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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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Congress Eyes Increased Transparency in Physician Group Ownership

Physician practices and hospitals would be required to report in-depth data on mergers, acquisitions, and general ownership structures under draft legislation now being considered in Congress. The move is part of a broader Congressional push for transparency across the U.S. health care system and stems from bipartisan concerns over broader consolidation trends in health care. It could add a layer of burdensome reporting requirements on top of what physicians and health systems already report annually to federal agencies.

Under the draft legislation, physician practices of more than 25 practicing doctors—including those owned by health plans, hospitals, private equity groups, and venture capital firms—would be required to report details on the business structure of their parent companies beginning on Jan. 1, 2024. Starting in 2025, the U.S. Department of Health and Human Services would make the data public, including changes in ownership or tax status and analysis of consolidation trends. Entities that failed to report could face civil monetary penalties of up to $5 million. Hospitals would face even more reporting requirements.

The legislative effort is being driven by the House Energy and Commerce Committee but also has champions in the Senate. APG, through feedback from its membership, will help to inform the legislative process.

Generic Drug Shortages Come Under White House, Congressional Scrutiny

Both the Biden Administration and Congress are seeking to address the disparate drivers of drug shortages and increase the availability and quality of generic drugs now in short supply.

White House officials have been meeting since January with a diverse group of stakeholders to create policies to boost the supply of medications. In Congress, the House Energy and Commerce Committee's oversight panel heard this week from witnesses about how myriad problems—ranging from overseas manufacturing to supply-chain gaps—have resulted in a five-year high of generic drug shortages. American Society of Hospital Pharmacists (ASHP), the trade association that represents pharmacy professionals, has identified about 247 active drug shortages, including for the cancer drugs cisplatin and carboplatin as well as medications for ADHD.

The overall complexity of the problem and friction between the White House and the U.S. Food and Drug Administration has slowed the process, according to a Bloomberg News report. APG continues to monitor the issue and will address it during the next Pharmaceutical Care Forum in June and in a series of planned webinars this summer.

Senate Zeroes In on PBM Reform as Key Panel Advances Legislation

Changes and greater transparency would be required in drug pricing contracts, and pharmacy benefit managers (PBMs) would have to pass price discounts along to employers and consumers, under legislation advanced this week by the Senate Committee on Health, Education, Labor & Pensions (HELP).

The closely watched legislation, dubbed the Pharmacy Benefit Manager Reform Act (S. 1339), cleared the HELP Committee on a bipartisan, 18-3 vote, with Republican Sens. Rand Paul (R-KY), Susan Collins (R-ME), and Mitt Romney (R-UT) opposing the measure.

PBM practices have been a growing bipartisan and bicameral concern for several years. The Senate Finance Committee is also expected to consider legislation curtailing practices such as spread pricing, in which PBMs charge insurers more for medications than they pay the pharmacy that disperses the medications. The House Committee on Oversight and Accountability has also launched an investigation into the industry.

APG continues to monitor developments and determine any potential effects on APG members.

House GOP Members Quarrel with CMS Innovation Center

House Republicans who've long decried the existence of CMS's Center for Medicare and Medicaid Innovation (CMMI) have zeroed in on another target: A CMMI model aimed at spurring pharmaceutical manufacturers to complete trials for drugs approved by the FDA under accelerated pathways.

The so-called Accelerating Clinical Evidence Model was unveiled last February by CMMI as part of a Biden administration suite of policies to lower drug prices. It would adjust Medicare Part B payments for drugs if manufacturers did not complete trials that confirmed early evidence of drugs' efficacy used as the basis for FDA approval.

CMMI says the model would ultimately enhance drug availability by giving public and private payers greater confidence in a drug's effectiveness, and sooner. But Republicans on the House Ways & Means health subcommittee contend it will harm pharmaceutical innovation and are calling for new guardrails over CMMI. Earlier this year, a group of Senate Republicans leveled complaints about the model as well.

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