CONGRESS MUST PASS THE LONG-TERM CARE PHARMACY DEFINITION ACT NOW (S.1574/ H.R.5632)

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

The Issue: Long-term care **(**LTC) pharmacies provide essential patient care services for more than two million Americans who live in long-term care (LTC) facilities, assisted living communities, and other communal and home settings. This care includes a broad range of services not typically provided by other types of pharmacy. Yet, when Congress legislates, when agencies regulate, or even when sub-regulatory guidance is needed, there is no clear statutory definition of "long-term care pharmacy." A statutory definition will allow the Congress, the agencies and others to be able to work with a clear definition, to improve legislation and regulation.

Why is a Definition Needed – Some Examples:

- **Congress:** In 2016, during consideration of the Comprehensive Addiction and Recovery Act, Congress proposed a "lock-in" provision that required Medicare Part D beneficiaries to use the same pharmacy for all prescriptions to limit "doctor shopping." The legislation was never intended to apply to LTC pharmacies (which usually contract with a single pharmacy and serve patients who do not doctor shop) but the lack of a clear LTC pharmacy definition made it very difficult for Congress to implement the exemption. While Congress eventually did so, the experience highlighted the need for a clear definition. This same issue resurfaced in 2018 when LTC pharmacy should have been exempted from some of the pharmacy provisions of the SUPPORT Act. Again, the Congress and Committees struggled to find the language to refer to LTC pharmacies.

- **FDA:** In 2013, Congress passed the Drug Quality and Security Act (DQSA) to strengthen the FDA's supervision of compounded drugs. This legislation required FDA to revise its "Repackaging" guidance. Repackaging is an essential function of LTC pharmacies (to move drugs into specialized compliance packaging). Yet, when working on its Guidance, FDA was advised by CMS that there was no definition of LTC pharmacy for them to use for an exemption. Given the lack of a clear reference, FDA was unable to include the exemption in its Guidance but announced it would exercise "enforcement discretion" for the LTC community. This was an unfortunate result that still has not been resolved. Yet, if a statutory definition had existed, FDA would have been able to appropriately address the issue.

- **COVID:** This absence of a clear definition became an issue during the COVID-19 pandemic as HRSA tried to implement the CARES Act Provider Relief Funding. Without a clear definition, HRSA was unable to include LTC pharmacies in their distribution mechanism, resulting in LTC pharmacies losing access to virtually all rural distributions and in many other instances access to any funds at all, even though the industry experienced an average revenue loss of 11% and 10% higher operating costs as a result of COVID – the very costs the Provider Relief Fund was supposed to cover.

- **CMS:** Although the Part D program has sub-regulatory guidance that it uses to address LTC pharmacy issues, other divisions of CMS who encounter LTC pharmacy care have no definition with which to work. For example, the lack of definition for LTC pharmacy will create unnecessary complexities in addressing patients who need higher levels of pharmacy care through the Home and Community Based Services (HCBS) program.

The Solution: Enact the Long-Term Care Pharmacy Definition Act (S.1574/ H.R.5632). This critical legislation will establish a clear statutory definition of LTC pharmacies—a crucial development that will modernize legislation and regulation and drive regulatory consistency for all federal agencies. Passing this legislation would serve current and future interests of all Americans who need LTC services and support.