March 17, 2023

Welcome to "Washington Update," the weekly e-newsletter on the latest health care happenings in the nation's capital that affect APG's members.

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APG Submits Comment Letter to CMS on Prior Authorization Proposed Rule

APG this week largely endorsed a proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) to streamline prior authorization of health care products and services through the electronic exchange of health care data.

The proposed rule, issued last December, would impose new and reworked prior authorization requirements for "impacted providers," including Medicare Advantage plans, state Medicaid and Children's Health Insurance Program (CHIP) Fee-for-Service programs, Medicaid managed care plans and CHIP managed care entities, and Qualified Health Plan issuers on the Federally Facilitated Exchanges.

In its comment letter, APG welcomed CMS's plan to replace multiple payers' rules and processes with consistent information exchange requirements across multiple payers. APG also recommended that CMS and other government agencies undertake the following steps:

- Require prior authorization decisions no sooner than within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests. If CMS moves instead to require turnaround within five days, these should be normal business days (i.e., weekdays), not calendar days, to reduce the administrative and cost burden on providers.

- Ensure that patients can use a planned patient-specific application program interface (API) to follow prior authorization decisions by measuring the number and share of patients who experience barriers accessing, or problems utilizing, information through the API.

APG also responded to specific CMS requests on several unrelated matters, such as the adoption of standards related to social risk factor data and improving the electronic exchange of information in the Medicare fee-for-service system (which is generally subject to very little prior authorization). APG recommended that CMS continue to refine and test the use of multiple sources of standardized data on social risk factors, and that it facilitates the exchange of information by more providers participating in fee-for-service Medicare by expanding the adoption of health IT beyond those providers that benefited from federal incentives in the American Reinvestment and Recovery Act (ARRA).

The timing of the final publication of CMS's proposed rule is uncertain but is generally expected to follow within a year.

Lawmakers Press Biden Health Officials for Answers on Medicare Advantage Rate Notice

Republican members of the Senate Finance Committee warned federal health officials this week that overhauling the risk adjustment model in Medicare Advantage "could trigger severe and unintended consequences for seniors." They also asked for detailed calculations behind the overhaul plans that were missing from the proposals initially put forward by the CMS in February.

Similar letters now circulating in the House—primarily from Republicans on the influential Ways and Means and Energy and Commerce committees—are also

raising concerns about CMS's proposals. In addition, two House Democrats from Florida, Rep. Darren Soto and Rep. Jared Moskowitz, wrote to CMS Administrator Chiquita Brooks-LaSure, arguing that the proposed changes could adversely affect seniors in marginalized and underserved communities.

The letters preview a potential line of questioning that Health and Human Services Department Secretary Xavier Becerra may face when he testifies about Biden administration budget proposals over the next two weeks. The secretary is scheduled to appear before the Senate Finance panel on March 22, and the Energy and Commerce committee on March 29. The Ways and Means Committee has not yet scheduled its budget hearing.

APG will continue to work with these committees in advance of the hearings to ensure that they are kept abreast of any new analyses that support APG's request to revamp or delay implementation of CMS's proposals.

FDA Announces Wind-Down, Withdrawal of COVID-19 Guidance and Policies

The Food and Drug Administration (FDA) will begin winding down COVID-19 related guidance and policies as the end of the federal public health emergency (PHE) approaches on May 11. APG's provider groups will want to be alert to implications of the changes that could affect patient care.

Among the 22 elements of guidance that the agency plans to withdraw are the following:

- Allowing outsourcing facilities and pharmacies to compound drugs needed to treat hospitalized COVID-19 patients;
- Allowing manufacturers to mail prescription drug samples directly to patients' homes at the request of a health care provider, to facilitate medication access for patients who normally get samples from their doctors;
- Requiring manufacturers to notify the agency of any significant disruption in the medical device supply chain during a PHE.

An additional 22 policies identified by FDA will stay in effect through November 7, 180 days after the expiration of the PHE. These provisions include FDA's policy not to pursue regulatory action over the distribution of unapproved computerized behavioral therapy and other digital health devices during the coronavirus pandemic, as well as its policy to allow the distribution and use of personal protective equipment that does not meet regulatory requirements under certain circumstances.

Also included in the announcement were 24 COVID-19-related aspects of guidance that FDA will revise but retain after the PHE ends, including a provision that COVID-19 vaccines should demonstrate at least 50% efficacy in placebo-controlled trials.

MACPAC Releases March 2023 Report to Congress

The Medicaid and CHIP Payment and Access Commission (MACPAC) recommended steps to improve the collection of race and ethnicity data from Medicaid applicants and to allow states to follow Medicare drug coverage decisions in its March 2023 Report to Congress released this week. The data-collection recommendations are aimed at collecting more accurate information on race and ethnicity from Medicaid applicants. The drug-coverage recommendations call for a legal change to allow states to follow "coverage with evidence development" provisions incorporated into any Medicare National Coverage Determinations pertaining to outpatient prescription drugs. MACPAC's report said that the latter recommendation would provide further encouragement to drug manufacturers to develop evidence of a drug's effectiveness in a timely manner.

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