Understanding the Support for Patient & Communities Act (SUPPORT Act)

And Exploring the Details….

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Relevant DEA Regulations

- **Security Requirements** – “All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”
  - “Substantial compliance [. . .] may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant.”
  - “In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:
    - (14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.”
  - 21 C.F.R. §1301.71(a) and (b)
Suspicious Order Monitoring – “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.”

21 C.F.R. § 1301.74(b)
Prior DEA Enforcement Efforts

• Various DEA settlements with large distributors over the past five years including McKesson, Cardinal and ABC.

- DEA can extract (and has extracted) significant monetary penalties and facility registration suspensions.

• DEA has engaged in administrative litigation with smaller distributors such as Masters Pharmaceutical, Morris and Dickson (but M&D successfully challenged the DEA Immediate Suspension Order; a temporary reprieve), KeySource Medical, among others.
More Recent DEA Enforcement Efforts

• “New” DEA enforcement tool includes use of the the civil injunction action and criminal prosecution.


  › Why now… ?

- “First ever” criminal felony charges: DEA and the Department of Justice criminally indicted distributor and CEO; head of compliance entered a guilty plea. Charges include unlawful distribution, conspiracy and failure to report suspicious orders.
The “SUPPORT” Act (H.R. 6; Pub. L. 115-271)

• SUPPORT for Patients and Communities Act. Also know as the:

Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act.

• Goal is to make medical treatment for treating opioid addiction more available, while also cracking down on the illicit use of opioids and other controlled substances.

• Signed into law by President Trump on October 24, 2018.

• Trump: “Single largest bill to combat the drug crisis in the history of our country.”

• Roll up of over 42 separate pieces of legislation related to the opioid crisis.
“SUPPORT” Act

• What are the SUPPORT Act’s provisions concerning regulation of controlled substances?
  • Codifies suspicious order reporting.
  • Establishes a centralized database for collecting industry reports.
  • Increases penalties for failing to report suspicious opioid orders.
  • DEA must publish distributor/pharmacy numbers for opioids.
  • A manufacturer or distributor who does not review and assess the newly available data will be penalized.
  • Codifies/limits how DEA quota is determined and apportioned; requires DEA to make specific findings to increase quota in response to a registrant’s request to do so.
  • Requires HHS to provide guidance to pharmacists on when they can refuse to fill descriptions.
  • Establishes statutory/mandatory recall authority; no other mandatory recall authority exists concerning drugs.
• Sec. 2003: Every Prescription Conveyed Securely:

- Establishes E-prescribing requirements for controlled substance prescriptions covered under Medicare Part D.
- Exceptions may be established through rulemaking by Secretary of HHS.
- Amendment effective January 1, 2021.
SUPPORT Act, Cont’d

• Sec. 3012: Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now (“SCREEN” Act): Notification, Non-distribution, and Recall of Controlled Substances. Amends FDCA Section 301; Section 569D.

• Gives DEA/HHS mandatory recall authority in certain instances.

• If there is a reasonable possibility that controlled substances would cause adverse health consequences or death, then the Secretary, after notice, may issue order requiring manufacturers, distributors, pharmacists to cease distribution and recall product.

• Not a product integrity issue, like other drug recall measures (and which are not mandatory).

• Any recall determination by government would be subject to post-order hearing process.
SUPPORT Act, Cont’d

• Sec. 3271: Using Data to Prevent Opioid Diversion Act of 2018
• Sec. 3272: Purpose is to provide manufacturers and distributors access to anonymized ARCOS data to help detect, report, and stop suspicious orders.

  Nothing in chapter shall absolve registrant from responsibility to identify, stop, and report suspicious orders, or maintain effective controls.

• The Act now requires distributors to review DEA ARCOS data, which was previously unavailable to the regulated industry.
• Distributors’ review of data provided by DEA, specifically, does not absolve distributors of their other specific SOM obligations set forth in the current regulations (and upcoming regulations).
SUPPORT Act, Cont’d

• Sec. 3273 (Amends 21 U.S.C. § 827): At least quarterly, DEA shall make ARCOS data available to manufacturers and distributors:
  • Total number of distributors that ship controls to a pharmacy/practitioner aggregated by name/address;
  • Total quantity and type of opioids distributed to pharmacy/practitioner;
  • Manufacturers/distributors are responsible for reviewing ARCOS information.

• DEA has made first few waves of data available.
• Is it useful? usable? helpful? unhelpful?
SUPPORT Act, Cont’d

- Sec. 3273 (cont’d) (Amends 21 U.S.C. § 873): Cooperative Arrangements: Every 6 months, DEA must make available to state agencies a standardized report with descriptive and analytic information on distribution patterns based on ARCOS data to include “outliers” and “trends of distributor and pharmacy registrants....”

- What exactly are “outliers” and “trends” of distributors/pharmacy registrants?
- Are outliers and trends suspicious orders?
- What will be communicated and what will be investigated?
SUPPORT Act, Cont’d


• NEW § 842(a)(17): Applies to Manufacturer/Distributor of Opioids: Civil Penalty of up to $100,000:
  • Failure to review most recent information, directly related to customers of the manufacturer/distributor made available by the Attorney General (DEA) (i.e., ARCOS data)
  • Violations related to the reporting of suspicious orders for opioids;
  • Failing to maintain effective controls against diversion of opioids. 21 U.S.C. § 842(c)(1)(B)(ii).

• Note: If committed by a registered manufacturer/distributor of opioids: the criminal fine under 18 U.S.C. shall not exceed $500,000 -- Including failure to report suspicious orders for opioids, maintain effective controls against diversion of opioids, or failure to review most recent information provided by the Attorney General (DEA).
SUPPORT Act, Cont’d

• 21 U.S.C. § 842(c)(2)(D) (criminal information or indictment; requires knowing violation as determined by trier of fact).

• Penalties not related to opioids for violations of record keeping requirements are set forth at 21 U.S.C. § 842 (a)(5), (a)(10) are $10,000; adjusted for inflation to $15,040. 83 Fed. Reg. 3944, 3946 (Jan. 29, 2018).

• Opioids are the target (but not the only consideration for registrants).
  • Reporting is critical.
  • Review of available information is critical.
SUPPORT Act, Cont’d

• Sec. 3274: Report: Within 1 year of enactment, Attorney General (DEA) shall submit a report to Congress on how the government is using ARCOS data to identify and stop suspicious activity, including whether considering aggregate orders from individual pharmacies to multiple distributors that in total are suspicious, even in no individual order rises to the level of a suspicious order to a given distributor.

• At this time this is still a “wait and see” period for distributors and other registrants concerning what this report will reveal about whether use of ARCOS data is effective in diversion detection.
• Sec. 3282: Strengthening Considerations for DEA Opioid Quotas (Amends 21 U.S.C. § 3282)
  DEA specifically will review as “covered controlled substances” quotas for fentanyl, oxycodone, hydromorphone, hydrocodone, oxymorphone. Will consider diversion in analysis for quota determination.

• First time that DEA will consider “diversion” of certain controlled substances in the quota calculation for certain substances.
• Affect on supply? How about legitimate patient access?
SUPPORT Act, Cont’d

• Sec 3292: Improvements to Prevent Drug Diversion: (a) Definition.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end the following:

“(57) The term ‘suspicious order’ may include, but is not limited to—

“(A) an order of a controlled substance of unusual size;

“(B) an order of a controlled substance deviating substantially from a normal pattern; and

“(C) orders of controlled substances of unusual frequency.”.

(b) Suspicious orders.—Part C of the Controlled Substances Act (21 U.S.C. 821 et seq.) is amended by adding at the end the following:
Section 312: Reporting.—Each registrant shall—

“(1) design and operate a system to identify suspicious orders for the registrant;

“(2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and

“(3) upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.
SUPPORT Act, Cont’d

• Codifies current regulatory definition of suspicious orders as including, but not limited to, orders of unusual size, frequency, and deviating from a normal pattern.

• Definition also includes a “series of orders.”

• Question whether enforcement pursuant to federal statute versus the DEA regulation will enhance government action is unknown at this early point yet likely

• Is the statute less susceptible to a legal challenge?

• (Still)…. Awaiting DEA’s SOM regulations.
SUPPORT Act, Cont’d

• Sec. 3292 (cont’d): Establishment of a centralized database of suspicious orders by DEA for registrants to report to rather than reporting to Administrator and individual local DEA offices.

• DEA is required to share collected suspicious order electronic data with states.

• What will states do with collected data?
QUESTIONS?

THANK YOU!

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