

May 16, 2016

The Honorable Bob Goodlatte  
Chairman  
Committee on the Judiciary  
United States House of Representatives  
Washington, D.C. 20515

The Honorable John Conyers, Jr.  
Ranking Member  
Committee on the Judiciary  
United States House of Representatives  
Washington, D.C. 20515

The Honorable Charles Grassley  
Chairman  
Committee on Judiciary  
United States Senate  
Washington, D.C. 20510

The Honorable Patrick Leahy  
Ranking Member  
Committee on Judiciary  
United States Senate  
Washington, D.C. 20510

Dear Chairman Goodlatte, Ranking Member Conyers, Chairman Grassley, and Ranking Member Leahy:

The pharmacy community is strongly committed to working with lawmakers in the fight against prescription drug misuse and abuse. Overall, we believe that S.524, the Comprehensive Addiction and Recovery Act (CARA) of 2016, will put programs in place that serve this purpose and we support the goal of the legislation to better enable a comprehensive approach to this national crisis. However, we are writing with a concern related to Title VI of the Senate legislation – Incentivizing State Comprehensive Initiatives to Address Prescription Opioid and Heroin Abuse – which includes a provision that would incentivize states to impose unnecessarily redundant and onerous requirements on pharmacists. We are concerned that if implemented by states, these requirements would significantly impact beneficiary access to their needed medications. Accordingly, we strongly urge you to support the House position, which does not include this language.

Specifically, Sec. 601 of the Senate legislation, establishing State Demonstration Grants for Comprehensive Opioid Abuse Response, would make grants available to states that have prescription drug monitoring programs (PDMPs) in place that (among other things) require prescribers and dispensers to consult their state PDMP database prior to prescribing and dispensing a Schedule II, III, or IV controlled substance prescription. We are concerned that imposing this requirement on pharmacists specifically would incentivize states to pursue mandates for pharmacists that are unnecessarily redundant and could place pharmacists in the position of second-guessing the medical judgment of prescribers, who upon issuing controlled substance prescriptions would have already reviewed patients' controlled substance history.

Given that there were approximately 494.8 million<sup>1</sup> controlled substance prescriptions dispensed in 2014, complying with such a mandate would require a collective 16.4-49.4 million additional hours per year to run a prescription drug monitoring program database report for all dispensed controlled

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<sup>1</sup> PHAST® Prescription Monthly, data drawn March 2015

substances prescriptions. Compliance with this requirement would have immediate and severe implications for patient access to important pharmacy services.

While we support policies and programs that ensure that pharmacists can access PDMPs, use of these programs should be determined by pharmacists' professional judgment. A DEA rule implementing the Controlled Substances Act (CSA) already requires pharmacists to ensure that controlled substance prescriptions are written for legitimate medical purposes by prescribers acting in the usual course of their professional practice under 21 C.F.R. § 1306.04 (a). DEA has interpreted this rule as requiring pharmacists to "exercise professional judgment" to determine whether a prescription is legitimate. *See Holiday CVS, LLC*, 77 FR 62316, 62321 (Oct. 12, 2012). The rule provides that failure to do so will result in substantial penalties under the CSA. In light of these and other requirements and penalties that are already in effect under the CSA, we believe that the proposed PDMP pharmacist mandates are unnecessary.

For the reasons discussed in our letter, we urge you to support the House position in conference. This would be in the best interest of patient care while also allowing pharmacists to continue to use PDMPs as an effective tool in guarding against prescription drug abuse and diversion.

The pharmacy community thanks you for considering our perspectives on this matter, and we welcome the ongoing opportunity to work with lawmakers on workable solutions to curbing prescription drug misuse and abuse.

Sincerely,

American Pharmacists Association  
National Association of Chain Drug Stores  
National Community Pharmacists Association

cc: Members of the House Committee on the Judiciary  
Members of the Senate Committee on the Judiciary  
Members of the House Committee on Energy and Commerce  
Members of the Senate Committee on Health, Education, Labor and Pensions  
Members of the House Committee on Education and the Workforce  
Members of the Senate Committee on Finance  
Members of the Leadership of the House of Representatives  
Members of the Leadership of the Senate