



Issues for the week ending November 4, 2022

Federal Issues

Legislative

Senate Finance Committee Issues Report on MA Marketing Activities

Senate Finance Committee Democrats have published a [report](#) summarizing their findings on marketing practices for Medicare Advantage (MA) plans. The report follows an inquiry into deceptive marketing practices launched by Chairman Ron Wyden (D-OR) in August, and it includes information provided by 14 states. According to the report, the investigation “found evidence that beneficiaries are being inundated with aggressive marketing tactics as well as false and misleading information.”

The report calls for action from the Center for Medicare and Medicaid Services (CMS) in four areas:

- Reinstate MA plan requirements loosened during the Trump Administration.
- Monitor MA disenrollment patterns and use enforcement authority to hold bad actors accountable.
- Require agents and brokers to adhere to best practices.

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- Implement robust rules around MA marketing materials and close regulatory loopholes that allow cold-calling.

- **General Assembly Finalizes Several Health Care Priorities as Legislative Session Winds Down**

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- **Independent Regulatory Review Commission Approves the Commonwealth's Medical Marijuana Program**

Senate Intelligence Chair Releases Cybersecurity Policy Paper

Sen. Mark Warner (D-VA), the Chairman of the Senate Select Committee on Intelligence, has [released](#) a policy options paper entitled, "[Cybersecurity is Patient Safety.](#)"

Why This Matters: The paper is intended to outline the potential cyber threats facing the health sector and solutions for improving cybersecurity across the industry.

The white paper includes the following:

- Areas that the federal government should address to improve national cybersecurity risk posture in the health care sector, including key challenges, current cybersecurity threats, and policy options for "shoring up" existing vulnerabilities.
- Ways that the federal government can help the private sector meet threats through potential mandates and voluntary incentives to adopt best practices.
- Policies that could help health care providers respond to attacks in the event of a cybersecurity failure and ways institutions can recover following successful cyberattacks.

Public comments in response to the paper are being accepted until Thursday, December 1, 2022.

Federal Issues

Regulatory

CDC Issues 2022 Clinical Practice Guideline for Prescribing Opioids for Pain

The Centers for Disease Control and Prevention (CDC) released updated and expanded [recommendations](#) for clinicians providing pain care for adult outpatients with short- and long-term pain.

According to the CDC, the 2022 Clinical Practice Guideline addresses the following areas:

- Determining whether to initiate opioids for pain;
- Selecting opioids and determining opioid dosages;
- Deciding duration of initial opioid prescription and conducting follow-up; and,
- Assessing risk and addressing potential harms of opioid use.

The CDC noted the guideline is voluntary and provides flexibility to clinicians and patients to support individualized, patient-centered care. The agency stated the recommendations “should not be used as an inflexible, one-size-fits-all policy or law or applied as a rigid standard of care or to replace clinical judgement about personalized treatment.”

Why This Matters: Millions of Americans suffer from opioid addiction. Promotion of evidence-based guidelines, such as the CDC guideline, are an integral part of the solution to the opioid epidemic.

HHS Renews Monkeypox Public Health Emergency

HHS has [renewed](#) the public health emergency (PHE) for the monkeypox outbreak for an additional 90 days. The PHE is now set to expire on January 31, 2023. HHS Secretary Xavier Becerra cited the “continued consequences of an outbreak of monkeypox cases across multiple states” as well as a “consultation with public health officials” for the decision to renew the PHE.

Cross-Sector Cybersecurity Performance Goals Released

The U.S. Department of Homeland Security, Cybersecurity & Infrastructure Security Agency (CISA) released [Cross-Sector Cybersecurity Performance Goals](#) (CPG) to provide for more consistency and a common set of practices for organizations that are part of the national critical infrastructure. The goals are intended as a benchmark to measure and improve their cybersecurity maturity.

CISA describes the CPGs as helpful for small- and medium-sized organizations to “kickstart” their cybersecurity efforts. Specifically, the Goals are:

- **Voluntary:** There are no new authorities to adopt the goals, nor do they provide for any reporting to any government agency.
- **Not Comprehensive:** The goals are neither comprehensive nor exhaustive; they do not identify all the cybersecurity practices needed to protect national and economic security and public health and safety. Rather, the CPGs capture a core set of cybersecurity practices that effectively reduce risk and are broadly applicable across sectors.
- **In Alignment with NIST:** The goals are intended to supplement [NIST’s Cybersecurity Framework \(CSF\)](#) and recommend an “abridged subset of actions” (i.e., described by CISA as a “QuickStart guide”) for the NIST CSF.

A series of Frequently Asked Questions (FAQs) are also available on the [CISA website](#). CISA is expected to provide more information on sector-specific goals in the coming weeks.

CMS Finalizes Two Medicare Payment Rules; Delays Retro 340B Payments to 2023 Rule

On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released two final rules updating Medicare payment policies and quality reporting requirements that generally apply starting January 1, 2023.

- First, CMS [finalized](#) Medicare payment rates for hospital outpatient and ambulatory surgical center (ASC) services for calendar year (CY) 2023 under the Hospital Outpatient Prospective Payment System (OPPS) final rule.

- Second, CMS [issued](#) the Physician Fee Schedule (PFS) final rule for CY 2023, which provides updates to physician payment rates and policies.

2023 OPPS Final Rule

In addition to updating Medicare payment rates for outpatient hospital departments and ASCs, the [CY 2023 OPPS rule](#) finalizes adoption of a new Medicare provider type for rural emergency hospitals, expansion of coverage for behavioral health services, and revision to quality measure reporting.

340B: Of note, CMS also finalized changes to the formula it uses to reimburse drugs purchased under the 340B program. CMS modified this formula in 2018 by reducing the payment rate, however, the Supreme Court held in June 2022 that this formula was unlawful. As a result, for 2023, CMS finalized a payment rate of average sales price (ASP) plus 6%, which is consistent with the Medicare policy for drugs not acquired through the 340B program and with the formula used prior to 2018. CMS will offset the increased rate applicable to 2023 claims by implementing an across the board –3.09% reduction to the payment rates for non-drug services. **CMS forecasted that it will publish rulemaking addressing potential remedies for the shortfalls during the 2018-2022 period sometime in 2023** in advance of the annual OPPS payment rule.

2023 PFS Final Rule

The [CY 2023 PFS final rule](#) includes updates and policy changes for payments under Medicare Part B, effective on or after January 1, 2023. The CY 2023 PFS conversion factor will decrease by \$1.55, meaning, physicians will generally see lower rates.

CMS also finalized a number of policies related to Medicare telehealth services, including making several services that are temporarily available as telehealth services during the PHE available at least through CY 2023.

Additionally, CMS updated several policies related to fee-for-service Medicare payment for dental services. Effective for CY 2023, CMS 1) finalized the proposal to clarify and codify when dental services are integral to treatment of a primary medical condition and thus covered, and 2) other clinical scenarios under which Medicare Part A and Part B payment can be made for dental services, such as dental exams and necessary treatments prior to, or contemporaneously with, organ transplants, cardiac valve replacements, and valvuloplasty procedures.

CMS Releases Tip Sheet for Special Enrollment Period

CMS released an updated tip sheet on the Special Enrollment Period (SEP) opportunity for low-income consumers at or below 150% of the Federal Poverty Level (FPL). The 150% FPL SEP is available to consumers who have applied for Marketplace coverage since Plan Year 2022 Open Enrollment ended and who didn't have access to another SEP from a recent life event, such as a loss of coverage, and will enable eligible consumers to enroll in a Marketplace plan. Eligible consumers can access this SEP until December 31, 2025. The tip sheet can be found [here](#).

CMS Releases Updated Medicaid and CHIP COVID-19 Data Snapshot

CMS released an update to the Medicaid and Children's Health Insurance Program (CHIP) COVID-19 data snapshot, which includes data through April 2022. Based on an analysis of T-MSIS submissions between March 2020 and April 2022, over 130 million Americans were enrolled in Medicaid or CHIP for at least one day during the public health emergency (PHE). 10.2 million Medicaid and CHIP beneficiaries were treated for COVID-19 during this period, and over 3 million of these individuals were under the age of 19. Medicaid and CHIP paid for nearly 85.5 million COVID-19 tests.

Why This Matters: The snapshot also provides insight into how non-COVID care patterns in Medicaid changed during the PHE. Preliminary data shows that the vaccination rate for all vaccines among beneficiaries under age 19 declined during the PHE period compared to averages from prior years, with the largest rate decreases seen in Hepatitis A, HPV and Influenza vaccinations. [Read More](#)

CMS to Pilot Direct Assister to Consumer Outreach as HealthCare.gov Enrollment Begins

CMS recently announced a new and innovative pilot to allow Navigators in certain Federal Exchange counties to reach out to consumers who may lose or have lost Medicaid or CHIP coverage.

Why This Matters: The pilot is in response to the expected coverage losses (as much as 15 million) expected from the future expiration of the COVID-19 public health emergency and the continuous coverage requirement on Medicaid agencies that comes along with the PHE declaration. The outreach effort will consist of a series of letters sent by HealthCare.gov during the open enrollment period underway as well as direct contacts (presumably, including unsolicited contact) in Maricopa County, Arizona; Miami-Dade, Broward, Hillsborough, and Orange Counties, Florida; and Mecklenburg and Guilford Counties, North Carolina.

CMS also announced that four out of five customers will be able to find plans for \$10 or less per month after tax credits, citing record affordability and competition due in large part to subsidies. A link to the press release can be found [here](#). Additionally, the final rates for marketplace plans were posted and can be found [here](#).

State Issues

Pennsylvania

Legislative

General Assembly Finalizes Several Health Care Priorities as Legislative Session Winds Down

The General Assembly last week finalized several hospital priorities and insurance related bills on what was the final session day scheduled before the General Election and likely one of the last voting days of the 2021–2022 legislative session.

[Senate Bill 225](#), sponsored by Senator Kristin Phillips-Hill (R-York), got final approval by the House and Senate. Governor Tom Wolf signed the bill into law on November 3 – now Act 146 of 2022. The bill reforms the prior authorization process to expedite approval of patient care and reduce administrative burdens for hospitals, physicians, and other health care providers.

Specifically, the legislation:

- Defines terms for the prior authorization process for all commercial insurers, including the state's Medicaid and Children's Health Insurance Program (CHIP) managed care plans
- Affirms that emergency treatment is not subject to prior authorization
- Requires insurers publish a list of all services and drugs that require prior authorization, as well as the criteria used to approve or deny coverage
- Establishes defined timeframes for insurers to respond to prior authorization requests and for providers to submit additional information
- Requires written documentation with specific reasons for denial decisions and instructions for how patients can appeal
- Sets minimum requirements for FDA-approved opioid use disorder treatments that must be available without prior authorization
- Creates a process where patients and physicians can request exceptions from step-therapy programs
- Outlines the sharing of electronic documents between the patient, physician, and insurer which continues to protect privacy of electronic medical records
- Effect dates: Section 2153 – Provider Portal: 18 months following January 1, 2023; The remainder of the sections: January 1, 2024

[House Bill 1630](#), sponsored by Representative Jonathan Fritz (R-Wayne), allows the state auditor general to review Medicaid managed care organizations' subcontracts with pharmacy benefit managers. Governor Wolf signed the bill into law on October 28 – now Act 98 of 2022.

[House Bill 2293](#), sponsored by Representative Timothy Bonner (R-Mercer), provides oversight of agencies that provide temporary staffing for long-term care providers. Governor Wolf signed the bill into law on November 3 – now Act 128 of 2022.

[Senate Bill 1201](#) (Pittman, R-Indiana) provides coverage of prescription eye drops refills if the refill is requested:

- Between 21 and 30 days after the original date for 30-day supplies or after the insured received the most recent refill;
- Between 42 and 60 days after the original date for 60-day supplies or after the insured received the most recent refill; and
- Between 63 and 90 days after the original date for 90-day supplies or after the insured received the most recent refill.

Senate Bill 1201 is Act 162 of 2022.

- [Senate Bill 522](#) (Baker, R-Luzerne) ensures pregnant women and children receive blood testing to detect lead poisoning and requires applicable insurance policies cover blood lead tests.

Senate Bill 522 is Act 150 of 2022.

Behavioral health: With few session days left, lawmakers are not expected to pass legislation acting on the blue-ribbon commission recommendations for spending the \$100 million in one-time, federal funding that was set aside in the state budget to support adult behavioral health care. However, all parties involved

remain committed to the investment and will work with lawmakers and the next governor in the new year to support Pennsylvanians' mental health.

Both chambers are slated to return the week of November 14 for their last scheduled session days before the year ends and a new legislative session begins.

Regulatory

Independent Regulatory Review Commission Approves the Commonwealth's Medical Marijuana Program

The Independent Regulatory Review Commission (IRRC) voted 4-0 on Oct. 20 to approve final regulations for the state's six-year-old medical marijuana program.

Background: Pennsylvania legalized medical marijuana in 2016 and the first dispensaries opened in 2018. Under the law, Pennsylvania residents who have a serious medical condition as certified by an approved physician are considered medical marijuana patients. Patients register for an ID card and use that card to obtain medical marijuana at Pennsylvania dispensaries.

On February 16, 2021, the IRRC received Proposed Regulation No. 1-219 (#3290) from the Department of Health (Department). The proposed regulation was published in the March 6, 2021 *Pennsylvania Bulletin* with a public comment period ending on April 5, 2021. The final-form regulation was submitted to the Commission on September 19, 2022. This regulation implements the state's medical marijuana program, replacing the current temporary regulations with permanent regulations as of October 20, 2022.

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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