NASCSA 2023 Conference

Legislative/Regulatory Update

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Agenda

- DEA Regulatory Actions and Focus
- Recent DEA & DOJ enforcement actions
- Ongoing Areas of Focus

2023 Regulatory Focus

- Suspicious Orders
- Telemedicine
- MAT
- Chemicals
- Scheduling
- Quotas
- Cannabis

Suspicious Orders

- DEA's proposed rule 85 FR 69282, (Nov. 2, 2020) now almost 3 years old and counting
- On January 20, 2023, DEA issued guidance Document reiterating DEA's position that they do not approve a specific system for suspicious orders.
- Current Reg Agenda Final Rule by "02/00/2024"
- Impact of Injunctive relief terms in Opioid litigation
- What will the Final Rule look like?

Telemedicine and Telepharmacy

- *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In Person Medical Evaluation*, 88 FR 12875, (Mar 1, 2023) (Proposed Rule)
- *Regulation of Telepharmacy Practice* (Nov. 17, 2021)(Proposed rule)
- Special Registration for Telemedicine ???
- DEA Public Listening Session

Telehealth and Online Pharmacies

- DEA extended COVID exceptions for telehealth through November 2023, while also highlighting telehealth's history of problematic prescribing practices and ongoing investigations
- Proposed rules received over 34,000 comments
  - No telemedicine options for Schedule II or Schedule III-V narcotic medications, which pre-COVID had required an initial in-person visit before issuing prescription
  - Sole exception is a prescription of buprenorphine for OUD (buprenorphine is a narcotic…), where a patient may receive an initial 30-day telemedicine prescription; refill still requires an in-person exam
  - For schedule III-V non-narcotic prescriptions, patient similarly may receive an initial 30-day telemedicine prescription prior to an in-person exam. Any "refill" (after initial 30-day supply) requires an in-person exam either by referring provider or dispenser

Telemedicine – Enforcement Action

- Recent enforcement aimed at telehealth providers and the pharmacies that dispense controlled substances to telehealth patients:
- Cerebral: DOJ and FTC launched separate investigations of Cerebral, a leading telehealth company offering treatment for mental health conditions
- Truepill: December 15, 2022: DEA issues an Order to Show Cause highlighting volume of stimulant prescriptions, risks of telehealth prescribing, acting as an online pharmacy without proper registration modification, filling inappropriate prescriptions

Proposed Telemedicine Rules Summary

Relationship between prescribing medical practitioner and patient	Prescribing a non-controlled medication	Prescribing Schedule III, IV, or V non-narcotic controlled medications	Prescribing buprenorphine as medication for opioid use disorder	Prescribing Schedule II and/or narcotic controlled medications
Prior in-person medical evaluation by prescribing medical practitioner	Permitted	Permitted	Permitted	Permitted
Referral under the proposed rules from medical practitioner who conducted prior in-person medical evaluation	Permitted	Permitted	Permitted	Permitted
Telehealth visit without: • Prior in-person medical evaluation by prescribing medical practitioner; or • Referral from a medical practitioner who conducted prior in-person medical evaluation	Permitted	• Up to 30-day initial prescription • In-person visit required for additional prescription	• Up to 30-day initial prescription • In-person visit required for additional prescription	Not permitted

- *Telemedicine prescriptions must be otherwise consistent with applicable state and federal laws.*

Buprenorphine Telemedicine Prescribing

- Expansion of Induction Of Buprenorphine via Telemedicine, 88 FR 12890 (March 1, 2023)
- Buprenorphine Telemedicine Proposed Rule is very similar to the General Telemedicine Proposed Rule.
- DEA proposes to authorize practitioners to issue prescriptions pursuant to 21 C.F.R. § 1306.34 *if and only if* the prescription is "issued for maintenance or detoxification treatment and . . . not . . . for any other purpose."
- Practitioner must be authorized, and not be prohibited by state law, to engage in the practice of telemedicine in both the state where the practitioner is located, as well as the state where the patient is located.

Telemedicine – Current Status

- DEA Telemedicine Listening Series, September 12 and 13 at DEA HQ
- Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription Controlled Medications, 88 FR 69870 (Oct. 10, 2023)
  - Join notice DEA and FDA
  - Extend current status until December 2024

Quotas

- DEA/FDA August 1, 2023 letter to "Americans"
  - Blame on manufacturing delays increased prescribing
  - Deflecting that quotas are responsible for shortages
  - Argument that manufacturers not using quota, only sold 70 percent of quota = 1 billion more dosage units
- *Management of Quotas for Controlled Substances and List I Chemicals*, Final Rule, Aug. 31, 2023

Quota Final Rule – Types of Quota

- Clarify definitions for three of quota for CI and CII Controlled Substances
- Four type for List I quota
- Mandatory Use of online Quota Management System
- Require abandonment of procurement quota in addition to individual manufacturing quota

Quota Rule – Support Act

- Authority to establish APQ, individual manufacturing and procurement quotas by dosage forms
- Must assist in avoiding overproduction, shortages or diversion
- Fixing individual manufacturing quotas by December 1
- Estimate the diversion for five controlled substances
- Information to be considered

Certification and Inventory Allowance

- Both manufacturers and distributors required to obtain certification of buyer's quota so DEA better able to maintain closed chain of distribution
- Procurement quotas
  - inventory allowance of 35% for dosage forms - suspension exceeds 50%;
  - 50 % for liquid-injectables - suspension exceeds 65%;
  - request additional quota if inventory less than 25% for all dosage forms, liquids inventory less than 40 %
- Individual mfr quotas
  - Inventory reduced from 50% to 40%;
  - suspends quotas if exceeds 55 %;
  - additional quota if inventory is less than 30%

Quota Rule – Subcategories

- DEA acknowledged it has already been imposing subcategories
- Subcategories
  - Commercial Sales
  - Transfer
  - Product Development
  - Replacement
  - Packaging/Repackaging; Labeling/Relabeling

Quota Rule – Deadlines

- Establishment of APQ changed from May 1 to September 1
- Issue Procurement quota changed from July 1 to December 1
- Adjust individual Manufacturing quota changed from March 1 to July 1

What Does DEA not Address in the Quota Rule?

- Timing – the extent to which DEA's delay in issuing quota or delay in issuing supplemental quota means a manufacturer cannot use the amount up by the end of the year. Thus DEA's statistics on unused quota lack a foundation.
- Explanation - DEA does not provide any findings or a basis for its quota decisions in issuing individual and procurement quotas. The lack of explanation for denial, or reduction of quota grant does not allow registrants to respond or clarify DEA's findings

Ascent Pharmaceuticals – Quota Lawsuit

- On September 27, 2023, Ascent Pharmaceuticals, Inc. filed a federal lawsuit against the Drug Enforcement Administration (DEA).
- On October 3, 2023, Ascent Pharmaceuticals filed an Emergency Motion for Mandatory Preliminary Injunction Relief in the Court of Appeals For the Second Circuit.
- The emergency motion seeks to force DEA to grant Ascent's quota request for manufacturing of generic ADHD drugs, after DEA denied Ascent's pending quota request.
- Apparently, DEA had been conducting an inspection audit of Ascent lasting the last year-and-a-half.
- Also, it appears DEA has withheld quota for 2023.

Special Surveillance List of Chemicals

- *Special Surveillance List of Chemicals, Prod*ucts . . .88 FR 39479 (Jun. 16, 2023)
- Has not been published since 1999
- Involves chemicals, lab supplies that can be used for illicit purposes
- No regulatory requirements
- Intent to inform individuals about potential misuse
- Remind companies of civil penalties for distribution of such products within 2 weeks of notice from DEA that an individual has used such products for illicit purposes

Partial Filling of CII Prescriptions

- *Partial Filling of Prescriptions for Schedule II Controlled Substances*, 88 FR 46983 (Jul 2023) (Final Rule)
- Requirements
  - not prohibited by State law and a valid prescription
  - requested by the patient, person acting on behalf of patient or practitioner
  - total quantity dispensed does not exceed the total quantity prescribed.
  - remaining portions must be filled not later than 30 days of the script date except emergency s
  - practitioner must record the quantity to be dispensed in each partial filling and pharmacist must document partial fill
  - must be communicated by the prescribing practitioner to the pharmacist at the time that the oral communication is taking place

Cannabis

- Growing number of state laws and regulations related to medical and recreational use
- September 2022, Biden Administration ordering federal government to reevaluate marijuana's designation
- August 2023, "letter" from HHS to DEA recommending rescheduling to schedule III
  - Assume this is the eight factor analysis required under the CSA
  - How have they determined "currently accepted medical use"
  - CIII would still require a prescription for a practitioner

Schedules Of Controlled Substances

- Continued scheduling of synthetic compounds in CI
- *Schedule of Controlled substances, Temporary Placement of Etizolam, Fluralprazolam, Conazolam, Flubromazolam and Diclazepam in Schedule I*, 88 FR 48112 (Jul 2023)
  - Findings of specific abuse of designer benzos in combination with opioids
  - Illicit benzos increase by 520 precent
  - 92 percent of overdose for benzos with opioids

Other Recent Final Orders of Note

- *Reporting Thefts or Significant Loss of Controlled Substances,* 88 FR 40707, June 22, 2023 (electronic filing and limited reason codes)
- *Transfer of Electronic Prescriptions for Schedules II-V Controlled substances Between Pharmacies for Initial Filling,* 88 FR 48365, July 27, 2023 (patient request, one time, must be communicated, remain electronic)
- *Implementation of Designer Drugs Steroid Act of 2014*, August 21, 2023 (add 22 new drugs, expand definition of anabolic steroid)
- *Dispensing of Narcotic Drugs to Relieve Acute Withdrawal Symptoms of Opioid Disorder*, 88 FR 53377 August 8, 2023 (3 days supply for purposes of detoxification)

ADMINISTRATIVE ACTIONS

Morris & Dickson License Revocation

- On May 30, 2023, four years after it conducted an administrative hearing on its Order to Show Cause (OTSC), DEA published a Decision and Order revoking M&D's DEA registrations at its two distribution centers
  - Effective date of revocation order suspended until August 28, 2023. Parties have indicated they will engage in settlement discussions.
  - M&D previously settled civil penalty claims in 2019 for $22 million and agreed to improve its compliance program, but failed to resolve the pending administrative action
  - News reports about DEA's failure to take action after 4 years just prior to release of Decision and Order
- Key allegations in 2018 OTSC included:
  - Shipping thousands of unusually large orders for oxy and hydro without resolving red flags or reporting the orders
  - From January 2014 until April 2018, reported only three SORs
  - Failed to follow its own anti-diversion policies
  - Failed to conduct meaningful due diligence and document the resolution of red flags

Morris & Dickson License Revocation

- DEA evidence at the ALJ hearing focused on several key areas:
  - List of exemplar customers where M&D's Pro Compliance Reports highlighted red flags for controls ratio, cash payments, and trinity dispensing, among others that were not resolved
  - Government's data analysis (utilizing Tukey for the first time) identified thousands of outlier orders that were not evaluated or reported
  - Evaluation of M&D deficient anti-diversion policies
- M&D admissions and acceptance of responsibility at ALJ hearing were not fully credited by ALJ to avoid revocation
- 1301.74(b) criteria are "not exclusive" and other considerations, such as business model, could render an order suspicious
- Notable testimony by DEA witness (area group supervisor) regarding specific M&D red flags:
  - Exceeding a 15% ratio of controls to non-controls is a red flag
  - Exceeding 9% cash for controlled substances is a red flag
  - DEA declined to adopt a specific percentages because Pro Compliance Reports used by M&D flagged these metrics for each customer reviewed

Civil Complaints and Monetary Penalties

- Continued Aggressive Enforcement Environment, Manufacturers, Distributors and Pharmacies
- DEA, Us Attorney's Office (AUSA) and DOJ – Office of Consumer Protection
- Expansion of Red Flags and Enforcement
- Settlement Agreements, MOAs and Consent Decrees
- 31 Civil Settlements to date in 2023

Amerisource Bergen Civil Complaint

- On December 29, 2022, DOJ filed a lawsuit against AmerisourceBergen (ABC) seeking civil penalties for the failure to report suspicious orders
- Complaint alleges from 2014 to present ABC failed to identify and report suspicious orders
- Key program deficiencies highlighted include:
  - ABC did not adequately implement and follow due diligence policies, which resulted in ABC servicing problematic pharmacies
  - In 2013 and 2014, ABC reported over 35,000 suspicious orders to DEA, but after a redesign of its program, the number of orders reported as suspicious fell to fewer than 350 per year
  - ABC team reviewing flagged orders was understaffed, inadequately trained and/or did not adequately investigate potentially suspicious orders
  - SOM system only flagged orders that hit on multiple suspicious order criteria
    - Flag based on volume and pattern; did not flag orders of unusual frequency
    - Did not flag orders with non-statistical "indicia of suspicion"
- Included allegations related to ABC 3PL

Amerisource Bergen Civil Complaint

- Timing is interesting given that other wholesalers settled similar cases years ago and same government players bring this lawsuit
- In March 2023, ABC filed a Motion to dismiss saying it was "a glaring — and dangerous — example of governmental overreach."
- More recently in a July 2023, filing ABC argued DEA didn't give the company proper guidance, so the government "unfairly set a trap for defendants, enabling the government to engage in the very sort of arbitrary enforcement."
- ABC is also arguing that DEA has had numerous opportunities to instruct defendants to change" its suspicious order monitoring program.

Rite Aid Complaint

- On March 13, 2023, DOJ filed a civil lawsuit against Rite Aid seeking civil penalties
- Civil complaint alleges that from May 2014 to June 2019, Rite Aid pharmacies filled hundreds of thousands of unlawful prescriptions, including: trinity, early fills, high dose opioids, bad prescribers
- Complaint argues that pharmacists routinely filled scripts without resolving red flags and had inadequate validation processes
- Claimed distributor raised issues about dispensing

Chain Settlements with State AGs

- Albertsons, CVS, Walmart, and Walgreens have each entered into settlement agreements with similar injunctive relief requirements
- Injunctive terms require certain compliance processes:
  - Prescription Validation Process
    - Patient red flags
    - Prescription red flags
    - Prescriber red flags
  - Prescriber Reviews
  - Proactive Diligence: data review to identify compliance issues
  - Site Visits: Annual site visits to review dispensing records, inventories, loss prevention, among other topics
- Familiarity with injunctive terms can better inform questions to chains during annual reviews and individual pharmacy location diligence

Pikeville Health, ED Ky, Dec 2022

- Pikeville Medical Center paid a $4,394,000 ci cl penalty, Settlement is one of the largest relating to CSA recordkeeping violations involving allegations of diversion at a hospital.
- Alleged Violations: Over a two-year period, PMC violated multiple provisions of the CSA relating to recordkeeping, including by failing to maintain complete and accurate inventories and dispensing records for Schedule II controlled substances.
- As a result of these failures, a PMC pharmacy technician was able to divert more than 60,000 dosage units of oxycodone, hydrocodone, and methadone from PMC's narcotics vault and Pyxis MedStations, from January 1, 2016 through September 7, 2018.
- The diverted controlled substances from PMC ultimately were distributed by the pharmacy technician's husband to the community.

PharmScript of KC, Dec 2022

- PharmScript of KS, LLC (long-term care pharmacy) paid $3,000,000 in civil penalty.\
- Alleged Violations:
  - PharmScript provides medication and pharmaceutical services to patients in skilled nursing facilities and to residents in assisted living facilities in Kansas and Missouri.
  - Between October 1, 2019, through March 31, 2021, PharmScript dispensed Schedule II substances for purported emergencies when quantities of the controlled substances dispensed were greater than what was adequate for the emergency period.
  - PharmScript failed to obtain written prescriptions within 7 days after a verbal authorization.
  - Other controlled substances were dispensed without a written prescription and when no verbal authorization was received from a physician.

People's Pharmacy, D. Colorado, March 2023

- Payment of $3,500,000 (requiring it to pay all of its remaining assets) and permanently forgo holding a pharmacy license or DEA registration.
- Owner will not dispense any c/s in the future.
- Between January 2014 and July 2020, People's Pharmacy unlawfully filled RXs despite presence of red flags indicating that the RXs were not issued for legitimate medical purposes. RXs filled included exceptionally high opioid dosages and dangerous drug combinations which can depress the central nervous system and the ability to breathe.
- The violations resulted in serious harms including both overdose deaths and unlawful diversion onto the street.

Chesire Medical Center, D. NH, June 2023

- Civil fine of $2,000,000; improvements voluntarily undertaken before and after the DEA investigation, CMC has agreed to additional security and recordkeeping measures.
- DEA began investigation after a nurse stole 23 intravenous bags of fentanyl solution from an automatic medication dispensing machine.
- CMC initially disclosed this theft to DEA in February 2022. CMC later reported that an additional 634 bags of fentanyl were unaccounted for.
- In April 2022, DEA conducted audits of 8 CMC's inpatient pharmacy; the audit revealed an additional 17,961 missing c/s units.

Clarest LLC, ProCare LTC New England LTC and ProCare LTC Pharmacy of Connecticut LLC, Aug 2023

- Payment of $499,525 and 3-year corrective action plan
- Clarest Health consists of 8 pharmacy; U.S. ProCare LTC Pharmacy of Connecticut services 65 long-term care ("LTC") facilities, skilled nursing facilities, assisted living locations, and rehab and nursing practices in Connecticut and Rhode Island.
- •In addition to filling prescriptions, it also fulfills orders for c/ss for LTC facilities' emergency stock needs. This emergency stock is commonly referred to as a facility's "emergency box."

Clarest LLC, ProCare LTC New England LTC; ProCare LTC Pharmacy of Connecticut LLC

- Between September 2020 and September 2022, ProCare violated the CSA and its implementing regulations when supplying controlled substances for LTC facilities' emergency box stock.
- ProCare distributed controlled substances to practitioners that were not registered to dispense those controlled substances on 96 occasions.
- ProCare failed to record certain required information on DEA Form 222s (order forms) on numerous occasions, such as dates, numbers of containers furnished, and DEA registration numbers.
- •ProCare failed to reject order forms that were not properly prepared, were incomplete, or had been altered.

Adam Runsdorf/Woodfield Distribution, SD Florida, Aug 2023

- Payment of $2.475 million and surrender of 7 DEA registrations
- From 2013 through 2016, Woodfield's Florida location failed to account for over 120 million dosage units of controlled substances; did not maintain a system for monitoring suspicious orders; failure to notify the DEA of over 200,000 dosage units of stolen; falsifying importation documents and the illegal importation of over 200 million dosage units of c/ss;
- In August 2022, a separate criminal investigation and guilty plea by owner
- Implications of a 3PL being shut down.

Questions?

Thank You!