

CONGRESS MUST ACT TO SUPPORT LTC PHARMACIES



DEFINE LONG-TERM CARE PHARMACY IN STATUTE

Without a Federal Statutory Definition, Unintended Consequences Cause Conflicting Regulatory Requirements and Legislation Risks Undermining Patient Care

Issue: Long-term care (LTC) pharmacies provide essential clinical and specialized services to more than two million Americans who live in LTC facilities, assisted living communities, and other community and home settings. Retail and mail order pharmacies typically do not provide this comprehensive array of services. Yet when Congress legislates and administrative agencies regulate, too often the results include conflicting statutory or regulatory obligations for LTC pharmacies that put patients at risk. A statutory definition will allow Congress and regulatory agencies to craft policy solutions that make sense for LTC pharmacies and the patients they serve.

Why is a Definition Needed – Some Examples:

- **Opioid Control Legislation:** In responding to the opioid crisis, Congress developed the Comprehensive Addiction and Recovery Act of 2016 and the SUPPORT Act of 2018. Both bills as introduced included sensible policies for patients living in the community served by retail and mail order pharmacies. These provisions, however, made no sense for patients in LTC facilities and the LTC pharmacies serving them, threatening patient care and imposing undue burdens on LTC pharmacies. If there had been a statutory definition of LTC pharmacy, Congressional legislative counsel would consider sensible modifications to avoid such unintended consequences as legislation was developed. Instead, LTC pharmacies to seek ad hoc changes to bill after introduction, a process only partially successful in recent opioid control legislation. With Congress poised to reauthorize the SUPPORT Act in 2023, now is the time to pass definition legislation to avoid similar problems in the future.
- **FDA Regulation:** In implementing the Drug Quality and Security Act of 2013, the FDA changed its guidance to pharmacies regarding repackaged drugs. The revamped guidance required a patient-specific prescription before the drugs could leave a pharmacy. While sensible for retail or mail order pharmacies living in the community, this change prevented LTC pharmacies placing emergency drugs at a LTC facility, risking patient care and subjecting LTC pharmacies to administrative penalties under Medicare and Medicaid requirements. Since there was no statutory definition of LTC pharmacy, the FDA had no basis on which to ground a formal exception for LTC pharmacies. Instead, the FDA has exercised discretion not to enforce the guidance against LTC pharmacies, an uncomfortable solution too easily changed on agency whim.
- **COVID-19:** Since there was no statutory definition of LTC pharmacy, neither the Trump Administration nor the Biden Administration would allow LTC pharmacies to receive compensation from the Provider Relief Fund since it could not legally differentiate between LTC pharmacies which provide clinical services to patients from retail and mail order pharmacies which do not. As a result, although LTC pharmacies lost substantial revenues due to COVID-19, they did not receive the assistance they deserve and, unlike many other providers, still have not recovered financially.

SOLUTION: Enact a statutory definition of long-term care pharmacy. The 116th Congress and the 117th Congress considered the Long-Term Care Pharmacy Definition Act. The 118th Congress should pass the bill as soon as possible. ■