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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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Calls For National Privacy Standard Renewed In Congressional Hearing

The long-simmering topic of a new national data privacy standard drew renewed bipartisan support this week at the fourth [hearing](#) convened recently by the House Energy and Commerce (E&C) committee – this one by the panel's health subcommittee. But amid ongoing opposition, it remains unclear whether any real momentum to enact new federal legislation will be achieved anytime soon.

Citing concerns about the use of patients' data in health care-related predictive algorithms, Subcommittee Chair Brett Guthrie (R-KY) asked, "How are we ensuring this user data is secure and ensuring that consumers have full control over this information and [it is] not being used or sold without their consent?" Ranking Committee Member Frank Pallone (D-NJ) said he shared the concern, and added that the existing federal health privacy law, HIPAA, isn't adequate to ensure privacy and data security.

Competing Approaches: Multiple bills have been introduced in recent years to establish a new federal data privacy law, including the [American Data Privacy Protection Act](#) (ADPPA), which Pallone and E&C Committee Chair Cathy McMorris Rodgers (R-WA) previously

cosponsored. Meanwhile, five states, led by California, have followed the lead of the European Union (EU) in enacting legislation along the lines of the EU's General Data Protection Regulation, or GDPR. Under that framework's so-called "rights-based" approach, individuals effectively own their personal information and have the legal right to control it. The ADPPA would preempt these state statutes, one of many reasons it has so far stalled.

In October, President Biden issued an [executive order](#) calling on Congress to enact similar new data privacy protections. In the meantime, he also directed federal agencies to take multiple steps to accelerate research in such areas as [cryptographic tools](#) and [digital watermarking](#) and directed the Department of Health and Human Services to develop a strategic plan for responsible deployment of AI in health and health care.



Biden Administration Announces New Efforts To Address Drug Supply Chain Issues

Patients and providers could eventually face fewer challenges accessing needed medications and supplies under new Biden Administration [efforts](#) announced this week to bolster the domestic supply chain for essential medicines. According to the Department of Health and Human Services (HHS), President Biden is set to issue a Presidential Determination broadening the agency's authorities under Title III of the Defense Production Act, which would enable investment in domestic manufacturing of essential medicines, medical countermeasures, and other critical inputs deemed essential to the national defense.

Once the Presidential Determination is issued, HHS says, the department will begin using new authorities and invest \$35 million in domestic production of key starting materials for sterile injectable medicines, such as those used in cancer treatment and anesthesia. HHS and the US Department of Commerce will also assess the US "public health supply chain" – the domestic entities producing medical devices, medical equipment, pharmaceutical products, and other products – to identify and address points of failure.

The announcement comes as roughly 140 drugs and injectables remain subject to [shortages](#) as counted by the Food and Drug Administration (other [sources](#) count roughly 300 shortages), the highest rates in a decade, in large part due to [global supply chain](#) issues. One recent [survey](#) of health system pharmacists showed that nearly one-third of respondents characterized the current state of drug shortages as critical, and 63% characterized them as moderate.



APG Announcements And Offerings

- APG will host an educational webinar on the 2025 Medicare Part C & D Proposed Rule (Monday, December 4 at noon ET; register [here](#)).
- APG will host a focus group to gather members' input for a comment letter on the 2025 Medicare Part C & D Proposed Rule (Tuesday, December 19 at noon ET; APG members can register [here](#)).
- As APG discussed in a webinar on October 4, CMS has introduced a new Making Care Primary Model and has kept the [Request for Applications \(RFA\) portal](#) open for two additional weeks. Applications are now due by Thursday, December 14, 2023.
- As APG discussed in a webinar on October 26, CMS has introduced a new Guiding an Improved Dementia Experience (GUIDE) Model and has opened the [Request for Applications \(RFA\) portal](#). Applications are due by January 30, 2024.



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