



April 7, 2025

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RE: Meeting request from the American Pharmacists Association to discuss the impact of thresholds, limits, and flagging of controlled substance orders by drug distributors on patients' access to medications

Dear Attorneys General,

The American Pharmacists Association (APhA) is writing to request a meeting with your offices and the State Compliance Review Committee¹ to discuss the implications of the thresholds, limits, and flagging of controlled substance orders by drug distributors following the national opioid settlements² that have resulted in suspended or terminated contractual relationships

¹ The State Compliance Review Committee was created within the Injunctive Relief, Section P, of the Distributor Settlement Agreement. Its initial membership consisted of members from the Attorneys General Offices of Connecticut, Florida, New York, North Carolina, Tennessee, and Texas. Distributor Settlement Agreement (July 21, 2021). Available at: https://nationalopioidsettlement.com/wp-content/uploads/2022/03/Final_Distributor_Settlement_Agreement_3.25.22_Final.pdf.

² Several defendants have reached settlements with plaintiffs regarding the national opioid litigation, which has resulted in different agreements. Those agreements are available at: <https://nationalopioidsettlement.com/>.

between pharmacies and drug distributors, and unintended but serious delays in patients' access to care.

APhA is the only organization advancing the entire pharmacy profession. It represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including—but not limited to—community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA members understand that your offices are committed to combatting the opioid crisis without compromising the quality of care that pharmacists and other health care providers nationwide. Many of your websites highlight the important work your offices are doing on this front.³ APhA appreciates all that your offices have been able to do to ensure patients have access to controlled substances while also implementing efforts to prevent diversion and misuse. It is also vital for your offices and the State Compliance Review Committee to address the significant barriers and concerns regarding unnecessary disruptions in the continuity of patient care due to community pharmacies' continued inability to fill valid, legitimate prescriptions for controlled substances when drug distributors flag orders and suspend or terminate pharmacy contracts. Particularly, the lack of transparency under distributor Controlled Substance Monitoring Programs (CSMPs) makes it almost impossible for pharmacies to anticipate ordering limits and if those limits or algorithms used by distributors to address the ratio of highly diverted controlled substances to non-controlled substances and ordering of controlled substances will surpass internal ordering thresholds leading to cancellations of distributor relationships and significant disruptions in patient care that puts patients health care at risk. While unintended, these settlements have inappropriately inserted distributors into the state-governed practice of medicine.

³ See *Combatting the Opioid Epidemic*. The Office of the Attorney General William Tong. Available at: <https://portal.ct.gov/ag/general/combating-the-opioid-epidemic>; *AG Moody Leaves Legacy of Fighting Fed Overreach, Protecting the Border, Prosecuting Traffickers, Combating the Opioid Crisis, Defending Life, Revolutionizing ORT Investigations, Recruiting Hundreds of LEOs, Modernizing Crime Reporting Nationwide and More*. Office of the Attorney General State of Florida. Available at: <https://www.myfloridalegal.com/newsrelease/ag-moody-leaves-legacy-fighting-fed-overreach-protecting-border-prosecuting-traffickers>; *Opioid Settlements*. Office of the New York State Attorney General. Available at: <https://ag.ny.gov/nys-opioid-settlement>; *Opioid Crisis*. North Carolina Department of Justice. Available at: <https://ncdoj.gov/responding-to-crime/opioid-epidemic/>; *Attorney General Skrmetti Applauds Tennessee's Opioid Abatement Efforts*. Office of the Attorney General State of Tennessee (Mar. 22, 2024). Available at: <https://www.tn.gov/attorneygeneral/news/2024/3/22/pr34-32.html>; *Opioid Crisis*. The Attorney General of Texas. Available at: <https://www.texasattorneygeneral.gov/initiatives/opioid-crisis>.

Numerous community pharmacies and pharmacists across the country, including in your respective states, report to APhA that their drug distributors have abruptly suspended or terminated their contracts, forcing them to find an alternative distributor and causing patients to experience delays in receiving their prescribed and necessary medications. Several news outlets have also documented this issue.⁴ When pharmacies are unable to fill these prescriptions, an unintended consequence is that patients suffer. For example, hospice patients and those suffering from anxiety, attention deficit hyperactivity, and addiction are just a handful of the groups of patients who are having significant difficulties accessing their prescribed medications. While the reasoning behind implementing limits or thresholds to combat potential diversion is logical, APhA does not believe the state attorneys general involved in settling the national opioid settlements intended to force pharmacies to turn away patients with valid controlled substance prescriptions or ration their available controlled substance allotments between those in hospice care and those experiencing excruciating pain following an accident or surgery when they settled the opioid lawsuits.

APhA believes that a listening session would provide your offices and the State Compliance Review Committee with a more comprehensive understanding of the concerns faced by our nation's pharmacists currently dealing with these issues, as well as to hear practical solutions from our members that can be implemented to address these concerns and restore patient access to these medications. One solution APhA recommends is permitting pharmacies that may have been unintentionally red-flagged, suspended, or terminated by their drug distributor to undergo a voluntary DEA inspection, ensuring that the controlled substance prescriptions they are filling are valid and for legitimate medical use. APhA believes this inspection would alleviate any concerns of the drug distributors, ensuring that the pharmacy's ability to order controlled substances is not impeded and the amounts of controlled substances are sufficient to meet the needs of the communities they serve. Currently, there are limited avenues that allow pharmacies to overcome these designations. As a result, pharmacies attempting to fill an increased number of valid, legitimate controlled substance prescriptions are penalized by having their orders flagged or accounts suspended or terminated by the supplier, forcing them to find an alternative drug distributor or refrain from dispensing controlled substances. All of these outcomes often result in unintentional decreases in patient access.

⁴ See Jewett C, Gabler E. *Opioid Settlement Hinders Patients' Access to a Wide Array of Drugs*. The New York Times (Mar. 13, 2023). Available at: <https://www.nytimes.com/2023/03/13/us/drug-limits-adhd-depression.html>; Swetlitz I. *Xanax and Adderall Access Is Being Blocked by Secret Drug Limits*. Bloomberg News (Apr. 3, 2023). Available at: <https://www.bgov.com/next/news/RSK7TKDWX2PS>; Aboulenein A. *Insight: U.S. Opioid Crackdown Hampers Some Patients' Access to Psychiatric Drugs*. Reuters (Dec. 12, 2022). Available at: <https://www.reuters.com/business/healthcare-pharmaceuticals/us-opioid-crackdown-hits-some-patients-access-psychiatric-drugs-2022-12-12/>.

During this listening session, APhA can share pharmacies' difficulties and patients' barriers to accessing these medications once the drug distributor has flagged their order or terminated their contractual relationship. Not only are community pharmacies confused about the metrics used by their drug distributors in decisions that result in the flagging of their orders as "suspicious" or the suspension or termination of their contracts, but they also face significant barriers in finding a new distributor after their distributor cancels their order or contract. When community pharmacies seek guidance from drug distributors, they are met with few answers, as the national opioid settlements prohibit drug distributors from sharing this information with the pharmacies. As such, APhA encourages your offices and the State Compliance Review Committee to ensure that drug distributors appropriately distinguish between "controlled substances" and "highly diverted controlled substances" when identifying and evaluating red flags.

APhA also draws your attention to the potential for a conflict of interest, as drug distributors may be able to flag orders and suspend or terminate contracts with competitors of those with whom they maintain extensive business relationships or financial interests. Given that the injunctive relief requires drug distributors to set the thresholds, drug distributors with financial interests in pharmacies could terminate contracts with other pharmacies to eliminate competition and drive customers to the pharmacies in which they have a financial stake. APhA encourages your offices, the State Compliance Review Committee, and other relevant parties to review data related to the flagging of orders and suspension or termination of contracts to ensure that there are no apparent biases or significant differences between independent pharmacies and those in which the drug distributors have any financial interest.

Additionally, your offices and the State Compliance Review Committee could hear firsthand how the fear of contract termination or suspension from distributors at pharmacies impacts patient care. APhA has received an alarming number of reports from pharmacies that are no longer accepting hospice prescriptions for controlled substances because of the quantity limits and alerts they are receiving from their drug distributor. This fear forces local hospice agencies to extend ample resources and time to locate these medications, often from pharmacies that are hours away from where their patients receive care. Accordingly, APhA proposes that your offices and the State Compliance Review Committee collaborate with other relevant parties to immediately exempt prescriptions for hospice care from threshold calculations or metrics, thereby preventing further delays in care for this vulnerable population.

APhA thanks your offices and the State Compliance Review Committee for their ongoing efforts in combating the opioid crisis. APhA looks forward to working with you in this role and meeting with you to discuss these critical issues and areas of collaboration that will help your offices achieve their goals. Please contact Michael Baxter, Vice President of Government Affairs,

at mbaxter@aphanet.org to arrange a convenient time to arrange a listening session to discuss these critical matters. We look forward to hearing from you soon.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Hogue". The signature is fluid and cursive, with the first name "Michael" and last name "Hogue" clearly distinguishable.

Michael Hogue, PharmD, FAPhA, FNAP
APhA Executive Vice President and CEO

CC: National Association of Attorneys General
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