NABP
National Association of Boards of Pharmacy

1600 Feehanville Dr
Mount Prospect, IL 60056

1.847.391.4406
help@nabp.pharmacy

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Media Contact: media@nabp.pharmacy

NABP to Develop National Adverse Event Reporting Clearinghouse for Compounded Medications

Association moves to close longstanding gaps in patient-safety tracking infrastructure and federal-state information sharing

MOUNT PROSPECT, IL – The National Association of Boards of Pharmacy® (NABP®) today announced a new initiative to develop a national adverse event reporting clearinghouse for compounded medications. The system will capture reports of patient harm and share that information among state boards of pharmacy and with the US Food and Drug Administration (FDA).

This initiative responds directly to a longstanding gap in the federal adverse event reporting system. Specifically, compounded preparations dispensed by 503A pharmacies fall outside the federal adverse event reporting system mandated by FDA for registered drug manufacturers and 503B outsourcing facilities. When a patient is harmed by a compounded medication from a dispensing pharmacy, no federal requirement ensures that the event is recorded. And, even if an event is voluntarily recorded, there is no central system that allows state boards and FDA to see the adverse report. NABP detailed this gap in its formal comment to the FDA Pharmacy Compounding Advisory Committee (PCAC), which recently convened to review seven peptide substances proposed for compounding under Section 503A.

"When a patient is harmed by a compounded medication, that information too often stays in one state, or never surfaces at all," says Lemrey “Al” Carter, PharmD, MS, RPh, executive director of NABP. "We cannot protect patients from risks regulators cannot see. A national clearinghouse would let the boards of pharmacy and FDA share what each of them learns, so that a harm detected in one state can protect patients in every other state. This is the type of project that NABP is uniquely positioned to conduct and, working with our member boards and the FDA, we intend to champion it."

In its comments to PCAC, NABP described how the recent surge in compounded GLP-1 medications and evolving business models has pushed compounding far past the small-scale, patient-specific model the current regulatory framework was built to support. These structural gaps grow more consequential as compounding volume increases. Other gaps NABP identified include limits on the information that federal and state regulators can share with one another, the absence of supply-chain traceability tools for compounded products, and the difficulty of verifying the bulk substances from which compounded medications are made.

The adverse event reporting clearinghouse is the first and most direct response to these gaps, and it is designed to strengthen the flow of safety information to eliminate weaknesses that sustain these gaps. In addition, NABP and its member boards intend to pursue a coordinated set of patient-safety measures:

- working with FDA to expand real-time information sharing within existing legal authority,
- developing model standards for verifying bulk drug substances used in compounding, and
- building coordinated referral pathways among boards of pharmacy, state medical boards, and state attorneys general for cases that cross jurisdictional lines.

In the coming months, the Association will convene boards of pharmacy, FDA, and other industry stakeholders to define the clearinghouse design, governance, and connection to state and federal reporting programs.

About NABP

NABP is the independent, international, and impartial 501(c)(3) nonprofit Association that assists its member boards of pharmacy in protecting public health. NABP was established in 1904 to assist the state boards of pharmacy in creating uniform education and licensure standards. Today, we help support patient and prescription drug safety through examinations that assess pharmacist competency, pharmacist licensure transfer and verification services, and various pharmacy accreditation and inspection programs.