

H.R. _____ (Lali's Law)

Below are the American Pharmacists Association's ("APhA") comments and recommendations regarding the proposed Sec. 317U Opioid Overdose Reversal Medication Access and Education Grant Programs.

(a) Grants to States

- Sec. 317U(a)(1) and (2) - *Expanding access to opioid reversal agents*. While the bill encourages standing orders as a means to increase opioid overdose reversal medication access¹, it does not reference other measures states use to increase access to opioid overdose reversal medication, such as collaborative practice agreements². Thus, limiting grants to only states who expand access to opioid overdose reversal medication through standing orders, does not capture all the mechanisms a state can employ to increase opioid overdose reversal medication access and the goals of the bill and its grant program.
 - *Recommendation*: Broaden the activities a state can perform to be eligible for a grant. Specifically, we suggest modifying Sec. 317U(a)(1) and (2) to replace standing order(s) with more general language that encompasses all the methods a state may use to increase access to pharmacist-provided opioid reversal agents.

- Sec. 317U(a)3(A) - *Guidelines and/or best practices for persons authorized to prescribe medication regarding prescribing opioids for the treatment of chronic pain*. Implementing chronic pain guidelines or best practices is included in the bill as a way for states to gain funding³; however, this provision appears to be outside the bill's scope which is focused on access to opioid overdose reversal medication. In addition, at this time, well-accepted guidelines and best practices, which should be in place prior to implementing this requirement, are lacking. Furthermore, not all chronic pain prescribing guidelines may discuss overdose reversal medications.
 - *Recommendation*: Remove or rephrase Sec. 317U(a)3(A) to clearly articulate that grant-eligible state activities must focus on increasing access to opioid overdose reversal medication.

- Sec. 317U(a)(4) - *Training materials*. APhA is concerned that this section, which allows states to receive a grant to develop or adapt training materials/methods, may lead to wasted resources and result in many versions of similar training materials. APhA believes producing these materials at the federal level would be more cost effective due to the fact that most of the information contained in opioid overdose reversal medication training/ education materials would not be state specific and should contain proven practices that should be consistently applied across all states.

¹ Sec. 2 Opioid Overdose Reversal Medication Access and Education Grant Programs inserts Sec. 317U(a)(1) & (2) where States may be eligible for a grant if it developed standing orders for pharmacies or encourages pharmacies to dispense opioid overdose reversal medication pursuant to a standing order.

² Under a collaborative practice agreement, a pharmacist is given authority from the patient's physician and the scope of authority a physician can delegate is dictated by state law. Collaborative practice agreements can be far-reaching as demonstrated in King County, Washington where a pharmacy received prescriptive authority (not patient-specific) for opioid overdose reversal medication when it partnered with public health agencies and the University of Washington Alcohol and Drug Abuse Institute.

³ Sec. 2 Opioid Overdose Reversal Medication Access and Education Grant Programs inserts Sec. 317U(a)(3) which provides the states the option to implement guidelines or best practices regarding (A) prescribing opioids for the treatment of chronic pain (B) co-prescribing opioid overdose reversal medication with opioids; and (C) discussing the purpose and administration of opioid overdose reversal medication with patients.

- *Recommendation:* To distribute and spend grant money efficiently and effectively, training materials should be developed at the federal level and states' incentives would be better targeted for activities like health professional training and mechanisms to operationalize the public education component, including reimbursing health care professionals for the time associated with providing the education.
- Sec. 317U(a) - *Research:* APhA believes that further research regarding opioid overdose reversal medication use is needed and perhaps should be done before implementing certain opioid overdose reversal medication-related policy. APhA does not believe that there has been sufficient evidence-based research regarding the barriers to opioid overdose reversal medication use by patients or the provision (e.g., prescribing, dispensing, administration) of these medications by health care providers. One such barrier, could be payment/ coverage by public and private payers which is not addressed in the legislation.
 - *Recommendation:* Research related to opioid overdose reversal agents should be an encouraged/ preferred activity under the legislation, especially to better inform policy makers of needs of patients and health care providers and action needed to operationalize better opioid overdose reversal medication access.

(b) Certain Requirement & (c) Preference in Making Grants

- Sec. 317U(b) & (c) - *Meaning of "authorized standing orders" and "issued standing orders."* Sec. 317U(b) references authorized standing orders as a condition of grant eligibility and Sec. 317U(c) gives preferences to states that have not issued standing orders. The bill does not distinguish authorized standing orders from issued standing orders, as a result, the eligibility criteria related to standing orders is not clear. In addition, provisions should be clarified whether grants go to states which have implemented the identified preferential activity or propose to implement the preferential activity.
 - *Recommendation:* In provisions pertaining to eligibility and preferences, more general terminology should be used so as to include all the state legislative or regulatory mechanisms to increase opioid overdose reversal medication access (see comments above).

(c) Preference in making grants

- *Sec. 317U(c) - Preference in making grants.* Pharmacists/ pharmacies are not explicitly included in the Sec. 317U(c) which details preferences in making grants. Due to the fact that one of the stated goals of the legislation (Section 317U(a)) is to encourage pharmacists' involvement, the pharmacist has more medication-related experience than any other health care professional, and the important role pharmacists play in being accessible providers in the community, we believe preference should be given to states that include pharmacists in their efforts to expand access to opioid reversal medications.
 - *Recommendation:* Include language which gives preferences to states which include or propose to include pharmacists/ pharmacies in activities to increase access to opioid overdose reversal medications.

- Sec. 317U (c)(2) - *Preference for community-based organizations*: The bill should provide more detail regarding the types of community-based organizations and non-profits eligible and conditions of these organizations' involvement that would give states preference in the grant selection process. Additionally, this provision includes the term "dispense," which is commonly interpreted by pharmacists and other health care professionals to be a service generally performed by pharmacists under state scope of practice authority. APhA believes that the legislation should specifically state that a health care professional, such as a pharmacist, must be engaged in these community-based or non-profit organizations when dispensing services are provided.
 - *Recommendation*: Remove "dispense" from Sec. 317U (c)(2), or require a pharmacist or other qualified health care professional to be present when dispensing activities occur at these community-based or nonprofit organizations.

(d) Grant Terms

- Sec. 317U(d)(3) - *Amount*. While APhA strongly supports providing grants to address opioid abuse, we are concerned that the amount a program can receive (up to \$500,000), may not be sufficient to develop and/ or implement certain programs and activities which could be impactful. For example, states that receive a grant may need to spend significant time and resources to create processes and update technology to meet the bill's reporting demands (e.g. the number of opioid overdose reversal medication doses dispensed with or without a person-specific prescription). While APhA has concerns that \$500,000 may not be sufficient to implement some of the desired changes highlighted in the legislation, we do not have a specific recommendation with regard to the appropriate amount of the grant.

(e) Applications

- No comments

(f) Reporting

- Sec. 317U(f)(1) - *Name and zip code of each pharmacy that dispenses opioid overdose reversal medication under a standing order*. We believe this provision as written is ambiguous and may exceed current state reporting requirements. It is not clear whether states will need to report pharmacies capable of dispensing opioid reversal medications (e.g. those pharmacies that are registered with the state to provide opioid overdose reversal medication under a standing order) or pharmacies that have actually dispensed the medications. Additionally, it is important to be aware that many states with standing orders do not maintain registries of pharmacies/ pharmacists that dispense opioid reversal agents and some standing orders are applicable to pharmacists not pharmacy. To satisfy this reporting requirement, states may have to develop registries and systems to obtain this information which may be costly and time consuming. APhA would appreciate talking with the authors of the legislation regarding what they hoped to accomplish by collecting this information to determine alternative approaches to achieve the intended goal.
 - *Recommendation*: Make reporting of pharmacies dispensing opioid overdose reversal medication voluntary and/ or any reporting requirements should be administratively

efficient, lead to meaningful data collection, and the cost of reporting should not outweigh the benefit of the grant.

- Sec. 317U(f)(1) - *Total number of opioid overdose reversal medication doses dispensed, specifying how many were dispensed with or without a person-specific information (Sec 317U(f)(1))*. APhA is not sure that pharmacy systems can capture and report information on whether a medication is dispensed with or without a person-specific prescription. Nor do we believe there are national standards recommending systems include this information. Therefore, this reporting requirement may be costly and overly burdensome as new software components may need to be developed to track and report opioid overdose reversal medication dispensed at the pharmacy and state levels. It is also important to consider that pharmacies may not even directly benefit from the grant. So new pharmacy requirements may negatively impact patient access to opioid overdose reversal medication as pharmacies may not participate in state efforts because of their inability to comply with reporting requirements. As noted above, APhA is interested in discussing the need for the information being requested, especially since the costs associated with reporting may exceed the value of the grant.
 - *Recommendation:* Only require the reporting of information regarding opioid overdose reversal medication prescriptions dispensed with or without a person specific provision if systems at the pharmacy and state levels already exist.

(g) Definitions

- No comments

(h) Authorization of Appropriations

- No Comments