CMS Issues Contract Year 2021 and 2022 Medicare Advantage and Part D Proposed Rule

CMS issued a proposed rule last month updating the Medicare Advantage and Part D programs. The proposed rule implements many of the programmatic changes resulting from recently passed legislation including the Bipartisan Budget Act of 2018, the 21st Century Cures Act, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. CMS proposed allowing Part D plan sponsors to establish a second, "preferred" specialty tier with lower cost sharing, and that each Part D plan implement a beneficiary real-time benefit tool that would allow plan enrollees to view real-time formulary and benefit information. CMS also proposed requiring plan sponsors to disclose to the agency the measures used to evaluate pharmacy performance in plan network agreements, a new disclosure requirement that will allow CMS to track how plans are measuring pharmacy performance and to publicly report this information to increase transparency. Read AMCP's summary of the proposed rule.

AMCP Members: On Monday, March 23, AMCP will hold a free webinar on CMS' proposed rule. In addition, AMCP is seeking feedback on the proposed rule to inform our formal comments. Please email your feedback to advocacy@amcp.org by April 3.

Eye on Washington

AMCP Shares CMS Resources for COVID-19 Response

CMS has issued preliminary guidelines for Medicare Part D plans on the handling of prescription drug supplies in response to the coronavirus outbreak. AMCP is following these developments, and will share these resources with our members as we become aware of them.

Senators Reintroduce Bill to Amend

Advocacy Tip

Stay up-to-date: Read AMCP's Letters, Statements and Analysis on all legislation and regulation impacting managed care pharmacy.

Medical Record Privacy

Sens. Joe Manchin (D-W.Va.) and Shelley Moore Capito (R-W.Va.) reintroduced the Protecting Jessica Grubb's Legacy Act on March 3, which would change existing privacy regulations, known as 42 CFR Part 2, surrounding medical records for those with substance use disorder. The bill aims to help ensure those in recovery are not accidentally prescribed opioids. 42 CFR Part 2 regulations protect the privacy of the medical records of patients with substance use disorder by prohibiting unauthorized disclosures of patient records, particularly by treatment centers and other third parties, except in limited circumstances. The proposed legislation would allow patients to opt-in to sharing their addiction medical records with additional health care providers for the purposes of treatment, payment, and health care operations. Patients would still be in control of their addiction treatment records and could rescind their consent to share. The legislation would also align the 42 CFR Part 2 regulations with current HIPAA requirements. Meanwhile, a final rule from the Substance Abuse and Mental Health Service Administration's (SAMHSA) to modernize 42 CFR Part 2 is under review by the Office of Management and Budget.

AMCP's Position: We support efforts to amend 42 CFR Part 2 to help combat the opioid epidemic and provide patients with more control over their health records. While we support SAMHSA's rule, we have called for legislation to fully bring the sharing of substance use records into the 21st century. Read about Protecting Jessica Grubb's Legacy Act

AMCP Submits Comments on Drug Importation Proposals

AMCP this month joined other national pharmacy groups in opposing the FDA's December 2019 proposed rule that would allow wholesale importation of prescription drugs from Canada. In a March 9 joint comment letter, AMCP and the other groups said drug importation poses risks to patients and would not likely produce meaningful cost savings. The pharmacy groups will continue to engage with FDA and other policymakers to identify policy solutions to reduce drug prices without risking public health and safety. Read AMCP's position statement on prescription drug importation.

CMS and ONC Release Final Rule on Interoperability

CMS and the Office of the National Coordinator for Health IT (ONC) released final rules on interoperability and patient access to electronic health records on March 9. The final rules allows patients to access and download their electronic medical records through third-party apps and establish secure, standards-based application programming interface (API) requirements to support a patient's control of their electronic health information. The ONC rule also identifies and finalizes the "reasonable and necessary" activities that do not constitute information blocking and establishes new rules to prevent information blocking practices by health care providers, developers of certified health IT, health information exchanges, and health information networks. ONC finalized an update to the electronic prescribing NCPDP SCRIPT standard, from standard version 10.6 to standard version 2017071, an update AMCP expressed support of in our comments on the proposed version of this rule. Learn more about the final rules.

FDA Releases Two Biologics Guidance Documents

FDA recently released two guidance documents related to biologics and biosimilars: (1) Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products – Questions and Answers, which details answers to questions that manufacturers may have when developing promotional materials and advertisements for biological reference products and biosimilar products, and (2) The "Deemed To Be a License" Provision of the BPCI Act, a final guidance offering information on the transition of certain new drug applications (NDAs) which are statutorily required to be converted to biologics license applications (BLAs) on March 23.

AMCP Members: AMCP is seeking feedback on the draft guidance on promotional labeling and advertising to inform our formal comments. Please email your feedback to advocacy@amcp.org by April 1.

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