



NEWS RELEASE

Premier Inc. Recommends FDA, DEA Reforms to Prevent Drug Shortages

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- Changes would provide greater flexibility to respond to surge demands and ensure that needed medications are readily available for patient care.

CHARLOTTE, N.C.--(BUSINESS WIRE)-- **Premier Inc.** (NASDAQ: PINC) today provided the U.S. Food and Drug Administration (FDA) and the U.S. Drug Enforcement Administration (DEA) with a list of reforms and regulatory waivers that the company believes should be extended beyond the COVID-19 pandemic and made permanent thereafter in order to prevent drug shortages.

“During the height of the COVID-19 pandemic, we saw demand for many common pharmaceuticals surge by an average of more than 150 percent,” said Blair Childs, Premier’s Senior Vice President of Public Affairs. “Waivers from the FDA and DEA cleared away cumbersome barriers and helped providers manage surges in demand to avoid drug shortages. Lessons learned during the pandemic response demonstrate that these flexibilities could be implemented safely and were effective in mitigating drug shortages that otherwise could have been detrimental to patient care. The Administration should act on all these recommendations, easing regulatory burden and improving options for patients.”

Specifically, Premier recommends to the FDA that 503B compounding facilities be allowed to continue producing specific drugs that are not on the drug shortage list based on specific criteria, such as a short-term or regional shortages or demand surges for certain dosage strengths and/or packaging sizes. This waiver proved particularly helpful during the pandemic, as it allowed 503B compounders to quickly and seamlessly fill capacity gaps and alleviate spot shortages before they became severe enough to spread nationwide and make it onto the FDA drug shortage list.

Premier also recommends that the FDA permanently abandon the arbitrary geographical limitation known as the “one-mile radius” provision for hospital compounding. This waiver allows hospitals to consolidate pharmacy services into a single hub to preserve personal protective equipment, maximize use of available pharmacy staff and avoid compounding at the patient bedside which can lead to increased rates of medication errors. Moving forward, Premier recommends that the FDA adopt a time-based standard rooted in scientific evidence for sterility and stability of the compounded product.

Also to prevent shortages, temporary increases in controlled substance quotas by the DEA were extremely helpful in preventing shortages for key injectable pain medications and sedation drugs that were already on the FDA drug shortage list and experiencing supply chain fragility. To ensure this issue is permanently resolved, Premier recommends a complete overhaul of the quota allocation process, abandoning quotas based on weight in favor of establishing quotas based on dosage form and differentiating between injectables and solid oral dosage forms. A revised quota allocation process rooted in a data-driven approach will allow the DEA and manufacturers to remain nimble and respond to surge demand in a pandemic, natural disaster or other unforeseen circumstance.

“Drug shortages are complex issues that require a broad array of measures to remediate,” concluded Childs. “While these policy levers will be important tools in our arsenal, they must be complemented by private sector solutions that create the right economic incentives for new market entrants, healthy competition and fair, long-term pricing.”

Recognizing the multi-faceted issues that lead to drug shortages, Premier has a successful record of creating business solutions that remediate the vulnerabilities in the economic model, most recently with the creation of its **ProvideGx®** program in 2019. Built on the backbone of Premier’s 15-year experience creating solutions to shared drug sourcing challenges, ProvideGx provides continuous and affordable access to shortage medications, as well as those in categories that lack competition. **Premier’s drug shortage programs** currently provide members access to more than 150 drugs that are or have been recently designated as shortage drugs. The programs also have successfully resolved national shortages for cysteine hydrochloride, vincristine and sterile water.

About Premier Inc.

Premier Inc. (NASDAQ: PINC) is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 175,000 other providers and organizations to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, N.C., Premier is passionate about transforming American healthcare. Please visit Premier’s news and investor sites on www.premierinc.com; as well as **Twitter**, **Facebook**, **LinkedIn**, **YouTube**, **Instagram** and **Premier’s blog** for more information about the

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