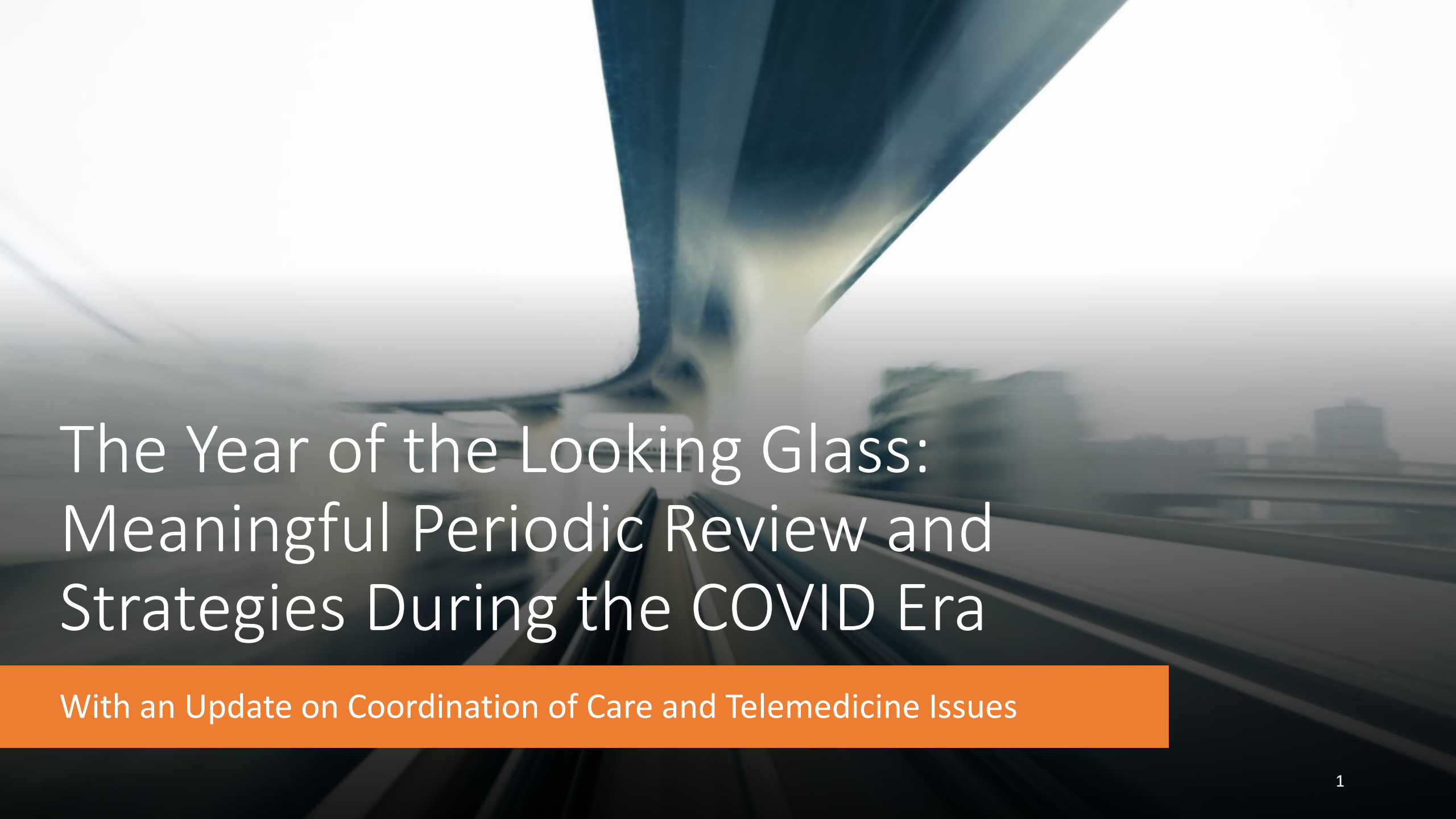

The Year of the Looking Glass: Meaningful Periodic Review and Strategies During the COVID Era

With an Update on Coordination of Care and Telemedicine Issues

Disclosures

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Learning Objectives

1. Review basic requirements periodic review and prescribing controlled substances during the COVID-19 PHE.
2. Through a case example, review basic requirements of patient counseling as part of the periodic review process, including addressing inconsistent drug test results with the patient and in the medical record.
3. Identify updated strategies for Coordination of Care and telemedicine strategies to facilitate a current and meaningful periodic review process.

Periodic Review and Risk Monitoring: Looking Backwards at to Move Forward

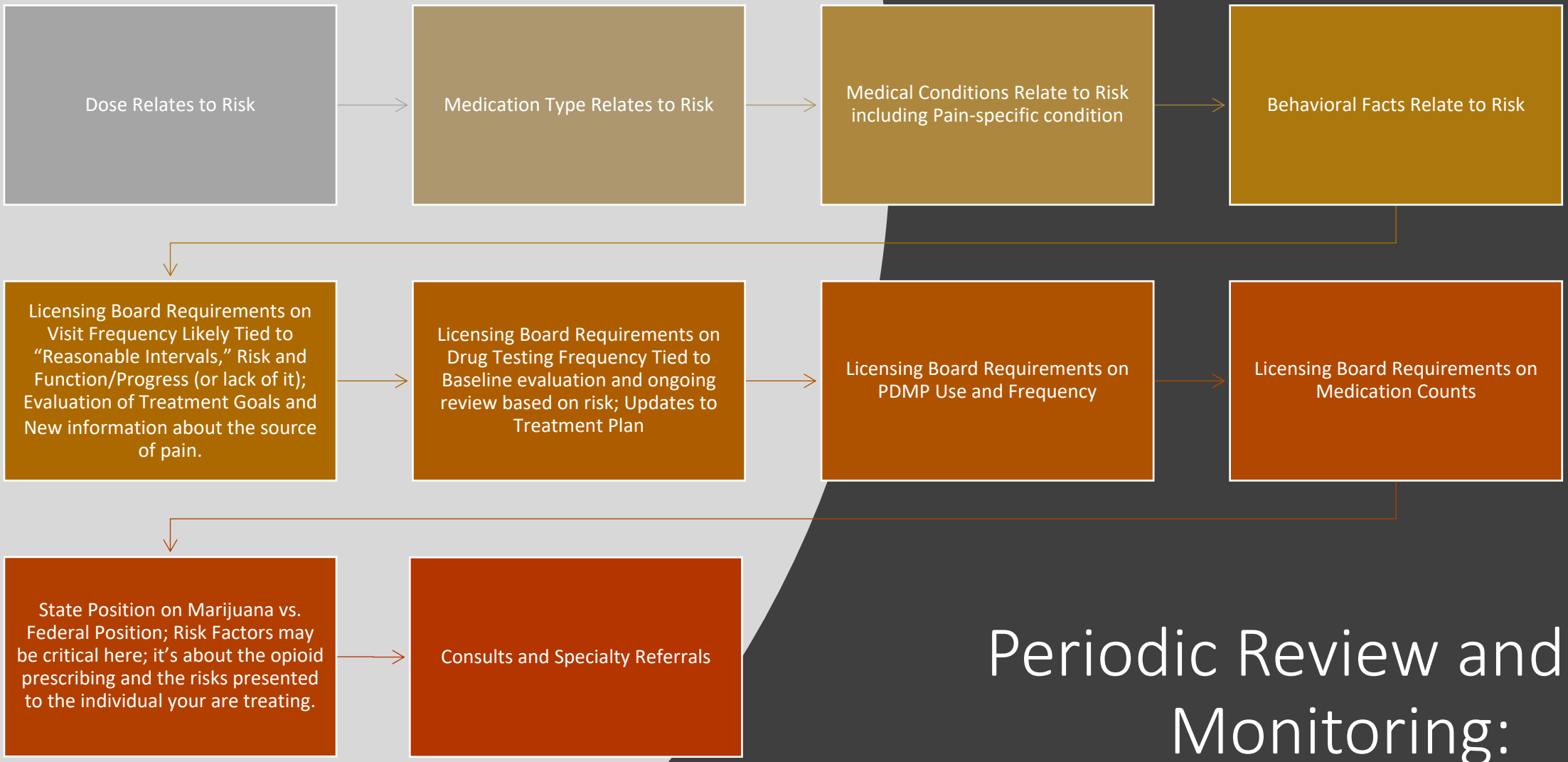
Objective 1

If we look in the review mirror, what do we see regarding Periodic Review and Risk Monitoring

Only a few states pushed hard boundaries on "how often" to see and monitor a patient on chronic opioid therapy

Enter Risk Mitigation (Evaluation, Stratification, Monitoring)

More states have identifiable boundaries associated with periodic review and risk monitoring



Periodic Review and Risk Monitoring: General Observations and Documentation Areas

(5) Periodic review of the treatment of chronic pain.

(A) The physician must see the patient for periodic review at reasonable intervals in view of the individual circumstances of the patient.

(B) Periodic review must assess progress toward reaching treatment objectives, taking into consideration the history of medication usage, as well as any new information about the etiology of the pain.

(C) Each periodic visit shall be documented in the medical records.

(D) Contemporaneous to the periodic reviews, the physician must note in the medical records any adjustment in the treatment plan based on the individual medical needs of the patient.

(E) A physician must base any continuation or modification of the use of dangerous and scheduled drugs for pain management on an evaluation of progress toward treatment objectives.

(i) Progress or the lack of progress in relieving pain must be documented in the patient's record.

(ii) Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, and/or improved quality of life.

(iii) Objective evidence of improved or diminished function must be monitored. Information from family members or other caregivers, if offered or provided, must be considered in determining the patient's response to treatr

(iv) If the patient's progress is unsatisfactory, the physician must reassess the current treatment plan and consider the use of other therapeutic modalities.

(v) The physician must periodically review the patient's compliance with the prescribed treatment plan and reevaluate for any potential for substance abuse or diversion. In such a review, the physician must consider obtainin
determine the presence of drugs in a patient, if any. If a physician determines that a repeat toxicology screen is not necessary, the physician must document in the medical record his or her rationale for not completing it.

(6) Consultation and Referral. The physician must refer a patient with chronic pain for further evaluation and treatment as necessary. Patients who are at-risk for abuse or addiction require special attention. Patients with chronic
co-morbid psychiatric disorders require even more care. A consult with or referral to an expert in the management of such patients must be considered in their treatment.

Sample Periodic Review Requirement – Texas Medical Board (TAC, Title 22, Part 9, Chapter 170, 170.3)(Minimum Requirements for the Treatment of Chronic Pain)

Basic Risk Monitoring Concepts and Self-Reflection Questions

Risk Monitoring

- How often will you see the patient?
- How often will you drug test the patient? What type of drug test will you use?
- Which controlled medication will you prescribe? Does it vary by risk stratification level? Are there boundaries regarding dose and quantity limitations? Does your board have these? What will you document if you exceed board-imposed levels? Does the answer change if you look to the CDC levels? Will you use medication counts? Just opioids or all controlled drugs?
- How will you handle coordination of care with other treating practitioners and referrals for specialty care?
- What are the consequences if the patient strays outside the treatment agreement? How do you document that discussion? Have you checked for boilerplate entries?
- Will naloxone be required because of the patient's evaluated risk level? How will you follow-up with the patient to determine if they filled the prescription? What happens if they do not?
- Will you engage in telemedicine visits with the established patient? Will the nature of the telemedicine visit vary by the patient's risk level, meaning an audio only call might be permitted for a low risk established patient, but a real-time, two-way, audio communication device will be required for an established high behavioral risk patient or even an in-person evaluation?
- Other considerations? Are you following your licensing board requirements for PDMP checks?

Part 2A - The Prescribing Standard and Periodic Review/Risk Monitoring – Case Example

SOURCE: DEA Decision and Order in Thomas Neuschatz, MD, December 17, 2013, available online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2013/fr1217.htm.

2013 – Relevant Portions of the Decision and Order for Thomas Neuschatz, MD (California)

- With respect to 2 patients, the Medical Board of California found that Neuschatz overprescribed controlled substances because he failed to establish a legitimate medical purpose for the use of the controlled substances and because he acted outside the usual course of professional practice in the manner in which he conducted his practice.
    - See Cal. Bus. & Prof. Code Sec. 725(c) (requiring a medical basis for prescribing controlled substances); 21 CFR 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose").
    - NEUSCHATZ only treated the patients with controlled substances, failed to document treatment plans, failed to [consider] the patient's past history of drug abuse, and continuously prescribed high doses of opiates without documenting any explanation for doing so in their medical records. **Stipulated Surrender, at 17-23.**

- SOURCE: DEA Decision and Order in Thomas Neuschatz, MD, December 17, 2013, available online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2013/fr1217.htm.

2013 – Relevant Portions of the Decision and Order for Thomas Neuschatz, MD (California)

- **DEA's Medical Expert explained:**
- NEUSCHATZ ignored signs of misuse with respect to one patient, and signs of misuse and diversion with respect to the other patient:
  - Signs of misuse on the part of [patient 1] did not seem to affect [Applicant's] prescribing practices";
  - [patient 2] requested specific controlled substances, reported stolen opioids, and reported persistent or increased pain at almost every visit, notwithstanding that "the opioid . . . doses had been significantly increased" and that NEUSCHATZ "fail[ed] to respond to clues that [patient 2] was misusing or diverting medication").
- Most significantly, with respect to both patients, the Government's Expert concluded that Applicant's treatment "fell far outside the usual professional practice of medicine."

- SOURCE: DEA Decision and Order in Thomas Neuschatz, MD, December 17, 2013, available online at https://www.deadiversion.usdoj.gov/fed_regs/actions/2013/fr1217.htm.

PERIODIC REVIEW AND RISK MONITORING FAILURES

(Source: Pompy Decision and Order, DEA 2019)

Inadequate monitoring drug the use of potentially abusable medications.	Unjustified dose escalation without adequate attention to risks, such as concurrent alcohol use, or to alternative treatment.	Relying excessively on opioids, particularly high dose opioids for chronic pain management, and continuing opioid therapy that does not meet clear and objective outcomes.	No using available risk mitigation tools, such as the state's PDMP, in advance of prescribing opioids and during ongoing monitoring.

SOURCE: Drug Enforcement Administration, Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749-57760.

PERIODIC REVIEW AND RISK MONITORING FAILURES IN THE POMPY CASE

How Pompy's Medical Records Appeared to the Government's Medical Expert

- Multiple dates of service with no clinical information at all.
- No documented responses to evidence of abuse or diversion.
- Ongoing prescribing of high-dose opioids without documenting a conversation with the patient about whether they had exhausted their previous supply.

SOURCE: Drug Enforcement Administration, Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749-57760.

PERIODIC REVIEW AND RISK MONITORING FAILURES IN THE POMPY CASE

How Pompy's Medical Records Appeared to the Government's Medical Expert

- Unnecessarily voluminous patient files due to "cut and pasted" segments repeated from note-to-note; poorly organized and frequently unintelligible.
- Negative symptoms usually noted for the musculoskeletal system element of the review of systems, though each patient was apparently being seen for a chronic pain diagnosis.
- No documentation of any contact with other healthcare providers (except imaging study reports).

SOURCE: Drug Enforcement Administration, Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749-57760.

Part 2B – Ideas for Creating Your Own Plan for Capturing Your Efforts to Engage in Appropriate Periodic Review and Risk Monitoring

Two sample tables you can use as you read the DEA Decisions and Orders associated with this OnDemand Series-MDL05, MDL06, MDL07

Ideas* for Creating Your Own Periodic Review and Risk Monitoring Work Board for ESTABLISHED PATIENTS

- *You are encouraged to review your licensing board material and other relevant documents describing risk mitigation in chronic pain management

Risk Item // Risk Level >	Low Risk	Moderate Risk	High Medical Risk	High Behavioral Risk
Frequency of Visit	Q1-3 months, depending on Board	Q1-2 months, depending on Board and Facts	Monthly	At least monthly, depending on other factors
Frequency of UDT* (Also subject to payor policies and documentation of medical necessity)	Q1-3x per year; Some states may require more	Q2-4 x per year; Check state board	Q2-4x per year	Q4-6*x per year; Check board and payor policies*
Frequency of PDMP check	Each visit* depending on board	Each visit	Each visit	Each visit
Dose	Individualized	Individualized	Individualized	Use caution if >50mg MME; Check state board
Types of Medication and Combinations	Individualized	Individualized	Individualized	Use caution if >50mg MME; Check state board
Coordination of Care	Required as necessary	Required as necessary	Required as necessary	Required and remember BH specialists
Medication Counts	Recommended	Required	Required	Required
Telemedicine	Once established and during period of COVID-19 PHE, subject to ongoing facts	Once established and during period of COVID-19 PHE, subject to ongoing facts	Periodic use or carefully documented use once established and during the period of COVID-19 PHE	In-person visits are best, but may be able to use a real-time, two-way, audio visual communication tools to improve ability to risk monitor.
Naloxone	Recommended	Required	Required	Required
Frequency of MD evaluation (when NPs are used)	Q1 to 2x per year	NLT 2x per year	NLT 2x per year	NLT 3x per year
Other				

Ideas* for Creating Your Own UDT Triage Work Board for ESTABLISHED Patients

Sample Low Risk Results	Sample Moderate Risk Results	Sample High Risk Results
• Rx medication is screened and believed to be present OR confirmed and present with metabolites • No illicit drugs • No unsanctioned Rx or old Rx drugs • Otherwise compliant patient	• Rx medication is confirmed and present with metabolites • Unexpected THC positive • Unsanctioned or unreported use of other Rx drugs (BAR, BZO, Sed-Hyp, SMR)	• Rx medication is unexpectedly negative or major metabolite is missing • Positive for illegal drugs other than THC • Positive for inconsistent BZO based on plan or multiple BZOs • Positive for non-Rx opioids • Positive for BUP and Naloxone

*You are encouraged to review your licensing board material and other relevant documents describing risk mitigation in chronic pain management and to review payor policies on medically necessary drug testing and required documentation.

Looking Glass Year - 2006

DEA Statement of Risk Evaluation and Monitoring

"Moreover, as a condition of being a DEA registrant, a physician who prescribes controlled substances has an obligation to take reasonable measures to prevent diversion. [21 U.S.C. 823(f)]."

"The overwhelming majority of physicians in the United States who prescribe controlled substances do, in fact, exercise the appropriate degree of medical supervision—as part of their routine practice during office visits—to minimize the likelihood of diversion or abuse."

"Again, each patient's situation is unique, and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound medical judgment and consistent with established medical standards."

SOURCE: DEA Final Policy Statement, Notice, FR Doc E6-14517 [Federal Register: September 6, 2006 (Volume 71, Number 172)] [Notices] [Page 52715-52723] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr06se06-137], Available online at https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm.

Part 4 – Coordination of Care and Telemedicine Considerations

What your board may not tell you about staying current during COVID-19 PHE

Basic Concepts - Coordination of Care

- Strive to keep the patient at the center of the relationship and actively communicate with his/her other treating health care providers to ensure the patient's "medical team" remain current on status of chronic opioid therapy and the patient's use of related medication.
- Coordination of care is a gatekeeping function to ensure all active treatment providers have critical information to include in their medical decision-making and efforts to mitigate risk for the patient.
  - Specialists should keep family physician informed and vice versa.
- All physicians should strive to work with behavioral health practitioners and vice versa.
  - You do not need to have every scrap of behavioral health chart, but understanding and coordinating who is going to prescribe and monitor which drugs is critical and keeping track of this even more so
- Monitoring follow-through with referrals is also critical

Key Items to Consider Adding to Informed Consent Process and Educational Updates During Patient Encounters - Based on COVID-19

Examine risk of respiratory depression with the use of opioids and other medication and how COVID-19 signs and symptoms may increase risk of an adverse event.

Examine whether increased risks if patient has existing renal and hepatic issues in light of ongoing use of opioids and signs/symptoms of COVID

Critical focus on need for naloxone in a home “emergency kit” because patient uses controlled substances and COVID is not under control. Increased education here.

Update (and probably a separate) informed consent to include or be specific to telemedicine use

Key Items to Consider Adding to Periodic Review and Risk Monitoring Based on COVID-19

1	Use of telemedicine for medication counts
2	Use of telemedicine for oral fluid sample collection
3	Use of telemedicine visits for check-in at a frequency greater than office visit schedule prior to COVID-19
4	Use of telemedicine if behavioral health treatment is needed
5	Use of telemedicine to verify naloxone prescription filled

Final Items to Remember about DEA Administrative Cases and Prescribing Standards: The Burden Shift AFTER the Government Proves its Case

- When the government has met its burden of showing that a DEA Registrant's continue registration is inconsistent with the public interest due to his numerous violations pertaining to controlled substance prescribing, . . . , as well as due to his non-compliance with State law, the burden shifts to the DEA Registrant to show why he can be entrusted with a new registration.

- DEA Administrators have held that a registrant who has committed acts inconsistent with the public interest MUST accept responsibility for those acts and demonstrate that he will not engage in future misconduct.

- A Registrant's responsibility must be unequivocal…A Registrant's candor during the investigation and hearing [is also] an important factor.

SOURCE: Drug Enforcement Administration, Lesly Pompy, MD, Decision and Order, Fed. Reg., Vol. 84, No. 208, October 28, 2019, p. 57749-57760.

THANK YOU!

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