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Federal Court Limits Copay Accumulators

- On October 3, a federal judge ruled against a government policy that allowed copay accumulators. These policies restrict a patient's drug manufacturer copay assistance funds from being counted towards their yearly deductible. The regulation will now allow insurers to only use copay accumulators when there is a generic equivalent for the branded drug. Pharmaceutical companies may offer programs that give patients copay assistance cards to cover their direct out-of-pocket costs. This amount may count towards their deductible and allow them to reach their out-of-pocket maximum faster. After a patient reaches their cost sharing maximum, services covered by the insurer are either paid in full or paid at a higher rate. Patient advocacy groups supported the decision which ultimately lowers the out-of-pocket costs for patients using high-cost drugs to treat conditions such as cancer or auto-immune disorders. Proponents of copay accumulators on the other hand argue that copay assistance pushes patients toward higher cost drug options and increase total healthcare costs, resulting in higher insurance premiums. About 20 states have enacted laws that prohibit insurers from using copay accumulators.

CMMI Preparing New Value-based Care Models

- In September, the Director of the CMS Innovation Center (CMMI), Liz Fowler, discussed agency plans for new models in behavioral health and maternal health. In an open forum, she confirmed that both models will have a large role in Medicaid. Behavioral health access has been a priority for the current administration while poor maternal health outcomes are an ongoing issue in the US, especially for black women. The agency is also exploring different ways to increase its value-based care offerings in specialty care, and recently opened a Request for Information (RFI) for stakeholder feedback on how to administer future episode-based payment models. As part of CMMI's Strategic Refresh, the agency is exploring how to enhance data sharing with primary care practices to help them manage spending on specialty care. CMMI currently has an ambitious target of including every traditional Medicare beneficiary in a value-based care model by 2030. It is also working to improve health equity and data integrity in its programs. Despite these goals, funding for new models may be complicated by federal government budget negotiations.

Senators Announce Legislation on Primary Care and Facility Fees

- In September, Senators Bernie Sanders (D-VT) and Roger Marshall (R-KS) announced a bipartisan legislative proposal to increase primary care funding programs. Funding would be allocated to graduate medical education teaching centers, community health centers, loan repayments, scholarships for healthcare providers in underserved areas, rural residency programs, and primary care and nurse training programs. The increases would be paid for by making multiple site of care payment reforms: banning anticompetitive hospital contracting practices, requiring a separate NPI for off-campus hospital outpatient departments, and restricting the scope of facility fee payments. The bill would bolster support for primary care and disease prevention while also making changes to site-neutral payment reforms which have recently gained bipartisan support. Right now Congress is currently focused on selecting a replacement for the House leadership position and the current budget deadline for the federal government of November 17. These priorities will likely limit the ability of Congress to pass meaningful healthcare reforms in the 2023 legislative session.

FDA Warns Brand-Name Drug Manufacturers on Improper Patent Listing

- On September 14, the Federal Trade Commission (FTC) released a statement regarding legal enforcement for illegitimate patent listings in the FDA "Orange Book." The patents listed in the Orange Book outline drug formulas and their method of use and allow generic manufacturers to navigate patent infringement. The FTC then describes the legal framework for generic drug approvals and the certification process for patents related to each drug in their statement. Drug manufacturers can file an infringement lawsuit for generic drugs that may be in violation of any Orange Book patent listings which typically lasts for 30 months – regardless of the claims' merit. The FTC notes that some brand-name pharmaceutical patent listings in the Orange Book do not meet regulatory requirements which has contributed to anti-competitive drug markets since the late 1990s. The FTC then describes how this practice constitutes a violation of fair-trade practices such as monopolization and will increase scrutiny and enforcement of proper Orange Book patent listings.

North Carolina Expands Medicaid Program

- On September 25, NC passed legislation that expanded the eligibility of their Medicaid program to adults with incomes up to 138% of the federal poverty level ($20,120 per year for a single adults). This makes NC the 41st state to expand their program because of enhanced federal matching for the program in the first 2 years of expansion. The federal government now covers 90% of the costs for the Medicaid expansion population and an additional 5% in the first 2 years of implementation. This change is expected to provide coverage to 600,000 state residents and can help support rural hospitals and improve state-wide health outcomes. The expansion will launch on December 1. Unlike other states that have expanded through programs by popular votes on ballot initiatives, NC's primarily Republican legislature chose to expand the program by making a deal that funds the program through an assessment tax on hospitals in exchange for relaxing certificate of need requirements for new facilities.

Other Policy News:

- The American Medical Association comments on CMS Physician payment rule, criticizing budget neutrality and burden of changes to MIPS
- PBMs continue to favor Humira over cheaper biosimilars now on the market
- Researchers highlight implications of generic drug limited supply agreements on Medicare price negotiations
- Supreme Court to hear cases on the regulatory power of federal agencies that could affect healthcare rulemaking
- CMS reminds both marriage and family therapists and mental health counselors that they will become eligible for Medicare reimbursement beginning in 2024
- New data released by CMS highlights the wait times in emergency rooms across all 50 states