NASCSA

National Association of State Controlled Substances Authorities

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Legislative and Regulatory Update

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Discussion Topics

- Legislation Trends
- Regulatory Actions
- Investigations and Enforcement
- Q&A

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Federal Legislative Trends

- *HR 2281 – Easy Medication Access and Treatment for Opioid Addiction Act.* (Nov 2020) Would require DEA to amend 21 CFR 1306.07(b) allowing practitioners to dispense not more than a 3 day supply of narcotic drugs to one person for initiating maintenance treatment or detoxification treatment, or both.
- *HR 8732- Preventing Pill Mills Through Data Sharing Act.* (Nov 2020). Would require ARCOS reports for all controlled substances from manufacturers and distributors; make such information available and provide penalties for failure to review the most recent information directly related to the customers of the manufacturer or distributor.
- *S.889- Prescription Drug Monitoring Act of 2021.* (Mar 2021) Each prescribing practitioner would be required to consult the PMP before initiating treatment with a prescription for a controlled substance in Schedule II, III or IV. Dispenser must report to PDMP within 24 hours. States to analyze data and make reports available to law enforcement and prescriber licensing boards Failure of state to comply could result in withholding funds provide to testate for PDMP.

Federal Legislative Trends

- *HR 1899 – Ensuring Compliance Against Drug Diversion Act of 2021. (Apr 2021).* Would codify the current regulatory requirement regarding termination o a DEA registration when a registrant dies, ceases legal existence or discontinues business or professional activities or surrenders registration. Also prohibits transfer except with permission of DEA.
- *HR 2379 – State Opioid Response Grant Authorization Act of 2021.* (Apr 2021). Establishes a grant program for states, and tribal organizations of not less than $4 million. Funds to be used carrying out activities that supplement activities pertaining to opioid and stimulant use and misuse. These include:
  - prevention activities,
  - establishing or improving PMPs,
  - training for health care practitioners,
  - supporting access to health services

Federal Legislative Trends

- *HR 2355 – Opioid Prescription Verification Act of 2021.* (Apr 2021). Amendment to SUPPORT Act which would to develop and disseminate information for pharmacists on how to verify the identity of individuals picking up prescriptions.
- Also provides grants to states and provide a preference for States that:
  - › maintain a PDMP,
  - › require dispensers to verify the identity of a person picking up RX by requiring a photo identification,
  - › require dispensers to enter certain information in PDMP including
    - » the NDC,
    - » quantity dispensed,
    - » name of the patient,
    - » name of the ultimate user,
    - » name of person picking up the controlled substance.

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Federal legislative Trends

- *HR 768 – Block, Report, And Suspend Suspicious Shipments Act of 2021* (May 2021). Codification of DEA Proposed Rule?
- Amend the definition of suspicious orders in the CSA
- Require that registrants
  - exercise due diligence,
  - establish and maintain a record of due diligence,
  - decline to fill the order or series of orders if due diligence fails to resolve the indicators that give rise to the suspicious would cause a violation of this title by the registrant or the prospective purchaser
  - notify the DEA

Federal Legislative Trends

- *S.1594 – DEA Enforcement Authority Act of 2021* (May 2021).
- Clarify the congressional intent behind requirements relating to immediate suspension orders and corrective action plans under the CSA.
- Controversy over whether prior amendment was too favorable to industry
- DEA ALJ law review article stated DEA could never bring an immediate suspension.
- The Act would strike the "substantial likelihood of an immediate threat" and insert "probable cause"
- Require that the registrant be provided the opportunity to submit corrective action plan prior to revocation or suspension.

Federal Regulatory Actions

DEA Regulatory Actions

- Most of the COVID Exemptions still in place: How many will remain?
- Lessons learned regarding distribution chain
- Importance of reform related to telemedicine
- Rules worthy of Note:
  - *Suspicious Orders of Controlled Substances* (Nov 2020 and Mar 2021)
  - *Amendment to Require Online Submission of Applications for Renewals of DEA registration* (Jan 2021)
  - *Clarification Regarding the Supplier's DEA registration on the Single-Sheet DEA Form 222* (July 2021)
  - *Registration Requirements for Narcotic Treatment Programs with Mobile Components* (June 2021)
  - *Addition of US Space Force as a Registration Waiver and Registration Fee Exempt Military Entity* (Sep 2021)
  - *Removal of Samidorphan from Control* (Apr 2021)

Suspicious Orders – Where have we been?

- 21 CFR 1301.76(a) - "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."
- Guidance letters in 2006, 2007, and 2012 and Distributor Initiative
- Enforcement actions and settlements, Southwood and Masters
- SUPPORT Act in 2018; codified definitions and requirements
- SORS Online in 2019
- DEA Notice of Proposed Rulemaking: *Suspicious Orders for Controlled Substances*. (November 2020; Comments period reopened in March 2021)
- DEA Regulatory Agenda: Final Rule - November 2021

Key Elements of Proposed Suspicious Order Rule

- Newly defined concept of Order Received Under Suspicious Circumstances ("ORUSC") as "potentially meeting" SO definition
- Two-option framework for handling ORUSCs: 1) immediately file SOR and do not ship, or 2) conduct due diligence with potential to ship
- New language in suspicious order definition: "…facts and circumstances that may be relevant indicators of diversion in determining whether a person (or a person submitting an order) is engaged in, or is likely to engage in, the diversion of controlled substances"
- Electronic reporting requirement with "what information and circumstances rendered the order actually suspicious"
- Projection of cost savings and limited burden
- No further specifics or guidance on size, pattern, and frequency

DEA Proposed Suspicious Order Rule

- DEA's proposed rule establishes three new definitions:
  - (1) "orders received under suspicious circumstances (ORUSC),"
  - (2) "order," and
  - (3) "due diligence."
- DEA's existing regulations only define a "suspicious order," which the PDDA codified in 2018 as including orders, or a "series of orders" of unusual size, pattern or frequency.
- Definition of Order " A]ny communication by a person to a registrant proposing or requesting a distribution of a controlled substance, regardless of how it is labeled by the person or the registrant". Raises questions when one considers the logistical and financial differences in the way that the regulated industry engages in distribution of controlled substances.
- DEA clarifies that proposed rule apply to practitioners when such distributions are made pursuant to the five percent rule.

DEA Proposed Suspicious Order Rule

- DEA defines its expectations for "due diligence" that a registrant must follow — within a seven calendar-day time period — before clearing an order to ship. The expansive definition of "due diligence" includes: a "reasonable and documented investigation" and "examination of all facts and circumstances."
- The new rule instead would require the registrant's "record" to include:
  - (1) how the registrant handled such orders;
  - (2) what information and circumstances rendered the order actually or potentially suspicious;
  - (3) what steps if any the registrant took to investigate the order;
  - (4) if the registrant investigated the order, what information it obtained during its investigation;
  - (5) where the registrant concludes that each suspicious circumstances had been dispelled the specific basis for each such conclusion

Registration Requirements for NTPS with Mobile Components, 86 Fed. Reg. 33,861 (June 28, 2021)

- DEA authorizing NTPs to operate MNTPs as a coincident activity waives the requirement that NTPs obtain a separate registration for each mobile unit. DEA previously authorized MNTPs to dispense remotely on an ad hoc basis, and placed a moratorium on new authorizations in 2007.
- NTPs must notify the local DEA office in writing of their intent to operate an MNTP and must receive explicit written approval from DEA before operating an MNTP.
- MNTPs can operate at any remote location or multiple locations, including correctional facilities. An MNTP can only operate in the state where the registered NTP is located and registered.
- There are no mileage limits on the range that MNTPs can travel and dispense but the MNTPs must return to the registered location upon completion of dispensing at the conclusion of each day dictates distance. DEA has concluded that requiring MNTPs to return to their registered location and securing the controlled substances reduces the risk that controlled substances will be diverted.
- However, NTPs can apply to DEA for a waiver to the requirement that MNTPs return to the registered location at the end of each day.

Clarification Regarding the Supplier's DEA Registration Number on the Single-Sheet DEA Form 222, 86 Fed. Reg. 38230 (July 20, 2021).

- DEA issued a direct final rule clarifying requirements about who may record the supplier's DEA registration number on a single-sheet DEA Form 222 ("single-sheet form").
- DEA had stated that consistent with the triplicate form, the supplier when filling the order to record their DEA registration number on the DEA-222. DEA noted the field on the triplicate form for the supplier's registration number is in the section marked "To Be Filled in By Supplier" while the field on the single-sheet form for the supplier's registration is in the section titled "To Be Filled In By the Purchaser."
- The final rule clarifies that either the purchaser or, if not entered by the purchaser, the supplier, may record the supplier's DEA number on a single-sheet form.
- Allowing the purchaser to omit a supplier's DEA registration number for the supplier to add later provides flexibility for when a supplier may have to fill an order from a different registered location than the one contemplated by a purchaser.

DEA Guidance Documents

- Clarification that DEA employee screening guidelines apply only to screening for prospective employees at a non-practitioners DEA registered location and does not apply to prospective employees who will be employed at non-registered locations such as corporate HQ or sales offices.
- A pharmacy may deliver a prescribed buprenorphine product to a practitioners for direct administration to a patient and must be administered by injection or implantation to the patient within 14 days after the date of the receipt of the controlled substance.
- DEA registrants participating in double-blind studies should indicate the total quantity on of each test material on requested n the DEA From 222. Upon completion of the study the supplier will notify the researcher of the actual name and quantity of the controlled substances provided
- Witnessed breakage or spillage of a controlled substance does not constitute a loss of controlled substance because it can be accounted for. No notification required.
- Black Bag Exception – DEA will permit a DEA registered physician to dispense controlled substances to travel to other unregistered locations in the same state on an “as-needed and random basis.

Federal Enforcement Actions

Administrative Actions

- 53 DEA Administrative actions since November 2020
- 45 were revocation decisions related to prescribers
- Many cases based on lack of state authority
- Continued themes involving failure to establish legitimate patient relationship and prescribing not for a legitimate medical purpose.

Civil Penalty Actions

- *Nor-Cal Pharmacies, dba Lockford Drug. Ed California*. Knowingly filling over 700 cs scripts not issued for a legitimate medial purpose. Use of injunctive relief.
- *Source One Pharmacy Services, ED Penn*. Paid $225,000 and consent judgement 3 year accountability and monitoring measures including reporting dispensing to DEA.
- *McElroy Pharmacy, Inc. , ED Penn*. Consent judgement would require payment of $2.9 million in civil penalties and permanently prohibit from dispensing controlled substances. False billings, knowingly filling prescriptions that were not legitimate, Disponing without a prescription, criminal plea.
- *Albert T. Nguyen, MD. WD* Oklahoma. Paid $325,000 in fines; two locations, left pre-signed blank prescriptions at second location which non-physicians. WD Oklahoma
- *Alixra RX, LLC, ND Georgia*. Paid $2.75 million in fines, long term care pharmacy routinely abused emergency script provision by obtaining oral scripts without an emergency. Engaged in cover-up by obtaining backdated prescriptions from the prescribing physician. Also false claims violations.

McLaren Health Care Corporation ("MHCC"), WD Michigan

- Settlement: $7,750,000 and 3-year Memorandum of Agreement that prescribes the system's drug-handling responsibilities, mandates external controlled substance audits, and requires MHCC to institute a broad-based educational program focused on preventing drug diversion in the workplace.
- Nation's largest settlement of its kind involving allegations of drug diversion at a health care system.
- Alleged Violations:
  - unregistered substance abuse treatment facility was improperly receiving controlled substances from an MHCC subsidiary pharmacy by calling in prescriptions for "office stock."
  - DEA expanded investigation controlled substances practices, at numerous facilities across Michigan, violated the CSA and its implementing regulations including McLaren Port Huron Pharmacy and McLaren Yale Pharmacy dispensed schedule II drugs without written prescriptions and despite "red flags" that those drugs were being diverted by MHCC's pharmacist-in-charge.
  - These violations, the government claimed, stemmed in part from certain facility policies that were inconsistent with the CSA's requirements and MHCC's failure to revise other legacy policies that remained in place after MHCC acquired corporate health care providers.

Saint Francis Medical Center, ED Missouri

- Civil penalty of $1,624,957.67.
- Allegations that physician employed by medical center issues scripts for CS without a legitimate medical purpose and prescribed cocktail drugs and ignored warning signs of diversion.
- Saint Francis cooperated with authorities in investigation of non-released individuals
- Education Program
  - Saint Francis voluntarily incorporated Foundation for Opioid Prescribing and Education
  - Funded foundation with initial $1 million contribution
  - Contribution used to fund education [programs for physicians and other healthcare professions in in Southeast Missouri on best practices in prescribing opioids and managing patients with chronic pain issues

Criminal Enforcement

- Operation “Wasted Daze”
- March 2021, forty-six defendants including two doctors, a nurse practitioner and five pharmacists were convicted of operating an $18 million pill mill scheme in Texas.
- The doctors, used a network to recruit individuals from the community and local homeless shelters to pose as “patients.” The “patients” were paid $50 to $200 to obtain prescriptions.
- Pharmacists filling the prescriptions charged recruiters between $200 and $800 per prescription. The clinic manager rather than the doctors examined many of the “patients,” and coordinated with the doctors to prescribe controlled substances without legitimate medical purpose.
- The doctors together reportedly prescribed more than 724,000 doses of hydrocodone, 485,000 doses of carisoprodol, 91,000 doses of alprazolam and over 2.4 million doses of promethazine with codeine over nine years.
- The doctors, clinic manager and pharmacists were convicted of, or plead guilty to, conspiracy to dispense a controlled substance and/or possession with intent to distribute a controlled substance; the recruiters plead guilty to conspiracy to distribute.

MDL Opioid Update

- Potential $26 billion settlement with state Attorney Generals involving the nations largest distributors and J&J. Need to have enough states join in the settlement to go forward. According to published reports, 42 states, five territories and Washington, D.C., signed on to the agreement.
- In May 2021, first bellwether trial began in West Virginia involving distributors and some manufacturers.
- On October 4, 2021 the first “bellwether” trial involving the nations largest chain pharmacies began related to Ohio counties of Lake and Trumbull on allegations of oversight failures at pharmacies that led to excessive amounts of opioid pills in their communities.
- Hundreds/thousands of cases still pending.

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QUESTIONS?

THANK YOU!

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