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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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#### Table of Contents

- **Senate Panel Targets Drug Shortages in Broader Legislative Package**
- **Legal Challenges Mount for Medicare Drug Price Negotiation**
- **Nursing Home Industry Pushes Back on Minimum Staffing Ratios**

#### **Senate Panel Targets Drug Shortages in Broader Legislative Package**

Pharmaceutical manufacturers would be required to report to federal health agencies at the earliest signs of potential drug shortages under [legislation](#) that cleared the Senate Health, Education, Labor and Pensions (HELP) Committee this week. The new measures, which were included in the bipartisan Pandemic and All-Hazards Preparedness and Response Act, could help alleviate the drug shortages of everything from cancer chemotherapy drugs to ADHD medications that have plagued

APG members and other health care providers in recent months. Overall, drug shortages now stand at a [10-year high](#).

Under the bill, which passed the HELP committee by 17-3, drug manufacturers would be required to notify the U.S. Food and Drug Administration when they encounter increases in demand, restrictions on exportations, or other occurrences that could result in shortages. The legislation would also extend reporting requirements to over-the-counter drugs and require additional reporting on potential supply chain concerns. Separately, the House Energy & Commerce Committee is developing its own framework for addressing drug shortages and may release it as soon as next week.

APG continues to monitor drug shortages and supply chain issues and brief its members on causes. In June, APG held a [Deep Dive Webinar](#) on the topic, “Drug Shortages: The Complex Why and What We Should Do to Mitigate Them.”

### **Legal Challenges Mount for Medicare Drug Price Negotiation**

Pharmaceutical industry lawsuits challenging the [Inflation Reduction Act](#) (IRA) provisions enabling the U.S. government to negotiate prices for some drugs under Medicare Part D appear headed to one place: the U.S. Supreme Court. This week, Johnson & Johnson and Astellas filed separate federal district court lawsuits contending that aspects of the law are unconstitutional – joining Merck, Bristol Myers Squibb, the Chamber of Commerce, and the Pharmaceutical Research and Manufacturers of America (PhRMA), whose recently filed lawsuits also alleged constitutional violations.

The timing is no accident, as the Centers for Medicare & Medicaid Services is scheduled to launch price negotiations soon by releasing the list of 10 top-selling drugs selected as the first candidates. Although the lawsuits’ probable journey through the courts is uncertain, framing the arguments as constitutional is clearly designed to vault the cases eventually to the nation’s highest court. The various cases, for example, invoke violations of the Fifth Amendment’s Takings Clause, which prohibits the government from taking private property for public use without providing just compensation, as well as the Fifth Amendment’s Due Process Clause.

In the meantime, aside from the dispute over price negotiations, other IRA provisions have gone into effect. The IRA has already capped Part D enrollees’ out-of-pocket costs for insulin drugs at \$35 per month and eliminated enrollee cost-sharing for recommended vaccines. In addition, under the Medicare Prescription Drug Inflation Rebates program, drug companies are required to pay rebates for raising prices that outpace inflation on certain Part B drugs--resulting in possible rebates that could lower coinsurance for enrollees in both traditional Medicare and Medicare Advantage. CMS recently [announced](#) that 43 Part B prescription drugs may now be subject to these rebates, potentially lowering coinsurance by between \$1 and \$149 per dose.

APG will hold a special breakout session updating members on the IRA and how it may affect them and their patients on Tuesday, Oct. 31, at its forthcoming Annual Fall Conference in Washington, D.C. Please stay tuned for other conference details, which will be released soon.

### **Nursing Home Industry Pushes Back on Minimum Staffing Ratios**

In the wake of COVID-19, the nation's post-acute care sector faces its own stresses and labor shortages – and value-based care providers increasingly face obstacles in getting their patients admitted to these facilities for timely care. So, it may come as little surprise that nursing home industry groups are pressing the Biden Administration to put the brakes on proposed minimum staffing requirements for skilled nursing facilities (SNFs). CMS is expected to release those requirements later this year, following the administration's 2022 [announcement](#) that such reforms were coming.

Federal law currently [requires](#) Medicare and Medicaid-certified nursing homes to provide 24-hour licensed nursing services “sufficient to meet nursing needs of [their] residents.” They must also utilize the services of a registered professional nurse at least 8 consecutive hours a day, seven days a week. But there is no current set of requirements for overall minimum staffing levels. One approach on the table could require 4.1 hours per resident day of total direct care staffing, including by registered nurses, licensed practical nurses, and nurse assistants. As SNFs struggle to meet even the existing requirements, the industry has [estimated](#) that new minimum standards along these lines could require hiring about 187,000 new nurses and cost the sector \$10 billion annually.

*Washington Update* will report on the release of new minimum staffing standards, when it occurs, and evaluate implications for APG member groups – even as it continues to follow other congressional action on the health care workforce.

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