



Federal Issues

Regulatory

CMS Issues Guidance on Part D Flexibilities Related to COVID-19 Oral Antiviral Drugs

On November 23, the Centers for Medicare & Medicaid Services (CMS) issued [guidance](#) for Part D sponsors regarding oral antiviral drugs for COVID-19 that become available under an Emergency Use Authorization (EUA). CMS explains that EUA-approved oral antiviral drugs initially will be procured by the federal government and dispensed free of charge to patients through contracts with certain pharmacies during the public health emergency (PHE). While pharmacies will obtain the drug at no cost, the procurement will not include payment of a dispensing fee.

Under the guidance, CMS will exercise enforcement discretion during the PHE to permit Part D sponsors to pay dispensing fees to pharmacies that submit claims for these drugs. CMS states that it urges Part D sponsors to pay such dispensing fees “to ensure eligible patients can access these drugs at available pharmacies.” Additionally, CMS “encourages sponsors to consider paying a dispensing fee for these drugs

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that may be higher than a sponsor's usual negotiated dispensing fees given the unique circumstances during the PHE." CMS further states that they "encourage plans to consider allowing out-of-network pharmacies to bill for dispensing fees" if it will improve access in certain areas.

Separately, the memorandum addresses prescription drug event (PDE) reporting for any dispensing fees paid by Part D plans.



HHS Releases New Surprise Billing Report, Secretary Becerra Defends Interim Final Rules

A new [report](#) released by the Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) highlights the impacts of surprise billing negotiation and arbitration laws already in effect in 18 different states. The report finds that, in some instances, state approaches to address surprise medical billing have led to increased health care costs, such as New York and New Jersey.

Why this matters: The ASPE report indicates that its findings informed the current federal rulemaking for the *No Surprises Act*. The interim final rules for the No Surprises Act direct that the arbitration process of surprise billing disputes begin with a presumption that the appropriate out-of-network reimbursement is the median contracted rate (the qualified payment amount).

HHS Secretary Xavier Becerra defended the Administration's approach in a recent [interview](#) with Kaiser Health News. When asked about concerns doctor groups and medical associations had over the direction of the current rules, Becerra said, "I don't think when someone is overcharging, that it's going to hurt the overcharger to now have to [accept] a fair price. Those who are overcharging either have to tighten their belt and do it better, or they don't last in the business."

Becerra also pointed to other factors that must be considered during the arbitration process, such as the provider's experience and the complexity of the case. "What we simply did was set up a rule that says, 'Show the evidence,'" he said. "It has to be relevant, material evidence. And let the best person win in that fight in arbitration."

COVID-19 Updates

- On November 26, the World Health Organization [classified](#) the SARS-CoV-2 variant B. 1. 1.529, first identified in South Africa, as a “variant of concern” and named it Omicron. The Centers for Disease Control and Prevention (CDC) issued a [statement](#) following the WHO classification, denoting that they were monitoring the path of the variant closely. President Biden issued a [proclamation](#) for suspension of entry from South Africa and seven other countries.
- On Friday, Merck and Ridgeback Biotherapeutics released the [results](#) of a study of the effectiveness of their COVID-19 antiviral drug molnupiravir. The analysis found that molnupiravir reduced the risk of hospitalization or death among high-risk patients by about 30 percent, down from 48 percent in an [earlier](#) analysis. The Food and Drug Administration is scheduled to [meet](#) November 30 to determine whether to provide emergency use authorization (EUA) to the drug. The Centers for Medicare & Medicaid Services (CMS) issued a [memo](#) last week to Part D plans regarding payment of dispensing fees to pharmacies if EUA is granted for oral antiviral therapeutics during the COVID-19 public health emergency.

State Issues

New York

Regulatory

Hospital Capacity Order

On Friday, Governor Kathy Hochul signed an Executive Order allowing the Department of Health (DOH) to limit non-essential, non-urgent procedures for in-hospitals or systems with limited capacity to protect access to critical health care services. Limited capacity is defined as below 10% staffed bed capacity, or as determined by DOH based on regional and health care utilization factors.

The new protocols will begin on Friday, December 3, and will be re-assessed based on the latest COVID-19 data on January 15. The Executive Order will also enable New York State to acquire more quickly any critical supplies to combat the pandemic.

Hospital Staffing Executive Order Extended

On November 26, Governor Hochul extended Executive Order 4, continuing the declaration of a statewide disaster emergency due to health care staffing shortages until December 26, which continues the requirement that plans suspend certain utilization review requirements and appeal time frames for institutions that submit a certification.

Industry Trends

Policy / Market Trends

CMS Releases Enrollment Snapshot for Week Three of Open Enrollment

The Centers for Medicare & Medicaid Services (CMS) [announced](#) that over 810,000 people selected individual market plans during the third week (November 14-20) of the 2022 Open Enrollment Period. To date, nearly 2,435,000 people have selected individual market plans in the 33 states that utilize the HealthCare.gov platform. Importantly, these numbers remain on par with last year's [2021 Open Enrollment Period](#).

Compared to last year's HealthCare.gov snapshot, 2022 Open Enrollment selection has increased by 6.8% for the same week (Week 3). In addition, for 2022, three states that transitioned to state-based marketplaces (Kentucky, Maine, and New Mexico), 2.1 million people signed up for health coverage during the 2021 Special Enrollment Period.

Consumers generally need to choose a plan by December 15, 2021 for their coverage to start January 1, 2022. To view this week's report, please [click here](#).

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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