and existing COVID-19 vaccine products. This should be used for all vaccine products described below.

### **Vaccine products (effective September 11, 2023):**

- New product codes (91318-91322) to identify monovalent vaccine products (Pfizer, Moderna); and
- Retention of existing Novavax product code (91304) for currently authorized vaccine product available for use in the U.S. and the updated (XBB.1.5) vaccine.

The CPT Panel guides that existing CPT codes that describe COVID-19 vaccine products and associated administration codes that are no longer authorized or are not approved by the FDA will be deleted effective November 1, 2023.

### **Resources:**

- [August CPT Assistant Guidance on New Vaccine Codes](#)
- [AMA CPT COVID-19 CPT Vaccine and Immunization Codes Homepage](#)
- [Category I Immunization Long Code Descriptors](#) (updated Sept. 15, 2023)
- [Category I Immunization Medium Code Descriptors](#) (updated Sept. 15, 2023)
- [Category I Immunization Short Code Descriptors](#) (updated Sept.15, 2023)
- [CMS New Vaccine Announcement](#) (Sept. 14, 2023)

- [CMS Vaccine Payment Allowance and Effective Dates](#) (Sept. 14, 2023)
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## **HHS Issues New Proposed Rule to Strengthen Prohibitions Against Discrimination in Government Health Programs**

The Department of Health and Human Services (HHS) Office of Civil Rights [issued a proposed rule](#), “Discrimination on the Basis of Disability in Health and Human Service Programs or Activities.”

The proposed rule updates, clarifies, and strengthens the implementing regulation for Section 504 of the Rehabilitation Act of 1973 (Section 504), the statute that prohibits discrimination against otherwise qualified individuals on the basis of disability—predating but consistent with the Americans with Disabilities Act mandate which extends beyond recipients of federal funding.

**Why this matters:** The proposed rule covers all health care and human services programs and activities funded by HHS, from hospitals and doctors that accept Medicare or Medicaid to states’ child welfare programs, for example. The proposed rule includes clarifications on obligations to provide services in the most integrated setting that meets a person’s needs, accessibility standards for websites, mobile applications and self-service kiosks, and provisions to ensure that medical treatment decisions are not based on biases and stereotypes about individuals with disabilities.

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## **FDA Updates Emergency Use of COVID-19 Vaccines**

The Food and Drug Administration [updated](#) COVID-19 vaccines to more closely target circulating variants and to provide better protection from hospitalization and death.

**Why this matters:** The FDA updated the formulations of the products that have full FDA approval and updated the formulations of the products which have emergency use authorizations (EUA). The new shots target the XBB.1.5 subvariant of Omicron, following the FDA's June [recommendation](#). The FDA approved new formulations of Comirnaty (Pfizer mRNA vaccine approved for use in people 12 years and older) and Spikevax (Moderna mRNA vaccine approved for use in people 12 years and older) and authorize for emergency use the updated formulations of the Pfizer mRNA vaccine in children 6 months to 11 years and the Moderna mRNA vaccine in children 6 months to 11 years.

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## **ACIP Recommends New COVID-19 Vaccine Formulations**

The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) [voted](#) to recommend that all persons aged 6 months and older receive a dose of a 2023-2024 monovalent COVID-19 vaccine designed to protect against the XBB lineage. CDC Director Mandy Cohen [approved](#) the ACIP recommendation.

The recommendation applies to use of the new formulations of Pfizer and Moderna vaccines. Novavax's updated formulation is still under FDA review, so ACIP did not vote on this vaccine.

**Why this matters:** ACIP discussed whether the recommendations should be broad or apply only to those most at risk, based on age or risk factors. Some ACIP members indicated that risk of severe illness, hospitalization, and death exist for all age groups, with and without risk factors; others noted the risk is not the same across age groups and risk factors. Some ACIP members also raised issues that a risk-based recommendation or one involving shared clinical decision-making could exacerbate equity issues.

At the meeting, drug manufacturers announced the prices of their vaccines for the upcoming season. Pfizer mRNA vaccines will be priced at \$120 per dose, Moderna vaccines will be priced at \$129 per dose, and Novavax vaccines will be priced at \$130 per dose.

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### **AHIP & BCBSA Highlight the Value of Fixed Indemnity Plans**

AHIP & BCBSA submitted [comments](#) on [proposed rules](#) from the Departments of Labor, Health and Human Services, and the Treasury ("the Departments") affecting short-term, limited duration insurance (STLDI) plans and supplemental health insurance benefits. AHIP requested the Departments not finalize the hospital and fixed indemnity rules as proposed.

**Why this matters:** AHIP's comments detail how **finalizing the proposed rules would make supplemental health insurance policies more expensive** while ultimately providing hardworking Americans fewer benefits and less overall value. AHIP & BCBSA instead recommend states remain the primary regulator of these products, focusing on regulatory actions that address improper, misleading, or fraudulent marketing.

AHIP, the American Council of Life Insurers (ACLI), and BCBSA released the results of a [new survey](#) that found millions of American businesses and their employees value the additional protection offered by fixed indemnity and specified disease plans, which cover costs not covered by traditional major medical insurance. AHIP's comments to the Departments underscore the survey's findings that supplemental health benefits are popular, and Americans want to continue to be able to choose these benefits.

However, the proposed rule would deprive hardworking families of existing benefits that are legal, effective, highly valued, and well-liked. AHIP urged the Departments to identify ways to curb the bad actors without regulations that are so broad as to undermine access to affordable, legitimate, and valued supplemental health insurance benefit.

- **Changes to the Tax Treatment of Employment-based Accident and Health Plans:** AHIP's detailed comments also urge the Administration to rescind the proposed changes to the tax treatment of employment-based accident and health plans. They note the tax changes are both a departure from operative statutory language and a significant shift in tax policy that imposes new taxes on working Americans and new burdens on employers.

- **Short-Term Limited Duration Insurance Plans:** On STLDI plans, AHIP’s comments note support for finalizing the proposal to limit STLDI to a coverage expiration date not more than 3 months after the effective date of the final rule and no longer than 4 months in total, including renewals or extensions. AHIP does note how short-term products can help fill gaps in coverage but are not intended to serve as a substitute for long-term, comprehensive health insurance coverage. AHIP’s comments also offer support for the Departments’ proposed changes to improve consumer notice requirements that include prominent display and information directing potential buyers to healthcare.gov, or employer-provided coverage. BCBSA recommended the final rule address Health Care Sharing Ministries by not considering them “insurance” under the Internal Revenue Code. Otherwise, the Departments should work with Congress to regulate these misleading products.
  - **Request for Information Regarding Medical Payment Products:** BCBSA also submitted a comment letter responding to the Consumer Financial Protection Bureau, Department of Treasury, Department of Health and Human Services’ Request for Information (RFI) Regarding Medical Payment Products (MPPs), issued on July 12th. BCBSA urged the Departments to carefully monitor and adopt appropriate standards for regulating medical payment products and their use by health care providers in order to protect patients’ financial well-being.
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## **CMS Issues Quarterly Update to List of Part B Drugs Subject to the Inflation Rebate Program**

CMS issued a [press release](#) updating the list of Part B drugs that will be subject to the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act. For the 34 Part B drugs beneficiary coinsurance may be lower from October 1 through December 31. The [impacted prescription drug list](#) is available in the quarterly ASP public file.

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## **State Issues**

### **New York**

#### Regulatory

### **Medicaid Managed Care Loss Ratio Clarified**

DOH last week clarified that the Medicaid MLR for mainstream Medicaid managed care and MLTC Partial Capitation plans will remain at 86% for FY24, and increase to 89% for the rate year beginning on April 1, 2024 (FY25). Reissued guidance also states that, “the MLR Reporting Period will align with the rating period for each line of business (42 CFR §438.8(b)).” Previously issued guidance mistakenly indicated that the MLR change was effective on April 1, 2023.

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## **COVID-19 Vaccine Coverage**

After last week's federal Food and Drug Administration approval of new COVID vaccines developed by Pfizer and Moderna, Governor Hochul announced that doses of the new vaccinations were on their way to New York – expected to arrive last Friday – and encouraged New Yorkers to get their shots. New York is offering vaccines free of charge to the uninsured through community clinics, county health departments and addiction treatment centers. For those with insurance, there was some initial confusion as some pharmacies were telling customers they might face high copayments because some health plan systems had not yet been updated to process claims for the new vaccines. Vaccines are considered preventive care and, as such, are covered with no copays if they are administered in-network.

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## **State Issues**

### **Pennsylvania**

Legislative

#### **Legislation Would Mandate Disclosure of AI in Utilization Review**

Pennsylvania lawmakers have filed legislation that would require insurers to disclose when artificial intelligence is used during the utilization review process to assess whether a medical treatment service is reasonable and necessary.

**Why this matters:** House Bill 1663 would mandate health insurers disclose to health care providers, covered individuals, and the general public when AI algorithms are used, not used, or will be used in the insurer's utilization review process.

Insurance companies would have to submit the AI algorithms and data sets used in the utilization review process to the state Insurance Department for transparency. Any violation of the requirement would be deemed an unfair method of competition and an unfair deceptive act or practice and could lead to insurer license revocation or even monetary fines.

**Next steps:** The bill was referred to the House Insurance Committee where it awaits action.

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## **Industry Trends**

Policy / Market Trends

### **BCBSA/BHI Analysis Found Costs for Common Procedures Significantly Higher in HOPDs**

Blue Cross Blue Shield Association (BCBSA) and Blue Health Intelligence (BHI) released an [analysis](#) of Blue Cross and Blue Shield claims data that examined the costs of common procedures, like mammograms and colonoscopies, and found that costs were significantly higher when the procedure was performed at a hospital outpatient department versus a physician's office or an ambulatory surgery center. This analysis builds off the *Affordability Solutions for the Health of America* that could save \$767 billion over the next 10 years.

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**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](http://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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